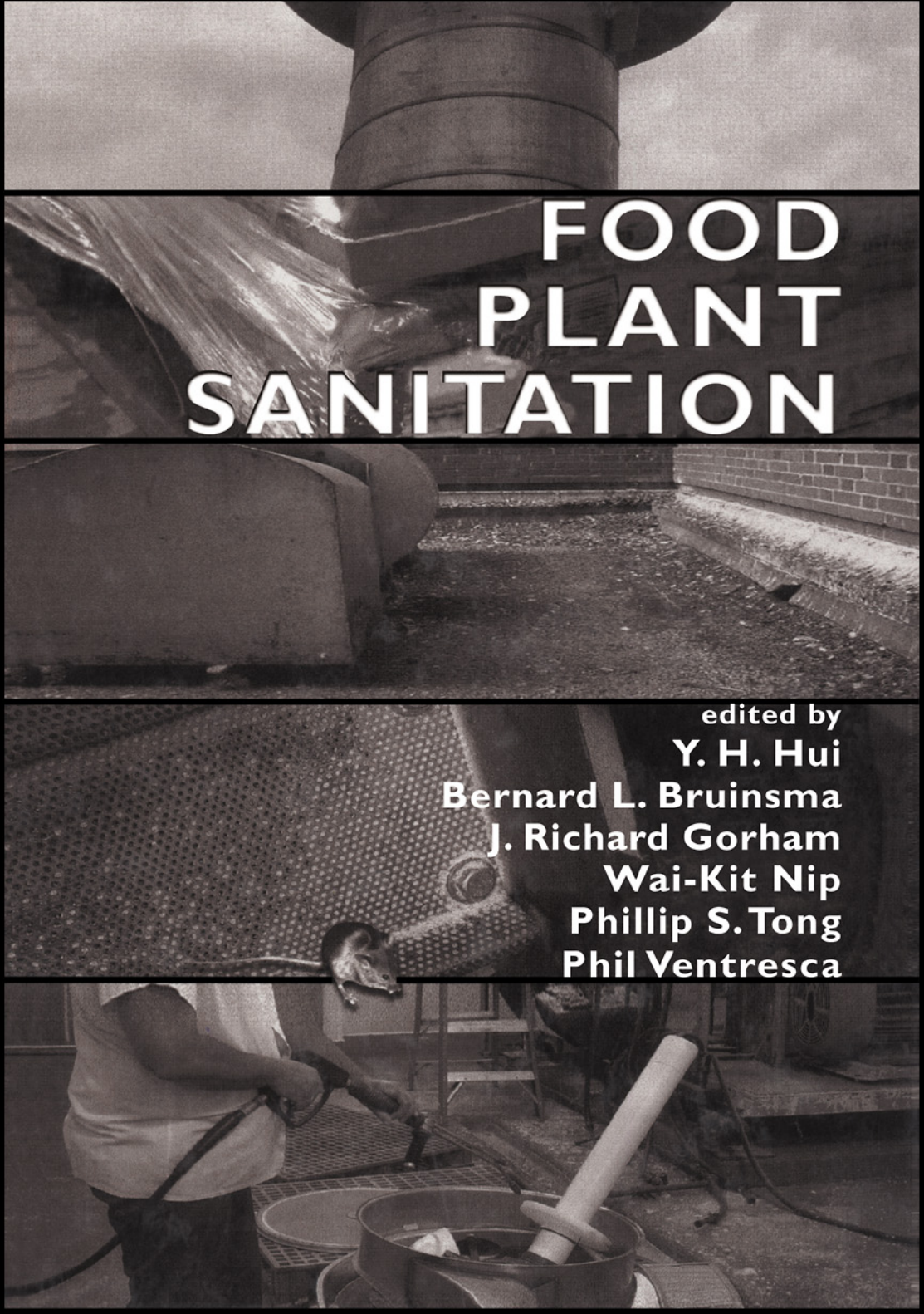

FOOD PLANT SANITATION

edited by
Y. H. Hui
Bernard L. Bruinsma
J. Richard Gorham
Wai-Kit Nip
Phillip S. Tong
Phil Ventresca

Also available as a printed book
see title verso for ISBN details

FOOD PLANT SANITATION

MARCEL DEKKER, INC.

NEW YORK • BASE

FOOD SCIENCE AND TECHNOLOGY

A Series of Monographs, Textbooks, and Reference Books

Madison

Processing and preservation **Gustavo V.Barbosa-Cánovas** Washington State University-Pullman

Safety and toxicology **Sanford Miller** University of Texas-Austin

1. Flavor Research: Principles and Techniques, *R.Teranishi, I.Hornstein, P.Issenberg, and E.L.Wick*

2. Principles of Enzymology for the Food Sciences, *John R.Whitaker*

3. Low-Temperature Preservation of Foods and Living Matter, *Owen R.Fennema, William D.Powrie, and Elmer H.Marth*

4. Principles of Food Science
Part I: Food Chemistry, *edited by Owen R.Fennema*
Part II: Physical Methods of Food Preservation, *Marcus Karel, Owen R.Fennema, and Daryl B.Lund*

5. Food Emulsions, *edited by Stig E.Friberg*

6. Nutritional and Safety Aspects of Food Processing, *edited by Steven R.Tannenbaum*

7. Flavor Research: Recent Advances, *edited by R.Teranishi, Robert A.Flath, and Hiroshi Sugisawa*

8. Computer-Aided Techniques in Food Technology, *edited by Israel Saguy*

9. Handbook of Tropical Foods, *edited by Harvey T.Chan*

10. Antimicrobials in Foods, *edited by Alfred Larry Branen and P.Michael Davidson*

11. Food Constituents and Food Residues: Their Chromatographic Determination, *edited by James F.Lawrence*

12. Aspartame: Physiology and Biochemistry, *edited by Lewis D.Stegink and L.J. Filer, Jr.*

13. Handbook of Vitamins: Nutritional, Biochemical, and Clinical Aspects, *edited by Lawrence J.Machlin*

14. Starch Conversion Technology, *edited by G.M.A.van Beynum and J.A. Roels*

15. Food Chemistry: Second Edition, Revised and Expanded, *edited by Owen R.*

Fennema

16. Sensory Evaluation of Food: Statistical Methods and Procedures, *Michael O'Mahony*

17. Alternative Sweeteners, *edited by Lyn O'Brien Nabors and Robert C.Gelardi*

18. Citrus Fruits and Their Products: Analysis and Technology, *S.V.Ting and Russell L.Rouseff*

19. Engineering Properties of Foods, *edited by M.A.Rao and S.S.H.Rizvi*

20. Umami: A Basic Taste, *edited by Yojiro Kawamura and Morley R.Kare*

21. Food Biotechnology, *edited by Dietrich Knorr*

22. Food Texture: Instrumental and Sensory Measurement, *edited by Howard R. Moskowitz*

23. Seafoods and Fish Oils in Human Health and Disease, *John E.Kinsella*

24. Postharvest Physiology of Vegetables, *edited by J.Weichmann*

25. Handbook of Dietary Fiber: An Applied Approach, *Mark L.Dreher*

26. Food Toxicology, Parts A and B, *Jose M.Concon*

27. Modern Carbohydrate Chemistry, *Roger W.Binkley*

28. Trace Minerals in Foods, *edited by Kenneth T.Smith*

29. Protein Quality and the Effects of Processing, *edited by R.Dixon Phillips and John W.Finley*

30. Adulteration of Fruit Juice Beverages, *edited by Steven Nagy, John A.Attaway, and Martha E.Rhodes*

31. Foodborne Bacterial Pathogens, *edited by Michael P.Doyle*

32. Legumes: Chemistry, Technology, and Human Nutrition, *edited by Ruth H. Matthews*

33. Industrialization of Indigenous Fermented Foods, *edited by Keith H.Steinkraus*

34. International Food Regulation Handbook: Policy • Science • Law, *edited by Roger D.Middlekauff and Philippe Shubik*

35. Food Additives, *edited by A.Larry Branen, P.Michael Davidson, and Seppo Salminen*

36. Safety of Irradiated Foods, *J.F.Diehl*

37. Omega-3 Fatty Acids in Health and Disease, *edited by Robert S.Lees and Marcus Karel*

38. Food Emulsions: Second Edition, Revised and Expanded, *edited by Kåre Larsson and Stig E.Friberg*

39. Seafood: Effects of Technology on Nutrition, *George M.Pigott and Barbee W. Tucker*

40. Handbook of Vitamins: Second Edition, Revised and Expanded, *edited by Lawrence J.Machlin*

41. Handbook of Cereal Science and Technology, *Klaus J.Lorenz and Karel Kulp*

42. Food Processing Operations and Scale-Up, *Kenneth J.Valerias, Leon Levine, and J.Peter Clark*

43. Fish Quality Control by Computer Vision, *edited by L.F.Pau and R.Olafsson*

44. Volatile Compounds in Foods and Beverages, *edited by Henk Maarse*

45. Instrumental Methods for Quality Assurance in Foods, *edited by Daniel Y.C. Fung and Richard F.Matthews*

46. *Listeria,* Listeriosis, and Food Safety, *Elliot T.Ryser and Elmer H.Marth*

47. Acesulfame-K, *edited by D.G.Mayer and F.H.Kemper*

48. Alternative Sweeteners: Second Edition, Revised and Expanded, *edited by Lyn O'Brien Nabors and Robert C.Gelardi*

49. Food Extrusion Science and Technology, *edited by Jozef L.Kokini, Chi-Tang* Ho, *and Mukund V.Karwe*

50. Surimi Technology, *edited by Tyre C.Lanier and Chong M.Lee*

51. Handbook of Food Engineering, *edited by Dennis R.Heldman and Daryl B. Lund*

52. Food Analysis by HPLC, *edited by Leo M.L.Nollet*

53. Fatty Acids in Foods and Their Health Implications, *edited by Ching Kuang Chow*

54. *Clostridium botulinum:* Ecology and Control in Foods, *edited by Andreas H.W. Hauschild and Karen L.Dodds*

55. Cereals in Breadmaking: A Molecular Colloidal Approach, *Ann-Charlotte Ellasson and Kåre Larsson*

56. Low-Calorie Foods Handbook, *edited by Aaron M.Altschul*

57. Antimicrobials in Foods: Second Edition, Revised and Expanded, *edited by P. Michael Davidson and Alfred Larry Branen*

58. Lactic Acid Bacteria, *edited by Seppo Salminen and Atte von Wright*

59. Rice Science and Technology, *edited by Wayne E.Marshall and James I. Wadsworth*

60. Food Biosensor Analysis, *edited by Gabriele Wagner and George G.Guilbault*

61. Principles of Enzymology for the Food Sciences: Second Edition, *John R. Whitaker*

62. Carbohydrate Polyesters as Fat Substitutes, *edited by Casimir C.Akoh and Barry G.Swanson*

63. Engineering Properties of Foods: Second Edition, Revised and Expanded, *edited by M.A.Rao and S.S.H.Rizvi*

64. Handbook of Brewing, *edited by William A.Hardwick*

65. Analyzing Food for Nutrition Labeling and Hazardous Contaminants, *edited by Ike J.Jeon and William G.Ikins*

66. Ingredient Interactions: Effects on Food Quality, *edited by Anilkumar G. Gaonkar*

67. Food Polysaccharides and Their Applications, *edited by Alistair M.Stephen*

68. Safety of Irradiated Foods: Second Edition, Revised and Expanded, *J.F.Diehl*

69. Nutrition Labeling Handbook, *edited by Ralph Shapiro*

70. Handbook of Fruit Science and Technology: Production, Composition, Storage, and Processing, *edited by D.K.Salunkhe and S.S.Kadam*

71. Food Antioxidants: Technological, Toxicological, and Health Perspectives, *edited by D.L.Madhavi, S.S.Deshpande, and D.K.Salunkhe*

72. Freezing Effects on Food Quality, *edited by Lester E.Jeremiah*

73. Handbook of Indigenous Fermented Foods: Second Edition, Revised and Expanded, *edited by Keith H.Steinkraus*

74. Carbohydrates in Food, *edited by Ann-Charlotte Eliasson*

75. Baked Goods Freshness: Technology, Evaluation, and Inhibition of Staling, *edited by Ronald E.Hebeda and Henry F.Zobel*

76. Food Chemistry: Third Edition, *edited by Owen R.Fennema*

77. Handbook of Food Analysis: Volumes 1 and 2, *edited by Leo M.L.Nollet*

78. Computerized Control Systems in the Food Industry, *edited by Gauri S.Mittal*

79. Techniques for Analyzing Food Aroma, *edited by Ray Marsili*

80. Food Proteins and Their Applications, *edited by Srinivasan Damodaran and Alain Paraf*

81. Food Emulsions: Third Edition, Revised and Expanded, *edited by Stig E.Friberg and Kåre Larsson*

82. Nonthermal Preservation of Foods, *Gustavo V.Barbosa-Cánovas, Usha R. Pothakamury, Enrique Palou, and Barry G.Swanson*

83. Milk and Dairy Product Technology, *Edgar Spreer*

84. Applied Dairy Microbiology, *edited by Elmer H.Marth and James L.Steele*

85. Lactic Acid Bacteria: Microbiology and Functional Aspects, Second Edition, Revised and Expanded, *edited by Seppo Salminen and Atte von Wright*

86. Handbook of Vegetable Science and Technology: Production, Composition, Storage, and Processing, *edited by D.K.Salunkhe and S.S.Kadam*

87. Polysaccharide Association Structures in Food, *edited by Reginald H.Walter*

88. Food Lipids: Chemistry, Nutrition, and Biotechnology, *edited by Casimir C. Akoh and David B.Min*

89. Spice Science and Technology, *Kenji Hirasa and Mitsuo Takemasa*

90. Dairy Technology: Principles of Milk Properties and Processes, *P.Walstra, T. J.Geurts, A.Noomen, A.Jellema, and M.A.J.S.van Boekel*

91. Coloring of Food, Drugs, and Cosmetics, *Gisbert Otterstätter*

92. *Listeria,* Listeriosis, and Food Safety: Second Edition, Revised and Expanded, *edited by Elliot T.Ryser and Elmer H.Marth*

93. Complex Carbohydrates in Foods, *edited by Susan Sungsoo Cho, Leon Prosky, and Mark Dreher*

94. Handbook of Food Preservation, *edited by M.Shafiur Rahman*

95. International Food Safety Handbook: Science, International Regulation, and Control, *edited by Kees van der Heijden, Maged Younes, Lawrence Fishbein, and Sanford Miller*

96. Fatty Acids in Foods and Their Health Implications: Second Edition, Revised and Expanded, *edited by Ching Kuang Chow*

97. Seafood Enzymes: Utilization and Influence on Postharvest Seafood Quality, *edited by Norman F.Haard and Benjamin K.Simpson*

98. Safe Handling of Foods, *edited by Jeffrey M.Farber and Ewen C.D.Todd*

99. Handbook of Cereal Science and Technology: Second Edition, Revised and Expanded, *edited by Karel Kulp and Joseph G.Ponte, Jr.*

100. Food Analysis by HPLC: Second Edition, Revised and Expanded, *edited by Leo M.L.Nollet*

101. Surimi and Surimi Seafood, *edited by Jae W.Park*

102. Drug Residues in Foods: Pharmacology, Food Safety, and Analysis, *Nickos A. Botsoglou and Dimitrios J.Fletouris*

103. Seafood and Freshwater Toxins: Pharmacology, Physiology, and Detection, *edited by Luis M.Botana*

104. Handbook of Nutrition and Diet, *Babasaheb B.Desai*

105. Nondestructive Food Evaluation: Techniques to Analyze Properties and Quality, *edited by Sundaram Gunasekaran*

106. Green Tea: Health Benefits and Applications, *Yukihiko Hara*

107. Food Processing Operations Modeling: Design and Analysis, *edited by Joseph Irudayaraj*

108. Wine Microbiology: Science and Technology, *Claudio Delfini and Joseph V. Formica*

109. Handbook of Microwave Technology for Food Applications, *edited by Ashim K. Datta and Ramaswamy C.Anantheswaran*

110. Applied Dairy Microbiology: Second Edition, Revised and Expanded, *edited by Elmer H.Marth and James L.Steele*

111. Transport Properties of Foods, *George D.Saravacos and Zacharias B. Maroulis*

112. Alternative Sweeteners: Third Edition, Revised and Expanded, *edited by Lyn O'Brien Nabors*

113. Handbook of Dietary Fiber, *edited by Susan Sungsoo Cho and Mark L.Dreher*

114. Control of Foodborne Microorganisms, *edited by Vijay K.Juneja and John N. Sofos*

115. Flavor, Fragrance, and Odor Analysis, *edited by Ray Marsili*

116. Food Additives: Second Edition, Revised and Expanded, *edited by A.Larry Branen, P.Michael Davidson, Seppo Salminen, and John H.Thorngate, III*

117. Food Lipids: Chemistry, Nutrition, and Biotechnology: Second Edition, Revised and Expanded, *edited by Casimir C.Akoh and David B.Min*

118. Food Protein Analysis: Quantitative Effects on Processing, *R.K.OwusuApenten*

119. Handbook of Food Toxicology, *S.S.Deshpande*

120. Food Plant Sanitation, *edited by Y.H.Hui, Bernard L.Bruinsma, J.Richard Gorham, Wai-Kit Nip, Phillip S.Tong, and Phil Ventresca*

Additional Volumes in Preparation

Characterization of Cereals and Flours: Properties, Analysis, and Applications, *edited by Gönül Kaletunç and Kenneth J.Breslauer*

Postharvest Physiology and Pathology of Vegetables: Second Edition, Revised and Expanded, *edited by Jerry A.Bartz and Jeffrey K.Brecht*

Handbook of Food Enzymology, *edited by John R.Whitaker, Alphons G.J. Voragen, and Dominic W.S.Wong*

International Handbook of Foodborne Pathogens, *edited by Jeffrey W. Bier and Marianne D.Miliotis*

Physical Chemistry of Foods, *Pieter Walstra*

FOOD PLANT SANITATION

edited by
Y.H.Hui
Science Technology System
West Sacramento, California, U.S.A
Bernard L.Bruinsma
Innovative Cereal Systems
Wilsonville, Oregon, U.S.A
J.Richard Gorham
Consultant
Xenia, Ohio, U.S.A
Wai-Kit Nip
University of Hawaii at Manoa
Honolulu, Hawaii, U.S.A.
Phillip S.Tong
California Polytechnic State University
San Luis Obispo, California, U.S.A.
Phil Ventresca
E.S.I. Qual International
Stoughton, Massachusetts, U.S.A.

MARCEL DEKKER, INC.
NEW YORK • BASEL

ISBN 0-203-91056-7 Master e-book ISBN

ISBN: 0-8247-0793-1 (Print Edition)

Headquarters
Marcel Dekker, Inc.
270 Madison Avenue, New York, NY 10016
tel: 212–696–9000; fax: 212–685–4540
This edition published in the Taylor & Francis e-Library, 2005.

To purchase your own copy of this or any of Taylor & Francis or Routledge's collection of thousands of eBooks please go to www.eBookstore.tandf.co.uk.

