
FOODBORNE
PATHOGENS
CAST - COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY
SEPTEMBER 1994
REVIEW
OF RECOMMENDATIONS

CAST

The Science Source for Food,
Agricultural, and Environmental Issues

Council for Agricultural Science and Technology
4420 West Lincoln Way, Ames, IA 50014-3447, USA
(515) 292-2125, fax: (515) 292-4512
Internet: cast@cast-science.org
World Wide Web: www.cast-science.org

Mission and Policies

The mission of the Council for Agricultural Science and Technology (CAST) is to identify food and fiber, environmental, and other agricultural issues and to interpret related scientific research information for legislators, regulators, and the media for use in public policy decision making. CAST is a nonprofit organization composed of 36 scientific societies and many individual, student, company, nonprofit, and associate society members. CAST's Board of Directors is composed of representatives of the scientific societies and individual members, and an Executive Committee. CAST was established in 1972 as a result of a meeting sponsored in 1970 by the National Academy of Sciences, National Research Council.

The primary mission of CAST is the publication of task force reports written by scientists from many disciplines. The CAST National Concerns Committee screens proposals from all sources and recommends to the board topics for approval as publication projects.

The CAST Board of Directors is responsible for the policies and procedures followed in developing, processing, and disseminating the documents produced. Depending on the nature of the publication, the society representatives may nominate qualified persons from their respective disciplines for participation on the task force. Aside from these involvements, the member societies have no responsibility for the content of any CAST publication.

Diverse writing groups and active participation by all task force members assures readers that a balanced statement on the topic will result.

The authors named in each publication are responsible for the contents. Task force members serve as independent scientists and not as representatives of their employers or their professional societies. They receive no honoraria, but are reimbursed for expenses. CAST publishes and distributes the documents.

Copies of *Foodborne Pathogens: Review of Recommendations* are available from CAST, 4420 West Lincoln Way, Ames, IA 50014-3447, (515) 292-2125. The 45-page report is $15.00 plus shipping. For more information, see inside back cover.

Membership

Foodborne Pathogens: Review of Recommendations

Council for Agricultural Science and Technology
Printed in the United States of America
Cover design by Lynn Ekblad, Different Angles, Ames, Iowa
Cover photograph courtesy of Silliker Labs, Inc., Chicago Heights, Illinois
ISBN 1-887383-14-X
ISSN 0194-407X
01 00 99 98 4 3 2 1

Library of Congress Cataloging in Publication Data

Foodborne pathogens : review of recommendations.
p. cm. — (Special publication, ISSN 0194-407X ; no. 22)
"October 1998."
Includes bibliographical references and index.
ISBN 1-887383-14-X
1. Foodborne diseases--Risk factors. 2. Foodborne diseases--Safety measures. 3. Foodborne diseases--Government policy--United States. I. Council for Agricultural Science and Technology. II. Series: Special Publication (Council for Agricultural Science and Technology) ; no. 22
RA601.5.F66 1998
614.4'3--dc22 98-35835
CIP

Special Publication
No. 22 October 1998

Council for Agricultural Science and Technology

Task Force Members

Peggy Foegeding (Cochair), Department of Food Science, North Carolina State University, Raleigh

Tanya Roberts (Cochair), U.S. Department of Agriculture, Economic Research Service, Food and Rural Economics Division, Washington, D.C.

Robert L. Buchanan, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Washington, D.C.

Michael P. Doyle, Center for Food Safety and Quality Enhancement, Department of Food Science and Technology, The University of Georgia, Griffin, Georgia

John E. Kvenberg, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Washington, D.C.

Elizabeth Lautner, National Pork Producers Council, Des Moines, Iowa

Joseph M. Madden, Neogen, Lansing, Michigan

Morris E. Potter, Centers for Disease Control and Prevention, Atlanta, Georgia

Joan B. Rose, Department of Marine Sciences, University of South Florida, St. Petersburg, Florida

James L. Smith, Eastern Regional Research Center, Microbial Food Safety Unit, Wyndmoor, Pennsylvania

Caroline Smith DeWaal, Center for Science and the Public Interest, Washington, D.C.

Katherine M. J. Swanson, The Pillsbury Company, St. Paul, Minnesota

Ewen C. D. Todd, Bureau of Microbial Hazards, Health Protection Branch, Sir Frederick G. Banting Research Centre, Ottawa, Ontario, Canada

R. Bruce Tompkin, Conagra Refrigerated Prepared Foods, Downers Grove, Illinois

Carol Tucker Foreman, Foreman and Heidepriem, Inc., Washington, D.C.

I. Kaye Wachsmuth, U.S. Department of Agriculture, Food Safety Inspection Service, Office of Public Health and Science, Washington, D.C.

Marleen M. Wekell, Food and Drug Administration, Seafood Products Research Center, Bothell, Washington

Stacey Zawel, Grocery Manufacturers of America, Washington, D.C.

Contents

Foreword

Following a recommendation by the CAST National Concerns Committee, the CAST Board of Directors authorized preparation of a special publication review of the recommendations contained in the CAST report *Foodborne Pathogens: Risks and Consequences* published in 1994.

Dr. Peggy M. Foegeding, Department of Food Science, North Carolina State University, Raleigh, and Dr. Tanya Roberts, Food and Rural Economics Division, USDA, Economic Research Service, Washington, D.C., agreed to serve as cochairs for the report. They also cochaired the 1994 CAST report on foodborne pathogens. A highly qualified group of 16 additional scientists served as task force members and participated in the writing and review of the document. They include individuals who represented a variety of organizations and backgrounds including consumers, producers, the food processing industry, governmental agencies, academicians, private consultants, epidemiologists, microbiologists, economists, and attorneys. They drew from their research experience, practical experience, experience in food processing and preparation, experience with consumers, knowledge of outbreaks, on-farm and producer experience, personal experience, experience with regulations, and theoretical information.

The task force utilized conference calls to discuss the recommendations and prepared an initial draft of the report. They revised all subsequent drafts of the report and reviewed the proofs. The CAST Executive and Editorial Review committees reviewed the final draft. The CAST staff provided editorial and structural suggestions and published the report. The authors are responsible for the report's scientific content.

On behalf of CAST, we thank the cochairs and authors who gave of their time and expertise to prepare this report as a contribution by the scientific community to public understanding of the issue. We also thank the employers of the scientists, who made the time of these individuals available at no cost to CAST. The members of CAST deserve special recognition because the unrestricted contributions that they have made in support of CAST also have financed the preparation and publication of this report.

This report is being distributed to members of Congress, the White House, the U.S. Department of Agriculture, the Congressional Research Service, the Food and Drug Administration, the Environmental Protection Agency, the Agency for International Development, and the Office of Management and Budget, and to media personnel and institutional members of CAST. Individual members of CAST may receive a complimentary copy upon request for a $3.00 postage and handling fee. The report may be reproduced in its entirety without permission. If copied in any manner, credit to the authors and to CAST would be appreciated.

David R. Lineback
President

Richard E. Stuckey
Executive Vice President

Kayleen A. Niyo
Managing Scientific Editor

Interpretive Summary

Introduction

In the last five years there has been a change in the public perception of food safety, including the legal responsibility and regulatory philosophy in the United States. Information continues to be the critical food safety problem. Pathogens cannot be seen with the naked eye, so the public cannot readily detect the safety of meals, foods, or ingredients purchased anywhere along the food continuum. The ability to link human illness with foodborne pathogens also is difficult. Thus, the majority of foodborne illness cases are unreported. The complexity of food safety from farm to table requires many types of scientific expertise to design sensible public and private interventions.

The original report *Foodborne Pathogens: Risks and Consequences* published by the Council for Agricultural Science and Technology (CAST) in 1994 was well-received and widely quoted. With encouragement of producer organizations, governmental employees, scientists, and public interest groups, the CAST Board of Directors authorized an update of the 15 recommendations from the original report. The update was completed and now contains 18 recommendations.

Recommendations

The task force strove to provide recommendations that are specific and practical with the goal that efforts involved in moving toward implementation of these recommendations would ensure real improvements in the safety of foods. Briefly stated, the recommendations are as follows.

Goal Setting

1. Base food safety policy on risk assessment and include risk management and risk communication strategies.
2. Base food safety regulations on risk assessment and risk management.
3. Set federal food safety goals and priorities.

Research Needs

4. Expand food safety information database by more complete reporting of the incidence of foodborne disease by pathogen, by food, and by contributory factors.
5. Conduct continued, rigorous epidemiologic studies to assist in establishing the cause of illness and effect of foodborne occurrence of a particular pathogen or toxin.
6. Improve and regularly update foodborne disease estimates.
7. Support research on mechanisms of chronic illnesses associated with foodborne pathogens.
8. Use dose-response modeling in the risk assessment process.
9. Conduct research to identify likely domestic and imported food and pathogen/toxin associations.
10. Encourage and support vigorous fundamental and applied research efforts related to foodborne pathogens.
11. Develop rapid, accurate detection methods for foodborne pathogens and toxins.

Production Control

12. Require producers, aquaculturalists, and seafood harvesters to adopt effective preharvest intervention strategies in the interest of enhancing public health.
13. Apply foodborne pathogen control practices from food source to consumption.
14. Harmonize international food safety standards.

Education

15. Educate the general public and food handlers relative to safe food preparation and handling.
16. Identify high-risk populations and provide food safety education.
17. Provide risk information relative to food choices to persons with enhanced disease susceptibility.
18. Use and evaluate food labeling to communicate safe food preparation and storage practices to

food preparers.

Summary

These recommendations reflect the combined expertise of the 18 individuals who served on the CAST task force and deliberated and debated to prepare this report during approximately the first nine months of 1998. The task force members represent a variety of organizations and backgrounds including consumers, producers, the food processing industry, governmental agencies, academicians, private consultants, epidemiologists, microbiologists, economists, and attorneys. They drew from their research experience, practical experience, experience in food processing and preparation, experience with consumers, knowledge of outbreaks, on-farm and producer experience, personal experience, experience with regulations, and theoretical information. The task force is keenly aware that other knowledgeable individuals could provide additional valuable recommendations. However, we offer these as a platform that we hope will focus and stimulate efforts toward food safety improvements.

Introduction

The original report *Foodborne Pathogens: Risks and Consequences* was published by the Council for Agricultural Science and Technology (CAST) in 1994 (Council for Agricultural Science and Technology, 1994) and has been well-received and widely quoted. The 1994 task force findings and recommendations are reprinted in Appendix C. As a result of the report's publication, Justin R. Morris, then president of CAST, was issued a special invitation to make a presentation regarding food safety at President Clinton's forum on *Meeting the Challenge: Health, Safety, and Food for America*. Dr. Morris's presentation on November 21–22, 1994 utilized the summary from the CAST report. This CAST report summary with a few modifications was used by the President's National Science and Technology Council and was sent to the U.S. Office of Management and Budget and to Congress for consideration during debate on the farm bill and funding for the next year's budget.

The Institute of Food Technologists issued a commendation of the report and praised its emphasis on the need to obtain more information about the incidence of foodborne diseases as well as the virulence of individual pathogens.

Dr. Peggy Foegeding, cochair of the report, was invited to testify on May 25, 1994 before the House of Representatives' Human Resources and Intergovernmental Relations Subcommittee of the Committee on Governance Operations. She subsequently spoke at hearings on *Reinventing the Federal Food Safety System*. On August 3, 1994, Dr. Dean O. Cliver, CAST member and author of the 1994 CAST report, testified at U.S. Department of Agriculture, Food Safety and Inspection Service hearings on the report's findings.

In May of 1997, CAST presented updates by several authors for President Clinton's national food safety initiative, *Food Safety from Farm to Table: A New Strategy for the 21st Century*.

In the last five years there has been a change in the public perception of food safety, including the legal responsibility and regulatory philosophy in the United States. Information continues to be the critical food safety problem. Pathogens cannot be seen with the naked eye, so the public cannot readily detect the safety of meals, foods, or ingredients purchased anywhere along the food continuum. The ability to link human illness with foodborne pathogens also is difficult. Thus, the majority of foodborne illness cases are unreported. The complexity of food safety from farm to table requires many types of scientific expertise to design sensible public and private interventions.

