

FOURTH EDITION

FOOD
CHEMICALS
CODEX

INSTITUTE OF MEDICINE

0052639

FOURTH EDITION

FOOD CHEMICALS CODEX

Effective July 1, 1996

COMMITTEE ON FOOD CHEMICALS CODEX

**Food and Nutrition Board
Institute of Medicine
National Academy of Sciences**

**NATIONAL ACADEMY PRESS
Washington, D.C. 1996**

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

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Stätllichemuseen in Berlin.

Organization of the Food Chemicals Codex, 1981-1995

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Center, San Antonio
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Bernadette M. Marriott, *Deputy Director*
(1993–1995)
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(1994–present)

Marcia S. Lewis, *Administrative Assistant*
(1991–1994)
Jamaine L. Tinker, *Financial Associate* (1994–
present)
Sue M. Wyatt, *Financial Associate* (1991–
1994)

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M. R. C. Greenwood, 1990–1993
Richard J. Havel, 1987–1990

Kurt J. Isselbacher, 1983–1987
Irwin Rosenberg, 1981–1983

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Donald B. McCormick, 1989–1992
*Hamish N. Munro, 1988–1989

Kurt J. Isselbacher, 1987–1988
Richard J. Havel, 1985–1987
Richard L. Hall, 1982–1985

*Deceased

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*Robert E. Rehwoldt, <i>Interim Project Director</i> , 1988	Geraldine Kennedo, <i>Project Assistant</i> , 1992–1993
Robert A. Mathews, <i>Project Director</i> , 1981–1987	Marcia S. Lewis, <i>Project Assistant</i> , 1989–1991
Sheila A. Moats, <i>Research Associate</i> , 1990–1993	Talitha D. Evans, <i>Secretary</i> , 1986
	Betty C. Guyot, <i>Secretary</i> , 1981–1983, 1986

*Deceased

Participants in Committee Activities and Other Programs*

FCC OPEN SESSION ON CARRAGEENAN (FCC Committee Meeting, July 26, 1994)

Harris "Pete" Bixler
James Carr
Donald H. Combs
Eunice M. Cuirle

Rodney J. H. Gray
Paul M. Kúznsof
Denis LaSota

Robert Mayer
Scott Rangus
Peter Salling

WORKSHOP ON ANALYTICAL METHODS FOR FOOD INGREDIENTS (In conjunction with AOAC International 107th Annual Meeting, July 29-30, 1993)

Charles H. Barnstein
Stephen Capar
Jonathan W. DeVries
Michael J. DiNovi
James T. Elfstrum

William Horwitz
Allen W. Matthys
Stan Omaye
Denis Page
Steve L. Taylor

Samuel M. Tuthill
Harriet Wallin
Charles Warner

WORKSHOP ON THE ALLERGENICITY OF FOOD-USE PROTEIN HYDROLYSATES (July 31, 1991)

Fred Atkins
A. Wesley Burks, Jr.
Robert K. Bush
Christopher Cordle
Cutberto Garza
Walter Glinsmann

Susan K. Harlander
Rolf Jost
John C. Kirschman
Zdenek Kratky
Paul M. Kuznesof
H. Lee Leary

Charles Manley
Lanny J. Rosenwasser
Hugh A. Sampson
R. Grant Smith
James A. Whitten

WORKING GROUP ON MICROBIOLOGICAL SPECIFICATIONS FOR FOOD CHEMICALS (August 30, 1991)

Cleve Denny
Maurice Fagan
Rodney J. H. Gray
John Humber

George Jackson
John C. Kirschman
Paul M. Kuznesof
Aubrey S. Outschoorn

Steve L. Taylor
Kay Wachsmuth

*The following lists comprise invited speakers, including committee members, and participants outside of the committee.

WORKSHOP ON LEAD SPECIFICATIONS FOR FOOD INGREDIENTS
(May 2, 1991)

Michael Adams
Herbert Blumenthal
Michael Bolger
Stephen Capar
Margaret A. Clarke
Janet Dudek

Lloyd J. Filer
Dee Graham
Clark Hartford
Joseph H. Hotchkiss
Paul M. Kuznesof
Kathryn Mahaffey

Peter Method
Richard Ronk
*Andrew J. Schmitz
Stephen G. Schulman
Steve L. Taylor
Samuel M. Tuthill

