Food Safety Policy, Science, and Risk Assessment: Strengthening the Connection: Workshop Proceedings

Food Forum, Food and Nutrition Board

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—Goethe

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Introduction

The Institute of Medicine's (IOM's) Food Forum was established in 1993 to allow science and technology leaders in the food industry, top administrators in several federal government agencies from the United States and Canada, representatives from consumer interest groups, and academicians to openly communicate in a neutral setting. The Food Forum provides a mechanism for these diverse groups to discuss food, food safety, and food technology issues and to identify possible approaches for addressing these issues by taking into consideration the often complex interactions among industry, regulatory agencies, consumers, and academia. The objective, however, is to illuminate issues, not to resolve them. Unlike study committees of the IOM, forums cannot provide advice or recommendations to any government agency or other organization. Similarly, workshop summaries or other products resulting from forum activities are precluded from reaching conclusions or recommendations but, instead, are intended to reflect the variety of opinions expressed by the participants.

On July 13–14, 1999, the forum convened a workshop on *Food Safety Policy, Science, and Risk Assessment: Strengthening the Connection.* The purpose of the workshop was to address many of the issues that complicate the development of microbiological food safety policy, focusing on the use of science and risk assessment in establishing policy and in determining the utilization of food safety resources. The purpose was not to find fault with past food safety regulatory activities or food safety policy decisions. Rather, the goal was to determine what actions have been taken in the past to address food safety issues, to consider what influences led to the policies that were put in place, and to explore how improvements can be made in the future.

This report is a summary of the workshop presentations (see Appendix A). It is limited to the views and opinions of those invited to present at the workshop and reflects their concerns and areas of expertise. As such, the report does not provide a comprehensive review of the research and current status of food safety policy, science, and risk assessment. The organization of the report approximates the order of the presentations at the workshop. The identification of a speaker as an "industry representative" or a "Food and Drug Administration representative" is not intended to suggest that the individual spoke for that organization or others who work there.

The workshop began with an overview of the utilization of science as the basis for food safety policy and how the food safety statutory authority differs among federal agencies. The next session focused on defining incidents that led to changes in food safety policy. Four case

studies were presented, including opinions on lessons learned and what could have been done differently. The afternoon session began with presentations of other factors (international, business, regulatory, consumer, and political considerations) that in addition to science, may influence the development of food safety policy. An open discussion among speakers and the audience ended the first day's program.

The second day of the workshop focused on the utilization of science-based risk assessments to develop food safety policy. Open discussion among all participants was again encouraged. Appendix B provides a list of participants.

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Science as the Basis for Food Safety Policy

This session was designed to reconfirm that the federal government considers science and risk assessment to be integral parts of the food safety decision-making process. However, other factors such as statutory authority and resources must be considered in making food safety decisions.

GOOD SCIENCE: CRITICAL TO REGULATORY DECISION-MAKING

Presented by Jane E. Henney, M.D.

Commissioner, Food and Drug Administration

Americans enjoy the safest and most bountiful food supply in the world. This is due in part to advances in science and technology that have enabled the identification of more than five times the number of food-borne pathogens than were known 50 years ago and the development of new solutions to prevent and control these pathogens. Yet each year in our country millions of people become ill and thousands die due to food-borne illness.

Recent trends in food consumption are a major reason that ensuring a safer food supply has become more challenging as Americans both choose a greater variety of foods from a continually expanding global supply and consume an increasing amount of foods prepared outside the home. It is because of the continuing threat of food-borne illness and the increasing complexity of the food supply that the Food and Drug Administration (FDA) and other agencies within the Department of Health and Human Services (DHHS) have deemed the protection of our nation's food supply a high priority. The importance of strong federal leadership in the area of food safety cannot be overstated.

The DHHS is organized to link science to its mission. The FDA is the lead agency for applying the food and environmental laboratory science to support the regulatory and nonregulatory food safety goals. The Centers for Disease Control and Prevention (CDC) is primarily responsible for the epidemiology and laboratory science to support the infectious and non infectious disease prevention goals, while the National Institutes of Health (NIH) is the premier agency for basic and clinical biomedical research. Together these agencies promote food safety, help prevent food-borne disease, and mitigate the clinical and social impact of infectious and noninfectious illnesses.

Effective and efficient solutions to the numerous public health threats posed by an ever-changing food supply can be achieved mainly through the development and application of sound scientific principles. Building and strengthening FDA's science base is a major priority. The impact of science on food safety policy in the past has been substantial and is illustrated in four main areas:

- Science has enabled the identification of recent technologies to detect new and changing public health hazards in food and FDA has instituted an expedited review process for these new technologies. For example, advances in food virological techniques are improving our ability to detect and combat the presence of food-borne viruses, such as the hepatitis A virus.
- Science has enabled the creation of more effective and efficient approaches to solving public health problems. For example, researchers have devised multiple means for improving the safety of sprouts including the evaluation of a wide range of potential agents as a means of decontaminating both seeds and finished sprouts. FDA developed, in just one year, Good Agricultural Practices for fresh fruits and vegetables. These guidelines are being applied both domestically and overseas. In addition, FDA developed a new approach for enhancing the safety of food imports, placing increased emphasis on evaluating underlying conditions in foreign countries. FDA is also working with the U.S. Customs Service to strengthen protection at the border to block importation of unsafe food.
- Science has enabled the evolution of regulatory approaches to reflect the current state of knowledge. For example, FDA was the first federal agency to issue science-based mandatory Hazard Analysis Critical Control Point (HACCP) regulations, in this case, for seafood. In addition, FDA has proposed to expand HACCP to fruit and vegetable juices and these regulations would include a mandatory performance standard. FDA issued final regulations for warning labels for unpasteurized juices, in time for the 1998 apple cider season. In the summer of 1999, FDA proposed new regulations to enhance the safety of shell eggs, while also announcing the joint development with the U.S. Department of Agriculture of a farm-to-table strategic plan for egg safety.
- Science has enabled the development of new ways to measure the public health impact of prevention and control efforts. For example, FDA recently completed a consumer study to identify food safety practices that consumers are employing and where trends exist.

These types of impacts are the reason risk assessment is leading the Department's food safety regulations in creating solutions and the reason the DHHS and its Public Health Service (PHS) are organized in a manner that clearly links science to the goal of reducing food-borne illness. The PHS bases its public health policy on the best science available.

Good science is critical to regulatory decision-making and FDA cannot solve this problem on its own. In order to achieve high standards of food safety based in sound science—a public health goal shared by FDA and other government agencies—public and private partnerships must be formed in addition to improving communication and coordination among federal and state agencies. It is only by enhancing the science underpinning decision-making that consumers will receive the level of public health protection that they expect and deserve.

STATUTORY AUTHORITY: DIFFERENCES AMONG AGENCIES

Presented by Catherine E. Woteki, Ph.D.

Undersecretary for Food Safety, U.S. Department of Agriculture

It is widely recognized that science and risk assessment are key to the development of effective food safety policy. However, factors such as statutory authority and the availability of resources, budget and staff often ultimately determine how and when science and risk assessment enter into food safety regulatory decisions.

Over the last century, Congress authorized numerous laws authorizing the work of the three federal food regulatory agencies—the Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). These agencies make a wide range of decisions based on the their statutory authority, nature of the food safety problem, time constraints, and resources.

The statutory framework guiding each of these agencies determines the different ways in which science and risk assessments are brought to bear. The FDA and FSIS apply many comparable statutory standards in determining the acceptability of food products, including the adulteration provisions of the Federal Food Drug and Cosmetic Act (FDCA), the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS is required under the latter three statutes to maintain a continuous inspection program for meat, poultry, and egg products. FSIS inspectors must determine that these products are not adulterated before moving into commerce. In contrast, no similar requirement exists under FDCA, and therefore FDA has the burden of proving that foods other than meat and poultry products are adulterated. These statutory differences probably related to the mindset of the public and the Congress at the time of the statute's enactment.

The EPA was established in 1970 long after the establishment of FSIS and FDA. It regulates pesticides under three major federal statutes: the Federal Insecticide, Fungicide and Rodenticide Act; the FDCA; and the Food Quality Protection Act. EPA's main duties under these acts are to register pesticides, prescribe labeling and other requirements to prevent adverse health and environmental effects, and establish tolerance levels for pesticide residues. Due to the requirement that EPA's decisions be based only on public health risk and not economics, the agency's activities are heavily based on risk assessment.

In 1993, President Clinton signed an Executive Order mandating that for regulations having an annual economic impact of at least $100 million (1994 dollars), all federal agencies must conduct thorough risk and cost benefit analysis. This analysis must make clear the nature of the risk, list alternative ways of reducing the risk, describe the reasoning that justifies the proposed rule, and make a comparison of the likely costs and benefits of reducing the risk. Although this Executive Order on regulatory planning and review is not a statutory authority, it is relevant because it establishes requirements for analysis of risk and cost benefit. It should be noted that cost-benefit is not a component of risk assessment.

In addition to making food safety policies within the boundaries imposed by these statutes, FSIS, FDA, and EPA are also limited by the amount of information and time available to make these decisions. To illustrate the impact of varying amounts of time and information, food safety decisions can be divided into four major categories. The first category includes the major policy changes or enactment of new legislation that can take years and sometimes decades to accomplish. An example is the focus that FSIS has placed in recent years on reducing the risks associated with microbial pathogens through a comprehensive farm-to-table approach to food

safety. A second category is the development of major rules, which can take months or years to complete. Third are the immediate regulatory decisions that agencies must make on a regular basis, ranging from weekly to annual decisions, such as the decisions a manager might make on allocating staff resources and setting priorities. The final category involves decisions that must be made in a matter of hours or perhaps weeks such as enforcement decisions that request the recall of adulterated products or the issuance of warning letters.

The urgency with which these decisions must be made determines the extent to which science and risk assessment methodologies can be applied. The first two categories often allow time for decisions that are based on multi-step, quantitative assessments, involving gathering and evaluating of scientific and economic data relevant to an issue; then presenting the data in an understandable form, crafting different approaches to solve the problem, soliciting public input, and making the regulatory choice. In contrast, rapid decisions are frequently needed in the latter two categories—leaving little or no time to conduct a formal risk assessment. However, in these situations, a qualitative assessment can be appropriate and may be more than sufficient for setting priorities and allocating resources.