Eastern Hemisphere Distribution
Marcel Dekker AG
Hutgasse 4, Postfach 812, CH-4001 Basel, Switzerland
tel: 41–61–260–6300; fax: 41–61–260–6333

World Wide Web
http://www.dekker.com

The publisher offers discounts on this book when ordered in bulk quantities. For more information, write to Special Sales/Professional Marketing at the headquarters address above.

Preface

As food professionals, we have noticed the monumental increase in awareness of food safety in the past decade. Professionally, this awareness manifests itself in many ways, with educational materials (print, Internet, videos, etc.) heading the list. Reference books on food safety are especially useful.

This book has three important goals: (1) to present the fundamental principles of food plant sanitation and their applications in the food industry; (2) to provide professionals with basic, hands-on information for the day-to-day operations in a food processing plant, (3) to review some of the industry's most recent developments.

To achieve these goals, the book covers nine major areas: federal and state regulations and guidelines, major biological and nonbiological contaminants, cleaning a food plant, sanitation and worker safety, housekeeping, product quality, commodity processing, retail food sanitation, and enforcement.

The book covers both basic sanitation practices and the latest information on the Hazard Analysis Critical Control Point (HACCP) program. However, HACCP is discussed as a peripheral consideration. Before one considers HACCP, one must make sure that each food processing plant has put in place an acceptable sanitation program in principle and in practice: Have the incoming raw materials been checked? Is there water (or debris) on the floor of the operations room? Does every worker wear a hairnet when handling food products or ingredients? Is the cold storage room maintained at the required temperature? Are there rat and bird droppings in the plant? There are these questions and more to consider.

This book differs from other food sanitation books in that its presentation is a compilation of multiple perspectives from more than 30 government, academia, and industry food safety experts. They cover more than 40 topics in food plant sanitation and HACCP and present the latest developments in retail food processing and sanitation. Last, but not least, the book provides examples of the enforcement activities of the U.S. Food and Drug Administration (FDA) in relation to food plant sanitation. The discussion is accompanied by a reproduction of the FDA's *Handbook of Food Defect Action Levels* in the appendix. In sum, the approach for this book is unique and makes it an essential reference for the food safety and quality professional.

The editorial team thanks all the contributors for sharing their experience in their fields of expertise. They are the people who made this book possible. We hope you enjoy and benefit from the fruits of their labor.

We know how hard it is to develop the content of a book. However, we believe that the production of a professional book of this nature is even more difficult. We thank the production team at Marcel Dekker, Inc., and express our appreciation to Ms. Theresa Stockton, coordinator of the entire project.

Y.H.Hui
Bernard L.Bruinsma
J.Richard Gorham
Wai-Kit Nip
Phillip S.Tong
Phil Ventresca

Contents

Contributors

Franklin Arthur Grain Marketing and Production Research Center, U.S. Department of Agriculture, Manhattan, Kansas, U.S.A.
Daniel W.Bena PepsiCo Beverages International, Purchase, New York, U.S.A.
Henry C.Carsberg Henry C.Carsberg & Associates, Anacortes, Washington, U.S.A.
Philip Cheng-Ming Chang Department of Food Science, National Taiwan Ocean University, Keelung, Taiwan
Tin Shing Chao Hawaii Occupational Safety and Health Division, U.S. Department of Labor, Honolulu, Hawaii, U.S.A.
T.C.Chen Poultry Science Department, Mississippi State University, Mississippi State, Mississippi, U.S.A.
Robert M.Corrigan RMC Pest Management Consulting, Richmond, Indiana, U.S.A.
P.Michael Davidson Department of Food Science and Technology, University of Tennessee, Knoxville, Tennessee, U.S.A.
Sharon L.Friedman Center for Veterinary Medicine, U.S. Food and Drug Administration, Laurel, Maryland, U.S.A.
John S.Gecan* Microanalytical Branch, U.S. Food and Drug Administration, Washington, D.C., U.S.A.
John B.Gingrich Department of Entomology and Applied Ecology, University of Delaware, Newark, Delaware, U.S.A.
J.Richard Gorham Consultant, Xenia, Ohio, U.S.A.
Jerry W.Heaps General Mills, Minneapolis, Minnesota, U.S.A.
Y.H.Hui Science Technology System, West Sacramento, California, U.S.A.
Wen-zhe Hwang Department of Food Science, National Chung Hsing University, Taichung, Taiwan
A.Jay Johnson Ringger Foods, Inc., Gridley, Illinois, U.S.A.
Sheng-dun Lin Department of Food and Nutrition, Hungkuang Institute of Technology, Taichung, Taiwan
Andrew Lock Safeline, Inc., Tampa, Florida, U.S.A.
Linda Mason Department of Entomology, Purdue University, West Lafayette, Indiana, U.S.A.
Sharon V.Mowery Department of Entomology, Kansas State University, Manhattan, Kansas, U.S.A.
Michael A.Mullen Grain Marketing and Production Research Center, Agricultural Research Service, U.S. Department of Agriculture, Manhattan, Kansas, U.S.A.
Wai-Kit Nip Department of Molecular Biosciences and Bioengineering, University of Hawaii at Manoa, Honolulu, Hawaii, U.S.A.
Richard D.O'Brien Fats and Oils Consultant, Piano, Texas, U.S.A.
Alan R.Olsen Microanalytical Branch, U.S. Food and Drug Administration, Washington, D.C., U.S.A.

Thomas E.Osterberg General Mills, Golden Valley, Minnesota, U.S.A.
Andi Shau-mei Ou Department of Food Science, National Chung Hsing University, Taichung, Taiwan

* Retired.

Thomas W.Phillips Department of Entomology and Plant Pathology, Oklahoma State University, Stillwater, Oklahoma, U.S.A.
Alfred J.St.Cyr AIB International, Manhattan, Kansas, U.S.A.
Cheryl Santucci Ringger Foods, Inc., Gridley, Illinois, U.S.A.
Peggy Stanfield Dietetic Resources, Twin Falls, Idaho, U.S.A.
Bhadriraju Subramanyam Department of Grain Science and Industry, Kansas State University, Manhattan, Kansas, U.S.A.
Michael D.Toews Department of Grain Science and Industry, Kansas State University, Manhattan, Kansas, U.S.A.
Sherri B.Turnipseed Animal Drugs Research Center, U.S. Food and Drug Administration, Denver, Colorado, U.S.A.
Gregory A.Umland Ringger Foods, Inc., Gridley, Illinois, U.S.A.
Chun-Shi Wang Institute of Food Science and Technology, National Taiwan University, Taipei, Taiwan
Ping-Lieh Thomas Wang Fieldale Farms Corporation, Baldwin, Georgia, U.S.A.
Yu-Ping Wei Institute of Food Science and Technology, National Taiwan University, Taipei, Taiwan
James Swi-Bea Wu Institute of Food Science and Technology, National Taiwan University, Taipei, Taiwan
Michael L.Zimmerman U.S. Food and Drug Administration, Albuquerque, New Mexico, U.S.A.

FOOD PLANT SANITATION

MARCEL DEKKER, INC.

NEW YORK • BASEL

1
An Overview of FDA's Food Regulatory Responsibilities

Y.H.HUI
Science Technology System, West Sacramento, California, U.S.A.

This chapter provides a summary of the legal requirements affecting manufacture and distribution of food products within and those imported into the United States. The last chapter in this book further expands the data. The United States Food and Drug Administration (FDA) has provided a description of these requirements to the public at large. The information has been translated into several languages and it is reproduced below with some minor updating by the author.

The FDA regulates all food and food-related products, except commercially processed egg products and meat and poultry products, including combination products (e.g., stew, pizza), containing 2% or more poultry or poultry products or 3% or more red meat or red meat products, which are regulated by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS). Fruits, vegetables, and other plants are regulated by the that department's Animal and Plant Health Inspection Service (APHIS) to prevent the introduction of plant diseases and pests into the United States. The voluntary grading of fruits and vegetables is carried out by the Agricultural Marketing Service (AMS) of the USDA.

All nonalcoholic beverages and wine beverages containing less than 7% alcohol are the responsibility of FDA. All alcoholic beverages, except wine beverages (i.e., fermented fruit juices) containing less than 7% alcohol, are regulated by the Bureau of Alcohol, Tobacco, and Firearms of the Department of Treasury.

In addition, the Environmental Protection Agency (EPA) regulates pesticides. The EPA determines the safety of pesticide products, sets tolerance levels for pesticide residues in food under a section of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and publishes directions for the safe use of pesticides. It is the responsibility of FDA to enforce the tolerances established by EPA.

Within the United States, compliance with the FD&C Act is secured through periodic inspections of facilities and products, analyses of samples, educational activities, and legal proceedings. A number of regulatory procedures or actions are available to FDA to enforce the FD&C Act and thus help protect the public's health, safety, and well-being.

Adulterated or misbranded food products may be voluntarily destroyed or recalled from the market by the shipper, or may be seized by U.S. marshals on orders obtained by FDA from federal district courts. Persons or firms responsible for violation may be prosecuted in the federal courts and if found guilty may be fined and/or imprisoned. Continued violations may be prohibited by federal court injunctions. The violation of an

injunction is punishable as contempt of court. Any or all types of regulatory procedures may be employed, depending upon the circumstances.

A recall may be voluntarily initiated by the manufacturer or shipper of the food commodity or at the request of FDA. Special provisions on recalls of infant formulas are in the FD&C Act. While the cooperation of the producer or shipper with FDA in a recall may make court proceedings unnecessary, it does not relieve the person or firm from liability for violations.

It is the responsibility of the owner of the food in interstate commerce to ensure that the article complies with the provisions of the FD&C Act, the Fair Packaging and Labeling Act (FPLA), and their implementing regulations. In general, these acts require that the food product be a safe, clean, wholesome product and its labeling be honest and informative.

The FD&C Act gives FDA the authority to establish and impose reasonable sanitation standards on the production of food. The enclosed copy of Title 21, Code of Federal Regulations, Part 110 (21 CFR 110) contains the current good manufacturing practice (GMP) regulations for manufacturing, packing, and holding human food concerning personnel, buildings and facilities, equipment, and product process controls, which, if scrupulously followed, may give manufacturers some assurance that their food is safe and sanitary. In 21 CFR 110.110, FDA recognizes that it is not possible to grow, harvest, and process crops that are totally free of natural defects. Therefore, the agency has published the defect actions for certain food products. These defect action levels are set on the basis of no hazard to health. In the absence of a defect action level, regulatory decisions concerning defects are made on a case-by-case basis.

The alternative to establishing natural defect levels in food would be to insist on increased utilization of chemical substances to control insects, rodents, and other natural contaminants. The FDA has published “action levels” for poisonous or deleterious substances to control levels of contaminants in human food and animal feed. However, a court in the United States invalidated FDA’s action levels for poisonous or deleterious substances on procedural grounds. In the interim we are using their “Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed” as guidelines which do not have the force and effect of law. The Agency has made it clear that action levels are procedural guidelines rather than substantive rules.

The FDA does not approve, license, or issue permits for domestic products shipped in interstate commerce. However, all commercial processors, whether foreign or domestic, of thermally processed low-acid canned foods (LACFs) packaged in hermetically sealed containers, or of acidified foods (AF-), are required by regulations to register each processing plant. In addition, each process for a LACF or AF must be submitted to FDA and accepted for filing by FDA before the product can be distributed in interstate commerce.

A low-acid food is defined as any food, other than alcoholic beverages with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85. Many canned food products are LACF products, and packers are therefore subject to the registration and processing filing requirements. The only exceptions are tomatoes and tomato products having a finished equilibrium pH less than 4.7. An acidified food is a low-acid food to which acid(s) or acid food(s) are added resulting in a product having a finished equilibrium pH of 4.6 or below.

The FDA's LACF regulations require that each hermetically sealed container of a low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. The required identification shall identify, in code, the establishment where the product is packed, the product contained therein, the year and day of the pack, and the period during the day when the product was packed [21 CFR 113.60(c)]. There is no requirement that a product be shipped from the United States within a stipulated period of time from the date of manufacture. If a LACF or AF is properly processed, it would not require any special shipping or storage conditions.

Regulations require that scheduled processes for LACFs shall be established by qualified persons having expert knowledge of thermal processing requirements for lowacid foods in hermetically sealed containers and having adequate facilities for making such determinations (21 CFR 113.83). All factors critical to the process are required to be specified by the processing authority in the scheduled process. The processor of the food is required to control all critical factors within the limits specified in the scheduled process.

The FDA has the responsibility to establish U.S. identity, quality, and fill of container standards for a number of food commodities. Food standards, which essentially are definitions of food content and quality, are established under provisions of the FD&C Act. Standards have been established for a wide variety of products. These standards give consumers some guarantee of the kind and amount of major ingredients in these products. A food which purports to be a product for which a food standard has been promulgated must meet that standard or it may be deemed to be out of compliance and, therefore, subject to regulatory action.

Amendments to the FD&C Act establish nutrient requirements for infant formulas and provide FDA authority to establish good manufacturing practices and requirements for nutrient quantity, nutrient quality control, recordkeeping, and reporting. Under these amendments, FDA factory inspection authority was expanded to manufacturer's records, quality control records, and test results necessary to determine compliance with the FD& C Act.

The FDA has mandated Hazard Analysis Critical Control Point (HACCP) procedures for several food categories including seafood and selected fruit and vegetable products. Such procedures assure safe processing, packaging, storage, and distribution of both domestic and imported fish and fishery products and fruit and vegetable products. The HACCP system allows food processors to evaluate the kinds of hazards that could affect their products, institute controls necessary to keep hazards from occurring, monitor the performance of the controls, and maintain records of this monitoring as a matter of routine practice. The purpose is to establish mandatory preventative controls to ensure the safety of the products sold commercially in the United States and exported abroad. The FDA will review the adequacy of HACCP controls in addition to its traditional inspection activities.

The food labeling regulations found in 21 CFR 101 and 105 contain the requirements which when followed result in honest and informative labeling of food. Mandatory labeling of food includes a statement of identity (common or usual name of the product—21 (CFR 101.3); a declaration of net quantity of contents (21 CFR 101.105); the name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5); and, if

fabricated from two or more ingredients, each ingredient must be listed in descending order of predominance by its common or usual name (21 CFR 101.4 and 101.6). Spices, flavoring, and some coloring, other than those sold as such, may be designated as spices, flavoring, and coloring without naming each. However, food containing a color additive that is subject to certification by FDA must be declared in the ingredients statement as containing that color.

On January 6, 1993, the FDA issued final rules concerning food labeling as mandated by the Nutrition Labeling and Education Act (NLEA). These rules, which are included in the enclosed food labeling booklet, significantly revise many aspects of the existing food labeling regulations, mainly nutrition labeling and related claims for food. The NLEA regulations apply only to domestic food shipped in interstate commerce and to food products offered for import into the United States. The labeling of food products exported to a foreign country must comply with the requirements of that country.

If the label on a food product fails to make all the statements required by the FD& C Act, the FPL A, and the regulations promulgated under these acts, or if the label makes unwarranted claims for the product, the food is deemed to be misbranded. The FD&C Act provides for both civil and criminal action for misbranding. The FPL A provides for seizure and injunction. The legal responsibility for full compliance with the terms of each of these acts and their regulations, as applied to labels, rests with the manufacturer, packer, or distributor when the goods are entered into interstate commerce. The label of a food product may include the Universal Product Code (UPC) as well as a number of symbols which signify that (1) the trademark is registered with the U.S. Patent Office; (2) the literary and artistic content of the label is protected against infringement under the copyright laws of the United States; and (3) the food has been prepared and/or complies with dietary laws of certain religious groups. It is important to note that neither the UPC nor any of the symbols mentioned are required by, or are under the authority of, any of the acts enforced by the U.S. Food and Drug Administration.

The FD&C Act requires premarket approval for food additives (substances whose use results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food). The approval process involves a very careful review of the additive's safety for its intended use. Following the approval of a food additive, a regulation describing its use is published in the Code of Federal Regulations. As defined in the CFR, the term *safe* or *safety* "means there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Premarket clearance under the FD&C Act does assure that the risk of adverse effects occurring due to a food additive is at an acceptably small level.

The FDA's regulation of dietary supplements is under the authority of the Dietary Supplements Health and Education Act of 1994. It ensures that the products are safe and properly labeled and that any disease or health-related claims are scientifically supported. The legal provisions governing the safety of dietary supplements depend on whether the product is legally a food or a drug. In either instance the manufacturer is obligated to produce a safe product. Premarket safety review by FDA is required for new drugs.

The label of a dietary supplement is to state what the product contains, how much it contains, how it should be used, and precautions necessary to assure safe use with all other information being truthful and not misleading. If the dietary supplement is a food, a review of any disease or health-related claim is conducted under the NLEA health claim provisions.

This book presents an important aspect of the stated requirements: the sanitation of an establishment that manufactures and distributes processed food.

2
Foodborne Diseases in the United States

P.MICHAEL DAVIDSON
University of Tennessee, Knoxville, Tennessee, U.S.A.

I. INTRODUCTION

While food is an indispensable source of nutrients for humans, it is also a source of microorganisms. Microorganisms in foods may be one of three types: beneficial, spoilage, or pathogenic. Beneficial microorganisms include those that produce new foods or food ingredients through fermentations (e.g., lactic acid bacteria and yeasts) and probiotics. The second type are those that cause spoilage of foods. Spoilage may be defined as an undesirable change in the flavor, odor, texture, or color of food caused by growth of microorganisms and ultimately the action of their enzymes. The final group are those microorganisms that cause disease. These microorganisms may grow in or be carried by foods. There are two types of pathogenic, or disease-causing, microorganisms: those causing intoxications and those causing infections. Intoxications are the result of a microorganism growing and producing toxin in a food. It is the toxin that causes the illness. Infections are illnesses that result from ingestion of a microorganism. Infectious microorganisms may cause illness by production of enterotoxins in the gastrointestinal tract or adhesion and/or invasion of the tissues. There are various types of pathogenic microorganisms that may be transmitted by foods including bacteria, viruses, protozoa, and helminths (Table 1). Certain molds (fungi) may also produce toxins (mycotoxins) in foods that are potentially toxic, carcinogenic, mutagenic, or teratogenic to humans and animals. Sources of these pathogenic microorganisms include soil, water, air, animals, plants, and humans.