At the request of producer organizations, government, scientists, and public interest groups, the CAST Board of Directors, given the national attention to food safety issues, approved an update of the 1994 CAST report recommendations as a valuable contribution to current food safety issues. Members of the original task force were invited to participate and new task force members were added.

The goal was to provide comments on the original recommendations indicating what progress had been made toward each recommendation, provide more detail about the research recommendations, and add new recommendations if warranted. The task force hopes that these updated and more detailed recommendations will be useful to public and private groups setting microbial food safety research agendas.

Goal Setting

Recommendation 1†: Base Food Safety Policy on Risk Assessment

We recommend that food safety policy be based on risk assessment, and include risk management and risk communication strategies. Risk assessments should use data from all sources to help draw correct inferences from the best data sources for both acute and chronic foodborne diseases. It is further recommended that government, industry, and consumer representatives be educated to understand the principles and practices of risk assessment and how these can lead to sound management policies.

Current Status

Risk assessment, risk management, and risk communication (collectively termed risk analysis) are becoming widely accepted in food safety public policy. Application of quantitative risk assessment to microbial food safety issues has been limited to date. However, there are a few notable examples: USDA's *Salmonella enteriditis* in eggs risk assessment and Canada's risk assessment of *E. coli* O157:H7 in ground beef hamburgers.

1. Acceptance and understanding of risk assessment and overall risk analysis terms are essential to further progress in development of risk assessments beyond the research stage. For consistency in domestic and international trade with respect to risk assessment, it is recommended that the definitions and approaches of the Codex Alimentarius[1] be adopted, with those knowledgeable having input into this process. Terms include hazards, risks, severity, consequences, dose response, and management options.
2. In practice, the application of risk assessment can be complex because food systems are complex. There often are several hazards of concern in a food consumption scenario, including hazards that may go unrecognized or to date may be unknown. Cultural anthropological differences in consumption patterns or food handling methods expose subpopulations to different levels of risk, and foods originating in new areas or produced in nontraditional areas may contain unanticipated hazards.
3. Clear national, state, and local food safety goals and priorities are needed to apply risk assessment effectively and to lead to appropriate risk management and risk communication strategies by industry and government.
4. The database of epidemiologic information relative to acute and chronic effects of infections with foodborne pathogens is being improved as FoodNet and other active population-based surveillance activities are being developed. Because active surveillance and studies of chronic effects of foodborne infections are extremely resource intensive, care must be taken in their design to assure that the surveillance areas, methods of case ascertainment, epidemiologic techniques, and analytic methods are selected for maximal efficiency and yield. The best available epidemiologic approaches need to be applied and new ones developed to improve the utility of epidemiologic data for quantitative risk assessment purposes.
5. Risk assessments should continue to be designed to show how interventions in a process can increase or decrease a risk to human illness, and thus help prioritize the implementation of specific control measures.

---

†Update for Recommendation No. 1 in Council for Agricultural Science and Technology, 1994. See Appendix C.

[1]The 1994 CAST document recommended following the risk assessment approach of the National Academy of Sciences (National Research Council, 1983). This is consistent with the United Nations Codex Alimentarius Commission approach. We now refer to the Codex Alimentarius approach because it has become available and is more familiar internationally. See Appendix B for Codex's draft definitions of terms. Note that various codex committees may use different definitions.

Recommendation 2†: Base Food Safety Regulations on Risk Assessment and Risk Management

We recommend that federal food safety regulations be based on risk assessment; thus, reflect that zero risk of foodborne illness is not always possible. Risk managers should seek input from affected parties before establishing food safety regulations.

Current Status

While our food supply is generally considered safe, this recommendation is about having a food safety system that is based on assessing risks to human health from foodborne pathogens and then taking appropriate steps to reduce the risk to consumers of contracting foodborne illness. Federal regulators are making progress toward that goal. The FSIS and the FDA are moving toward "science-based" policies and recognizing the importance of risk assessment in setting policies.

1. Providing absolute safety from all hazards in food for all consumers may not be feasible. There always will be some risk associated with foods available to consumers. Certain processes are highly effective at minimizing risk so that if properly executed the risk is so small as to be negligible (e.g., foods that are canned to achieve commercial sterility and pasteurized, refrigerated milk).
2. Federal authorities should seek input from risk assessors, affected industry, and consumers through transparent, public processes. Federal agencies should facilitate public discussion on acceptable levels of risk for microbiological hazards, establish appropriate risk-based standards and food safety policies, and communicate this information to all affected parties to minimize the occurrence of foodborne disease. The acceptable level of protection should consider the estimate of risk to consumers for both normal and high-risk subpopulations.
3. Resulting federal regulations should reflect the public health impact of the hazard, the technological feasibility of controlling the hazard, economic implications, and societal concerns.
4. Wherever possible, tolerances should be based on risk assessment rather than solely on the lower limit of detection as provided by available analytical procedures, current industry practice, or a goal of zero risk.
5. Estimates of foodborne disesase risk associated with a specific pathogen and/or food should be recalculated as new information becomes available.
6. Insufficient data on infectious dose or toxigenic thresholds for most foodborne pathogens and their toxic metabolites deter meaningful estimation of risk, particularly for newly emerging microbial hazards, because the level of uncertainty is great. This lack of critical information can lead to risk management options that are inappropriate (likely overly conservative) for the microbial hazard. Furthermore, there are hazards that are unknown and uncontrolled. Hence, there is an ongoing need for periodic review of regulatory policies and tolerances to ascertain their appropriateness or need for modification.
7. To facilitate the adoption of risk management options that are commensurate with the actual risk of human illness associated with a hazard, a concerted effort should be given to establishing a framework to develop and organize data to clarify the infectious or toxigenic dose (see Recommendation 8).

---

†Update for Recommendation No. 12 in Council for Agricultural Science and Technology, 1994. See Appendix C.

Recommendation 3†: Set Federal Food Safety Goals and Priorities

We recommend that federal food safety goals and priorities be set so that resources may be allocated and targeted appropriately to address hazards in the food supply.

Current Status

Some, albeit minimal, goal setting has been undertaken, specifically in *Healthy People 2000* and the National Food Safety Initiative.

1. The selection of criteria for setting goals and priorities, such as any strategic planning process, should be discussed in a national dialogue seeking input from all stakeholders. Criteria for consideration include the numbers of acute illnesses; numbers of chronic complications; numbers of deaths and disabilities; types of food products implicated; types of production, harvesting, or processing deficiencies or handling errors identified; impact on certain subpopulations that society has a heightened responsibility to protect (e.g., children); and economic losses to society.
2. The agencies charged with food safety regulation should be structured appropriately and funded adequately to provide regulatory oversight of the food industry and to protect and promote the public health. Recommendations from the National Academy of Sciences, the General Accounting Office, and other independent sources should be considered in reorganizing or consolidating food safety functions in the federal government.
3. The federal government should coordinate with state and local governments, where appropriate, to maximize protection of public health.
4. When Hazard Analysis Critical Control Point (HACCP) systems are implemented and demonstrated to be effective in decreasing pathogen contamination of meat and poultry products, outmoded and duplicative regulatory functions, such as the practices of carcass-by-carcass visual inspection by government inspectors in slaugher plants and continual inspection by government inspectors in some meat processing plants should be discontinued and resources should be redirected to areas where they are more urgently needed.
5. Public discussion and understanding of the costs and effectiveness of control measures will be requisite.

---

†Update for Recommendation No. 13 in Council for Agricultural Science and Technology, 1994. See Appendix C.

Research Needs

Recommendation 4†: Expand Food Safety Information Database

We recommend that the food safety information database be expanded to provide more complete information on the incidence of foodborne disease by pathogen, by food, and by contributing factor. Comprehensive data sharing and database creation are recommended to assist risk assessment studies from farm-to-table in pinpointing pathogen entry, survival, and propagation and the likely impact of control options.

Current Status

Epidemiologic studies and microbiologic studies of production, slaughter, and marketing have improved our understanding of potential hazards in foods of animal origin, but considerable gaps remain. Some progress is being made in our understanding of incidence and risk of foodborne infections with a few pathogens. The National Food Safety Initiative (NFSI) is aiding this cause by increasing resources for identifying risk factors. At present, however, only a limited number of pathogens, nearly all bacterial, are included in the active laboratory-based surveillance component of FoodNet. Toxigenic foodborne illness also is excluded. Identification of risk factors of infection, including information on the food vehicles responsible for transmission, is occurring slowly because of limited national capacity to conduct case-control studies of sporadic foodborne disease.

1. The capacity for rapid and accurate identification of and response to outbreaks of foodborne disease must be improved at the local, state, and federal levels. Much of this capability will depend on development of appropriate methods as detailed in Recommendation 5. Additional resources for active surveillance, population-based surveys, and case-control studies of a broad range of sporadic bacterial, parasitic, and viral foodborne illnesses must be made available to local, state, federal, and international public health agencies so that important agents of foodborne disease can be identified, quickly and correctly attributed to a food source, and the factors that contributed to the transmission of the agent from food to consumers can be determined.
2. Standardized, effective protocols for collecting, compiling, and analyzing data on the incidence of foodborne illnesses and the acute and chronic effects of foodborne disease must be developed and/or used to harmonize the qualitative and quantitative aspects of foodborne disease data within the United States and internationally. Similar standardized protocols are needed for quantitative food microbiology databases.
3. The National Animal Health Monitoring System (NAHMS) and other U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) programs should be improved and expanded to increase their contribution to our understanding of the epidemiology and ecology of foodborne pathogens during food production, processing, and handling.
4. Collaboration between government and industry should be encouraged for better data utilization. Mechanisms for pooling data on food consumption, microbial characteristics of foods, and human disease, which protect patient confidentiality and sensitive commercial information and assure standards of data quality, would be an asset. Support for development of such a database and coincident gatekeeping methods for both deposition of and access to data to assure the quality and appropriateness of use will be critical to this becoming a reality.
5. Risk assessors are interested in separating variability (observable differences) from uncertainty (lack of knowledge) in their models. It is very useful for researchers to report the raw data and/or some form of statistical analysis that explains the degree of uncertainty in their data. Journals should encourage their authors to report details on test sensitivity, test specificity, sampling protocols, and assumptions in studies of pathogen

†Update for Recommendation No. 2 in Council for Agricultural Science and Technology, 1994. See Appendix C.

survival/growth/destruction and assumptions and approximations in risk assessment models. Authors should be encouraged to retain their raw data sets, report cumulative distributions of data sets, report any conclusions, and analyze uncertainties associated with either the data or the model. Differences among pathogen serotypes or strains is increasingly recognized as an important source of variability and should be explicitly addressed. In the future, publication of raw data on the Internet, in journals, or in other formats should be encouraged.

Recommendation 5†: Continue Rigorous Epidemiologic Studies

We recommend that continued rigorous epidemiologic studies be conducted to assist in establishing the cause of illness and effect of foodborne occurrence of a particular pathogen or toxin.

Current Status

With the techniques and resources available to date, these epidemiologic functions largely have been carried out through outbreak investigations. Routine passive surveillance based on laboratory or physician diagnoses has provided little useful information in this regard. Carefully conducted outbreak investigations have been the more efficient epidemiologic method for identifying new foodborne hazards, new food/pathogen combinations, or the impact on society of foodborne exposures in outbreak settings.