In conclusion, there are many types of science-based decisions that food safety agencies must make within specific statutory frameworks and timeframes that result in unique decisions by FSIS, FDA, and EPA. Despite multiple barriers and constraints, food regulatory agencies have been able to accomplish significant improvements under current authority. Examples include the Hazard Analysis Critical Control Point (HACCP) system for meat, poultry, and seafood; a single risk-based pesticide standard for raw and processed food; and the establishment of FoodNet and PulseNet, two hazard identification networks that are playing important roles in outbreak investigations.

Future progress in this area includes the development by the President's Food Safety Council of a full assessment report that will identify the best regulatory solutions for reducing food-borne illness as well as detect both gaps and statutory barriers to the implementation of these approaches. The need for statutory change can then better be determined and, if necessary, legislative principles developed that will assist food safety agencies in creating optimal solutions for resource allocation according to risk.

ROLE OF THE JOINT INSTITUTE FOR FOOD SAFETY RESEARCH

Presented by William F. Raub, Ph.D.

Deputy Assistant Secretary for Science Policy

U.S. Department of Health and Human Services

The Joint Institute for Food Safety Research is a new administrative entity that is to be jointly funded, staffed, and operated by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). The purpose of the Institute is to develop a strategic approach that unifies the research agendas and thus strengthens the coordination of food safety activities in three areas: among various U.S. government agencies; between the federal government and the private sector; and between the federal government and academia. The creation of the Institute was driven by the President of the United States and his plan for an expanded food safety research agenda to improve the safety of America's food.

In anticipation of the Institute, an interagency working group on food safety research has developed an extensive plan to achieve its mission of coordinating food safety research activities. Details of the estimated $1 million per year plan include:

- Appointment of up to ten people on a rotating 2-year basis as full time staff for the Institute, headed by a leading food safety scientist, possibly using the mechanism of the Intergovernmental Personnel Act.
- Creation of a new public advisory committee that would incorporate outside expertise into Institute processes.
- Development of a policy and budget committee to ensure connections with pertinent food safety agencies across the Federal Government.

In addition to developing a strategic plan to coordinate research agendas, the interagency group was also tasked with gathering and assessing an inventory of federal food safety research, in particular research funded or conducted by the USDA, the DHHS, or the Environmental Protection Agency (EPA). The assessment was organized in broad terms of the risk paradigm into two categories: the management of food-associated risks and the assessment of food-associated risks. The category on management of food-associated risks was further subdivided into detection and control of food-borne hazards. The category on assessment of food-associated diseases was subdivided into six groups: pathogenicity of food-borne microbes; drug resistance and susceptibility of food-borne microbes; epidemiology of food-associated organisms and diseases; risk assessment methods and data; food handling, distribution, and storage; and finally, economic factors associated with food safety.

Analysis of the research inventory was conducted to identify undue overlap or duplication, future needs and opportunities and, to the extent possible, facilitate agency consensus regarding research priorities. In doing this, the interagency group became aware of three major differences among agencies. First, USDA, DHHS, and EPA use vastly different systems for classifying food safety research. Second, the agencies record information at different resolutions and within different time frames. Finally, agencies have generally incompatible data systems, making interoperability even more challenging.

Nevertheless, for fiscal year 1998, the inventory revealed that approximately $156 million was spent on food safety-related research by the three agencies, with the breakdown being DHHS at $87 million, USDA at $64 million, and EPA at about $5 million. Approximately 900 projects were identified of which almost 500 were accounted for by the agencies within DHHS. A mechanism for regularly updating the inventory and analysis will allow further opportunity to compare and collect data of this sort and thus highlight areas for future focus.

In conclusion, food safety research is essential for the further innovation of tools that can quickly detect dangerous pathogens and for the development of better interventions and solutions to reduce the risk of contamination of our food. There are increasing opportunities to base policies and practices on science to achieve these goals, and the Joint Institute for Food Safety Research should be a significant asset in that quest.

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Defining Incidents Leading to Changes in Food Safety Policy

This session defined incidents leading to changes in food safety policy. Four case studies— vegetable sprouts, meat and poultry hazard analysis and critical control points (HACCP), *Escherichia coli* O157:H7 and *Listeria monocytogenes*, and the implementation of the 1996 Food Quality Protection Act—were presented. The purpose was to look at the evolution of knowledge, including lessons learned, and to think about what was done and what could have been done differently.

VEGETABLE SPROUTS

Presented by Robert L. Buchanan, Ph.D.

Senior Scientist, Center for Food Safety and Applied Nutrition

Food and Drug Administration

The microbiological safety of sprouted seeds is a unique problem for the Food and Drug Administration (FDA). It emerged as an issue in 1994 when the National Advisory Committee on Microbiological Criteria for Food—a multi-agency committee that evaluates scientific issues related to the microbiological safety of foods—identified it as a vector for food-borne disease in a white paper on the microbiological safety of fresh produce.

Sprouts represent a distinct problem as the conditions in which the seeds are germinated foster the growth of bacteria. The presence of pathogens on the seeds or seed surfaces during germination, even at extremely low levels, can be amplified by the sprouting process causing an increased health hazard. To date, no technique exists that can completely sterilize the seeds without destroying them.

Despite the risks associated with sprout consumption, shifts in consumer trends towards more healthful lifestyles over the past decade have resulted in increased consumption of raw sprouts and subsequently a dramatic increase in the incidence of outbreaks due to sprouts. These outbreaks continue in the United States, Europe, and other locations throughout the world.

Historically, sprouts have been implicated in a number of food-borne outbreaks since 1973. However, it was not until 1995 that an elevation in the number of food-borne outbreaks raised FDA concerns about the safety of sprouted seeds. At that time, FDA and the Centers for Disease Control and Prevention (CDC) met with the sprout industry to inform them of government

concerns about recent sprout outbreaks and discuss ways to address the problem. Three years later, in 1998, FDA issued an interim advisory for high-risk persons about the consumption of sprouts and initiated rapid approval of potential interventions. The same year, FDA also issued a nationwide field assignment to determine current sprout industry practices from seed to final product. Also, they held several public meetings on the safety of sprouts to provide a forum for discussion of the current situation, consumer perspectives, agricultural practices, the state of the science, and possible intervention methods.

One of the immediate concerns that FDA had to deal with in combating the problem was that most of the sprout producers were and remain extremely small businesses, around five employees or less. An inherent problem with this is the fundamental lack of available intellectual or fiscal resources to conduct research or to purchase improved technologies to conquer the problem. In addition, few sprout production facilities are actually registered and thus are hard to locate. To overcome these problems, a formal task force was set up through the National Center for Food Safety and Technology, the FDA, and the U.S. Department of Agriculture's Agricultural Research Service to coordinate research and develop a mechanism of pooling money from sprout producers to fund the research necessary to solve the problem.

In 1999, the National Advisory Committee on Microbiological Criteria for Foods, at the request of FDA and CDC, completed a thorough safety evaluation and assessment of the current state of science associated with sprouts. Specific recommendations provided by the committee include:

- Expansion of education programs on the microbiological safety of sprouts for those groups in need of information, ranging from the seed producer to the consumer.
- Increased efforts and more in-depth evaluation on how to limit the potential for contamination at the seed milling stage.
- Multiple treatments of seeds to reduce the levels of pathogenic bacteria prior to sprouting.
- Classification of all sprout production facilities as food processing operations.
- Requirement for testing of sprouts for pathogenic activity with irrigation water prior to harvest.
- Development of technologies appropriate to industry.
- Establishment of an expedited review process to assess the different interventions that have been developed to help seeds or treat sprouts.
- Creation of improved trace-back mechanisms and recalls.
- Development of methods to prevent or retard pathogen growth during germination.
- More comprehensive evaluation of seed characteristics.

This review of the current science associated with sprouts illustrates the general framework that FDA uses to deal with many emerging health problems. First, the agency focused on the primary goal of safeguarding public health. Second, the agency gathered the best science and scientists available to evaluate the problem and identify solutions. Third, FDA responded to the problem by creating solutions appropriate for the level of risk and resources involved. Finally, FDA actively involved stakeholders at all levels, and encouraged innovation.

Currently, FDA continues to resolve the distinct food safety and resource issues of the sprout industry. As surveillance and evaluation of sprout facilities continues, the agency will keep generating alerts to the industry and consumers about emerging risks associated with sprouts, provide guidance on ways to reduce those risks, and maintain involvement with stakeholders on a routine basis in order to foster new ideas and solutions. The FDA recognizes the complexity of

dealing with food safety hazards and will continue to provide the public with the safest food supply possible through application of science-based solutions to emerging food safety problems.

MEAT AND POULTRY HAZARD ANALYSIS CRITICAL CONTROL POINTS

Presented by Thomas J. Billy

Administrator, Food Safety and Inspection Service

U.S. Department of Agriculture

The Hazard Analysis Critical Control Point (HACCP) approach is a system of preventative process controls that is widely recognized by scientific authorities nationally and internationally and used throughout the food industry to produce products in compliance with health and safety requirements. About five years ago, the U.S. Department of Agriculture (USDA) decided to apply HACCP to meat and poultry products as a result of a major policy change that focused USDA efforts more effectively on risks associated with pathogens. The implementation of the system is expected to be complete in January 2000. Since the establishment of this rule, the incidence of food-borne illness associated with meat and poultry products continues to be monitored and impacts thus far appear favorable.

The need to focus more heavily on pathogenic microorganisms, and to implement preventive approaches such as HACCP, was established and supported by studies conducted over the past 15 years by the National Academy of Sciences, the Government Accounting Office, and the USDA. In 1994, the Council for Agricultural Science and Technology estimated that 6.5 to 33 million cases of food-borne illness and up to 9,000 deaths occur each year because of food-borne illness and related problems. However, public support for change in the food safety system did not truly begin to emerge until the 1993 outbreak of food-borne illness associated with *Escherichia coli* O157:H7 in undercooked hamburgers. Thus, a comprehensive strategy for change was developed with HACCP and pathogen reduction as the centerpiece.