The U.S. Centers for Disease Control and Prevention (CDC) estimates that there are 6.5 to 76 million cases of foodborne illness per year in the United States [1]. The actual number of confirmed cases documented by CDC is much lower (Table 2). The reason for the difference in estimated and confirmed cases is that foodborne illnesses are

Table 1 Primary Microbial Pathogens Associated with Food Products

Bacteria	Protozoa	Nematodes	Viruses
Aeromonas hydrophila	*Cryptosporidium parvum*	*Trichinella spiralis*	Hepatitis A
Bacillus cereus	*Cyclospora cayetanensis*		SRSV

Campylobacter jejuni	*Giardia lamblia*	Calicivirus
Clostridium botulinum	*Toxoplasma gondii*	Astrovirus
Clostridium perfringens		
Escherichia coli		
Listeria monocy to genes		
Salmonella		
Shigella		
Vibrio cholerae		
Vibrio parahaemolyticus		
Vibrio vulnificus		
Yersinia enterocolitica		

often self-limited and non-life threatening. Therefore, affected persons often do not seek medical attention and their illnesses are not documented. To improve foodborne illness surveillance, CDC began a program in 1996 called *FoodNet*. Initially, surveillance included laboratory-confirmed cases of *Campylobacter, Escherichia coli* O157, *Listeria monocytogenes, Salmonella, Shigella, Vibrio,* and *Yersinia enterocolitica* infections by clinical laboratories in Minnesota, Oregon, and selected counties in California, Connecticut, and Georgia. In 1997, surveillance was expanded to include *Cryptosporidium* and *Cyclospora cayetanensis*. By 2000, the surveillance area expanded to include all of Connecticut and Georgia and counties in Maryland, New York, and Tennessee. The FoodNet surveillance population is 29.5 million persons and represents 10.8% of the U.S. population. Cases represent isolation of a pathogen from a person by a clinical laboratory and are not necessarily linked to food sources. Data for the entire period of FoodNet surveillance are shown in Table 3.

Disease incidence is related to susceptibility of the consuming population. Subpopulations at increased risk for foodborne illness include individuals under 5 years of age,

Table 2 Confirmed Cases and Deaths in the United States as Reported by the United States Centers for Disease Control and Prevention, 1973–1997

Bacteria	Outbreaks	Cases	Deaths
Bacillus cereus	93	2,247	0
Campylobacter	106	2,821	5
Clostridium botulinum	304	683	59
Clostridium perfringens	287	18,807	13
Escherichia coli	103	4,691	12
Listeria monocytogenes	—	323	70
Salmonella	1,696	109,651	139

Shigella	172	20,742	4
Staphylococcus aureus	459	20,339	5
Vibrio species	46	1,561	14

Source: Refs. 6, 7, 8.

Table 3 Illnesses per 100,000 Population Detected by the Centers for Disease Control and Prevention's Foodborne Active Surveillance Network (FoodNet) in the United States, 1996–2000

Microorganism	1996	1997	1998	1999	2000	Change
Campylobacter	23.5	25.2	21.4	17.5	20.1	−3.4
Crypto sporidium	NR	3.7	2.9	1.8	2.4	—
Cyclospora	NR	0.4	0.1	0.1	0.1	—
Escherichia coli O157	2.7	2.3	2.8	2.1	2.9	+0.2
Listeria monocytogenes	0.5	0.5	0.6	0.5	0.4	−0.1
Salmonella	14.5	13.6	12.3	13.6	12.0	−2.5
Shigella	8.9	7.5	8.5	5.0	11.6	+2.7
Vibrio	0.2	0.3	0.3	0.2	0.3	+0.1
Yersinia	1.0	0.9	1.0	0.8	0.5	−0.5

Source: Ref. 12.

over 60 years of age, immunocompromised individuals, those with chronic diseases, AIDS patients, and pregnant females. The immunocompromised include persons receiving immune suppressive drug treatments or antibiotic therapies and organ transplant patients. Chronic diseases predisposing persons to foodborne illness may include diabetes; asthma; and heart, liver, and intestinal diseases [1].

II. BACTERIAL FOODBORNE DISEASES

A. *Aeromonas hydrophila*

This microorganism occurs widely in nature, especially in water. As a result of its occurrence in water, it is also found in foods. The microorganism has been isolated from raw milk, cheese, ice cream, poultry, meats, fresh vegetables, finfish, oysters, and other seafoods [2]. *Aeromonas hydrophila* is a facultatively anaerobic, gram-negative rod that is motile with a polar flagellum. The microorganism has a temperature range of 4–5 °C up to 42–43°C with an optimum of 28°C [2]. The pH range is 4.5–9.0 and the maximum concentration of salt for growth is 4%. It is pathogenic to fish, turtles, frogs, snails, alligators, and humans. Evidence suggests that *A. hydrophila* causes gastroenteritis in humans and infections in persons immunocompromised by treatment for cancer. *Aeromonas hydrophila* forms hemolysins, enterotoxins, and cytotoxins, all of which

could be related to its pathogenicity. The microorganism has a $D_{48°c}$ of 5.2 min in saline and 4.3 min in raw milk with a z value of 6.21°C [2].

B. *Bacillus cereus*

Bacillus cereus is a gram-positive, aerobic, sporeforming, rod-shaped bacteria. Most strains have an optimum temperature for growth of 30°C and a range of 15–55°C. Some strains are psychrotrophic and able to grow at 4–6°C. The normal habitat and/or distribution for *B. cereus* is dust, water, and soil. The bacterium may be found in many foods and food ingredients. Some other species of *Bacillus* have been associated with foodborne illness, including *B. thuringiensis, B. subtilis, B. licheniformis,* and *B. pumilis* [3].

Because the microorganism is a sporeformer, it is heat resistant. Most spores are of moderate heat resistance ($D_{121°C}$ of 0.3 min) but some have high heat resistance ($D_{121°C}$ of 2.35) [3, 4]. The pH range for the microorganism is 5.0–8.8 and the water activity minimum is 0.93 depending upon acidulant and humectant, respectively.

B*acillus cereus* produces two types of gastroenteritis: emetic and diarrheal. The diarrheal syndrome (also called *C. perfringens*-like) is caused by an enterotoxin that is a vegetative growth metabolite formed in the intestine. The toxin is a protein (50 kDa) that is heat labile (56°C, 5 min) and trypsin sensitive. The illness onset for this syndrome is 8–16 hr and it has a duration of 6–24 hr. The symptoms include nausea, abdominal cramps, and diarrhea. Foods associated with the diarrheal syndrome include cereal dishes (corn and corn starch), mashed potatoes, vegetables, minced meat, liver sausage, meat loaf, milk and milk products, some rice dishes, puddings, and soups. The number of cells required for outbreak of this type of syndrome is 5–7 log CPU (colony forming unit) per gram of food [3].

The emetic syndrome (also called *S. aureus*-like) is caused by a cyclic polypeptide toxin which is much smaller (5000 Da) and may be preformed in certain foods [3]. As opposed to the diarrheal toxin, the emetic toxin is heat (>90 min at 121 °C) and trypsin stable. The illness onset is very short, from 1 to 6 hr and the duration is <24 hr. Symptoms include nausea and vomiting (more severe than diarrheal). The illness is not generally fatal, although there was a report of liver failure associated with the illness [5]. Foods associated with *B. cereus* emetic syndrome include primarily boiled or fried rice along with pasta, noodles, mashed potatoes, and vegetable sprouts. The number of cells required for an outbreak is ca. 8 log CFU/g.

From 1983 to 1997, there were 93 confirmed outbreaks and 2247 cases of *B. cereus* foodborne illness [6–8] in the United States. Most outbreaks involved Chinese food or fried rice.

C. *Campylobacter*

Campylobacter jejuni was first recognized in 1913 as a disease in sheep and cattle. It was originally called *Vibrio fetus.* The human pathogens that are foodborne include *C. jejuni, C. coli, C. lari,* and *C. upsaliensis* [9]. The most common foodborne pathogens (>90% cases) are *C. jejuni, C. coli,* and *C. lari*. *Campylobacter* is a gram-negative,

nonsporeforming, vibroid (helical, S-shaped, gull wing-shaped) rod (0.2–0.5 μm×1.5–5.0 μm). It is motile by a single polar flagellum. The microorganism is microaerophilic requiring 5% O_2 and 10% CO_2 [9]. The temperature for growth ranges from 30 to 45.5°C and its optimum is 37–42°C. The microorganism is associated with warm-blooded animals, especially poultry, and can be found in raw milk, insects, and water.

C*ampylobacter jejuni* is not extremely tolerant to environmental stresses. It survives to a maximum sodium chloride level of <3.5% and is inhibited by 2.0%. It has a very low heat resistance. Heat injury occurs at 46°C and inactivation at 48°C. The microorganism has a $D_{55°C}$ of 0.64–1.09 min in 1% peptone and 2.12–2.25 min in chicken [4]. The pH range for growth of the microorganism is 4.9–9.0. *Campylobacter jejuni* survives for 2 weeks in milk at 4°C or water and meat at −25°C.

C*ampylobacter jejuni* causes a gastroenteritis called campylobacteriosis that has an onset time of 2–5 days and has primary symptoms of severe diarrhea and abdominal pain. Fever and headache may also be present. The duration is <1 week without treatment and the mortality rate is very low. An infectious dose may be as low as 500 cells [9]. The primary targets for *C. jejuni* are infants and young children under 5 years and those 20–40 years old. Complications and sequelae of campylobacteriosis include relapse (5–10%), bacteremia, acute appendicitis, meningitis, urinary tract infections, endocarditis (primarily *C. fetus*), peritonitis, Reiter's syndrome (see Sec. II.I) and Guillain-Barré Syndrome. The latter occurs in 0.2–2 cases per 1000 cases of campylobacteriosis and involves paralysis and demyelination of nerves [10]. The mechanism of pathogenicity is not entirely clear but may involve attachment, invasion of intestinal epithelia, and/or enterotoxin formation.

Most cases of campylobacteriosis are sporadic, i.e., not associated with an outbreak. There have been few outbreaks documented by CDC. From 1973–1987, there were 53 outbreaks, 1547 cases, and two deaths in the United States [6]. From 1988–1997, there were also 53 outbreaks with 1274 cases and three deaths [7, 8]. While there are a low number of confirmed cases of campylobacteriosis, the epidemiological estimate of cases in the United States is 2.5 million annually [11], making it the most prevalent food poisoning microorganism. The FoodNet surveillance system revealed that campylobacteriosis occurs at a rate similar to or higher than salmonellosis (see Table 3) [12]. Foods involved in outbreaks of campylobacteriosis have primarily been raw milk. Up to 70% of sporadic cases are associated with cross-contaminated or undercooked or raw poultry. Crosscontamination occurs due to transfer of the microorganism to uncooked foods via contamination of surfaces or food workers' hands.

D. *Clostridium botulinum*

The illness botulism was first recognized around 900 AD. Emperor Leo VI of Byzantium forbade consumption of blood sausage because of its relationship to illness [13]. Before it was recognized as a microbial illness, botulism was termed "sausage poisoning" as the illness and deaths were first associated with sausage. In fact, the term *botulus* is Latin for sausage. The microorganism associated with the illness was first identified in 1897 by E.Van Ermingem and named *Bacillus botulinus*.

The microorganism is a motile gram-positive rod that is a strict anaerobe. It is a

sporeforming bacterium with oval to cylindrical, terminal to subterminal spores. There are four groups of *C. botulinum* (I, II, III, IV) based on physiological and phylogenetic relationships containing seven strains that produce antigenically different types of toxins (A through G) [14]. Groups I and II, types A, B, and E are most common in human disease. The habitat of the microorganism is soil or water. Type A is often found in western U.S. soils, while type B is more often found in the eastern United States. Type E is primarily of marine origin.

The optimal temperature for growth of *C. botulinum* is 30–40°C. Temperature ranges depend upon type, with A, B, and F at 10–50°C and type E at 3.3–45°C. The spore heat resistance of *C. botulinum* is very high. Type A spores have a maximum identified $D_{121°C}$ of 0.21 min in phosphate buffer, pH 7. The heat resistance of type A *C. botulinum* spores in other heating media is shown in Table 4. Type B spores (proteolytic, group I) have a $D_{110°C}$ of 1.19–2.0 min in phosphate buffer, pH 7.0, while nonproteolytic (group II) strains have a $D_{82.2°C}$ of 1.49–73.61 min. Type E spores are the least resistant, with a $D_{80°C}$ of 0.78 min in oyster homogenate and a $D_{82.2°C}$ of 0.49–0.74 min in crab meat [4]. The pH minima for types A, B, and E are within 4.7–4.8. The water activity minima are 0.94 for types A and B and 0.97 for type E.

Table 4 Heat Resistance of *Clostridium botulinum* Strain 62A (Type A) Spores at 110°C

Product	D value (min)	z value (°C)
Asparagus, canned, pH 5.04	1.22	8.8
Asparagus, canned, pH 5.42	0.61	7.9
Corn, canned	1.89	11.6
Macaroni Creole, pH 7.0	2.48	8.8
Peas, puree	1.98	8.3
Peas, canned, pH 5.24	0.61	7.6
Peas, canned, pH 6.0	1.22	7.5
Spanish rice, pH 7.0	2.37	8.6
Spinach, canned, pH 5.37	0.61	8.4
Spinach, canned, pH 5.39	1.74	10.0
Squash	2.01	8.2
Tomato juice, pH 4.2	1.50–1.59[a]	9.43
Tomato juice, pH 4.2	0.92–0.98	—
Phosphate buffer, M/15, pH 7.0	0.88	7.6
	1.74	10.0
	1.34	9.8
	1.6–1.9	8.1–9.2
	1.01	9.1
Distilled water	1.79	8.5

[a] Strain A16037
Source: Ref. 4.

The foodborne illness termed botulism is an intoxication. The onset time is 12–36 hr, and the symptoms are blurred or double vision, dysphagia (difficulty swallowing), general weakness, nausea, vomiting, dysphonia (confused speech), and dizziness. The intoxication is due to a neurotoxin which first affects the neuromuscular junctions in the head and neck. The toxin causes paralysis which progresses to the chest and extremities. Death occurs when paralysis reaches the muscles of the diaphragm or heart. Duration of the illness can be from 1 day to several months. A high proportion of patients require respiratory therapy. Death occurs without treatment in 3–6 days. The mortality rate was very high (30–65%) in the early part of the 20th century but has been reduced significantly in recent years due to better detection and treatment. The treatment for botulism is administration of an antitoxin. Its success depends upon timing since the toxin binds to myoneural junctions irreversibly.

C*lostridium botulinum* toxins are proteins (150 kDa) produced by the cell as inactive protoxins. These are activated to the toxic form by trypsin or bacterial proteases [14]. *Clostridium botulinum* toxin is one of the most toxic substances known; *C. botulinum* type A produces 30,000,000 mouse LD_{50}/mg. The approximate human LD_{50} is 1 ng/kg. The toxin is absorbed into bloodstream through respiratory mucous membranes or walls of stomach or small intestine. It then enters the peripheral nervous system and attaches at the myoneural junction blocking release of acetylcholine and causing paralysis of the muscle. Heat resistance of the toxin is low, with 5 to 10 min at 80°C (type A) or 15 min at 90°C (type B) required to inactivate.

Because of the seriousness of the illness, incidence statistics for the microorganism have been kept for over 100 years. From 1899–1973, there were 274 outbreaks of botulism, with the highest proportion of associated foods being vegetables, fish and fish products, and fruits. The same trend held in outbreaks from 1983–1992, with approximately 50% associated with vegetables and 19% fish and fish products. From 1988 to 1997, there were 73 outbreaks involving 189 cases of *C. botulinum* food poisoning and 12 deaths (6.3%) [7, 8].

Foodborne botulism outbreaks have traditionally been associated with low-acid canned vegetables and meats and vacuum-packaged fish and seafoods. Most outbreaks or cases associated with low-acid foods are home-preserved. This is most likely due to insufficient heat processing during the home canning procedure. Recent outbreaks have been associated with unique products that are primarily home-preserved products. Consumption of home-canned jalapeno pepper hot sauce (type B toxin), baked potatoes, potato salad/ three bean salad, sauteed onions used to make patty melt sandwiches, garlic or roasted vegetables in oil, home-pickled eggs, and uneviscerated fish have all led to outbreaks. The outbreaks associated with potato salad and baked potato were due to baking the potatoes in aluminum foil followed by severe temperature abuse. The aluminum foil caused the atmosphere between the foil and potato to be anaerobic and allowed growth of the *C. botulinum*. Two of the most famous commercial outbreaks involved underprocessed commercially produced soup in 1971 which resulted in 1 death [15] and an outbreak of type E *C. botulinum* in 1963 associated with smoked vacuum-packaged whitefish in Tennessee, Kentucky, and Alabama that resulted in 17 cases and 5 deaths [13].

Infant botulism was first recognized in 1976 in California. Infants less than 1 year old

are susceptible to this illness. In adults, preformed *C. botulinum* toxin must be ingested. In infants, if as few as 10–100 spores of *C. botulinum* are ingested, they may germinate in the intestinal tract and produce toxin [14]. The illness occurs in infants most likely because their intestinal microflora are not established enough to prevent *C. botulinum* colonization. Types A and B are primarily involved. Symptoms of the illness are weakness, loss of head control, and diminished gag reflex. Food sources for the illness are characterized by no terminal heat process and include honey and corn syrup.

E. *Clostridium perfringens*

Clostridium perfringens (formerly *C. welchii)* is a gram-positive, nonmotile, anaerobic rod. Spores are present but difficult to demonstrate. The optimal temperature for growth is 43–46°C (15–50°C range) [16]. *Clostridium perfringens* may be found in soil, water, dust, air, and certain raw foods such as meats and spices. *Clostridium perfringens* spores have a $D_{90°C}$ of 0.015–8.7 min in phosphate buffer, pH 7.0, and a $D_{98.9°C}$ of 31.4 min in beef gravy [4]. The microorganism is not known to survive commercial sterilization for low-acid canned foods. The pH range for growth of *C. perfringens* is 5–9, and the optimum is 6–7. The minimum a_w for growth is 0.95–0.97. The microorganism has a sodium chloride maximum of 7–8% and is inhibited by 5% [16]. *Clostridium perfringens* is relatively sensitive to freezing. At −15°C for 35 days, a greater than 99.9% kill occurs [17].

The gastroenteritis syndrome is an infection and is the result of an enterotoxin formed in the intestine. Onset time is 8–24 hr and primary symptoms include diarrhea and abdominal cramps. The duration is 12–24 hr and the mortality is low. The microorganism produces a protein enterotoxin (35 kDa) during sporulation, and concentration of the toxin is greatest immediately prior to cell lysis. Sporulation occurs at a high rate in the gut. The number of cells to cause an illness is around 6–8 log CPU.

C*lostridium perfringens* accounts for approximately 10% of total food poisoning outbreaks in the United States. From 1988–1997, the microorganism was associated with 97 CDC-confirmed outbreaks involving 6573 cases [7, 8]. This number of cases was second only to *Salmonella*. Foods associated with *C. perfringens* are primarily meat based. Beef, turkey, and ethnic dishes with meat are all risks. A typical food poisoning outbreak scenario would involve a meat dish, especially one with gravy or sauce, that is inadequately heated to completely destroy spores. Inadequately cooling causes germination and outgrowth of the spores. Inadequate reheating (<75°C) allows survival of high numbers of *C. perfringens.* A major problem locale is food service steam tables.

F. *Escherichia coli*

Escherichia coli was first described in 1885 by T.Escherich, who called it *Bacterium coli commune. Escherichia coli* is a gram-negative, nonsporeforming rod which is motile with peritrichous flagella. It is a facultative anaerobe. The temperature growth range is 15 to 45°C and the optimum is 37°C. One source of the pathogenic strains of the microorganism is the gastrointestinal tract of warm-blooded animals. Tolerances are similar to generic *E. coli,* with an optimum pH of 6.5–7 (with the exception of *E. coli*

O157:H7; see following discussion) and water activity minimum of 0.96.

