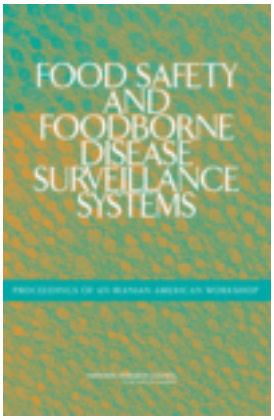

Food Safety and Foodborne Disease Surveillance Systems: Proceedings of an Iranian-American Workshop

Office for Central Europe and Eurasia, National Research Council, in cooperation with Research Center for Gastroenterology and Liver Diseases Shaheed Beheshti University of Medical Sciences, Iran, World Health Organization, Food and Agriculture Organization

ISBN: 0-309-65424-6, 138 pages, 6 x 9, (2006)

FOOD SAFETY AND FOODBORNE DISEASE SURVEILLANCE SYSTEMS

PROCEEDINGS OF AN IRANIAN-AMERICAN WORKSHOP

Edited by Glenn Schweitzer, Mohammad Reza Zali, and George Jackson

Office for Central Europe and Eurasia
Policy and Global Affairs

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

in cooperation with

Research Center for Gastroenterology and Liver Disease
Shaheed Beheshti University of Medical Sciences, Tehran

World Health Organization

Food and Agriculture Organization

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, N.W. Washington, DC 20001

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This study was supported by the National Research Council. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the organizations or agencies that provided support for the project.

International Standard Book Number 0-309-10033-X

One copy of this report per request is available from the Office for Central Europe and Eurasia, National Research Council, 500 Fifth Street, N.W., Washington, DC 20001; (202) 334-2644; Fax (202) 334-2614

Additional copies of this report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu.

Printed in the United States of America

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

The **National Academy of Sciences** is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Ralph J. Cicerone is president of the National Academy of Sciences.

The **National Academy of Engineering** was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Wm. A. Wulf is president of the National Academy of Engineering.

The **Institute of Medicine** was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Harvey V. Fineberg is president of the Institute of Medicine.

The **National Research Council** was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Ralph J. Cicerone and Dr. Wm. A. Wulf are chair and vice chair, respectively, of the National Research Council.

www.national-academies.org

NATIONAL RESEARCH COUNCIL COMMITTEE ON THE U.S.-IRANIAN WORKSHOP ON FOOD SAFETY

Michael P. Doyle (*chair*)
Director/Professor, Department of Food Science & Technology
University of Georgia

William E. Keene
Senior Epidemiologist, Acute and Communicable Disease Program
Oregon Department of Human Services

Mansour Samadpour
Assistant Professor of Environmental and Occupational Health Sciences
University of Washington

NRC STAFF

Glenn Schweitzer
Director
Office for Central Europe and Eurasia

Sara Gray
Senior Program Associate
Office for Central Europe and Eurasia

Amy Moore
Program Assistant
Office for Central Europe and Eurasia

Preface and Acknowledgments

In October 2004 the Research Center for Gastroenterology and Liver Disease of Shaheed Beheshti University hosted in Tehran an Iranian-American workshop on Food Safety and Surveillance Systems for Foodborne Diseases. The purposes of the workshop were to initiate contacts between Iranian and American specialists, exchange information about relevant activities in the two countries, and set the stage for future cooperation in the field. The participants also identified important aspects of food safety that should be addressed more intensively by both countries, including surveillance, research, international trade, and risk assessment. The framework for the workshop had been developed during a meeting of Iranian and American specialists in June 2003 in Les Treilles, France.

The Research Center for Gastroenterology and Liver Diseases selected the Iranian participants in the workshop, and the U.S. Institute of Medicine selected the American participants. Representatives of the World Health Organization and the Food and Agriculture Organization also made brief presentations. Altogether more than 100 specialists participated in the workshop in their personal capacities. The documents developed during and following the workshop reflected their personal views and not the views of their organizations.

These proceedings include a number of papers that were presented at the workshop together with summaries of discussions following presentation of the papers. Upon completion of the workshop, the American participants had the opportunity to continue their discussions with counterparts at their institutions and to visit several production, research, and clinical facilities in the Tehran area. The workshop papers and the discussions during the workshop and during

the subsequent visits provide a good basis for continuing international cooperation in this field, which is of growing importance to all countries.

The specialists and officials that participated in this activity are identified in the appendixes. Their contributions are greatly appreciated. Dr. Mohammad Reza Zali deserves particular recognition for his continuous efforts in ensuring that the activities would be professionally rewarding for the specialists. The contributions of the staffs of the Research Center for Gastroenterology and Liver Disease of Shaheed Beheshti University of Medical Science and of the Food and Nutrition Board of the Institute of Medicine, particularly Ricardo Molins, also deserve recognition.

Special appreciation is extended to the Academy of Medical Sciences of Iran and to the National Academies of the United States for their assistance in facilitating the holding of the workshop, and to the National Research Council (NRC), which provided funding for this project.

This volume has been reviewed in draft form by individuals chosen for their technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for quality. The review comments and draft manuscript remain confidential to protect the integrity of the process.

We wish to thank the following individuals for their review of selected papers: Kathryn Boor, Cornell University; Michael Doyle, University of Georgia; Jocelyne Rocourt, Pasteur Centre of Cameroon; and Allison Yates, ENVIRON.

Although the reviewers listed above have provided constructive comments and suggestions, they were not asked to endorse the content of the individual papers. Responsibility for the final content of the papers rests with the individual authors.

-Glenn E. Schweitzer
Director, Office for Central Europe and Eurasia
National Research Council

-George Jackson
Microbiologist, Food and Drug Administration
(Retired)

-Mohammad Reza Zali
President, Research Center for Gastroenterology
and Liver Disease
Shaheed Beheshti University of Medical Sciences

Contents

DAY 1

Opening Session 1

Morning Session

Overview of Food Safety Issues and of Diseases Arising from Food of Animal and Plant Origin in the United States 5

Overview of Safety Issues in Iran for Food Derived from Animals or Plants 18

The Role of the ISIRI in Food Safety 22

Discussion 28

Afternoon Session

Surveillance for Foodborne and Diarrheal Diseases, Including Outbreak Investigations: An American Perspective 31

Foodborne Disease Investigations, Including Surveillance: A Collaborative Pilot Project 46

Discussion 51

DAY 2

Morning Session

Inspection and Investigation: Tools for Detecting Sources of Food Contamination and Preventing Illness Outbreaks 55

Food Monitoring, Investigation, and Inspection Infrastructure in Iran 63

Discussion 68

Afternoon Session

Food Traceability: A Response to Consumers 73

The Role of Risk Analysis in a Science-Based Approach to Food Safety 76

The Hazard Analysis and Critical Control Point System 94

Implementing and Auditing HACCP Systems and Difficulties In Iran 97

The History of Food Safety in Iran 100

Discussion 103

DAY 3

Final Plenary Session: Future Steps and Opportunities 107

Closing Session 110

APPENDIXES

A Workshop Agenda 113

B Participant List 117

Opening Session

Dr. Mohammadreza Razailashkajani
Research Center for Gastroenterology and Liver Disease
Shaheed Beheshti University of Medical Sciences

The opening session began with a recitation of verses from the Holy Koran, followed by a rendition of Iran's national anthem.

Professor Peyravi, the chancellor of Shaheed Beheshti University of Medical Sciences, was the first to welcome the workshop guests and participants. He highlighted the scientific importance and economic impact of food safety issues and the necessity for international collaboration in improving many aspects of food safety.

Professor Mohammad Reza Zali, the president of the Research Center for Gastroenterology and Liver Disease, welcomed the guests and participants on behalf of the main host of the workshop. He spoke of the great burden that foodborne diseases annually impose on human health and the global economy. Dr. Zali stated that although food safety concerns traditionally focus on end products, a more comprehensive approach is needed, one that covers the "farm to fork" spectrum. He called for multidisciplinary cooperation in all aspects of food safety at both the national and international levels and expressed the hope that opportunities such as the workshop would attract the support of the relevant parties in his country.

Mr. Glenn Schweitzer, program director at the U.S. National Academies, referred to this workshop as a highly significant and ambitious activity. He stressed that the exchange of views among experts from Iran and the United States would contribute to a richer global perspective on food safety. Pointing to the so far insufficient contributions of countries in the Middle East to the international

food safety dialogue, he commended the technical competence of Iranian scientists and their enthusiasm for the topic, as well as Dr. Zali's perseverance in organizing this important venue to consider a topic of increasing international importance.

Dr. Abdorrashid, the Food and Agriculture Organization's (FAO's) representative in Iran, underlined the economic and scientific importance of food safety in the world today. He declared that many developing countries not only suffer from outbreaks of foodborne and zoonotic diseases but also incur severe economic losses due to rejection of their food exports because these are not in compliance with international standards. He also mentioned that Iran has made considerable progress toward achieving international standards and developing effective food safety systems. Emphasizing the importance of international collaboration, he listed four international projects on food safety that were joint endeavors of the FAO and Iran's Ministry of Jihad-e-Agriculture. Finally, he called for more awareness of food safety issues by regulatory bodies and expressed the hope for increased attention to the cultural aspects of this topic.

Dr. Rajab-beygi, the representative of Iran's Ministry of Jihad-e-Agriculture, stated that recent agricultural advances have raised new challenges in food safety. These include problems associated with foodborne pathogens, heavy metals, and residues of agricultural and veterinary drugs that can compromise public health. He added that the Ministry of Jihad-e-Agriculture in collaboration with the FAO is developing new strategies in food safety and is working toward a more holistic approach. He also declared that Iran is trying to establish an effective food safety system and the Ministry of Jihad-e-Agriculture laboratories are now equipped with technologies for detecting and measuring drug residues and performing microtrace measurements.

Dr. Gooya, the representative of the Center for Disease Control of Iran's Ministry of Health, stressed the importance of collaboration between the Ministry of Health and the Research Center for Gastroenterology and Liver Disease in developing a surveillance system for foodborne diseases in Iran.

Dr. Niño, an FAO consultant, expressed his gratitude to Dr. Zali and other organizers of the workshop and emphasized the important role of food and food safety as part of every nation's life and culture. He pointed to the significance of the FAO/World Health Organization Codex Alimentarius, its special focus on food standards, and the important role of Iranian representatives on its committees.

Day 1

Morning Session

Overview of Food Safety Issues and of Diseases Arising from Food of Animal and Plant Origin in the United States

Overview of Safety Issues in Iran for Food Originating from Animals or Plants

The Role of the Institute of Standards and Industrial Research of Iran in Food Safety in Iran

Discussion

Overview of Food Safety Issues and of Diseases Arising from Food of Animal and Plant Origin in the United States

Karl R. Matthews
Department of Food Science, Rutgers University

Food safety and foodborne diseases are topics of global concern. Food safety encompasses many areas, including pesticide and antibiotic residues, the presence of mycotoxins and foodborne pathogens, and all aspects of food production and preparation. Many issues associated with these topics are common to all countries. Decisions must be made by each nation to determine priority areas that should be addressed to ensure the health of its citizens. In the United States, despite significant strides in microbiological food safety, continued effort is required to combat this complex human health issue.

The Centers for Disease Control and Prevention (CDC) estimates that 76 million persons in the United States annually contract foodborne illness (Mead et al., 1999). Surveillance data from the Foodborne Disease Active Surveillance Network (abbreviated as FoodNet) suggest that the infection incidence for target foodborne pathogens in the year 2003 was lower than the average annual incidence in the United States for the years 1996-1998 (Vugia et al., 2004). FoodNet determines the burden and sources of specific foodborne diseases by surveying laboratories in selected states. The estimated incidence of several infections declined significantly during the evaluation period. Infections decreased 49 percent, 42 percent, 28 percent, and 17 percent for *Yersinia, Escherichia coli* O157:H7, *Campylobacter*, and *Salmonella,* respectively. The incidence of *Cryptosporidium* infection decreased 51 percent. The incidence of *Listeria* and *Shigella* varied considerably during the observation period but did not change significantly. Only the incidence of *Vibrio* infections increased.

The changes in incidence of the above infections occurred during a period when control measures were implemented with new or renewed effort by government agencies and the food industry. The U.S. Department of Agriculture

(USDA) through its Food Safety Inspection Service (FSIS) launched Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations for meat and poultry slaughter operations and processing plants in 1996. The U.S. Food and Drug Administration (FDA) introduced several intervention strategies designed to control foodborne diseases in the products they regulate. These include the produce safety guidance of 1998 (http://www.foodsafety.gov/~dms/prodguid.html), the sprout safety guidance of 1999 (http://www.isga-sprouts.org/sprougd1.htm), the requirements for refrigeration and safety labeling of shell eggs in 2001 (http://www.foodsafety.gov/~dms/fs-toc.html), and implementation of HACCP regulations for the seafood industry in 1997 (http://vm.cfsan.fda.gov/~lrd/fr951218.html) and the juice industry in 2002 (http://www.cfsan.fda.gov/~lrd/fr01119a.html).

Food safety policies and practices must continue to evolve as new technologies, production practices, and food manufacturing processes are developed. The complex relationships among pathogens, the host, and the environment also ought to be taken into consideration when addressing foodborne illnesses. For the purposes of this paper, food safety and foodborne disease issues are categorized broadly as those of either animal or plant origin.

The microbiological quality and safety of animal products is influenced by an array of factors. They include production practices, use of antibiotics, consumer demand, and the global nature of the marketplace. Meat animal production has increased significantly in the United States over the past 30 years. Concurrently, meat animal production practices have changed. Perhaps most notable is the change to higher-intensity production practices. Pathogenic microorganisms are more likely to spread among animals confined in a limited space (IFT, 2002). To ensure the health and promote the growth of livestock, antibiotics are often added to animal feed. Indeed, approximately one-half of the antibiotics produced today are added to animal feed (WHO, 2002). This may contribute to the development of antibiotic-resistant human pathogens that have animal reservoirs (Smith et al., 2005). The microbiological safety of meat and meat products requires concerted effort from government agencies, livestock producers, and meat processors.

A number of well-publicized outbreaks of foodborne illness and recalls of meat and meat products have occurred during the past decade. Many millions of kilograms of ground beef and luncheon meat have been recalled because of potential contamination with *E. coli* O157:H7 and *Listeria monocytogenes*, respectively. A large outbreak in the early 1990s due to *E. coli* O157:H7 contaminated hamburgers resulted in four deaths and hundreds of illnesses; this prompted the development of the USDA/FSIS PR/HACCP rule mentioned above. Indeed, a single foodborne pathogen has completely changed the beef industry in the United States.

The cost of concerns about *E. coli* O157:H7 contamination in beef production in the United States was estimated at a staggering $2.7 billion in the past 10

years (Kay, 2003). This cost is associated with recalls, lost consumer demand, implementation of food safety intervention strategies, and increased operating expenses. The poultry industry has also experienced greater production expenses to control *Salmonella* and *Campylobacter* associated with poultry products and eggs. Going beyond the egg refrigeration rule, the FDA proposed measures to prevent *S. enteritidis* contamination of shell eggs during egg production.

Salmonella, Campylobacter, and *E. coli* O157:H7, more so than other pathogens, are of significant concern in beef and poultry processing. *Listeria monocytogenes*, ubiquitous in the environment, has caused several large outbreaks of foodborne illness linked to luncheon meats and hot dogs. Contamination of these products is generally thought to occur post-processing.

Listeria monocytogenes can be found in a variety of foods; however, many outbreaks have been associated with ready-to-eat foods. In a continuing effort to prevent *L. monocytogenes* illness and control this pathogen, the FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the CDC developed the Listeria Action Plan (http://www.foodsafety.gov/~dms/lmr2plan.html). Six areas for action have been identified at the government, processor, and consumer levels to reduce significantly the risk of illness and death caused by *L. monocytogenes* in ready-to-eat foods. The FDA is also reexamining the U.S. regulatory policy on *L. monocytogenes* in food. A proposal has been put forth to eliminate the zero tolerance policy for food products that do not support the growth of *L. monocytogenes.*

Clearly, no single measure can prevent contamination of animal products with microorganisms potentially hazardous to human health. In the United States, government programs are in place, guidance plans have been developed for industry, and consumer education information is available to guide the public in the proper handling of animal products. Such strategies are also in use to ensure the safety of fresh fruits and vegetables.

The microbial safety of fresh fruits and vegetables is of global concern with respect to human health (WHO, 1998). In the United States the number of outbreaks of human illness associated with the consumption of fresh produce has increased in recent years (Beuchat, 2002; Sivapalasingam et al., 2004). This has been attributed to a variety of factors, including increased consumption, changes in agronomic and harvesting practices, and increased importation (Beuchat, 2002). The increase in cases of foodborne illness linked to consumption of fresh fruits and vegetables has spurred research addressing the preharvest interactions between foodborne pathogens and growing plants.

Recent studies by the USDA's Economic Research Service and by the FDA's CFSAN addressed issues of importation and contamination of imported produce (Jerardo, 2003; http://www.cfsan.fda.gov/~dms/prodsur6.html; http://www.cfsan.fda.gov/~dms/ prodsur10.html). The percentage of fruits and vegetables that were imported into the country more than doubled from 1985 to 2001. Import of fresh fruits went from 9 percent to 23 percent and for vegetables from

8 percent to 17 percent (http://www.ers.usda.gov/publications/fau/july03/fau7901/fau7901.pdf). During the 1990s, at least 12 percent of foodborne illness outbreaks were linked to fresh produce items. An FDA survey of domestic produce indicated that approximately 1 percent (12 of 1028) of samples were positive for target foodborne pathogens (http://www.cfsan.fda.gov/~dms/prodsur10.html). Approximately 2.6 percent, 1.6 percent, and 1.8 percent of the cantaloupe, cilantro, and lettuce, respectively, were contaminated with *Salmonella*. In a survey of imported produce > 4 percent (44 of 1003) of samples were positive for either *Salmonella* (35 or 80 percent) or *Shigella* (9 or 20 percent) (http://www.cfsan.fda.gov/~dms/ prodsur6.html).

Numerous avenues exist during the production, harvesting, transport, and marketing of fresh produce for the introduction of pathogens (Beuchat, 2002). Contaminated manure, irrigation water, wash water, equipment, and farm workers are all potential vectors for the transmission of pathogens to fresh fruits and vegetables (Beuchat, 2002). A recent expert report from the Institute of Food Technologists (IFT) stated that "the complexity of the pre-harvest, harvest, and post-harvest environments makes it impossible to control all potential sources of microbial contamination" (IFT, 2002). The microbiological quality of water used for the irrigation and the washing and rinsing of vegetables post-harvest may be the single largest factor in contaminating produce.

The USDA's National Agricultural Statistics Service classifies irrigation methodologies into four categories: sprinkler systems, gravity-flow systems, drip or trickle methods, and subirrigation (USDA, 1998). Sprinkler systems apply water to crops from overhead pipes that are towed into position. Water droplets fall onto the edible portions of the plants as well as onto the soil surface. If the water is contaminated with a pathogen, the edible portion of the plant and the surrounding soil will likely also become contaminated. The advantage associated with sprinkler systems is the potential for more exact water management than with surface irrigation.

The remaining three irrigation techniques all involve the direct application of water onto the soil surface by a series of levees, furrows, and underground tubing. Here and throughout this paper these methods are collectively referred to as surface irrigation. With surface irrigation, water contacts primarily the roots of the growing plants. Data from the most recent census (1998) indicated that approximately 50 million acres of farmland were irrigated annually in the United States (USDA, 1998). Of that, 22.9 million acres were irrigated using sprinkler systems and the remainder by surface irrigation. For lettuce specifically, 58 percent of the annual harvest was sprinkler irrigated (USDA, 1998).

Studies show that *Salmonella* and *E. coli* O157:H7 can survive for extended periods (> 40 days) in well, river, and lake water (Moore et al., 2003; Rice et al., 1999; Wang and Doyle, 1998). Therefore, a very real possibility exists for the contamination of crops in the field through exposure to contaminated irrigation water.

At present, chlorine at a concentration of 50-200 ppm is the primary post-harvest sanitizing agent in routine use for fresh produce (Beuchat, 1998); however, this level of chlorine has repeatedly been demonstrated to be ineffective at eliminating pathogens from fruits and vegetables (Beuchat, 2002; Weissinger et al., 2000). Indeed, chlorine is often added to the wash water to reduce the microbial load of the water, not necessarily to kill the specific pathogens that contaminate the produce.

While extremely effective against *E. coli* O157:H7 in aqueous systems (Rice et al., 1999), the efficacy of chlorine is greatly reduced on raw fruits and vegetables. Beuchat et al. (1998) stated that the loss of activity likely occurs when chlorine interacts with organic material such as plant tissues. Numerous other sanitizers including ozone have been examined for use on fresh produce (Koseki et al., 2001), electrolyzed water (Kim et al., 2003), hydrogen peroxide (Lin et al., 2002), lactic acid (Lin et al., 2002), and chlorine dioxide (Han et al., 2000). Under the conditions studied and commercial practices, sanitizing agents are generally not able to reduce by more than 1 or 2 $\log_{10}$ CFU the levels of pathogens on fresh produce (Beuchat et al., 1998). Although other sanitizing agents such as chlorine dioxide and ozonated water are available, chlorine remains the chemical sanitizer most widely used by the produce industry.

The efficacy of sanitizers on fresh produce depends largely on the target pathogen's accessibility. That foodborne pathogens can infiltrate plant tissues is of grave concern since microorganisms present within plants are protected from the actions of surface decontamination practices. *Escherichia coli* O157:H7 has been shown to localize preferentially on cut edges of lettuce leaves as opposed to intact leaf surfaces (Takeuchi and Frank, 2000). Seo and Frank (1999) demonstrated that cells of *E. coli* O157:H7 were able to penetrate the interior of cut tissue, becoming entrapped 20-100 μm below the surface. Cells present at these subsurface locations were protected from inactivation with chlorine (Burnett and Beuchat, 2002).

The uptake of human pathogens by the root systems of growing crops has also been investigated (Guo et al., 2002; Solomon et al., 2002; Wachtel et al., 2002). The reported uptake of *E. coli* O157:H7 by the roots of growing lettuce plants (Solomon et al., 2002; Wachtel et al., 2002) and *Salmonella* by hydroponic tomato plants (Guo et al., 2002) has led to the hypothesis that foodborne pathogens may exist as endophytes within growing plants. It is most likely that internalized bacteria are protected from sanitation by virtue of their inaccessibility.

Harvesting practices and equipment can have a significant impact on the microbiology of fresh produce. Approximately 90 percent of fruits and vegetables are harvested by hand (USDA, 2001). Farm workers may transfer pathogens from their hands to the crop or from crop to crop during the harvesting process. The tools used for harvesting (e.g., knives and machetes) and containers used for storage and transport (bins, buckets, and trailers) should be properly washed and

sanitized; however, reports indicate that washing and sanitizing, respectively, are done only about 75 percent and 30 percent of the time (USDA, 2001).

A relatively new segment of the produce industry, "Fresh Cut," has emerged in the last 15 years in the United States. Fresh-cut products have been physically altered from the original form, but remain in a fresh state. Products include, for example, salad mixes, sliced or diced tomatoes, and papaya halves. Some processors have moved the early stages of processing lettuce to the field. For example, heads of lettuce are cut at their stems, exterior leaves and core are removed, and the heads are immersed in wash water containing up to 200 ppm chlorine. The lettuce heads are then loaded by conveyor belt into bins lined with a plastic bag and cooled within two hours. There is concern that bringing processing onto the farm could increase the likelihood for microbial contamination.

The USDA and the FDA have developed guidelines to minimize foodborne illness associated with fresh produce consumption (http://vmcfsan.fda.gov/~dms, http://www.foodsafety.gov/~dms/prodplan.html). These guidelines include the implementation of Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), and HACCP systems. GAPs encompass irrigation water quality, manure handling, equipment cleaning, and worker education. Other areas being addressed focus on increased communication among growers, packers, and consumers, and increased support of research relevant to fresh produce.

Microbial food safety issues with fresh fruits and vegetables will likely always exist since the products are consumed raw; however, contamination can be minimized through comprehensive control strategies from the farm to the table. GAPs must be coupled with GMP and HACCP programs at the postharvest stage to limit contamination of a product with foodborne pathogens. Such control practices must be implemented not only in the United States but also in countries from which the fresh produce has been imported.

Safety of the food supply throughout the world is a major concern as new pathogens emerge and known pathogens reemerge. The foodborne pathogens *E. coli* O157:H7 and *Shigella* present significant problems for the food industry and the consumer in part because of their ability to survive under a broad range of conditions. Although these pathogens traditionally have been linked to animal products (eggs, poultry, beef, and dairy products), more recent outbreaks have been associated with water (well and municipal), produce, and processed foods that likely were cross-contaminated. Characterization of these target pathogens has also demonstrated that they are often resistant to one or more antibiotics (Aarestrup and Wegener 1999; Bower and Daeschel, 1999; Bryan et al., 2004).

Transmission of pathogens to food occurs at various levels: in the field; during harvesting, processing, and shipping; or in the home. Routes of contamination include water used to irrigate fields, contaminated feed, colonized animals, cross-contamination from fecal matter, the use of improperly composted manure, improper sanitation of processing equipment, and human handling (Beuchat and Ryu, 1997; Wang et al., 1996). Methods employed to enhance the

safety of food along the production and processing path should focus not just on slowing or preventing the growth of pathogens but also on eliminating them. Such methods include the use of antibiotics on the farm, sanitizers in the processing plant to prevent cross-contamination, the use of preservatives in foods to prevent and retard growth, and various processes, including pasteurization, to eliminate pathogens.

Antibiotics are used in plant and fruit production for disease control and in animal agriculture for therapy, prophylaxis, and growth promotion (Gustafson and Bowen, 1997). A wide range of antibiotics is used (-lactams, sulfonamides, and macrolides) in animal agriculture and, depending on the type of animal (dairy cattle, beef cattle, sheep, poultry, or fish), the target may be treated individually or as a group (herd or flock). Reports indicate that a greater percentage of *E. coli* O157:H7 and *Shigella* isolates and other pathogens are antibiotic resistant today compared with 10 to 15 years ago (Sahm et al., 2001; Tollefson and Miller, 2000; Van den Bogaard and Stobberingh, 1999), with many strains exhibiting multiple antibiotic resistance (Kim et al., 1994; Mevius et al., 1999).

Antibiotic use on the farm has come under increased scrutiny in light of an increase in the emergence of antibiotic-resistant pathogens. Broad-spectrum antibiotics are typically used for livestock at subtherapeutic levels to promote feed efficiency and growth as well as to control disease (Gustafson and Bowen, 1997). An increase in pathogens resistant to antimicrobials, including *E. coli* O157:H7 and *Shigella,* may contribute to the higher prevalence of such resistant bacteria in commensal flora and vice versa. Widespread use of antimicrobials in commercial farming may result in the release of antimicrobial agents into the environment, subsequently causing the emergence of resistant commensal bacteria. Antibiotics excreted by farm animals or incorporated into feed or drinking water can ultimately be dispersed into the environment through the fertilization and irrigation of fields. Often farm wastes (manure, bedding, and feed) are collected in lagoons and pit systems and spread or sprayed onto fields. A range of microorganisms—including *Staphylococcus aureus*, nongroupable streptococci, enterobacter, enterococci, and *E. coli*—isolated from farm workers were significantly more resistant to antibiotics than when isolated from other individuals (Aubry-Damon et al., 2004).