The pathogen reduction and HACCP rule consists of four mandatory provisions. First, it requires all plants to have standard operating procedures for sanitation. The second provision requires slaughter plants to test carcasses for generic *Escherichia coli*, an indicator of fecal contamination. Third, all meat and poultry plants must implement HACCP systems as a means of preventing or controlling contamination from pathogens, as well as other hazards. Under HACCP, plants identify and evaluate the hazards that could affect the safety of their products and institute controls necessary to prevent those hazards from occurring or at a minimum, keep them within the acceptable limits. Finally, to make sure HACCP systems are working as intended, the rule mandates performance standards for salmonella at slaughter and grinding plants.

One of the key guiding principles of the rule was the clarification that industry is responsible for producing and marketing products that are safe, unadulterated, and properly packaged and labeled. With industry assuming its proper responsibility, federal agencies can use limited resources more efficiently and effectively. Another key concept was the combination of HACCP and performance standards for pathogen reduction. HACCP has to be combined with objective means of verifying food safety compliance. Up until this time, microbial performance standards for raw products, with the exception of *Escherichia coli* O157:H7 in ground beef, had not been established. The development of these rules was broadly supported by the public through numerous public meetings soliciting input.

Although the implementation of HACCP is still underway, preliminary data indicates positive results. Salmonella prevalence in broilers, swine, ground beef, and ground turkey was significantly lower after HACCP implementation than in the baseline studies that were conducted before implementation. Data released this year from the FoodNet Active Surveillance System for food-borne illness show that during 1998, the rate of campylobacter, salmonella, and cryptosporidium infections declined nationwide, and that *Salmonella enteritidis* infections declined in all states but Oregon.

Concurrent with HACCP and its implementation within meat and poultry slaughter and processing establishments, USDA's broad food safety strategy addresses every step in the food production process, from animals on the farm, to slaughter and processing, and to product distribution and preparation. The USDA is working through the Partnership for Food Safety and Education and the Fight BAC!™ Campaign to ensure that consumers know how to properly prepare, handle, and store foods. Additionally, USDA is implementing many regulatory reform initiatives to convert traditional regulations to performance standards, thus clarifying the roles and responsibilities of industry and allowing them more flexibility to develop and introduce new technologies to improve food safety.

Many lessons have been learned throughout this process. First is the need to base changes on the best science available and then make adjustments as new information becomes available. Second is the importance of making HACCP mandatory for all plants to ensure that consumers receive safe food regardless of the size of the establishment from which it originates. The third lesson learned is the need to implement HACCP in the context of a broad farm-to-table strategy to enable the far-reaching changes that are necessary to effectively reduce the incidence of food-borne illness. Finally, it is important to have public participation in the process to ensure the discovery and application of the best possible scientific solutions available.

HACCP, as part of a broad-based food safety strategy, is working as intended to reduce the incidence of food-borne illness associated with meat and poultry products. Although many scientific gaps continue to exist that prevent the establishment of “pure” public health standards, revisions in the standards will occur, as new data becomes available. For the future, USDA plans to improve efforts to quantitate the public health risks associated with certain pathogens and foods and ensure that ongoing research will provide sufficient and accurate information on which to base regulatory decisions and develop new preventative procedures. To the extent possible, regulators must continue to focus efforts on designing policies and focusing resources on the most immediate and significant public health risks.

ESCHERICHIA COLI O157:H7 AND LISTERIA MONOCYTOGENES

Presented by Michael P. Doyle, Ph.D.

Regents Professor of Food Microbiology and Director of the Center for Food Safety and Quality Enhancement, University of Georgia

Over the past two decades, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) have been conducting investigative studies to determine the origin and methods of prevention for two food-borne pathogens, *Escherichia coli* O157:H7 and *Listeria monocytogenes.* Many technologies have been developed, preventive processes implemented, and lessons learned throughout this process. Following are case studies on these pathogens, with brief overviews of what the

agencies discovered, how they responded to these findings, and ideas about what should be done in the future to prevent and reduce the incidence of these and other food-borne illnesses.

Escherichia coli O157:H7

The human pathogen *Escherichia coli* O157:H7 emerged as threat in 1982 when it was identified by CDC in two outbreaks (see Table 3-1 for history of significant outbreaks) associated with ground beef sandwiches. In a series of similar outbreaks over the next 10 years, CDC was able to determine several characteristics about the organism, most importantly that cattle were a principal source or host carrier and that contaminated cattle manure was likely the source of many infections. Studies also revealed that *Escherichia coli* O157:H7 caused hemorrhagic colitis, had no unusual heat tolerance and could be controlled by proper cooking temperatures, had a very unusual acid tolerance, and could survive fermentation of meat.

However, it was not until 1993, after a serious outbreak involving more than 700 illnesses and four deaths from eating undercooked hamburgers, that FDA changed the Food Code, which previously recommended cooking temperatures for ground beef that were insufficient to kill large populations of *Escherichia coli* O157:H7. The new Food Code criteria indicated that ground beef patties be cooked to an internal temperature of 155 degrees for 15 seconds. In addition, USDA required that safe handling labels be used for raw meat and poultry products. A year later, USDA declared *Escherichia coli* O157:H7 an adulterant in raw ground beef, established a zero tolerance, and initiated end product testing for raw ground beef. However, food-borne illness continued to increase and it was clear that further action was necessary.

Consequently, between 1995 and 1997, USDA published a rule on pathogen reduction, FDA approved irradiation of red meat, and CDC introduced the FoodNet system, an active surveillance system that monitors the occurrence of illnesses associated with selected food-borne pathogens. Additionally, CDC, USDA, and the food industry initiated the Fight BAC!™ campaign, a program which educates consumers about proper food handling techniques in the home. In 1998, USDA published a document recommending that a thermometer be used to measure the temperature of cooked ground beef patties. Currently, regulatory agency efforts to reduce food-borne illness due to *Escherichia coli* O157:H7 continue, with USDA planning to implement HACCP in all meat processing plants by the year 2000.

Listeria monocytogenes

In the mid-1980s, CDC published a case-control study on sporadic cases of listeriosis which revealed that about 20 percent of the cases were attributed to consumption of hot dogs or undercooked chicken (see Table 3-2 for history of significant outbreaks). In addition, inoculation studies revealed that *Listeria monocytogenes* can multiply rapidly in certain ready-to-eat processed meat products at refrigeration temperatures and that growth is prevented or delayed in highly acidic foods such as summer sausage. As a result, USDA initiated an end-product testing program for ready-to-eat meats. This program was shown to be ineffective as a case of listeriosis expanded its finished product testing to more products and increased the sample size of the foods from 1 gram to 25 grams. By May 1999, USDA had tested 24,500 samples of product with a positive contamination rate of 3.1 percent.

TABLE 3-1 Significant Escherichia coli O157:H7 Associated Events

Year	Noteworthy Events	Action Taken
1982	CDC conducts investigative studies to identify *E. coli* O157:H7 and its association with two outbreaks from ground beef sandwiches.	CDC identifies *E. coli* O157:H7 as a human pathogen and determines that it causes haemorrhagic colitis.
1984	Studies indicate that *E. coli* O157:H7 has no unique or unusual heat tolerance.	
1985	Several women handling manure-encrusted potatoes become ill.	Outbreak points to manure as a possible source of the pathogen.
1986	CDC investigates a farm identified as source of *E. coli* O157:H7 outbreak associated with unpasteurized milk.	CDC isolates *E. coli* O157:H7 in cattle, the first evidence that cattle can be a reservoir or carrier of this organism.
1992	Studies conducted to evaluate fate of *E. coli* O157:H7 in raw fermented salami.	Determined that organism has some very unusual acid tolerances and could survive sausage-making process.
1993	23 cases of *E. coli* O157:H7 infection associated with dry, cured salami in California.	USDA requires that processing techniques used in salami production implement critical control points. No outbreaks have occurred since.
	Outbreak involving more than 700 cases, four deaths associated with undercooked ground beef served by a fast-food restaurant chain on the West Coast.	Determined that patties cooked less than 140° F were the source. FDA responds by changing Food Code to require patties are cooked to an internal temperature of 155° F for 15 seconds.
		USDA issues a rule requiring that safe handling labels be used for raw meat and poultry products.
1994		USDA declares that *E. coli* O157:H7 is an adulterant in raw ground beef and establishes a zero tolerance.
		USDA initiates end-product testing for raw ground beef.
1995		CDC introduces FoodNet system, an active surveillance system that enables monitoring of many of the illnesses attributed to food-borne pathogens.
1996		USDA publishes rule on pathogen reduction that includes the HACCP program.
		FDA approves irradiation of red meat.
1997		CDC, FDA, USDA, and food industry initiate the Fight Bac Campaign to educate consumers on proper food handling practices.
1998		USDA requires implementation of HACCP for large meat processing plants.
		USDA publishes a key facts document recommending that a thermometer be used to measure the temperature of cooked patties.
		CDC FoodNet results reveal that *E. coli* O157:H7 infections increased in 1998, slightly above 1996 levels.
1999		USDA implements HACCP for small meat processing plants.

TABLE 3-2 Significant Listeria monocytogenes Associated Events

Year	Noteworthy Events	Action Taken
1986–1987		CDC publishes case-control study results revealing that about 20 percent of listeriosis cases were attributed to consumption of hot dogs or undercooked chicken.
1987		USDA initiates finished product testing program for ready-to-eat meats.
1987–1989	266 cases of illness in U.K. out-break associated with pate.	
1988	Listeriosis case in woman who had eaten a turkey frank.	Continual evidence that frankfurters may be a source of *L. monocytogenes.* Therefore, USDA expands its finished product testing to more products and increases sample size in testing from 1 to 25 grams of food.
1989–1999		During this time period, USDA tests 24,500 samples with positive rate of 3.1 percent of *L. monocytogenes.* Results of extensive testing indicate that certain foods, such as bratwurst and frankfurters, enable the growth of this organism at refrigeration temperatures.
1992	Outbreaks in Europe associated with meat, pate, and jellied pork tongue.	
1998	101 cases of listeriosis associated with frankfurters and possibly some deli meat.	
1999		USDA advises meat processors to reassess HACCP plans and critical control points to identify the levels of *L. moncytogenes* on source materials, the validation of processes that kill *Listeria*, steps to control environmental contamination, growth characteristics of *Listeria* in products and also finished product. USDA also provided guidance to meat processors recommending environmental and end-product testing and increased educational efforts targeted at high-risk consumers.

