

EXHIBIT 2005

MICRO- ORGANISMS IN FOODS



MICROBIOLOGICAL TESTING
IN FOOD SAFETY
MANAGEMENT

ICMSF



KLUWER ACADEMIC /
PLENUM PUBLISHERS

PRINTED IN U.S.A.

Microorganisms in Foods 7

Microorganisms in Foods 7

Microbiological Testing in
Food Safety Management

ICMSF



**KLUWER ACADEMIC /
PLENUM PUBLISHERS**

233 Spring Street, New York, New York 10013-1578

PRINTED IN U.S.A.

Library of Congress Cataloging-in-Publication Data

International Commission on Microbiological Specifications for Foods.
Microbiological testing in food safety management / ICMSF ; editorial committee, R.B. Tompkin . . . [et. al.].
p. cm.—(Microorganisms in foods ; 7)
Includes bibliographical references and index.

ISBN 0-306-47262-7

1. Food—Microbiology. 2. Food—Standards. I. Tompkin, R.B. (R. Bruce) II. Title. III. Series.

QR115.I46 2001

664'.001'579—dc21

2001053529

Copyright © 2002 Kluwer Academic/Plenum Publishers
233 Spring Street, New York, NY 10013

<http://www.wkap.nl>

All rights reserved.

No part of this work may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, microfilming, recording, or otherwise, without written permission from the Publisher, with the exception of any material supplied specifically for the purpose of being entered and executed on a computer system, for exclusive use by the purchaser of the work.

Editorial Services: Joan Sesma
Library of Congress Catalog Card Number: 2001053529
ISBN: 0-306-47262-7

Printed in the United States of America

1 2 3 4 5

Introduction

Microorganisms in Foods 7: Microbiological Testing in Food Safety Management was written by the International Commission on Microbiological Specifications for Foods (ICMSF/the Commission) with assistance from a limited number of consultants.

Microorganisms in Foods 7 is based upon Part I of *Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications* (2nd ed. 1986). In the 1980s, control of food safety was largely by inspection and compliance with hygiene regulations, together with end product testing. *Microorganisms in Foods 2* put such testing on a sounder statistical basis through sampling plans, which remain useful at port-of-entry when there is no information on the conditions under which a food has been produced or processed. At an early stage, the Commission recognized that no sampling plan could ensure the absence of a pathogen in food. Testing foods at ports-of-entry, or elsewhere in the food chain, could not guarantee food safety.

This led the Commission to explore the potential value of Hazard Analysis Critical Control Point (HACCP) for enhancing food safety, particularly in developing countries. *Microorganisms in Foods 4: Application of the Hazard Analysis Critical Control Point (HACCP) System to Ensure Microbiological Safety and Quality* (1988), illustrated the procedures used to identify the microbiological hazards in a practice or a process, to identify the critical control points at which those hazards could be controlled, and to establish systems by which the effectiveness of control could be monitored. In addition, recommendations were included for the application of HACCP from production/harvest to consumption, together with examples of how HACCP could be applied at each step in the food chain.

Effective implementation of HACCP requires knowledge of the hazardous microorganisms and their response to conditions in foods (e.g., pH, a_w , temperature, preservatives). The Commission concluded that such information was not collected together in a form that could be assessed easily by food industry personnel in quality assurance, technical support, research and development, and by those in food inspection at local, state, regional, or national levels. *Microorganisms in Foods 5: Characteristics of Microbial Pathogens* (1996) is a thorough, but concise, review of the literature on growth, survival, and death responses of foodborne pathogens. It is intended as a quick reference manual to assist in making judgements on the growth, survival, or death of pathogens in support of HACCP plans and to improve food safety.

Microorganisms in Foods 6: Microbial Ecology of Food Commodities (1998) is intended for those primarily involved in applied aspects of food microbiology such as

food processors, food microbiologists, food technologists, veterinarians, public health workers, and regulatory officials. Addressing 16 commodity areas, it describes the initial microbial flora and the prevalence of pathogens, the microbiological consequences of processing, typical spoilage patterns, episodes implicating those commodities with food-borne illness, and measures to control pathogens and limit spoilage.

This book, *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management* (2002), illustrates how systems such as HACCP and good hygiene practices (GHP) provide greater assurance of safety than microbiological testing, but also identifies circumstances where microbiological testing still plays a useful role in systems to manage food safety. It continues to address the Commission's objectives to: (a) assemble, correlate, and evaluate evidence about the microbiological safety and quality of foods; (b) consider whether microbiological criteria would improve and ensure the microbiological safety of particular foods; (c) propose, where appropriate, such criteria; (d) recommend methods of sampling and examination; (e) provide guidance on appraising and controlling the microbiological safety of foods.