Resistant bacteria present on food crops intended for human consumption may prove to be a major route of infection. *Enterobacteriaceae* are not only found in abundance in the environment but are pathogens and commensals of the human gastrointestinal tract. A Finnish study investigated the potential for raw vegetables to serve as a source of resistant strains of *Enterobacteriaceae* (Osterblad et al., 1999). The researchers concluded that bacteria from vegetables were not responsible for the high prevalence of resistant *Enterobacteriaceae* in fecal flora in Finland.

Transfer of antibiotic-resistant determinants may occur in vivo between enteric microorganisms. Gene transfer between pathogens is not a new concern and

has been reported in both humans and animals. Interspecies gene transfer in vivo occurred in association with an outbreak of shigellosis in 1983 (Tauxe et al., 1989). The *Shigella* isolate associated with this outbreak carried a plasmid that encoded resistance to ampicillin, carbenicillin, streptomycin, sulfisoxazole, tetracycline, and trimethoprim/sulfamethoxazole; this was identical to the antimicrobial resistance of an *E. coli* isolated from a case patient's urinary tract infection that had occurred prior to the onset of shigellosis. Others have investigated the potential for transfer of an apramycin-resistant plasmid from *E. coli* to *S. typhimurium* in calves (Hunter et al., 1992).

E. coli O157:H7 strains initially associated with human illness were susceptible to most antibiotics used against Gram-negative pathogens. During the last two decades the antibiotic susceptibility profile of *E. coli* O157:H7 has changed drastically. Only 2 of 200 strains of *E. coli* O157:H7 collected by the CDC between 1983 and 1985 were resistant to antibiotics (Bopp et al., 1987). Subsequent screening of 125 *E. coli* O157:H7 (n = 118) and O157:NM (n = 7) revealed that 24 percent were resistant to at least one antibiotic and 19 percent were resistant to three or more antibiotics (Meng et. al., 1998). In a longitudinal study of beef cattle feedlots, *E. coli* O157:H7 isolates were resistant to six of the eight antibiotics that are used to treat *E. coli* infections in food animals (Galland et. al., 2001). Perhaps surprisingly, less than one-half of the isolates were resistant to tetracycline, one of the most extensively used antibiotics on feedlots. Compared with other foodborne pathogens or with other *E. coli* isolates, the level of antibiotic resistance of *E. coli* O157:H7 is generally low and basically limited to tetracycline, streptomycin, and sulfamethoxazole.

Shigella, although associated with foodborne illness, accounts for only a fraction of the total cases of foodborne illnesses that occur in the United States (Mead et al., 1999; Shiferaw et al., 2004). A large outbreak in 1987 was likely the result of transmission by food, water, and person to person (Wharton et al., 1990). The outbreak strain was resistant to ampicillin, tetracycline, and trimethoprim-sulfamethoxazole.

Contamination of crops with *Shigella* through application of contaminated manure to fields or contaminated irrigation water may occur. Fresh raw agricultural ingredients associated with prepared foods are also often implicated as the source of *Shigella* (CDC, 1999). In 2000 a nationwide outbreak of shigellosis involving 406 persons was traced to a commercially prepared five-layer dip (Kimura et al., 2004). The outbreak was probably the result of a food handler shedding the pathogen since the guacamole and salsa used were also sold as stand-alone products, and in that context were not linked to illnesses.

The potential for the spread of antibiotic-resistant *Shigella* from one country to another should not be ignored. A recent study from South Asia indicates that all *Shigella* isolates evaluated were resistant to ampicillin, tetracycline, nalidixic acid, and ciprofloxacin (Bhattacharya et al., 2003). Perhaps most alarming is that small outbreaks of shigellosis due to ciprofloxacin-resistant strains have been

detected (Bhattacharya et al., 2003). These reports underscore the potential role that food handlers and agricultural production practices in one country may have on the occurrence of *Shigella* that are multiply resistant to antimicrobials in countries with which they trade. Indeed, a recent study conducted in Karaj, Iran, indicated that approximately 91 percent and 88 percent, respectively, of *Shigella* isolates were resistant to one or more antimicrobial agents and 88 percent were multidrug resistant (MoezArdalan et al., 2003).

The issue of vancomycin-resistant *Enterococcus faecium* (VREF) is worrisome. Reservoirs for VREF include food and other sources, such as cattle, swine, poultry, minced pork or beef, and pet food. The concern stems from the use of streptogramin antibiotics as growth promoters and therapeutic agents in farm animals, and the use of streptogramins to treat patients with VREF infections. Streptogramin-resistant organisms are now common in the food supply, although factors associated with foodborne transmission need to be clarified (McDonald et al., 2001). Sampling of chicken carcasses revealed that 237 of 407 carcasses were positive for streptogramins-resistant *E. faecium* (McDonald et al., 2001). Risk modeling recently suggested that banning the use of virginiamycin in chickens would have little impact on human morbidity and mortality (Cox and Popken, 2004). However, carriage of resistance by commensal bacteria and transfer of resistance is unpredictable; therefore the effects of agricultural use of antibiotics on human health remains uncertain (Smith et al., 2005).

The continued safety of the U.S. food supply requires a proactive approach. Science-based means must be used to establish food safety guidance and regulations. Greater funding must be made available to support needed research and the development of expert panels to aid in establishing food safety objectives. Food safety objectives may focus on anything from the use of antibiotics in agriculture to distribution of resources by public health organizations. Since there is no all-encompassing solution to foodborne disease, establishing objectives will permit the allocation of limited resources that have the greatest impact on food safety. Human foodborne disease surveillance systems, use of microbiological risk assessment, and statistical process control are scientific tools that regulators can use when developing compliance with regulations. Programs such as GAPs, GMPs, and HACCP must be further developed to prevent contamination of food during its journey from the farm to the table.

International coordination is required to develop effective food safety measures. In a global society and marketplace it is possible for people, food, and pathogens to circle the world in a single day. To combat the spread of pathogens, greater consumer participation is required. For example, practicing personal hygiene (e.g., hand washing) and proper food handling will reduce the spread of foodborne pathogens and help to control or kill pathogens in foods prior to consumption (i.e., cook the food thoroughly in order to kill potentially harmful bacteria). Food safety will be realized through the melding of science and common sense, ultimately protecting consumers throughout the world.

REFERENCES

Aarestrup, F. M., and H. C. Wegener. 1999. The effects of antibiotic usage in food animals on the development of antimicrobial resistance of importance for humans in *Campylobacter* and *Escherichia coli*. Microbes and Infection 1(8):639-644.

Aubry-Damon, H., K. Grenet, P. Sall-Ndiaye, D. Che, E. Cordeiro, M. Bougnoux, E. Rigaud, Y. Le Strat, V. Lemanissier, L. Armand-Lefèvre, D. Delzescaux, J. C. Desenclos, M. Liénard, and A. Andremont. 2004. Antimicrobial resistance in commensal flora of pig farmers. Emerging Infectious Diseases 10:873-879.

Beuchat, L. R. 1998. Surface decontamination of fruits and vegetables eaten raw: A review. Available at http://www.who.int/foodsafety. Accessed November 18, 2005.

Beuchat, L. R. 2002. Ecological factors influencing survival and growth of human pathogens on raw fruits and vegetables. Microbes and Infection 4:413-423.

Beuchat, L. R., and J. H. Ryu. 1997. Produce handling and processing practices. Emerging Infectious Diseases 4:459-465.

Beuchat, L. R., B. V. Nail, B. B. Adler, and M. R. S. Clavero. 1998. Efficacy of spray application of chlorinated water in killing pathogenic bacteria on raw apples, tomatoes, and lettuce. Journal of Food Protection 61:1305-1311.

Bhattacharya, S. K., K. Sarkar, G. Balakrish Nair, A. S. G. Faruques, and D. A. Sack. 2003. Multidrug-resistant *Shigella dysenteriae* type 1 in South Asia. The Lancet: Infectious Diseases 3:755.

Bopp, C., K. Greene, F. Downes, E. Sowers, J. Wells, and I. Wachsmuth. 1987. Unusual verotoxin-producing *Escherichia coli* associated with hemorrhagic colitis. Journal of Clinical Microbiology 25:1486-1489.

Bower, C. K., and M. A. Daeschel. 1999. Resistance responses of microorganisms in food environments. International Journal of Food Microbiology 50:33-44.

Bryan, A., N. Shapir, and M. Sadowsky. 2004. Frequency and distribution of tetracycline resistance genes in genetically diverse, non-selected, and non-clinical *Escherichia coli* strains isolated from diverse human and animal sources. Applied Environmental Microbiology 70:2503-2507.

Burnett, S. L., and L. R. Beuchat. 2002. Comparison of methods for fluorescent detection of viable, dead, and total *Escherichia coli* O157:H7 cells in suspensions and on apples using confocal scanning laser microscopy following treatment with sanitizers. International Journal of Food Microbiology 74:37-45.

CDC (Centers for Disease Control and Prevention). 1999. Outbreaks of *Shigella sonnei* infection associated with eating fresh parsley—United States and Canada. July-August 1998.

Cox, L. A., and D. A. Popken. 2004. Quantifying human health risks from virginiamycin used in chickens. Risk Analysis 24:271-288.

Galland, J. C., D. R. Hyatt, S. S. Crupper, and D. W. Acheson. 2001. Prevalence, antibiotic susceptibility, and diversity of *Escherichia coli* 0157:H7 isolates from a longitudinal study of beef cattle feedlots. Applied Environmental Microbiology 67:1619-1627.

Guo, X., M. W. van Iersel, J. Chen, R. E. Brackett, and L. R. Beuchat. 2002. Evidence of association of salmonellae with tomato plants grown hydroponically in inoculated nutrient solution. Applied Environmental Microbiology 68:3639-3643.

Gustafson, R. H., and R. E. Bowen. 1997. Antibiotic use in animal agriculture. Journal of Applied Microbiology 83:531-541.

Han, Y., R. H. Linton, S. S. Nielsen, and P. E. Nelson. 2000. Inactivation of *Escherichia coli* O157:H7 on surface-uninjured and -injured green pepper (*Capsicum annuum* L.) by chlorine dioxide gas as demonstrated by confocal laser scanning microscopy. International Journal of Food Microbiology 17:643-655.

Hunter, J. E. B., J. C. Shelley, J. R. Walton, C. A. Hart, and M. Bennett. 1992. Apramycin resistance plasmids in *Escherichia coli*: Possible transfer to *Salmonella typhimurium* in calves. Epidemiology and Infection 108:271-278.

IFT (Institute of Food Technologists). 2002. Emerging Microbiological Food Safety Issues, Implications for Control in the 21st Century. Chicago: Institute of Food Technologists.

Jerardo, A. 2003. Import share of U.S. food consumption stable at 11 percent. USDA FAU-79-01. Available at http://www.ers.usda.gov. Accessed December 1, 2005.

Jones, R., C. H. Ballow, D. J. Biedenback, J. A. Deinhart, and J. J. Schentag. 1998. Antimicrobial activity of quinupristin-dalfopristin (RP 59500, Synercid) tested against over 28,000 recent clinical isolates from 200 medical centers in the United States and Canada. Diagnostic Microbiology and Infectious Disease 30:437-451.

Kay, S. 2003. The cost of *E. coli* O157:H7. Meat and Poultry 2:26-34.

Kim, C., Y. C. Hung, R. E. Brackett, and C. S. Lin. 2003. Efficacy of electrolyzed water in inactivating *Salmonella* on alfalfa seeds and sprouts. Journal of Food Protection 66:208-214.

Kim, H. H., M. Samadpour, L. Grimm, C. R. Clausen, T. E. Besser, M. Baylor, J. M. Kobayashi, M. A. Neill, F. D. Schoenknecht, and P. I. Tarr. 1994. Characteristics of antibiotic-resistant *Escherichia coli* in Washington State, 1984-1991. Journal of Infectious Diseases 170:1606-1609.

Kimura, A. C., K. Johnson, M. S. Palumbo, J. Hopkins, J. C. Boase, R. Reporter, M. Goldoft, K. R. Steonek, J. A. Farrar, T. J. Van Gilder, and D. J. Vugia. 2004. Multi-state shigellosis outbreak and commercially prepared food, United States. Emerging Infectious Diseases 10:1147-1149.

Koseki, S., K. Yoshida, S. Isobe, and K. Itoh. 2001. Decontamination of lettuce using acidic electrolyzed water. Journal of Food Protection 64:652-658.

Lin, C. M., S. S. Moon, M. P. Doyle, and K. H. McWatters. 2002. Inactivation of *Escherichia coli* O157:H7, *Salmonella enterica* serotype Enteritidis, and *Listeria monocytogenes* on lettuce by hydrogen peroxide and lactic acid and by hydrogen peroxide with mild heat. Journal of Food Protection 65:1215-1220.

McDonald, L. C., S. Rossiter, C. Mackinson, Y. Y. Wang, S. Johnson, M. Sullivan, R. Sokolow, E. DeBess, L. Gilbert, J. A. Benson, B. Hill, and F. J. Angulo. 2001. Quinupristin-dalfopristin resistant *Enterococcus faecium* on chickens and in human stool specimens. New England Journal of Medicine 345:1155-1160.

Mead, P. S., L. Slutsker, V. Dietz, L. F. McCraig, J. F. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. Emerging Infectious Diseases 5:607-625.

Meng, J., S. Zhao, M. P. Doyle, and S. W. Joseph. 1998. Antibiotic resistance of *Escherichia coli* 0157:H7 and 0157:NM isolated from animals, food, and humans. Journal of Food Protection 61:1511-1514.

Mevius, D. J., M. J. Sprenger, and H. C. Wegener. 1999. EU conference "The microbial threat." International Journal of Antimicrobial Agents 11:101-105.

MoezArdalan, K. M. R. Zali, M. M. Dallal, M. R. Hemami, and S. Salmanzadeh-Ahrabi. 2003. Prevalence and pattern of antimicrobial resistance of *Shigella* species among patients with acute diarrhea in Karaj, Tehran, Iran. Journal of Health, Population, and Nutrition 21(2):96-102.

Moore, B. C., E. Martinez, J. M. Gay, and G. H. Rice. 2003. Survival of *Salmonella enterica* in freshwater and sediments and transmission by the aquatic midge *Chironomus tentans* (Chironomidae: Diptera). Applied Environmental Microbiology 69(8):4556-4560.

Osterblad, M., O. Pensala, M. Peterzens, H. Heleniusc, and P. Huovinen. 1999. Antimicrobial susceptibility of *Enterobacteriaceae* isolated from vegetables. Journal of Antimicrobial Chemotherapy 43:503-509.

Rice, E. W., R. M. Clark, and C. H. Johnson. 1999. Chlorine inactivation of *Escherichia coli* O157:H7. Emerging Infectious Diseases 3:461-463.

Sahm, D. F., D. C. Mayfield, R. N. Master, C. Thornsberry, and J. A. Karlowsky. 2001. Prevalence of antimicrobial resistance among *Shigella* spp.—A current view. In Proceedings of the 101st General Meeting of the American Society for Microbiology, May 20-24, 2001, Orlando. A-82.

Seo, K. H., and J. F. Frank. 1999. Attachment of *Escherichia coli* O157:H7 to lettuce leaf surface and bacterial viability in response to chlorine treatment as demonstrated by using confocal scanning laser microscopy. Journal of Food Protection 62:3-9.

Shiferaw, B., S. Shallow, R. Marcus, S. Segler, D. Soderlund, F. P. Hardnett, and T. Van Gilder. 2004. Trends in population based active surveillance for shigellosis and demographic variability in FoodNet sites, 1996-1999. Clinical Infectious Diseases 38(Suppl 3):S175-180.

Sivapalasingam, S., C. R. Friedman, L. Cohen, and R. V. Tauxe. 2004. Fresh produce: A growing cause of outbreaks of foodborne illness in the United States, 1973 through 1997. Journal of Food Protection 67:2342-2353.

Smith, D. L., J. Dushoff, and J. G. Morris. 2005. Agricultural antibiotics and human health. PLoS Medicine 2(8):232. Available at http://www.plosmedicine.org. Accessed December 2, 2005.

Solomon, E. B., S. Yaron, and K. R. Matthews. 2002. Transmission of *Escherichia coli* O157:H7 from contaminated manure and irrigation water to lettuce plant tissue and its subsequent internalization. Applied Environmental Microbiology 68:397-400.

Takeuchi, K., and J. F. Frank. 2000. Penetration of *Escherichia coli* O157:H7 into lettuce tissues as affected by inoculum size and temperature and the effect of chlorine treatment on cell viability. Journal of Food Protection 63:434-440.

Tauxe, R. V., T. R. Cavanagh, and M. L. Cohen. 1989. Interspecies gene transfer in vivo producing an outbreak of multiply resistance shigellosis. Journal of Infectious Diseases 160:1067-1070.

Tollefson, L., and M. A. Miller. 2000. Antibiotic use in food animals: Controlling the human health impact. Journal of AOAC International 83:245-254.

USDA (U.S. Department of Agriculture, National Agricultural Statistics Service). 1998. 1997 census of agriculture: 1998 farm and ranch irrigation survey. Available at http://www.nass.usda.gov/census/census97/fris/fris.htm. Accessed December 5, 2005.

USDA. 2001. Fruit and vegetable agricultural practices—1999. Available at http://www.usda.gov/nass/pubs/rpts106.htm. Accessed December 2, 2005.

Van den Bogaard, A. E., and E. E. Stobberingh**.** 1999. Antibiotic usage in animals: Impact on bacterial resistance and public health. Drugs 58:589-607.

Vugia, D., A. Cronquist, J. Hadler, P. Blake, D. Blythe, K. Smith, D. Morse, P. Cieslak, T. Jones, D. Goldman, J. Guzewich, F. Angulo, P. Griffin, R. Tauxe, and K. Kretsinger. 2004. Preliminary FoodNet data on the incidence of infection with pathogens transmitted commonly through food—selected sites, United States, 2003. Available at http://www.findarticles.com/p/articles/mi_m0906/is_16_53/ai_117257698. Accessed November 18, 2005.

Wachtel, M. R., L. C. Whitehand, and R. E. Mandrell. 2002. Association of *Escherichia coli* O157:H7 with pre-harvest leaf lettuce upon exposure to contaminated irrigation water. Journal of Food Protection 65:18-25.

Wang, G., and M. P. Doyle. 1998. Survival of enterohemorrhagic *Escherichia coli* O157:H7 in water. Journal of Food Protection 61:662-667.

Wang, G., T. Zhao, and M. P. Doyle. 1996. Fate of enterohemorrhagic *Escherichia coli* O157:H7 in bovine feces. Applied Environmental Microbiology 62:2567-2570.

Weissinger, W. R., W. Chantarapanont, and L. R. Beuchat. 2000. Survival and growth of *Salmonella baildon* in shredded lettuce and diced tomatoes, and effectiveness of chlorinated water as a sanitizer. International Journal of Food Microbiology 5:62:123-131.

Wharton, M., R. A. Spiegel, J. M. Horan, R. V. Tauxe, J. G. Wells, N. Barg, J. Herndon, R. A. Meriwether, J. N. MacCormack, and R. H. Levine. 1990. A large outbreak of antibiotic-resistant shigellosis at a mass gathering. Journal of Infectious Diseases 162:1324-1328.

WHO (World Health Organization/FSF/FOS). 1998. Surface decontamination of fruits and vegetables eaten raw: A review. Available at http://www.who.int/foodsafety/publications/fs_management/en/surface_decon.pdf. Accessed December 2, 2005.

WHO. 2002. Use of antimicrobials outside human medicine. Available at http://www.who.int/emc/diseases/zoo/antimicrobial.html. Accessed December 2, 2005.

Willems, R. J. L., J. Top, N. van den Braak, A. van den Braak, H. Endtz, D. Mevius, E. Stobberingh, A. van den Bogaard, and J. D. A. Embden. 2000. Host specificity of vancomycin-resistant *Enterococcus faecium*. Journal of Infectious Diseases 182:816-823.

Overview of Safety Issues in Iran for Food Derived from Animals or Plants

Dr. M. R. Akbarian
HACCP Food Safety Consultant, Iran Veterinary Organization

Food security (sufficient and safe food for all individuals) has become a top priority because of the world's growing population and its limited resources. According to such international organizations as the United Nations' Food and Agriculture Organization (FAO) and the World Health Organization (WHO), the situation is considered problematic when nearly 25 percent of produced food is destroyed by spoilage, especially degradation by microbial agents, and fails to reach consumers. Apart from safety aspects, spoilage imposes severe economic burdens on many countries and producers.

Another aspect concerns the increase in urban populations and decline of rural communities. This development has caused fundamental changes in food consumption patterns, food processing, and even food hazards. Not so long ago, the most important etiological agents of disease from contaminated foods were bacteria, parasites, and viruses. These agents still play major roles in causing consumer health problems, but new hazards—such as veterinary drug residues, pesticides, chemicals like heavy metals, and other environmental contaminants—are as important as the biological factors.

According to WHO and FAO studies and reports, illness due to contaminated food is one of the world's most widespread health problems and an important factor in reduced economic productivity, especially in developing and underdeveloped countries.

When we define food security, it is for all people, at all times. We say that there should be access to sufficient, safe, and nutritious food to meet dietary needs and satisfy food preferences for an active and healthy life. Actually, this makes food safety a basic human right. It must, therefore, be given a higher priority by all governments.

Currently, millions of people worldwide are suffering from diseases caused by contaminated food, which inflicts heavy social and economic burdens. The incidence and types of foodborne disease differ in different parts of the world. In developed countries many such diseases do not exist at all or have been largely prevented by food safety education, higher standards of hygiene, improved water supplies and sanitation, and better technologies for producing safe food. Nevertheless, significant portions of the population in industrial countries are affected by foodborne diseases despite the demanding standards and advanced measures.

As mentioned above, food safety is viewed as an essential public health issue of increasing importance. Therefore, for the well-being of society all governmental and nongovernmental agencies should assume responsibility for the production of safe food.

FOOD SAFETY SYSTEM IN IRAN

Food production, processing, marketing, and distribution systems in Iran are complex. They also are fragmented and involve a large number of intermediaries between the producer and the consumer. From producing and processing points of view we have in Iran both traditional means and industrial methods; the differences between these two raise problems when trying to apply the new concepts of food safety.

Responsibility for food safety is shared by Iran's government, industries, and consumers. At the government level three ministries provide consumer protection: the Ministry of Health and Medical Education, the Ministry of Jihad-e-Agriculture, and the Ministry of Industry. For all three there are legislative acts delineating their responsibilities.

Here I will mention only the safety issues concerning foods of animal origin for which the IVO (Iran Veterinary Organization) is responsible. The IVO works under the auspices of the Ministry of Jihad-e-Agriculture, and the basic law for its duties is the Veterinary Organization Act ratified on June 14, 1971. This act includes 21 articles and 1 amendment. The purposes of establishing this organization were to provide for the good health of animals, for safe products of animal origin, and to prevent and control animal diseases and zoonoses. The IVO has several basic principles with which it seeks to attain these goals, achieve optimum consumer protection, and ensure food safety.

INTEGRATED FARM-TO-TABLE CONCEPT

To achieve optimum consumer protection, it is essential that safety be embodied in food products from production through consumption. This calls for an integrated farm-to-table approach in which the producer, processor, transporter, vendor, and consumer all play vital roles.

To ensure adequate consumer protection and to effectively control, reduce,

or minimize food safety risks, a preventive approach was developed and appropriate preventive measures were introduced into all stages from farm to table. Prevention, control at the source, and identification of unsuitable products at an early stage make better scientific and economic sense compared to the traditional approach to food control, which relied mainly on final product inspection and testing.

The IVO started these new activities a decade ago and based them on the principles of good animal husbandry practices, animal biosecurity measures, good hygiene practices for animal farms, and application of good hygiene practices (GHPs) and Hazard Analysis and Critical Control Point (HACCP) regulations to the production of raw foods of animal origin. All this was done in conformity with World Organization for Animal Health (OIE), Codex Alimentarius, and European Commission guidelines. At the moment, this new approach to food safety is being applied comprehensively to fishery products. In 1998 Iran was placed on the list of countries approved for exporting fish and fishery products to European nations. For other raw foods of animal origin, such as meat, poultry products, and milk, the IVO started this new approach to food safety four years ago. Currently, prerequisite HACCP programs are applied in all slaughter houses and at all processing and packaging sites. In the near future these activities will introduce full HACCP systems to these sites.

In brief, the important activities performed by the IVO are:

- Hygienic control of the infrastructure and site aspects of animal farms and aquaculture centers.
- Hygienic control of live animals at farms and screening to control or eradicate major diseases according to OIE guidelines.
- Monitoring of veterinary drug residues and supervision of the use of these drugs to prevent unauthorized applications and bar unauthorized materials. The IVO also supervises the interval between medication withdrawal and slaughter.
- Hygienic control of establishments producing animal feed in terms of infrastructure, site, and application of good manufacturing practice (GMP) and GHP principles.
- Safety and hygienic control of animal feed with respect to biological, chemical, and physical hazards in order to prevent these hazards from impacting consumers.
- Supervision and hygienic control of the means for transporting animals and animal products in order to prevent illegal traffic. The IVO has also installed quarantine check-points across the country and at the borders.
- Hygienic control and supervision of slaughter houses, processing sites, and packaging establishments for raw animal products. The IVO has placed health inspectors in these establishments to monitor all stages of production and processing.

- All these establishments must be designed and built according to GMP and GHP prescriptions; HACCP systems have been fully implemented for fishery products to protect consumers against hazards.
- Hygienic control and supervision of food of animal origin at retail markets.
- Conducting of regular training courses for IVO inspectors and related personnel, especially in HACCP, GMP, GHP, and auditing skills.
- Application of quality assurance systems, such as ISO 17025, in laboratories that test raw foods of animal origin as well as the establishment of a reference laboratory to control veterinary drug residues, heavy metals, and other contaminants in animal products.
- Participation in international meetings, such as the Codex Alimentarius committees.
- Cooperation with the FAO, with this organization providing technical and logistical support for a project to control veterinary drug residues in food of animal origin.

REFERENCES

CAC (Codex Alimentarius Commission). 2003. Food Hygiene Basic Texts. Codex Alimentarius Commission.Third Edition. Rome: FAO Publication.

FAO (Food and Agriculture Organization). 1996. Declaration on World Food Security. Report of the World Food Summit. Rome: FAO Publication.

FAO/WHO (Food and Agriculture Organization/World Health Organization). 1992. World Declaration and Plan of Action for Nutrition. Final Report of International Conference on Nutrition. Rome: FAO Publication.

FAO/WHO. 2002. Global Forum of Food Safety Regulators. Morocco, 28-30 Jan. Rome: FAO Publication.

WHO/SDE/PHE/FOS. 1999. Food Safety: An Essential Public health Issue for the New Millennium. Geneva: World Health Organization.