E*scherichia coli* is classified by serotyping based upon the O antigen (heat stable somatic; >170 groups), K antigen (capsular; heat labile somatic; >100 groups), and H antigen (flagellar; 56 groups). There are at least five groups of pathogenic *E. coli,* including enteropathogenic (EPEC), enterotoxigenic (ETEC), enteroinvasive (EIEC), enterohemorrhagic (EHEC), and enteroaggregative (EaggC). Disease manifestations vary with pathogenic type.

Enteropathogenic *E. coli* involves primarily sporadic cases, and outbreaks are usually associated with neonatal or infantile diarrhea. The pathogenesis of neonatal and infantile diarrhea involves colonization of the intestine, adherence, effacement, and invasion. This probably causes most diarrhea. Some strains produce toxins and cytotoxins.

Enterotoxigenic *E. coli* causes traveler's diarrhea. Onset time is 1–3 days and primary symptoms include abdominal cramps, diarrhea, headache, and moderate fever. The duration is 24–72 hr and mortality rate is very low. The microorganism attaches to epithelial cells and colonizes the epithelium. It produces heat-labile (LT) or heat-stable (ST) enterotoxins that cause diarrhea. The heat labile enterotoxin (60°C, 30 min) has two subunits (A and B) and is an adenyl cyclase that increases cAMP. The heat stable enterotoxin (100°C, 15 min) is a low molecular weight (2000 Da) peptide that is a guanylate cyclase. Foods associated with ETEC outbreaks have included Brie cheese, turkey, salad vegetables, and seafood (Table 5) [18].

Enteroinvasive *E. coli* produces no enterotoxins but causes bloody diarrhea, cramps, vomiting, fever, and chills. Onset time is 12–72 hours and the duration may be days to weeks. The disease is similar to dysentery. The microorganism adheres and invades epithelial tissue in the colon causing necrosis. One food involved in an outbreak was Brie cheese contaminated by water used to clean cheesemaking equipment (Table 5).

Enterohemorrhagic *E. coli* includes various serotypes (O4:nonmotile, O11:NM, O26:H11, O45:H2, O111:nonmotile, O111:H8, O104:H21, O145:nonmotile, O157:H7). Primary symptoms of EHEC are diarrhea (often bloody) and abdominal cramps. The microorganism apparently originates in dairy cattle (healthy), deer, sheep, and water and is also transmitted person to person. *Escherichia coli* O157:H7 is unique among the *E. coli* in that it survives low pH very well. The optimal temperature for the microorganism is 30–42°C and it does not grow at 44.5°C. The minimal temperature for growth is 8–10° C. The heat resistance of the microorganism is $D_{64.3°C}$ of 9.6 sec. It survives freezing well.

Table 5 Selected Outbreaks of *Escherichia coli* Associated Foodborne Illnesses

Date	Location	Cases	Type	Food	Notes
1971	Several U.S. states	387	EIEC (O124:B17)	Imported brie and camembert cheese	Source: contaminated water
1982	MI, OR	47	EHEC	Ground beef	Fast-food outlet
1983	DC, IL, WI, GA,	169	ETEC (O27:H20)	Brie cheese	

CO				
1984 NE	34 (4 deaths)	EHEC (O157:H7)	Ground beef	Nursing home
1984 ME	42	ETEC	Seafood	
1990 ND	70 (2 HUS)	EHEC	Roast beef	
1993 WA, ID, NV, CA	582 (5 deaths)	EHEC	Ground beef	Undercooked, served at fastfood outlet
1993 NH	8	ETEC	Salad	
1993 RI	47	ETEC	Salad	
1994 WA, CA	23	EHEC	Salami	
1994 Scotland	100 (1 death)	EHEC	Pasteurized milk	
1995 TN, GA	10	EHEC	Ground beef	Undercooking or cross-contamination
1996 Western U.S.		EHEC	Unpasteurized apple cider	Dropped apples; Deer contamination?
1996 Japan	>6,000	EHEC	Radish sprouts	
1996 Scotland	501 (21 deaths)	EHEC	Cooked meat, gravy	
1997 MI, VA	~80	EHEC	Alfalfa sprouts	
1997 CO	15	EHEC	Ground beef	

Source: Refs. 18, 27, 44–49.

The illness caused by EHEC has an onset time of 12–60 hr. The duration of the illness may be 2–9 days with an average of 4 days. A sequelae that occurs in 2–7% of patients (most often younger age groups and the elderly) is development of hemolytic uremic syndrome (HUS), characterized by hemolytic anemia, thrombocytopenia, and renal failure. Damage to renal endothelial cells is caused by blood clotting in the capillaries of kidney and accumulation of waste products in blood, which results in a need for dialysis. The death rate associated with HUS is 3–5%. Thrombotic thrombocytopenic purpura is an involvement of the central nervous system that occurs primarily in elderly adults. This can lead to blood clots in the brain. The infectious dose of EHEC for susceptible persons is estimated to be as low as 2 to 2000 cells [19]. The site of attack is the colon with bloody diarrhea occurring due to attachment and effacement of cells. Enterohemorrhagic *E. coli* produces Shiga toxin I (Stx I), also known as verocytotoxin or verotoxin (70 kDa), and Shiga toxin II. The former is a protein with two subunits, A and B. Stx I A subunit (32 kDa) cleaves a specific adenine residue from 28S subunit of rRNA and inhibits protein synthesis. Stx I B subunit (5 per molecule, 7.7 kDa each) binds to galactose α-(1–4)-galactose-β-(1–4)-glucose ceramide (Gb3) receptors [19]. Kidney endothelial cells and colon endothelial cells are both high in these receptors. Foods implicated have included

ground beef, roast beef, raw milk, apple cider, meat sandwiches, mayonnaise, lettuce, dry salami, as well as person-to-person transmission and from domestic animals to persons.

Enteroaggregative *E. coli* is a recognized agent of watery mucoid diarrhea, especially in children. It is associated with persistent diarrhea of >14 days. The microorganism is thought to adhere to the intestinal mucosa and produce enterotoxins and cytotoxins [20].

There have been numerous outbreaks of all types of pathogenic *E. coli* (Table 5). Confirmed outbreaks, cases, and deaths associated with unspecified types of pathogenic *E. coli* in 1973–1997 were 103, 4691, and 12, respectively [6–8]. The FoodNet surveillance system has shown that *E. coli* O157 occurs in the United States at a rate of 2.9 cases per 100,000 population (Table 3) [12].

G. *Listeria monocytogenes*

That *L. monocytogenes* may infect humans and animals was recognized as early as the 1910s. However, the microorganism was only recognized as a food-transmitted pathogen in 1981, possibly owing to difficulty in isolation and identification.

L*isteria monocytogenes* are nonsporeforming, gram-positive rods that are facultatively anaerobic to microaerophilic (5–10% CO_2). The microorganism is motile via peritrichous flagella at 20–25°C, but not at 37°C [21]. It has an optimal growth temperature of 30–37° C and a 3–45°C range. Because it can grow relatively well at low temperatures, the microorganism is known as a psychrotroph. *Listeria monocytogenes* is truly ubiquitous in that it can be found in many places. It occurs in human carriers (1–10% of the population), healthy domestic animals, normal and mastitic milk, silage (especially improperly fermented, i.e., high pH), soil, and leafy vegetables. The microorganism is very tolerant to environmental stresses compared to other vegetative cells. *Listeria monocytogenes* has a high vegetative cell heat resistance (Table 6), but is not known to survive pasteurization of milk. It grows in >10% salt and survives in saturated salt solutions. It has a pH range for growth of 5–9. Human listeriosis may be caused by any of 13 serotypes of *L. monocytogenes,* but the majority of cases are due to 1/2a, 1/2b and 4b [21].

Listeriosis causes an estimated 2500 serious illnesses and 500 deaths in the United States each year [22]. Listeria often may pass through the digestive systems of healthy

Table 6 Heat Resistance of *Listeria monocytogenes* in Selected Products

Product	$D_{60°c}$ value (min)
Ground meat	3.12
Ground meat, cured	16.7
Fermented sausage	9.2–11
Roast beef	3.5–4.5
Beef	3.8
Beef homogenate	6.27–8.32
Naturally contaminated beef	1.6

Weiner batter	2.3
Chicken leg	5.6
Chicken breast	8.7
Chicken homogenate	5.02–5.29
Carrot homogenate	5.02–7.76
Raw milk, raw skim milk, raw whole milk, cream	$D_{52.2}$=24.08–52.8 $D_{5.78}$=3.97–8.17 $D_{63.3}$= 0.22–0.58 $D_{66.1}$=0.10–0.29

Source: Ref. 4.

people, causing only mild, flulike symptoms or without causing any symptoms at all. The main target populations for listeriosis include pregnant women (or more precisely their fetuses), immunocompromised persons, persons with chronic illnesses, and elderly persons. Antacids or laxatives may predispose persons to listeriosis if given in large doses [21]. Most cases of listeriosis are sporadic.

Foodborne illness caused by *L. monocytogenes* in pregnant women can result in miscarriage, fetal death, and severe illness or death of a newborn infant. Pregnant women are most frequently infected in the third trimester [21]. The mother's symptoms are influenza-like (chills, fever, sore throat, headache, dizziness, low back pain, diarrhea). During the illness the microorganism localizes in the uterus in the amniotic fluid resulting in abortion, stillbirth, or delivery of an acutely ill baby. Once the fetus is aborted, the mother becomes asymptomatic. In newborns infected with the microorganism, perinatal septicemia involving the central nervous system, circulatory system, or respiratory system or meningitis may occur. For other target groups, meningitis, meningoencephalitis, or bacteremia are the most common outcomes [23]. It is not known why the microorganism has an affinity for the central nervous system. In target populations the onset time for listeriosis can be as short as 1 day or as long as 91 days. The illness has been successfully treated with parenteral penicillin or ampicillin. In food-related human infections, *L. monocytogenes* likely enters the host via intestinal epithelial cells or Peyer's patches and are phagocytized and transported to the liver where they cause infection. Several surface proteins and enzymes, including internalin, listeriolysin O, and phosphatidylinositol phospholipase C, are virulence factors.

The first recognized outbreak of foodborne listeriosis occurred in Nova Scotia in 1981. The outbreak was associated with coleslaw and resulted in 41 cases with 17 deaths, primarily among infants. The cause of the outbreak was determined to be fertilizing cabbage with manure from sheep with listeriosis (circling disease). The cabbage was harvested and placed in cold storage (4°C) for a long period, thereby selecting for *L. monocytogenes*. In 1983, in Massachusetts, *L. monocytogenes* 4b in pasteurized milk was theorized to be the source of an outbreak producing 49 cases (42 adults) and 14 deaths. The reason for the outbreak was unknown as no defects were found in the pasteurization system, although *Listeria* were present in a dairy herd supplying the milk processor. The largest outbreak in the United States was in California in 1985 and implicated *L.*

monocytogenes 4b in a Mexican-style cheese called queso bianco. There were 142 cases and 48 deaths in the outbreak. The cause was theorized to be due to use of raw milk in the cheese and/or general contamination of the processing plant and workers. In 1997, there were 45 cases of listeriosis due to contaminated chocolate milk [24]. In Switzerland, between 1983 and 1987, at least 122 cases and 34 deaths occurred due to consumption of Vacherin Mont d'Or cheese. In France, in 1992, 279 cases, 22 abortions, and 63 deaths occurred because of consumption of pork tongue in aspic contaminated with *L. monocytogenes.* Also in France, in 1995, 17 cases, two stillbirths, and two abortions were associated with *L. monocytogenes* contaminated Brie de Meaux soft cheese. In 1998–1999, at least 50 cases of listeriosis were caused by consumption of hot dogs and/or deli meats contaminated with *L. monocytogenes* 4b [25]. While there are few outbreaks of listeriosis, the illness occurs at a rate of 0.4 cases per 100,000 population in the United States according to CDC FoodNet (Table 3) [12].

L*isteria monocytogenes* accounted for the greatest number of food recalls in the United States during the period 1993–1998 [26]. That is due to a zero tolerance policy for the microorganism in many foods. Foods involved in the recalls have primarily included dairy products (e.g., ice cream bars, soft cheeses), meats (hot dogs, etc.), shellfish, and salads. In 2001, the FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service released a draft risk assessment of the potential risks of listeriosis from eating certain ready-to-eat foods and an action plan designed to reduce the risk of foodborne illness caused by *L. monocytogenes* [22]. The agencies advised consumers to use perishable precooked or ready-to-eat items as quickly as possible, clean refrigerators regularly, and use a refrigerator thermometer to ensure that temperatures are 40°F to reduce risk of listeriosis. For pregnant women, the elderly, and immunocompromised individuals, they recommended avoidance of hot dogs or luncheon meats (unless heated until "steaming hot"), soft cheeses (e.g., feta, Brie or Camembert, blue-veined cheeses, queso bianco fresco), refrigerated paté or meat spreads, refrigerated smoked seafood unless part of a cooked dish, and raw milk.

H. *Salmonella*

Nontyphoid or foodborne illness associated *Salmonella* was first discovered in 1888 by A.A.H.Gaertner in Germany. The microorganism caused an outbreak with 50 cases due to consumption of raw ground beef (*Salmonella* serovar Enteritidis). *Salmonella* are gramnegative, nonsporeforming rods that are motile by peritrichous flagella (except *S.* Pullorum and *S.* Gallinarum, which are chicken pathogens). They are facultatively anaerobic. The growth range for *Salmonella* is 5–47°C. Lowest growth temperatures observed were *S.* Heidelberg at 5.3°C and *S.* Typhimurium at 6.2°C [27]. The optimal temperature for growth of the microorganism is 37°C.

S*almonella* are classified based upon biochemical characteristics, antigenic characteristics, DNA homology, and electrophoretic patterns [28]. The latest classification scheme recognizes two species: *Salmonella bongori* and *Salmonella enterica*. The latter has six subspecies: *arizonae, diarizonae, houteane, indica, salamae,* and *enterica. Salmonella enterica* ssp. *enterica* contains most of the serovars (1427) involved in foodborne illness, including Dublin, Enteritidis, Heidelberg, London,

Montevideo, Pullorum, Tennessee, Typhi, and Typhimurium [29].

S*almonella* occur in the intestinal tract of animals such as birds, reptiles, farm animals, humans, and insects, in water, and in soil. They may also be found in animal feeds and foods, including raw milk, poultry (up to 70%), raw meats, eggs, and raw seafood.

The pathogen generally has a pH range of 3.6–9.5 and an optimum of 6.5–7.5. The minimum a_w for growth is ca. 0.94. Salt concentrations of >2% delay growth of the microorganism. *Salmonella* is very tolerant of freezing and drying. The most heat resistant serovar is *S.* Senftenberg with the following D values: $D_{55°C}$=24 min in microbiological medium, $D_{60°C}$=6.25 min in 0.5% NaCl and 10.64 min in green pea soup, $D_{65.5°C}$=0.66 min in beef bouillon and 1.11 min in skim milk, $D_{71.1°C}$=1.2 sec in milk, and $D_{90°C}$ = 30–42 min in milk chocolate [4]. Increased tolerance to various environmental stresses has been demonstrated for *Salmonella* strains exposed to acid [30].

The nontyphoid foodborne illness caused by *Salmonella* is a gastroenteritis called *salmonellosis.* It is classified as an infection. The onset time is 8–72 hr and duration is ca. 5 days. The primary symptoms include nausea, vomiting, abdominal pain, headache, chills, mild fever, and diarrhea. Salmonellosis may progress to septicemia or chronic sequelae such as ankylosing spondylitis, reactive arthritis, Reiter's syndrome (see Sec. II.I) or rheumatoid arthritis [28]. The mortality rate associated with the illness is low (<1%) but is age dependent. The number of cells required to produce symptoms varies with individual and strain and can be as low as 1 CFU/g of food or up to 7 log. It was estimated that 6 cells per 65 g of ice cream caused a massive outbreak of salmonellosis in 1994 [31]. Populations at highest risk for *Salmonella* infections are infants, the elderly, and those with chronic illnesses.

S*almonella* cells attach to and invade gastrointestinal tissue in the small intestine. Invasion of the intestinal epithelial cells triggers leukocyte influx and an inflammation. *Salmonella* also produce an endotoxin, enterotoxin, and cytotoxin. The enterotoxin activates host adenyl cyclase resulting in diarrhea. Some serovars require plasmids for virulence.

Epidemiological estimates suggest that there are 2 to 3 million cases of salmonellosis annually in the United States [11]. Historically, salmonellosis has been associated with the greatest number of confirmed foodborne illnesses, with 790 outbreaks and 55,864 cases from 1973 to 1987 [7]; 549 outbreaks, 21,177 cases, and 38 deaths from 1988–1992 [6]; and 357 outbreaks, 32,610 cases, and 13 deaths from 1993–1997 [8]. The CDC's FoodNet has shown that salmonellosis is the second most prevalent foodborne illness (12–14.5 cases per 100,000 population) behind campylobacteriosis (Table 3) [12]. *Salmonella* Typhimurium and *S.* Enteritidis are the two serovars responsible for the greatest number of cases.

Foods historically involved in salmonellosis outbreaks include eggs and egg products, poultry, meats, ice cream, and potato salad. The microorganism has recently been involved in a number of outbreaks involving fruits and vegetables such as tomatoes, melons, and sprouts. The highest percentage of outbreaks occur in May, June, July, and August.

The largest outbreak of salmonellosis in U.S. history was in 1985 in the Chicago area. The implicated food was pasteurized milk and the serovar isolated was Typhimurium.

There were an estimated 150,000 cases, >16,000 culture-confirmed cases, 2777 hospitalizations, and seven deaths. The suspected cause for the outbreak was a leaking valve connecting the raw and pasteurized milk systems in a large milk processing operation. Several outbreaks of salmonellosis have been associated with melon products, e.g. (year, number of cases, causative agent, food): 1989, 295 cases, *S.* Chester, cantaloupe; 1991, 143 cases, *S.* Poona, cantaloupe; 1991, 39 cases, *S.* Javiana, watermelon. In each of these cases it was suggested that the microorganism contaminated the outside of the melon and the interior melon surface was inoculated when sliced. In some cases, these melons were placed on salad bars in restaurants which had little or no temperature control. This allowed the *Salmonella* to increase to infective levels over the course of the storage. In 1995, there were 63 cases of salmonellosis in Florida caused by consumption of unpasteurized orange juice contaminated with *S.* Hartford. A similar outbreak involving *S.* Muenchen in unpasteurized orange juice with over 200 cases occurred in Washington, Oregon, several other U.S. states, and Canada in 1999 [32]. In 1994, another large outbreak with ca. 2000 documented cases (estimated ca. 224,000 cases nationwide) occurred involving *S.* Enteritidis in commercially processed ice cream. The milk that was used to make the ice cream was contaminated by raw eggs during transport in a tank truck [33]. *Salmonella* Enteritidis may contaminate raw eggs in the ovaries of the hen. This is known as transovarian transmission. Approximately 1 in 20,000 eggs is infected and the level of *S.* Enteritidis per egg is ca. 10–20 cells.