**FCC FORUM ON FUNCTIONS AND ACTIVITIES FOR DEVELOPMENT FOR
FCC IV**
(November 17-18, 1987)

Joseph T. Brady
Rhys Bryant
Durward F. Dodgen
James T. Elfstrum
F. J. Francis

Paul F. Hopper
Julia C. Howell
John C. Kirschman
Harold M. McNair

*Roger Middlekauf
Richard Ronk
Daniel Rosenfield
Jan Stofberg

**FOOD CHEMICALS CODEX WORKSHOP ON LEAD, HELD IN CONJUNCTION
WITH THE HEALTH PROTECTION BRANCH OF HEALTH AND WELFARE
CANADA**
(August 14-15, 1986)

Michael Bolger
Kenneth W. Boyer
Harry Conacher
Robert W. Dabeka
Steve Gilbert

Don Grant
Sol W. Gunner
Bev L. Huston
Diane Kirkpatrick

Kathryn Mahaffey
Deborah C. Rice
John W. Salminen
Jacqueline Sitwell

TASK FORCE ON HYDROCHLORIC ACID 1981-1984

1—June 1, 1981; 2—February 28, 1983; 3—August 1, 1983; 4—February 13, 1984

Samuel M. Tuthill
Chair
Bruce H. Campbell
Member

John P. Fletcher
Member
*Fred A. Morecombe
Member

*Jessie M. Norris
Member
Robert A. Mathews
FCC Staff

Others Who Provided Assistance, 1981-1995*

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Don Ayerlee	Joseph Fordham	
	Larry Fosdick	Patricia L. Lawson
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James K. Baker	John V. Fratus	J. H. Lichtenbelt
William Balke	James Freeman	C. I. Luckhoo
Rasma B. Balodis	Carl Frey	
Stephen Barker	William J. Frost	Janine Manhart
Gerrit Bekendam	John Fry	Alton E. Martin
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Bruce M. Bertram	A. A. Gaballa	Duane McDowell
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Anthony P. Bimbo	James E. Geyer	William McMullen
Gary Blair	Curtis E. Gidding	Carolyn Merkel
Louis Blecher	Jo Gilbert	Inge Meyland
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Edwin Bontenbal	J. A. Gosselin	John P. Modderman
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Kyd D. Brenner	Karl H. Griessmann	Donald D. Naragon
Simon Brooke-Taylor		June M. Neades
Franta J. Broulik	Martin J. Hahn	Lyle Nehls
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Duane Chase	David H. Hickman	Philip M. Olinger
James P. Clark	Jerry Hjelle	
Warren S. Clark	Connie Horn	Juhani Paakkanen
Richard E. Cristol	Julia C. Howell	Barbara Pagliocca
Ray Croes		G. R. Parikh
	Kenji Ishii	Robert Patti
Roger Dabbah	Glen Ishikawa	W. Penning
David E. Dalsis		Glyn O. Phillips
Christopher C. DeMerlis	Walter S. Jeffery	Walter Pilnik
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Mario Diaz-Cruz	Isabelle Kamishlian	Rinske Potjewijd
Gontran Dondain	Sam Kennedy	
Doug Drogosh	Warren W. Kindt	B. Quock
	Charles L. King	
Lee Elwell	Donald L. Kiser	Arthur Raczynski
Joseph E. Englesberg	Lorie Klopff	Robert M. Reeves
Elizabeth Erman	Catherine Knoka	Joe M. Regenstein
Robert Evans	Willem Kohl	Jill Rickman
	Kohei Kojima	Marion Riordan
Roger W. Fenstermaker	John Kropiewnicki	Larry Roberts

*The listing of individuals in this section, which includes those not listed in the preceding sections, does not necessarily indicate that their contributions were less significant than those made by individuals listed in the preceding sections.

J. A. Robertson
Daniel A. Roman
Louis Rothschild, Jr.
John Rotruck

Wayne Sander
Jean Savigny
Patricia Scarbinsky
David R. Schoneker
Mark A. Seese
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Elisabeth A. Snipes
Charles Sokol
Joan M. Stapleton

Jim Steinke
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Ralph J. Tenney
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Helen R. Thorsheim
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Jean Turner
William C. Twieg

Richard Ungvarsky

Joseph G. Valentino
John A. van Velthuysen

Florian M. Ward
Alan Warren
Jerry Weigel
Jerry Wertz
Brian Whitehouse
Wayne Wolf
John T. Woodward

Tony Yates
Gary L. Yingling

James Zawecki
Patricia S. Zawislak

Preface

The fourth edition of the *Food Chemicals Codex* is the culmination of efforts of the many members, past and present, of the Committee on Food Chemicals Codex (FCC). The current committee, formed in the fall of 1992 at the request of the U.S. Food and Drug Administration, has brought all these efforts to fruition with this edition. The charge to the committee states that "the committee shall (1) provide information on matters related to the purity of food ingredients used in the United States and shall be knowledgeable of the purity of food ingredients used in other countries; (2) provide information on food-grade specifications for food additives, GRAS substances, and any other food substances used as ingredients; and (3) publish specification monographs in a fourth edition of the *Food Chemicals Codex*. To provide such information, the committee shall review proposals from industry, government, or any other source."