The Role of the Institute of Standards and Industrial Research of Iran in Food Safety

M. H. Sh. Hassanpour
Head of Food Department, Institute of Standards and Industrial Research of Iran

The concept of food standards in Iran is historic, as old documents attest. One document published about two centuries ago as *Makhzan*-O-L Advieh, written by Mohammad Hossein Aghili Khorasani, offers recommendations to those who purchase spices and condiments. What are called *jayyed mokhtar* or best characteristics can be translated as standards today. On the other hand, the Holy Koran emphasizes that Moslems ought to choose or avoid certain foods and divides all foods into *halal* (permitted for use) and *haram* (not permitted). This was the first food rule or set of food standards for Moslems.

Food safety and food quality terminology may sometimes be confusing. Food safety is concerned with all aspects**,** whether immediate or long-term, that may make food unsafe for the consumer**.** Therefore, safe foods or foodstuffs contain nothing that is hazardous or injurious. Food quality includes all other attributes that influence a product's value. This includes such negative attributes as spoilage, contamination with nontoxic and noninfectious filth, discoloration, and odors and such positive attributes as freshness, appetizing color and flavor, pleasing texture, and favorable origins, as well as the results of processing methods that make food more edible. This distinction between safety and quality has implications for public policy and influences the nature and content of the food control system suited to meet predetermined national objectives. Therefore, food control is defined as follows:

> A mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome, and fit for human consumption; that they conform to quality and safety requirements; and that they are honestly and accurately labeled as prescribed by law.

ELEMENTS OF FOOD SAFETY

While the components and priorities of food safety may vary from country to country, most systems will typically comprise the following components:

- Food laws and regulations;
- Food control management;
- Inspection, surveillance, and sampling;
- Laboratory services for food monitoring and epidemiological data; and
- Information, education, communication, and training.

FOOD SAFETY IN IRAN

Responsibility of food control in Iran, like most other countries, is shared by different ministries and agencies. These include:

- Ministry of Health, Treatment, and Medical Education;
- Institute of Standards and Industrial Research of Iran (ISIRI); and
- Ministry of Jihad-e-Agriculture (the previous Ministry of Agriculture).

THE ROLE OF THE ISIRI

According to Iranian law, the ISIRI has the sole authority for the determination, compilation, and publication of all official national standards in Iran. It is also the only authorized body for supervising the implementation of standards and regulations and directing research in related fields; however, pharmaceutical standards and supervision of their implementation is the duty of the Ministry of Health.

PREPARATION OF NATIONAL STANDARDS

The ISIRI has issued more than 7000 national standards in all areas of industry, over 2000 of which (28 percent) are for food products. For preparing food standards and regulations at the national level, the technical committees try to apply international standards (ISO), Codex Alimentarius, national data, and standards of other countries (especially when safety parameters have to be adapted to national values and local considerations).

Technical committees cover all authorized agencies, including nongovernmental organizations, academic groups, the private sector, manufacturers, and consumer protection associations. These food standards (2000 standards) are classified into the following three groups: (1) specifications, (2) test methods, and (3) codes of hygienic practice.

All food standards include the following quality and safety factors: physical,

chemical, and microbiological specifications; contaminants (e.g., heavy metals); toxins such as mycotoxin; additives; packaging; labeling; and sampling.

IMPLEMENTATION OF NATIONAL STANDARDS

With approval of the Supreme Council of Standards, the ISIRI may declare the implementation of standards for goods (or components) and codes of practice as compulsory standards in regard to safety, public health protection, product quality assurance, consumer protection, and other welfare or economic considerations. The ISIRI may determine the time limits for implementation, which must be at least three months. More than 100 items in the food standards are compulsory. These cover all domestic food production and imported and exported foods.

Whenever the implementation of standards is declared compulsory for certain goods, within determined time limits, production, storage, distribution, and sale of such goods that have a lower quality than the standard and are not branded with the ISIRI mark are forbidden. The infringer may be sent to applicable courts. The ISIRI is responsible for implementation of compulsory national standards.

To receive the ISIRI mark for meeting compulsory standards, all producers must establish acceptable good manufacturing practice (GMP) and quality monitor systems and be found at least three times to conform fully with the quality specifications adopted for a commodity and also to the related national standards.

INSPECTION

The administration of food laws and their implementation requires a qualified, trained, efficient, and honest food inspection service. This service has an important role in food safety and ensures consumer confidence in imported and exported foods and in the ISIRI mark, which indicates adequate quality for domestic foods.

ISIRI inspectors and experts are authorized to enter production sites, as well as sites of packaging, storage, supply, sale of goods, and rendering service sites—all places covered by compulsory standards—in order to inspect and take samples.

LABORATORY SERVICES

Laboratories are essential components of a food control system. The establishment of laboratories requires considerable investment for they are expensive to maintain and operate. Therefore, careful planning is necessary to achieve optimum results.

ISIRI laboratories are recognized as nationally accredited labs for the deter-

mination of product characteristics, for adherence to relevant standards, and for the calibration of measuring instruments.

The ISIRI has 28 branches throughout the country. These execute ISIRI objectives and policies and protect consumers. They have adequate facilities for physical, microbiological, and chemical analyses and they use accredited laboratories for testing and monitoring. All methods that are used are verified and based on certified references such as ISO, Codex Alimentarius, Association of Analytic Communities International, and American Oil Chemists' Society. To improve laboratory performance and ensure the reliability, accuracy, and repeatability of results, ISIRI laboratories participate in proficiency testing administered by international assurance programs. This is especially important for mycotoxin analysis and microbiological determination.

INFORMATION, EDUCATION, COMMUNICATION, AND TRAINING

An increasingly important role for food control systems is the delivery of information, education, and advice to all stakeholders across the farm-to-table spectrum. Such activities provide an important means of building food control expertise and skills in all interested parties, and thereby they have an essential preventive function.

The ISIRI has a scheduled program for training of all stakeholders to improve their knowledge of food safety. This program consists of training university students and quality control officers in factories, giving television interviews, publishing educational pamphlets, conducting classes in laboratory analysis, and test result reporting.

NATIONAL STANDARDS FOR FOOD SAFETY MANAGEMENT

The shift in focus by quality control systems from finished products to a food's entire farm-to-table span has opened a new horizon for food control systems. In accordance with this new concept, international organizations designed and recommended quality assurance (QA) systems such as food safety management and Hazard Analysis and Critical Control Point (HACCP) to local and national authorities in Iran.

The first national HACCP guideline and the first national GMP text were prepared and published by the ISIRI. They were based on Codex Alimentarius, 1997, and were subsequently revised to conform to the latest Codex Alimentarius standards. Many codes of hygienic practice for different food commodities were prepared in accordance with Codex Alimentarius, scientific evidence, and national standards.

To promote QA systems (such as HACCP) in the country, an Iranian National Committee for HACCP has been formed in the Ministry of Health. The committee's aims are the following:

- promote QA systems for related agencies;
- encourage the producers to establish HACCP in their plants;
- coordinate such activities throughout the country;
- train and educate staff at different levels; and
- compile educational materials based on national standards and guidelines.

GLOBAL CONSIDERATIONS

The expanding world economy, food trade liberalization, growing consumer demands, advances in food science and technology, improvements in transport and communication, international trade in fresh and processed food, the increase in food varieties, and the requirements of food safety all mandate a linking of ministries and related agencies; this linking should be on both a national and an international scale.

The Iranian Coordinating Council for Codex Alimentarius was established in 1980 and reorganized according to a new plan in 1998. The council has a section called Iranian National Codex (Alimentarius) Committee (NCC) that covers 21 technical committees (TCs) that include all stakeholders. It is noteworthy that ISIRI is the only contact point for the World Health Organization/Food and Agriculture Organization Codex Alimentarius Commission in Iran. The main goals of NCC are as follows:

- Participate in the preparation of international standards by considering them national priorities and opportunities;
- Participate actively in Codex Alimentarius meetings;
- Elevate the level of national standards by basing them on international levels, especially in safety and health requirements; and
- Combine scientific and technical information for informing producers, consumers, and all stakeholders.

The ISIRI is also a member of the ISO and has established a national TC34 counterpart committee so that authorized local organizations and stakeholders can participate in ISO activities.

CONCLUSION

Since food safety is pivotal to health and development, it is mandatory to coordinate all activities at the national level.

Considering the national situation in Iran, all authorized organizations and agencies must carry out their duties in accordance with the law and forward all data to designated departments for proper management of the information.

Considering the importance of food safety management systems, such as HACCP, it is necessary to expand the establishment of such systems throughout the country.

In food safety fields promotion of public awareness is very important and it should be developed by organizing special programs that will involve all related organizations.

Discussion

Dr. Mohammadreza Razailashkajani
Research Center for Gastroenterology and Liver Disease
Shaheed Beheshti University of Medical Sciences

Panel:
Dr. Jackson, Dr. Matthews, Dr. Montes Niño, and Dr. Jamdar

Dr. Jackson first challenged the audience with the question, "What is food safety?" He asked the question in relation to the immune status of a population. *Vibrio* in seafood became a focus of the discussion. A scientist from the Pasteur Institute of Iran pointed to the role of food transportation as a cause of *Vibrio* contamination. He also mentioned anaerobic bacteria as important contaminants of seafood in Iran.

Another challenge came from Dr. Matthews. It concerned the routes by which *Salmonella* may contaminate vegetables and fresh produce. He explained the role of irrigation water, manure, and the low level of hygiene among farm workers in contributing to the problem of contaminated produce imported into the United States.

Enterococcus faecalis resistance to vancomycin and the ways *Staphylococcus aureus* could contaminate food were the next topics. Dr. Salmanzadeh, a microbiologist from the Research Center for Gastroenterology and Liver Disease, raised a question about the methods used in the United States to estimate incidence of Shiga-toxin-producing *Escherichia coli*.

The safety of food produced using bioengineering and the ways of implementing food safety measures in the United States were the next topics. Dr. Matthews answered the final questions, which addressed the role of chlorine as a disinfectant in slaughterhouses, future alternatives, and the ways that the government of the United States controls imported foods.

Day 1

Afternoon Session

Surveillance for Foodborne and Diarrheal Diseases, Including Outbreak Investigations: An American Perspective

Foodborne Disease Investigations Including Surveillance: A Collaborative Pilot Project

Discussion

Surveillance for Foodborne and Diarrheal Diseases, Including Outbreak Investigations: An American Perspective

William E. Keene, Ph.D., M.P.H.
Senior Epidemiologist, Acute and Communicable Disease Program,
Oregon Public Health Services

CASE STUDIES

Case studies of three important foodborne disease outbreaks are presented to illustrate how disease surveillance works in the United States and the evolution of outbreak investigative methods. These outbreaks can be reviewed in detail in the original literature (see also Barrett et al., 1994; Bell et al., 1994; CDC, 2004; Cody et al., 1999; Griffin et al., 1994).

Outbreak 1 was the 1992-1993 Jack-in-the-Box outbreak of *Escherichia coli* O157:H7 infections that affected several western states. The outbreak was caused by widespread undercooking of contaminated frozen ground beef hamburger patties at many outlets of the Jack-in-the-Box fast food chain. Although infections from this source began to appear in California and Nevada as early as November 1992, the outbreak was not detected until it reached Washington state in late December. At that time only Washington state was conducting routine surveillance for these infections. In California and Nevada, in contrast, the infection was not reportable, and few laboratories ever used the special media needed to identify the pathogen. Physicians and the general public there were largely unaware of this pathogen; in the absence of recognized outbreaks, there was no publicity and no public education. This outbreak was a landmark event in modern epidemiological history. It had an enormous effect on the public's perception of the problem of foodborne illness. The political ripples from this event continue to this day. We can quite reasonably talk about foodborne disease epidemiology in the United States before and after Jack-in-the-Box. The outbreak illustrates how large outbreaks with many hospitalizations and even fatalities can

easily escape notice, investigation, and control in the absence of routine disease surveillance.

Outbreak 2, which occurred in 1997, involved *E. coli* O157:H7-contaminated, unpasteurized commercial Odwalla-brand apple juice. Advances in molecular subtyping of this organism and integration of laboratory subtyping with routine surveillance data made it easy (at least in Washington state) to identify this outbreak. Once the outbreak was identified, the source was quickly identified through traditional case interviews and a case-control study. The outbreak led to changes in the way fresh juices were labeled and processed.

Outbreak 3, of *Salmonella* Enteriditis infections linked to consumption of raw almonds in the United States and Canada, was first identified and investigated in May 2004. But in retrospect, cases may have occurred as early as 2002. The outbreak led to changes in almond processing by industry, which is moving toward a ban on the sale of untreated almonds (i.e., raw almonds or those not processed in a way that would kill pathogens).

INTRODUCTION TO DISEASE SURVEILLANCE

Public health epidemiology has a number of goals. One is to monitor the health status of the population (e.g., indexes of morbidity and mortality) as well as the contributors to that health status (e.g., access to medical care, level of personal hygiene, and food consumption histories). Another is to manage health crises as they occur, including the investigation and control of disease outbreaks and the emergence of new pathogens (e.g., SARS, avian influenza, and bovine spongiform encephalopathy). Public health epidemiologists are also charged with providing and interpreting available scientific information to help inform public policy decisions.

In this context, disease surveillance plays a major role. Surveillance was famously defined by Langmuir (1963) as the "ongoing systematic collection, collation, analysis, and interpretation of data; and the dissemination of information to those who need to know in order that action be taken." Surveillance activities involve the collection of raw data, the "cleaning" (correction and standardization) of those data, and the organization and analysis of those data. It is axiomatic in modern public health practice that data are collected in order to be used, and in order to be used they must be disseminated to relevant parties, which may include the medical and academic communities, other public health agencies (domestic or international), policy makers in both public and private sectors, and the general public.

In the United States, communicable disease epidemiology and disease surveillance practices are largely set by state government agencies, not by the federal government. The federal government is a significant source of funding for state programs, and it is a source of logistic and technical support for state agencies, but has surprisingly little authority to investigate disease outbreaks or

take control measures directly. Rather, individual states determine which diseases must be reported, and the procedures by which such reporting will be done. As a result, while the approach is broadly similar in most states, there are considerable variations in public health practice from jurisdiction to jurisdiction. In addition to legal differences, public health agencies vary considerably in funding, staffing levels, and degrees of experience and expertise, and these differences result in different capacities.

Reporting practices in the state of Oregon (a relatively large but sparsely populated state on the Pacific coast, with 3.5 million people spread over 250,000 km^2) are fairly typical of many states. By law the state public health agency specifies a list of diseases and conditions that must be reported by both physicians and laboratories.[1] (Bear in mind that—in the United States—medical care is almost entirely in the private sector.) These lists are distributed to laboratories and clinicians on printed posters, in newsletter reminders, through website postings, and other media. Most notifiable conditions are specifically named infections or defined conditions (e.g., salmonellosis, campylobacteriosis, listeriosis, hepatitis A, meningococcal infection, and lead poisoning). There are also several catch-all categories, including any suspected common-source outbreak (e.g., multiple people in a group with acute gastroenteritis) or any unusual disease of potential public health significance (e.g., imported exotic diseases such as SARS or avian influenza). Both laboratory-confirmed and suspect or presumptive diagnoses are reportable. As a practical matter, although reporting requirements apply both to physicians and to laboratories,[2] in practice most clinicians are not very compliant with reporting laws. The vast majority of reports originate in laboratories. Periodic audits of private laboratories in Oregon indicate that this reporting is reasonably complete (95-100 percent for specified conditions). Of course, the nonspecific conditions (e.g., outbreaks) are aimed at non-laboratory-confirmed cases, so they would have to originate from clinicians, as would presumptively diagnosed cases. Physician reporting of these conditions is relatively incomplete.

ABOUT FOODBORNE DISEASE

Foodborne disease is surprisingly difficult to define, and some reports may have little if anything to do with food, or with transmission by food. The specific route of transmission for most cases of reported enteric illness is unknown, and the proportion that is transmitted by contaminated food is difficult to estimate with precision. “Foodborne” is often used casually to cover almost any

[1]In the United States, the great majority of medical care and diagnostic laboratory work is done in the private sector. Reporting laws apply equally to the private and public sectors.

[2]Such that, at least in theory, cases diagnosed based on a specific lab test should be reported twice.

enteric disease, notwithstanding that many illnesses transmitted by food are not gastrointestinal (GI), and that many GI illnesses can have routes other than food, including waterborne, person-to-person, and direct animal-to-person transmission.

Foodborne and diarrheal diseases can be caused by a wide range of bacterial, viral, and parasitic agents. The incidence of these illnesses varies considerably around the world, reflecting differing practices in agriculture and animal husbandry, food processing, consumer behaviors, diet, local and regional ecology, and many other factors.

PROCESSING DISEASE REPORTS

The legal requirements and mechanisms for reporting potential foodborne diseases are completely merged with reporting laws for all communicable diseases. All reports for all diseases funnel through the same public health agencies. Depending on the size of those agencies, however, different people may be responsible for tracking different diseases. In Oregon, for example, communicable disease epidemiology is divided into three main groups: HIV and other sexually transmitted diseases, tuberculosis control, and everything else (which includes foodborne and diarrheal disease, hepatitis, rabies, meningitis, zoonotic diseases, and hospital infections).

Again referring to Oregon practices, individual case reports stream in primarily from private laboratories and occasionally from private physicians. By law, reports must be made within one day of a laboratory turning out the relevant result—and, while not perfect, most reporting is indeed quite rapid (within a day or two).[3] For most common diseases, case reports result in some type of investigation, initially conducted by local health department nurses or environmental health specialists.[4] Following disease-specific investigative guidelines developed by state epidemiologists, an attempt is made to interview patients (or their parents or other proxy) and collect a variety of demographic, clinical, and epidemiological data using standardized, disease-specific forms. These guidelines and forms, as well as other information about reporting practices in Oregon, are available on our department's webpage (http://www.dhs.state.or.us/publichealth/acd/disrpt.cfm#forms).

Cases include questions about a variety of recognized risk factors for most infections. Persons with nontyphoidal salmonellosis, for example, are asked about

[3]Pilot projects are under way to allow "instant" electronic reporting directly from major private laboratories, but this is proving a complicated and very expensive proposition.

[4]Local (county) health departments are the frontline public health agencies in Oregon and most states. Oregon's 35 counties range in population from < 2,000 to 675,000, and the local health departments vary correspondingly in size and sophistication.

consumption of meat and poultry, eggs, unpasteurized milk and cheese, and sprouts; meals away from home; contact with reptiles (unfortunately, rather popular pets in the United States and a regular source of these infections); other pets, livestock, sick and incontinent people; and recent travel. The time period of interest for these questions corresponds to the likely exposure period, which is derived from the patient's date of onset and the pathogen's typical incubation period. Thus, cases with *E. coli* O157:H7-infected patients might be asked about the period from 1 to 10 days before onset (with emphasis on 2 to 6 days), while salmonellosis cases would consider the 1 to 5 days before onset. A "yes" answer to one or more question does not, of course, confirm the source of infection. Most individuals report multiple potential sources—and no doubt forget or neglect to mention other possibilities. In the short term these responses are used to help frame various health education messages (e.g., about the risks of pet reptiles or the importance of good hand-washing behavior). Exposure data are considered more systematically if suspicions of common-source outbreaks are raised. These interviews are generally conducted by telephone. Local health department staff generally find telephone numbers by contacting the patient's physician, who is named on the laboratory report. Most individuals are relatively easy to contact, but there are exceptions, of course. Only a very small number of individuals refuse to cooperate with these interviews.

Case reports are forwarded (usually by fax, or increasingly, electronically) from local health departments to the state public health department as soon as interviews are concluded. This is typically within 2 to 3 days of the initial laboratory report, and often within 24 hours. Even if the patient cannot be contacted, a report is filed with as much information as possible (e.g., demographic information obtained from the clinician).

Surveillance data are entered into a customized database at the state level. The Oregon database currently includes case reports back through 1988—some 75,000 as of August 2005. State epidemiologists have immediate access to both individual case reports and the ability to generate on-demand generic or ad hoc summary reports (e.g., the number of reported cases of *Salmonella* serotype Newport affecting males between the ages of 15 and 35 in counties *X*, *Y*, and *Z* during each of the past 15 years). This information is critical to assessing what is normal and what might constitute an aberration (e.g., an outbreak). To work effectively, these data must flow quickly. For most enteric infections the lag from first laboratory identification to local health department notification to investigation to report to state authorities is 2 to 4 days.

THE ROLE OF THE PUBLIC HEALTH LABORATORY

Communicable disease epidemiology requires partnerships with effective public health laboratories (PHLs). Every state has a PHL, which by law is the primary reference laboratory for public health-related microbiology, virology,

and other areas. Public health laboratory staff and epidemiologists work together closely. The capacities of these laboratories vary considerably, and they are supplemented by formal and informal collaborations with neighboring state laboratories, as well as laboratories of the U.S. Centers for Disease Control and Prevention (CDC).

In Oregon, diagnostic laboratories are required not only to report but also to forward (at their own expense) isolates of specified pathogens[5] to the PHL. These specimens usually arrive within a few days of initial isolation. The identity of these pathogens is confirmed at the PHL, and many of the isolates are now being subtyped by a combination of traditional and molecular methods.

Although rarely of any clinical importance (and hence not attempted by for-profit private laboratories), subtyping is of critical importance for epidemiology. For example, all *Salmonella* isolates are serotyped by the Kaufmann-White scheme; all *Shigella* and *Vibrio* isolates are speciated. We currently use nationally standardized methods to subtype all isolates of *E. coli* O157, *Salmonella*, and selected *Shigella* received by pulsed-field gel electrophoresis (PFGE). Subtyping proceeds as quickly as staff time allows, with most results being available within 2 to 8 days of receipt. Laboratory subtyping data are added to the epidemiological case database. Molecular subtyping data are also shared with other laboratories around the country through CDC's national PulseNet network (http://www.cdc.gov/pulsenet/). States that do not get this kind of laboratory data, or who cannot get it quickly, are rarely able to identify or solve the epidemiologic puzzles that come along.

DATA LIMITATIONS

Official statistics only reflect numbers of reported cases, and they are an incomplete and imperfect index of disease incidence. Many factors affect the likelihood that an infection will be reported. Asymptomatically infected individuals, for obvious reasons, are unlikely to be identified, as are symptomatic individuals who, for whatever reason (e.g., mild symptoms, lack of health insurance, inconvenience), do not seek medical care. Even if they do see a physician, they must be given an appropriate test (e.g., a stool culture) and they must test positive. Depending on the disease, probably only a minority—and for most enteric illnesses, probably only a small minority—of infected persons are reported. The numbers are not only reduced, but reported cases are a biased sample of infected persons—biased to include those most likely to be tested or diagnosed (e.g., hospitalized individuals, others with more severe illness, very young children, and those with better health insurance). Surveillance statistics must always be interpreted with caution.

[5]Including all *Salmonella*, *Shigella*, *E. coli* O157, *Vibrio*, *Yersinia*, and *Listeria* isolates, to name the potentially foodborne agents.

ABOUT OUTBREAKS

Based on identified epidemiological connections to other cases, we informally classify enteric disease reports into one of three categories: sporadic, household, or outbreak. Sporadic cases have no recognized epidemiological links to any other cases. Household cases are linked to other illnesses within the same household but not elsewhere. Outbreak cases are epidemiologically linked to cases in other households. Thus, as few as two cases may be sufficient to define an outbreak, given adequate epidemiological information.[6] Cases are reclassified as new information becomes available.

While outbreak cases gather much of the attention and most of the publicity, the great majority of enteric disease case reports are sporadic. For example, although we have investigated more than 30 outbreaks of *E. coli* O157 infections since 1990, totaling 430 reported cases, most cases reported since then—1110 (63 percent) of 1743 as of October 2004—are considered sporadic. Almost by definition the causes of sporadic cases are unknown. Even in the aggregate (e.g., large and expensive FoodNet case-control studies), most analyses fail to explain many new exposures of great importance.

We investigate outbreaks for a number of reasons, some of which are obvious:

- To stop ongoing transmission (e.g., from a contaminated commercial product that is still available in stores or in consumers' homes);
- To facilitate diagnosis and proper treatment or prophylaxis in the setting of a community outbreak;
- To identify risk factors for infection (e.g., consumption of unpasteurized milk or alfalfa sprouts, or recent antibiotic use);
- To stimulate research (e.g., when outbreaks raise questions regarding food microbiology or consumer behavior); or
- To provide the information necessary to develop sensible long-term prevention strategies.

Outbreak investigations also provide important training opportunities for public health workers and a chance to develop and test new investigative approaches. Even experienced staff need to keep in practice.

Outbreak cases and outbreak investigations have proven to be disproportionately important to public health practice (Keene, 1997). Given a successful investigation, the specific sources of transmission can be identified, and risk factors associated with pathogen amplification and transmission (e.g., food han-

[6]Larger outbreaks tend to get more attention than very small ones. Very small outbreaks (< four cases) may get only a cursory review, depending on circumstances.

dling practices or time or temperature abuse) can be confirmed. Given an identified exposure time, we can calculate incubation periods. Some outbreaks provide useful natural experiments, which can provide insight into important data, such as infectious dose or host risk factors for illness (e.g., immunocompetence, age, or concurrent medication). Not least of all, outbreaks can provide an opportunity for health education that is amplified through the private media. (In the United States, for example, outbreaks often provide the only context for public health representatives to have access to television news, which is privately controlled.)

Outbreak investigations typically begin with one of two scenarios. The most common, which we can call "Type 1," begin when a private citizen (or, less often, a physician or infection control nurse) contacts the local health department to report that "a bunch of people became sick" after some event (e.g., a wedding, a shared restaurant meal) or that illness rates seem abnormally high at some institution (e.g., a prison, school, camp, or nursing home). These clusters are most commonly caused by Norwalk-like viruses (noroviruses), and less often by other infections or intoxications (e.g., *Clostridium perfringens*, *Bacillus cereus*, *Staphylococcus aureus*, or scombroid). Laboratory confirmation of an etiology generally depends on public health resources, both for specimen collection and for testing. Testing for Norwalk-like viruses—by far the most common cause of identified outbreaks, and perhaps sporadic gastrointestinal illness as well—is essentially unavailable in the private sector. Diagnosis (by polymerase chain reaction) only occurs in public health labs, and often only in the case of outbreaks.

The second category of outbreaks, which we can call "Type 2," begin as scattered routine surveillance reports of laboratory-confirmed cases (e.g., salmonellosis, *E. coli* O157). It is usually not apparent to the patient (or the physician) that these cases are part of a cluster. Instead, this becomes apparent only when epidemiological and laboratory data are pooled over an extended area (multiple counties, multiple states) and time period (days to months). For example, more than one case with an uncommon *Salmonella* serotype or *E. coli* O157 PFGE pattern might be reported within a short time period. These investigations may begin slowly, but quickly become high-priority investigations, often involving multiple epidemiologists and complicated liaisons with other public health agencies inside and outside the state (e.g., other state health departments, CDC, and state and federal regulatory agencies, such as the Food and Drug Administration [FDA] or the U.S. Department of Agriculture).