I. *Shigella*

Shigella are gram-negative, nonsporeforming rods that are weakly motile and lactose negative [34]. They are facultative anaerobes with a growth range of 6–48°C and an optimum of 37°C. Four species of *Shigella* are grouped biochemically and on O antigens: *S. dysenteriae* (serogroup A), *S. flexneri* (serogroup B), *S. boydii* (serogroup C), and *S. sonnei* (serogroup D). Shigella shares many similarities with EIEC. The microorganisms are primarily of human origin and are spread to food by carriers and contaminated water. The pH minimum for *Shigella* is 4.9 and its maximum is 9.3. The a_w minimum for growth is approximately 0.94 and the maximum salt concentration is ca. 4–5%. The microorganism is not particularly heat resistant.

S*higella* gastroenteritis, called *shigellosis,* or bacillary dysentery, is an infection with an onset time of 1–4 days and a duration of 5–6 days. Primary symptoms are variable but worst cases involve bloody diarrhea, mucus secretion, dehydration, fever, and chills. The mortality rate is generally very low, but in susceptible populations (young, elderly, immunocompromised) death may occur. *Shigella dysenteriae* causes the most and *S. sonnei* the least severe symptoms. *Shigella flexneri* and *S. boydii* are intermediate in severity. The number of cells to cause the illness is estimated at 10–100. A sequelae associated with shigellosis is Reiter's syndrome, also called reactive arthritis. Symptoms are swelling of joints, conjunctivitis, and urethritis. It follows foodborne infection such as shigellosis, salmonellosis, campylobacteriosis, or yersiniosis. Reiter's patients have predisposition to syndrome due to presence of histocompatibility antigen (HLA B27) [35]. In the sequelae, bacteria attack the host cell causing production of antigen which reacts with HLA B27. The site of *Shigella* attack is the colon. Cells attach to the

epithelium, invade, and multiply in the cells causing damage to the mucosal layer by inflammation and necrosis. *Shigella flexneri* produces an enterotoxin (ShET1), while 80% of other Shigella produce another enterotoxin (ShET2) [34]. Shiga toxin is an enterotoxin produced by *S. dysenteriae* Type I.

The estimate of annual cases of foodborne and waterborne shigellosis in the United States is 90,000–150,000 [11]. Strains involved in U.S. cases are primarily *S. sonnei* (65%) and *S.flexneri* (31%). Outbreaks, cases, and deaths associated with *Shigella* in the United States have been as follows for the periods specified: 1961–1975, 72 outbreaks, 10,648 cases; 1973–1987, 104 outbreaks, 4488 cases, two deaths; 1988–1992, 25 outbreaks, 4788 cases, no deaths; and 1993–1997,43 outbreaks, 1555 cases, no deaths [6–8, 36]. According to FoodNet, in 2000 there were 11.6 cases of *Shigella* foodborne illness per 100,000 population in the United States (Table 3) [12].

Foods most associated with shigellosis are those with a high degree of handling or ones which could be contaminated by waterborne *Shigella*. The most implicated foods are salads (potato, shrimp/tuna, chicken) and seafood/shellfish. Many outbreaks have occurred in food service establishments such as hospital cafeterias and restaurants.

J. *Staphylococcus aureus*

Staphylococcus aureus was first shown to be associated with food in 1914 when M.A. Barber implicated the microorganism in an illness associated with milk from a cow with staphylococcal mastitis [37]. The microorganism presents as gram-positive cocci that grow in clusters and is facultatively anaerobic. The growth range for *S. aureus* is 7–48°C, and it has an optimal temperature of 37°C. A primary source for *S. aureus* in foods is humans. The microorganism is carried in the nasal cavity, on the skin (arms, hands, face), and by wounds (boils, carbuncles). *Staphylococcus aureus* may also be found in air and dust and on clothing. It may be associated with mastitis infection in dairy cattle. The pH range for *S. aureus* is 4.0–9.8 and its optimum is 6–7. It is uniquely tolerant to low water activities with growth at a minimum of 0.86 and in the presence of ca. 20% salt [37].

S*taphylococcus aureus* gastroenteritis is an intoxication. It has a very short onset time of around 4 hr (range 1–6 hr). Primary symptoms include nausea, vomiting, and severe abdominal cramps (secondary symptoms: diarrhea, sweating, headache, prostration, temperature drop). The duration is 24–48 hr and the mortality rate is very low.

Foods associated with *S. aureus* gastroenteritis are generally made by hand and improperly refrigerated. The estimated cases per year are 1.1 to 1.5 million [11]. Documented numbers of cases are low owing to sporadic cases not being reported. From 1988–1997, there were 92 CDC-confirmed outbreaks of *S. aureus* gastroenteritis involving 3091 cases and one death [7, 8]. Foods involved in *S. aureus* outbreaks are shown in Table 7.

>

Toxins produced by *S. aureus* are proteins of 26–30 kDa and are very resistant to proteolytic enzymes (trypsin, chymotrypsin) and heat. Coagulase production and heatstable thermonuclease production by the microorganism are highly associated with toxin production. There are ten serologically different forms of the toxin: staphylococcal enterotoxin A (SEA), SEB, SEC_1, SEC_2, SEC_3, SED, SEE, SEE, SEG, and SEH. The

first named is involved in more cases of foodborne illness than any of the other enterotoxins. The toxins are extremely heat resistant. Over 27 min at 121°C are required to inactivate 5 μg/ mL SEA in beef bouillon and >7 min at 121 °C are required to inactivate an unspecified amount in whole milk [4]. Relative thermal resistance of the enterotoxins is as follows: SEA>SEB>SEC. In contrast to toxin heat resistance, the vegetative cells have a $D_{65.5}$ of 2.0–15.08 min, depending upon suspending medium.

Table 7 Outbreaks of *Staphylococcus aureus* Foodborne Illness Associated with Various Food Products

Food Product	1961–1973	1975–1981	1983–1992
Ham	137	57	16
Turkey	52	14	4
Chicken	50	10	1
Beef and pork	60	0	11
Dairy products	14	4	1
Baked goods	55	14	7
Eggs	17	0	1
Salads	31	34	10
Others	108	27	25
Total	578	194	76

Source: Refs. 6, 7.

Production of toxin is favored by optimal growth conditions and the minimum water activity for production is 0.90 (SEA). Production of SEA is less sensitive to pH than SEB. The temperature range for production is 10–46°C and the optimum is 40°C. Minimal time is 4–6 hr and sufficient production occurs during late log or stationary phases. The number of cells necessary to produce enough toxin for symptoms (1 μg) is 1,000,000–10,000,000. The maximal amount of toxin produced is 5–6 (μg/mL. Toxin assay procedures are biological methods (feeding to cats, rhesus monkeys, chimps), reversed passive latex agglutination (sensitivity of 1 ng/mL), and ELISA.

K. *Vibrio*

Several species of *Vibrio* are known foodborne pathogens, including *V. parahaemolyticus, V. cholerae,* and *V. vulnificus.* This bacterium is a gram-negative, nonsporeforming, straight to curved rod. *Vibrio parahaemolyticus* is motile by polar flagella, while *V. cholerae* and *V. vulnificus* may be nonmotile. All are facultative anaerobes. The growth range for *V. parahaemolyticus* is 13–45°C and its optimum is 22–43°C. For *V. cholerae* the temperature range is 10–43°C and the optimum is 37°C. The primary habitat for *Vibrio* is seawater.

V*ibrio parahaemolyticus* has a pH range of 4.8–11 and an optimum of 7.8–8.6, while the range and optimum for *V. cholerae* is 5–9.6 and 7.6 and for *V. vulnificus* is 5–10 and

7.8. The water activity minima for each species are as follows: *V. cholerae,* 0.97; *V. parahaemolyticus,* 0.94; and *V. vulnificus,* 0.96. Each species requires some amount of NaCl. The optimum for each species is 0.5, 3, and 2.5%, respectively. The heat resistance for each species depends upon heating medium. *Vibrio cholerae* has a $D_{54°C}$ of 1.04 min, 5.02 min, and 0.35 min in 1% peptone, crab meat homogenate, and oyster homogenate, respectively [4]. *Vibrio parahaemolyticus* has a $D_{55°C}$ of 0.02–0.29 min and 2.5 min in clam homogenate and crab homogenate, respectively. The heat sensitivity of *V. vulnificus* is similar to *V. parahaemolyticus* [4].

V*ibrio parahaemolyticus* gastroenteritis was first recognized in 1950. The onset time is 8–72 hr with a median of 18 hr [38]. The primary symptoms include diarrhea and abdominal cramps along with nausea, vomiting, and mild fever. The duration is 48–72 hr and the mortality rate is low. The number of cells required to initiate disease is around 5.0 to 7.0 log cells. More than 95% of stool isolates causing *V. parahaemolyticus* gastroenteritis produce a hemolysin to sheep or human red blood cells. Strains that produce the hemolysin are termed kanagawa positive.

V*ibrio cholerae* has over 150 serogroups but only O1 and O139 have been linked to epidemic cholera. The O1 serogroup has three serotypes and two biotypes. The serotypes are known as Ogawa, Inaba, Hikojima. The O1 biotypes are classical and El Tor. Classical has a negative Voges-Proskauer reaction, while El Tor's is positive. In addition, classical is nonhemolytic, while El Tor produces β-hemolysis on sheep blood [38]. *Vibrio cholerae* O139 Bengal was first discovered in 1992 in India and Bangladesh and has a biotype similar to O1 El Tor. Onset time for *V. cholerae* is 6 hr to 5 days. The primary symptom is watery diarrhea (up to 1 L/hr), also called "rice water stools." This condition brings about severe dehydration, salt imbalance, and hypertension. Treatment is fluid and electrolyte replacement. Antibiotic treatment may reduce volume and duration of diarrhea. The infectious dose is 6 log depending upon the buffering capacity of the contaminated food. The microorganism produces cholera enterotoxin (CT), a protein of 85 kDa which has A and B subunits. The B subunits bind the cell membrane of the intestinal cells, and the A subunit stimulates adenyl cyclase in the cells. This leads to increased cAMP in the cell, increased chloride secretion, decreased NaCl absorption by the villus cells, and electrolyte movement into the lumen of the intestine. The osmotic gradient produced results in water flow into the lumen and resultant diarrhea. *Vibrio cholerae* also has pathogenic non-O1/O139 biotypes. These are nonepidemic and are associated with gastroenteritis, soft tissue infections, and septicemia. The gastroenteritis syndrome has been highly associated with consumption of contaminated raw oysters. The symptoms are diarrhea, abdominal pain, and nausea.

Human illness caused by *V. vulnificus* has been associated primarily with consumption of raw oysters. It may cause a soft tissue infection or septicemia, especially in immunocompromised individuals. Individuals at risk for septicemia include persons with liver or blood-related disorders such as alcoholic cirrhosis or hemochromatosis [38]. Other predisposing conditions include use of immunosuppressive drugs and illnesses such as diabetes, renal disease, and gastric diseases. The onset time is 7 hr to several days [38]. If untreated, death can occur in 3–5 days and the mortality rate for the septicemia is 50%.

From 1973 to 1987, there were 31 confirmed outbreaks involving *Vibrio* (eight *V.*

cholerae, 23 *V. parahaemolyticus*) with 1462 cases and 12 deaths [6]. All deaths involved *V. cholerae.* From 1988 to 1997, there were 15 outbreaks (five *V. cholerae,* nine *V. parahaemolyticus,* one *V. vulnificus*), 99 cases and two deaths (one *V. cholerae,* one *V. vulnificus*) [7]. *Vibrio parahaemolyticus* is the leading cause of food poisoning in Japan. Foods involved with confirmed outbreaks have been primarily fish and shellfish. Foods associated with *V. cholerae* outbreaks have involved shrimp, raw oysters, crab, fish, and mussels.

L. *Yersinia enterocolitica*

Yersinia enterocolitica was first described in 1939 in New York and was named *Bacterium enterocoliticum*. It is a gram-negative, nonsporeforming rod that is facultatively anaerobic. Like *L. monocytogenes, Y. enterocolitica* is psychrotrophic with a growth range of -2 to 45°C. Its optimal temperature range is 28–29°C. The microorganism may be found naturally among swine, birds, cats, dogs, wild animals, raw milk, soil, and water. Pigs are thought to be the primary source for serotypes pathogenic for humans. The bacterium has a pH range of 4.2–9.6 and it tolerates high pH well. The bacterium has a $D_{62.8°C}$ of 0.01–0.96 min in milk with a z value of 5.11–5.78°C [4].

The gastroenteritis caused by the microorganism is called yersiniosis. It has an onset time of 3–7 days and a duration of 5–14 days. The symptoms include watery diarrhea, vomiting, fever, and severe abdominal cramps. The illness mimics appendicitis and victims may have appendectomies performed. The illness is rarely fatal. Reactive arthritis may follow the primary illness. Clinical symptoms vary with age of the patient.

Pathogenic serotypes of *Y. enterocolitica* vary geographically. Serotype O8 is predominant in North America and is one of the more virulent strains. Its primary reservoir is swine. Serotypes O3, O9, O5, and 27 are found in Japan, Europe, and Canada. A number of avirulent strains exist. From 1973 to 1987 there were five CDC-documented outbreaks of yersiniosis involving 767 cases and no deaths [6]. The FoodNet surveillance system listed 0.5 cases of yersiniosis per 100,000 U.S. population in 2000, which was approximately 50% of the previous four years (Table 3) [12]. In a 1976 outbreak in New York, 222 children were made ill through consumption of chocolate milk. Eighteen unnecessary appendectomies were performed on the children. Serotype O8 was implicated. In the outbreak, contaminated chocolate syrup was added to pasteurized milk. Eighty-seven cases of yersiniosis occurred in 1982 in Washington state due to consumption of contaminated tofu. Serotype O8 was implicated and the source of the microorganism was contaminated water used in processing. In 1982, pasteurized milk was theorized to be the source of an outbreak in Tennessee, Arkansas, and Mississippi. Serotype O13a,b was responsible for 172 cases and 17 appendectomies. It was suggested that pasteurized milk in plastic jugs had become contaminated by plastic crates which had been stored on a hog farm and then were used in a milk processing facility without washing.

III. MYCOTOXINS

Toxins may be produced by molds as secondary metabolites. They are formed when large pools of primary metabolic precursors (e.g., amino acids, acetate, pyruvate, etc.) accumulate and are synthesized to remove primary precursors. Synthesis is initialized at the onset of stationary phase and occurs with lipid synthesis.

Aflatoxins were the first mycotoxins discovered. In 1960, 100,000 turkey poults died in England after eating peanut meal imported from Africa and South America. This was called Turkey X disease. It was later determined that a toxin produced by *Aspergillus* species was responsible for the turkey deaths. This toxin was named *aflatoxin,* from *Aspergillus flavus* toxin. The toxin is actually produced by *A. flavus, A. parasiticus,* and *A. nomius.* The environmental conditions that influence production most appear to be temperature and water activity. The optimal temperature for production is 24–28°C and the optimal a_w is 0.93–0.98.

There are several types of aflatoxins, including B_1, B_2, G_1, G_2, M_1, and M_2. The mycotoxins are fluorescent under ultraviolet light and fluoresce blue (hence, B! and B_2), green (G_1 and G_2) and blue, blue-violet (M_1 and M_2). The latter are produced in milk, which is why they are designated by M. Toxicity of the aflatoxins is, in decreasing order, $B_1>M_1>G_1>B_2>G_2$, M_2. Aflatoxins are hepatotoxic to birds, certain mammals, and fish (trout) and are also carcinogenic to rats and trout. Aflatoxin B! is acutely toxic to humans and may be involved in liver cancer. The toxin is metabolized by animals to the toxic dihydroxyaflatoxin and carcinogenic aflatoxin epoxide [39]. Foods in which aflatoxin may be produced include peanuts, peanut butter, other nuts, fresh beef, ham, bacon, milk, cheese (through contaminated feed to dairy cattle), beer, cocoa, raisins, soybean meal, corn, rice, wheat, and cottonseed.

Many other mold genera produce mycotoxins in various foodstuffs (Table 8).

Table 8 Selected Mycotoxins, Mycotoxigenic Molds, Foods Associated with the Mycotoxin, and Animals Affected and Illnesses

Toxin	Mold	Food	Animal/illness
Fumonisins	*Fusarium moniliforme*	Corn	Equine leucoencephalomalacia; porcine pulmonary edema syndrome; lung edema in pigs and horses; poultry toxicity (immunosuppression), human esophageal cancer suspected
Ochratoxin A	*Aspergillus* sp. *(A. ochraceus), Penicillium* sp. *(P. viridicatum, P.*	Grains, beans, peanuts, citrus	Pigs; humans (renal disease); nephrotoxic, hepatotoxic, teratogenic, carcinogenic

	cyclopium, P. verrucosuni)	fruits, nuts, country-cured ham	
Patulin	*Penicillium* sp. *(P. patulum, P. claviforme, P. expansum), Aspergillus* sp. *(A. clavatus, A. terreus), Byssochlamys* sp. *(B. fulva, B. nivea)*	Apples, apple products, bread, sausage, other fruits, moldy feeds	Poultry; mammals (cattle); fish; toxic, mutagenic, carcinogenic, teratogenic
Sterigmatocystin	*Aspergillus versicolor, A. nidulans, A. rugulosus*	Cheese, wheat, oats, coffee beans	Hepatotoxic, carcinogenic
Zearalenone	*Fusarium graminearum, F. cul*	Corn, wheat, oats, barley, sesame	Reproductive and infertility problems in poultry, swine, dairy cattle, sheep

Source: Refs. 39, 50.

IV. VIRUSES

Diseases caused by foodborne viruses may be grouped as viral gastroenteritis or viral hepatitis. The majority of viral gastroenteritis outbreaks are caused by small round structured viruses (SRSV), of which Norwalk/Norwalk-like virus, Snow Mountain, Montgomery County, and Hawaii are members. To a lesser extent, astroviruses or caliciviruses may be involved. Other enteric viruses, such as adeno virus and groups A and B rota viruses have not been fully demonstrated to be foodborne [40]. Viral hepatitis caused by hepatitis A virus may also be carried by foods.

Illness caused by a Norwalk/Norwalk-like virus has an onset time of 1–2 days and a duration of 1–6 days. Symptoms include severe nausea and vomiting. Secondary symptoms may be diarrhea, abdominal pain, headache, and low grade fever. Stools do not contain blood, mucus, or white cells. The infectious dose is 10–100 virus particles [40]. Norwalk/Norwalk-like viruses are unaffected by low pH (ca. 3) and heat at 60°C for 30 min [4]. They are completely inactivated by free residual chlorine at 10 mg/L [4, 40]. At 3.75 mg/L chlorine, the virus was only partially inactivated.