In 1998, a major outbreak of listeriosis occurred involving 101 cases associated with frankfurters and possibly deli meat. As a consequence, USDA advised meat processors to reassess their HACCP plans and critical control points to include measurement of *Listeria monocytogenes* levels on source materials, further classification of growth characteristics of the pathogen, and re-evaluation of processes thought to kill *Listeria.* USDA also provided guidance to meat processors, recommending both environmental contamination and end-product testing as well as increased educational efforts targeted at high-risk consumers.

Lessons Learned

Listeria monocytogenes and *Escherichia coli* O157:H7 are dangerous food-borne organisms requiring the institution of many preventive efforts. Many lessons have been learned and will continue to be discovered from trying to control such pathogens. Many opportunities for improvement emerged upon evaluation of the regulatory actions taken to reduce the incidence of food-borne illness in these two cases. These include: addressing the limitations of end-product testing, defining critical control points that have the greatest impact on product safety, applying the majority of inspection resources at these critical control points, increasing safety efforts at processing facilities where critical control points are not well-defined, and identifying more effective ways to educate consumers.

Although many of the preventive efforts that were implemented previously are beginning to appear effective, there are still many opportunities to improve the current state of food safety. These include: introducing HACCP from the farm to the table, developing and implementing effective and practical critical control points for on-farm use by producers, and overcoming the major limitations with end product testing. End product testing is a particular problem because if entire lots of product are not retained by food producers, a major portion of the contaminated lot will have been consumed by the time the product is recalled. Furthermore, because of the sporadic distribution and low level prevalence and concentration of pathogens in these foods, end-product testing may frequently not detect contaminated product. However, advancements in technology and science will facilitate further improvements in these areas.

Items to consider for the future include: defining the level of danger at which corrective federal action should be initiated, identifying and developing the roles and responsibilities of industry in solving the pathogen problem, and finding out what treatments or practices are useful for food processors and food service establishments to substantially reduce the risk of pathogen contamination of foods. Most importantly, agencies need to determine the level of responsibility consumers are willing to take in adopting safe food handling practices. It is only through the implementation of preventive approaches from farm-to-table that food safety hazards will be eliminated.

1996 FOOD QUALITY PROTECTION ACT

Presented by Joyce A. Nettleton, Ph.D.

Director of Science Communications, Institute of Food Technologists

A brief review of the statutory history indicates that the first time health was mentioned in relationship to food safety occurred in the 1954 Miller amendment to the Federal Food Drug and Cosmetic Act (FDCA). This amendment required manufacturers to submit health and safety data prior to the registration of a pesticide used on raw agricultural commodities. In 1958, the Food Additives Act was passed to regulate pesticides in processed foods. In 1993, the National Academy of Sciences (NAS) published its report, *Pesticides in the Diets of Infants and Children*, a significant event leading up to the Food Quality Protection Act. In this report it was pointed out that children differ from adults quantitatively and qualitatively in their toxicologic responses to synthetic chemicals and exposure to pesticides. It was also suggested that estimates of exposure to chemical pesticides should include both dietary and nondietary exposures and that tolerance-setting for agricultural chemicals should consider both health and agricultural factors.

In 1996, Congress passed the Food Quality Protection Act (FQPA), which amended the FDCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The FQPA made major changes in the regulation of pesticides. FQPA adopted the FIFRA definition of a pesticide chemical, which is anything that will prevent, destroy, repel, or mitigate any pest. It mandated that tolerances for pesticide residues would be established on the basis of safety, defined as a reasonable certainty that no harm will result from aggregate exposure to a pesticide by not only adults. FQPA also provided for the Environmental Protection Agency (EPA) to add an additional ten-fold safety factor to protect infants and children. Further, it required the screening of agricultural pesticides for effects on endocrine disruption.

FQPA also extended the concept of pesticides to include both raw agricultural commodities and processed foods. It restricted the consideration of the benefits of using pesticides in the process used to establish pesticide tolerances. Tolerances, the legal safe limit for pesticide residues, would be established on the basis of safety and safety meant reasonable certainty that no harm will result from exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. Aggregate exposure to pesticide residues includes food, water, and residential use.

The FQPA further mandated the review of the registration of all pesticides over the next 15 years and allowed EPA to require new data at any time in the consideration of the registration of any given pesticides. EPA must also review the tolerances for all of the more than 9,000 registered pesticides within 10 years, with a third of these reviews coming in the first 3 years and two-thirds of the total completed in 6 years.

So great was the concern from the agricultural community about the potential loss of an array of agricultural chemicals upon which the agricultural system has become highly dependent, that pressure was brought to bear on the government to ensure that there would be adequate transition time. In April 1998, a memorandum from Vice President Gore to EPA Administrator Browner and U.S. Department of Agriculture (USDA) Secretary Glickman, requested EPA to consult and work with USDA to ensure that the implementation of FQPA conformed with sound science. It allowed for transition time and integration with evolving integrated pest management techniques. It mandated a transparent decision-making process and it requested that both USDA and EPA consult with the public and other stakeholder groups in the implementation of FQPA.

Many questions have been raised because the FQPA is fairly new and implementation is just beginning. The FQPA will stimulate the accumulation of large amounts of data for the reregistration of pesticides, the registration of new pesticides, and the reassessment of tolerances. Stiffer data requirements for registration and the cancellation of existing registrations will stimulate the search for more environmentally friendly, less risky pesticides. Revisions to the application rates of pesticides, for example, are another approach that could markedly reduce exposure to and levels of residue. Developments in agricultural biotechnology will allow plant breeders to develop pest resistant varieties that express their pest resistant properties for only a short time or under limited circumstances. The encouragement of biocontrol measures and agricultural biotechnology holds immense promise to further reduce dependence on synthetic chemical pesticides. The FQPA is likely to accelerate research and development.

The opportunities for science to inform the legislative and policy environment and the whole spectrum of food production from farm-to-table are enormous. Science can contribute importantly to the implementation of policy, not just FQPA, but other food safety policies as well. Science can help develop better models for estimating exposures to and risks from chemical pesticides, develop alternative use patterns for existing and emerging chemical

pesticides, and provide data on the environmental fate of pesticides and hazards associated with breakdown products of agricultural chemicals. Science is already providing impetus for the development of safer pesticides, with lower risks to health and the environment. Finally, science is providing umbrella opportunities for greater harmonization of food safety policy among regulatory agencies.

4

Other Factors Influencing the Development of Food Safety Policy

This session focused on other factors—international, regulatory, business, consumer, and political—that in addition to science and risk assessments, can influence the development of food safety policy. Often all of these factors are weighed against one another in managing food safety hazards and determining the most acceptable level of risk.

INTERNATIONAL CONSIDERATIONS

Presented by Fritz Käferstein, D.V.M., Ph.D.

Distinguished Visiting Scientist, Food and Drug Administration and Food Safety Inspection Service, U.S. Departments of Health and Human Services and Agriculture

The Codex Alimentarius Commission is an intergovernmental body, consisting presently of 165 member states, concerned with protecting the health of consumers and ensuring fair practices in international food trade through the development of the Codex Alimentarius. The Codex Alimentarius, or food code, is an international agreed set of food standards, recommendations, and guidelines for consumers, food producers and processors, national food control agencies, and the international food trade. The Codex Alimentarius system itself is unique in that it provides an opportunity for all its member countries to join the international community in the development of such standards, recommendations, and guidelines.

In recent years, participants at the Uruguay Round of Multilateral Trade Negotiations raised the issue that many food laws and regulations adopted by countries to protect the health and safety of their consumers could become disguised barriers to trade as well as being discriminatory. As a result, Codex standards became the international reference standards for harmonization and it became clear that deviations from Codex standards code would need to be justified. The Codex Alimentarius Commission, in anticipation of this new paradigm, realized the need to examine and evaluate the process of risk assessment methodologies on which standards were based. More challenging, the Commission is also faced with determining to what extent other legitimate factors beyond science, such as social, economic and ethical issues, should be considered in its decisions.

Thus in 1995, the Codex Alimentarius Commission adopted four statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account. Of these, the first two are relevant to this discussion on international considerations influencing the development of food safety policy. First, the Commission deemed that food standards, guidelines, and other recommendations developed by the Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information in order that the standards assure the quality and safety of the food supply. The second principle stated that when elaborating and deciding upon food standards, the Codex will have regard for other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

Ever since, the Commission has been trying to find an answer to the question of what are the "other legitimate factors". The decisions it has taken since are rather inconsistent. On the one hand, in 1995 the Commission adopted, after a stormy debate and with only a small majority of its votes, the standards for four growth hormones (Estradiol 17-B, Progesteron, Testosteron, Zeranol). On the other hand, it refused to adopt after another stormy debate and with only a small majority, the standard for bovine somatotrophin (BST). However, both groups of substances, the growth hormones and BST, had been dealt with in identical ways: first in the Joint FAO/WHO Expert Committee on Food Additives (JEFCA) and thereafter in the Codex Committee on Residues of Veterinary Drugs in Food.

In spite of many time consuming debates over all of the years in the Commission itself and in some of its subsidiary committees, in particular in the Codex Commission on General Principles, the only agreement so far reached regarding the meaning of "other legitimate factors" was not to agree.

REGULATORY CONSIDERATIONS

Presented by Morris Potter, D.V.M.

Director, Food Safety Initiative, Food and Drug Administration

U.S. Department of Health and Human Services

Current U.S. food safety policies can be considered accumulations of several decades of mainly independent efforts to address specific problems, primarily based on the concepts that equate safety with cleanliness. In general, these policies respond to obvious hazards that pose clear risks in three ways. For hazards that have straightforward technical fixes, regulations have been crafted that require the application of those technologies and establish regulatory standards at the performance limit of the technology. For hazards without solutions or technologies that mitigate the problem, two other regulatory responses are exercised. The first is to keep the hazardous food entirely out of the marketplace. An alternative response is to assume that consumers can protect themselves and, therefore, regulation is inappropriate or undesirable.