Finding the source of outbreaks can be quite challenging, particularly if states do not have enough cases locally to develop specific hypotheses regarding possible sources. Many investigations are unsuccessful. Delayed reporting and a failure to obtain clinical specimens, such as stool samples, are common problems. Coordination between agencies is sometimes excellent, and sometimes poor—often more a matter of personalities and chance than we would like to admit. The CDC often plays a useful role in coordinating efforts between states,

and can provide technical assistance if needed. Sometimes the CDC is bogged down in internal bureaucratic procedures and is more of a hindrance than a help.

Type 2 outbreaks demand regular and timely review of surveillance data. In Oregon these lab data are monitored by epidemiology staff throughout the day. Reporting totals must be interpreted in the context of historical norms. Outbreak cases are sometimes first recognized as such following reports or inquiries from public health agencies outside our state. We have almost daily contacts by e-mail or telephone with our counterparts in neighboring states, and less often with other epidemiologists around the country and in Canada. E-mail networks and Listservs provide a fast, convenient way to query other public health agencies. For example, someone might post an e-mail notice saying: "Our state seems to be getting more than our usual number of *Salmonella* Braenderup's over the past few weeks. Are you seeing any in your state?" This kind of inquiry would then prompt a comparative review of epidemiological and laboratory data, and potentially we would join with the other state(s) to look for a source using common questionnaires and methods. Once primarily done just by epidemiologists, nowadays these kinds of inquiries go from laboratory to laboratory, from laboratory to epidemiologist, from epidemiologist to laboratory, as well as from epidemiologist to epidemiologist. Molecular subtyping data have become critical to these efforts over the last five years in the United States.

OUTBREAK INVESTIGATIONS

While following certain general patterns, each outbreak investigations is unique. In Oregon, local health agencies take the lead in the investigation and control of most Type 1 outbreaks, which tend to be less complicated. Investigations typically involve both public health nursing staff and environmental health specialists—the same people who conduct routine inspections of restaurants, swimming pools, and child care establishments (among other duties). Different places have a different array of licensing and regulatory agencies that cover wholesale and retail establishments, including restaurants, food processing plants, markets, bakeries, schools, hospitals, and nursing homes, and investigations demand coordination between these agencies. Epidemiologists take the lead in these investigations, which are usually collaborative efforts involving environmental health, nursing services, regulatory agencies, and others.[7] (In the United States, epidemiologists almost never have any regulatory authority; we have little if any enforcement power, nor do we issue fines or penalties of any kind.)

Type 1 outbreaks tend to reflect local problems—most commonly poor food handling practices or inadequate worker hygiene. Despite our best efforts, experience suggests that such outbreaks are easier to explain than they are to prevent.

[7]At least we epidemiologists like to think we're in charge….

State epidemiologists provide technical assistance in questionnaire development and data analysis. If local staff are overwhelmed, state personnel help with interviews and occasionally will go into the field. We try to encourage our staff to go into the field more often, as it is by far the best way to investigate outbreaks; but competing demands from other projects, family responsibilities, and budget constraints can limit these opportunities.

We have developed a system of templates that Oregon epidemiologists use to quickly develop outbreak-specific questionnaires, data entry databases, and data analysis programs.[8] These templates save a great deal of time and help us focus more efforts on data collection and interpretation and less on raw data shuffling and preparation. Given enough cases, we usually attempt some type of cohort or case-control study to determine specific source(s) of infection.

Oregon state epidemiologists are always available to consult with local health departments and offer technical advice, often designing questionnaires and performing data analysis after interviews conducted by local staff. One of a pool of staff epidemiologists is always available on call outside normal office hours and if necessary, staff are usually available to travel on short notice to support or direct investigations in the field. Disseminated, surveillance-anomaly-driven Type 2 outbreak investigations are almost always run by state epidemiologists, as they require more sophisticated epidemiological training and experience, as well as (usually) much more liaison between agencies inside and outside Oregon. Besides the official agencies, we sometimes enlist the assistance of persons in academic or other institutions who may have special expertise (e.g., to conduct experimental tests not available at PHLs). In some states with fewer resources, federal epidemiologists from the CDC (usually trainees with close supervision by more experienced staff in Atlanta) play these supporting roles more often.

At the outset of these investigations we often have no idea what connects the cases, other than their illness. We scrutinize the routine reports that we typically already have on these individuals for demographic or behavioral clues (e.g., similar ethnic backgrounds, unusual age or sex distributions, attendance at the same mass event or different outlets of the same restaurant chain). Failing any immediate success from such a review, we will re-interview cases with hypothesis-generating questionnaires about recently consumed food.[9] Of course, in the meantime we compare notes with our counterparts in nearby states, as already mentioned. This type of case finding is often critical to uncovering enough cases to yield statistically meaningful sample sizes. As specific hypotheses emerge we may conduct case-control or other studies to test them.

---

[8]See http://www.healthoregon.org/acd/keene.cfm for a more extensive description of these and related tools.

[9]Again, refer to http://www.healthoregon.org/acd/keene.cfm and particularly our "shotgun" questionnaire.

Outbreak investigations should be treated as matters of extreme urgency. Staff schedules are rearranged as needed, and staff may work evenings and weekends until the source is identified. It is often easier to reach people by telephone in the evening, for example, so we have to be able to call when our targets are available, no matter how inconvenient it may be for us. Moreover, delayed reporting is the rule, not the exception, and memories can quickly fade.

Case-control methods vary, but we often target households with matching telephone prefix numbers as controls for cases.[10] Once initiated, these kinds of studies can usually be completed quickly, and rarely take more than 24 to 48 hours. We emphasize speed, because our basic premise is that the problems may be ongoing. Delays could mean additional morbidity and mortality.

Once a source is identified, we may advise the public through press releases if there is a public health purpose to be served by doing so (e.g., recall of contaminated product). If dangerous products are identified that may still be available to consumers (e.g., ground beef contaminated with *E. coli* O157:H7), press releases are issued without delay. Decisions to issue press releases are usually made by senior public health staff, but without political input. While we are aware of the adverse consequences of such publicity on business interests, this is usually given little if any consideration. We work closely with regulatory agencies on product recalls, but often we have to keep prodding them to move as quickly as we epidemiologists can. In part this reflects the more formal legal structure at the federal level of, say, an FDA-instigated product recall.

It is important to note that confirmation of an outbreak source only rarely involves recovery of a pathogen from an implicated product. In fact, culture of food products typically plays a very small role in outbreak investigation and is often all but irrelevant to the conduct of the investigation. Contaminated foods are often long gone before outbreaks are even recognized, or contamination may occur at such a low and intermittent level as to be very difficult to detect. Confirmation means establishment of strong epidemiological evidence linking consumption of a product to illness, corroborated by biological plausibility and usually compatible information about product distribution, even if not (yet) having convincing product trace-back or trace-forward information. More detailed information about product distribution is usually sought as soon as possible, but in general we do not delay public notification for such information unless it is necessary to confirm the source. Food testing is often attempted after the fact, and is sometimes successful (more often not), but we never wait for such results to notify the public if the epidemiological evidence is compelling.

For many years regulatory agencies in the United States were very uncom-

[10]For example, if the case's number is 503-731-4024, we might start with 503-731-4025, and continue -4026, -4027, . . . until we found willing respondents who were eligible (e.g., not recently ill, similar age bracket).

fortable with this—often to the infuriation of epidemiologists—but over the last 5 to 10 years regulators have become much better about proceeding based on epidemiological evidence alone. The credibility of epidemiologists is on the line every time we conduct these studies and draw conclusions from them, so this work must be done carefully and thoroughly to avoid either false negative or (usually worse) false positive results (i.e., implicating a product that had nothing to do with the illness).

Even in our state of only 3.5 million people, we lead or participate in these types of studies (i.e., Type 2) about once or twice each month. In just the last year we have used these approaches to link salmonellosis outbreaks to produce (alfalfa sprouts and honeydew melons), almonds, and processed food (commercial egg salad being distributed at a chain of grocery stores in several western states).

Type 1 investigations begin much more frequently—about two or three per week—in our state, with an investigation resulting in some kind of cohort or case-control study perhaps once a week. This means that our staff can obtain considerable experience developing questionnaires and carrying out these investigations under realistic time pressures. While many investigations are relatively inconsequential, this experience is invaluable as training. In addition, it can be difficult to predict at the outset which investigations will be the most consequential. We have made highly significant discoveries in the course of investigations of very small clusters (Keene, 1997).

OUTBREAK REPORTING

We ask our state or local health department epidemiologists to summarize outbreak investigations, using a standardized questionnaire.[11] This practice is state-specific, and many states do not track investigations as completely as we do. In addition to paper records, including questionnaires, outbreak summaries are logged into a computer database. Foodborne and waterborne outbreaks are routinely reported to the CDC (nationally). Interesting or instructive outbreaks are sometimes presented at national meetings or written up for publication in peer-reviewed journals. We average about three to five such outbreaks per year. Fifteen to 20 outbreaks each year merit at least local or regional attention.

With increased funding and staffing over the last 10 years, our department has become much better at investigating outbreaks and in particular at logging investigations when they occur. The number of outbreaks logged annually has increased from less than 10 in 1995 to over 180 in 2004. The great majority (85 percent) represent clusters of acute gastroenteritis. About one-half of these out-

[11]The Foodborne Outbreak Summary form is posted on our Web page (http://www.dhs.state.or.us/publichealth/acd/foodrpt.cfm). There are similar forms for nonfoodborne outbreak investigations.

breaks are clearly foodborne, and a significant proportion of the rest had indeterminate routes of transmission (i.e., may have been at least in part foodborne). As previously noted, the most commonly identified etiology by far for reported outbreaks in Oregon are Norwalk-like viruses (noroviruses). Since our PHL became able to assay stool specimens for Norwalk by reverse transcription-polymerase chain reaction in 1999, the number of these outbreaks logged has steadily increased. Multicounty and multistate outbreaks (typically salmonellosis) are investigated with some regularity.

We encourage reporting through whatever channels possible. We assure local health department staff that the more they report, the better we think they are doing. One of the biggest hurdles is convincing people in medical institutions and local health agencies that outbreaks do not reflect badly on them; indeed, it is just the opposite. We know that common-source clusters are occurring with great regularity everywhere and that we hear of only a minority that take place. So the better the surveillance is, the more outbreaks we will hear of. It's that simple.

To return to Langmuir's original dictum, we must appreciate that surveillance data do not originate in a vacuum, and that we cannot long succeed without providing feedback to our data sources and other collaborators. We go to considerable lengths and expense to maintain contacts with the community of laboratory scientists, clinicians, infection control practitioners, and public health nurses who provide us with our raw data. We mail a biweekly newsletter (http://www.dhs.state.or.us/publichealth/cdsummary/index.cfm) to all licensed physicians in the state; the newsletter provides information and news of epidemiological interest and in general reminds clinicians that we exist. We also regularly speak to medical, academic, and lay audiences around the state. We present outbreak reports and other topics at scientific meetings and prepare manuscripts for publication in peer-reviewed medical journals. We have regular contact with the news media concerning outbreaks and other developments. There is an obvious feedback loop at work here, as news about outbreaks and other surveillance data generates interest and heightens awareness, which in turn improves reporting, which in turn facilitates the identification of new outbreaks, which in turn generates more news. If outbreaks are not publicized, or the public is not made aware of the function, existence, and value of public health investigations, few outbreaks will be identified.

Although not covered in this presentation, we also participate in collaborative research projects concerning foodborne and diarrheal disease under the FoodNet umbrella.[12] Oregon has been a FoodNet site since the program's inception in 1995. FoodNet sites have special grant funding from the federal government that enhances epidemiological capacity. FoodNet states conduct all the usual

[12]See http://www.cdc.gov/foodnet/ for more information on FoodNet.

functions of state health departments, but also participate in special multistate projects aimed at identifying causes of foodborne and diarrheal disease. These projects are often very resource intensive. These kinds of projects presuppose well-established, mature surveillance networks.

CONCLUSIONS

Surveillance for foodborne and diarrheal disease is a complex and collaborative effort that involves laboratory, environmental health, and epidemiological resources. Regulatory, industry, and academic agencies also contribute to the process. Surveillance protocols in the United States depend on clearly defined legal responsibilities and authorities, generally specified at the state level, which give selected public health agencies access to otherwise confidential medical information, and ensure the availability of specimens for specialized characterization for epidemiological and other purposes.

Mandatory reporting of selected diagnoses and laboratory test results is a pillar of our system, which in turn depends on at least a significant number of people seeking medical care for their illnesses and ending up being cultured or otherwise tested to determine a specific etiology. Meaningful follow-up to disease reports depends on rapid communication between public health officials, physicians, and patients. Data are collected using standardized instruments and rapidly pooled for analysis at local, state, and national levels. Informal and unstructured contacts between state and national public health agencies are among the most important means of pursuing potential common source outbreaks that may involve multiple jurisdictions. Trained epidemiologists are available to respond to presumptive anomalies, including outbreaks of disease. Database development and maintenance are important considerations for both routine case reporting and outbreak investigations.

Epidemiologists, laboratorians, regulators, and academics have attempted to integrate reports from outbreak investigations and other surveillance data, laboratory characterization of pathogens, and food sampling programs conducted by regulatory agencies and industry to achieve a “big picture” of the causes of foodborne disease. While progress has been made, these efforts have proven frustratingly inconclusive. Large and expensive population-based case-control studies of sporadic cases, for example, often end up explaining relatively few cases. Outbreak investigations, while often definitive, are difficult to extrapolate from. Routine epidemiological data are often biased—sometimes seemingly hopelessly so. Questions of attributable risk (e.g., How much campylobacteriosis comes from undercooked poultry? How important is poor hand washing by restaurant workers to disease transmission? Is imported produce more of a problem than domestic produce?) remain largely unanswered. There is no consensus about how to solve these problems, or even agreement that they can be solved.

Despite all these problems, public health agencies probably deserve much of

the credit for stimulating changes in food processing and handling practices at both commercial and consumer levels, not to mention improving the quality of related medical care. Good surveillance data can be used to assess temporal trends in the incidence of foodborne and diarrheal disease, and most indicators suggest that a number of them may be declining in the United States over the last few years. Of course, foodborne-illness-associated morbidity and mortality are greatly reduced from levels seen 100 years ago, reflecting improved hygiene and sanitation at all levels.

The American system of disease surveillance is expensive, complicated, and not at all an idealized model. It can be maddeningly bureaucratic and inefficient. At the same time, there is a great tradition of hard and often productive work that often translates to rapid identification, investigation, and resolution of public health problems with consequent prevention of unnecessary morbidity and mortality. It is a tradition that we are happy to share with our counterparts in Iran in hopes that this will help stimulate the development of your own protocols and traditions, in turn benefiting the health of the Iranian people.

REFERENCES

Barrett, T. J., H. Lior, J. H. Green, R. Khakhria, J. G. Wells, B. P. Bell, K. D. Greene, J. Lewis, and P. M. Griffin. 1994. Laboratory investigation of a multi-state food-borne outbreak of *Escherichia coli* O157:H7 by using pulsed-field gel electrophoresis and phage typing. Journal of Clinical Microbiology 32:3013-3017.

Bell, B. P., M. Goldoft, P. M. Griffin, M. A. Davis, D. C. Gordon, P. I. Tarr, C. A. Bartleson, J. H. Lewis, T. J. Barrett, J. G. Wells, R. Baron, and J. Kobayashi. 1994. A multi-state outbreak of *Escherichia coli* O157:H7-associated bloody diarrhea and hemolytic uremic syndrome from hamburgers: The Washington experience. Journal of the American Medical Association 272:1349-1353.

CDC (Centers for Disease Control and Prevention). 2004. Outbreak of *Salmonella* serotype Enteritidis infections associated with raw almonds—United States and Canada, 2003-2004. Morbidity and Mortality Weekly Report 53:484-487.

Cody, S. H., M. K. Glynn, J. A. Farrar, K. L. Cairns, P. M. Griffin, J. Kobayashi, M. Fyfe, R. Hoffman, A. S. King, J. H. Lewis, B. Swaminathan, R. G. Bryant, and D. J. Vugia. 1999. An outbreak of *Escherichia coli* O157:H7 infection from unpasteurized commercial apple juice. Annals of Internal Medicine 130:202-209.

Griffin, P. M., B. P. Bell, P. R. Cieslak, J. Tuttle, T. J. Barrett, M. P. Doyle, A. M. McNamara, A. M. Shefer, and J. G. Wells. 1994. Large outbreak of *Escherichia coli* O157:H7 infections in the western United States: The big picture. In Recent Advances in Verocytotoxin-Producing *Escherichia coli* Infections, eds. M. A. Karmali and A. G. Goglio, pp. 7-12. Amsterdam: Elsevier.

Keene, W. E., E. Sazie, J. Kok, D. H. Rice, D. D. Hancock, V. K. Balan, T. Zhao, and M. P. Doyle. 1997. An outbreak of *Escherichia coli* O157:H7 infections traced to jerky made from deer meat. Journal of the American Medical Association 277:1229-1231.

Langmuir, A. D. 1963. The surveillance of communicable diseases of national importance. New England Journal of Medicine 268:182-192.

Shefer A. M., D. Koo, S.B. Werner, E. D. Mintz, R. Baron, J. G. Wells, T. J. Barrett, M. Ginsberg, R. Bryant, S. Abbott, and P. M. Griffin. 1996. A cluster of *Escherichia coli* O157:H7 infections with the hemolytic-uremic syndrome and death in California: A mandate for improved surveillance. Western Journal of Medicine 165:15-19.

Foodborne Disease Investigations, Including Surveillance: A Collaborative Pilot Project

Ali Ardalan
Epidemiologist, Research Center for Gastroenterology and Liver Disease

Surveillance of foodborne diseases is receiving increased priority in the public health agenda of many countries. It is instrumental in estimating the burden of foodborne disease, assessing its relative impact on health and economics, and evaluating disease prevention and control programs. It allows rapid detection and response to outbreaks. In addition, it is a major source of information for conducting risk assessment and, more broadly, for risk management and communication.

Ideally, foodborne disease surveillance should be integrated with food monitoring data along the entire feed-food chain. Integrating such data would result in robust surveillance information and allow appropriate priority setting and public health intervention. For this purpose, intersectoral and interinstitutional collaboration are of paramount importance. Therefore, within Iran a strategic plan was developed by the highest authorities. Proposing a plan to integrate the different organizational activities that are involved in food safety is the concern of the Commission on Health and Medicine of the Iranian Parliament.

The main organization in charge of foodborne disease surveillance is the Department of Food and Waterborne Disease at the Center for Disease Control in the Ministry of Health (MOH).

The focus of the current system is the Health Network, mainly active in rural areas, to report dysentery and cholera and to detect outbreaks; however, sporadic cases are not receiving sufficient attention. Physicians in Iran must report cases of certain diseases, such as polio, measles, and diphtheria, but there is no obligation to report cases of foodborne disease. In addition, in the Health Network, physicians are expected to report cases of dysentery and suspect cholera, but there is no reporting of other foodborne diseases. The same is true about

outbreaks of these illnesses, and most outbreaks go undetected unless they are huge or cause severe signs and symptoms or mortality. Hence, many cases of foodborne disease and the relevant outbreaks may never be reported.

When a person becomes ill with a foodborne disease, he or she may be part of an outbreak or may have a sporadic illness that is not part of a recognized outbreak. Based on 1997 statistics, the U.S. Centers for Disease Control and Prevention (CDC) estimates that 76 million Americans have foodborne illnesses each year, although only approximately 400 to 500 outbreaks are reported to the CDC each year, accounting for only 10,000 to 12,000 persons with foodborne illness. There is no supportive evidence that we are in a better situation. Consequently, sporadic cases should be the prime target for prevention efforts because sporadic cases are far more common than outbreaks; however, it does not mean ignoring outbreaks.

Traditional passive surveillance systems or laboratory-based reporting cannot provide precise estimates to evaluate food safety reforms and program changes, or tell us how they will affect the incidence of foodborne disease. These systems rely on a number of events. First, an individual with foodborne illness must seek medical care. Then, the physician must order a test and request laboratory analysis. Next, results must be reported locally and, finally, to the national health system. If any step in the process is missed, the case will go unreported. Before the active foodborne surveillance system project, the CDC estimated that only 1 percent to 5 percent of foodborne disease cases were reported. The CDC conducts surveillance for foodborne diseases in the United States in several different ways to obtain the necessary information. So, it seems the only practical solution is a multipronged approach to overcome our information deficiency about foodborne diseases. The main objective of this collaborative pilot project is to develop a model for a National Foodborne Disease Surveillance System (FBDS) in Iran.

The organizations involved are the Department of Food and Waterborne Disease, MOH, and the National Department of Foodborne Diseases of the Research Center for Gastroenterology and Liver Disease (RCGLD) at Shaheed Beheshti University of Medical Sciences. Joining policy makers and administrators with researchers can be a valuable opportunity that we have often missed in our country. This has led to a waste of limited resources in administration, training, and research.

The project has some specific objectives, including developing the following:

- An FBDS plan with such stages or sections as formulation of objectives, case definition, data sources, data collection instruments, communication system, analysis strategies, feedback system, and assessment;
- An outbreak investigation package;

- Training courses on establishing FBDS at the national, regional, and provincial levels; and
- An FBDS network for information exchange, learning, and training.

The main criteria of the model should include:

- Compliance with MOH policy;
- Accuracy;
- Cost-effectiveness;
- Feasibility; and
- Resource adjustment.

The main parts of the project will be the following:

- Laboratory-based surveillance;
- Physician-based surveillance;
- Population-based survey;
- Outbreak investigation;
- Case-control studies; and
- An FBDS network.

A most critical step is selecting the appropriate location for the project. The following criteria should be considered for selecting the project site and population: feasibility, representativeness, and cooperation of the authorities.

Regarding the aforementioned criteria, it seems that Karaj district is appropriate. It is located 48 km west of Tehran, about a 30 minute drive. The RCGLD has the experience of conducting a foodborne project there, its health authorities are cooperative, and its demography is representative of the country. In addition, an important point is that it is a large city. Since the main current and future problems of an FBDS are large cities, the Karaj project would be a valuable experience for establishing a national system.

I wish to review a summary of the results of a study the RCGLD conducted in seven health centers, three hospitals, and three private clinics in the Karaj district. Note that no private physician's office was included because of our resource limitations. In total, 734 stool samples of patients receiving the diagnosis of acute diarrhea were studied. The annual incidence of shigellosis was 17 percent with the most common type being *S. flexneri* comprising up to 45 percent of the cases. The seasonal trend of shigellosis decreased from the hot to cold seasons although the pathogen existed all year without leading to outbreaks.

Let us return to the Foodborne Disease Surveillance Pilot Project and the different stages of the project.

Laboratory-Based Surveillance

- Include laboratories that conduct microbiological testing of stool samples to determine the culture-confirmed cases of foodborne illnesses.
- Propose a guideline to laboratories to standardize their practices for processing and culturing samples.
- Conduct diagnostic accuracy studies at the beginning and end of the project.
- Conduct a molecular epidemiology study based on culture-confirmed samples to determine the serotypes of pathogens.

Physician-Based Surveillance

- Include physicians in both the public and private sectors to determine the cases of public health emergency illnesses, such as botulism.
- Include reporting of diarrheal cases by Health Network physicians on a regular basis.
- Conduct surveys to estimate the burden of diarrheal diseases over time and to determine how often and under what circumstances physicians order tests.

Population-Based Survey

To estimate the numbers of diarrheal cases that occur in the catchment area over time, the proportion of persons with diarrhea who seek health care, the proportion of patients who follow the physician's order for stool testing, and these patients' food handling behaviors and practices are particularly important.

Outbreak Investigation

- Conduct epidemiological studies followed by molecular studies to investigate the source of outbreaks.
- Develop an outbreak investigation package including a manual that covers investigation design, forms, the analysis plan, required software, and report format.

Case-Control Studies

Case-control studies consist of interviews with selected persons who had laboratory-confirmed cases of *E. coli (*including *E. coli* O157:H7*), Shigella, Salmonella,* and *Campylobacter* and a randomly selected control group of people in the community who were not ill. The objective is to statistically determine risks associated with different foods and to obtain information on potential exposure.

Developing an FBDS Network for Information Exchange, Learning, and Training

We are going to turn the "alley" of information exchange into a "super highway" in our community through developing a website and establishing an e-mail group, including national and international experts and authorities. The website could be a part of the existing RCGLD Web site at http://www.rcgld.org. A very important point is that these activities will be managed by the Network Committee, which will work with others. It means that there will be no disturbance of other administrative activities of the project. The necessary documents will also be developed, both in hard and soft copy about the FBDS process and about lessons learned from FBDS and the outbreaks. There will be the reports of the FBDS and the investigations.

An important aspect of the network will be the just-in-time lectures on the noted subjects during different stages of the project. The main idea is a super-course, run by a Pittsburgh University team, in the form of a freely available online library of public health. It has a Web-based, icon-driven format, mainly with PowerPoint slides, graphic presentation, and a multilingual text. The super-course developer, Professor LaPorte, named it *Hypertext Comic Book*. Examples of lectures on foodborne outbreaks can be found on the website.

You can find another example of these lectures about the disease surveillance system in the town of Bam, which has been developed by the Center of Disease Management, in the MOH after the disastrous earthquake in 2003. It is of great importance that all parts of this system and all activities be evaluated to ensure the main objectives are met.

In summary:

- The collaborative pilot project will develop a national model for a foodborne disease surveillance system.
- It is a multipronged approach by the MOH and the RCGLD to correct our lack of information about foodborne illness.
- The collaborative pilot project will be enriched by molecular studies and by the Foodborne Disease Network.

Discussion

Dr. Mohammadreza Razailashkajani
Research Center for Gastroenterology and Liver Diseases
Shaheed Beheshti University of Medical Sciences

Panel:
Dr. Keene, Professor Mohraz, Dr. Gooya, Dr. Nadim, and Dr. Ardalan

Professor Minoo Mohraz, the president of the Iranian Association of Infectious Diseases, urged that Iranian clinicians and scientists working in the fields relevant to foodborne disease grasp opportunities like this workshop to benefit from the experiences of their American colleagues. She also expressed her concerns about the increase of zoonoses in Iran that could be controlled by stricter food safety measures.

Responding to a question from an Iranian attendee on ways to improve reporting of foodborne disease in Iran, Dr. Keene mentioned that laboratory and physician monitoring systems should be developed in Iran. He stressed that these systems should be well funded and supported by the government in order to be successful. Dr. Keene also addressed the question of how state governments in the United States send surveillance reports and data on foodborne disease to the federal government. The final point was from Dr. Ardalan on the challenges faced by a new food surveillance system in integrating it into the established public health sector.

Day 2

Morning Session

Inspections and Investigation: Tools for Detecting Sources of Food Contamination and Preventing Illness Outbreaks

Food Monitoring, Investigation, and Inspection Infrastructure in Iran

Discussion

Inspection and Investigation: Tools for Detecting Sources of Food Contamination and Preventing Illness Outbreaks

George J. Jackson
Former Dean of the Staff College,
Center for Food Safety and Applied Nutrition,
U.S. Food and Drug Administration

Abstract Regulatory agencies such as the U.S. Food and Drug Administration use trained inspectors to monitor the hygienic status of the food supply and of the food production and distribution environments. Inspectors may take samples for laboratory analysis. Investigations are undertaken when standard inspection and analysis do not solve such problems as food contamination or illness outbreaks from unknown sources. These investigations are conducted by teams that may include inspectors, laboratory analysts, and epidemiologists.