The FCC project, currently under the administrative supervision of the Food and Nutrition Board of the Institute of Medicine/National Academy of Sciences, began in 1961, soon after the passage of the 1958 Food Additives Amendment to the federal Food, Drug, and Cosmetic Act. Although the U.S. Food and Drug Administration had by regulations and informal statements defined in general terms quality requirements for food chemicals generally recognized as safe and other food additive chemicals, these requirements were not sufficiently specific to serve as release, procurement, and acceptance specifications for manufacturers and users of food chemicals. Therefore, regulators and other interested parties believed that the publication of a book of standards designed especially for food chemicals would promote uniformity of quality and added assurance of safety for such chemicals. For these reasons, the Food Protection Committee of the National Academy of Sciences/National Research Council received requests in 1958 from its Industry Liaison Panel and other sources to undertake a project to produce a *Food Chemicals Codex* comparable in many respects to the *United States Pharmacopeia* and the *National Formulary* for drugs. As a result of these requests, representatives of industry and government agencies agreed that there was a definite need for such a *Codex* and that the Food Protection Committee was a suitable agency to undertake the project.

The first edition, published in 1966, was supported by a Public Health Service grant and more than 100 supplementary grants from industry, associations, and

foundations. Its goal, which is still that of the *Food Chemicals Codex*, was to define the quality of food-grade chemicals in terms of identity, strength, and purity based on the elements of safety and good manufacturing practice. Later editions were supported by direct contracts with the U.S. Food and Drug Administration. Although sponsorship has not been continuous, it has been sufficient to have supported the publication of 3 earlier editions and 11 supplements in a 35-year span.

SCOPE

The scope of the *Food Chemicals Codex* has expanded with each new edition. Substances included in the first edition were limited to chemicals added directly to foods to achieve a desired function. Succeeding editions included these substances as well as those that come into contact with foods, such as processing aids (including enzymes, extraction solvents, filter media, and packaging materials and ingredients), and those that are regarded as foods, such as fructose and dextrose, rather than as additives. This fourth edition includes 773 monographs from the third edition; 142 monographs, including those for 69 flavor chemicals, added in the four supplements to the third edition; and 52 new monographs, including 33 for flavor chemicals, new to this fourth edition, bringing the total to 967.

Three monographs included in the third edition have been deleted from the fourth edition. These are Carrageenan, Cinnamyl Anthranilate, and Methyl Formate (see list of deletions, page xxxii). Since the publication of the third edition in 1981, the following events provided the impetus for the deletions: (1) A second type of Carrageenan, a semi-refined grade, was introduced into the marketplace. Its regulatory status in terms of nomenclature, specifications, and labeling was, at press time, unresolved by the U.S. Food and Drug Administration, with several food additive petitions pending. Therefore, the Committee on Food Chemicals Codex decided to wait for the resolution of the regulatory issues before including one or more Carrageenan monographs in the fourth edition of the Codex. (2) The use of Cinnamyl Anthranilate in foods has been banned by the U.S. Food and Drug Administration (see 50 FR 42932, October 23, 1985). (3) The regulatory authority for fumigants/insecticides, including those for food use, such as Methyl Formate used on raisins, was transferred from the U.S. Food and Drug Administration to the Environmental Protection Agency.

UPDATING AND DEVELOPING SPECIFICATIONS

Substantive changes in the fourth edition resulted from changes in committee policies (see the *General Provisions*) and scientific advances during the 15 years since the appearance of the third edition in 1981. Symposia and various meetings with the affected industry (see pages viii–ix) were sponsored by the Committee on Food Chemicals Codex to guide the committee in its deliberations.

The committee has invariably sought to define, using physicochemical and microbiological parameters, ingredients prepared under good manufacturing practices as safe for human consumption. Special emphasis has been placed on reducing contaminants, including trace elements, particularly lead. The need for practical, sensitive analytical methods to achieve this goal was recognized, and industry participation was enlisted. As a result, several quantitative procedures to measure low lead levels are new to

this edition. This effort also led to collaboration with the Agricultural Research Service of the U.S. Department of Agriculture and the International Life Sciences Institute in developing a program to validate an atomic absorption graphite furnace method to quantitate lead in water-soluble sweeteners at levels below 0.1 mg/kg.