1. Foodborne disease surveillance activities are a crucial part of food safety programs. Of the available surveillance data, knowledge of factors that affect contamination of foods, and survival and growth of etiologic agents is critically important information upon which to base preventive and control actions. A database reflecting the relative importance of sources and modes of contamination, practices that allowed pathogens to survive processing and preparation, and means by which pathogenic bacteria or toxigenic mold proliferate, provides focus for ongoing food safety programs. Therefore, determining and reporting factors that contributed to foodborne disease outbreaks should receive particular emphasis. Such a database can suggest measures that are vital for prevention, direct attention to critical control points, and show that certain control activities are making only minor, if any, impact. Hence, this information should be used to guide food safety programs and educational activities. The International Association of Milk, Food and Environmental Sanitarians (IAMFES) has published a guide to epidemiological investigation (International Association of Milk, Food and Environmental Sanitarians, 1998).
2. Resources that are becoming available through the National Food Safety Initiative (NFSI) are adding substantially to the possibilities of enhancing "rigorous epidemiological studies." For example, improved diagnostic and food microbiologic techniques are being developed and transferred to the state and local levels, and this should decrease the number of outbreaks of unknown etiology. While the progress made to date has been modest, improved diagnostic methods for a range of bacterial, protozoan, and viral pathogens have been added to laboratories in a number of states.
3. Likewise, broad application of improved and standardized subtyping methods will enhance epidemiologic studies enabling better classification of patient and food isolates. Development, standardization, and training in these methods are occurring at various levels for a number of bacterial, protozoan, and viral pathogens. One example is *E. coli* O157:H7 subtyping embodied in the PulseNet system.
4. The increased number of epidemiologists and microbiologists and their training in advanced techniques in foodborne disease programs at the CDC and in some state health departments will increase the number and quality of epidemiologic studies and hazard analyses at all stages of the food chain, from primary production through the postconsumption outbreak period.
5. Carefully designed case-control studies of sporadic cases of foodborne illness (made possible with NFSI resources) are identifying the most common sources of foodborne illness outside outbreak[2] settings. However, the present level of resources permits few such studies, so progress in this regard is slow.

[1]Update for Recommendation No. 5 in Council for Agricultural Science and Technology, 1994. See Appendix C.

[2]A foodborne disease outbreak is defined as an incident in which persons experience a similar illness resulting from the ingestion of a common food.

Recommendation 6†: Improve and Update Foodborne Disease Estimates

We recommend that foodborne disease estimates be improved and regularly updated to better identify the extent and consequences of foodborne disease and to document progress in controlling foodborne pathogens.

Current Status

The estimates in the statement from the original CAST report (Council for Agricultural Science and Technology, 1994, p. 4), ". . . Although the microbial foodborne disease burden of the United States is not known with accuracy, estimates from the literature indicate and the general consensus of CAST task force members is that cases likely range from 6.5 million to 33 million annually and that deaths may be as high as 9,000 annually (the CDC estimates that there are 9,000 microbial foodborne deaths annually). . . . ," were a consequence of the best available literature and have been widely quoted. However, these numbers are estimates and are controversial because they rely on limited information supplemented by expert opinions and assumptions. The CDC has recently begun a multidisciplinary effort to revise these national estimates for foodborne illness (Broome, 1998).

FoodNet is identifying the incidence of acute diarrheal disease at seven sites across the United States and these data will provide a better basis for generating national estimates of acute illness, severity distributions, and death rates for diarrheal disease than obtainable in the past. However, progress is limited in other areas.

The CAST task force recommends the following:

1. National estimates of foodborne illness, hospitalizations, and deaths will require careful analysis of FoodNet data and other surveillance sources to generate reliable multipliers to account for missing lab tests, stool samples, ill persons not seeking medical attention, and medical reports not reaching agencies responsible for carrying out investigations. These multipliers are likely to be different for each pathogen and to vary with severity of illness. After a set of estimates for the major foodborne pathogens has been developed by the CDC and collaborators, a scientific conference should be convened to discuss methodological issues and to suggest improvements. This will build national confidence in the source and accuracy of the estimates.
2. Acute disease estimates for new foodborne pathogens (such as *Cyclospora*, Shigatoxin-producing *E. coli* other than O157, and *Salmonella typhimurium* DT 104) or nondiarrheal disease caused by foodborne pathogens (such as neurological impacts) await better estimates and should be added to FoodNet or other active population-based surveillance programs in a timely manner.
3. A national study should be funded to determine whether acute illnesses and deaths from septicemia, bacteremia, and other systemic illnesses are related to foodborne pathogens to a significant extent.
4. Chronic complications associated with most foodborne pathogens are occasionally lifelong, and cause a diverse array of conditions ranging from arthritis, paralysis, and colitis to heart disease (See Recommendation 7). Although infrequent, these chronic complications can cause great hardship, and attempts should be made to better quantify the incidence of foodborne causes of chronic conditions, their severity, and their duration.
5. Estimates of medical costs and productivity losses caused by foodborne pathogens need to be expanded to address more pathogens and more chronic complications. The methodology for estimating human illness costs should be standardized across government agencies in the United States and coordinated with international bodies. Where possible, estimates of the value to society of decreasing the risk of foodborne illness should

†Update for Recommendation No. 7 in Council for Agricultural Science and Technology, 1994. See Appendix C.

be included in the estimates.

6. Public costs of investigation and control also should be documented. Costs to the industry associated with foodborne pathogens also should be documented. Such costs include recall and destruction of food, legal liability cases, lost tourism, and lost domestic and export markets for foods. Savings due to decreased spoilage and avoiding double-counting should be considered as well.
7. A better mechanism to obtain information from consumer experience with foodborne illness is needed, perhaps including more information from state epidemiologists.

Recommendation 7†: Support Research on Chronic Illnesses Associated with Foodborne Pathogens

We recommend support of research on the mechanisms of chronic illnesses with which foodborne pathogens are associated so that appropriately targeted detection and control strategies can be developed.

Current Status

Limited progress has been made in this area in the past four years.

1. Research related to mechanisms of chronic illnesses and populations at elevated risk of chronic disease due to foodborne pathogens is ongoing in government and university laboratories. This research is more costly and long-term than research on acute illnesses. The time from initiation of the research to understanding of the disease to having an impact on public health is relatively long; thus, funding and interest in the research is difficult to obtain.
2. It is likely that the costs of chronic illnesses outweigh the costs of acute diseases; hence, this recommendation remains critical.
3. A great diversity of microorganisms may cause chronic sequelae and a variety of chronic consequences may occur (see Table 1 [Council for Agricultural Science and Technology, 1994, Table 2.2] for a summary of organisms and consequences). Epidemiologic studies are hindered by the low frequency of diseases (estimates indicate a maximum of 1 to 3% of the population with certain enteric infections develop chronic illnesses).
4. Studies are progressing slowly on the epidemiology, pathogenesis, pathology, clinical aspects, diagnosis, and therapy of these diseases. Prevention of such diseases needs greater emphasis.

---

†Update for Recommendation No. 8 in Council for Agricultural Science and Technology, 1994. See Appendix C.

Table 1. Certain foodborne infections and their complications (adapted from Mossel, 1988)

Bacterial and parasitic infection transmitted by foods	Complication/sequelae
Bacterial infections	
Aeromonas hydrophila enteritis	Bronchopneumonia, cholecystitis
Brucellosis	Aortitis, epididymo-orchitis, meningitis, pericarditis, spondylitis
Campylobacteriosis	Arthritis, carditis, cholecystitis, colitis, endocarditis, erythema nodosum, Guillain-Barré syndrome, hemolytic-uremic syndrome, meningitis, pancreatitis, septicemia
Escherichia coli (EHEC-types) enteritis	Erythema nodosum, hemolytic uremic syndrome, seronegative arthropathy, thrombotic thrombocytopenic purpura
Q-fever	Endocarditis, granulomatous hepatitis
Salmonellosis	Aortitis, cholecystitis, colitis, endocarditis, epididymoorchitis, meningitis, myocarditis, osteomyelitis, pancreatitis, Reiter's disease, rheumatoid syndromes, septicemia, splenic abscesses, thyroiditis, septic arthritis (sickle-cell anemic persons)
Shigellosis	Erythema nodosum, hemolytic-uremic syndrome, peripheral neuropathy, pneumonia, Reiter's disease, septicemia, splenic abscesses, synovitis
Vibrio parahaemolyticus enteritis	Septicemia
Yersiniosis	Arthritis, cholangitis, erythema nodosum, liver and splenic abscesses, lymphadenitis, pneumonia, pyomyositis, Reiter's disease, septicemia, spondylitis, Still's disease
Parasitic infections	
Cryptosporidiosis	Severe diarrhea, prolonged and sometimes fatal
Cyclosporosis	Severe watery diarrhea, cramping, abdominal pain, nausea, vomiting, extreme fatigue, low grade fever, weight loss, anorexia, abdominal bloating, depression
Giardiasis	Cholangitis, dystrophy, joint symptoms, lymphoidal hyperplasia
Taeniasis	Arthritis, cysticercosis (*T. solium*)
Toxoplasmosis	Encephalitis and other central nervous system diseases, pancarditis, polymyositis
Trichinosis	Cardiac dysfunction, neurologic sequelae
Viral infections	
Hepatitis A virus	Various liver diseases

Recommendation 8†: Use Dose-Response Modeling in the Risk Assessment Process

Dose-response modeling is a critical component of the risk assessment process. Without adequate dose-response information, the exposure assessment, significant levels of contaminants, and enhanced safety measures may not be adequately evaluated.

Current Status

Some data sets are available that can be used to determine the likely human response resulting from consumption of a specified dose of pathogen. However, there are several critical areas that need to be addressed for dose-response models to be used with confidence.

We recommend the following:

1. Dose-response data of infectious microorganisms and microbial toxins need to be critically reviewed with assessment of the "independent-action" (or single-organism) hypothesis. This hypothesis states that each microbial cell acts independently and has the potential to initiate colonization (or the infection process); this theory is analogous to the sperm and egg concept. Alternatively, the potential of a threshold, which is some level of pathogenic bacteria, viruses, or protozoa that particular individuals can tolerate without becoming infected, needs to be evaluated. Dose-response data can be significantly different between different bacteria, viruses, and protozoa, for different strains of these microorganisms, and for different subpopulations and individuals.
2. The various models that can be used to describe these data should be examined using scientific criteria of best-fit.
3. Animal models rarely closely mimic human infectious disease, particularly for intestinal diseases. But in some instances, nonruminants may have the potential to describe and model human intestinal infections (dose-response) and enteric disease. These may be useful to address some of the above concerns. Animal models also may be useful for some nonenteric foodborne diseases. Extreme care must be exercised when extrapolating from animal data to estimates of human infections.
4. Frequency distributions of the various outcomes should be described by infection, severity (e.g., duration and types of treatment, hospitalization, and death) and the individual's immune status (and/or specific high-risk populations) or susceptibility. The outcomes should be quantified with specific description of the numerator and denominator in the various data sets (e.g., clinical data sets with defined populations as opposed to reported cases extrapolated to the total U.S. population).
5. Synergistic and antagonistic effects on the dose-response associated with various food types should be assessed. Foods or drugs with buffering capacity can lower the dose-response curve by protecting some of the microorganisms as they pass through the stomach.
6. Multiple exposures to the same or different infectious pathogens or toxins need to be evaluated to determine the risk if exposed more than once in various time periods.
7. Outbreak investigations should be enhanced to include better assessment of exposure (evaluating the contaminated food, survival of pathogen to the process, and propagation of etiologic agent due to process and time of exposure) and outcome (attack rates [numbers of individuals ill/ numbers of individuals exposed], symptomatic ratios [numbers of individuals ill/numbers of individuals infected], severity and secondary spread [numbers of individuals who become ill after coming in contact with other individuals]). These data should be used to test and refine the dose-response models. This will be critical to the application of quantitative risk assessment for making decisions for effective and efficient protection of public health.
8. Models need to be developed to account for different demographic groups with varying susceptibil-

†Update for Recommendation No. 6 in Council for Agricultural Science and Technology, 1994. See Appendix C.

ity to foodborne pathogens, multiple hazards, different food matrices that affect survival and growth of pathogens, limited data on infective or intoxicating doses, and the use of outbreak data with factors contributing to outbreaks. The models should consider "worst case" scenarios, yet those may not always be the most appropriate basis for regulatory action.