This book introduces the reader to a structured approach for managing food safety, including sampling and microbiological testing. The text outlines how to meet specific food safety goals for a food or process using GHP and the HACCP system.

The concept of a food safety objective (FSO) is recommended to industry and control authorities to translate "risk" into a definable goal for establishing food safety management systems that incorporate the principles of GHP and HACCP. FSOs provide the scientific basis for the industry to select and implement measures that control the hazard(s) of concern in specific foods or food operations, for control authorities to develop and implement inspection procedures to assess the adequacy of control measures adopted by industry, and for quantifying the equivalence of inspection procedures in different countries.

Microbiological testing can be a useful tool in the management of food safety. However, microbiological tests should be selected and applied with knowledge of their limitations, as well as their benefits and the purposes for which they are used. In many instances other means of assessment are quicker and more effective.

The need for microbiological testing varies along the food chain. Points in the food chain should be selected where information about the microbiological status of a food will prove most useful for control purposes. Similarly, in a food operation, samples may be collected from different points in a process for control purposes.

Finally, a framework is provided by which importing countries can assess whether foods from other countries have been produced in a manner that provides a level of protection equivalent to that required for domestically produced foods.

This book illustrates the insensitivity of even statistically based sampling plans and encourages a rational approach to the use of microbiological testing in systems that manage food safety through GHP and HACCP. Several new chapters are based on the experience of the food industry in controlling salmonellae, *Listeria monocytogenes* and *Escherichia coli* O157:H7, on tightened or investigational sampling, on microbiological testing of the processing environment, and the use of statistical process control to detect trends and work toward continuous improvement.

The book is intended to be useful for anyone who is engaged in setting microbiological criteria for the purpose of governmental or industry food inspection and control. For students in food science and technology it offers a wealth of information on food safety management and many references for further study.

EDIT

R. B.

T. A.

M. v

M. E

ICM

Chai

Secr

Trea

Men

Con

J. B.

S. D.

P. D.

J. M.

B. I.

W. C.

L. C.

Cor

D. K.

EDITORIAL COMMITTEE

R. B. Tompkin (Chairman)
 T. A. Roberts
 M. van Schothorst
 M. B. Cole

L. Gram
 R. L. Buchanan
 S. Dahms

ICMSF Members during Preparation of Book 7

<i>Chairman</i>	T. A. Roberts (1991–2000)	M. B. Cole (from 2000)
<i>Secretary</i>	M. van Schothorst	
<i>Treasurer</i>	A. N. Sharpe (1989–1998) F. F. Busta (1998–2000)	J. M. Farber (from 2000)
<i>Members</i>	A. C. Baird-Parker (retired 1999) R. L. Buchanan J.-L. Cordier S. Dahms (from 1998) M. P. Doyle (resigned 1999) M. Eyles (resigned 1999) J. Farkas (retired 1998) R. S. Flowers B. D. G. M. Franco (from 2000) L. Gram (from 1998)	F. H. Grau (retired 1999) J.-L. Jouve A. M. Lammerding (from 1998) S. Mendoza (retired 1998) Z. Merican J. I. Pitt F. Quevedo (retired 1998) P. Teufel R. B. Tompkin

Consultants

J. Braeunig (2000)	L. Gram (1997, 1998)
S. Dahms (1997, 1998)	H. Kruse (1999, 2000)
P. Desmarchelier (1999)	A. M. Lammerding (1997, 1998)
J. M. Farber (1998)	B. Shay (1999)
B. D. G. M. Franco (1998, 1999)	K. Swanson (2000)
W. Garthwright (1999)	A. von Holy (1997)
L. G. M. Gorris (2000)	