Described in detail are two investigations: a food-associated illness outbreak caused by the bacterium *Yersinia enterocolitica* from an unexpected source and a series of illness outbreaks caused by the parasitic protozoa *Cyclospora cayetanensis* that was difficult to detect in food. Investigators must consider that food can become contaminated at all its steps from farmland or fishing waters to the consumer's fork.

There are at least two generalities to remember when discussing microbial foodborne illness. Experience has taught us that there is no strict distinction between so-called foodborne pathogens that infect by way of the alimentary canal and so-called waterborne pathogens that infect the consumer by that route. Although a pathogen's prevalence may differ in water and in food, it may also differ in different types of food. Generally, a waterborne pathogen will ultimately finds its way into food.

A foodborne pathogen is usually easier to detect in an ill patient than in the contaminated food that caused the illness. In food the pathogen tends to be few in number, and in a dormant or even injured state, whereas there are likely to be

many pathogens in an acutely ill patient. The invaders exist in an active growth phase in the ill patient. In food there are competitive microorganisms and varied test inhibitors that make detection difficult, whereas in patients single infections are more common and inhibitors are more constant.

Regulatory agencies, such as the U.S. Food and Drug Administration (FDA), routinely conduct inspections of the food supply and of the food production and distribution environments. These inspections are carried out by trained sanitarians who make observations, take measurements (e.g., pH, temperature, chlorine concentration), and may gather samples for subsequent laboratory analysis. They determine the general safety of the food supply and the general hygiene of the surroundings in which food is handled. For many years they operated on the basis of common sense and historical knowledge about the food supply. More and more, though, the systematic Hazard Analysis/Critical Control Points approach is being implemented in decisions about what, where, and how much to inspect.

Investigations are undertaken when a problem arises, such as a foodborne illness outbreak or a food contamination from an unknown, undetermined, or unsuspected source. Sanitarians, laboratory analysts, and often an epidemiologist work together on investigations. Such a team may be assembled from different agencies and usually includes local officials, the FDA, and the Centers for Disease Control and Prevention (CDC) when the problem is large and widespread. The investigators will apply both standard procedures and special procedures necessitated by the particular case in determining which food caused the illness and/or how that food became contaminated. They will try to correlate their results with clinical information about the patients. From hard data and circumstantial evidence, they will proceed with reason, imagination, and caution to unravel the chain of events that caused contamination and illness. Detailed descriptions of two different outbreaks, one historical and the other rather recent, are given below to illustrate the characteristics of the investigation process.

YERSINIA ENTEROCOLITICA: FACT AND THEORY OF A FOODBORNE ILLNESS OUTBREAK

This incident involved milk that had been commercially pasteurized. The milk came from cows, but, another species of farm animal was also involved. The year was 1982, and in three south-central states of the United States—Tennessee, Arkansas, and Mississippi—up to 19,000 people became ill with diarrhea and other symptoms of clinical yersiniosis. Testing of 172 patients showed that the likely causative agent was the bacterium *Yersinia enterocolitica* of serogroup O:13 and typically the isolates carried a 42 megadalton plasmid.

The number of ill individuals was quite large, yet all seemed to be the customers of a single dairy. Milk from that supplier was the sole consumable item all these people had in common. That information surprised one of

the investigators on the team assembled to try to understand the situation. He was the FDA's Dr. Calvin Aulisio, and he knew that the O:13 serotype of *Y. enterocolitica* is associated endemically not with dairy cattle but, rather, with pigs. Another anomaly was that there appeared to be no contamination in the milk as sold by the dairy. All pasteurization records indicated that the required kill step for pathogens had been taken properly. Aulisio wanted to know if there was any association between the dairy and pigs. Interviewing practically everyone at the dairy from top officials down, he always received the same reply. No one knew of any contact, any connection between the dairy and pigs—until he came to the last person on his list: the employee on the dairy's loading dock. That man told Aulisio that outdated, unsold milk returned to the dairy was not destroyed but sold to a pig farm as feed for the pigs; however, there still seemed to be no contact between the pigs and the dairy, because all the milk and even the milk containers were left at the pig farm.

Aulisio decided to follow the dairy's delivery truck with the outdated milk to the pig farm. He did this several times and observed that although the pig pens were on a hill, the truck stopped at the bottom of the hill and that is where the crates containing the milk cartons and bottles were placed on the ground. Then the cartons and bottles were removed from the crates, which were placed back on the truck. In rainy weather, feces from the pig pens were washed down the hill and became mixed into the soil at the bottom of the hill where the truck parked and the crates were unloaded. When the reloaded empty crates reached the dairy again, they were washed with hot water; however, some soil remained in indentations in the outside bottoms of the crates. In other words, the washing was not thorough enough. Aulisio cultured soil from the bottom of the hill at the pig farm and soil remaining on the crates; both were positive for *Y. enterocolitica* serogroup O:13 carrying the 42 megadalton plasmid (Aulisio et al., 1982).

What likely happened? When containers of freshly pasteurized milk were placed in the incompletely washed crates and the crates were stacked on top of each other under refrigerated conditions, moisture accumulated and caused remnants of soil with the bacteria to drip down onto the milk containers below. Consumers either contaminated their hands when handling the milk containers and/or inoculated the milk inside when they opened the container. Pasteurized milk with its lack of a competitive microflora is a good growth medium for cold-tolerant *Yersinia* species. Experiments were conducted to determine whether the strain of *Yersinia* involved in the outbreak could survive on the outside of refrigerated milk containers (Stanfield et al., 1985). It survived well for as long as 21 days. So did some other foodborne pathogens. That gave support to the theory that the outside of food packaging can play a role in the transmission of infections. Lessons learned include that we must keep the outside of food containers clean and that persistence pays off in investigations.

SPRINGTIME FOR *CYCLOSPORA*: AN OUTBREAK STUDY WITH INTERNATIONAL ASPECTS

An illness with outbreaks in Canada and the United States during spring and early summer of 1996 had unusual features. Its symptoms were those of a strong, very long-lasting diarrhea. In addition, people described feeling "jet lag." The malady seemed to strike those who ate at upscale events—banquets, receptions, and country club gatherings. Identified in stool samples from the afflicted was a microorganism, presumably the cause of the illness that had been described and classified only 3 years earlier. It was a single-cell animal, a parasitic protozoa given the name *Cyclospora cayetanensis* (Ortega et al., 1993). The number of people who became ill with cyclosporiasis during the months of May, June, and very early July was 1465, about one-half of them having been to what one pundit termed "posh parties at plush places." Yet no cases occurred west of the Rocky Mountains. These circumstances caught the attention of the news media and stimulated the public's imagination.

It took time to determine what food at those expensive events had caused the illness. The list of possibilities came down to two fresh produce items: strawberries and raspberries; and it was the latter to which the data from interviews and questionnaires finally pointed (Herwaldt et al., 1997). The raspberries, it was then realized, had been imported and the country of their origin was Guatemala in Central America.

The raspberry is not native to Guatemala. It began to be cultivated there as a cash crop at the urging of international agencies and was intended mostly for export to Canada and the United States at those times of the year when there were gaps in the two countries' raspberry supply. Spring and autumn became the high points of Guatemalan raspberry production because the northern nations grew their own raspberries in summer and had been importing South American raspberries in winter. Guatemala's raspberry exports increased considerably from 1994 to 1996, the year the associated outbreaks of illness were so numerous they could not be overlooked.

To confirm the epidemiologic implication that Guatemalan raspberries were the carriers of cyclospora, scientists looked for the organism on the berries but could not find it. Several elution methods and detection techniques were tried, including direct observation by microscopy and genetic identification by the polymerase chain reaction. Detected by these means in the berry washes was not cyclospora but one of its relatives, another parasitic protozoa, an eimeria that is a parasite of birds and some mammals but does not cause human infections. This was a valuable finding. It showed that the analytical methods being used did work to some extent, but perhaps needed more refinement. It also showed that something from animals was getting onto the berries, and people wondered whether it was some animal that was contaminating the raspberries with cyclospora.

Government agencies in the United States and Canada were, however, expected to do more than develop finer detection methods and speculate about the source of infections. The next crop of raspberries from Guatemala would be arriving in the autumn of 1996. Should they be allowed entry?

It was suspected, but not definitely known, that the fall season was not the right one for cyclosporiasis. In Guatemala the illness was associated with the spring rainy season and was thought to be the cause or at least one of the causes of the country's long familiar springtime diarrheas.

Guatemalan raspberries were allowed into Canada and the United States in the autumn of 1996 and no associated illness outbreaks occurred. The real worry was the next springtime crop, in 1997. Guatemala was asked to inspect its raspberry fincas (farms) and only those classified as low risk for contamination would be allowed to export to Canada and the United States. The criteria used for the risk classification were not spelled out precisely. Again illnesses occurred. There were 762 cases in 41 clusters plus 250 sporadic cases that fit the definition of long-lasting diarrhea in April and May of 1997, a total of 1012 presumed cyclospora infections. They occurred in 17 states of the United States and in the District of Columbia, as well as in the same two Canadian provinces as the previous year. This time the spread was from the East Coast all the way to the West Coast and did not stop after the Rocky Mountains. Again the epidemiology pointed to fresh Guatemalan raspberries as the vehicle for the parasites, even though they were supposedly from low-risk farms.

In consultation the governments of Guatemala, Canada, and the United States decided to conduct risk analyses of the situation. The possible ways that berries became contaminated with cyclospora were several: (1) spraying with insecticide and fungicide dissolved in water that was not potable; (2) touching by the hands of the fieldworkers when being felt for ripeness and when being picked; (3) contamination through animal vectors; (4) exposure to physical forces (wind with dust, splatter from rain) in the fields; (5) accidental or intentional intermingling of berries from high-risk farms (i.e., unsanitary ones) with those from low-risk (i.e., sanitary farms); and (6) sabotage, the intentional contamination of berries with fecal matter that may have contained cyclospora.

Remedies were possible for some of the risks: (1) placing filters (1 μm) to exclude cyclospora (the infective oocyst has a diameter of 8-10 μm) in the spray apparatus for the insecticide and fungicide solutions; (2) monitoring fieldworkers' hand washing and general hygiene. Unfortunately, nothing effective could be done about risks 3 and 4, except deploying scarecrows to keep birds off the fields. Other risks were addressed by labeling berry containers to indicate the particular farm and day of harvest (risk 5); and security measures to discourage intermingling of produce from different farms and facilitate trace-backs in the event of illness outbreaks (risk 6). Risks 3 and 4 were considered much less likely to occur than the other risks. Remedies 1, 2, 5, and 6 together with farm

inspections and health checks of farm workers by an independent authority were implemented as a model plan of excellence for raspberry production in Guatemala. The Guatemalan government would assure importing nations that only those raspberries grown, packaged, and transported according to the plan would be exported.

Doing the risk analysis, implementing the remedies, and instituting the inspections took time. In 1998 much of the work had not been accomplished, and the United States decided not to accept any Guatemalan raspberries that spring. No cyclosporiasis outbreaks were detected in the United States that season. Canada did import fresh raspberries from Guatemala in the spring of 1998 and had 336 typical cases. Unintentionally, this amounted to a "controlled" epidemiological experiment. In 1999 the model plan of excellence (Jackson et al., 1999) for exporting raspberries was in full operation. The United States imported Guatemalan spring raspberries and experienced no cyclosporiasis outbreaks. Canada, careful due to its 1998 laxity, did not accept fresh Guatemalan spring raspberries again until 2002. The United States had no cyclosporiasis due to Guatemalan raspberries in 1999, 2001, 2002, or 2003. There were 63 cases in 2000, all traceable to a single farm, thanks to the labels on the raspberry containers. It is suspected that this farm experienced sabotage. The owner of the farm was found murdered.

Although it was demonstrated that contamination of raspberries with cyclospora could be prevented by following the plan, the total story of Guatemalan raspberry exports has a sad ending. The costs of implementing the plan, a sequence of years with too much rain for optimal raspberry production, and competition from other Latin American countries that presumably did not have endemic cyclosporiasis and so did not have to institute expensive preventive plans combined to make Guatemalan raspberry exports noncompetitive and not profitable. Still, there was a benefit. Guatemala has applied elements of the model plan of excellence to other farm crops, and these now have a high reputation for microbial safety on the world market.

There is a subplot to the story of investigating Guatemalan raspberries that concerns the detection methodology for *Cyclospora cayetanensis*. There is also a side story about Guatemalan blackberries and a sequel about raspberries from Chile.

Detection Methodology. Microscopy of raspberry washings took much time. Although eventually the *C. cayetanensis* oocyst was detected visually, as some *Eimeria* spp. oocysts had been in 1996 and 1997, the procedure was abandoned as impractical. Initial results with the polymerase chain reaction (PCR) were negative because of interfering substances, particularly when the raspberries were not fresh. Since these interfering substances could be removed by special filters (from Fraser Technology Australia), PCR became the method of choice (Lopez et al., 2001; Orlandi et al., 2004).

Why Raspberries and Not Blackberries? Raspberries and blackberries were grown in adjacent fields of the same Guatemalan farms during the same seasons. Why were just the raspberries implicated as vehicles for cyclosporiasis? (Actually, fresh Guatemalan springtime blackberries may have caused a small number of cyclosporiasis cases in Canada.) Blackberries have a smooth surface and are more washable than raspberries. Raspberries are covered by fine, sticky hairs to which all sorts of microscopic objects adhere: dust particles, pollen grains, and the cysts and oocysts of parasites.

Cyclosporiasis and Raspberries from Chile. In the winter of 2002 an outbreak in the United States of 22 cases of cyclosporiasis was traced to raspberries from Chile. It is thought that there is no endemic cyclosporiasis in Chile. How were the Chilean berries contaminated? Investigation (Schrimpf et al., 2003) suggested two possibilities: either by guest crop pickers from endemic countries, such as Peru, or because the infection is endemic in Chile but has not yet been detected owing to the limited number of surveys to date.

LESSONS LEARNED AND LESSONS TO BE LEARNED

Persistence again proved to be valuable in investigating the North American outbreaks of cyclosporiasis, tracing many of them to fresh raspberries (canning or freezing kill *C. cayetanensis*) and, by way of a risk analysis, suggesting interventions, such as the model plan of excellence, for the production and distribution of the berries. Other items of fresh produce that have caused some cyclosporiasis outbreaks in international trade are lettuce, basil, and as mentioned, blackberries. There is much yet to learn about cyclosporiasis. Why is it so seasonal? Where is it between seasons? Are there reservoir hosts or transfer hosts for the parasite? In how many countries and what environments is it endemic?

WHY ARE THERE SO MANY FOODBORNE INFECTIONS?

If one considers the passage of food from farmland or fishing waters to the consumer's fork, it is apparent that contamination control was for many years concentrated on food processing. The earlier steps of food growth and the later steps of distribution, sale, and consumer handling were not completely controlled or were not controlled at all. That situation improved somewhat in certain countries in the later 1990s. In the United States the improvement was spurred by the nation's Food Safety Initiative. Yet, the large size of food production firms and the wide distribution of their products magnifies incidents of contamination. Canning, which kills most pathogens, has been partially replaced by freezing, which may preserve the pathogen. Recycling, for economic purposes, of food waste back into the food chain also may recycle microbes. The use of antibiotics and preliminary heat in food production and processing

may be causing microbial resistance due to microbial adaptations and even mutations. The percentage of immunocompromised consumers has grown. More raw food is being eaten for dietary reasons in prosperous countries. As cities grow, particularly in poorer nations, there are more street vended foods and fewer supplies of potable water. Prevention advice is not always understood. For these and other reasons foodborne infections are still a problem in the 21st century.

ACKNOWLEDGMENTS

Much of the work discussed in this paper was done by staff members of agencies of the government of the United States, particularly the FDA and the CDC. Among those prominently involved were Calvin Aulisio, John Stanfield, Barbara Herwaldt, Palmer Orlandi, Jeffrey W. Bier, John J. Guzewich, Israel Santiago, and Julie Schrimpf.

REFERENCES

Aulisio, C. C. G., M. T. Lanier, and M. A. Chappel. 1982. *Yersinia enterocolitica* O:13 associated with an outbreak in three southern states. Journal of Food Protection 45:1263.

Herwaldt, B. L., Ackers M. L., Cyclospora Working Group. 1997. An outbreak in 1996 of cyclosporiasis associated with imported raspberries. New England Journal of Medicine 336:1548-1556.

Jackson, G. J., L. A. Solorzano, J. E. Kvenberg, L. G. Flores, J. D. Mooney, and R. Castaneda. 1999. Routes by which *Cyclospora cayetanensis* may contaminate food. In Food microbiology and food safety into the next millennium. Proceedings, 17th Conference, International Committee on Food Microbiology & Hygiene, Veldhoven, Netherlands, eds. A. C. J. Tuijtelaars, R. A. Samson, F. M. Rombouts, and S. Notermans. Pp. 49-51.

Lopez A. S., D. R. Dodson, M. J. Arrowood, P. A. Orlandi Jr., A. J. da Silva, J. W. Bier, S. D. Hanauer, R. L. Kuster, S. Oltman, M. S. Baldwin, K. Y. Won, E. M. Nace, M. L. Eberhard, and B. L. Herwaldt. 2001. Outbreak of cyclosporiasis associated with basil in Missouri in 1999. Clinical Infectious Diseases 32:1010-1017.

Orlandi, P. A. Jr., and Fishman, P. H. 1998. Filipin-dependent inhibition of cholera toxin: Evidence for toxin internalization and activation through caveolae-like domains. Journal of Cell Biology 141:905-915.

Ortega, Y. R., C. R. Sterling, R. H. Gilman, V. A. Cama, and F. Diaz. 1993. Cyclospora species—A new protozoan pathogen of humans. New England Journal of Medicine 328:1308-1312.

Schrimpf, J. E., G. J. Jackson, J. J. Guzewich, I. Santiago, and T. Hill. 2003. FDA and Chile: Sharing science for produce safety. In 9th Annual Science Forum—FDA Science: Protecting America's Health; FDA, Rockville, Maryland, USA. P. 83.

Stanfield, J. T., G. J. Jackson, and C. C. G. Aulisio. 1985. *Yersinia enterocolitica*: Survival of a pathogenic strain on milk containers. Journal of Food Protection 48:947-948.

Food Monitoring, Investigation, and Inspection Infrastructure in Iran

Dr. S. Farzad Talakesh and Dr. Hamid Khaneghahi
Public Health Department, Iran Veterinary Organization

Food safety is an issue of increasing concern worldwide and prioritization of food safety as an essential public health function has been advocated recently in Iran by the following bodies:

- Iranian parliament ratifies the laws and regulations.
- The administrative branches of the Iranian Government (IVO,[1] MOH,[2] ISIRI[3]) prepare and suggest legal drafts and forward them to special committees of parliament for ratification. Because of the separate efforts, there are overlaps that create obstacles to progress on food safety.

ELEMENTS OF NATIONAL FOOD MONITORING AND INSPECTION SYSTEM IN IRAN

Most of Iran's organizations related to the health of plants, animals, and humans focus on maintaining and developing food safety standards through the ISIRI and the PPO.[4] There are five aspects as follows:

Food laws and regulations (IVO, MOH);
Food control management (IVO, MOH);

[1]Iran Veterinary Organization.
[2]Ministry of Health.
[3]Institute of Standards and Industrial Research of Iran.
[4]Plant Protection Organization.

Inspection services (IVO, MOH);
Laboratory services (IVO, MOH, ISIRI, PPO, AEO[5]) ; and
Information, education, communication, and training (IVO, MOH).

The laws and regulations on food safety in Iran include the following:

- The food, drug, and cosmetics act—MOH;
- The veterinary act—IVO;
- The standards act—ISIRI;
- The plant protection act—PPO; and
- The environmental protection act—EPO.

We know that Iranian citizens have become more aware not only of food safety issues but also want to know who is responsible for such issues. Iranian food safety programs aspire to be risk-based, science-based, and transparent; however, most of these acts are rudimentary and need strengthening in order to implement new monitoring and surveillance programs and achieve improved food safety. In addition, each administrative branch has specific legislation, and the results of a branch's activities are disseminated widely. Expert advisory committees and public meetings sometimes help in the preparation and ratification of the pertinent laws and regulations.

At a time when issues such as globalization, self-regulation, hazard analysis and critical control points, and quality control have become so important, Iranian food safety principles incorporated in regulations are considered as urgent national priorities to meet the needs, demands, and concerns of industry and citizens. These principles include the following:

- Foods must be safe and wholesome to be marketed.
- Regulatory decisions regarding food safety must be based on sound science.
- The government has enforcement authority.
- Processors, manufacturers, distributors, importers, and others engaged in food marketing must comply with the law.
- The regulatory process should be transparent and should be made accessible to the public (through MOH, IVO, ISIRI Web sites).

The principal objectives of the food control system are:

[5]Atomic Energy Organization.

- Promoting public health by reducing the risk of foodborne illnesses (IVO and MOH);
- Protecting consumers against unsanitary, unwholesome, mislabeled, or adulterated raw food of animal origin (IVO) and processed food of animal and plant origin (MOH);
- Contributing to economic development by maintaining consumer confidence in the food system and providing a sound regulatory foundation for the domestic and international trade in food (IVO's Quarantine and International Affairs Office is responsible for this aspect);
- Encompassing all the food produced, processed, and marketed within the country, including imported and exported food; and
- Maintaining a statutory basis that is mandatory in nature.

Administrative branches and their responsibilities include the following:

- The Food, Drug, and Cosmetics General Office of the MOH is responsible for most foods, particularly processed ones.
- The General Health Office for Food Establishments of the MOH is responsible for the control of health measures in food establishments, except those for animal products.
- The General Public Health Office of the IVO—particularly the Animal Health, Food Safety, and Inspection Service—is responsible for meat, fish, egg, poultry, and other products of animal origin as well as for monitoring drug residues.
- The General Quarantine Office of the IVO, especially, is responsible for animal transport and certification of animal products for export and import.
- PPO is responsible for pesticide registration and plant health inspection.
- The AEO is responsible for radioactivity assessment in foodstuffs.

The national food monitoring and inspection system activities include the following:

- Inspecting for compliance with the hygienic and other requirements in standards and regulations;
- Evaluating Hazard Analysis and Critical Control Point (HACCP) plans and their implementation (HACCP is now mandatory in fish and shrimp processing plants, and many food processing plants also follow HACCP plans);
- Sampling food during harvest, processing, storage, transport, or sale to establish compliance, gather information for risk assessments, and to identify offenders;
- Detecting different types of food decomposition by organoleptic assessment to determine which food is unfit for human consumption or which is otherwise sold deceptively to the consumer, and taking the necessary remedial action;

- Detecting, collecting, and transmitting evidence when breaches of law occur, and appearing in court to assist in prosecution;
- Encouraging voluntary compliance, particularly by means of quality assurance procedures;
- Inspecting, sampling, and certifying food for import and export; and
- Risk-based audits in establishments working under such safety assurance programs as HACCP.

The following are the needs and requirements for laboratory services, an essential component of a food control system:

- More capital investment;
- Well-qualified staff;
- Continuous updating of knowledge and skills at the international level;
- Qualifying the national food reference laboratory to deal with each type of animal that is a source of food; and
- Adoption by regional analytic laboratories of instrumentation and methodology that have been standardized and validated by the national reference laboratory.

Food control agencies currently identify the specific training needs of their food inspectors and laboratory analysts as a high priority. These activities provide an important means of building food control expertise and skills in all interested parties, and thereby serve an essential preventive function. They include:

- Delivery of information, education, and advice to stakeholders across the farm-to-table continuum;
- Provision of balanced factual information to consumers;
- Information packages and educational programs for key officials and workers in the food industry; and
- Provision of reference literature to extension workers in the agriculture and health sectors.

BUREAU OF PUBLIC HEALTH OF IVO

The Bureau of Public Health has six offices that are involved in food safety functions:

1. Animal Health and Sanitary Office, whose role is policy making and providing standards for, and hygienic control of, farms and processing plants. It is responsible for application of good animal husbandry practices and good man-

ufacturing practices (GMPs) in farms and processing plants and issuance of health licenses for animal husbandry and for processing plants.

2. Animal Feed Inspection Office, whose role is policy making and providing standards and hygienic control of the animal feed chain. It is responsible for the application of GMPs in animal feed manufacturing and chemical and microbiological monitoring of animal feed.

3. Edible Animal Products Inspection Office, whose role is policy making and providing standards and hygienic control of edible animal products. It does this through application of HACCP systems and risk assessment and management.

4. Chemical Residues Monitoring Office, whose role is to set maximum residue limits for veterinary drugs. It does this through sampling for residue assessment and monitoring of veterinary drugs and other chemicals, such as heavy metals, in foodstuffs.

5. Meat Inspection and Abattoirs Supervision Office, which is responsible for policy making and providing standards and hygienic control of abattoirs (slaughterhouses). These activities include upgrading and modernizing abattoirs, tracking animal diseases, application of HACCP systems in abattoirs, and risk assessment and management.

6. Nonedible Animal Products Inspection Office, which is responsible for policy making and providing standards and hygienic control of nonedible animal products, such as casings. It does this through risk assessment and management and application of HACCP systems.

What Does the National Food Control System Need?

In summary, the system needs the following elements:

- Policy and operational coordination at the national level;
- Delineation and implementation of clearly defined leadership functions and administrative structures, including accountability;
- An integrated national food control strategy;
- Implementation and operation of a national food control program;
- Establishment of regulatory measures;
- Monitoring of performance systems;
- Facilitation of continuous updating and improvement;
- Overall policy guidance;
- Additional funds and resource allocation;
- Setting of advanced standards and regulations;
- Compliance with international organizations, in particular with Codex Alimentarius; and
- Participation in international activities related to food control.

Discussion

Dr. Mohammadreza Razailashkajani
Research Center for Gastroenterology and Liver Disease
Shaheed Beheshti University of Medical Sciences

Panel:
Dr. Montes Niño, Dr. Jamdar, Dr. Talakesh, and Dr. Jackson

The discussion started with consideration of cross-state food inspection points in the United States and the role of the Food and Drug Administration (FDA) in outbreaks involving several states. The regulatory bodies for food safety were the next topic. Dr. Keene and Dr. Jackson stated that most recalls are not required by law but are voluntarily performed by companies and food manufacturers. Regulatory bodies usually make recommendations that are almost always accepted by food manufacturers. The role of the press and lawsuits against food manufacturers and restaurants are other important factors in food safety.

Dr. Morowati from the Plant Pest and Disease Institute of Iran presented a short profile of his institute and the pesticide residue laboratory. He raised questions regarding mycotoxins, pesticide residues, and chronic diseases related to them. Dr. Jackson mentioned the association of heavy-metal toxicity with seafood consumption and the roles of the FDA and Environmental Protection Agency. Dr. Niño declared that it is very difficult to find such associations, and Dr. Keene added that there was no special surveillance program in the United States for chronic diseases associated with pesticide residues.