Calicivirus infection is characterized by diarrhea and vomiting following a 1–3 day incubation period. Respiratory symptoms sometimes are evident. Infants and young children are most commonly infected. Duration is ca. 4 days. Astro virus infection has an onset of 3–4 days. Primary symptoms include fever, diarrhea, headache, nausea, and

malaise. Neither calicivirus nor astro virus is inactivated by low pH, but both are inactivated by 10 mg/L free residual chlorine [40].

Hepatitis A (infectious hepatitis) is characterized by a sudden onset of fever, nausea, anorexia, and abdominal discomfort and is followed by jaundice. The onset is 1–7 weeks with an average of 30 days. The illness is transmissible until 1 week after the appearance of jaundice. The duration is 1–2 weeks up to months. All populations are susceptible but the illness is more common in adults. Hepatitis is spread by infected food handlers or fecal contamination of foods or food contact surfaces (fecal-oral route). Foods involved in hepatitis A outbreaks include those that require significant handling, often in food service situations, and those contaminated by polluted water. In 1997, an outbreak of hepatitis A in Michigan was linked to consumption of strawberries imported from Mexico [41]. The strawberries were thought to have been contaminated in the field. Other foods involved in outbreaks are shellfish, salads, and deli foods. Hepatitis A virus is not inactivated by low pH (ca. 3). At 60°C in buffer, the virus was reduced by 0.3 log (infective units) after 10 min, while at 80°C the reduction was 4.3 log [4]. It is inactivated by 70% ethanol and 10 mg/L free residual chlorine [40]. The virus showed a 90% decrease in viability in mineral water at 4°C and room temperature after 519 days and 89 days, respectively [4].

V. PROTOZOA

Cryptosporidium parvum causes an illness known as *cryptosporidiosis,* which is transmitted via fecal contamination of water or food. Onset time is 1–2 weeks and the duration is 2 days to 4 weeks. The microorganism forms oocysts that are resistant to chlorine and persist for long periods in the environment. Oocysts are susceptible to freezing, dehydration, high temperatures, and certain chemical sanitizers such as hydrogen peroxide, ozone, and chlorine dioxide [42]. They may be removed from municipal drinking water supplies by filtration. Symptoms include severe watery diarrhea, abdominal pain, and anorexia. Surveillance for cases of cryptosporidiosis began in 1997 via the FoodNet surveillance system of the CDC [12]. The incidence rate in 2000 for the illness was 2.4 cases per 100,000 population, which was down from a high of 3.7 cases in 1997 (Table 3).

Cyclosporiasis is caused by *Cyclospora cayetanensis,* a coccidian parasite that occurs in tropical waters. The illness is characterized by watery diarrhea, abdominal cramps, anorexia, weight loss, nausea, and vomiting. It has an onset of 1–11 days and lasts for up to several weeks. The microorganism is carried by contaminated water and foodborne outbreaks have been associated with raspberries, basil, and lettuce. According to CDC's FoodNet, cyclosporiasis occurs at a rate of 0.1 cases per 100,000 U.S. population and has remained constant for three years (Table 3) [12].

G*iardia lamblia,* the causative agent of giardiasis, is one of the most common protozoal infections of humans worldwide [42]. Several animal hosts may serve as reservoirs for human infections. Human illnesses result from consumption of *Giardia* cysts through poor hygiene (fecal-oral route), drinking contaminated water, or from infected food handlers contaminating foods. High risk groups are infants, young children,

and immunosup-pressed individuals. Symptoms include diarrhea, cramps, and bloating. The onset is 5 to 24 days and the illness may last from several weeks to years.

T*oxoplasma gondii* is a protozoa that is the causative agent of toxoplasmosis. The primary host for the microorganism is the cat. Humans may become infected by consuming infected meat or water or contacting cat feces. Meat from lambs, poultry, and wild game animals may serve as a source for the microorganism. In humans, the illness resembles mononucleosis. Most infected newborns do not exhibit clinical symptoms, but mental retardation may occur later in life [42]. Toxoplasmosis is sometimes seen in AIDS patients. Temperatures of 61°C or higher for 3.6 min or freezing at—13°C will inactivate oocysts and cysts in meat [42].

VI. NEMATODES (ROUNDWORMS)

Trichinella spiralis is the organism that causes trichinosis. The illness is transmitted to humans by consumption of infected meats of carnivores, including pork and wild game such as bear and cougar. Dogs may also be infected. The majority of individuals infected by *Trichinella* are asymptomatic [43]. Symptomatic illness begins with gastroenteritis symptoms including nausea, vomiting, diarrhea, and fever. Onset is 72 hr and the infection may last 2 weeks. Following initial symptoms, edema, muscle weakness, and pain occur as the larvae migrate and encyst in the muscles. Respiratory and neurological manifestations may also occur. Without treatment, trichinosis may cause death. Prevention is achieved by preventing contamination of meat or destroying the trichinae (encysted larvae) in meat by cooking to 71°C, freezing meat less than 15 cm thick for 6 (−29°C) to 20 (−15°C) days, or applying irradiation [42].

REFERENCES

1. S Doores. Food safety: current status and future needs. American Academy of Microbiology, Washington, DC, 1999.
2. S Palumbo, GN Stelma, C Abeyta. The *Aeromonas hydrophila* group. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1011–1028.
3. PE Granum, TC Baird-Parker. 2000. *Bacillus* species. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1029–1039.
4. ICMSF. Microorganisms in Foods 5: Microbiological Specifications of Food Pathogens. London: Blackie Academic, 1996.
5. H Mahler, A Pasi, JM Kramer, P Schulte, AC Scoging, W Bar, S Krahenbuhl. Fulminant liver failure in association with the emetic toxin of *Bacillus cereus*. N Engl J Med 336:1142–1148, 1997.
6. NH Bean, PM Griffin. Foodborne disease outbreaks in the United States, 1973–1987: pathogens, vehicles and trends. J Food Prot 53:804–817, 1990.
7. NH Bean, JS Goulding, C Lao, FJ Angulo. Surveillance for foodborne disease outbreaks—United States, 1988–1992. Morb Mort Weekly Rep 45(SS5):1–55, 1996.
8. SJ Olsen, LC MacKinon, JS Goulding, NH Bean, L Slutsker. Surveillance for

foodborne disease outbreaks—United States, 1993–1997. Morb Mort Weekly Rep 49 (SS01):1–51, 2000.
9. NJ Stern, JE Line. *Campylobacter*. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp. 1040–1056.
10. BM Allos, MJ Blaser. Potential role of lipopolysaccharides of *Campylobacter jejuni* in the development of Guillain-Barré syndrome. J Endotoxin Res 62:53–57, 1995.
11. CAST. Foodborne pathogens, risks and consequences. Task Force Rep. 122. Ames, IA: Council for Agricultural Science and Technology, 1994.
12. CDC. Preliminary FoodNet data on the incidence of foodborne illness—selected sites, United States, 2000. Morb Mort Weekly Rep 50:241–246, 2001.
13. GM Dack. Characteristics of botulism outbreaks in the United States. In: KH Lewis, K Cassel Jr, eds. Botulism. Cincinnati, OH: U.S. Dept. Health Education and Welfare, Public Health Service, 1964, pp 33–40.
14. BM Lund, MW Peck. *Clostridium botulinum.* In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp. 1057–1109.
15. The deadliest poison. Nutr Today 10(5):4–9, 1975.
16. RG Labbe. *Clostridium perfringens.* In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp. 1110–1135.
17. CB Hoskins, PM Davidson. Recovery of *Clostridium perfringens* from food samples using an oxygen-reducing membrane fraction. J Food Prot 51:187–191, 1988.
18. GA Willshaw, T Cheasty, HR Smith. *Escherichia coli.* In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp. 1136–1177.
19. RL Buchanan, MP Doyle. Foodborne disease significance of *Escherichia coli* O157:H7 and other enterohemorrhagic *E. coli.* Food Technol 51(10):69–76, 1997.
20. T Vande Venter. Emerging foodborne diseases: a global responsibility. Food Nutr Agric 26: 4–13.
21. JM Farber, PI Peterkin. *Listeria monocytogenes.* In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1178–1231.
22. CFSAN, FSIS. Interpretive Summary: Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. Washington, DC: Center for Food Safety and Applied Nutrition, Department of Health and Human Services and Food Safety Inspection Service, U.S. Department of Agriculture, 2001.
23. J Rocourt, P Cossart. *Listeria monocytogenes.* In: MP Doyle, LR Beuchat, TJ Montville, eds. Food Microbiology: Fundamentals and Frontiers. Washington, DC: ASM Press, 1997, pp 337–352.
24. CB Dalton, CC Austin, J Sobel, PS Hayes, WF Bibb, LM Graves, B Swaminathan, ME Proctor, PM Griffin. An outbreak of gastroenteritis and fever due to *Listeria monocytogenes* in milk. N Engl J Med 336:100–105, 1997.
25. CDC. Update: multistate outbreak of listeriosis—United States, 1998–1999. Morb Mort Weekly Rep 47:1117–1118, 1999.
26. S Wong, D Street, SI Delgado, KC Klontz. Recalls of foods and cosmetics due to microbial contamination reported to the U.S. Food and Drug Administration. J Food Prot 63:1113–1116, 2000.

27. JM Jay. Modern Food Microbiology, 6th Ed. Gaithersburg, MD: Aspen, 2000.
28. J-Y D'Aoust. *Salmonella.* In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1233–1299.
29. J-Y D'Aoust. *Salmonella* species. In MP Doyle, LR Beuchat, TJ Montville, eds. Food Microbiology: Fundamentals and Frontiers. Washington, DC: ASM Press, 1997, pp 129–158.
30. GJ Leyer, EA Johnson. Acid adaptation induces cross-protection against environmental stresses in *Salmonella typhimurium.* Appl Environ Microbiol 59:1842–1847, 1993.
31. KJ Vought, SR Tatini. *Salmonella enteritidis* contamination of ice cream associated with a 1994 multistate outbreak. J Food Prot 61:5–10, 1998.
32. CDC. Outbreak of *Salmonella* serotype Muenchen infections associated with unpasteurized orange juice—United States and Canada, June 1999. Morb Mort Weekly Rep 48:582–585, 1999.
33. TW Hennessy, CW Hedberg, L Slutsker, KE White, JM Besser-Wiek, ME Moen, J Feldman, WW Coleman, LM Edmonson, KL MacDonald, MT Osterholm. A national outbreak of *Salmonella enteritidis infections from ice cream. N Engl J Med 334:1281–1286, 1996.*
34. KA Lampel, JM Madden, IK Wachsmuth. *Shigella* species. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1300–1316.
35. JL Smith, PM Fratamico. Long-term consequences of foodborne disease. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1545–1562.
36. K Wachsmuth, GK Morris. *Shigella.* In: MP Doyle, ed. Foodborne Bacterial Pathogens. New York: Marcel Dekker, 1990, pp. 447–462.
37. TC Baird-Parker. *Staphylococcus aureus.* In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp. 1317–1335.
38. CA Kaysner. *Vibrio* species. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1336–1362.
39. MO Moss. Toxigenic fungi and mycotoxins. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1490–1517.
40. EO Caul. Foodborne viruses. In: BM Lund, TC Baird-Parker, GW Gould, eds. The Microbiological Safety and Quality of Food. Gaithersburg, MD: Aspen, 2000, pp 1457–1489.
41. CDC. Hepatitis A associated with consumption of frozen strawberries—Michigan. Morb Mort Weekly Rep 46:288,295, 1997.
42. CA Speer. Protozoan parasites acquired from food and water. In: MP Doyle, LR Beuchat, TJ Montville, eds. Food Microbiology: Fundamentals and Frontiers. Washington, DC: ASM Press, 1997, pp 478–493.
43. CW Kim. Helminths in meat. In: MP Doyle, LR Beuchat, TJ Montville, eds. Food Microbiology: Fundamentals and Frontiers. Washington, DC: ASM Press, 1997, pp 449–462.
44. CDC. Update: multistate outbreak of *Escherichia coli* O157:H7 infections from hamburgers—western United States, 1992–1993. Morb Mort Weekly Rep 42:258–263,

1993.
45. CDC. Foodborne outbreaks of enterotoxigenic *Escherichia coli*—Rhode Island and New Hampshire, 1993. Morb Mort Weekly Rep 43:81,87–89, 1994.
46. CDC. *Escherichia coli* O157:H7 outbreak linked to commercially distributed dry-cured salami—Washington and California. Morb Mort Weekly Rep 44:157–160, 1995.
47. CDC. Outbreak of *Escherichia coli* O157:H7 infection—Georgia and Tennessee, June 1995. Morb Mort Weekly Rep 45:249–251, 1996.
48. CDC. *Escherichia coli* O157:H7 infections associated with eating a nationally distributed commercial brand of frozen ground beef patties and burgers—Colorado, 1997. Morb Mort Weekly Rep 46:777–778, 1997.
49. CDC. Outbreaks of *Escherichia coli* O157:H7 infection associated with eating alfalfa sprouts—Michigan and Virginia, June-July 1997. Morb Mort Weekly Rep 46:741–744,1997.
50. CAST. Mycotoxins—economic and health risks. Rep. 116. Ames, IA: Council for Agricultural Science and Technology, 1989.

3
The FDA's GMPs, HACCP, and the *Food Code*

Y.H.HUI
Science Technology System, West Sacramento, California, U.S.A.

WAI-KIT NIP
University of Hawaii at Manoa, Honolulu, Hawaii, U.S.A.

J.RICHARD GORHAM
Consultant, Xenia, Ohio, U.S.A.

I. INTRODUCTION

Nearly 25 years ago, the United States Food and Drug Administration (FDA) started the approach of using umbrella regulations to help the food industries to produce wholesome food as required by the Federal Food, Drug, and Cosmetic Act (the Act). In 1986, the FDA promulgated the first umbrella regulations under the title of Good Manufacturing Practice Regulations (GMPR). Since then, many aspects of the regulations have been revised [1].

Traditionally, industry and regulators have depended on spot checks of manufacturing conditions and random sampling of final products to ensure safe food. The current good manufacturing practice regulations (CGMPR) form the basis on which the FDA will inform the food manufacturer about deficiencies in its operations. This approach, however, tends to be reactive rather than preventive and can definitely be improved.

For more than 30 years, FDA has been regulating the low-acid canned food (LACF) industries with a special set of regulations, many of which are preventive in nature. This action aims at preventing botulism. In the last 30 years, threats from other biological pathogens have increased tremendously. Between 1980 and 1995, FDA has been studying the approach of using hazard analysis and critical control points (HACCP). For this approach, FDA uses the LACF regulations as a partial guide. Since 1995, FDA has issued HACCP regulations (HACCPR) [2] for the manufacture or production of several types of food products. These include the processing of seafood and fruit/vegetable juices.

Since 1938, when the Act was first passed by Congress, FDA and state regulatory agencies have worked hard to reach a uniform set of codes for the national regulation of food manufacturing industries and state regulation of retail industries associated with food, e.g., groceries, restaurants, caterers, and so on. In 1993, the first document, titled *Food Code,* was issued jointly by the FDA and state agencies. It has been revised twice since then. This chapter discusses CGMPR, HACCPR, and the *Food Code*. The appendices present: (a) the FDA's good manufacturing practice regulations (complete); (b) guidelines for HACCP (complete); (c) the *Food Code 2001* (Table of Contents only);

and (d) an excerpt of the *Handbook of Food Defect Action Levels*.

II. CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS

The current good manufacturing practice regulations cover the topics listed in Table 1. These regulations are discussed in detail here. Please note that the word *shall* in a legal document means mandatory and is used routinely in FDA regulations published in the U.S. Code of Federal Regulations (CFR). In this chapter, the words *should* and *must* are used to make for smoother reading. However, this in no way diminishes the legal impact of the original regulations.

A. Definitions (21 CFR 110.3)

The FDA has provided the following definitions and interpretations for several important terms.

1. *Acid food* or *acidified food* means foods that have an equilibrium pH of 4.6 or below.
2. *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Table 1 Contents of the Current Good Manufacturing Regulations

21 CFR 110.3	Definitions
21 CFR 110.5	Current good manufacturing practice
21 CFR 110.10	Personnel
21 CFR 110.19	Exclusions
21 CFR 110.20	Plant and grounds
21 CFR 110.35	Sanitary operations
21 CFR 110.37	Sanitary facilities and controls
21 CFR 110.40	Equipment and utensils
21 CFR 110.80	Processes and controls
21 CFR 110.93	Warehousing and distribution

3. *Blanching,* except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
4. *Critical control point* means a point in a food process where there is a high probability that improper control may cause a hazard or filth in the final food or decomposition of the final food.
5. *Food* includes raw materials and ingredients.
6. *Food-contact surfaces* are those surfaces that contact human food and those surfaces

from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Food-contact surfaces include utensils and food-contact surfaces of equipment.

7. *Lot* means the food produced during a period of time indicated by a specific code.
8. *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term *undesirable microorganisms* includes those microorganisms that are of public health significance, that promote decomposition of food, or that indicate that food is contaminated with filth.
9. *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and insect larvae.
10. *Plant* means the building or facility used for the manufacturing, packaging, labeling, or holding of human food.
11. *Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.
12. *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
13. *Safe moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity, a_w. An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.
14. *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
15. *Water activity* (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

B. Personnel (21 CFR 110.10)

Plant management should take all reasonable measures and precautions to ensure compliance with the following regulations.

1. Disease Control. Any person who, by medical examination or supervisory observation, is shown to have an illness, open lesion, including boils, sores, or infected wounds, by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, should be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel should be instructed to report such health conditions to their supervisors.
2. Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials should conform to hygienic practices while on duty. The methods for maintaining cleanliness include, but are not limited to, the following:

a. Wearing outer garments suitable to the operation to protect against the contamination of food, food-contact surfaces, or food-packaging materials.
b. Maintaining adequate personal cleanliness.
c. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
d. Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against their contamination of the food, food-contact surfaces, or food-packaging materials.
e. Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
f. Wearing, where appropriate, hairnets, headbands, caps, beard covers, or other effective hair restraints.
g. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
h. Confining the following personal practices to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
i. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

3. Education and Training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.
4. Supervision. Responsibility for assuring compliance by all personnel with all legal requirements should be clearly assigned to competent supervisory personnel.

C. Plant and Grounds (21 CFR 110.20)

1. Grounds. The grounds surrounding a food plant that are under the control of the plant manager should be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to, the following:

a. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

b. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
c. Adequately draining areas that may contribute contamination to food by seepage or foot-borne filth or by providing a breeding place for pests.
d. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in an acceptable manner, steps must be taken to exclude pests, dirt, and filth that may be a source of food contamination. Implement inspection, extermination, or other countermeasures.

2. Plant Construction and Design. Plant buildings and structures should be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities should

a. Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
b. Take proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.
c. Taking proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including
   Using protective coverings
   Controlling areas over and around the vessels to eliminate harborages for pests
   Checking on a regular basis for pests and pest infestation
   Skimming the fermentation vessels as necessary
d. Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
e. Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safetytype light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
f. Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes

the potential for contaminating food, foodpackaging materials, and food-contact surfaces.

g. Provide, where necessary, adequate screening or other protection against pests.