Limits on contaminants, specifically lead and heavy metals, have been reduced by a minimum of one-half in more than 71 and more than 111 monographs, respectively, in this edition. This trend is expected to continue. Manufacturers and suppliers of food ingredients are encouraged to inform the committee of their ability to supply food ingredients with lead and heavy metals limits lower than those specified in this edition. The arsenic specification remains in only about 110 articles in this edition where (1) the ingredient or additive is a high-volume consumption item (greater than 25 million pounds a year), (2) the ingredient or additive is derived from a natural (mineral) source where arsenic may be an intrinsic contaminant, and/or (3) there is reason to believe that arsenic constitutes a significant part of the total heavy metals content.

The committee has been cognizant of the need for international harmonization of specifications in today's world. Efforts were made, where feasible, to harmonize the specifications in this edition with those of other standards-setting organizations, in particular with those in the *Compendium of Food Additive Specifications* published by the FAO/WHO Joint Expert Committee on Food Additives.

FORMAT

Generally the presentation follows that of the third edition, but a number of significant changes and additions have been made. As expected, the passage of 15 years since the appearance of the third edition has been accompanied by changes, not only substantive in character, but also of common, accepted scientific terminology.

- The *General Provisions* has been expanded and retitled to *General Provisions and Requirements* to more accurately reflect the material contained therein.
- For easy reference, most of the material in Chapter 8 of the third edition has been moved to an information section in the front of this edition (pages xix–xxxii) preceding the requirements sections.
- A new section on *Validation of Codex Methods* has been added to the information section to serve as a guide to all interested parties who want to suggest revising existing FCC analytical methods and limits or to suggest new methods for committee consideration.
- The analytical methods for flavor chemicals, especially for quantitative measurements, have, in keeping with present common laboratory practices, been revised significantly from mostly wet-chemical methods to gas chromatographic procedures and are presented with the tabular specifications for flavor chemicals.
- The general analytical test procedures listed alphabetically in Chapter 6 of the third edition have been recast, by virtue of their utility or purpose, into ten distinctive appendixes that appear at the end of the book. This eliminates the need to provide repetitive page references to those procedures referenced in the monographs that are needed to demonstrate compliance with specific limits and identification tests.

- Additional information, in terms of CAS (Chemical Abstracts Services) Registry and INS (International Numbering System of the FAO/WHO Codex Alimentarius) numbers, has been added to specific monographs where definitive numbers could be identified for the referenced article.

- In this edition, all *cis* and *trans* isomers have been changed to (Z) and (E), *zusammen* and *entgegen*, respectively.

- The designation "molecular weight" has been revised to "formula weight," a term that more broadly defines the sum of the atomic weights of the referenced article without regard to its intrinsic nature.

- Odor tests have been deleted, especially where the substance generated, for example, acrolein, may pose a hazard to the analyst.

- The mention of highly toxic solvents, for example, carbon tetrachloride and benzene, has been eliminated where such reference has been purely informational and replaced where a suitable substitute could be identified.

FUTURE REVISIONS

The introduction of new food additives as well as constant changes and advances in manufacturing processes and analytical sciences lead to a need for continued revision of this compendium. The first supplement to this edition may be expected 18 months after the edition's release.

Users of this edition are requested and encouraged to submit suggestions for updating the specifications as well as the general analytical methods. Constructive criticism and notification of errors should also be brought to the attention of the Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418. The worth of the *Food Chemicals Codex* to its users (food additive manufacturers, food processors, and national and international regulatory bodies) would be enhanced by the continuity of the project and revision of this edition through appropriate and timely support.

LEGAL STATUS

The *Food Chemicals Codex* enjoys international recognition by manufacturers, vendors, and users of food chemicals. The specifications herein serve as the basis for many buyer and seller contractual agreements.

In the United States, the first edition was given quasi-legal recognition in July 1966 by means of a letter of endorsement from FDA Commissioner James L. Goddard, which was reprinted in the book. The letter stated that "the FDA will regard the specifications in the *Food Chemicals Codex* as defining an 'appropriate food grade' within the meaning of Sec. 121.101(b)(3) and Sec. 121.1000(a)(2) of the food additive regulations, subject to the following qualification: this endorsement is not construed to exempt any food chemical appearing in the *Food Chemicals Codex* from compliance with requirements of Acts of Congress or with regulations and rulings issued by the Food and Drug Administration under authority of such Acts."