This regulatory paradigm is most effective in areas of clearly defined risks when broad public concern and support for government intervention exists, and public confidence in the safety technology is high. Examples of food safety problems that have been successfully addressed by this regulatory paradigm include the application of low acid canned food regulations to control botulism; fermentation to preserve cheese, sausage, and yogurt; and the creation of water quality standards for shellfish growing waters to control shellfish-associated typhoid fever.

However, in many situations, risks are not clearly defined, traditional food safety approaches and food technologies poorly address contemporary hazards, and public confidence in new

technologies is low. An additional barrier to successful mitigation of food safety hazards is the difficult task of identifying the point of contamination along the line of production. It is not always clear whether a pathogen was introduced during distribution, processing, packaging, preparation, or in the growing fields. Without a defined point of contamination, effective and efficient regulatory action to prevent recurrence is impossible.

A traditional method for reducing food-borne illness that continues to be an important point of intervention is ensuring that safe food handling and preparation practices are used immediately prior to consumption. However, for foods prepared in a manner that can kill pathogens, the history of outbreaks associated with those foods highlights the difficulty in maintaining behaviors and practices in homes and commercial kitchens that assure an acceptable level of risk. In addition, for many foods, traditional handling in the kitchen has minimal impact on pathogens that may be present, for example, the clear water rinses that we use on fresh produce or the mild to no heating that we apply to many egg-containing dishes. Therefore, the focus is shifting towards improving the level of control of food-borne pathogens before foods reach the kitchen.

Implementing practices and policies that will eliminate pathogens from the food chain before foods arrive in the kitchen presents a regulatory challenge for several reasons. Our inability to accurately predict the public health outcomes of exposure; the restricted distribution of some disease, either geographically or to a more susceptible subpopulation; and the lack of understanding of the relative risk of various food/pathogen combinations under various conditions of handling can make it difficult to mobilize consumers and industry behind a comprehensive food safety policy. Another problem arises when the food industry responds to consumer demands with product innovation that result in unanticipated hazards.

Despite these complications, regulatory agencies are committed to forming the best scientific base possible to achieve food safety and public health goals. Agencies are working to achieve these goals by investing in research to develop and test new hazard elimination methods. They are also using risk assessments to identify needs, allocate resources, and characterize food-borne risks as correctly and publicly as possible. It has often been difficult to determine the best combination of guidance, regulation, public advisories, and warning labels or bans to apply while methods to assure the safety of these foods are designed and implemented. However, regulatory agencies will continue to make certain that new information to manage risks is put into practice as quickly and effectively as possible.

BUSINESS CONSIDERATIONS

Presented by Dane Bernard, M.S.

Vice President for Food Safety Programs, National Food Processors Association

It seems to some that the integration of scientific information with the relatively new discipline of risk assessment to inform food safety policy decisions is being done without full consideration of the impact of the potential policy alternatives on business. Worse, in cases where scientific knowledge is insufficient for conducting risk assessments or economic analyses, new food safety challenges are often met with a strong regulatory response (such as establishing a politically popular but ultimately self-limiting “zero tolerance”). Even when equally effective approaches are available, regulatory solutions are often chosen over other alternatives because regulations represent concrete, politically saleable solutions that are perceived as more acceptable to the public. This model of food policy establishment however, can significantly

impact businesses, not only in terms of daily operations but growth and profitability as well. This model also virtually ignores the fact that industry self control initiatives result in conducting more microbiological testing, chemical testing, on-site audits, field inspections, and other food safety activities, than the combined efforts of government agencies. With the recent movement toward control programs such as Hazard Analysis Critical Control Points (HACCP), in conjunction with on-going industry activities, the question arises: Should food safety issues continue to be addressed only through the existing paradigm of regulation, or is it time to consider a new framework that expands on the roles and responsibilities of industry?

To fully consider this question, we should first take a brief look at the economic importance of the industry and the potential impact of new regulations. A brief look at the food service industry shows that over the past 20 years the sector has grown by a phenomenal 300 percent, a trend that continues despite industry consolidations in other areas of the food industry. In the early 1980s, almost a quarter of the private jobs in the United States were related, in some way, to the food industry, with the highest proportion in the food service sector. In the United States, 99.7 percent of all businesses are classified as small, and in this sector food-related businesses, and in particular, food service is the number one employer, both in terms of the numbers of people employed and in the rate of growth in the employment sector. This trend however, appears to be opposite of that in the manufacturing sector.

New regulations directed at tightened controls on the food industry often increase the cost of doing business, and these can be felt disproportionately by small businesses. Between 1965 and 1985, consolidations of processing facilities shut down an average of about 4 percent of these locations per year resulting in industry concentration and removal of private sector jobs, often in more rural areas. This trend continues, and while consolidations create efficiencies, they can also be demanding in terms of providing employment for those that are dislocated. The increased costs of complying with regulatory requirements contribute to an increase in consolidation pressures.

International food trade also creates numerous challenges and opportunities for the food industry. Trade in food and food ingredients is a global industry. While this is by no means a new trend, the amount of imports as well as the origins of these goods continues to expand. While Americans enjoy the most abundant and diverse food supply in the world, the expanding import market as well as the increase in U.S. goods that are exported place more demands on the government agencies that must set standards and for the businesses that must abide by them. Among the challenges are such questions as, What level of inspection should be devoted to determining that tolerances for agricultural chemicals are met? While chemical residues on imports have been reported to be higher than on domestic products, the actual amount of the chemicals and the percentages of products that show positive for residues are so small that the real difference in scientific terms appears inconsequential. Furthermore, it is beyond government capability to provide the quantity of inspections to give the safety net that consumers seem to expect. Other questions include, Considering that the risk involved is probably trivial, does this situation warrant a high level of official scrutiny? How should such issues be conveyed to a public that appears to be uncomfortable with the concept that risk, even a trivial risk, might be associated with foods? What are the alternatives to stricter regulations, increased domestic inspection levels, and import standards in an era of limited government resources?

In lieu of absolute assurances of safety, labeling has been offered by some as one solution to consumer protection. Advocates of this approach say that warning labels for foods such as unpasteurized juices would help to protect consumers. However, a General Accounting Office

report indicated that, in their opinion, this is a costly option with little real benefit. Another possible measure would be to expand risk communication efforts with consumers to collect their perceptions of risk and create dialogue on the real cost of mitigation and reduction of these hazards.

Too often, past attempts at risk communication have been reactive rather than proactive and have been initiated in response to each individual crisis instead of addressing the system as a whole. In the future, risk communication needs to be proactive and must, in my opinion, balance industry capability with consumer preferences in establishing appropriate levels of protection.

As the number of recognized food safety hazards and the demands on regulatory agencies increases, it may be time to consider a new food safety paradigm—a paradigm that recognizes and expands upon industry's unique roles, knowledge, and resources. This paradigm should include a strong component of risk communications as well as the costs to the individual in addressing problems. Scientific details and value choices need to be separated and put into context through the risk communications process in order to elucidate those problems that can be solved by science and those that cannot. Alternatives to regulation need to be considered in order to minimize the financial and operational burdens on government, industry, and consumers. It is only through the combined efforts of industry, consumers, and regulatory agencies that the most effective means for reducing the incidence of food-borne illness can be identified and implemented.

CONSUMER CONSIDERATIONS

Presented by Edward Groth, III, Ph.D.

Director of Technical Policy and Public Service, Consumer's Union

In managing food safety hazards, in addition to relying on science and risk assessment, the costs, benefits, and rights and responsibilities of various sectors of society must also be weighed against one another to determine the most acceptable level of risk. To accomplish this, it is important that all stakeholders participate in the process and that the process be transparent. In particular, the boundaries between what can be resolved by science and what are “other factors” and value choices need to be clearly defined.

Consumer participation in food safety debates is fundamental. Consumers have a right to know and to choose what they are eating and a right to participate in determining what level of food safety risk is acceptable. However, many scientists and regulators are afraid consumers might reject something that is perfectly safe for reasons that cannot be supported by science. A complex issue, this raises many questions: To what extent should industry and government paternalistically decide what level of risk consumers should accept? How much influence should consumers have in determining what products or processes they are willing to accept? And to what extent should other factors such as values be incorporated into the food safety debate?

There is generally no forum to discuss such issues, and food safety debates often unduly emphasize what is scientifically known about a food safety hazard when the issue at hand is really a conflict of values. In considering scientific uncertainty, government and industry may need to accept that consumers might prefer a more precautionary approach. Consumers have diverse preferences and will differ on what they consider an acceptable level of risk, and consumer perception of the benefits associated with particular technologies or production methods is also variable. Overall, consumer preferences can be a powerful market force, guiding the use of technology. Consumers need to be informed and made aware of costs, risks, and

benefits and these facts should be conveyed as part of a more comprehensive communication process.

Labeling is emerging as a possible solution for dealing with the boundaries between government regulations and consumer choices. In the past, this type of a solution has often been rejected because much label information relates to subjective preference values other than safety. Furthermore, defining which factors should be dealt with by labeling and which by setting standards has not yet been integrated into risk analysis discussions.

The bottom line for industry and regulatory agencies is to acknowledge that consumers want to be a part of the market and have their preferences and requests expressed. Consumers want to participate in decisions about which products will be adopted and what they will put on the table. In order to achieve this, all stakeholders must continue to grapple with the issue of what is acceptable for consumers to decide in the marketplace and define those factors beyond science that should be included as part of the food safety and food quality discussion.

POLITICAL CONSIDERATIONS

Presented by Eric Juzenas, J.D.

Professional Staff Member, U. S. Senate Agricultural, Nutrition and Forestry Committee

Federal and public entities alike support a science-based regulatory system that directs its resources towards those food safety and health hazards that represent the greatest risks and that will achieve the greatest benefits in public health. Unfortunately, defining the greatest risks and best approaches for solving food safety problems is not always straightforward. More often than not, agencies must make policy decisions based on insufficient science and technology information. Additionally, all stakeholders must face the more challenging issue of determining the level of risk federal agencies should consider in making decisions despite inadequate information.