D. Sanitary Operations (21 CFR 110.35)

1. General Maintenance. Buildings, fixtures, and other physical facilities of the plant should be maintained in a sanitary condition and should be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the Act. Cleaning and sanitizing of utensils and equipment should be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
2. Substances used in cleaning and sanitizing and in storage of toxic materials:

   a. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures should be free from undesirable microorganisms and should be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
      Those required to maintain clean and sanitary conditions
      Those necessary for use in laboratory testing procedures
      Those necessary for plant and equipment maintenance and operation
      Those necessary for use in the plant's operations

   b. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals should be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

3. Pest Control. No pests should be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures should be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.
4. Sanitation of Food-Contact Surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, should be cleaned as frequently as necessary to protect against contamination of food.

   a. Food-contact surfaces used for manufacturing or holding low-moisture food should be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they should, when necessary, be sanitized and thoroughly dried before subsequent use.

   b. In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces should be cleaned and sanitized

before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment should be cleaned and sanitized as necessary.

c. Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

d. Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and should be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

e. Sanitizing agents should be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

5. Storage and Handling of Cleaned Portable Equipment and Utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

E. Sanitary Facilities and Controls (21 CFR 110.37)

Each plant should be equipped with adequate sanitary facilities and accommodations including, but not limited to,

1. Water Supply. The water supply should be sufficient for the operations intended and should be derived from an adequate source. Any water that contacts food or food-contact surfaces should be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, should be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials or for employee sanitary facilities.
2. Plumbing. Plumbing should be of adequate size and design and adequately installed and maintained to

a. Carry sufficient quantities of water to required locations throughout the plant

b. Properly convey sewage and liquid disposable waste from the plant

c. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition

d. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor

e. Provide that there is no backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing

3. Sewage Disposal. Sewage disposal should be made into an adequate sewerage system or disposed of through other adequate means.

4. Toilet Facilities. Each plant should provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by

   a. Maintaining the facilities in a sanitary condition
   b. Keeping the facilities in good repair at all times
   c. Providing self-closing doors
   d. Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternative means have been taken to protect against such contamination (such as double doors or positive airflow systems).

5. Hand-Washing Facilities. Hand-washing facilities should be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing

   a. Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands
   b. Effective hand-cleaning and sanitizing preparations
   c. Sanitary towel service or suitable drying devices
   d. Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands
   e. Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
   f. Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

6. Rubbish and Offal Disposal. Rubbish and any offal should be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

F. Equipment and Utensils (21 CFR 110.40)

1. All plant equipment and utensils should be so designed and of such material and workmanship as to be adequately cleanable and should be properly maintained. The design, construction, and use of equipment and utensils should preclude the adulteration of food with lubricants, fuel, metal fragments, contami-nated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces should be corrosion resistant when in contact with food. They should be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food and, if applicable, cleaning compounds and sanitizing agents. Food-

contact surfaces should be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
2. Seams on food-contact surfaces should be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
3. Equipment that is in the manufacturing or food-handling area and that does not come into contact with food should be so constructed that it can be kept in a clean condition.
4. Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, should be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
5. Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms should be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.
6. Instruments and controls used for measuring, regulating, or recording temperature, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food should be accurate and adequately maintained and adequate in number for their designated uses.
7. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment should be treated in such a way that food is not contaminated with unlawful indirect food additives.

G. Processes and Controls (21 CFR 110.80)

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food should be conducted in accordance with adequate sanitation principles. Appropriate quality control operations should be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant should be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions should be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous material testing procedures should be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the Act should be rejected, or if permissible, treated or processed to eliminate the contamination.

1. Raw materials and other ingredients.

   a. Raw materials and other ingredients should be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and should be stored under conditions that will protect against contamination and minimize deterioration. Raw materials should be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying

food should be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

b. Raw materials and other ingredients should either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they should be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
c. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins should comply with current FDA regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.
d. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material should comply with applicable FDA regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification or examination of these materials for contamination.
e. Raw materials, other ingredients, and rework should be held in bulk or in containers designed and constructed so as to protect against contamination and should be held at such temperature and relative humidity as to prevent the food from becoming adulterated. Material scheduled for rework should be identified as such.
f. Frozen raw materials and other ingredients should be kept frozen. If thawing is required prior to use, it should be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.
g. Liquid or dry raw materials and other ingredients received and stored in bulk form should be held in a manner that protects against contamination.

2. Manufacturing operations.

a. Equipment and utensils and finished food containers should be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment should be taken apart for thorough cleaning.
b. All food manufacturing, including packaging and storage, should be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing,

dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

c. Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, should be held in a manner that prevents the food from becoming affected. Compliance with this requirement may be accomplished by any effective means, including
   Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved
   Maintaining frozen foods in a frozen state
   Maintaining hot foods at 140°F (60°C) or above
   Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures

d. Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, should be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

e. Work-in-process should be handled in a manner that protects against contamination.

f. Effective measures should be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they should not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor should be protected against contamination as necessary.

g. Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food should be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

h. Effective measures should be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

i. Food, raw materials, and other ingredients that are adulterated should be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it should be reconditioned using a method that has been proven to be effective or it should be reexamined and found not to be adulterated before being incorporated into other food.

j. Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming should be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces and by using time and temperature controls at and between each manufacturing step.

k. Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used should be safe and of adequate sanitary quality.

l. Batters, breading, sauces, gravies, dressings, and other similar preparations should be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:
   - Using ingredients free of contamination
   - Employing adequate heat processes where applicable
   - Using adequate time and temperature controls
   - Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them
   - Cooling to an adequate temperature during manufacturing
   - Disposing of batters at appropriate intervals to protect against the growth of microorganisms

m. Filling, assembling, packaging, and other operations should be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including
   - Use of a quality control operation in which the critical control points are identified and controlled during manufacturing
   - Adequate cleaning and sanitizing of all food-contact surfaces and food containers
   - Using materials for food containers and food-packaging materials that are safe and suitable
   - Providing physical protection from contamination, particularly airborne contamination
   - Using sanitary handling procedures

n. Food such as, but not limited to, dry mixes, nuts, intermediate-moisture food, and dehydrated food, which relies on the control of a_w for preventing the growth of undesirable microorganisms, should be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:
   - Monitoring the a_w of food
   - Controlling the soluble solids/water ratio in finished food
   - Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level

o. Food, such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable micro-organisms should be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices: Monitoring the pH of raw materials, food-in-process, and finished food. Controlling the amount of acid or acidified food added to

low-acid food,

p. When ice is used in contact with food, it should be made from water that is safe and of adequate sanitary quality, and should be used only if it has been manufactured in accordance with current good manufacturing practice.
q. Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

H. Warehousing and Distribution (21 CFR 110.93)

Storage and transportation of finished food should be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

I. Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard (21 CFR 110.110)

1. Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
2. Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
3. The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the Act, regardless of the defect level of the final food.
4. A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained from the FDA in printed or electronic versions.

III. HAZARD ANALYSIS CRITICAL CONTROL POINTS REGULATIONS

In 1997, FDA adopted a food safety program that was developed nearly 30 years ago for astronauts and is now applying it to seafood and fruit and vegetable juices. The agency intends to eventually use it for much of the U.S. food supply. The program for the astronauts focuses on preventing hazards that could cause foodborne illnesses by applying science-based controls, from raw material to finished products. The FDA's new system will do the same.

Many principles of this new system, now called hazard analysis and critical control points, are already in place in the FDA-regulated low-acid canned food industry. Since

1997, FDA has mandated HACCP for the processing of seafood, fruit juices, and vegetable juices. Also, FDA has incorporated HACCP into its *Food Code,* a document that gives guidance to and serves as model legislation for state and territorial agencies that license and inspect food service establishments, retail food stores, and food vending operations in the United States.

The FDA now is considering developing regulations that would establish HACCP as the food safety standard throughout other areas of the food industry, including both domestic and imported food products. The National Academy of Sciences, the Codex Alimentarius Commission (an international, standard-setting organization), and the National Advisory Committee on Microbiological Criteria for Foods have endorsed HACCP. Several U.S. food companies already use the system in their manufacturing processes, and it is in use in other countries including Canada.

A. What is HACCP?

Hazard analysis and critical control points involves seven principles.

1. Analyze hazards. Potential hazards associated with a food and measures to control those hazards are identified. The hazard could be biological, such as a microbe; chemical, such as a toxin; or physical, such as ground glass or metal fragments.
2. Identify critical control points. These are points in a food's production—from its raw state through processing and shipping to consumption by the consumer—at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection.
3. Establish preventive measures with critical limits for each control point. For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any harmful microbes.
4. Establish procedures to monitor the critical control points. Such procedures might include determining how and by whom cooking time and temperature should be monitored.
5. Establish corrective actions to be taken when monitoring shows that a critical limit has not been met—for example, reprocessing or disposing of food if the minimum cooking temperature is not met.
6. Establish procedures to verify that the system is working properly—for example, testing time and temperature-recording devices to verify that a cooking unit is working properly.
7. Establish effective recordkeeping to document the HACCP system. This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems.

Each of these principles must be backed by sound scientific knowledge such as published microbiological studies on time and temperature factors for controlling foodborne pathogens.

B. Need for HACCP

New challenges to the U.S. food supply have prompted FDA to consider adopting a HACCP-based food safety system on a wider basis. One of the most important challenges is the increasing number of new food pathogens. For example, between 1973 and 1988, bacteria not previously recognized as important causes of foodborne illness (such as *Escherichia coli* O157:H7 and *Salmonella enteritidis*) became more widespread. There also is increasing public health concern about chemical contamination of food, for example, the effects of lead in food on the nervous system.

Another important factor is that the size of the food industry and the diversity of products and processes have grown tremendously, in both the amount of domestic food manufactured and the number and kinds of foods imported. At the same time, FDA and state and local agencies have the same limited level of resources to ensure food safety. The need for HACCP in the United States, particularly in the seafood industry, is further fueled by the growing trend in international trade for worldwide equivalence of food products and the Codex Alimentarius Commission's adoption of HACCP as the international standard for food safety.

C. Advantages and Plans

The HACCP system offers a number of advantages over previous systems. Most importantly, HACCP

Focuses on identifying and preventing hazards from contaminating food

Is based on sound science

Permits more efficient and effective government oversight, primarily because the recordkeeping allows investigators to see how well a firm is complying with food safety laws over a period rather than how well it is doing on any given day

Places responsibility for ensuring food safety appropriately on the food manufacturer or distributor

Helps food companies compete more effectively in the world market

Reduces barriers to international trade

Here are the seven steps used in HACCP plan development:

1. Preliminary steps.

   a. General information.
   b. Describe the food.
   c. Describe the method of distribution and storage.
   d. Identify the intended use and consumer.
   e. Develop a flow diagram.

2. Hazard analysis worksheet.

   a. Set up the Hazard Analysis Worksheet.

b. Identify the potential species-related hazards.
c. Identify the potential process-related hazards.
d. Complete the Hazard Analysis Worksheet.
e. Understand the potential hazard.
f. Determine if the potential hazard is significant.
g. Identify the critical control points (CCP).

3. HACCP Plan Form

a. Complete the HACCP Plan Form.
b. Set the critical limits (CL).

4. Establish monitoring procedures.

a. What?
b. How?
c. Frequency?
d. Who?

5. Establish corrective action procedures.
6. Establish a recordkeeping system.
7. Establish verification procedures.

It is important to remember that apart from HACCPR promulgated for seafood and juices, the implementation of HACCP by other categories of food processing is voluntary. However, the FDA and various types of food processors are working together so that eventually HACCPR will become available for many other food processing systems under FDA jurisdiction. Using the HACCPR for seafood processing as a guide, the following discussion for a HACCP plan applies to all categories of food products being processed in the United States.

D. Hazard Analysis

Every processor should conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of product being processed in the absence of those controls.

E. The HACCP Plan

Every processor should have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. A

HACCP plan should be specific to

Each location where products are processed by that processor
Each kind of product processed by the processor

The plan may group kinds of products together or group kinds of production methods together if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed are identical for all products so grouped or for all production methods so grouped.

1. The Contents of the HACCP Plan

The HACCP plan should, at a minimum,

1. List the food safety hazards that are reasonably likely to occur, as identified, and that thus must be controlled for each product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following: natural toxins; microbiological contamination; chemical contamination; pesticides; drug residues; decomposition in products where a food safety hazard has been associated with decomposition; parasites where the processor has knowledge that the parasite-containing product will be consumed without a process sufficient to kill the parasites; unapproved use of direct or indirect food or color additives; and physical hazards.
2. List the critical control points for each of the identified food safety hazards, including, as appropriate, critical control points designed to control food safety hazards that could be introduced in the processing plant environment and critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest.
3. List the critical limits that must be met at each of the critical control points.
4. List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.
5. Include any corrective action plans that have been developed to be followed in response to deviations from critical limits at critical control points.
6. List the verification procedures, and frequency thereof, that the processor will use.
7. Provide for a recordkeeping system that documents the monitoring of the critical control points. The records should contain the actual values and observations obtained during monitoring.

2. Signing and Dating the HACCP Plan

The HACCP plan should be signed and dated either by the most responsible individual on site at the processing facility or by a higher-level official of the processor. This signature should signify that the HACCP plan has been accepted for implementation by the firm upon initial acceptance; upon any modification; and upon verification of the plan.

3. Sanitation

Sanitation controls [3] may be included in the HACCP plan. However, to the extent that they are otherwise monitored, they need not be included in the HACCP plan.

4. Implementation

This book is not the proper forum to discuss in detail the implementation of HACCPR. Readers interested in additional information on HACCP should visit the FDA HACCP website http://vm.cfsan.fda.gov/, which lists all the currently available documents on the subject.

IV. THE FDA *FOOD CODE*

The FDA *Food Code* (the Code) [4] is an essential reference that guides retail outlets such as restaurants and grocery stores and institutions such as nursing homes on how to prevent foodborne illness. Local, state, and federal regulators use the FDA *Food Code* as a model to help develop or update their own food safety rules and to be consistent with national food regulatory policy. Also, many of the over one million retail food establishments apply *Food Code* provisions to their own operations. The *Food Code* is updated every two years to coincide with the biennial meeting of the Conference for Food Protection. The conference is a group of representatives from regulatory agencies at all levels of government, the food industry, academia, and consumer organizations that work to improve food safety at the retail level [5]. A brief discussion of the Code is provided here. Further information, including access to the Code, may be obtained from the Food Safety Training and Education Alliance (www.fstea.org).

The Code establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities; and provides for food establishment plan review, permit issuance, inspection, employee restriction, and permit suspension. The Code discusses the good manufacturing practices for equipment, utensils, linens, water, plumbing, waste, physical facilities, poisonous or toxic materials, compliance, and enforcement. The Code also provides guidelines on food establishment inspection, HACCP guidelines, food processing criteria, model forms, guides, and other aids. A brief introduction to the *Food Code* in this chapter is important for two reasons: First, at the end of this book, two chapters cover retail food protection from the perspectives of food sanitation. The *Food Code* forms the backbone of these chapters. Second, although this guide is designed for retail food protection, more than half of the data included are directly applicable to food processing plants, e.g., equipment design (cleanability), CIP system, detergents and sanitizers, refrigeration and freezing storage parameters, water requirements, precautions against "backflow" (air, valve, etc.), personnel health and hygiene, rest rooms and accessories, pest control, storage of toxic chemicals, inspection forms, inspection procedures, and many more. Some of the data in the present book can be readily traced to the Code.

The Code consists of eight chapters and seven annexes. Some of the information found

in the Code will be further explored in two chapters at the end of this book. The annex that covers inspection of a food establishment applies equally as well to both retail food protection and to sanitation in food processing. According to the Code, the components of an inspection would usually include the following elements:

Introduction
- Program planning
- Staff training
- Conducting the inspection
- Inspection documentation
- Inspection report
- Administrative procedures by the state/local authorities
- Temperature measuring devices
- Calibration procedures
- HACCP inspection data form
- Food establishment inspection report
- FDA electronic inspection system
- Establishment scoring

Details of these items will not be discussed here; some are further explored in various chapters in this book (please consult the index for specific topics). Instead, the next two sections trace the history and practices of food establishment inspection and how basic sanitation controls are slowly evolving into the prerequisites for HACCP plans in both retail food protection *and* food processing plants.

A. Purpose

A principal goal to be achieved by a food establishment inspection is to prevent foodborne disease. Inspection is the primary tool a regulatory agency has for detecting procedures and practices that may be hazardous and for taking actions to correct deficiencies. *Food Code*—based laws and ordinances provide inspectors science-based rules for food safety. The *Food Code* provides regulatory agencies with guidance on planning, scheduling, conducting, and evaluating inspections. It supports programs by providing recommendations for training and equipping the inspection staff, and attempts to enhance the effectiveness of inspections by stressing the importance of communication and information exchange during regulatory visits. Inspections aid the food service industry in the following ways:

1. They serve as educational sessions on specific Code requirements as they apply to an establishment and its operation.
2. They convey new food safety information to establishment management and provide an opportunity for management to ask questions about general food safety matters.
3. They provide a written report to the establishment's permit holder or person in charge so that the responsible person can bring the establishment into conformance with the Code.

B. Current Applications of HACCP

Inspections have been a part of food safety regulatory activities since the earliest days of public health. Traditionally, inspections have focused primarily on sanitation. Each inspection is unique in terms of the establishment's management, personnel, menu, recipes, operations, size, population served, and many other considerations.

Changes to the traditional inspection process were first suggested in the 1970s. The terms "traditional" or "routine" inspection have been used to describe periodic inspections conducted as part of an ongoing regulatory scheme. A full range of approaches was tried and many were successful in managing a transition to a new inspection philosophy and format. During the 1980s, many progressive jurisdictions started employing the HACCP approach to refocus their inspections. The term "HACCP approach" inspection is used to describe an inspection using the hazard analysis and critical control point concept. Food safety is the primary focus of a HACCP approach inspection. One lesson learned was that good communication skills on the part of the person conducting an inspection are essential.

The FDA has taught thousands of state and local inspectors the principles and applications of HACCP since the 1980s. The State Training Branch and the FDA Regional Food Specialists have provided two-day to week-long courses on the scientific principles on which HACCP is based, the practical application of these principles including field exercises, and reviews of case studies. State and local jurisdictions have also offered many training opportunities for HACCP.

A recent review of state and local retail food protection agencies shows that HACCP is being applied in the following ways:

1. Formal Studies. Inspector is trained in HACCP and is using the concepts to study food hazards in establishments. These studies actually follow foods from delivery to service and involve the write-up of data obtained (flow charts, cooling curves, etc.).
2. Routine Use. State has personnel trained in HACCP and is using the hazard analysis concepts to more effectively discover hazards during routine inspections.
3. Consultation. HACCP-trained personnel are consulting with industry and assisting them in designing and implementing internal HACCP systems and plans.
4. Alternative Use. Jurisdiction used HACCP to change inspection forms or regulations.
5. Risk-Based. Jurisdiction prioritized inventory of establishments and set inspection frequency using a hazard assessment.
6. Training. Jurisdiction is in the active process of training inspectors in the HACCP concepts.