Subsequently, the specifications in the second edition, followed by those in the third edition, were cited, by reference, in the U.S. *Code of Federal Regulations* to define specific safe ingredients under title 21, in various parts of sections 172, 173, and 184.

In Canada, the current edition of the *Food Chemicals Codex*, including its supplements, is officially recognized in the *Canadian Food and Drug Regulations* under Section B.01.045(b) as the reference for specifications for food additives. The New Zealand government, under its food regulation 245(6)(a), defines a food additive as being of appropriate quality "if it complies with the monograph for that food additive (if any) in the current edition of the *Food Chemicals Codex* published by the National Academy of Sciences and the National Research Council of the United States of America in Washington, D.C." Similarly, the national food authority of Australia frequently refers to the *Food Chemicals Codex* specifications to define food additives.

ACKNOWLEDGMENTS

A compendium of this breadth can only result from the cooperation of many individuals and organizations. Underlying this, the support provided by U.S. Food and Drug Administration contract number 223-92-2250, monitored by project officer Paul M. Kuznesof, is gratefully acknowledged.

Several monographs and various sections in this edition have extensive portions based on other publications, and are used with permission granted by the parent organizations: United States Pharmacopeial Convention, Inc.; the American Oil Chemists Society; AOAC International; and the American Society for Testing and Materials. This edition of the *Food Chemicals Codex* directly references the procedures in the seventh edition of the *FDA Bacteriological Analytical Manual* (BAM) for its microbial limit tests. Where the sample size is not defined in the limit, the results are based on the sampling procedures described in BAM.

While participating individuals have been listed on pages viii–xi, the following organizations have also been active participants:

- American Dairy Products Institute
- American Oil Chemists Association
- American Spice Trade Association
- Corn Refiners Association
- Enzyme Technical Association
- European Association of the Chewing Gum Industry
- Flavor and Extract Manufacturers Association
- Gelatin Manufacturers of Europe
- Gelatin Manufacturers Institute of America
- International Food Additives Council
- International Glutamate Technical Committee
- International Hydrolyzed Protein Council
- International Life Sciences Institute
- International Pectin Producers Association
- International Pharmaceutical Excipients Council

International Technical Caramel Association
Japan Food Additives Association
National Association of Chewing Gum Manufacturers
National Association of Color Manufacturers
National Soft Drink Association
Salt Institute
Seaweed Industry Association of the Philippines
Synthetic Amorphous Silica and Silicate Industry Association

Members of the National Academy Press, namely James M. Gormley, Sally S. Stanfield, Estelle H. Miller, Dawn M. Eichenlaub, and William B. Mason, and IOM Reports and Information Office staffers Claudia M. Carl and Michael A. Edington provided valuable support to the FCC staff toward the publication of this edition.

Success in the complex task of completing the fourth edition is due to the dedication and determination of the members of the Committee on Food Chemicals Codex under the focused leadership of its chair, Steve L. Taylor, and its vice-chair, Samuel M. Tuthill, during the past 30 months.

Washington, D.C.
September 1995

FATIMA N. JOHNSON
Project Director

General Information

OPERATING PROCEDURES OF THE *FOOD CHEMICALS CODEX*

Organization

The Food Chemicals Codex (FCC) project is an activity of the Food and Nutrition Board, a unit of the Institute of Medicine of the National Academy of Sciences. The immediate responsibility for developing the *Food Chemicals Codex* lies with the Board's Committee on Food Chemicals Codex. The committee consists of 12 to 15 members, chosen for their expertise in the various aspects of the committee's work, who are appointed, upon recommendation of the Food and Nutrition Board and the President of the Institute of Medicine, by the Chairman of the National Research Council. Committee members are paid no consulting fees or honoraria and are reimbursed only for expenses incurred while attending meetings and other activities of the committee.

Functions of the Committee on Food Chemicals Codex

The committee's principal functions are as follows:

- To establish the general policies and guidelines by which FCC specifications are prepared.
- To evaluate comments submitted by interested parties on any aspect of the specifications and test procedures.
- To propose means by which the specifications may be kept current in reflecting food-grade quality on the basis of product safety and good manufacturing practice.
- To provide information on issues dealing with specifications for particular substances and analytical test procedures.
- To seek the advice of specialists when additional expert opinion is needed in making decisions regarding the appropriateness of specifications.
- To establish working groups consisting of committee members and other experts to address specific issues relevant to monograph development and to report their findings and recommendations to the full committee.