To deal with these uncertainties, agencies have incorporated, often at Congress's behest, many information management techniques such as risk assessment and cost-benefit analysis to frame available information into a format that is understandable to the public and private sectors and which can contribute to decision-making. When good data and methodologies exist to drive risk-assessment and cost-benefit analyses, they can help “depoliticize” decision-making by allowing decisions to be based on objective factors. However, one of the dangers of many broad-based regulatory reform proposals is that they force agencies to base decisions on these quantitative tools when there may not be reasonable available data or methodologies to support such a heavy reliance. In essence, most regulatory reform proposals simply assume that there are sufficient data and methodologies available or that they can be developed, and all that Congress needs to do is direct federal agencies to use them more.

Furthermore, even incorporating well-done analyses into regulatory decisions can be complex since the rulemaking process often becomes centered on issues such as public values, funding, and resource availability, that are very difficult to quantify precisely. In food safety this means that, even with the best quantitative analysis, it still must be decided how much is too much and how many tax dollars can be spent.

In general, three main areas demonstrate the countervailing pressures that Congress faces when trying to link science and food safety policy: the pressure to demonstrate results from food safety programs, the need for enhanced harmonization and coordination of food safety activities,

and the need for a better understanding of how to best implement a risk-based food safety regulatory system.

Presently, an effective way to illustrate the benefits and thus rank the effectiveness of food safety programs at the federal program level in a manner truly driven by objective data does not exist as traditionally these programs have not been authorized by Congress. Current surveillance and trace-back networks in food safety seem insufficient to provide the quantitative estimates necessary to accurately define the benefits (in terms of lives saved or illnesses prevented) of a given regulatory program. In fact, I do not think that people know what it would take in practical terms to develop an information infrastructure for such an analysis. Without quantitative data to link programs and outcomes, support for public health programs like food safety from the Congress and the private sector can be hard to generate. Recent efforts to alleviate this problem include PulseNet and FoodNet, two surveillance and monitoring systems that were developed to aid in tracing food-borne illness. Given adequate funding, these networks seem to have the potential to provide quality data to allow fairly accurate estimates of the national burden of food-borne illness.

Another area challenging Congress is determining how to better coordinate food safety activities across the different federal agencies and identify the necessary changes in existing food safety statutes. Possible solutions thus far include establishment of a unified budget authority, creation of a single food safety agency, and/or conception of an integrated process for food safety programs. A recent attempt to address this problem was initiated in 1998 with the creation of the President's Council on Food Safety, a committee charged with the task of coordinating budgets and developing programs for food safety activities across agencies. Much remains to be resolved regarding the extent of changes necessary to make the system more effective and several different legislative programs proposing alterations to the system are being reviewed by Congress.

Finally, perhaps one of the greatest challenges that Congress faces in addressing public health issues in today's environment is identifying which aspects of the regulatory system need to change to foster better decision-making practices. As mentioned above, agencies have developed many information management techniques to deal with these issues. But public and industry participation will be key in determining these changes and making this process transparent. A good example of recent efforts to create these types of solutions are Hazard Analysis Critical Control Points (HACCP) based systems—systems that identify critical hazard points along food production lines and then develop specific techniques to control these.

In conclusion, there are many countervailing pressures that regulatory agencies must take into consideration when developing food safety policy. These range from identifying which products present the greatest risks to determining how to include all stakeholders in decision-making processes. Agencies are currently identifying ways to increase industry and consumer involvement in developing alternatives to command and control regulations and recent efforts to incorporate such solutions have yielded many valuable lessons. Effective navigation of these issues will determine the level of success that food safety agencies have in achieving the most cost effective risk reductions possible while sustaining a food supply that consumers can rely on.

5

Using Science-Based Risk Assessment to Develop Food Safety Policy

The purpose of this session was to explore how science-based risk assessments are utilized to develop food safety policy. The session began with an overview of the risk assessment process, followed by the promises and pitfalls of risk assessment, the recently completed federal government microbiological risk assessment of *Salmonella enteriditis* in eggs, and risk communication. The session ended with a report on a series of World Health Organization consultations on microbiological risk assessments.

HISTORICAL PERSPECTIVE OF RISK ASSESSMENT AND REVIEW OF STEPS IN THE PROCESS

Presented by Joseph V. Rodricks, Ph.D.

Managing Director, The Life Sciences Consultancy

Risk assessment is the process through which information on risks is identified, organized, and analyzed in a systematic way to get a clear, consistent presentation of the data available for practical decision-making. It is not a formula, but an analytical framework that defines the types of data and methodologies that are to be used to analyze a risk, and explains why, and also details the uncertainties and problems associated with particular assessments. The results of the risk assessment process are then the basis for risk management process, the process by which solutions for controlling risks are obtained. The purpose of risk management is public health protection.

The first attempts to deal with hazardous agents began in the 1940s to 1950s, when toxicologists looked at data on hazardous chemicals, such as pesticides and food additives, and derived limits on exposure in order to protect human health. In 1954, two Food and Drug Administration (FDA) toxicologists, Lehman and Fitzhugh, published a paper that defined the basis for what is now referred to as the acceptable daily intake (ADI), a level thought to be a threshold intake of a chemical for a very large population of people, below which there should be no significant toxicity risks. In this paper, the toxicologists not only characterized a procedure for defining the ADI, they also described the use and application of safety factors and how animal data would be used so that interested individuals could understand how the ADIs were derived. The development of the ADI was based on the notion that hazardous chemicals will not be a

problem unless a threshold dose is exceeded. All substances would express toxicity at sufficiently high doses, but under the Lehman-Fitzhugh model, all such substances would be safe (i.e., pose no significant risks) unless the threshold dose was exceeded. The problem they attempted to solve was to identify the threshold dose for a large and variable human population.

This threshold model was not applied to carcinogens. Exposure to carcinogens at any level above zero was thought to increase the probability of a carcinogenic process moving along toward completion. This gave rise to the phrase "no safe level" and the Delaney Clause, which required zero tolerance for any intentionally introduced food additive that could be demonstrated to cause cancer in lab animals or man. For this reason, regulatory agencies often avoided dealing with carcinogens, and either banned them where it was easy to diagnose, or ignored them, or resorted to criteria unrelated to health for decision-making. In 1973 FDA developed a model for the relationship between exposure and carcinogenic risk that assumed the absence of a threshold and a direct proportionality between dose and risks. Through the use of this model, the FDA made decisions that human health could still be protected at a very small predetermined level of risk and that scientific uncertainties would be based on conservative health protective assumptions.

In 1983, in response to a Congressional request to set up a separate, nonfederal institution to conduct risk assessments to keep then "untainted" by the regulatory process, the National Academy of Sciences published a report titled *Risk Assessment in the Federal Government.* This report, for the first time ever, clearly elucidated a framework for both the risk assessment and risk management processes. An updated version of the report was published by the Academy in 1994 that further promoted the rise of explicit regulatory guidelines for risk assessments to ensure that risk assessments would not be manipulated, on a case-by-case basis, to achieve predetermined regulatory outcomes.

The risk assessment and management processes were developed for two major reasons. One of the most important reasons is that, in almost all cases, it is beyond current technological capabilities to directly measure risks to large populations from chemical agents, pathogens, and other hazards. Without going through the risk assessment process, there is no scientific basis for regulatory decision-making. Another reason is that statues require premarket determinations of safety so that the level of risk of a substance to human health can be evaluated prior to exposure.

Initial risk evaluation of an agent involves defining its characteristics, specifically its inherent hazardous properties. This includes describing the kind of toxicity or the type of illness it causes, as well as whether the information is derived from human, animal, or other studies. Further evaluation frames the dose-response assessment. This analysis defines how the severity or incidence (or both) of adverse effects change with exposure conditions.

The final stage in the evaluation of an agent is the risk characterization process that estimates the risks involved as well as describes the potential uncertainties to the population being evaluated. This step defines the distribution of a population around a predetermined threshold or estimates the probability of an effect to the population over a period of time. It answers the question of how many people might be affected by this agent and to what degree.

From this information, risk management decisions can be made about exposure levels that pose insignificant risks for large populations, taking into account not just the data, but its limitations and applicability to large populations.

In analyzing and working with the data, two areas requiring special consideration are accounting for variability and identifying exceptions. Currently, adequate research is not available to provide data on distributions for either thresholds or effects in populations or to

specify the effects of particular levels of exposure. Thus, variability is dealt with through the use of uncertainty factors that are typically factors of 10. Additionally, risk is still described as a function of dose for a range of exposures above zero by the use of linear models.

A more common way that food safety decisions are currently made is to define risk goals and apply regulatory measures at specific hazard and dose response levels. Regardless of the method used, controversies arise in both these decision-making models over the amount of data needed to make these types of decisions.

Risk assessment and management processes continue to be scrutinized and improved upon in order to create effective processes for incorporation into the public health or regulatory decision-making process. Currently, efforts at improvement are being focused on issues such as variability and risk distributions in a population rather than relying on point estimates. Despite some weaknesses in these methodologies, both risk assessment and risk management will continue to be valuable analytical techniques for organizing data on hazardous agents in order to make practical decisions.

PROMISE AND PITFALLS OF RISK ASSESSMENT

Presented by George M. Gray, Ph.D.

Deputy Director, Harvard Center for Risk Analysis

The role of risk assessment in food safety is growing. Evaluations of food-borne pathogens, pesticide residues, and genetically modified organisms inform and influence important policy decisions. Risk assessment has great promise for guiding food safety policy, but several pitfalls must be avoided. If these shortcomings are addressed we can be confident that risk assessment will help us make the best use of scientific information in food safety decisions. Years of risk assessment experience in engineering, environmental evaluation, and food safety have highlighted four pitfalls:

1. *Ignoring Variability.* Variability is important because everyone in a population is not at the same risk. The public understands sources of variability like differences in food consumption or water intake and expects risk assessors to reflect these facts. Quantification of variability can aid risk management in identifying high-risk groups or new mitigation strategies. Reporting risks as population averages hides too much information.
2. *Ignoring Uncertainty.* Risk assessments often must proceed in the face of incomplete data and knowledge. We may not know the true range of consumption of a particular food, for example. The presence of this uncertainty means that single point estimates of risk are insufficient. Risk assessors must quantify uncertainty to help risk managers and the public understand how well a risk is known and to guide future research and data gathering efforts.
3. *Favoring Consistency Over Science.* There are often concerns that risks are assessed on a case-by-case basis and a lack of standards will allow evaluations to be manipulated. On the other hand, science shows us that hazards are rarely similar and standard methods cannot reflect the diversity of sources of risk.