The zero-tolerance policy of the government of the United States on *Listeria monocytogenes* was questioned by Iranian specialists. Dr. Matthews, Dr. Keene, and Dr. Jackson all agreed that historical events were instrumental in producing this legislation. Dr. Keene added that in enforcing a zero-tolerance policy, one should keep a balance between cost and risk.

Consumer education in food safety policies was the next topic discussed. Consumer education is an integral part of FDA food safety measures. Professor Yoe pointed to the role of health education for children and cited a website devoted to food safety education issues that school teachers should consider for their classes.

Day 2

Afternoon Session

Food Traceability: A Response to Consumers

The Role of Risk Analysis in a Science-Based Approach to Food Safety

The Hazard Analysis and Critical Control Point System

Implementing and Auditing Hazard Analysis and Critical Control Point Systems and Difficulties in Iran

The History of Food Safety in Iran

Discussion

Food Traceability: A Response to Consumers

Dr. Alfredo M. Montes Niño
International Consultant, Food and Agriculture Organization—World Health Organization

I will start with some definitions of traceability as it refers to food. This term and the concept behind it also apply to other industrial products. In the food area, traceability is important for commercial and safety reasons. Definitions allow us to distinguish the scope covered by this concept and establish legal requirements. Possible consequences of the legal requirements are violations of established rules that end up as disputes or cases.

The importance of Codex Alimentarius definitions, as you may know, is that these standards have been adopted by the World Trade Organization (WTO) in its Sanitary and Phytosanitary Agreement as practically the highest standards that a country can set for its import requirements.

- Codex Alimentarius: "Traceability is the ability to follow the food movement through its specified stages at production, processing, and distribution" (WHO/FAO, 2004).

The European Union (EU) has established its own definition. This has to be considered in cases of exports to that region despite the right of countries to initiate actions within the scope of WTO procedures.

- Rule EC 178/2002, Article 3: "The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed through all stages production, processing and distribution" (EU, 2002).

As mentioned, definitions are needed for different purposes, but for practical purposes a more descriptive explanation is necessary.

Traceability is a group of actions, measures, and procedures that reveal a product's history, from its birth until the end of the commerce chain, passing through all intermediary production processes.

Traceability in the food chain was initially raised as a proposal of the EU. Originally it was created to control taxes along the wide and varied commercial channels through which cattle moved within that ever more communal territory. The trigger was the mad cow disease crisis in 1996 that generated mandatory and voluntary requirements for the traceability of cattle and beef in the EU. Consumers' frustration and general discredit of the traditional control systems prompted the implementation of a new system that would generate greater credibility among consumers. This crisis also led to changes in the organization of food control within the European Commission and to the creation of the European Food Safety Agency. In the wake of the latter, corresponding institutions were created in the EU's member countries.

Implementation of a total traceability system for cattle and beef requires the following two elements: identification and registration of bovine animals and labeling of beef and beef products.

Needed to achieve such a system are the following:

- documentation concerning the origin and all transportation or relocation of bovine animals;
- regaining the consumer's confidence in beef by labeling it with information concerning origin and slaughtering; and
- obtaining at least minimum information on the beef imported from third-party countries.

Currently, the identification of each animal is under discussion. A decision on mandating animal identification has been postponed. For the moment the accepted means of identification include the following:

- ears tags;
- a passport;
- a record of all transport from birth (or importation) to slaughter of each animal, with this record in a central database within each member state; and
- individual registries on each farm.

Although a voluntary system has been in place since January 1, 2005, a traceability system ought to be established for all food. The labeling of beef has already been implemented and the system's main characteristics are:

- an indication of the member state(s) or other countries where the animal was born, fattened, and slaughtered;
- the abattoir's and deboning hall's approval numbers; and
- a reference number that links the meat and the animal.

As mentioned above, traceability of products through the food supply chain is in response to the European consumer's desire for full traceability in order to guarantee safety, quality, authenticity, and rapid response. The final response to these needs is still in process and a final definition of traceability has yet to emerge from the diverse numbering systems, barcodes, electronic tags, biological markers, and communication systems.

The effectiveness of responding rapidly to these increasing consumer demands was proven during the recent bovine spongiform encephalopathy and avian influenza crises. Certain supermarkets in the United Kingdom had already gained a reputation for selling products that were traceable. Consequently, the sale of the sensitive products at these shops did not decrease during the crisis; they increased considerably.

The above scenario provides an example for countries that want to maintain, increase, and even diversify their food exports. The safety of their food products must be linked clearly to practical, efficient, and transparent identification systems capable of offering importers a useful tool for satisfying both the new legal requirements in their countries and consumers' demand for reliable information.

REFERENCES

EU (European Union). 2002. Regulation (EC) No 178/2002 of the European Parliament and of the Council, Official Journal of the European Communities. Available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf. Accessed November 18, 2005.

WHO/FAO Codex Alimentarius Commission, Report of the Twenty-Seventh Session, Geneva, 28 June-3 July 2004. WHO/FAO, Rome, 2004. Available at http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/007/y5549e/y5549e00.htm. Accessed November 18, 2005.

The Role of Risk Analysis in a Science-Based Approach to Food Safety

Charles Yoe
Professor of Economics, College of Notre Dame of Maryland

Traditional food safety management systems with their focus on end-product testing no longer suffice to deal with the complex, persistent, pervasive, and rapidly changing food safety problems of a global economy. Science-based approaches to food safety systems are increasingly in use. Many science-based approaches to food safety have already been implemented successfully. Risk analysis, a process comprising risk management, risk assessment, and risk communication, is an essential element of any science-based food safety system. Risk analysis is a problem-focused paradigm designed to work with ambiguous data, using many people to find the best solution now while looking toward the best solution in the future. Disease surveillance both provides risk assessment with data and is guided by the research needs identified by risk assessment.

TRADITIONAL FOOD SAFETY SYSTEMS NO LONGER SUFFICE

Food safety is an essential public health issue for all countries. Foodborne diseases present a real and formidable problem in both developed and developing countries, causing great human suffering and significant economic losses. Up to one-third of the population of developed countries is affected by foodborne diseases each year, and the problem is likely to be even more widespread in developing countries. The true dimensions of the problem are unknown because most cases of foodborne disease are not reported. This absence of reliable data hinders the effectiveness of public health professionals and food safety regulators.

Effective food safety systems are vital to public health, in order to maintain consumer confidence in the food system and provide a sound regulatory founda-

tion for domestic and international trade in food, which in turn supports economic development. The emphasis of food safety regulatory agencies must continue to be on prevention, reduction, or elimination of foodborne hazards throughout the food chain. New international trade agreements developed under the auspices of the World Trade Organization (WTO) have shown how necessary it is that regulations governing international trade in foods be based on scientific principles. The Sanitary and Phytosanitary Agreement (SPS), for example, permits countries to take legitimate measures to protect the life and health of consumers, animals, and plants with the provisos that such measures can be justified scientifically and do not unnecessarily impede trade.

Food safety is the responsibility of everyone in and along the food chain, from regulators to producers to consumers; however, governments are responsible for providing an enabling institutional and regulatory environment for food control. Traditional food safety systems are no longer sufficient to meet the food safety needs of either the developed or the developing world.

The focus of traditional food safety systems has often been on hygiene, inspection, and end-product control. These systems may include food laws and regulations, food control management, inspection and laboratory services, and mechanisms for information, education, and communication. Decision making in traditional systems has often been ad hoc, relying on one or more of the following:

- precedent;
- trial and error;
- expert opinion;
- compromise;
- safety assessment;
- the precautionary principle;
- professional judgment;
- inspection;
- zero tolerance; or
- ignorance.

Much progress has been made with these traditional approaches to food safety problems, but these systems are now inadequate. Among other failings, traditional approaches:

- do not adequately detect and resolve many current problems;
- do not effectively deal with the complexity and rapid pace of change;
- do not effectively integrate science and social values in decision making; and
- do not address the entire food chain.

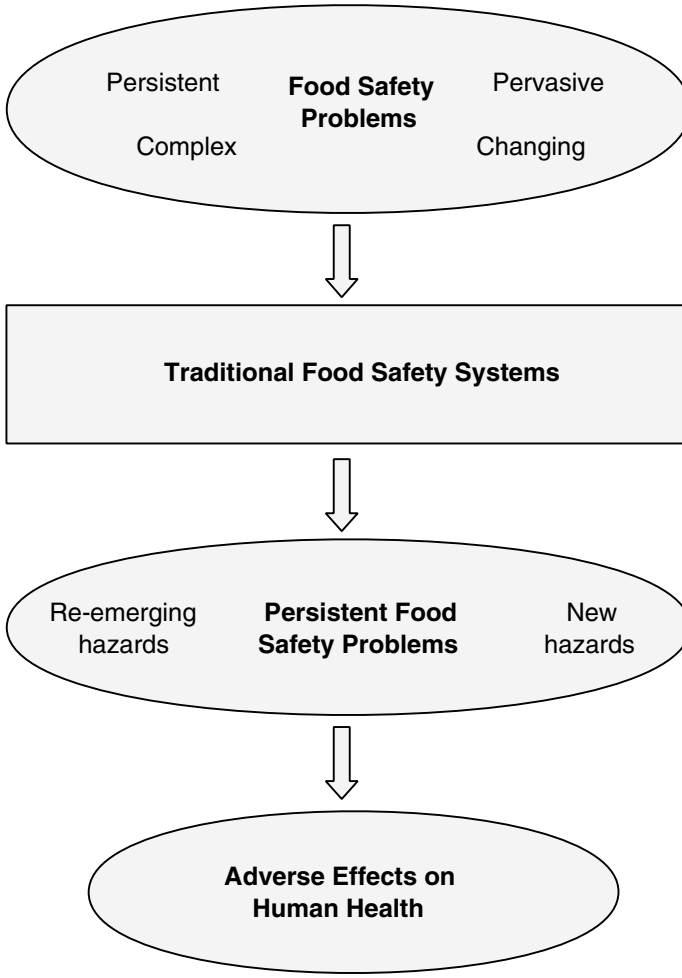

FIGURE 1 Shortcomings of traditional food safety systems.

Although traditional food safety systems have been somewhat effective in reducing food hazards in the past, they are unable to detect and resolve many current problems and deal effectively with the full range of complex, persistent, and pervasive challenges confronting different parts of the food chain (see Figure 1). Too many complex, persistent, and pervasive food problems are escaping the traditional systems. Re-emerging and newly emerging pathogens are but examples of these problems. The toll on human health around the globe is unacceptable, all the more so because many of these problems can be addressed.

PERSISTENT PROBLEMS

Traditional systems no longer suffice to solve the world's food safety problems. The food hazard concerns of virtually all nations include one or more of the following:

- misuse of food additives, colors, and flavors;
- veterinary drug residues and use of growth promoters;
- animal feed additives;
- fertilizer and growing aids;
- irradiation;
- microbiological contamination that is ubiquitous, re-emerging, or newly emerging;
- mycotoxins and other naturally occurring food toxicants;
- pesticide residues;
- pollutants;
- defective packaging and labeling;
- adulteration and tampering; or
- extraneous matter.

When these hazards exist within the context of global changes in food production and consumption, the result is a growing number of food safety problems. Production of food on a large scale means that a single mistake can have more extensive and far-reaching consequences than the small-scale production of the past could. Many more people can be affected by a single incident.

The desire for more year-round foods means nations must import from new producers who may lack the knowledge about good agricultural practices, good manufacturing practices, and good hygiene practices that exists among nations more experienced with these foods.

In the United States more food is being consumed outside the home where consumers have less control over the conditions under which the food is being prepared. Much of this food is being prepared by relatively untrained food workers. A great deal of this food is being prepared in large quantities and served in such institutions as schools, nursing homes, and prisons.

Consumers are increasingly interested in more exotic foods and imports. In the United States raw vegetables and fruits, sushi, sashimi, raw shellfish, and other underprocessed foods expose consumers to a greater variety of hazards that can be relatively unknown in the countries where they are eaten. As life expectancies increase and health care improves, there are more immunocompromised consumers than ever. These populations are often more vulnerable to many of the modern food safety hazards. The increasing importance of international trade makes it likely that many of these trends will continue to spread around the world.

SCIENCE-BASED FOOD SAFETY SYSTEM

A number of developing countries are already taking steps to improve and strengthen their systems for food safety management. Several are moving away from the traditional approach focused on end-product control toward a science-based process. Food safety regulators in many countries are already implementing different types of science-based actions and decision making in their day-to-day work (see Box 1). Science and good data are essential to decision making in a modern food safety system.

A science-based approach strengthens the capacity of traditional food safety systems to meet current challenges and improve the availability of safe food for consumers. Scientific evidence can be used to minimize the occurrence of foodborne hazards, to reduce and manage risk, and to improve the outcomes of decision making. A science-based approach enhances the ability of food safety regulators to identify hazards, characterize the nature and extent of those hazards, assess exposure to the identified hazards, and estimate the likelihood of the resulting risks and potential impacts on human health.

Risk analysis is an important part of a science-based approach to food safety (see Figure 2). Risk analysis provides a means to strengthen the ability of traditional food safety systems to meet current challenges. It provides a framework to effectively manage, assess, and communicate risks through the cooperation of the diverse stakeholders involved. Most importantly, it aids decision makers and supports decision making with evidence.

As a concept a science-based approach to food safety is not completely new. It is related to such processes as good agricultural practices, good hygiene practices, good manufacturing practices, and the Hazard Analysis and Critical Control Point (HACCP) system, which are already used in many countries. What is new is the use of risk analysis as a framework to view and respond to food safety

BOX 1
Examples of Science-Based Activities

Implementing Hazard Analysis and Critical Control Point (HACCP) systems
Establishing acceptable daily intakes for chemical additives in food
Estimating maximum allowable exposure levels to pesticides
Using labels to warn consumers about potential food allergens
Using risk assessment to support food safety regulations and other decision making
Establishing product safety standards, performance standards, and specifications for use in international trade
Resolving trade disputes based on the WTO Sanitary and Phytosanitary Agreement

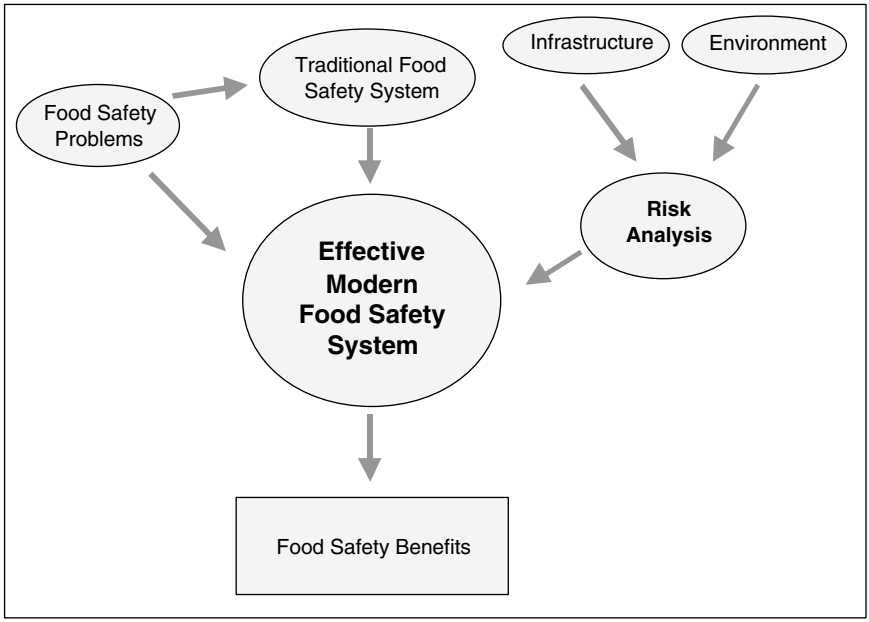

FIGURE 2 An effective modern food safety system.

problems in a systematic, structured, and scientific way in order to enhance the quality of decisionmaking throughout the food chain.

A science-based risk analysis framework builds on the traditional systems and creates a need for modern food safety and public health institutions and infrastructures as well as an overall environment that values and supports the risk analysis paradigm. Risk analysis is just one part of an effective food safety system. It will also be necessary to develop and improve other essential components of food safety systems, such as national food safety policies and infrastructure, food legislation and inspection services, laboratories, epidemiological surveillance of foodborne diseases, monitoring systems for chemical and biological contamination, and the update and harmonization of standards.

RISK ANALYSIS IS A PARADIGM

Risk analysis is more than an activity. It is a way of thinking about things and organizing resources to solve problems. It is a science-based approach to problem solving, but it is more than science. It is the interface between science and the values of an organization or society. It is a paradigm designed to make decisions in the face of uncertainty.

As a paradigm, risk analysis has several distinctive features. First, it is purpose oriented to find the right problem. The initial activities in a risk analysis model focus on carefully defining the problem to be addressed and on setting priorities among multiple problems. Second, risk analysis copes well with soft data. It tolerates ambiguity. It is a decision-making approach that is designed to recognize and address the fact that decisions must be made in the absence of all the data we would like to have to make those decisions. Third, risk analysis seeks needed information from a variety of sources. In so doing it involves many people. Fourth, it is flexible and can be updated. Risk analysis has a future-focused vision of the solution after the next one. In other words, risk analysis supports the best decision possible given the state of our understanding of the problem and of current social values. As data gaps are filled and understanding improves or as values change, risk analysis recognizes that the next solution may differ from the current one. As such, risk analysis is suited to continuously improving decisions.

What are the benefits of risk analysis? The list below provides a preliminary answer to this question.

- It improves the quality of our thinking before a decision is made. Uncertainty is ubiquitous, so identifying and addressing it is essential for good decision making.
- It can help assure a safe domestic food supply.
- It provides information needed to protect human, animal, and plant life and health.
- It is essential for international trade (e.g., SPS). Many international organizations and agreements rely on its use, including the WTO, the Food and Agriculture Organization/World Health Organization Codex Alimnetarius Commission, Office Internationale des Epizooites, and the International Plant Protection Convention.
- Freed from the burden of proving safety, often an impossible task, it allows industry to innovate.
- It is, this author believes, better than the alternatives.

Risk analysis always exists within a context. Organizations use risk analysis. Thus, risk analysis takes place within an organizational culture. Within an organization a structure and decision-making process already exists. The organization has a mission, goals, objectives, and legal and resource constraints that define its reality. Within this organization there are decisions to be made. Risk analysis is a process and a paradigm, a way of approaching problems and decisions that will look different in every organization that uses it.

RISK ANALYSIS DEFINED

As a structured decision-making process, risk analysis includes three distinct but closely connected components: risk management, risk assessment, and risk communication (see Figure 3).

Multiple definitions of risk analysis and its components exist. The definitions adopted by the Codex Alimentarius Commission are the ones most commonly used in the international food safety community. Nonetheless, it can be instructive to consider informal definitions of the risk analysis tasks as well as the formal definitions.

Risk analysis provides food safety regulators with the information and evidence they need for effective decision making. The process usually begins with risk management, which defines the problem, articulates the goals of the risk analysis, and defines the questions to be answered by the risk assessment. The science-based tasks of measuring and describing the nature of the risk being analyzed are performed during the risk assessment. Risk management and assessment are performed within an open and transparent environment based on communication and dialogue. Risk communication encompasses an interactive exchange of information and opinions among risk managers, risk assessors, the risk analysis team, consumers, and other stakeholders. The process often culminates with the implementation and continuous monitoring of a course of action by risk managers. Risk analysis is a highly interactive, iterative, and ongoing process.

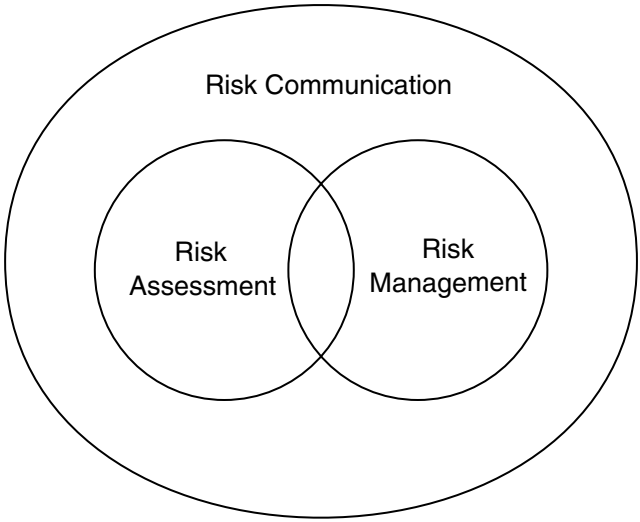

FIGURE 3 Components of risk analysis.
SOURCE: (FAO/WHO, 2001, p. 44).

Risk analysis is a decision-making framework that describes an ongoing mode of operation rather than a discrete activity that is initiated and completed and returned to the shelf until it is needed again. As such, risk analysis represents a paradigm shift, a new way of approaching food safety problems.

In the past, food safety decision-making paradigms have relied on professional judgment and expert opinion, precedent, trial and error, inspections, zero tolerance, and precaution. These methods have been inadequate for solving existing, newly emerging, and re-emerging food safety problems due in part to a rapidly increasing pace of change and compounding complexity in an increasingly international world.

Risk analysis is a new decision-making paradigm that is designed to integrate science and social values in the face of ubiquitous uncertainties. It is purpose oriented to find the right problem and to define it carefully. Risk analysis copes well with soft data and seeks needed information from a variety of sources. In the process it involves many people. Risk analysis tolerates ambiguity. The current best solution is rarely going to be the final resolution of an issue. Risk analysis offers the advantage of being able to identify the best available solution while retaining the flexibility to deal with a future-focused vision of the solution after this one. Consequently, it is flexible, updateable, and well suited to continuously improving food management decisions.

RISK MANAGEMENT

Risk analysis activities usually begin with the risk manager. Risk management can be defined informally as the work required to answer the following questions:

- What questions do we want the risk assessment to answer?
- What can be done to reduce the impact or likelihood of the risk described?
- What are the trade-offs of the available management options?
- What is the best way to address the described risk?

Codex Alimentarius defines risk management as follows:

> Risk Management The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options (FAO/WHO, 2001, p. 44).

The four-step risk management model in Figure 4 lists several specific tasks undertaken in each step. Some of these rely directly or indirectly on good scientific evidence obtained from an integrated surveillance and monitoring system.

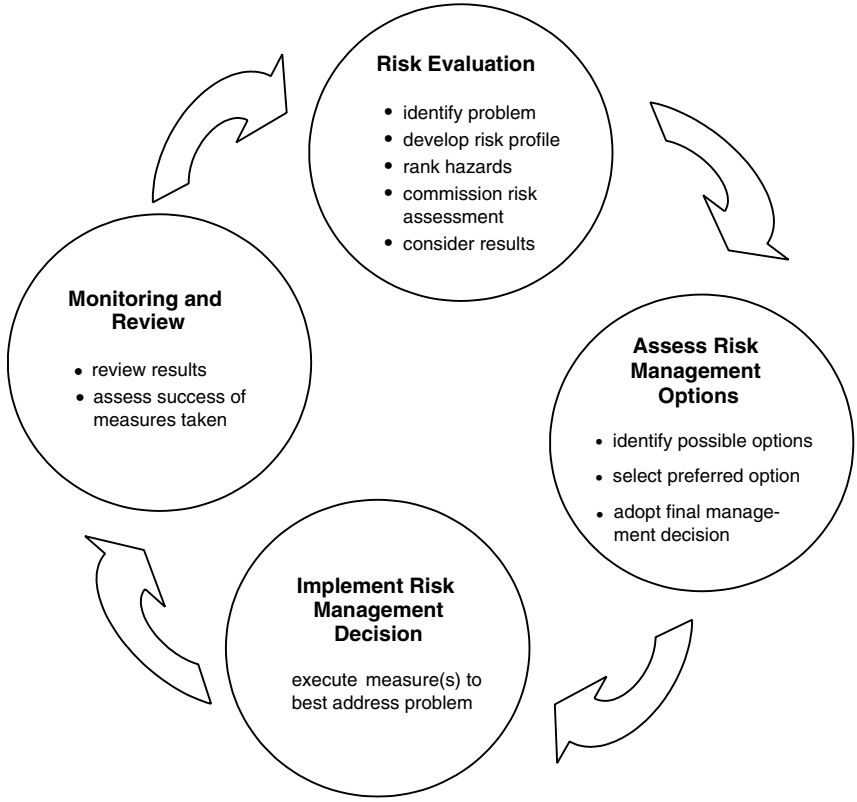

FIGURE 4 Codex Alimentarius food safety risk management model.

The integral role of surveillance and monitoring in risk management is clearly evident in this model.

RISK ASSESSMENT

Sometimes a risk assessment may be needed to collect scientific data required by the risk manager for decision making. Risk assessment can be defined informally as the work required to answer these following questions:

- What can go wrong?
- How can it happen?
- How likely is it?
- What are the consequences?

Codex Alimentarius defines risk assessment as follows:

> Risk Assessment A scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties (FAO/WHO, 2001, p. 44).

Figure 5 presents the codex definitions of the steps of a risk assessment. The first three steps rely directly on scientific evidence. The risk characterization step provides a risk estimate that is based on the information from the three preceding steps.

RISK COMMUNICATION

All risk management and risk assessment activities take place in an environment of risk communication. Risk communication can be defined informally as the work required to answer the following questions:

- Why are we communicating?
- Who is our audience?
- What do our audiences want to know?
- What do we want to get across?
- How will we communicate?
- How will we listen?
- How will we respond?

Codex Alimentarius defines risk communication as follows:

> Risk Communication The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions (FAO/WHO, 2001, p. 44).

Risk communication tasks can be divided broadly into internal and external risk communication. Internal communications are those interactions between risk managers and risk assessors that are critically important to the risk analysis process. External risk communication tasks involve the members of the risk management team, their stakeholders, and other interested parties external to the food safety organization that is doing the risk analysis.