Contributors

D. Kilsby, R. B. Smittle, J. H. Silliker

- Prof. M. P. Doyle, Center for Food Safety & Quality Enhancement, University of Georgia, Georgia Station, Griffin, GA 30223, USA (resigned 1999)
- Dr. M. Eyles, CSIRO, Division of Food Science & Technology, P.O. Box 52, North Ryde, NSW 2113, Australia (resigned 1999)
- Prof. J. Farkas, Vice Rector, Department of Refrigeration and Livestock Products Technology, Faculty of Food Industry, University of Horticulture and Food Industry, H-1118 Budapest, Menesi ut 45, Hungary (retired 1998)
- Dr. R. S. Flowers, Silliker Laboratories, 900 Maple Road, Homewood, IL 80430, USA
- Prof. Bernadette D. G. M. Franco, Departamento de Alimentos e Nutricao Experimental, Faculdade de Ciencias Farmaceuticas, Universidade de São Paulo, Av. Prof. Lineu Prestes 580, 05508-900, São Paulo, SP, Brazil.
- Prof. Lone Gram, Danish Institute for Fisheries Research, Department of Seafood Research, Soltafts Plads, Danish Technical University, Bldg 221, DK-2800 Kgs. Lyngby, Denmark
- Dr. F. H. Grau, CSIRO, Division of Food Science & Technology, Brisbane Laboratory, P.O. Box 3312, Tingalpa DC, QLD 4173, Australia (retired 1999)
- Prof. Jean-Louis Jouve, European Commission, DG Health and Consumer Protection, Rue Belliard, 232-Room 6/14, B-1040 Brussels, Belgium
- Dr. Anna M. Lammerding, Food Safety Risk Assessment Unit, Health of Animals Laboratory, 110 Stone Road West, Guelph, Ontario N1G 3W4, Canada
- Dra. Silvia Mendoza, Division of Biological Sciences, Department of Biological and Biochemical Process Technology, Simon Bolivar University, P.O. Box 89.000, Caracas 1080 A, Venezuela (retired 1998)
- Ms. Zahara Merican, Technical Services Centre, Malaysian Agricultural Research & Development Institute (MARDI), P.O. Box 12301 GPO, 50774 Kuala Lumpur, Malaysia
- Dr. John I. Pitt, Chief Research Scientist, Food Science Australia, P.O. Box 52, North Ryde, NSW 1670, Australia
- Prof. Dr. F. Quevedo, Food Quality & Safety Assurance International, F. Villareal National University, Las Petunias 140, Dpt. 201, Urb. Camacho, Lima 12, Peru (retired 1998)
- Dr. Paul Teufel, Director and Professor, Institute for Hygiene and Food Safety, Federal Dairy Research Centre, Hermann-Weigmann Strasse 1, D-24103 Kiel, Germany
- Dr. R. Bruce Tompkin, Vice President Product Safety, ConAgra Refrigerated Prepared Foods, 3131 Woodcreek Drive, Downers Grove, IL 60515-5429, USA

PAST MEMBERS OF THE ICMSE

NAME	COUNTRY	MEMBERSHIP
Dr. A. C. Baird-Parker	UK	1974-1999
Dr. M. T. Bartram	USA	1967-1968
Dr. H. E. Bauman	USA	1964-1977
Dr. F. L. Bryan	USA	1974-1996 ¹
Dr. L. Buchbinder*	USA	1962-1965
Prof. F. F. Busta	USA	1985-2000 ²
Dr. R. Buttiaux	France	1962-1967
Dr. J. H. B. Christian	Australia	1971-1991 ³
Dr. D. S. Clark	Canada	1963-1985 ⁴
Dr. C. Cominazzini	Italy	1962-1983

Dr. C. E. Dolman*	Canada	1962-1973
Dr. M. P. Doyle	USA	1989-1999
Dr. R. P. Elliott*	USA	1962-1977
Dr. Otto Emberger	former Czechoslovakia	1971-1986
Dr. M. Eyles	Australia	1996-1999
Dr. J. Farkas	Hungary	1991-1998
Mrs. Mildred Galton*	USA	1962-1968
Dr. E. J. Gangarosa	USA	1969-1970
Dr. F. Grau	Australia	1985-1999
Dr. J. M. Goepfert	Canada	1985-1989 ⁵
Dr. H. E. Goresline*	USA/Austria	1962-1970
Dr. Betty C. Hobbs*	UK	1962-1996
Dr. A. Hurst	UK/Canada	1963-1969
Dr. H. Iida	Japan	1966-1977
Dr. M. Ingram*	UK	1962-1974 ⁶
Dr. M. Kalember-Radosavljevic	former Yugoslavia	1983-1992
Dr. K. Lewis*	USA	1962-1982
Dr. John Liston	USA	1978-1991
Dr. Holger Lundbeck*	Sweden	1962-1983 ⁷
Dr. S. Mendoza	Venezuela	1992-1998
Dr. G. Mocquot	France	1964-1980
Dr. G. K. Morris	USA	1971-1974
Dr. D. A. A. Mossel*	The Netherlands	1962-1975
Dr. N. P. Nefedjeva	USSR	1964-1979
Dr. C. F. Niven, Jr.	USA	1974-1981
Dr. P. M. Nottingham	New Zealand	1974-1986
Dr. J. C. Olson, Jr.	USA	1968-1982
Dr. H. Pivnick	Canada	1974-1983
Dr. T. A. Roberts	UK	1978-2000 ⁸
Dr. F. Quevedo	Peru	1965-1998
Dr. A. N. Sharpe	Canada	1985-1998 ⁹
Dr. J. Silliker	USA	1974-1987 ¹⁰
Mr. Bent Simonsen	Denmark	1963-1987
Dr. H. J. Sinell	Germany	1971-1992
Dr. G. G. Slocum*	USA	1962-1968
Dr. F. S. Thatcher*	Canada	1962-1973 ¹¹