9. Current dose-response models are empirical in nature, being based on the fitting of experimental data sets. Research should be encouraged on the development of mechanistic models based on the physiological characteristics of the pathogen and humans. Likewise, research should be supported to develop alternative approaches for assessing dose-response relations for pathogens that are not amenable to human trials or animal studies.

Recommendation 9†: Conduct Research to Identify Likely Food and Pathogen/Toxin Associations

We recommend that research be conducted to identify domestic and imported foods likely to be associated with specific pathogens or toxins and to establish controls to minimize risk. It should be determined whether new preharvest practices or processing/preparation methods create an environmental niche for pathogens; contribute to survival, growth, or spread of pathogens; or permit development of microbial antibiotic resistance.

Current Status

Research of this nature is conducted and/or funded by the federal government, industry or grower/producer trade organizations, universities, and individual food companies. Progress is steady yet slower than is desired. Only recently have preharvest practices received serious attention relative to their impact on food safety.

1. Research to better identify which pathogens are associated with specific foods should include

   - study of the ecology of foodborne pathogens or toxins in the environment, in processing, packaging, marketing, distribution, retail, storage, preparation, and in the human;
   - improved methods for rapid detection and identification of foodborne pathogens and toxins (see Recommendation 11);
   - challenge testing of high-risk foods and the processes they undergo to ensure that pathogens of historical concern as well as emerging pathogens are controlled;
   - hazard analysis of food production, harvesting, distribution, marketing, processing, and preparation operations;
   - development of effective procedures or practices for both pre- and postharvest intervention strategies that eliminate or control pathogens and their toxins; and
   - study of the development of antibiotic resistance in bacteria associated with the food supply, where in the food continuum increased resistance may be occurring, what practices are contributing to its increase, and medical significance of increases.

2. To effectively minimize risk of human illness depends on identifying pathogens that are associated with specific foods, identifying where pathogens enter the farm-to-table food continuum, and identifying the effectiveness of preventive and control measures. Contamination and controls may occur at any step from the grower/harvester through the processor/handler/preparer and include food handling practices during food transportation, storage, and display. The wealth of current knowledge should be applied.
3. The composition or formulation of the food also plays a significant role in the probability of pathogen survival or growth. Food composition may (a) affect the type and extent of contamination by the nature of the raw product or ingredients that compose the food; (b) influence heat penetration, which affects survival of the contaminants according to the rapidity of heating and cooling; and/or (c) provide nutrients and other intrinsic properties (e.g., pH, oxygen availability, presence of natural antimicrobials), which may allow, encourage, or discourage microbial growth. The food composition also will impact the presence and growth of other microorganisms. The competitive microbiota may encourage, discourage, or have no effect on growth of the pathogen.
4. While indicators and surrogates have been used to establish performance criteria and controls, the inadequacy of some of these (e.g., coliforms for the prediction of resistance of viruses or protozoa to chemical disinfection) has been demonstrated. Qualitative and quantitative similarities and differences between various microorganisms need to be addressed so that surrogates or substitute microorganisms can be used with confidence for determining the adequacy of treatments and various control measures.

---

†Update for Recommendation No. 9 in Council for Agricultural Science and Technology, 1994. See Appendix C.

Recommendation 10†: Support Foodborne Pathogen Research

Recognizing that advances in knowledge of foodborne disease prevention and control are essential to advancing food safety, we recommend that vigorous fundamental and applied research efforts related to foodborne pathogens be encouraged and supported. In addition, we also recommend that current knowledge about factors that contribute to food safety be implemented.

Current Status

This recommendation is similar to the 1994 recommendation. What is new is a discussion of setting research priorities. Much of the fundamental research on food safety is funded by the Agricultural Research Service (ARS), the FDA, the Cooperative State Research Education and Extension Service (CSREES), the National Institutes of Health (NIH), and the National Research Initiative (NRI). Recently, funding for the NRI has been expanded somewhat; however, other funds administered through the CSREES have diminished simultaneously. Funding for microbial food safety research in the FDA has increased in FY1998 as a result of the National Food Safety Initiative.

1. Critical areas of basic and applied research include

   - microbial ecology of pathogenic bacteria, parasites, and viruses in pre- and postharvest environments, including the ecology of biofilms in processing facilities;
   - mechanisms of enhanced tolerance of foodborne pathogens to acid, heat, and environmental conditions;
   - mechanisms of virulence in pathogens, genetic transfer of virulence determinants, and the potential of growth conditions and other environmental factors that affect (enhance or decrease) virulence;
   - development of innovative procedures or practices for both pre- and postharvest intervention strategies that effectively eliminate or control pathogens and their toxins;
   - quantifying the variability within and among strains of pathogens in response to control procedures or practices; and,
   - applications of current technologies for tracking organisms in the environment and in epidemiologic investigations and for identifying factors that contribute to contamination, survival, and growth.
   - Other specific research areas are detailed in Recommendations 9 and 11.

2. The food safety research agenda should be developed based on federal food safety goals and priorities (see the call for a national consensus conference on priorities in Recommendation 3). A process should be developed to enable identification of specific research agendas for topics of high priority. The process should include a mechanism to regularly review and modify research agendas based on new information and to inform the public, scientific community, and industry about progress in addressing research needs. Coordination of research across governmental agencies with food safety responsibilities and academic and private institutions in both the pre- and postharvest areas is needed. To facilitate this coordination, a national food safety research database encompassing both public and private sector research should be developed (see Recommendation 4).

---

†Update for Recommendation No. 3 in Council for Agricultural Science and Technology, 1994. See Appendix C.

Recommendation 11†: Develop Rapid, Accurate Detection Methods

We recommend that new rapid, reliable, sensitive, and economical methods continue to be developed to allow rapid (ideally, online) and accurate detection of hazardous organisms and their toxins.

Current Status

Development of new and improved methods is an area that continues to receive a great deal of research attention and a reasonable amount of private and public sector funding. Progress has been good, and given that opportunities are great for continued advancement, continued strong support appears warranted.

1. Genome-based detection methods show enormous promise in enhancing specificity, sensitivity, and possibly speed of detection of pathogenic organisms. These methods must be applied cautiously in instances where there is a need to know whether the organism detected is still viable or infectious, as they presently are often incapable of distinguishing viable and disease-causing cells from dead cells.
2. Improved diagnostic and subtyping methods for foodborne bacterial, parasitic, and viral pathogens in clinical, food, and environmental specimens must be developed and transferred to appropriate laboratories. Managed by the CDC, PulseNet has been initiated in several states to serve as a subtyping database resource. Serotyping and molecular methods have proven important for epidemiologic investigations and in tracing organisms through the food chain, but implementation has not always been sufficient for distinguishing epidemics from sporadic cases resulting from exposure to a common source of contamination.
3. It should be recognized that determining the safety of foods is not presently possible through microbiological end-product testing alone, and that the purpose of new tests is not routine prerelease clearance of food products because a negative test result does not provide absolute evidence of safety.
4. Laboratory testing is valuable to validate HACCP systems to control microbial hazards. Use of quantitative tests for indicator organisms at critical control points, at locations where contamination is likely to be highest, and in final products can provide actionable information to verify process control and direct process improvements.
5. Online assays might be applicable to monitoring at critical control points in HACCP systems, to enable remediation when results exceed critical limits. Microorganisms sought in this application probably would not be pathogens.
6. The proposed new tests should serve to detect quickly, and ideally to quantify, pathogens in foods suspected as vehicles in outbreaks—to allow prompt intervention to reduce risk of further transmission.
7. Such new tests also may be used to estimate human exposure levels in risk assessment studies. However, random surveys for extremely low-incidence pathogens in food should be evaluated carefully on a cost-benefit basis (as a component of risk management).
8. Hazards due to toxin-forming pathogens could be possibly identified by genome-based methods, yet techniques for direct detection or quantitation of the toxin molecule are required for more accurate indication of a potential public health risk. To this end, immunoassays, coupled with sensitive reporter systems, offer potential.
9. Improved methods to identify and/or concentrate viral particles, cells, or toxins from foods are being investigated and should improve both sensitivity and speed of detection.
10. Improved (rapid and sensitive) reporter systems, e.g., those relying on electrical signals, coupled to nucleic acid or antibody technologies are likely to become available in the near future. This type of

†Update for Recommendation No. 4 in Council for Agricultural Science and Technology, 1994. See Appendix C.

advance should enhance speed and may decrease the cost of testing.

11. Improved sampling techniques are needed to detect low levels or sporadic prevalence of pathogens that eliminate or decrease the need for enrichment steps.

Production Control

Recommendation 12†: Require Producers to Adopt Effective Intervention Strategies

We recommend when practical and effective intervention strategies at the farm, aquaculture facility, seafood harvesting, and on-site preharvest levels are made available, that producers, aquaculturists, and seafood harvesters be required to use the strategies in the interest of enhancing public health. This is a new recommendation. The importance of preharvest practices has been highlighted by several recent developments: the increasing identification of fruits and vegetables in U.S. outbreaks of foodborne disease, the specter of bovine spongiform encephalopathy (BSE) in United Kingdom (U.K.) cattle and *E. coli* O157:H7 in U.S. cattle, worldwide increases in bacterial resistance to antibiotics, and improved testing for the presence of pathogens in animal production. Produce and animal preharvest practices are important opportunities for controlling or minimizing spread of foodborne pathogens. Attention should be given to development of practical and effective control strategies at this level.

Current Status

Pathogens and their toxins can enter the food chain in the preharvest environment in several ways. Pathogens can be directly introduced to plant and animal products by use of improperly or incompletely treated animal manure, insufficiently treated human wastes, contaminated water, contaminated soils, or contaminated feeds. Once introduced, pathogens can colonize soils and animals and become incorporated into cycles of recontamination by manure, water, and animal transport. In animal production, bacterial and parasitic pathogens are the primary concern. Both therapeutic and subtherapeutic use of antibiotics in animals can foster development of resistant pathogens, such as *Salmonella typhimurium* DT104.

We recommend the preharvest community continue to develop and apply effective intervention strategies to decrease the risks of foodborne pathogens. The intervention strategies should provide control measures that decrease or exclude pathogens and break the cycles of contamination. New control options also must pass the cost-benefit test and adoption must offer net benefits to society.

1. Primary options for focus are
   - decreasing human pathogens occurring in the gastrointestinal tract of animals;
   - improving animal manure management (including a "kill" step for pathogens, such as high heat through carefully controlled composting or other means) when needed according to its intended use;
   - assuring that human sludge and sewage is appropriately treated before being used in crop production;
   - minimizing pasture and feedlot runoff to maintain sanitary water quality and sewage disposal; and
   - working with the FDA Center for Veterinary Medicine, USDA, and CDC to continue to identify and evaluate the risk of adverse consequences of animal drugs.
2. It is important not to overlook on-farm grower/producer and on-site seafood harvesting concerns relative to the importance of research, development of intervention strategies for safer food production and seafood harvesting/handling practices, and educational programs.

†This is a new recommendation.

Recommendation 13†: Apply Control Practices from Food Source to Consumption

This recommendation expands the 1994 CAST Recommendation 14, which stated, "We recommend that control practices be applied from food source to consumption." We recommend controlling the most severe hazards and applying control practices at the most cost-beneficial points in the food continuum, from food source to consumption. We advocate that both the federal government and industry trade associations continue to develop demonstration HACCP materials.

Current Status

Substantial progress has been made in instituting voluntary and publicly mandated HACCP systems for animal products, seafood, and produce. Risk assessment should be the foundation for developing HACCP systems. The HACCP framework provides a systematic approach for identifying, evaluating, controlling, and monitoring the microbial hazards from food source to consumption.

Pathogens or toxins can enter the food continuum in the postharvest environment if they are present on animals to be slaughtered, raw foodstuffs, or are introduced into the food by contaminated water, workers, or other means. Once introduced, the pathogens can contaminate other foods or the environment, survive, grow, and produce toxin. Methods to prevent or to control pathogens and their toxins differ with each food and food pathogen, and may involve excluding contaminated food ingredients, practicing good sanitation, refrigerating, cooking, or irradiating. Control methods affect specific pathogens and toxins differently; no one method will eliminate all pathogens or their toxins from the food chain. Pathogens or their toxins may be controlled by preventing their entry into the food, by decreasing the amount present, or by preventing or delaying growth.