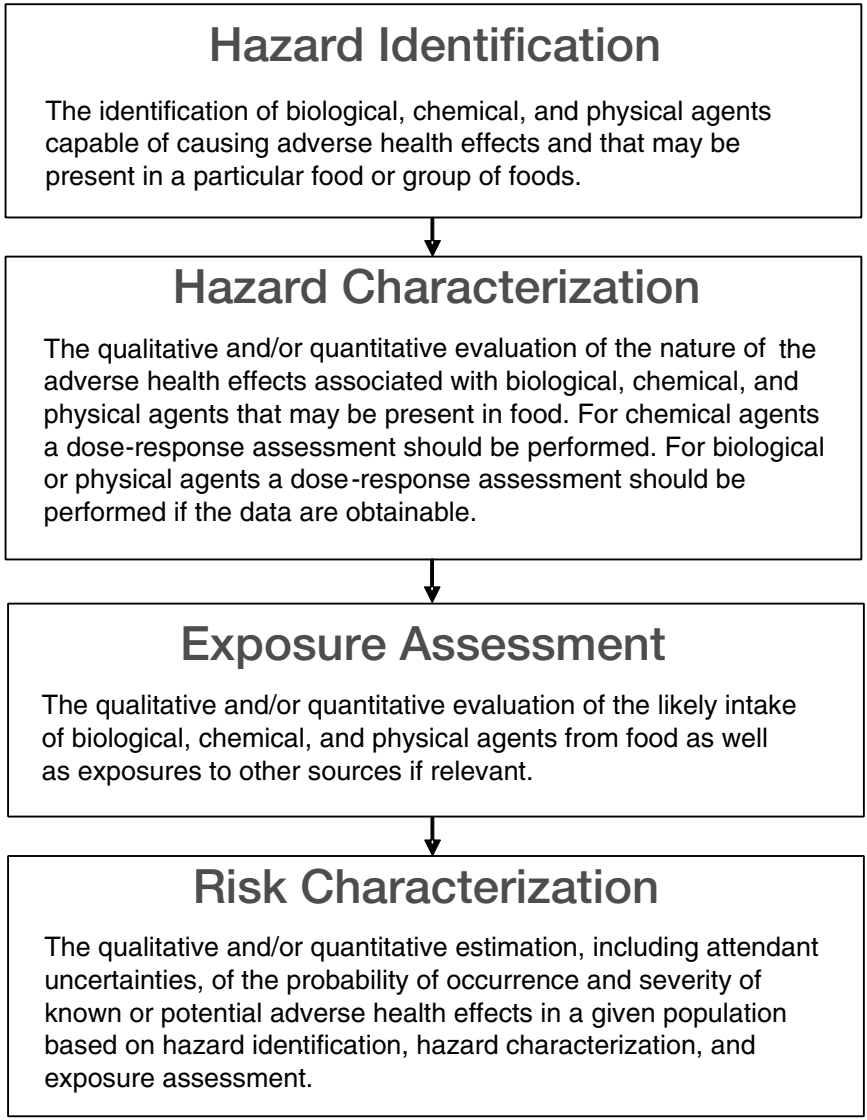

FIGURE 5 Steps in the risk assessment process (Codex Alimentarius).

NECESSARY CONDITIONS FOR RISK ANALYSIS

Several essential conditions are necessary for a nation to effectively incorporate the risk analysis paradigm into its food safety system. These include the following:

A functional food safety system. Countries need to have the essential foundations of a food safety system in place, including adequate food laws and regulations, a national food control strategy, effective inspection and laboratory services, scientific and technical capacity, infrastructure, foodborne disease surveillance, epidemiological data, food monitoring, and mechanisms for integrating this information with education, and communication.

Knowledge about risk analysis. Government officials and decision makers at the highest levels must be aware of risk analysis and the value it adds to a nation's public health program. Similarly, food safety regulators and scientists who become risk managers and risk assessors need to learn what risk analysis is, why it is carried out, and how to perform the three tasks of risk analysis. Although government has the main role in performing risk analysis, it is also important to ensure that the food industry and consumers understand the essence of risk analysis.

Support and participation of key stakeholders. Risk analysis will be effective only if it takes place in an environment in which government, industry, academic institutions, and consumers recognize, value, and participate in the process. Industry must find value in the results of risk analysis. Academic institutions must produce information that meets the needs of risk analysis. Consumers and businesses must be able to recognize and derive clear benefits from the risk analysis process. Similarly, mechanisms must be in place to enable stakeholders to participate in the development of risk analysis policy, as well as in the various activities performed during risk analysis.

DISEASE SURVEILLANCE IS ESSENTIAL TO SUCCESS OF RISK ANALYSIS

According to Thacker and Berkelman (1998) as quoted in the National Research Council report *Scientific Criteria to Ensure Safe Food* (2003), "Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of health-outcome-specific data for use by the public health sector to reduce morbidity and mortality and to improve health."

Potter et al. (2000) provide three traditional reasons for foodborne disease surveillance:

1. To identify, control, and prevent outbreaks of foodborne disease;

2. To monitor trends and determine the targets and efficacy of control measures;
3. To determine the burden of specific diseases on public health.

To these can be added:

4. To provide the scientific evidence necessary for the successful incorporation of risk analysis into a modern food safety management system.

The information gathered through surveillance and monitoring is critical to the conduct of risk assessments. Hazard characterization and exposure assessments may make extensive use of the epidemiological data obtained from disease surveillance systems. Figure 6 shows the role of surveillance in the cycle of public health protection in a circular flow of information and activity. This cycle is then shown to influence the conduct of risk assessments and, in turn, to be influenced by the needs of risk assessment.

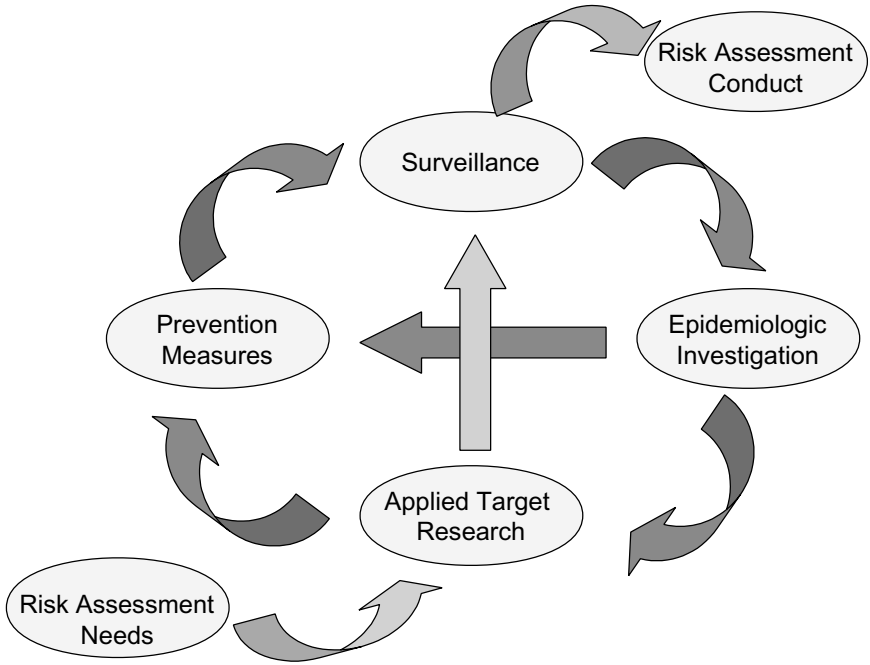

FIGURE 6 Surveillance systems and risk assessment.
SOURCE: Adapted from NRC (2003, Figure 2.1, p. 29).

In general, foodborne disease surveillance has been essential for the following:

- Estimating the burden of foodborne diseases, and monitoring trends;
- Identifying priorities and setting policy in the control and prevention of foodborne diseases;
- Detecting, controlling, and preventing foodborne disease outbreaks;
- Identifying emerging food safety issues; and
- Evaluating foodborne disease prevention and control strategies.

It is not evident that surveillance is essential to successful risk assessment, although it is an undeniable fact that surveillance supports better risk assessment. Several strategies (NRC, 2003) in public health surveillance may be helpful to the risk analysis process. Each is discussed briefly below.

Routine Surveillance. Surveillance of human illness provides information about illnesses possibly due to food. Monitoring case reports of specific, notifiable infections is important for defining trends, identifying outbreaks, and evaluating food safety programs. These data provide the essential information needed by risk analysts to characterize hazards and exposures to these hazards and to set national priorities for risk assessment. Some surveillance tasks, such as monitoring levels of antimicrobial resistance in foodborne pathogens, can be important to real-time risk assessments. Timely analysis and dissemination of the results of this surveillance to regulators, industry, the public, and risk assessors and managers is essential.

Sentinel Site Surveillance. Investigating and reporting specific outbreaks or specific illnesses can provide more detailed information than a national surveillance system. Such systems may serve as a platform for conducting case-control studies to identify risk factors. These data in turn can be instrumental in enabling risk managers to pinpoint their assessments and resulting risk mitigation options.

Foodborne Outbreak Reporting. It is important to distinguish the relationship between exposure and infection, and between exposure and illness. Investigating and reporting clusters of cases of specific infections helps risk managers determine their risk management priorities. These data also provide information essential to the risk assessors' hazard characterization and when possible, exposure assessments. This type of surveillance strategy, along with the others mentioned here, provides valuable evidence for risk managers to assess the success of the measures taken to reduce risks. The ongoing nature of risk analysis requires the continual reduction of data gaps and development of up-to-date databases.

Specialized Surveys of Behavior. Systematically obtaining data on the behavior of the population and their resulting exposure to specific risks is essential to the conduct of sound hazard characterization and exposure assessment. Behavior data has been one of the most persistent data gaps in the first generation

of microbial risk assessments. In general, the lack of relevant food-related behavioral information has been a weak link in the risk assessment chain, regardless of the hazard.

Food monitoring is also essential to good quantitative risk assessment. Rapid and early pathogen identification and illness prevention have become high priorities for all parties interested in the safety of the food chain. The development of effective, reliable, and cost-effective methods to control or eliminate pathogens throughout the complete food chain, from farm to table, has become correspondingly more important. New methods for rapid bacterial detection, antimicrobial intervention, and food safety inspection have been developed to help prevent or reduce foodborne illness. The data acquired from these techniques needs to be made available in a timely and effective manner to support the risk analysis paradigm.

The detection of pathogenic microorganisms is needed to enhance food safety for consumers and to minimize the potentially adverse economic impact on producers resulting from false-positive tests. Public concern over the presence of undesired chemical residues in raw and processed foods resulting from the use of antibiotics, hormones, pesticides, fungicides, and the like is increasing. Foodborne illness outbreaks caused by consumption of perishable and minimally processed foods are growing problems of contemporary society. It is of paramount importance that detection methods be precise, reliable, sensitive, specific, and rapid so that any pathogens and toxins in foods may be identified rapidly and accurately prior to their spread over the marketplace. And it is of paramount importance to the future of risk assessment that prevalence, concentration, and load data be made available in a useful form that supports probabilistic risk assessment.

Predictive microbiology is crucial to the accurate modeling of relationships critical to reasonable risk characterizations. Information about the temporal distribution and frequency of occurrence of a pathogen, its concentration and spatial distribution, its seasonality, and any niche it might occupy are essential for risk assessors' understanding and estimation of the survival, persistence, amplification, attenuation, control, and treatment of the pathogen of interest.

It is not just the collection of data that is necessary to risk assessors; the form is equally important. In the past it may have been sufficient to summarize food monitoring data with a mean and a standard deviation of pathogen concentration. Many data were reported as detects and nondetects. In some studies, data were summarized in categorical classes, such as one log or less.

Risk assessors seek rich databases. They want to be able to use all the data. A dataset with actual pathogen loads in a sample is preferred over any of the previous examples. Risk assessment may require reorienting the data collection practices of bench scientists and perhaps even epidemiologists.

The World Health Organization (WHO, 2001, p. 20) offered six conclusions

and recommendations on the interaction between surveillance and risk analysis, also provide a fitting summary for this paper:

1. To achieve a risk-based food safety program to reduce or prevent foodborne diseases, countries which are WHO members should invest resources in public health surveillance and the integration of epidemiologic and risk analysis activities at the national and international levels.

2. Risk managers, in consultation with epidemiologists, risk assessors, and other stakeholders, should develop a prioritized list of pathogens and/or foods for which extra data are needed.

3. Countries which are WHO members should encourage epidemiologists and risk assessors to identify characteristics of outbreaks that may provide relevant data for quantitative risk assessment and secure adequate laboratory support. Countries should also develop mechanisms for collecting and collating enhanced food microbiologic information that can be obtained in outbreak settings by developing mechanisms to obtain food samples and to quantitatively analyze these samples.

4. Countries should move toward integrating surveillance systems for human and animal disease and monitoring systems for food contamination. Integration would also assist quantitative risk assessment.

5. WHO should establish clearinghouses or other exchange mechanisms for raw data and results of data analysis as well as appropriate control of use of shared data.

6. WHO should support the efforts of developing countries to assess their capacity to collect and use basic epidemiological data. WHO should foster partnerships between developed and developing countries for active support (i.e., technology transfer or financial support) of the latter.

REFERENCES

FAO/WHO (Food and Agriculture Organization/World Health Organization). 2001 Joint FAO/WHO Food Standards Programme. Codex Alimentarius. Commission on General Principles. Procedural Manual, 12th ed. Rome: Food and Agriculture Organization of the United Nations/World Health Organization. Available at http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/005/Y2200E/y2200e00.htm. Accessed December 1, 2005.

NRC (National Research Council). 2003. Scientific Criteria to Ensure Safe Food. Washington, D.C.: The National Academies Press.

Potter, M., D. Archer, A. Benson, F. Busta, J. Dickson, M. Doyle, J. Farber, B. B. Finlay, M. Goldblatt, C. Hedberg, D. Hoober, M. Jahncke, L.-A. Jaykus, C. Kaspar, A. P. Liang, J. Lindsay, J. Pestka, M. Pierson, P. Slade, R. B. Tompkin, and M. L. Tortorello. 2000. Emerging Microbiological Food Safety Issues: Implications for Control in the 21st Century. Chicago: Institute of Food Technology.

Thacker, S. B., and R. L. Berkelman. 1988. Public health surveillance in the United States. Epidemiological Review 10:164-190.

WHO (World Health Organization). 2001. Global surveillance of foodborne disease: Developing a strategy and its interaction with risk analysis. WHO/CDS/CSR/EPH/2002.21. Geneva, Switzerland. Available at http://www.who.int/foodsafety/publications/foodborne_disease/surveillance_strategy/en/. Accessed December 1, 2005.

The Hazard Analysis and Critical Control Point System

Dr. A. Djazayery
Professor of Nutrition, School of Public Health and Institute of Public Health Research
Tehran University of Medical Sciences

With traditional methods of food control in food processing plants it has been usual to take a sample of the final product leaving the factory and perform laboratory analyses on this sample. When a bacterial contamination was detected, there was no way to know its source or pinpoint exactly where in the processing line it had occurred. Observation, experience, and controlled research showed that contamination could occur at any stage; from the point at which raw materials entered to the final point of the product leaving the processing plant, including outside exposures to contaminants. The source(s) of contamination in the plant could potentially be raw materials, machinery, equipment, or personnel.

Thus, food processors and control experts adopted the Hazard Analysis and Critical Control Point (HACCP) system, which has had wide application and success in other industries. In this system it is possible to detect contamination at its origin (biological, chemical, or physical) and take appropriate remedial action. The HACCP system is different from traditional control methods and can play an effective role in promoting food safety and consequently in food security (i.e., access to sufficient, safe food by the community).[1]

[1]According to the U.S. Department of Agriculture (USDA), "Hazard Analysis and Critical Control Points (HACCP) is a production control system for the food industry. It is a process used to determine the potential danger points in food production and define a strict management system to monitor and manage the system ensuring safe food products for consumers. HACCP is designed to prevent the potential hazards, including: microbiological, chemical, and physical. Juice, meat and poultry, and seafood are regulated at the federal level. Meat and Poultry HACCP systems are regulated by the USDA, and juice and seafood systems are regulated by the FDA." More information about the HACCP is available at http://www.nal.usda.gov/fsrio/topics/tphaccp.htm and http://vm.cfsan.fda.gov/~lrd/haccp.html.

The HACCP system is based on the following well-known principles:

1. *Analyzing hazards*. Identification of potential hazards associated with a food and of measures to control those hazards.
2. *Identifying critical control points*. These are points in a food's production (from its raw state through processing and shipping to consumption by the consumer) at which the potential hazard can be controlled or eliminated.
3. *Establishing preventive measures with critical limits for each control point*. For a cooked food, for example, this could include setting the minimum cooking temperature and the time required to ensure the elimination of any harmful microorganisms.
4. *Establishing procedures to monitor the critical control points*. Such procedures could include determining how and by whom cooking time and temperature should be monitored.
5. *Establishing corrective actions to be taken when monitoring shows that a critical limit has not been met.* Examples include reprocessing or disposing of food if the minimum cooking temperature is not met.
6. *Establishing procedures to verify that the system is working properly.* Examples include testing time-and-temperature-recording devices to verify that a cooking unit is working properly.
7. *Establishing effective record keeping for documentation of the HACCP system*. This could include records of hazards and their control methods, of the monitoring of safety requirements and the action taken to correct potential problems.

Today the HACCP system is being used in many food processing plants worldwide. Over the last decade or so, action has been taken in Iran to introduce the system to food processors (requiring or at least encouraging them to adopt it) as well as to the relevant authorities and personnel in the health, agriculture, and industry sectors, to food standard authorities, and to food legislators.

In the development of an HACCP plan, five preliminary tasks need to be accomplished before an HACCP plan can be developed which include assembling the HACCP team, describing the food and its distribution, describing the intended use, developing a flow diagram that describes the process, and verifying the flow diagram. The development of an HACCP plan involves 12 phases as follows:

1. *Assembling the HACCP team*. HACCP teams consist of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP plan.
2. *Describing the food and its distribution*. This consists of a general description of the food, ingredients, and processing methods. The method of distri-

bution should be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature.

3. *Describing the intended use and consumers of the food.* Describe the normally expected use of the food. The intended consumers may be the general public or a particular group of the population (e.g., infants, immunocompromized individuals, the elderly).

4. *Developing a flow diagram that describes the process.* The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process.

5. *Verifying the flow diagram.* The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. After these five preliminary tasks have been completed, the seven principles of HACCP are applied.

The next seven phases are application of the seven principles described above. The last phase (Phase 12, Principle 7), as described above, is to establish a record-keeping and documentation system. Generally, the records maintained for an HACCP system should include the following:

1. A summary of hazard analysis;
2. HACCP Plan that lists the HACCP team and assigned responsibilities, description of the food, its distribution, intended use and consumer, verified flow diagram, and the HACCP plan summary table. The table should include information on steps in the process that are critical control points, the hazard(s) of concern, critical limits, monitoring, corrective actions, verification procedures and schedule, and record-keeping procedure;
3. Support documentation, such as validation records; and
4. Records that are generated during the operation of the plan.

Four basic steps in establishing an HACCP system in food industry in a country are as follows:

1. Preparation of relevant national standards by the food standard agency (general guidelines for HACCP-system establishment in the food industry, plus standards for specific food or food group);
2. Introduction of the HACCP system to food processors and the relevant government authorities and personnel through short training courses, seminars, and workshops;
3. Development of an HACCP plan in a food processing unit as a pilot; this involves the 12 phases (see above); and
4. Implementation, expansion of the system throughout the province or country.

Implementing and Auditing Hazard Analysis and Critical Control Point Systems and Difficulties in Iran

Sassan Rezaie
Assistant Professor of Microbiology
Tehran University of Medical Sciences

As is well known to this audience, the Hazard Analysis and Critical Control Point (HACCP) system is used for food safety and for controlling food processing. I will review the basic aspects of the system that have been widely documented in the scientific literature. I will not attempt to cite the many references that I am sure are well known to our American guests.[1]

HACCP is usually referred to as a preventive, documented, and verifiable system. It is preventive because it focuses basically on the entire process and not merely on the final product. It is documented because there are procedure manuals as well as work instructions for implementing HACCP and there is also a record-keeping system for control. Finally, HACCP is verifiable because its effectiveness can be checked and verified by such methods as internal audits and final product examination. This preventive, documented, and verifiable system will control food hazards by identifying and characterizing all food hazards from farm to fork, followed by determining critical control points at which a monitoring system for detecting the hazards triggers corrective action. To implement

[1]According to the U.S. Department of Agriculture (USDA), "Hazard Analysis and Critical Control Points (HACCP) is a production control system for the food industry. It is a process used to determine the potential danger points in food production and define a strict management system to monitor and manage the system ensuring safe food products for consumers. HACCP is designed to prevent the potential hazards, including: microbiological, chemical, and physical. Juice, meat and poultry, and seafood are regulated at the federal level. Meat and Poultry HACCP systems are regulated by the USDA, and juice and seafood systems are regulated by the FDA." More information about the HACCP is available at http://www.nal.usda.gov/fsrio/topics/tphaccp.htm and http://vm.cfsan.fda.gov/~lrd/haccp.html.

and also audit HACCP systems in food processing industries we have three basic requirements as follows:

- It begins with management requirements that are usually referred to as management responsibilities. The first management requirement is setting a hygiene policy. This is done by top management. This policy will give the organization a hygienic direction. The second management responsibility is the determination of the HACCP system's scope; this locates the implemented HACCP system in the big picture of "from farm to fork." The third management responsibility is designating the HACCP team, which is usually selected from the company's middle managers following the implementation of the HACCP system.
- The second group of responsibilities concerns the operational prerequisites. These prerequisites are referred to as good manufacturing practice principles as well as hygiene training. The basic aspects involved include the following:

1. Operating conditions for the equipment used in food processing.
2. Rooms in operating facilities should be indicated as clean and unclean areas in food processing and include any cold rooms. Old infrastructures in many companies usually do not meet the requirements for this aspect of the operation and money should be spent on infrastructure renovation in order to separate the clean from the unclean areas.
3. Cleaning and disinfection procedures in processing areas for the general environment as well as for the machinery.
4. Sanitary services and facilities.
5. Drainage.
6. Lighting.
7. Ventilation.
8. Pest control, particularly in geographic areas with warm climates like Iran. This is an important operational prerequisite in HACCP. There are three strategies in pest control: preventing the entrance of pests into the operations area, preventing the nesting and growth of any entered pests in the operations area, and finally killing the insects and pests.
9. Waste disposal.
10. Water supply: in HACCP we always need detailed and precise water analysis data to control the waterborne pathogens and contamination in food processing.
11. Personal hygiene: all workers and operators should have been tested and certified by the Ministry of Health in Iran. In addition, their protective clothes in clean areas should be prescribed by HACCP documents.
12. Hygiene training is a basic requirement in implementing HACCP. To be effective, hygiene training must change or improve hygienic attitude and behavior.

• Other operational steps and requirements for implementing HACCP are as follows:

1. Operational requirements originate from product specifications. The ingredients of food as well as its formulation and all additives with their amount should be determined here.
2. The second step is the process description, drawing a flow diagram and finally confirming it at the operation site.
3. The third step is the first principle of a HACCP system. All potential hazards—biological, chemical, and/or physical—should be classified in three groups: hazards due to raw materials, hazards caused by cross-contamination, and hazards that are resistant to the elimination process during the operation.
4. The fourth step is the second principle of an HACCP system. A critical control point (CCP) is a stage in the process that can be controlled, and controlling it can decrease or eliminate a determined hazard.
5. The fifth step is the third principle of an HACCP system. For each CCP we should have at least one critical limit.
6. The sixth step is installation of monitoring systems for the critical limits at CCPs that will monitor hazards.
7. The seventh step is corrective actions that must be performed when monitoring indicates a deviation from the critical limit of a CCP.
8. The eighth step is verification: this means internal audits plus microbiological, chemical, and/or physical tests of the final product, as well as investigations of customer complaints regarding the product.
9. The ninth step is documentation; documentation should cover all procedures and work instructions in use as well as the recording system.
10. The final step is revision and updating of the HACCP system; this should happen at least once a year and focus on all possible problems that could affect the system.

The History of Food Safety in Iran

M. Ebrahimi Fakhar
Food and Drug Deputy, Ministry of Health

Based on the 1967 Food Safety Law, each food factory must be approved by the Food Safety Department as to good manufacturing practices (GMPs), good laboratory practices, and generalized system of preferences. Each food factory must employ a food technologist (at the B.S.-degree level or higher) approved by the Food Safety Department. This individual is responsible for quality control in the factory at three levels: quality control of raw materials, quality control of processing, and quality control of the finished product. The food technologist must send monthly reports to the Food Safety Department. In addition, the Food Safety staffs in the provinces periodically inspect food factories and check them by testing random samples. At the distribution level there is a post-marketing surveillance system in order to control finished products in the market. Recently, the Food Safety Department has encouraged food factories to establish Hazard Analysis and Critical Control Point (HACCP) systems and this will become obligatory in the near future.

The supervisory administration for food, drink, cosmetics, and sanitary stuffs started teaching HACCP in 1994, in keeping with World Health Organization (WHO) aims. It has promoted and encouraged the development and use of HACCP systems. In recent years many workshops and seminars on GMPs and HACCP systems have been organized by the above-mentioned administration or by medical science universities. WHO tutors and consultants have served as tutors and lecturers.

The first food safety meeting and related workshops were held in August 1996. The participants were managers and experts of the Supervisory Administration of Food and Sanitary Stuffs from Iran's medical science universities. The second meeting was held in November 1996; it was sponsored by Tabriz Univer-

sity of Medical Sciences in East Azerbaijan province and lasted for three days. Subsequently, many HACCP workshops were held in 1997 in Bushehr, Fars, Isfahan, Khorasan, Tehran, and Azerbaijan. The supervisory administrations have translated and published papers on hazards and critical control points and, in this respect, the Institute of Standard and Industrial Research of Iran can be said to have published standards of practice (SOPs).

To coordinate all food safety programs in different organizations, the Food and Drug Administration of the Ministry of Health established a committee in March 1999 to help plan and harmonize HACCP systems. This committee consists of experts from different responsible organizations and ministries. It meets under the auspices of the Supervisory Administration of Food, Cosmetics, and Sanitary Products. Other organizations from the veterinary and fishery sectors have performed similar work adapting HACCP systems to veterinary and fishery products.

This committee started work on food safety through the use of HACCP and tried to replace old control methods with HACCP systems. Exclusive use of HACCP is now mandatory for potentially hazardous products such as dairy and meat.

Since 2000 the committee has performed the following main actions:

1. Established committees in provincial universities of medical science for improving HACCP systems;
2. Published various educational pamphlets and sent them to whereever needed (including provincial committees). These pamphlets include the following:
   - A general guide on HACCP in food industries;
   - National Standard No. 4557. SOPs for hazard analysis and critical control points;
   - National Standard No. 1836. SOPs for the main sanitary principles in food production units;
   - A guide to HACCP system validation;
   - Elementary programs and a revised work sheet for HACCP systems;
   - A hazard analysis and critical control points book; and
   - A checklist of differentiation patterns for HACCP systems based on conventional international methods.
3. Provided a list of the expert consultants and user information at various levels;
4. Trained the nuclear group of the committee;
5. Held workshops for related experts in collaboration with corporate teaching centers, university scientists, and committee teachers;
6. Held a three-day workshop in 2002 on GMP principles taught by WHO consultants;
7. Established a Web site hosted by the Food and Drug Office's Web site;

8. Developed an HACCP system data bank for users worldwide;
9. Identified HACCP rules, proposals for each foodstuff, and how to determine and validate hazards in food industry systems;
10 Established SOPs for using an HACCP system on pistachios; participated in national Codex Alimentarius committees; developed a proposal for control and screening of pistachio contamination;
11. Established an HACCP SOP system for raisins;
12. Collaborated with the Iran Accreditation System;
13. Prepared a data bank for producer units that could obtain HACCP certificates;
14. Validated HACCP systems in production units and issued the permit for using HACCP certificates on labels or in advertisements;
15. Prepared a checklist for validation of dairy production for GMPs and HACCP; and
16. Established HACCP system certification requirements for the import of processed materials, such as dried milk.

