

ECOTOXICOLOGY AND ENVIRONMENTAL QUALITY SERIES

**Regulatory Aspects of Carcinogenesis
and Food Additives:
The Delaney Clause**

**EDITED BY
Frederick Coulston**

REGULATORY ASPECTS OF CARCINOGENESIS AND FOOD ADDITIVES: THE DELANEY CLAUSE

edited by

FREDERICK COULSTON

Institute of Comparative and Human Toxicology
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ORGANIZING COMMITTEE

Frederick Coulston

Institute of Comparative and Human Toxicology, Albany Medical College
of Union University

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Eppley Institute for Research in Cancer, University of Nebraska

Morris Cranmer

National Center for Toxicological Research, Jefferson, Arkansas

Albert C. Kolbye, Jr.

Bureau of Foods, United States Food and Drug Administration,
Washington D. C.

PARTICIPANTS

Rajender Abraham Institute of Comparative and Human Toxicology, Albany Medical College, 47 New Scotland Avenue, Albany, New York 12208

Richard H. Adamson Laboratory of Chemical Pharmacology (ET, DCT, NCI), National Institutes of Health Bldg. 10-6N 119, 9000 Rockville Pike, Bethesda, Maryland 20014

James G. Aftosmis E.I. Du Pont de Nemours & Co., Haskell Lab, Elkton Road, Newark, Delaware 19711

Elizabeth Anderson RD 689, US EPA, 401 M Street, SW, Washington, D.C. 20460

Roy Albert Institute of Environmental Medicine, New York University Medical Center, 550 First Street, New York, New York 10016

Stephanie P. April Exxon Corporation, P.O. Box 45, Linden, New Jersey 07036

Bernard D. Astill Eastman Kodak Company, Health, Safety, and Human Factors Laboratory, B-320, Kodak Park, Rochester, New York 14650

Emilio Astolfi University of Buenos Aires, Ayacucho 1337, Buenos Aires (1111), Argentina

Emilio Astolfi, Jr. St. Paul's College, Ayacucho 1337, Buenos Aires (1111), Argentina

M. C. Bachman IMC Chemical Group, Inc., P.O. Box 207, Terre Haute, Indiana 47808

Robert C. Baldwin Rohm and Haas Company, Toxicology Department, Norristown & McKean Roads, Spring House, Pennsylvania 19477

Donald G. Barnes Office of Assistant Administrator for Toxic Substances,
EPA, 401 M Street, SW, Washington, D.C. 20460

J. D. Behun Mobil Chemical Company, P.O. Box 240, Edison, New Jersey
08817

Etcyl H. Blair Dow Chemical Company, 2020 Dow Center, Midland, Michi-
gan 48640

Marvin Bleiberg Bureau of Foods Division of Toxicology, HFF-185, 200 C
Street, SW, Washington, D.C. 20204

Herbert Blumenthal FDA, Washington, D.C. 20460

Gale Boxill WYETH Laboratories, P.O. Box 861, Paoli, Pennsylvania 19301

Jackson B. Browning Union Carbide Corporation, 270 Park Avenue, New
York, New York 10017

Jerry Brunton Animal Health Institute, 1717 K Street, NW, Suite 1009,
Washington, D.C. 20006

W. H. Butler Imperial Chemical Industries Ltd., Pharmaceuticals Division,
Experimental Toxicology Section, Safety of Medicines Department, Mereside
Alderley Park, Macclesfield, Cheshire SK10 4TG, England

Jim Elfstrum Stauffer Chemical Company, Environmental Service Depart-
ment, Westport, Connecticut 06880

B. P. Cardon Arizona Feeds, P.O. Box 5526, Tucson, Arizona 85703

Thomas W. Carmody Union Carbide Corporation, 270 Park Avenue, New
York, New York 10017

Kathy Chamberlin Kirkland & Ellis, 1776 K Street, NW, Washington, D.C.
20460

Roger Chamberlin Dow Chemical Company, 1800 M Street, NW,
Washington, D.C. 20036

C. Chappel FDC Consultants, Inc., 364 Robin Avenue, Beaconsfield,
Quebec, Canada H9W1R8

John J. Clary Celanese Corporation, 1211 Avenue of the Americas, New
York, New York 10036

David Clayson Eppley Institute for Research in Cancer, University of Nebraska, 42nd & Dewey Avenues, Omaha, Nebraska 68105

David J. Clegg Health Protection Branch, Ottawa Foods Directorate, Toxicological Evaluation Division, Tunney's Pasture, Ottawa, Ontario K1A 0L2 Canada

Nicholas Clesceri Fresh Water Institute, Rensselaer Polytechnic Institute, Troy, New York 12181

James T. Conner Mobay, 1140 Connecticut Avenue, NW, Washington, D.C. 20036

Eileen Coulston 17 Woodlawn Avenue, RD #2, Rensselaer, New York 12144

Frederick Coulston Institute of Comparative and Human Toxicology, Albany Medical College of Union University, 47 New Scotland Avenue, Albany, New York 12208

Eugene F. Cox Carnegie-Mellon Institute of Research, 4400 Fifth Avenue, Pittsburgh, Pennsylvania 15213