Specifically, the CAST authors recommend the following:

1. Implementation of voluntary HACCP and Good Agricultural Practices (GAPs)/Good Manufacturing Practices (GMPs) throughout the food chain. The latest edition of the National Advisory Committee on Microbiological Criteria in Foods (NACMCF) principles and guidelines for HACCP (National Advisory Committee on Microbiological Criteria in Foods, 1998) should be used as the basis for training and HACCP plan development, implementation, and verification. Regulated HACCP should, however, be reserved for products presenting a true threat to public health, based on risk assessment, thereby focusing limited resources on areas having the greatest potential impact on public health.
2. Controls for each food-pathogen combination should be evaluated separately. This is a joint industry-government responsibility.
3. While government can fund some research by employees (e.g., ARS, FDA, and CDC) and academics (through the CSREES, National Research Initiative, etc.), government's greatest impact is through providing economic incentives for industry innovations at all three stages: invention, commercial scale-up, and widespread adoption. One such incentive is to inform the industry about the health protection benefits of new technologies, such as food irradiation and pasteurization of beef carcasses, that significantly decrease pathogens.
4. The major responsibility for developing new food safety technologies remains with industry and its trade associations, as industrial personnel know best the production processes, options, and competition. This includes food harvesters.
5. The federal, state, and local governments and university personnel have important roles in providing food safety information to industry and consumers. This information includes reporting results of microbial tests, identifying emerging foodborne pathogens, estimating the annual incidence of acute and chronic complications associated with foodborne pathogens, identifying the foods with which various pathogens are associat-

†Update for Recommendation No. 14 in Council for Agricultural Science and Technology, 1994. See Appendix C.

ed, and identifying contributing risk factors. The federal government (especially the FDA, USDA, and CDC) also has a role in research and methods development to facilitate scientifically based enforcement strategies and to maintain first-hand knowledge of the latest scientific developments. Agencies (e.g., state and local) and universities also have contributed to identifying emerging foodborne pathogens.

6. To facilitate the scientific basis of hazard analyses and risk assessments (either qualitative or quantitative), both industry and government have critical roles in finding innovative solutions to create databases for use by all researchers and policy makers.
7. When considering new regulations, the cost of implementing regulations should be considered, along with the efficacy of pathogen control to encourage the most cost and public health-beneficial options.
8. There are different views about the most cost-beneficial interventions, depending on whether the perspective is that of a consumer, taxpayer, society-at-large, regulator, lawyer, food producer, food retailer, or a firm conducting microbial tests. The CAST authors advocate that the approach taken by government regulators at the federal, state, county, and local levels is that which is best for society in terms of most effectively protecting public health in a cost effective manner.
9. Existing industry and government HACCP guidelines can be improved by acknowledging that

    - HACCP is not a panacea; for example, it will not detect emerging hazards and no minimal level of safety is guaranteed;
    - detecting "deviations" from a HACCP plan and taking corrective action is a sign that the HACCP plan is working, because "things will go wrong" whether they be flukes of nature or equipment breakdowns (although deviations should go down over time);
    - HACCP approach is a dynamic process, and refinements and adjustments will continually need to be made in HACCP plans as new foodborne hazards are detected, formulae or recipes are modified, ingredients come from different sources, equipment is added, processes are modified, or new scientific advances are incorporated into process-control technologies;
    - HACCP systems should focus on safety and exclude quality-control processes to maintain the focus on truly critical safety control measures;
    - HACCP control options should draw on the best models in reliability engineering and elsewhere that other industries have used to evaluate process-control systems; and
    - extensive work is needed to provide small firms with the resources needed to develop, implement and maintain effective HACCP plans.

10. Essential to the success of food safety are improved communications and information sharing among all parties. For example, efforts to implement HACCP are enhanced by enlisting the aid of personnel, short courses, and information from Extension, State Departments of Agriculture, the International HACCP Alliance, scientific societies (such as the Institute of Food Technologists [IFT], the International Association of Milk, Food and Environmental Sanitarians [IAMFES]), the National Advisory Committee on Microbiological Criteria for Foods, the International Commission on Microbiological Specifications for Foods (ICMSF), and others along with the activities of regulatory agencies, consumer groups, and industry and their trade associations.

Recommendation 14†: Harmonize International Food Safety Standards

Increases in global trading of food have led to the increased need to consider the differences in food safety standards among countries. These differences are justified when they address food safety hazards that are unique to different regions or susceptible populations, but should not be used to erect barriers to trade that cannot be justified scientifically. We recommend that food safety standards be, to the fullest extent possible, harmonized internationally based on achievement of equivalent levels of consumer protection or risk control.

Current Status

This is a new recommendation that has been added to reflect the importance of and attention to international free trade, where food safety has and will continue to serve as a nontariff trade barrier.

1. We recognize each country retains its sovereignty to protect its citizens from hazards in the food supply, regardless of whether those hazards are microbial, chemical, or physical. National food safety standards that are more stringent than are international standards (e.g., standards developed by Codex Alimentarius) must be pertinent to realizing a scientifically justified public health objective.
2. Public health protection must be the principal underlying initiatives to harmonize food safety standards internationally.
3. Production and processing requirements should be flexible, as long as an equal level of protection can be demonstrated.
4. Equivalence should be based on determining equal levels of consumer protection between trading partners, with consideration given to regional and technological production, processing, and distribution practices.

†This is a new recommendation.

Education

Recommendation 15†: Educate the Public and Food Safety Professionals

We recommend that the public be well educated regarding safe food handling and risks of foodborne illness. Knowledge of the motivation of people to decrease these risks and effective risk communication will be requisite to effective education. The effectiveness of messages to consumers and other food handlers should be measured and evaluated. We recommend increased support of higher education for food safety professionals. This recommendation is expanded from Recommendation 15 of the original report.

Current Status

Many food safety education messages are sent to the public, consumers, and other food handlers; yet for effective communication these messages must be received. Furthermore, to improve food safety, the information must result in altered behavior on the part of the consumer, purchaser, and/or preparer. A variety of messages have been sent by various means (e.g., television, food labels, magazine articles, training materials) in the hope that some will be effective. Some undoubtedly are effective, but knowledge is lacking as to the effectiveness of the educational tools. Furthermore, the multitude of messages complicates the educational mission.

1. Food safety information must compete effectively with other communication messages in the marketplace. Thus, an understanding of communication of food safety information (both the specific message and delivery system) with consumers and food handlers is needed to obviate the current perceived need to provide blanket coverage by all possible means as frequently as the opportunity presents itself. This will necessitate that food safety specialists collaborate with communications specialists.
2. To improve food safety, the educational message must result in behavior modification that decreases foodborne illnesses; thus, knowledge of the public's (consumers, purchasers, and preparers) behavior and attitudes about foodborne hazards and risk-taking will be needed. This will necessitate that food safety specialists collaborate with those knowledgeable in human behavior and behavior modification through education.
3. Effective education will require information on existing knowledge and behavior of the public and food safety professionals; developing and testing messages and symbols; testing the effectiveness of various delivery systems (e.g., package labels, teachers/classrooms, the Internet, newspaper articles, labels on foodservice menus, videos, or other systems); evaluating the most effective age to target; understanding the motivation required by the public, consumers, or food safety professionals to alter behavior; and other similar fundamental information.
4. Develop an overall coordinated strategy to reach all appropriate and receptive audiences (e.g., gender, age, health status) with relatively few simple messages designed to have the greatest impact on improving food safety based on scientific determinations.
5. The effectiveness of the educational message to the public, consumers, and food safety professionals should be scientifically measured and evaluated in controlled experiments and surveys.
6. Educational programs developed jointly by government, the food industry, marketing boards, food associations, consumer organizations, and professional societies should be encouraged in a coordinated, collaborative effort. One current example is the Partnership on Food Safety Education developed by industry, consumer associations, and government with funding provided by the food industry. The resulting "FightBac" campaign is based on four simple, effective messages—washing hands thoroughly, cooking food to the appropriate temperature, refrigerating foods immediately after use, and keeping foods separate. Pending better knowledge related to communications and behavior modification, it is rec-

†Update for Recommendation No. 15 in Council for Agricultural Science and Technology, 1994. See Apppendix C.

ommended that these four messages be repeated, using the same symbols and words, in other food safety campaigns. They also should appear on food packages, at point of sale, in restrooms, wherever food is prepared and served, in food advertising, and in education materials for schools. It is further recommended that a joint government-industry funding effort be developed to repeat these messages frequently in extensively read print media, and on radio and prime viewing times on television.

7. Education at the primary and secondary school level reaches three audiences—the teacher, the children, and, indirectly, their parents. Therefore, elementary, middle, and high school educators should be encouraged to recognize that lessons relative to safe food handling provide valuable lifelong skills and are appropriate to incorporate into science, health, and home economics curricula.
8. Messages should emphasize that all consumers are not equally susceptible to food safety risks, and the programs (including studies on effective communication and behavior modification strategies) should include components that are specific for targeted high-risk populations and their caretakers, those who consume high-risk foods, and those who prepare food under conditions where outbreaks have previously occurred (e.g., home catering, barbecuing, picnics, food service, preparation, and catering).
9. We recommend increased support of higher education for food safety professionals. This includes both funding for undergraduate and graduate programs, as well as additional support for continuing education programs. For example, the call for increased use of risk assessment means that we need to train people to be able to accomplish the task.

Recommendation 16†: Identify High-Risk Populations and Provide Education

We recommend that populations at high risk of illness caused by common and opportunistic pathogens be identified, and that special educational programs be tailored to inform these populations and their caretakers of their high-risk status so those at risk can be protected.

Current Status

Although some high-risk populations are known and may be reasonably knowledgeable of their risk status, other high-risk populations and individuals are poorly informed. Undoubtedly, there is more to learn about populations at elevated risk for selected disease; in particular, little is known about relative risk status for chronic foodborne disease. Several approaches are needed to increase our knowledge in this area.

1. Effective educational programs are essential (see Recommendation 15), especially for high-risk populations or their caretakers. For high-risk populations, education should include the medical profession and employ its educational means, e.g., publications, to target the elderly, cancer patients, parents of infants and young children, pregnant women, and other immunosuppressed populations. While there have been efforts to develop educational programs for the general public, an organized national campaign that effectively communicates food safety information to high-risk populations and health care providers is needed.
2. Rigorous epidemiologic studies are required to identify populations at high risk for specific pathogic, toxic, and viral agents, or other foodborne hazards. Subpopulations can be at high risk because their activities, eating habits, or food preferences increase their likelihood of exposure; their underlying medical condition or age may make them more likely either to become ill following exposure or to suffer serious disease consequences; or their lack of access to medical care (e.g., the homeless) may increase the risk of disease progression. Several data sources such as FoodNet can improve our understanding and identification of high-risk populations, and better data are being provided in response to additional resources that are part of the National Food Safety Initiative and other funding programs.
3. Population surveys being conducted at FoodNet sites and as a part of the national Behavioral Risk Factor Surveys are identifying demographic characteristics of persons whose activities and food preferences put them at elevated or lower risk of exposure to foodborne hazards. Case-control studies in outbreak settings and of sporadic cases in FoodNet and other active surveillance settings will identify physiologic states associated with increased risk of infection and increased risk of serious illness, long-term sequelae, and death due to foodborne illnesses.
4. Easy methods for assessing the immune status of individuals in outbreak investigations/surveys should be developed.

---

†Update for Recommendation No. 10 in Council for Agricultural Science and Technology, 1994. See Appendix C.