*Founding member

¹Secretary, 1981-1991²Treasurer, 1998-2000³Chairman, 1980-1991⁴Secretary-Treasurer, 1963-1981⁵Treasurer, 1987-1989⁶Ex-officio member, 1962-1968⁷Chairman, 1973-1980⁸Chairman, 1991-2000⁹Treasurer, 1989-1998¹⁰Treasurer, 1981-1987¹¹Chairman, 1962-1973

MEMBERS OF THE LATIN AMERICAN SUBCOMMISSION

Chairperson

Dra. Maria Alina Ratto, General Manager, Microbiol S.A., Joaquin Capello 222, Lima 18, Peru, e-mail: microbl@terra.com.pe

Secretary/Treasurer

Lic. Ricardo A. Sobol, Director Tecnico, Food Control S.A., Santiago del Estero 1154, 1075 Buenos Aires, Argentina, e-mail: 50601@foodcontrol.com

Honorary Members

Prof. Fernando Quevedo, Food Quality and Safety Assurance International, Buenos Aires 188, Miraflores, Lima 18, Peru, e-mail: fquevedo@amauta.rcp.net.pe

Prof. Sebastião Timo Iaria, Av. Angelica 2206, apto 141, 01228-200, Sao Paulo, SP, Brazil, e-mail: stiarra@aol.com.br

Prof. Silvia Mendoza, Conjunto Residencial E1, Av. Washington Torre 1A, piso 12 apto 123, Caracas, Venezuela, e-mail: silmendoza@cantr.net

Prof. Nenufar Sosa de Caruso, Alimentarius, Tomas de Tezanos 1323, Montevideo, Uruguay, e-mail: alimenta@adinet.com.uy

Members

Prof. Bernadette D. G. M. Franco, Departamento de Alimentos e Nutricao Experimental, Faculdade de Ciencias Farmaceuticas, Universidade de São Paulo, Av. Prof. Lineu Prestes 580, 05508-900, São Paulo, SP, Brazil, e-mail: bfranco@usp.br

Dra. Eliana Marambio, Coventry 1046, Depto 405, Ñuñoa, Santiago, Chile, e-mail: emarambio@entelchile.net

Prof. Janeth Luna Cortéz, Universidad de Bogota, Carrera 4 No. 22-61 Of 436, Santafé de Bogotá, DC, Colombia, e-mail: ingenieria.alimentos@utadeo.edu.co

Dra. Dora Martha González, Sarmiento 2323, Montevideo, Uruguay, e-mail: dmgonzal@adinet.com.uy

Prof. Pilar Hernandez S., Universidad Central de Venezuela, Apartado 40109, Caracas 1040-A, Venezuela, e-mail: hernands@camelot.rect.ucv.ve

Former Members of the Latin-American Subcommission

Dra. Ethel G.V. Amato de Lagarde, Argentina

Dr. Rafael Camperchioli, Paraguay

Dr. Cesar Davila Saa, Ecuador

Dr. Mauro Faber de Freitas Leitao, Brazil

Dra. Josefina Gomez-Ruiz, Venezuela (former chairperson)

Dra. Yolanda Ortega de Gutierrez, Mexico

Dr. Hernan Puerta Cardona, Colombia

Dra. Elvira Regus de Pons, Dominican Republic

MEMBERS OF THE SOUTH-EAST ASIAN SUBCOMMISSION

Chairperson

Dr. Zahara Merican, Food Technology Research Centre, Malaysian Agricultural Research and Development Institute, P.O. Box 12301, GPO 50774 Kuala Lumpur, Malaysia

Secretary/Treasurer

Dr. Pho Lay Koon, Section Head, Plant Biotechnology & Agrotechnology, Chemical Process & Biotechnology Dept., Singapore Polytechnic, Dover Road, Singapore 0513.