Personnel of every sort of food establishment should have one or several copies of the *Food Code* readily available for frequent consultation.

V. APPLICATION TO FOOD PLANT SANITATION

The sanitary requirements in the CGMPR and the *Food Code* serve as the framework for the chapters in this book. The HACCPR will be touched on when they help to clarify the

discussion. Essentially, this book shows how to implement the umbrella regulations provided under the CGMPR. Each chapter handles one aspect of these complicated regulations. Most chapters discuss the regulations applicable to all types of food products being processed. Several chapters concentrate on the sanitary requirements from the perspectives of the processing of a specific category of food. The appendix of this book reproduces the complete coverage of CGMPR in 21 CFR 110.

REFERENCES

1. FDA. Title 21, Code of Federal Regulations, Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. Washington, DC: U.S. Government Printing Office, 2001.
2. FDA. Title 21, Code of Federal Regulations, Part 120, Hazard Analysis and Critical Control Point (HACCP) Systems. Washington, DC: U.S. Government Printing Office, 2001.
3. CM Nolan. Developing an integrated sanitation program using innovative techniques. Food Safety Magazine 7(4): 18, 19, 21, 39, 40, 43, 44, 2001.
4. FDA. *Food Code.* Washington, DC: U.S. Department of Health and Human Services, 2001.
5. G Lewis, PA Salisbury. Safe food at retail establishments. Food Safety Magazine 7(4): 13–17, 2001.

4
Food Plant Inspections

ALFRED J.ST.CYR
AIB International, Manhattan, Kansas, U.S.A.

I. INTRODUCTION

Food manufacturing plants continue to increase in complexity, and the potential for issues to develop that adversely affect the consumer increase accordingly. To avoid being in a negative spotlight, food plants have developed numerous programs and policies designed to meet their challenges. Good manufacturing practice (GMP) policies, hazard analysis and critical control point (HACCP) programs, plant policies and practices, production parameters, preventive maintenance programs, and sanitation/hygiene programs, along with others, assist facilities in meeting their obligations. One critical program that must be in place to verify that all objectives are being met on a consistent basis includes plant inspections [1].

Plant inspections are used by several different entities to achieve the same goal. Regulatory agencies utilize plant inspections for the enforcement of food laws. A company's customers utilize inspections to determine the risks of doing business with a particular firm, using either their own resources or a third-party professional organization, to conduct the inspection. Perhaps the most important aspect of the inspection program, however, is the self-inspection program undertaken by a facility's own personnel to monitor the conditions in the plant. Personnel must identify potential food safety risks and take actions to correct deficiencies that develop.

The internal inspection process should be conducted by a well-organized committee dedicated to ensuring a high level of compliance with all the plant's internal policies and all external requirements (those of business partners, federal and state regulatory agencies, etc.) [2]. The committee usually consists of management personnel from production, plant sanitation and maintenance, as well as from the quality control and human resources departments. More and more often, the committee includes hourly employees, who have an equal commitment to the success of the plant. The mix of these various personnel offers the committee the opportunity to view the plant from different perspectives and to evaluate the programs using a more comprehensive approach. Often the plant manager will participate in the process to lend a higher visibility to the program as well as to accelerate the corrective actions needed.

Once the committee members have been selected, their responsibility becomes one of assessing what has been neglected and also compiling a report detailing solutions to the food safety risks identified. Generally, these risks are beyond the capability or authority of the individual responsible for the area of concern. This report, called a Corrective Action Report, requires a specific action to be taken within a designated time frame. It

also allows for follow-up actions since the issue remains open until it has been corrected.

II. PLANT POLICIES

Food plants can expect regulatory agencies, customers, and even corporate personnel (both in-house inspectors and inspectors from supplier companies) to conduct evaluations of plant operations and conditions (see Chapter 21). This is often an inconvenience and sometimes a traumatic experience. The better prepared your facility is to meet these challenges, the less likely your personnel will be tense and make costly mistakes by providing the wrong information or behave in a manner that raises concerns. Each facility should be prepared ahead of time by having a clearly written and understood policy concerning inspections by outside personnel.

The policy should include and spell out clearly what actions are to be taken and by whom when an inspector arrives at the facility. Policies concerning photographs, samples, and records that can be reviewed with inspectors must be clear to give personnel the proper guidance. Policies should indicate the member of the management team to accompany the inspectors and answer the questions. The personnel assigned this responsibility should be familiar with the policy and their responsibilities and should be able to outline the firm's policies for the inspectors during the initial meeting. Having clear policies that are understood by all parties can help you avoid costly misunderstandings and controversy during the inspections. Encountering a facility that is clearly in control of this aspect of their operations sends a very positive message to any investigator regarding the commitment and understanding of the obligation a firm has when manufacturing food. Rarely is an inspection of your facility a pleasant experience; however, it can go relatively smoothly if you take the time to be prepared.

III. REGULATORY INSPECTIONS

The Food, Drug, and Cosmetic Act of 1938 allows for the inspection of food manufacturing plants by government investigators from various federal, state, and local health agencies to determine if the facility complies with the current statutes. The authority to conduct the inspections was further supported by the United States vs. Dotterweich decision (U.S. Supreme Court 1943, 320 U.S. 277,64S.CT 134) rendered by the high court in 1948. The federal inspection program is divided between the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). Though each is charged with different responsibilities, they share the common goal of protecting the health and welfare of the American consumer.

It is important to understand that a visit by an investigator from a government agency such as the FDA is the beginning of a legal process—specific protocols must be followed. Both parties have specific rights or privileges granted under the law that must be respected. Since the FDA commonly inspects a variety of food manufacturing plants, we will review the process commonly followed by that agency (the USDA programs are aimed mainly at the meat and poultry industries).

The initial visit by an investigator from the FDA is likely to be an unannounced event. The investigator (the number varies from one to several) will arrive at the facility during what has been determined as reasonable business hours, which can mean that inspectors can arrive any time the business is open. However, since the visit will likely require contact with senior management personnel, the investigator will normally arrive at some point during typical business hours unless there is a significant urgency to the issue.

Security personnel, if they are the first company personnel encountered, should direct the investigator to the proper reception area. Though every effort should be made to expedite the investigator meeting with the correct personnel, certain protocols should be met. Every investigator should present his or her official identification credentials prior to proceeding beyond this point. If not voluntarily provided, these should be requested. Inquiries should be made concerning the reason behind the visit. This will likely produce FDA form 482, "Notice of Inspection," that will state that the investigator is there to conduct an inspection of the facility and that this is the beginning of the process. The form will not state whether the investigation is for routine GMP compliance or whether a specific violation is being investigated. It is important to ask the investigator for this information.

The vast majority of investigations conducted by the FDA are considered routine as required by law. However, due to the complexities of food manufacturing in the United States, conditions found in one distribution center or manufacturing facility may lead investigators to your facility in their effort to determine the extent and/or source of a particular risk to the public health. This may involve tracking an infestation or a contamination issue introduced into interstate commerce. An excellent guide to help you understand what inspectors are likely to evaluate in your facility is available in the manual "Inspectional Methods Taught by FDA: Inspections by Specific Food Categories" [3].

Regardless of the reason for the inspection conducted by outside personnel, it is important to have only one spokesperson for your firm. This policy can reduce the potential for confusion and misunderstanding between parties. In addition, if the spokesperson is not familiar with the information requested, he or she should so state and then get back to the inspector after obtaining the correct information.

At the conclusion of the FDA inspection, the investigator will issue a "List of Observations" (form 483) and present the observations to management prior to leaving the facility. This form should be carefully reviewed and any points that appear unclear or incorrect should be corrected with the investigator at that time. All corrections completed during the visit should also be noted on this form. It is very important that management take appropriate action to ensure that a repeat of the issues noted does not occur on subsequent inspections.

The inspectors may take samples of finished products, in-process ingredients, or other sources of evidence such as insects or insect fragments, foreign matter, or rodent evidence during an inspection. The FDA will provide you with a "Receipt for Samples" (form 484) for the samples taken during the course of the inspection. It is important that you obtain a sample from the same source. The best option is to split the sample taken by the FDA investigator. Find out what tests will be conducted on the samples and then expedite having your samples tested by an independent laboratory using

the same methods outlined by the investigator.

IV. SELF-INSPECTION PROGRAM

The preceding section outlined the legal aspects of the inspection process. There is little doubt that any person involved in any way with the production, storage, and distribution of food items has a legal responsibility to comply with the established regulatory statutes. Though important, the legal requirements cover only part of the issues. We cannot overlook the moral obligation that we in the food industry have to those who purchase and consume our products. All of us are dependent on other people to provide us with safe, wholesome products. The impact of failing to meet the expectations of our customers and putting their health and welfare at risk often results in a far more severe economic impact on business than the fines imposed by regulatory agencies.

To avoid events that lead to failures, an effective food safety program should be designed with attention to the interrelationships between all departments in the food plant and between management and hourly employees. When you consider that the number of employees represents the number of opportunities for program success or failure, it pays to invest in each employee to ensure your success. Only when all employees personally accept the responsibility for the products under their control and accept that they will be held accountable for their actions can we truly succeed.

A. Preparing for Self-Inspections

One common excuse used to justify the failure of a viable self-inspection program is a lack of time to do the inspection. Adequate preparation and notification of the members of the committee designated to conduct the inspection can reduce the time required to conduct the inspections and ensure that they are carried out with sufficient detail in order to identify and correct potential food safety issues.

Since the self-inspection program is an extension of employee training programs and is also used to assess the needs of the facility, the conduct of the inspection committee members is critical to the success of the program. Having the tools (ladders, manlifts, keys for access, etc.) available ahead of time and discussing issues identified with area employees can only improve the acceptance of the program and participation by everyone.

Conducting a good inspection requires considerably more than collecting a long list of issues for someone to correct. Far too often, without proper training of the inspectors, the process becomes bogged down in personal conflicts. The task requires a person to review a situation, identify the deficiency, determine a corrective action, and follow through to its implementation.

Perhaps the two most important things a person can bring to the self-inspection process are a blank mind and a blank notepad to document the findings. If you embark on an inspection tour of the facility looking for specific issues, you will likely find those issues. However, there may be other significant issues you overlook in your pursuit because your mind’s eye is closed to them. Since no one has perfect memory, the notepad allows you

to document the issues you identify and thus facilitate follow-up by the proper personnel.

Proper note taking during inspections is a difficult task in itself. The inspection notes are your primary method of conveying your concerns to others. You will, subsequently, have to prioritize the corrective actions required to remedy the various defects observed. At a minimum, the notes you take to document the findings should include what was wrong, why you felt it was an issue, a suggestion for correction, and, perhaps most important, the exact location in the facility where the observation was made. Understand very clearly that the personnel reading your inspection report were likely not with you; so your task is to create, through the least amount of words, an image that motivates them to corrective action. Always provide the facts clearly. Poorly written inspection reports incorporating inaccurate or misleading comments may very well compromise the company's confidence in both the self-inspection program in the inspector conducting it.

Also useful during facility inspections are simple tools that permit you to make clearer observations. Aside from dressing properly for conducting an inspection by including safety shoes and safety equipment required by plant policy and having maintenance resources available, other tools that may be useful to help identify opportunities include

Bright flashlight
Various spatulas
Screwdrivers
Extension inspection mirrors
Small adjustable wrench
Other specialized tools for the operation

Individual systems may require specific tools to obtain access. Regardless of the plant or system you are inspecting, communication and following safety protocols are imperative. Rely on the operators to provide access to equipment since they likely have a very comprehensive knowledge of the system. Rely on them as a resource for information to answer your questions. Since their participation is critical to the success of the programs, involving them in the inspection process is an opportunity to provide instruction and solicit their cooperation.

B. Inspecting the Plant

Though individual inspectors would appear to have their own unique techniques for inspecting a food plant, close observation of their work will reveal that most of them pursue a logical path, following the production process either from start to finish or vice versa. Doing so can often make it easier for those reading the final report to better visualize the flow the inspection took and improve their understanding of the issues noted.

Usually, inspectors will follow the flow of production from beginning to end. However, there are a few exceptions to this practice that you must consider. First, there may be microbiological considerations in the process that would not allow you to start at the beginning of a process. A facility such as a dairy would require that the raw milk receiving area be inspected at the conclusion of the inspection to avoid the potential for transfer of a microbiological contaminant from this area to the remainder of the facility.

You may encounter similar issues in other processes where beginning the inspection in the final processing areas would be the most appropriate.

C. Raw Material Receiving

The raw material receiving area of the facility requires a thorough review of the materials stored there and also close observation of the procedures followed to allow materials to be accepted into the food plant. Each ingredient or material arriving from outside the plant must be treated as suspect and treated as though each offers the potential for the introduction of a problem. Personnel in these receiving areas must become familiar with the potential problems they may encounter and be vigilant in their inspection of incoming materials and the vehicles in which they arrived.

The inspection of raw materials in the storage warehouse provides an excellent opportunity to further identify issues with suppliers and must be paid the appropriate attention. By its design, this area of the plant houses all of the materials acquired from countless “unknown” sources. No other area of the plant provides a higher risk for hazards to impact the plant.

Confirm that all of the programs the facility has developed to identify and correct issues regarding receipt of raw materials from suppliers are in place and followed. Verify proper dating or coding of materials and ensure that storage practices conform to the requirements of the product and the facility. Particular attention should be paid to the receipt documentation and pest control records for these areas to attempt to identify trends that may have developed with a particular product or supplier. Insect monitoring devices such as insect light traps and pheromone traps should certainly be regarded as valuable sources of information.

Inspection of the area around the incoming products should be undertaken with a three-dimensional approach. Too often we tend to limit ourselves to the easily accessible areas or fail to fully identify the extent of an issue because the scope of the search was equally limited. By making observations from an elevated vantage point that provides a broad overview of a certain section of the facility, the inspector may be able to identify a breakdown of a specific program or a potentially serious isolated issue that might go unobserved at ground level. In a storage area for ingredients, for example, the observation of dust and debris accumulations on numerous pallet stacks might signal a widespread defect in stock rotation or cleaning programs. By spotting just one pallet stack that appears to be out of sequence in the stock rotation system, the inspector is prompted to call attention to a specific issue that may have escaped the attention of the responsible plant personnel.

It is well worth the effort while you are in this area of the plant to inspect and confirm the use of the product safety devices established to monitor incoming materials. Sifters, strainers, magnets, metal detectors, filters, and other devices should be closely examined and their documented records checked to determine if failures have occurred and actions taken in response to these failures. This task is one that provides the opportunity to involve the area personnel in the inspection process and enables them to demonstrate their capabilities and participation in the overall product safety program.

D. Production Areas

The production areas of factories offer a variety of challenges and opportunities. Often congested with equipment and in a state of haste, extra caution is required by the individual inspecting these areas. Even the most knowledgeable employees have been known to make simple errors of judgment that have caused serious injury. Always be aware of and concerned about the effect your actions may have while working in busy areas of the facility.

Though a human brain is indeed a marvelous tool, it has limitations. A limited amount of data can be taken in, processed, analyzed, and interpreted. The volume of data challenging the inspector in the production/processing area can be overwhelming. We may believe we are making a comprehensive survey of an area when we attempt to scan the entire area at one time, but in reality our mind's eye tends to deceive us about how little we actually see.

To overcome this, the inspector should break down (or cube) the area into small, manageable parts to better evaluate conditions, with smaller volumes of data handled individually rather than as a whole. To accomplish this, simply establish boundaries in a given room and thoroughly evaluate that space before moving on to the adjacent space. Use a piece of equipment or any solid object to help you focus on that object and the surrounding space before moving on to the next piece of equipment.

A primary objective of the inspection conducted in processing areas is often to establish that all of the policies and procedures in place are in fact being followed. Personnel given this responsibility need to recognize that their greatest asset is their ability to observe and then to correlate the observations with the sum total of the processing operations. To do so, the auditor must have a comprehensive understanding not only of the guidelines established within the organization, but also of the potential impacts of nonconformance with those guidelines.

This knowledge becomes increasingly relevant when the time for corrective action requires the participation of the production area employees. Your ability to explain the deficiency and what will be required for correction in a logical and meaningful way to the personnel working in a given area will likely facilitate implementation of the correction far more quickly than if it is perceived that you do not know what you are talking about. When you can relate the need for change in such a way that the responsible employee sees it as a personal advantage, then compliance with the change easily follows.

Recognize that the production facility changes throughout the day and that inspections conducted at various times will likely reveal different issues. This is partially dictated by the access you have to the systems at various times. Realizing this, the plant inspection program should be conducted during the different shifts in an attempt to obtain a varied assessment of conditions in the operation.

E. Production Periods

Inspections conducted in production areas during production periods offer an opportunity to observe personnel practices and the operational methods employed, as well as the overall state of repair of the facility, systems integrity, and policy compliance. Since

personnel are often a source of concern, time spent on the production floor during these periods is extremely valuable. However, recognize the limitations you will encounter if your objective is to inspect the condition of the production equipment; access to critical elements of the system will probably not be available for inspection except during production downtime.

The inspection of the processing areas encompasses the GMP issues. Due to lack of available time and scheduling constraints that do not allow for separate and distinct evaluations, many companies combine both GMP and production/processing evaluations in abbreviated formats to be conducted during the same visit to the facility. More detailed audits can then be performed if the information collected warrants further action. This is especially the case when there is a critical process control that also involves a food safety risk. Verification that processes are being held within the critical limits established for the product, as well as verifying the integrity of the system, is often incorporated into the inspection process [4].

F. Packaging Areas

Special attention is required when inspecting the packaging area of any facility. This area is the last point in the process where you have the opportunity to remove those products not conforming to established specifications. Your inspection should focus on the ability of the systems used to identify failures (magnets, metal detectors, sieves, etc.) and the level of compliance by area personnel in the proper monitoring of these systems.

The inspection process should provide for a very thorough review to identify any and all possible defects that might pass through the system and to ensure that they are detected and corrected. It should be standard practice to test the metal detection equipment and verify its effective operation by using the appropriate test blanks (see also Chapter 23). You should confirm that area personnel responsible for the validation procedures follow the proper test protocols and, if necessary, then make sure that these same people make the appropriate adjustments. In addition, the inspection procedures should include a verification of code date systems and proper packaging for the products.

Packaging systems, ventilation systems, and electrical elements have become increasingly complex and are often sensitive to the intrusion of untrained personnel performing routine inspections. Due to these complexities, many plant managers are reluctant to allow access to these systems frequently enough to insect infestations or other sources of contamination to develop. To limit the potential for these unwanted outcomes to occur, you must provide training to develop the skill level and competence of the personnel in these areas.

G. Support Areas

Though often overlooked or de-emphasized during plant inspections, support areas can have a significant impact on the rest of the facility. Many inspectors will gauge the level of tolerance for policy compliance by the way the mechanical or utility areas are maintained. A general lack of GMP or plant policy compliance identified in these areas will often raise suspicions in other areas as well. All plant policies should be uniformly