   An example comes from the world of environmental risk assessment. The standard and consistently applied methods of cancer risk assessment used by the Environmental Protection Agency (EPA) assume a dose-response function that is linear in the low-dose region and has no threshold. There is evidence that some agents, like certain types of radiation and directly mutagenic chemicals, may indeed have this type of dose-response relationship. However, many

scientists believe the linear, no-threshold approach to risk estimation is inappropriate for many other chemicals, such as some that are not direct mutagens

This means that when EPA applies standard procedures to all chemicals, regardless of how appropriate they might be for a given substance, the amount of conservatism in a risk estimate varies greatly. A risk estimate for a powerful direct mutagen may be quite close to the calculated "plausible upper bound" while for a nonmutagenic compound the estimate may be an extreme overestimate of plausible risk. Two risk estimates that are generated through consistent procedures may have very different levels of scientific plausibility. Risk assessment guidelines should be sufficiently flexible to reflect the science.

4. *Not Evaluating the Influence of Assumptions.* Risk assessors must choose specific data and models when undertaking an analysis. Often there are other scientifically plausible data or models that would have large effects on the results of an assessment. To avoid misleading risk managers and the public, risk assessors must present risk estimates characterized by alternative assumptions and methods. If possible, the choices with the greatest scientific support should be identified.

Managing these pitfalls will require the development of strong connections and lines of communication between the scientific and risk assessment communities. Risk assessment is often dismissed in the scientific community when it is perceived to ignore relevant science. At the same time, many in the scientific community are not aware of the methodological developments of state of the art risk assessment. Risk assessors must reach out to scientists to aid with characterization of hazards and consequences and in constructing and interpreting models.

Peer review of both the science and the methods of a risk assessment will improve the analyses and increase the credibility of the results. Transparency in the process is necessary to building trust with all stakeholders. Anyone should be able to recreate a risk assessment based upon the documentation of the study. As risk managers, scientists, and risk assessors begin to address these pitfalls, risk assessment will become a more useful and effective tool for food safety.

USING RISK ASSESSMENT TO ESTABLISH FOOD SAFETY POLICY: SALMONELLA ENTERIDITIS

Presented by Robert L. Buchanan, Ph.D.

Senior Scientist, Center for Food Safety and Applied Nutrition

Food and Drug Administration

Risk assessment techniques are increasingly being applied to microbiological food safety hazards. These techniques are powerful tools for incorporating science, identifying priorities, reducing complexity, and evaluating strategies in the regulatory process. Their purpose is to provide the information necessary for decision-making. This information can include, but is not limited to, known and unknown factors, the level of uncertainty and variability, the amount of bias or constraints present, and methods for making the entire process transparent. One of the first quantitative microbial risk assessments undertaken in direct support of a regulatory decision-making process was with the case of the human pathogen, *Salmonella enteriditis.*

Salmonella enteriditis is one of the most common serotypes associated with food-borne illness and can cause primary gastroenteritis, a potentially life-threatening illness in high-risk populations. From 1976 to 1995, there was an approximately eightfold increase in *Salmonella*

enteriditis cases with outbreaks appearing regionally in both the United States and Europe. Due to the increased number of outbreaks and rate at which *Salmonella enteriditis* was being isolated in the environment, the Centers for Disease Control and Prevention and the Food and Drug Administration conducted detailed studies of this emerging food safety concern. From these studies, the agencies concluded that outbreaks were almost always associated with the consumption of undercooked, otherwise clean shell eggs and that the source of the contamination was primarily associated with an increased incidence of transovarian infection within chickens before the egg is formed. The cause of the infection, which is associated with infections of either the ovaries or the oviduct of the chicken, is under active investigation.

In 1996, both in response to a risk assessment clause requiring the U.S. Department of Agriculture (USDA) to conduct a risk assessment prior to undertaking any new major regulatory action and to the increased incidence and illnesses related to *Salmonella enteriditis*, the USDA's Food Safety Inspection Service (FSIS) in conjunction with several other USDA and U.S. Department of Health and Human Services agencies initiated a microbial risk assessment. The assessment was also undertaken to evaluate the public health impact of a 1991 Congressional amendment mandating that shell eggs packed in containers destined for consumers be stored and transported at an ambient temperature not to exceed 45° F and that the containers be labeled to state that refrigeration is required.

As a preface to the steps taken by the *Salmonella enteriditis* risk assessment team, it is important that several unique characteristics of the microbial risk assessment process be highlighted. Unlike a chemical risk assessment, a microbial risk assessment deals with a single cell or one unit of infection and the primary interest is in finding and/or developing appropriate mitigations to minimize risk rather than setting exposure limits or ranges. Microbial risk assessments are usually categorized as either risk ranking exercises or product pathogen pathway analyses. Risk ranking exercises prioritize multiple risks for resource allocations. Product pathogen pathway analyses assess the entire process from beginning to end and then elucidate the risk for an adverse reaction within a given population. This type of analysis is a method used to model specific combinations of pathogens and products in order to identify the risks and contributing factors associated with a particular hazard.

In the case study on *Salmonella enteriditis*, the core team employed a product pathogen pathway analysis to assess the pathogen. The team divided the analysis into five modules to track the movement of contaminated eggs through 16 different pathways. Hazard identification and dose response were known and risk characterization was defined by using multiple endpoints.

The product pathogen pathway analysis proved to be an extremely powerful tool, not only to identify data gaps and areas of research needs, but because it gave risk managers the ability to evaluate a variety of mitigation or risk reduction strategies quantitatively. For example, refrigeration temperature as mandated under the 1991 amendment was evaluated as an effective risk reduction strategy. Using the model, it was determined that there would be an approximate 8 percent decrease in human illness if shell eggs were handled under 45° F ambient temperature during distribution, reflecting the fact that under certain conditions *Salmonella enteriditis* multiplies in eggs at ambient temperatures of 50° F and above. Therefore, FSIS made the decision to use the ambient temperature of 45° F as the requirement for the distribution, display, and storage of shell eggs. FSIS is currently expanding the egg product model to develop scientifically sound guidance for the egg product producers.

In summary, product pathogen pathway analysis is a powerful new tool for organizing information, evaluating potential risk reduction strategies, and identifying and prioritizing future

research needs. Since models can be updated and expanded readily as new data become available, it is also an effective method for quantitatively linking regulatory programs to actual public health consequences and forecasting predictions. However, it is not an answer unto itself, and the weaknesses and possible pitfalls inherent in the technique need to be recognized. It should be stressed that the process must be as transparent and understandable as possible in order to be effective. Scientists, risk managers, policy makers, and the public need to work together to develop a food safety system that meets the level of tolerable risk and then continue to improve upon on it.

RISK COMMUNICATION: DEFINING A TOLERABLE LEVEL OF RISK

Presented by Susan L. Santos, Ph.D.

Founder, Focus Group

The National Research Council (NRC) in its 1996 in report, *Understanding Risk*, defined risk communications: “Risk communication is an interactive process or exchange of information and opinions among individuals, groups, and institutions. It involves multiple messages about the nature of risk, and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management”.

Risk communication is a process by which all stakeholders are given the access and information they need to understand and participate in an issue. To be effective, risk communication must be an interactive process involving not just the scientific aspects of a risk. The public needs access to information to gain more knowledge about the issues involved. Risk communication is often an emotional and value-laden process, and the dilemma facing many risk managers is developing ways to incorporate and balance the weight of social and scientific factors. The problem more simply stated is that technical experts tend to focus primarily on the science rather than societal concerns. How can this dilemma be avoided or solved?

First, it is important to highlight and further elucidate the complex construct associated with risks. The risk assessment process involves both variability and uncertainty and risk characteristics are both objective and subjective, the nature of which is often reflected in the public's response. Risks are not one-dimensional and must be viewed in cultural, social, and political dimensions. Problems arise when known scientific facts, estimations and assumptions, and legitimate social and political factors are poorly differentiated for both scientists and stakeholders or when legitimate factors beyond science are not included in the assessment. The definition and assessment of risk must be both a scientific and social process and should include what the 1996 NRC report referred to as a broader “analytic-deliberative” process to fully define and characterize risks. It is the dichotomy between the scientific and social issues that sometimes confuse the risk assessment and communication processes and how they are translated for decision-making.

Barriers to effective risk communication include not only a lack of understanding by the public of the technical issues involved in risk assessment, but also the public's lack of trust in science, particularly the government and industry. Scientists are not trained in communicating to lay audiences and thus complex and confusing messages are often produced in an effort to transmit information about an issue. Media distortion is also an obstacle to effective communication and the media often focuses on one side of the issue at the expense of another. How can the gaps between how the public and media view and discuss risk and the way

scientists and decision-makers talk about it be understood and bridged? And how do scientists gain the trust of the public?

One of the most useful techniques for overcoming these barriers to communication is by ensuring that the target audience or stakeholder group understands and is involved in defining the scope of issue analysis as well as the deliberation. To do this, risk communicators must first determine who is the target audience, that is, who will see the issue as relevant and salient and then, tailor a clear message to that particular audience using the most efficient delivery channels available.

Risk communicators must be also transparent and open about the risk assessment and risk management decision-making process and explore opportunities to make risks less involuntary, to create a climate of trust, and to allow a better exchange of information with stakeholders. Risk managers must translate scientific findings into understandable terms that can be both given to the media and appropriately communicated to the public. Risk assessors and communicators need to adapt to and comprehend how stakeholders frame risk issues and risk managers must recognize the role of those qualitative dimensions in risk management. They must also acknowledge that the questions and concerns of the public and experts are likely to be different and that both are valid.