Members

Dr. Srikandi Fardiaz, Head of Food Microbiology Laboratory, Inter University Centre for Food & Nutrition, Bogor Agricultural University, P.O. Box 220, Bogor, Indonesia (deceased 2000)

Ms. Quee Lan Yeoh, Food Technology Research Centre, Malaysian Agricultural Research and Development Institute, PO Box 12301, GPO 50774 Kuala Lumpur, Malaysia

Dr. Reynaldo C. Mabesa, Assoc. Professor, Institute of Food Science and Technology, University of the Philippines at Los Banos, Los Banos, Laguna 4031, Philippines

Ms. Chakamas Wongkhalaung, Deputy Director, Institute of Food Research and Product Development (IFRPD), Kasetsart University, P.O. Box 1043 Kasetsart, Bangkok 10903, Thailand

Dr. Lor Kim Loon, Senior Manager, Food Research and Development, SATS Catering Pte Ltd., SATS Inflight Catering Centre, P.O. Box 3 Singapore Changi Airport, Singapore 918141

MEMBERS OF THE BALKAN-DANUBIAN SUBCOMMISSION

Chairperson

Dr. Hajnalka Domjan Kovacs, Food Bacteriologist, National Food Investigation Institute, Pf. 1740, H-1465 Budapest 94, Hungary

Secretary/Treasurer

Dr. Vladimir Spelina, CSc. Center of Hygienes of Nutrition, Institute of Hygiene and Epidemiology, Srobarova 48, CZ-100 42 Praha 10 - Vinohrady, Czech Republic

Members

Dr. Milica Kalember-Radosavljevic, Military Medical Academy, Institute of Hygiene, Crnotravska 17, 11000 Beograd, Ljermmonrova 22, Yugoslavia

Prof. Livio Leali, Professore Associato di Igene del Latte, Universita di Milano, Via Celoria 10, I-20133 Milano, Italy

Doz. Dr. vet. Ivan Kaloyanov, Central Veterinary Research Institute, 15 Pencho Slaveikov Blvd., BG-Sofia 1606, Bulgaria

Former Members of the Balkan-Danubian Subcommission

Dr. Vladimir Bartl, former Czechoslovakia (former chairperson)

Dr. Zora Bulajic, former Yugoslavia
Dr. Deac Cornel, Romania
Dr. Corneliu Ienistea, Romania
Dr. John Papavassiliou, Greece
Prof. Dr. Oscar Prandl, Austria
Prof. Dr. Mirko Sipkaformer, Yugoslavia (first chairperson)
Dr. H.J. Takacs, Hungary (former chairperson)
Dr. Zenai Muammer Tancman, Turkey
Dr. S. Tzannetis, Greece
Doc. Dr. Muammer Ugar, Turkey
Dr. Fuad Yanc, Turkey
Prof. Dr. Z. Zachariev, Bulgaria

MICROORGANISMS IN FOOD 7

Consultants

Dr. J. Braeunig, Germany, 2000
Dr. S. Dahms, Germany, 1997, 1998 (member since 1998)
Dr. P. Desmarchelier, Australia, 1999
Dr. J. M. Farber, Canada, 1998 (member since 1998)
Dr. B. D. G. M. Franco, Brazil, 1998, 1999 (member since 2000)
Dr. W. Garthwright, USA, 1999
Dr. L. G. M. Gorris, Netherlands, 2000
Dr. L. Gram, Denmark, 1997, 1998 (member since 1998)
Dr. H. Kruse, Norway, 1999, 2000
Dr. A. M. Lammerding, Canada, 1997, 1998 (member since 1998)
Dr. B. Shay, Australia, 1997, 1999
Dr. K. M. J. Swanson, USA, 2000
Dr. A. von Holy, South Africa, 1997

Contributors to Microorganisms in Food 7

Dr. D. Kilsby (UK), Dr. R. B. Smittle (USA), Dr. J. H. Silliker (USA)

Reviewers

Dr. V. N. Scott (USA), Dr. D. Kilsby (UK), Dr. P. Bodnaruk (USA), Dr. J. N. Sofos (USA), Dr. W. P. Pruett (USA)