Recommendation 17†: Provide Risk Information Relative to Food Choices

We recommend that consumers be allowed access to the widest possible range of food choices yet be informed of the relative personal risk status of the foods. For example, if the consumer is pregnant; young; elderly; a cancer or acquired immune deficiency syndrome (AIDS) patient; a transplant recipient; taking steroids, antibiotics, antacids, or certain other medications; under high stress; or has certain other conditions, the person's immune system may be altered or depressed so that the individual has enhanced disease susceptibility. Persons with enhanced disease susceptibility would be at increased risk of acute as well as chronic foodborne illnesses and need to be more aware of the hazards that may be associated with consumption of various types of foods. This means that not all foods will be appropriate for all consumers.

Current Status

This recommendation was originally included, and is included now, to acknowledge that there are risks in food selection and consumption and that the risks vary with the individual. Most consumers want the widest possible range of choice in food products, but often do not have information about the risks associated with a particular food product. Consumers desire choices and the freedom to make them, thus the risk associated with the choice must be made clear. It would be inappropriate to treat all food as though it is intended for consumption by a particular high-risk population as this excessively and unnecessarily limits choice.

1. Foods from local, national, and international sources should meet agreed-upon food safety criteria (see Recommendation 14).
2. All consumers and caregivers, and particularly those at high risk of foodborne disease because of age or health status, should be educated about hazards associated with food choices and measures to eliminate, prevent, or decrease the hazard. Clearly, consumer education (see Recommendation 15) relative to safe food handling and preparation is important when choice is available, given that choice would include raw and processed fruits and vegetables and muscle foods, and would include exotic foods for which safe handling practices may be unfamiliar to the individual.
3. Processing or cooking to enhance safety has been required for certain foods with documented success in limiting the spread of disease (e.g., pasteurization of milk, use of pasteurized milk for cheese manufacturing, and the requirement for thorough cooking of hamburgers served in food service establishments) and should be considered for other foods (e.g., pasteurization of apple juice, oysters, or eggs for food service could be options) where there is a clearly established link between lack of heating or other processing and disease. For example, pasturized eggs are required for nursing homes (U.S. Food and Drug Administration, 1997).
4. The food service and processing industries have a responsibility to take precautions to protect high-risk populations from known hazards by use of pasteurization, proper cooking and handling, and other interventions applicable to the product. Primary producers (e.g., growers, harvesters, and others) also have a responsibility to minimize contamination to the extent possible for their product, thereby decreasing the potential for sale of contaminated product. Government, industry, and academia should collaborate to develop appropriate risk-decreasing technologies and good agricultural practices (GAPs) for voluntary implementation.
5. Consumer choice is expanded if low-risk food products are identified with a label that creates real, informed choice (see Recommendation 18). If consumers can identify low-risk products, they are more likely to buy a low-risk product if they

†Update for Recommendation No. 11 in Council for Agricultural Science and Technology, 1994. See Appendix C.

wish to prepare a high-risk recipe (such as lightly cooking eggs or meat), if they are at high risk of contracting a foodborne illness, or if they are risk avoiders. Because of the potential for increased sales for low-risk products, food companies have an increased incentive to invest in research to find new methods of producing safer foods. Reliable and consistent labeling standards will be critically important to consumer protection and to consumer confidence.

Recommendation 18†: Use and Evaluate Food Labeling

We recommend that labeling be used to communicate safe food preparation and storage practices to food preparers. Labeling also may be an important informational tool to identify foods treated to improve their level of safety and to identify foods that pose elevated risk. Furthermore, we recommend that the use of labeling be evaluated for its effectiveness.

Current Status

This is a new recommendation. Since the last report, safe food handling labels have been required on raw meat and poultry by the Food Safety and Inspection Service (FSIS).

1. Labeling certain raw foods regarding proper storage and food preparation methods (such as cooking, prevention of cross-contamination, and hand washing) is helpful to consumers and can enhance food safety. Instructions should be clear and offer specific actions for consumers and commercial food handlers.
2. Scientific research on alternative label contents should be conducted to determine their effectiveness in changing the behavior of consumers and/or commercial food handlers.
3. Current safety certification programs by the EPA (for water purifiers) and the FSIS (for processes in meat and poultry slaughter and processing that "significantly reduce pathogens") could be used as models for consumer level food safety certification programs. Certification could include certifying safer food products or certifying instruments such as food, oven, and refrigerator thermometers or timers that are used by consumers to handle food. Such certification needs to be scientifically validated.
4. The use of warning labels should be limited to food systems where no other critical control points will be applied.

†This is a new recommendation.

Appendix A: Acronyms and Abbreviations

AIDS	acquired immune deficiency syndrome
ARS	Agricultural Research Service
BSE	bovine spongiform encephalopathy
CAST	Council for Agricultural Science and Technology
CDC	Centers for Disease Control and Prevention
CSREES	Cooperative State Research, Education, and Extension Service
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
FSIS	Food Safety Inspection Service, USDA
GAP	good agricultural practice
GMP	good manufacturing practice
HACCP	Hazard Analysis Critical Control Point
IAMFES	International Association of Milk, Food and Environmental Sanitarians
ICMSF	International Commission on Microbiological Specifications for Foods
IFT	Institute of Food Technologists
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
NAHMS	National Animal Health Monitoring System
NFSI	National Food Safety Initiative
NIH	National Institutes of Health
NRI	National Research Initiative
USDA	United States Department of Agriculture

Appendix B: Glossary

Codex Alimentarius Commission (Codex). The major international mechanism for encouraging fair international trade in food while promoting the health and economic intersts of consumers. Visit their web site for further information: http://www.fsis.usda.gov/OA/codex/index.htm. E-mail address is USCODEX@aol.com.

Consequence. An outcome produced by a cause or something produced by a cause (hazard) or something necessarily following from a set of conditions (hazard). This can result in colonization, infection, intoxication, morbidity of varying degrees of severity, sequelae, carrier state, injury or mortality and accompanying expenses associated with treatment, loss of work or social time, investigation of the associated incident, recalls, food destruction, loss of future sales, and deterioration of product reputation.

Control[3]. (a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The state in which correct procedures are being followed and criteria are being met.

Control measure[3]. Any action or activity that can be used to prevent, eliminate, or decrease a significant hazard.

Control point[3]. Any step at which biological, chemical, or physical factors can be controlled.

Corrective action[3]. Procedures followed when a deviation occurs.

Criterion[3]. A requirement on which a judgment or decision can be based.

Critical Control Point[3]. A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or to decrease it to an acceptable level.

Critical Limit[3]. A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a critical control point to prevent, eliminate, or decrease to an acceptable level the occurrence of a food safety hazard.

Deviation[3]. Failure to meet a critical limit.

Dose-response assessment[3]. The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological, or physical agent and the severity and/or frequency of associated adverse health effects (response).

Exposure assessment[3]. The qualitative and/or quantitative evaluation of the unlikely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

---

[3]Codex Alimentarius Commission. 1997. *Report of the Thirtieth Session of the Codex Commission on Food Hygiene, ALINORM 99/13.* Codex Alimentarius Commission, Rome. Note that these are draft definitions and that other Codex committees may use different definitions. National Advisory Committee on Microbiological Criteria for Foods. 1998. Hazard Analysis and Critical Control Point Principles and Application Guidelines. *J Food Prot* 61(6):762-775.

FightBac. National food safety education campaign jointly conducted by industry, consumer, and government representatives. Visit their Web site for further information: http://www.fightbac.org.

Foodborne disease outbreak. An incident in which persons experience a similar illness resulting from the ingestion of a common food.

FoodNet. FoodNet was established in 1995 in Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia. The system is a collaborative project of the Centers for Disease Control and Prevention (CDC), the USDA's Food Safety and Inspection Service, the Food and Drug Administration, and the participating sites. The goals of FoodNet include determining the burden of foodborne illness, monitoring trends in foodborne illness over time, and identifying the proportion of foodborne illness due to eating specific foods.

Hazard[3]. A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard analysis[3]. The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Hazard Analysis Critical Control Point (HACCP)[3]. A systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles: (1) conduct a hazard analysis, (2) determine the critical control points (CCPs), (3) establish critical limits, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, (7) establish record-keeping and documentaion procedures.

Hazard Analysis Critical Control Point Plan[3]. The written document that is based on the principles of HACCP and that delineates the procedures to be followed.

Hazard Analysis Critical Control Point System[3]. The result of the implementation of the HACCP plan.

Hazard characterization[3]. The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of Microbiological Risk Assessment, the concerns relate to microorganisms and/or their toxins.

Hazard identification[3]. The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Healthy People 2000. A prevention agenda to improve the nation's health. Visit their web site for details: http://web.health.gov/healthypeople.

Monitor[3]. To conduct a planned sequence of observations or measurements to assess whether a critical control point is under control and to produce an accurate record for future use in verification.

National Animal Health Monitoring System (NAHMS). The

USDA's Animal and Plant Inspection Service (APHIS) data collection program on farm animals. Visit their web site for further information: http://www.aphis.usda.gov/vs/ceah.

National Food Safety Initiative (NFSI). A joint program of the U.S. executive branches (Food and Drug Administration, Department of Agriculture, Centers for Disease Control and Prevention, Environmental Prevention Agency) outlined in the May 1997 report to the President with an ongoing and developing research agenda for improving foodborne disease surveillance, risk assessment of farm-to-table interventions, consumer education, etc. Visit their web sites for further information: http://vm.cfsan.fda.gov/~dms/fsreport.html and http://vm.cfsan.fda.gov/~dms/fs-toc.html#coord.

Prerequisite Programs[3]. Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

Qualitative risk assessment[3]. A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk.

Quantitative risk assessment[3]. A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties (stated in the 1995 Expert Consultation definition on Risk Analysis).

Risk[3]. A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk analysis[3]. A process consisting of three components: risk assessment, risk management, and risk communication.

Risk assessment[3]. A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk characterization[3]. The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment.

Risk communication[3]. The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers, and other interested parties.

Risk estimate[3]. Output of risk characterization.

Risk management[3]. The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

Sensitivity analysis[3]. A method used to examine the behaviour of a model by measuring the variation in its outputs resulting from changes to its inputs.

Severity. The magnitude of the hazard or the degree of consequences that can result when a hazard exits. It relates to the outcome of the hazard if it is not prevented or controlled and from a disease perspective can be life threatening, severe, moderate, or mild. Therefore, severity relates to dose and host response. It also considers the steps in the process that the hazards are occurring and relates to (1) initial populations of pathogens; (2) concentrations of toxic chemicals; (3) size or numbers of physical substances; (4) whether a process resulted in inactivation, injury, or survival; and (5) the population or concentration that resulted from propagation.

Severity[3]. The seriousness of the effect(s) of a hazard.

Step[3]. A point, procedure, operation, or stage in the food system from primary production to final consumption.

Transparent[3]. Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgments, decisions, limitations, and uncertainties of the expressed determination are fully stated, documented, and accessible for review.

Uncertainty analysis[3]. A method used to estimate the uncertainty associated with model inputs, assumptions, and structure/form.

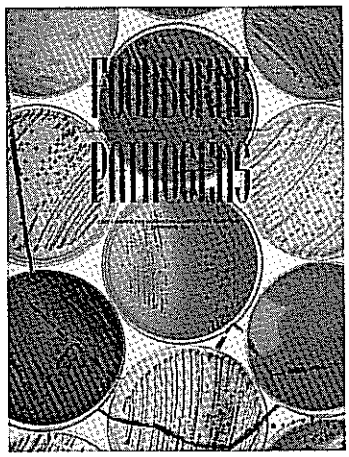
Validation[3]. That element of verification focused on collecting and evaluation scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards.

Verification[3]. Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

Appendix C: Original 1994 Findings, Recommendations, and Recent Comments

Charge to the Task Force

In 1983, the National Research Council (NRC) recommended that risk assessment procedures be applied to strengthen the scientific basis of risk decisions within the government. Risk assessment, risk management, and risk communication are the three components of risk analysis. In 1985, the NRC recommended that microbial pathogen risk assessment be the foundation for the nation's meat and poultry inspection system. In 1989, the Council for Agricultural Science and Technology (CAST) created a task force to determine the state of knowledge about U.S. foodborne disease risks. Recently several groups have emphasized the need for foodborne disease risk assessment, and improvements based on a risk assessment approach have been proposed (Bromley, 1993; Hathaway, 1994; U.S. General Accounting Office, 1992).