In closing, risk communicators and managers need to analyze and better understand the ways the public receives information and improve their understanding of the public's concerns and information needs. Risk managers need to find ways of incorporating qualitative values and information into decision-making. A framework must be developed via a coordinated effort between the public and scientists that helps to outline what messages, what channels, and what spokespersons are used to communicate risk. The issue of trust and credibility must continue to be addressed along with transparency in decision-making. Defining a “tolerable level of risk” clearly requires good science and risk managers who are willing to open up to and value all stakeholder contributions to the process.

JOINT FAO/WHO CONSULTATION ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOOD

Presented by Lester M. Crawford, D.V.M.

Director, Georgetown Center for Food and Nutrition Policy

The fourth and final report in a series of World Health Organization (WHO) and Food and Agriculture (FAO) consultations on microbial risk assessment was recently released. The consultations were designed to institutionalize microbial risk assessment as a tool for international food safety.

The first consultation was held in 1995 to examine whether or not microbial risk assessment was feasible internationally to solve the microbiological problems that beset international food trade and also international public health. Since there are many conflicts around the world with respect to food safety issues, it was thought that microbial risk assessment could be used as an international instrument to bring the nations closer together.

The task of the final consultation was to determine how microbial risk assessment should be done. It was determined that the WHO and FAO under the rubric of Codex Alimentarius would be the providers of expert advice. In addition to providing expert advice, WHO and FAO would be the clearinghouse for individuals to work with individual nations. They would review and interpret the microbial risk assessments and provide advice on how to use these at the national

level. One of the first things that will be done is to develop a model for a microbial risk assessment. Then they will have to tell nations how to use the microbial risk assessment and its advantages.

One of the things that risk assessment does if it becomes the national and international instrument, is that it will identify risk managers and will train them on how to deal with risk assessments. The interface between risk assessors and risk managers will be the most difficult part of the process. The report calls for WHO and FAO to be the stimulus for regional and international risk training.

One of the products of WHO and FAO activities will be a communications network that will flow from a central focus to countries that have and have not made progress in microbial risk assessment. It is hoped that WHO and FAO will also build a body of literature on an international level with cooperation from national institutions. In addition, regional offices such as the Pan American Health Organization and others should go out and promote microbial risk assessment. Most importantly, the WHO and FAO should develop a decision support tool or tools and offer technical cooperation.

The report suggests that resources for these activities should come from national governments. In addition, bilateral agencies should be involved and the case studies should be collaborations between developed and developing nations. A bilateral agency such as the World Trade Organization (WTO) has been very important in dealing with conflicts between nations such as the ban by Europe on meat from animals treated with anabolic steroids or hormones. When the WTO overturned the European ban on hormone-treated meat, Europe demanded 15 months to do a risk assessment because this was done before Europe took action. Had the European Union analyzed the risks earlier, much embarrassment could have been avoided.

6

Overview

The purpose of this workshop was to focus on many of the issues that complicate the development of microbiological food safety policy, focusing on the use of science in establishing policy and in determining the utilization of food safety resources. A large array of themes and issues were illuminated during the workshop. Although the Food Forum cannot make conclusions or recommendations based on the presentations at the workshop, the following is an overview of the issues that were illuminated.

WHERE DO WE GO FROM HERE?

Presented by M. Jaye Nagle

Director, Scientific Relations, Kraft Foods

The specific goal of this symposium was to explore the issues that exist between the use of science in both establishing food safety policy and utilizing food safety resources. The presenters successfully accomplished this goal through a variety of perspectives, rich discussion, and provocative questions. The following is a brief overview of the major issues that were illuminated during the conference and raised for future consideration.

During the symposium, it became clear that most of the participants thought that there is a need for:

- utilization of science in risk assessments to lead to better food safety policy;
- more and better data related to food safety, and recognized that FoodNet and PulseNet, food-borne illness monitoring systems, are important in that regard;
- enhanced coordination among food safety agencies, academia, and the private sector in order to facilitate effective and efficient utilization of all food safety resources and to direct food safety research priorities;
- broad stakeholder involvement and engagement on food safety policy issues;
- proactive responses/reactions to food safety threats and issues as opposed to reactively addressing emerging hazards;
- compelling and effective food safety education across the food chain, especially targeted to “at risk” consumers;

- consideration of other factors beyond hard science and the extent to which the other factors should play a role, with or without formal recognition, in risk assessment processes;
- inclusion of better risk communication approaches;
- open and transparent risk management and regulatory decision-making processes;
- the importance of establishing a logical framework for the risk managers and stakeholders, in particular identifying and clearly distinguishing variability and uncertainty; and
- receptivity to new data and information, both negative and positive.

In contrast to the above issues, there are also areas where differences of opinion exist and these include:

- whether current statutory authorities, in some ways, impede the application of science and risk assessment in food safety policy decisions;
- how best to employ Hazard Analysis Critical Control Point (HACCP) and pathogen reduction strategies and how to define the limitations on some end product testing programs;
- how to best apply inspection resources and monitoring programs across the farm-to-table continuum for maximum assurance of food safety;
- "how safe is safe enough;" what does "tolerable level of risk" mean;
- how much and which information should go on labels;
- defining the best approach or mix of regulatory tools to achieve food safety public health goals; does it include guidance, consumer advisories, warning labels, or regulation;
- how best to integrate factors beyond hard science into decision-making; and
- whether social scientists should be brought in to help shape and communicate information about risk and to what extent.

Finally, emerging areas for future consideration were also discussed, such as:

- defining guidelines on the application and interpretation of legitimate factors other than science that are relevant in the risk management process;
- creating a systematic structure or process to modify, update, and redesign existing regulations;
- enhancing the use of full risk characterizations in the regulatory decision-making process as well as advancing state of the art in risk assessment;
- enhancing the communication between scientists and risk assessors; and
- bridging the communication gap between the public/stakeholders and the risk managers and/or risk communicators.

Clearly, ensuring food safety is truly a common goal. Many lessons have been learned and improvements made as techniques and regulations are generated and applied to create a safer food supply, yet much room for improvement remains. There are a number of fora where food safety improvement are being discussed such as the Joint Institute for Food Safety Research, the Codex Alimentarius process, the President's Food Safety Council, the National Advisory Committee on Microbiological Criteria for Foods, and ongoing microbial risk assessments. Although the Food Forum does not make recommendations, everyone can participate in making suggestions to any of the above fora.

Appendix A

Workshop Agenda

Tuesday, July 13, 1999

I. Welcome and Introduction to the Topic

8:45 am	Welcome and Introduction *Sandra A. Schlicker*, Director, Food Forum *Michael P. Doyle*, Chair, Workshop *Fergus M. Clydesdale*, Chair, Food Forum

II. Science as the Basis for Food Safety Policy
Moderator: *Fergus M. Clydesdale*, Chair, Food Forum

9:00 am	Good Science: Critical to Regulatory Decision-making *Jane E. Henney*, Commissioner, FDA
9:20 am	Statutory Authority: Differences among Agencies *Catherine E. Woteki*, Undersecretary for Food Safety, USDA
9:45 am	Role of the Joint Institute for Food Safety Research *William F. Raub*, Deputy Assistant Secretary for Science Policy, DHHS

III. Defining Incidents Leading to Changes in Food Safety Policy
Moderator: *Marsha N. Cohen*, Member, Food Forum

10:00 am	Vegetable Sprouts *Robert L. Buchanan*, Senior Scientist, FDA
10:25 am	Meat and Poultry Hazard Analysis Critical Control Points (HACCP) *Thomas J. Billy*, Administrator, Food Safety and Inspection Service, USDA
10:50 am	Break

11:10 am	*Escherichia coli* O157:H7 and *Listeria monocytogenes* *Michael P. Doyle*, Director, Center for Food Safety and Quality Enhancement, University of Georgia
11:35 am	1996 Food Quality Protection Act *Joyce A. Nettleton*, Director, Science Communications, Institute of Food Technologists
12:00 pm	Audience Discussion with Presenters
1:00 pm	Lunch

IV. Other Factors Influencing the Development of Food Safety Policy
Moderator: *Stephen H. McNamara,* Member, Food Forum

2:10 pm	International Considerations *Fritz U. Käferstein*, Distinguished Visiting Scientist, USDA and FDA
2:30 pm	Regulatory Considerations *Morris Potter*, Director, Food Safety Initiative, FDA
2:50 pm	Business Considerations *Dane Bernard*, Vice President for Food Safety Programs, National Food Processors Association
3:10 pm	Consumer Considerations *Edward Groth III*, Director of Technical Policy and Public Service, Consumer's Union
3:30 pm	Political Considerations *Eric Juzenas*, Professional Staff Member, U.S. Senate Agricultural, Nutrition and Forestry Committee
3:50 pm	Break
4:10 pm	Audience Discussion with Presenters
4:50 pm	Summary of Sessions II, III, and IV *Michael P. Doyle*, Chair, Workshop
5:00 pm	Adjourn

Wednesday, July 14, 1999

8:30 am Opening Remarks
Fergus M. Clydesdale, Chair, Food Forum

V. USING SCIENCE BASED RISK ASSESSMENT TO DEVELOP FOOD SAFETY POLICY
Moderator: *Michael P. Doyle*, Chair, Workshop

8:45 am Historical Perspective of Risk Assessment and Review of Steps in the Process
Joseph V. Rodricks, Managing Director, The Life Sciences Consultancy

9:10 am Promise and Pitfalls of Risk Assessment
George M. Gray, Deputy Director, Harvard Center for Risk Analysis, Harvard University

9:35 am Using Risk Assessment to Establish Food Safety Policy – *Salmonella enteriditis*
Robert L. Buchanan, Senior Scientist, FDA

10:00 am Risk Communication: Defining a Tolerable Level of Risk
Susan L. Santos, Founder, Focus Group

10:25 am Break

10:45 am Joint FAO/WHO Consultation on Risk Assessment of Microbiological Hazards in Food
Lester M. Crawford, Director, Georgetown Center for Food and Nutrition Policy, Georgetown University

11:10 am Audience Discussion

VI. OVERVIEW

12:05 pm Where Do We Go from Here?
M. Jaye Nagle, Director, Scientific Relations, Kraft Foods

12:20 pm Closing Remarks
Michael P. Doyle, Chair, Workshop

Appendix B

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