Activities of the National Committee for Coordinating and Planning HACCP Implementation, 2000-2004:

Number of approvals and administrative actions	94
Number of committee sessions	81
Number of pamphlets	6
Number of established training workshops	49
Number of educated individuals	4,779
Hours of training	784
Number of pamphlets in Persian and English	30
Number of establishments successfully setting up HACCP systems	88

The government of Iran continues to be committed to establishing and implementing appropriate food safety measures, including HACCP systems for various food products. It is hoped that these measures will improve food safety throughout Iran.

Discussion

Dr. Mohammadreza Razailashkajani
Research Center for Gastroenterology and Liver Disease
Shaheed Beheshti University of Medical Sciences

Panel:
Dr. Yoe, Professor Djazayeri, Mr. Ebrahimi Fakhar, Dr. Sassan Rezai, and Dr. Jamdar

Mr. Schweitzer asked about the reaction of the Iranian population to government messages on food risks and hazards. Iranian participants noted that this was a poorly developed area of concern. Labeling of fast food in the United States was then the focus of attention. Dr. Jackson said that ingredient content and nutritional information are on the menus of some individual restaurants and fast food chains, but not yet uniformly so. This may become obligatory in the future. A discussion ensued on food labeling and food allergies. Food advertisement regulation in the United States was another issue. Dr. Jackson stated that health claims in food advertisements are regulated. Dr. Djazayeri mentioned that some standards for food advertisements exist in Iran.

Dr. Keene was eager to know about the experience of Iranian counterparts with foodborne disease outbreaks, and several Iranian experts responded. Other discussion topics included risk communication, influence of food import executives on food safety legislation in Iran, and high counts of *Campylobacter* that Research Center for Gastroenterology and Liver Disease researchers had found in some foods compared with the counts found in feces. The last item was believed to be a technical mistake by most experts at this session.

Day 3

Final Plenary Session: Future Steps and Opportunities

Closing Session

Final Plenary Session: Future Steps and Opportunities

Glenn Schweitzer
National Research Council

Dr. Keene summarized the view of the American participants on how a foodborne disease surveillance system can be operationalized in a country.

To begin, the purpose of a surveillance system should be clear. The sources of information must be identified, as this information can come from a number of sources, such as laboratories, physicians, hospitals and clinics, infection control staffs, public reports, media reports, inspectors, and pharmaceutical distribution data.

There are a variety of legal considerations that should be addressed at the very outset of administering a surveillance system. Adequate legal authority to collect surveillance information and to investigate outbreaks is necessary. If such authority is not in place, new legislation may be required. The system's design needs to address the question of who would have access to confidential medical records and to determine whether disease reporting will be compulsory and if so, by whom and to whom. Another consideration is whether diagnostic laboratories should be required to provide isolates to reference laboratories. Attached to the legal issues of surveillance are the implications of using surveillance data. It must be clear how the data will be disseminated and to whom. At the outset there must be a determination of whether specialists have the legal authority and the motivation to take action that may hurt business interests. Similarly, will the specialists have the necessary credibility with the public and the medical community? The sources of financial support should be clearly determined, and need to be stable, given the infrastructure and personnel required for a surveillance system to function.

Turning to laboratory considerations, the system will require access to specimens for analyses. The system must be capable of confirming diagnoses and

subtyping isolates to identify possible linkages. The laboratories will need to respond to requests for their services in a timely manner.

In conclusion, not all diseases are well suited to comprehensive reporting. In the United States the legal framework for enteric disease surveillance is integrated with other diseases, but other countries may need to find the approach that will work best in that country, keeping in mind that outbreak investigation is a developing skill.

Dr. Massoumi-Asl presented Iranian views on future steps toward a foodborne disease surveillance system in Iran. The disease control system of the Iranian Center for Disease Control is a well-organized, countrywide health network that includes 15,000 health houses and 500 health centers. The system incorporates health specialists of 40 medical universities who monitor communicable and noncommunicable diseases in their districts, and the district activities are supervised by provincial and national experts. The district health centers with health laboratories are controlled by provincial health laboratories. There is a reference laboratory in Tehran for each disease control program.

The foodborne disease surveillance program is a recent addition to Iran's disease control center. It is located within the Foodborne and Waterborne Disease Department. The center's activities since its inception include two case-control studies, as well as the investigation of nine disease outbreaks occurring between April and September 2004. Of these outbreaks 40 percent were foodborne and 60 percent waterborne. Over 1600 people were affected, with three fatalities reported. While the program is in its nascence, many important facilities and infrastructure already exist; however these need better linkages and coordination. Iranian specialists believe that a national commitment to link the facilities is essential.

The objective of the foodborne disease surveillance program in Iran is to reduce mortality and morbidity. To this end it is necessary to establish a laboratory-based, integrated surveillance system. Intersectoral coordination between disease control components involved in food safety and surveillance is as important as linking the local facilities. It would be possible to create local and provincial laboratory centers that operate under the supervision of the Research Center for Gastroenterology and Liver Disease, which would then provide a reference laboratory. The centers would provide health education for all target groups and carry out basic, clinical, and field research. Monitoring and evaluation would be important to ensure the quality of services.

Dr. Jamdar and Dr. Yoe then spoke about future steps that could be taken by both Iran and the United States in the process of analyzing risks to food safety and foodborne disease surveillance. They stressed that international cooperation, and in particular regional cooperation, is important in identifying common interests and in sharing resources. Iran and the United States have a number of opportunities for cooperation, including data sharing by clearinghouses, jointly sponsoring professional development, exchanging personnel, and participating in a

risk assessors network. In Iran the development of risk analysis capacity is particularly important. The needs of various ministries should be clarified and the relevant paradigms addressed. Risk assessment is an area that could be particularly fruitful for cooperation.

Dr. Jackson and Dr. Djazayeri each presented their team's perspective on areas of common interest to both Iran and the United States in the areas of food safety and foodborne disease surveillance. Dr. Jackson stressed a common interest in methodology, including reporting systems, investigation tools, the latest and best laboratory tests and methods, and the comparability of standard measurements. Examination of established and emerging food pathogens, including those developing antibiotic resistance, is also an area of common interest. Dr. Djazayeri spoke about the possibility of establishing a food safety collaboration center, which would allow for an exchange of expertise and information. It could also hold long-term training courses and workshops on such topics as food safety and quality, help in the establishment of pilot projects, and work on technology transfer and capacity building.

Dr. Matthews and Dr. Poorshafi presented a short review of the highlights of the meeting. Of the points covered in the workshop, they stressed the following topics as some of the most significant. Foodborne diseases are a significant human health issue for Iran and the United States. Many government agencies of both countries are concerned about the potential threat to public health, and many of the issues faced by agencies are common in the two countries. Among the issues of common concern are the following: poultry processing, food sold by street vendors, imported foods, mycotoxins, and bacteria. The presenters stressed the immature state of Iranian foodborne surveillance and the need for a functioning surveillance system.

In the final section of the closing session the participants considered the reports of three working groups on food safety, foodborne disease surveillance, and risk assessment. All groups agreed that further exchanges of ideas were necessary. Some of the observations and suggestions for future cooperation are as follows.

There is a need to identify important websites that address methodological questions in food safety. Developing consumer groups that can defend food safety principles is an important aspect of food safety in both countries. To offer specific recommendations on food surveillance in Iran, the American team would need a better understanding of the Iranian health care system. Pilot projects could probably be useful in developing an expanded surveillance program in Iran. Risk analysis is necessary for priority setting, and each relevant organization should define the specific tasks for its risk assessors. International collaboration in risk assessment is highly desirable. In particular, further measures are needed to stop international trade in unsafe food, which poses many risks.

Closing Session

Dr. Mohammadreza Razailashkajani
Research Center for Gastroenterology and Liver Disease
Shaheed Beheshti University of Medical Sciences

Mr. Schweitzer expressed the appreciation of the American specialists for the opportunity to participate in the discussions. The Americans were impressed by the number of organizations that are sufficiently interested in food safety to have made presentations at the workshop. He noted that coordination is important in Iran just as it is in the United States.

Professor Zali expressed his pleasure in having a dual opportunity at the workshop to meet enthusiastic young Iranian researchers and to have distinguished colleagues from the U.S. National Academies participate.

Appendixes

Appendix A

Workshop Agenda

SATURDAY, OCTOBER 2, 2004

8:30 - 9:30	**Opening Ceremony**
9:30 - 10:30	Chair: Dr. Jackson ……. Co-Chair: Dr. Jamdar **Overview of Food Safety Issues and of Diseases Arising from Food of Animal and Plant Origin in the United States of America** Karl R. Matthews, Associate Professor, Department of Food Science, Cook College, Rutgers University
10:30 - 11:00	**Break**
11:00 - 11:30	**Overview of Safety Issues with Foods of Animal and Plant Origin in Iran** Dr. M. R. Akbarian, Iranian Veterinary Organization
11:30 - 12:00	**The Role of ISIRI in Food Safety in Iran** Mr. M. H. Hasanpour, Director of Food and Agriculture for the Institute of Standards and Industrial Research of Iran (ISIRI)

11:30 - 12:30	**Discussion Session** Panel: Dr. Jackson, Dr. Matthews, Dr. Montes Nino, and Dr. Jamdar
12:30 - 14:00	**Lunch**
14:00 - 15:00	Chair: Dr. Keene …… Co-Chair: Dr. Nadim **Surveillance for Foodborne and Diarrheal Diseases, and Investigation of Foodborne Disease Outbreaks in the United States: Three Examples** Dr. W. E. Keene, Senior Epidemiologist, Acute and Communicable Disease Program, Oregon Public Health Services
15:00 - 16:00	**Foodborne Diseases Reporting** Dr. W. E. Keene, Senior Epidemiologist, Acute and Communicable Disease Program, Oregon Public Health Services
16:00 - 16:30	**Break**
16:30 - 17:30	**Foodborne Diseases Surveillance, Including Epidemiology (Data Collection, Organization, Analysis, Interpretation and Reporting)** Dr. M. Gooya, Director General of CDC (Center for Disease Control) Dr. A. Ardalan, Epidemiologist
17:30 - 18:30	**Discussion Session** Panel: Dr. Keene, Dr. Gooya, Dr. Nadim, Dr. Ali Ardalan, and Dr. Minoo Mohraz

SUNDAY, OCTOBER 3, 2004

9:00 - 10:00	Chair: Dr. A. Montes Niño …….. Co-Chair: Dr. Jamdar **Inspection and Investigation: Tools for Detecting Sources of Food Contamination and Preventing Illness Outbreaks** Dr. G. J. Jackson, Microbiologist, former Dean of the Staff College, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration
10:00 - 10:30	**Break**

10:30 - 11:30	**Food Monitoring, Investigation and Inspection** Dr. Talakesh, Public Health Officer, Iran Veterinary Organization
11:30 - 12:30	**Discussion Session** Panel: Dr. A. Montes Niño, Dr. Jamdar, Dr. Talakesh, and Dr. Jackson
12:30 - 14:00	**Lunch**
14:00 - 15:00	Chair: Dr. Yoe …… Co-Chair: Prof. Djazayeri **Food Traceability** Dr. Alfredo Montes Niño
15:00 - 16:00	**Risk Analysis, Including the Role of Risk Analysis in 1) Identifying High Impact Intervention Points in Food Systems to Reduce Human Illness and 2) Risk Ranking Foods Associated with Foodborne Illness Caused by Specific Pathogens** C. E. Yoe, Professor of Economics, College of Notre Dame of Maryland
16:00 - 16:30	**Break**
16:30 - 17:00	**Hazard Analysis and Critical Point Systems (HACCP)** Dr. Djazayeri, Professor of Nutrition, School of Public Health and Institute of Public Health Research, Tehran University of Medical Sciences Dr. S. Rezaie, Assistant Professor, Faculty of Health, Tehran University of Medical Sciences
17:00 - 17:30	**Risk Analyses** Mr. M. Ebrahimi Fakhar
17:30 - 18:30	**Discussion Session** Panel: Prof. Yoe, Prof. Djazayeri, Mr. Ebrahimi Fakhar, Dr. Sassan Rezaie, and Dr. Jamdar

MONDAY, OCTOBER 4, 2004

8:30 - 8:50	**Highlights of Meeting** Dr. Matthews, Dr. Poorshafi
8:50 - 9:10	**Common Interests - Common Problems** Dr. G. J. Jackson, Prof. Djazayeri
9:10 - 9:30	**Future Steps - Surveillance** Dr. W. E. Keene, Dr. A. Ardalan
9:30 - 9:50	**Risk Assessment** Dr. C. E. Yoe, Dr. M. Jamdar
9:50 - 10:30	**Break**
10:30 - 11:30	**Draft Preparation of Proposals**
11:30 - 12:30	**Closing Ceremony**

Appendix B

Participant List

UNITED STATES

Karl R. Matthews
Associate Professor of Microbiology
Department of Food Science, Cook College, Rutgers University
New Brunswick, NJ 08901 USA
Tel: +1-732-932-9611 x219
Fax: +1-732-932-6776
matthews@aesop.rutgers.edu

William E. Keene
Senior Epidemiologist
Acute & Communicable Disease Program,
Oregon Public Health Services
800 NE Oregon Street (#772)
Portland, OR 97232 USA
Tel: +1-503-731-4024
Fax: +1-503-731-4798
william.e.keene@state.or.us

George J. Jackson
Microbiologist, retired from the U.S. Food and Drug Administration
1435 Fourth Street SW
Washington, DC 20024 USA
Tel: +1-202- 488-8635
gorgon7@his.com

Charles Yoe
Professor of Economics
College of Notre Dame of Maryland
4701 N. Charles Street
Baltimore, MD 21210 USA
Tel: +1-410- 744 -0940
cyoe1@comcast.net

Glenn Schweitzer
Director, Office for Central Europe and Eurasia, The National Academies
500 5th Street NW
Washington, DC 20001 USA
Tel: +1-202-334 -2172
gschweitzer@nas.edu

FAO

Alfredo Montes Niño
Director President of Microbioticos (FAO Representative)
Av. Brig. Luiz Antonio, 2.344-Sobrelojia-CEP
0402-900-Sao Paulo-SP, Brazil,
Tel:(11) 3286-0666; 214/(11) 3253-3301
amontes@microbioticos.com

RESEARCH CENTER FOR GASTROENTEROLOGY AND LIVER DISEASES (RCGLD), SHAHEED BEHESHTI UNIVERSITY OF MEDICAL SCIENCES

Mohammad Reza Zali
RCGLD President
Professor of Gastroenterology, Shaeed Beheshti University of Medical Sciences,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
Tel: 98-21-2417283, 2416848
Fax: 98-21-2402639
nnzali@hotmail.com, zali@ams.ac.ir

Mahnaz Taremi
Research Manager
National Research Department of Foodborne Diseases
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
mmtaremi@yahoo.com, taremi@rcgld.org

Siavosh Salmanzadeh Ahrabi
Assistant Professor
Shaheed Beheshti University of Medical Sciences
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
salmanzadeh1@yahoo.com

Maryam Kheradpezhouh
Research Assistant
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
mkherad@hotmail.com

Mohammadreza Rezailashkajani
Research Assistant, Health Informatics Department
Research Center for Gastroenterology and Liver Disease,
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
docreza@yahoo.com, rezai@rcgld.org

Delnaz Roshandel
Research Assistant, Health Informatics Department
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
delnaz53@yahoo.com

Ali Ardalan
Epidemiologist
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
Ali_ardalan@hotmail.com, aardalan@gmail.com
Tel: +98-912-3050192

Seyed Mohsen Mousavi
Community Medicine Specialist
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
smmousavi@yahoo.com

Negar Behrouz
Research Assistant, Food & Nutrition Department
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
Negar_behrouz@yahoo.com

Effat Habibi
Laboratory Technologist
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
ehabibi77@yahoo.com

Fereshteh Jaafari
Laboratory Technologist
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
f_jaafari580@yahoo.com

Koorosh Zolfagharian
Laboratory Technologist
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
kzolfagharian@yahoo.com

Sanaz Moez Ardalan
Laboratory Technologist
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
smardalan@yahoo.com

Ali Moghaddam Gol Mohammadi
Laboratory Technologist
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
ali_moghaddam69@yahoo.com

Haleh Edalatkhah
Laboratory Technologist
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
hedalatkhah@yahoo.com

Mohammad Ghazanfari
Research Assistant
National Research Department of Foodborne Diseases,
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
mohghazanfari@yahoo.com

Padideh Ghaempanah
Research Assistant, Lower GI Scientific Group
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
padid2000@yahoo.com

Naghmeh Jafarynia
Research Coordinator
Research Center for Gastroenterology and Liver Disease
Taleghani Hospital, Parvaneh Street, Velenjak, Tehran, Iran
jafarynia@rcgld.org

IRAN VETERINARY ORGANIZATION

Maghsoud Jamdar
Head of Public Health Office
Iran Veterinary Organization
S. J. Assadabadi Avenue, Valia-e-Asr Street
Tehran, Iran
Tel: +98214194501-2, +989123874249
Fax: +98214196963
mjamdar@hotmail.com

Seyed Farzad Talakesh
Head of Edible Animal-Origin Food Office
Iran Veterinary Organization
S. J. Assadabadi Avenue, Valia-e-Asr Street
Tehran, Iran
Tel: +98218962380
sftalakcsh8@hotmail.com

Farahmand Salehzadeh
Public Health Officer
Iran Veterinary Organization
S. J. Assadabadi Avenue, Valia-e-Asr Street
Tehran, Iran
salczad@yahoo.com

Hossein Khaneghahi
Public Health Officer
Iran Veterinary Organization
S. J. Assadabadi Avenue, Valia-e-Asr Street
Tehran, Iran
ivopublichealth@ivo.org.ir

Amir Raffi
Animal Establishment Health Officer, Public Health Officer
Iran Veterinary Organization
S. J. Assadabadi Avenue, Valia-e-Asr Street
Tehran, Iran
araoofii22@yahoo.com

Hamid Khaneghahi
Deputy of Public Health Department
Iran Veterinary Organization
S. J. Assadabadi Avenue, Valia-e-Asr Street
Tehran, Iran
ivopublichealth@ivo.org.ir

Mahmoud Akbarian
HACCP Consultant (private sector)
Iran Veterinary Organization
S. J. Assadabadi Avenue, Valia-e-Asr Street
Tehran, Iran
Tel: +989121057988
mrakbarian@hotmail.com

Reza Mousavi
Head of Public Health Office
Isfahan Veterinary Network
Tel: +983117762995
ivoesfahan@ivo.org.ir

Ahmad Raji
Head of Public Health Office
Gilan Veterinary Network
Tel: +983117762995
ivogilan@ivo.org.ir

Hadi Tabarrai
Head of Public Health Office
Tehran Veterinary Network
Tel: +98214194941
ivotehran@ivo.org.ir

Gaphar Attarbashi
Head of Public Health Office
Khorasan Veterinary Network
Tel: +985116028383
ivokhorasan@ivo.org.ir

Hamid Zeinali
Head of Public Health Office
Ghazvin Veterinary Network
Tel: +98281-3347047
ivoghazvin@ivo.org.ir

ISIRI (INSTITUTE OF STANDARDS AND INDUSTRIAL RESEARCH OF IRAN)

Hengameh Yousefzadeh
Supervisor of Fats and Oil Lab
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Tehran, Iran
Tel: +982612803889
hengameh_abi@yahoo.com

Nadia Ahmadi
Expert of Dried Fruit and Mycotoxin Lab
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Tehran, Iran
Tel: +982612803889
nady_2000ca@yahoo.com

Khosrow Barazandegan
Supervisor of Meat and Dairy Products Lab
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Tehran, Iran
Tel: +982612803889
baraz1956@hotmail.com

Tahereh Hashemi
Deputy Director General
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Tehran, Iran
Tel: +982612803889
tahereh_langroudi@yahoo.com

Farnaz Dastmalchi
Research Assistant
Institute of Standard and Industrial Research of Iran
P.O. Box 31585-163
Tehran, Iran
Tel: +982612803889
mehrabantavan@yahoo.com

Mohammad Hossein Shahrokh Hassanpour
Director General, Deputy of Food and Agriculture
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Tehran, Iran
Tel: +982612803889
msh_55@yahoo.com

Rahim Abouali
Director of Biology and Microbiology Research Center
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Karaj, Iran
Tel: +982612808120
r_abouali@isiri.or.ir

Fattaneh Shokrollahi
Deputy Director of Biology and Microbiology Research Center
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Karaj, Iran
Tel: +982612808120
shokrollahi@isiri.or

Fatemeh Zandvaili
Head of Soft Drinks and Canned Products-Microbiology Group
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Karaj, Iran
Tel: +982612808120
zandvakili@isir.or.ir

Gholam Hassan Ebrahemi
Head of Meat and Dairy Products-Microbiology Group
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Karaj, Iran
Tel: +982612808120
emam@isiri.or.ir

Akram Sadat Fayazi
Head of Cereal and Confectionery Products-Microbiology Group
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Karaj, Iran
Tel: +982612808120
fayazi@isir.or.ir

Fatemeh Kabiri
Senior Expert
Institute of Standards and Industrial Research of Iran
P.O. Box 31585-163
Karaj, Iran
Tel: +982612808120
bitokabiri@yahoo.com

MINISTRY OF JIHAD-E-AGRICULTURE

Modjtaba Rajabbaigy
Director General, International & Regional Organization Bureau
Ministry of Jihad-e-Agriculture
17th floor,
Keshavarz Blvd,
Tehran, Iran
Tel: +98218960284
m.rajabbaigy@irob.ir

Mohammad Reza Abbaspour
Expert in Codex Alimentarius & International & Regional Organizations Bureau
Ministry of Jihad-e-Agriculture
17th floor,
Keshavarz Blvd,
Tehran, Iran
Tel: +98218960284
m.abbaspour@irob.ir

Amin Hadi Dindoust
Expert in Codex Alimentarius & International & Regional Organizations Bureau
Ministry of Jihad-e-Agriculture
17th floor,
Keshavarz Blvd,
Tehran, Iran
Tel: +98218960284
a.dindoust@irob.ir

Seyed Morteza Zarei
Expert in Codex Alimentarius & International & Regional Organizations Bureau
Ministry of Jihad-e-Agriculture
17th floor,
Keshavarz Blvd,
Tehran, Iran
Tel: +98218960284
m.zarei@irob.ir

DEPARTMENT FOR FOOD AND DRUG, MINISTRY OF HEALTH

Vahid Mofid
Director General
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +9821646344, +9821646344
vmofid@yahoo.com

Vahideh Shaygean
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216404268, +989123272101
vshayegan@yahoo.com

Mosoumeh Takalou
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216404268
taklou200@yahoo.com

Haleh Samiee
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216954437, +989123085601
h.samiee@hotmail.com

Leila Roozbeh Nasiraie
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216954437
leila-roozbeh@yahoo.com

Mehdi Ebrahimi Fakhar
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216404268

Ladan Lotfi
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216404268
ladlot@yahoo.com

Bahmineh Zarreh
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216468989
bzarreh@yahoo.com

Maryam Alejamshid
Food Control Expert
Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216954440, +982122256606
alejamshid@yahoo.com

Atefeh Fooladi Moghaddam
Food Control Expert, Department for Food and Drug, Ministry of Health
No. 11365 Hafez Street, Ministry of Health, Tehran, Iran
Tel: +98216964438, +98218276609
fooladi-50@yahoo.com

CENTER FOR DISEASE CONTROL, MINISTRY OF HEALTH

Mohammad Mehdi Gooya
General Director
Center for Disease Control, Ministry of Health
Tel: +98218827265
mgoya57@yahoo.com

Seyed Mohsen Zahraei
Deputy Director General for Communicable Disease
Center for Disease Control, Ministry of Health
Tel: +98218827265
zahraeicdc@yahoo.com

Mahmoud Soroush
Head of Foodborne & Waterborne Disease Department
Center for Disease Control, Ministry of Health
Tel: +98216621645
dmsoyosh@yahoo.com

Hossien Masoumi Asl
Senior Expert of Foodborne & Waterborne Disease Department
Center for Disease Control, Ministry of Health
Tel: +982183000434
dr-masoumiasl@yahoo.com

Mohamad Taghi Afshani
Senior Expert of Foodborne & Waterborne Disease Department
Center for Disease Control, Ministry of Health
Tel: +982183000434
afshani-taghi@yahoo.com

Afshin Safaie
Senior Expert of Public Health Lab
Center for Disease Control, Ministry of Health
Tel: +98218812953
safoue-afshin@yahoo.com

PASTEUR INSTITUTE OF IRAN

Ali Haeri
Research Director
Pasteur Institute of Iran
69, Pasteur Ave.
Tehran, Iran
Tel: +98216953311/20
Fax: +98216465132
haeria@pasteur.ac.ir

Firouzeh Farahtaj
DMT, Researcher, WHO-Collaborating Center for Reference & Research on Rabies
Pasteur Institute of Iran
69, Pasteur Ave.
Tehran, Iran
Tel: +98216403496
Fax: +98216480777
farahtaj@pasteur.ac.ir

Mohammad Reza Pourshafie
Head of Microbiology Section
Pasteur Institute of Iran
69, Pasteur Ave.
Tehran, Iran
Tel: +98216953311/20
Fax: +98216465132

Mohammad Mehdi Aslani
Microbiologist, Researcher, Microbiology Section
Pasteur Institute of Iran
69, Pasteur Ave.
Tehran, Iran
Tel: +98216405535
Fax: +98216465132
mmaslani@pasteur.ac.ir

SCHOOL OF PUBLIC HEALTH, TEHRAN UNIVERSITY OF MEDICAL SCIENCES

Minoo Mohraz
Professor of Infectious Diseases
Tehran University of Medical Sciences
Tel: +98218078065/+98218303413
Fax: +98218078065
minoomohraz@ams.ac.ir

Abolghasem Djazayery
Professor of Nutrition, School of Public Health & Institute of Public Health Research
Tehran University of Medical Sciences
Tel: +98218951404
djazayery@yahoo.com

Sassan Rezaie
Assistant Professor of Microbiology, Division of Molecular Biology, Department of Medical Mycology & Parasitology, School of Public Health
Tehran University of Medical Sciences
P.O. Box 14155-6446
Tehran, Iran
Tel: +98218951392
Fax: +9821646 2267
srezaie@sina.tums.ac.ir

Mohammad Mehdi Soltan Dalal
Professor of Microbiology, Division of Microbiology, Department of Pathobiology School of Public Health
Tehran University of Medical Sciences
P.O. Box 14155-6446
Tehran, Iran
Tel: +98218951392
Fax: +9821646 2267
solancy@sph.tums.ac.ir

Mohammad Reza Khoramizadeh
Assistant Professor of Biotechnology, Division of Biotechnology, Department of Pathobiology, School of Public Health
Tehran University of Medical Sciences
P.O. Box: 14155-6446
Tehran, Iran
Tel: +98218951392
Fax: +9821646 2267
khorami@yahoo.com

Mohammad Mehdi Feizabadi
Associate Professor of Microbiology, Department of Microbiology
Azzahra University
Tel: +989121767987
feizabad@azzahra.ac.ir

PLANT PEST AND DISEASE INSTITUTE OF IRAN

Mohssen Morowati
Researcher, Pesticide Research Department
Plant Pest and Diseases Institute of Iran
M_Morowati@yahoo.com