The CAST task force framed the issue by addressing the following questions:

- What types of human health risks are associated with microbial pathogens in food?
- What foods harbor these pathogens and are the causes of human disease?
- How many acute microbial foodborne illnesses and deaths occur annually?
- How many chronic human illnesses and deaths are caused by foodborne pathogens?
- What are the economic costs of these foodborne diseases annually?
- Are risk assessment databases adequate or are improvements needed to reduce uncertainty about the incidence of acute and chronic foodborne diseases?
- What preventive actions will reduce the incidence and severity of microbial foodborne disease?

Task Force Findings

1. A comprehensive system of assessing the risks of human illness from microbial pathogens in the food supply has yet to be devised.

   - The Centers for Disease Control and Prevention's (CDC) foodborne surveillance system is limited by the data it receives from state departments of health and other sources and thus reports only a fraction of foodborne disease outbreaks.
   - In 1994, the Council of State and Territorial Epidemiologists pointed out that final decisions regarding foodborne disease surveillance are made by each state and that 12 states have no surveillance staff assigned to monitor food related or waterborne pathogens; thus, outbreaks are unlikely to be reported from these states.
   - The last systematic CDC study to estimate the actual incidence of foodborne bacterial, viral, and parasitic infections was conducted in 1983 and relied greatly on expert judgment (Bennett et al., 1987; Voelker, 1994). A new study is needed urgently.
   - Trends in the CDC's reported foodborne outbreaks may not reflect changes in actual cases accurately. New pathogens always are underreported because testing procedures are nonstandardized or have not been developed, or because doctors tend to request tests for familiar pathogens. For *Campylobacter jejuni*, the causes of reported outbreak cases and of sporadic cases not reported but detected by special investigations differ. Similar differences may exist for other pathogens.
   - For some illnesses, it may take thousands of cases for an outbreak causing diarrheal illness randomly in a large urban area to be detected

by public health authorities (Berkelman et al., 1994).

- Any assessment based solely on currently known pathogens and disease syndromes likely is incomplete. New etiologies continue to be added as the science base expands, but nearly half of the recorded outbreaks and cases still are of unknown etiology (Bean et al., 1990a, 1990b).

Although the microbial foodborne disease burden of the United States is not known with accuracy, estimates from the literature indicate and the general consensus of CAST task force members is that cases likely range from 6.5 million to 33 million annually and that deaths may be as high as 9,000 annually (the CDC estimates that there are 9,000 microbial foodborne deaths annually).

2. Although foods of animal origin most often are identified as the vehicles of foodborne disease outbreaks reported to the CDC, a wide variety of foods are associated with foodborne illness (Bean et al., 1990a, 1990b).
3. No agreed-upon method for setting food safety priorities exists. The U.S. Health and Human Service's *Healthy People 2000* report used, without a clear definition, both case number and severity to set targets for *Campylobacter jejuni*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella enteritidis* (U.S. Department of Health and Human Services, 1991).
4. It is difficult to use available statistics, which are based on all routes (including nonfoodborne) of infection or intoxication, to identify the foodborne component of total human illness.
5. Pathogens and their toxins can enter the food chain at any point from the farm to the kitchen. Pathogens or toxins may be present on raw foodstuffs or may be introduced into the food by contamination in the postharvest environment, e.g., by processing plant workers or by foodhandlers. The ability to survive, to grow, and to produce toxin and the persistence of active toxins are consequences of organism, environment, and treatment process. Thus, methods to prevent or to control pathogens differ and may involve excluding contaminated feed and food ingredients, practicing good sanitation, refrigerating, cooking, or irradiating. Control methods affect specific pathogens and toxins differently; no one method will eliminate all pathogens and their toxins from the food chain. Pathogens or their toxins may be controlled by preventing their entry into the food, by reducing the amount present, or by destroying that which is present.
6. Application of hazard analysis critical control point (HACCP) systems can reduce the likelihood of foodborne illness. Control systems must recognize the diversity and the variability of pathogens, the vagaries of detection, and the wide range of control options. The cost and efficacy of HACCP systems differ considerably, and creative solutions may be pathogen-specific. In each instance, the efficacy of a HACCP system depends on the rigor and consistency with which it is designed and implemented and the use of (a) critical control point(s) that will control pathogens.

Task Force Recommendations

The task force acknowledges that zero risk of foodborne illness is neither possible nor practical. We offer the following recommendations for reducing foodborne illness.

1. **We recommend that food safety policy be based on risk assessment** using all available data for acute and chronic foodborne disease.
2. **We recommend that the food safety information database be expanded** to provide more complete information on the incidence of foodborne disease by pathogen and by food risk assessment use. The database should be accessible through a computer network to all potential users (public health officials, regulatory authorities, food companies, food safety scientists, and others). The CDC should take the lead in creating the new database with input from the Food Safety Inspection Service (FSIS); the U.S. Food and Drug Administration (FDA); state departments of health; and other individuals or organizations, e.g., the database should include consumer illness complaints and survey data. This integrated database would allow identification of the points at which pathogens occur in the food chain and would facilitate identification of pathogen control points, estimation of control option costs, and tracking of intervention success in terms of reduced human illness and death.
3. Recognizing that advances in knowledge of foodborne disease prevention and control are essential to advancing food safety, **we recommend that vigorous fundamental and applied research efforts related to food safety be encouraged and supported.** Research on the biology and the ecology of pathogens is especially

important in areas such as microbial ecology of pathogenic bacteria and viruses; genetic transfer of virulence determinants; mechanisms of virulence; potential of growth conditions to enhance virulence; sensitivities of pathogens and toxins to control procedures; activities and responses of organisms in natural environments, e.g., biofilms in processing facilities; and applications of current technologies for tracking organisms in the environment and in epidemiological investigations.

4. **We recommend that new rapid, reliable, sensitive, and economical methods continue to be developed to allow fast and accurate detection of hazardous organisms and their toxins.** This objective is especially important for detection of viruses in food, environmental, and fecal samples because viral detection methods are inadequate.
5. We acknowledge that epidemiological studies to link incidence of a foodborne pathogen to illness will be increasingly important as detection method sensitivity for pathogens or for their toxins increases. Therefore, **we recommend continued rigorous epidemiological studies to assist in establishing cause of illness and effect of the occurrence of a particular pathogen or toxin.**
6. We acknowledge that both **dose response and minimum infective or intoxicating dose** are difficult types of data to accumulate (because the use of human volunteers is unacceptable) yet **we recommend that**, to the extent possible, **these data and doses be determined or estimates be improved** using data from well-documented outbreaks.
7. **We recommend that estimates of (a) numbers of acute illnesses, chronic illnesses, and deaths; (b) costs of foodborne diseases; (c) severity of illnesses; and (d) duration of chronic illnesses be improved.**
8. **We recommend that research be conducted on the mechanisms of chronic illnesses** with which foodborne pathogens are associated, so that appropriately targeted detection and control strategies can be developed.
9. **We recommend that research be conducted to identify foods likely to be associated with specific pathogens or toxins**, i.e., high-risk foods such as raw foods of animal origin, **and to establish risk minimization controls.** Whether new processing methods create an environmental niche for pathogens should be determined.
10. **We recommend that populations at high risk for opportunistic pathogens causing acute or chronic illnesses be identified and that special control programs be tailored to inform these populations of their high-risk status** so that they can protect themselves. An interactive computer database could be established on Internet to list foods likely to harbor the pathogen of interest, to improve understanding of the safest handling and preparation procedures for specific foods, and to help high-risk populations select optimal food/safety combinations. These populations may include persons with low stomach acidity, high-iron blood level, or diabetes; alcoholics; children; pregnant women; adults over 50 or 60; those with organ transplants, cancer, or acquired immunodeficiency disease syndrome (AIDS); or others. Educational strategies must acknowledge that the risk status of individuals is not constant.
11. **We recommend that consumers be allowed choices in the types of food available** to them yet be made aware of their relative risk status, including their risks of acute as well as chronic illnesses. It should not be required that all foods be safe for consumption by high-risk consumers; this would greatly limit food choices, e.g., to canned or irradiated food, excluding fresh meat, poultry, and seafood. Special federal programs could be established to certify the safety of specific operations to produce foods for high-risk individuals; these foods probably would be priced higher.
12. **We recommend that federal food safety regulations and policies be modified to reflect that zero risk of foodborne illness is not possible.** This change will allow honest and effective risk management.
13. **We recommend that food safety goals and priorities be set so that resources may be allocated and targeted appropriately.** Public discussion and understanding of the costs and effectiveness of control measures will be requisite.
14. **We recommend that control practices be applied from food source to consumption**, including the incorporation of HACCP principles from the farm or other source through consumption. The HACCP systems provide a systematic process-control approach focusing on food safety. Development of new procedures to control foodborne illness agents, as well as understanding of existing control steps and control procedure costs, should be encouraged so that proper and effective

application is ensured. Controls for each food pathogen combination should be evaluated separately. New scientific advances should be incorporated into control practices.

15. Given that risk communication is critical because zero risk is impossible, **we recommend that the public be well educated regarding safe food handling and the relative and changing risk status of individuals.** Education is essential if consumers are to protect their own health and to recognize the political and regulatory complexities of the issue so that they can participate in setting food safety goals. From grades K–12, science education should be strong and education concerning the hazards of foodborne diseases, their causes, and their means of prevention should be integrated into health and science curricula. Health agency personnel and university outreach programs should inform consumers about populations at risk for foodborne illness, the relative safety of various food choices, safe food handling procedures, appropriate control strategies, and the relative effectiveness of controls.

Recent Comments

The CAST office has received many media requests for information about the basis of the estimates of foodborne illness cases and deaths. Kate Murphy from *Business Week* called to verify the source of the estimates of 6 million to 33 million illnesses and 9,000 deaths used by President Clinton in a radio broadcast and reported by Marian Burros in *The New York Times*, numbers that were cited in the CAST report summary (Council for Agricultural Science and Technology, 1994, pp. 1, 4). These estimates, which were based on existing scientific literature (Bennett et al., 1987; Todd, 1989a, 1989b), continue to generate interest and questions in 1998. In a recent letter by CAST task force cochair Dr. Tanya Roberts to the *Columbia Journalism Review* (see CAST Web site, www.castscience.org), she quotes from page 1 of the 1994 CAST report regarding the basis of the estimates of foodborne illness cases and deaths:

> . . . A comprehensive system of assessing the risks of human illness from microbial pathogens in the food supply has yet to be devised. Although the microbial foodborne disease burden of the United States is not known with accuracy, estimates from the literature indicate and the general consensus of CAST task force members is that cases likely range from 6.5 million to 33 million annually and that deaths may be as high as 9,000 annually. . . .

On August 7, 1998 to further clarify the matter, Dr. Claire V. Broome, Acting Director of the Centers for Disease Control and Prevention (CDC), wrote in a letter to administrators of the Food and Drug Administration (FDA), the Food Safety Inspection Service (FSIS), and the Environmental Protection Agency (EPA):

> Recent reports in *Food Chemical News* and other print media suggest that the Centers for Disease Control and Prevention (CDC) has revised estimates of the burden of foodborne illness and death and that recent FoodNet data demonstrate a substantial decline in the incidence of foodborne infections. These reports are inaccurate and may have caused confusion. The following information should clarify the status of efforts underway at CDC to improve our understanding of occurrences of foodborne illnesses and indicates the interagency collaboration involved in these efforts.
>
> In 1987, CDC used surveillance and outbreak data, published reports, and expert opinion to estimate the overall incidence of illness and the number of deaths caused by foodborne microorganisms in the United States. The incidence of symptomatic illness was estimated at 6.5 million cases annually, with about 9,000 related deaths. These estimates were published in a Carter Center document, *Closing the Gap: the Burden of Unnecessary Illness*, and were part of the basis for estimates published in 1994 by the Council for Agricultural Science and Technology.
>
> CDC has recently begun a multidisciplinary effort to revise these national estimates for foodborne illness. This is a complex process that will draw upon new sources of data, including results for active surveillance at FoodNet sites, as well as sources used previously, and the revised estimates will be accompanied by documentation of all data sources and assumptions. Efforts currently underway involve CDC scientists from the National Center for Infectious Diseases and the National Center for Health Statistics. CDC will seek input from its National Food Safety Initiative partners at the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA) as the process of revision proceeds. The

revised estimates will not be available for several months. While the data used for these estimates will be greatly improved from those in the 1987 report, substantial future efforts will be required to further improve estimates of the burden of illness caused by certain bacterial, parasitic, and viral foodborne pathogens. . . . (Broome, 1998)

Literature Cited

Archer, D. L. and J. E. Kvenberg. 1985. Incidence and cost of foodborne diarrheal diseases in the United States. *J Food Prot* 48:887–894,

Bennett, J. V., S. D. Holmberg, M. F. Rogers, and S. L. Solomon. 1987. Infectious and parasitic diseases. Pp. 102–114. In R. W. Amler and H. B. Dull (Eds.). *Closing the Gap: The Burden of Unnecessary Illness.* Oxford University Press, New York.

Broome, C. V. 1998. Letter dated August 7, 1998 from C. V. Broome, M.D., Acting Director, The Center for Disease Control and Prevention, to Administrators of the Food Safety Inspection Service, the Food and Drug Administration, and the Environmental Protection Agency.

Codex Alimentarius Commission. 1997. *Report of the Thirtieth Session of the Codex Commission on Food Hygiene, ALINORM 99/13.* Codex Alimentarius Commission, Rome.

Council for Agricultural Science and Technology. 1994. *Foodborne Pathogens: Risks and Consequences.* Council for Agricultural Science and Technology, Ames, Iowa.

International Association of Milk, Food, and Environmental Sanitarians. 1998. *Procedures to Investigate Foodborne Illness.* 5th ed. International Association of Milk, Food, and Environmental Sanitarians, Des Moines, Iowa. In press.

Mossel, D. A. A. 1988. Impact of foodborne pathogens on today's world, and prospects for management. *Anim Hum Health* 1:13–23.

National Advisory Committee on Microbiological Criteria for Foods. 1998. Hazard Analysis and critical Control Point Principles and Application Guidelines. *J Food Prot* 61(6):762-775.

National Research Council. 1983. *Risk-Assessment in the Federal Government: Managing the Process.* National Academy Press. Washington, D.C.

Todd, E. C. D. 1989a. Preliminary estimates of costs of foodborne disease in Canada and costs to reduce salmonellosis. *J Food Prot* 52:586–594.

Todd, E. C. D. 1989b. Preliminary estimates of costs of foodborne disease in the United States. *J Food Prot* 52:595–601.

U.S. Food and Drug Administration. 1997. *Food Code: 1997 Recommendations of the United States Public Health Service, Food and Drug Administration.* National Technical Information Service Publication PB97-133656. P. 73. U.S. Food and Drug Administration, Washington, D.C.

Index

Recent CAST Publications

Foodborne Pathogens: Review of Recommendations. SP22, October 1998, 45 pp., $15.00; Interpretive Summary, 2 pp., free

The Proposed EPA Plant Pesticide Rule. IP10, October 1998, 8 pp., $3.00

Feasibility of Prescription Pesticide Use in the United States. IP9, August 1998, 10 pp., $3.00

Food Safety, Sufficiency, and Security. SP21, June 1998, 78 pp., $26.00; Interpretive Summary, 4 pp., free

Naturally Occurring Antimicrobials in Food. R132, April 1998, 103 pp., $28.00; Interpretive Summary, 2 pp., free

Examination of Dietary Recommendations for Salt-Cured, Smoked, and Nitrite-Preserved Foods. IP8, November 1997, 8 pp., $3.00. (Price includes shipping.)

Contribution of Animal Products to Healthful Diets. R131, October 1997, 64 pp., $24.00; Interpretive Summary, 2 pp., free

The Well-Being of Agricultural Animals. R130, September 1997, 40 pp., $16.00; Interpretive Summary, 2 pp., free

Grazing on Public Lands. R129, December 1996, 70 pp., $20.00; Interpretive Summary, 2 pp., free

Integrated Animal Waste Management. R128, November 1996, 87 pp., $20.00; Interpretive Summary, 2 pp., free

Future of Irrigated Agriculture. R127, August 1996, 76 pp., $20.00; Interpretive Summary, 2 pp., free

Radiation Pasteurization of Food. IP7, April 1996, 10 pp., $3.00 (Price includes shipping.)

Diversifying U.S. Crop Production. IP6, February 1996, 12 pp., $3.00 (Price includes shipping.)

Quality of U.S. Agricultural Products. R126, January 1996, 288 pp., $40.00; Summary and Conclusions, 21 pp., $10.00; Interpretive Summary, 2 pp., free

Scientific Societies: Conversations on Change. SP20, January 1996, 23 pp., $10.00; Interpretive Summary, 2 pp., free, Video, 12 min., $20.00

Competitiveness of U.S. Agriculture and the Balance of Payments. R125, October 1995, 34 pp., $12.00; Interpretive Summary, 2 pp., free

Forthcoming Reports

Benefits of Biodiversity (Issue Paper)

Contributions of Animal Agriculture to Meeting Global Human Food Demand

Impact of EPA Implementation of the Food Quality Protection Act

Global Climate Change

Hypoxia in the Gulf of Mexico

Integrated Pest Management

Johne's Disease (Issue Paper)

Movement and Impacts of Detrimental Non-Native Organisms Affecting Agricultural Production and Natural Resource Environments (Pests) (Issue Paper)

Movement and Impacts of Detrimental Non-Native Organisms Affecting Agricultural Production and Natural Resource Environments (Plants) (Issue Paper)

Mycotoxins: Risks and Impacts in Plant and Animal Systems

Transmissible Spongiform Encephalopathy (TSE) (Issue Paper)

Vertical Integration of Agriculture and its Impact on Rural America (Issue Paper)

Foodborne Pathogens: Review of Recommendations

Eighteen scientists provide revised recommendations for current food safety issues. Co-chairs: Peggy M. Foegeding, Department of Food Science, North Carolina State University, Raleigh, and Tanya Roberts, Economic Research Service, U.S. Department of Agriculture. SP22, October 1998, 45 pp., $15.00. Interpretive Summary, 2 pp., free.

This report is available on the World Wide Web at www.cast-science.org.

Foodborne Pathogens: Risks and Consequences

Better data on microbial risks are needed to make the U.S. food supply safer. R122, September 1994, 87 pp., $15.00. A 2-page interpretive summary is available on request.

Publication Orders

Orders may be sent toll-free by fax, 1-800-375-CAST.

Shipping: U.S. and Canada, please add $3.00 for the first publication, $1.00 for additional publications; other countries, add $4.00 per publication. Add $10 per publication for international air mail service. Shipping is included in the price of issue papers. Orders of 6 through 99 copies are discounted 25%; 100 or more, 35%.

Checks must be in U.S. funds on a U.S. bank. Major credit cards accepted. CAST can invoice for publications. Orders from nonmembers outside the U.S. must be prepaid.

Membership

Century Club members ($100/year) receive reports, special publications, issue papers, and *NewsCAST*. Individual members ($40/year) receive *NewsCAST*, issue papers, and interpretive summaries of reports and special publications. They may request one free copy of each report within one year of release. (Please include shipping fees with your request.) Student membership is $20.00 per year.

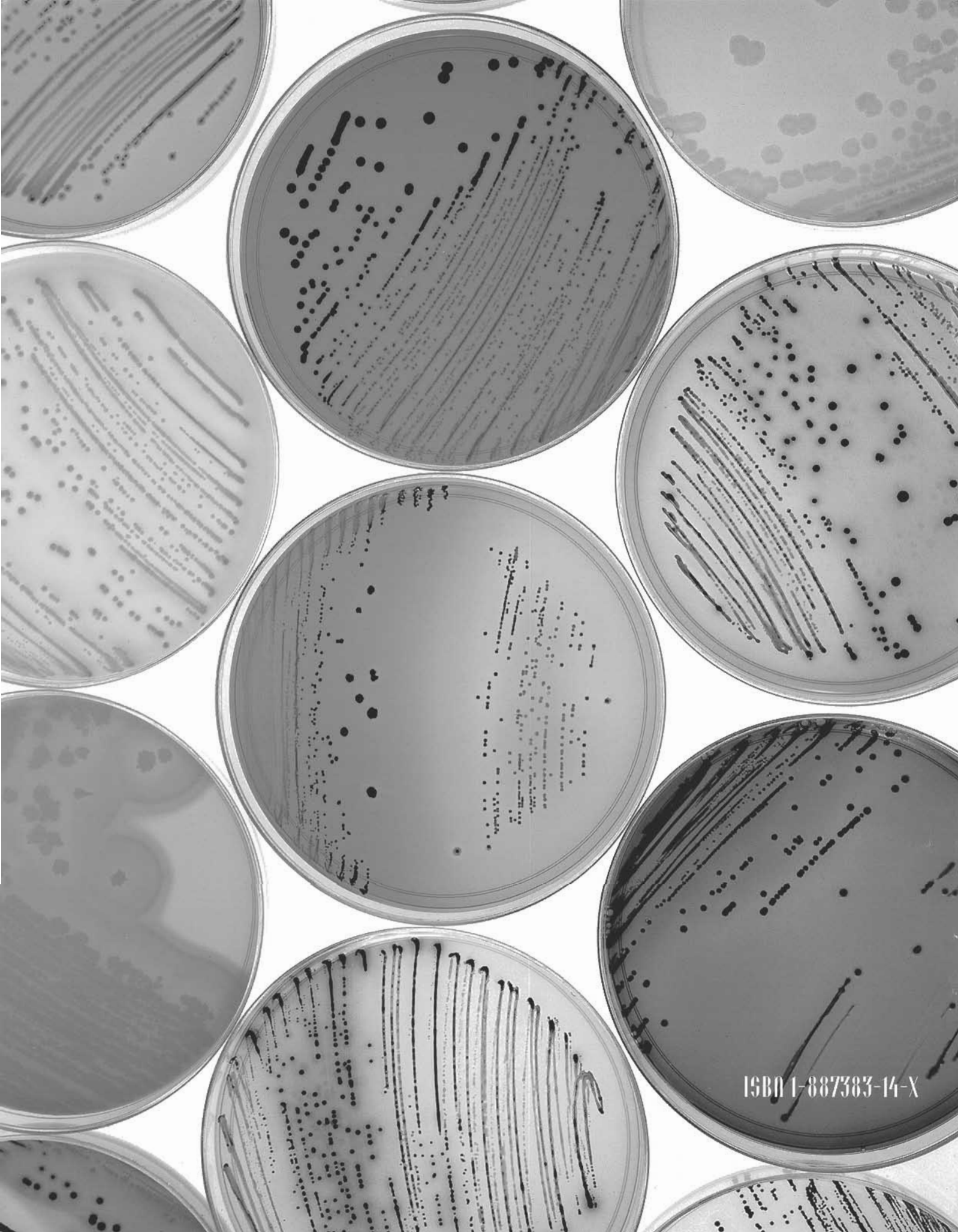
Subscriptions for libraries and institutions are $95.00 per calendar year. An international air mail subscription is $100.00 per calendar year.

World Wide Web

See the CAST World Wide Web site, www.cast-science.org for text of issue papers, interpretive summaries, news releases, and some reports; our publications catalog; a list of forthcoming publications; links to web sites of member societies; and more information about CAST.

Council for Agricultural Science and Technology

4420 West Lincoln Way, Ames, IA 50014-3447, USA
(515) 292-2125, fax: (515) 292-4512, e-mail: cast@cast-science.org
World Wide Web: www.cast-science.org



ISBN 1-887383-14-X