Thomas H. Cox E.I. Du Pont de Nemours & Co., Biochemicals Department, 14360 Brandywine Bldg., Wilmington, Delaware 19899

P. Craig G.D. Searle & Co., Box 5110, Chicago, Illinois 60680

Morris F. Cranmer National Center for Toxicological Research, Jefferson, Arkansas 72079

William Darby The Nutrition Foundation, Inc., 489 Fifth Avenue, New York, New York 10017

Drew M. Davis National Soft Drink Association, 1101 16th Street, NW, Washington, D.C. 20036

Philip H. Derse Warf Institute, Inc., Box 7545, Madison, Wisconsin 53707

Frederick J. DiCarlo Office of Toxic Substances (WH-557), U.S. EPA, 401 M Street, SW, Washington, D.C. 20460

Richard M. Dowd Science Advisory Board, EPA, Room 1129 West Tower, 401 M Street, SW, Washington, D.C. 20460

David F. Dunning Calorie Control Council, 64 Perimeter Center East, Atlanta, Georgia 30346

Harold Egan Department of Industry, Laboratory of the Government Chemist, Cornwall House, Stamford Street, London, England

R. G. Eggert American Cyanamid Company, P.O. Box 400, Princeton, New Jersey 08540

Howard E. Everson Diamond Shamrock Corporation, 1100 Superior Avenue, Cleveland, Ohio 44114

Alfred Farah Sterling-Winthrop Research Institute, Rensselaer, New York 12144

Kelvin H. Ferber Allied Chemical Corporation & Buffalo Color Corporation, Box 1069, Buffalo, New York 14240

John Foderaro E.I. Du Pont de Nemours & Co., Wilmington, Delaware 19899

John P. Frawley Toxicology Department, Hercules Inc., 910 Market Street, Wilmington, Delaware 19899

William Frunkos FDA, Bureau of Foods, 200 C Street, SW, HFF-185, Washington, D.C. 20204

Robert H. Furman Eli Lilly & Company, 307 East McCarty Street, Indianapolis, Indiana 46206

Paul J. Garvin Standard Oil Company (Indiana), 200 East Randolph Drive, Chicago, Illinois 60601

Hyman R. Gittes FDA, 200 C Street, SW, Washington, D.C. 20204

Harvey S. Gold Velsicol Chemical Corporation, 910 17th Street, NW, Suite 1000, Washington, D.C. 20006

Louis S. Grasso Hoechst-Roussel Pharmaceuticals, Inc., Route 202-206, North, Somerville, New Jersey 08876

R. E. Hagen National Food Processors, 1133 20th Street, NW, Washington, D.C. 20036

- Jim Hanson Dow Chemical Company, 303 Hubbard Street, Midland, Michigan
- Anna J. Harrison Chemistry Department, Mt. Holyoke College, Carr Laboratory, South Hadley, Massachusetts 01075
- Yvonne Harrison Hoffmann-La Roche, Inc., Nutley, New Jersey 07110
- Richard Hart Dow Chemical Company, 2030 Dow Center, Midland, Michigan 48640
- Richard H. Hill Health Effects & Science Policy, Office of Assistant Administrator for Toxic Substances, EPA, 401 M Street, SW, Washington, D.C. 20460
- William L. Hollis National Agricultural Chemical Association, 1155 15th Street, NW, Washington, D.C. 20005
- Vilma R. Hunt Science Advisory Board, EPA, 401 M Street, SW, Washington, D.C. 20046
- Peter B. Hutt Covington & Burlington, 888 16th Street, NW, Washington, D.C. 20006
- Jerry T. Hutton Foremost Foods Company, One Post Street, San Francisco, California 94104
- Carol Jennings Hill & Knowlton, Inc., 633 Third Avenue, New York, New York 10017
- Daniel Jones FDA, Bureau of Foods, 200 C Street, SW, Washington, D.C. 20204
- Charles J. Kensler Arthur D. Little, Inc., 35 Acorn Park, Cambridge, Massachusetts 02140
- Georg Kimmerle Bayer AG, Institute of Toxicology, 56 Wuppertal 1, Friederich-Ebert-Str. 217, West Germany
- William H. Kirby Medical Services, Control Data Corporation, 301 N Charles Street, Baltimore, Maryland 21201
- Charles J. Kokoski FDA, 200 C Street, SW, Washington, D.C. 20204
- Albert C. Kolbye, Jr. Bureau of Foods, HFF-100, Food and Drug Administration, Washington, D.C. 20204

F. Korte Technische Universität München, Lehrstuhl für Ökologische Chemie, Institute für Chemie, Weihenstephan Am Löwentor, D-805 Weihenstephan, West Germany

Herman F. Kraybill Carcinogenesis, DCCP, National Cancer Institute, Landow Building, Room C337, Bethesda, Maryland 20014

C. J. Krister E.I. Du Pont de Nemours & Co. Inc. (Retired), Biochemicals Department, 1007 Market Street, Wilmington, Delaware 19898

William C. Krumrei The Procter and Gamble Company, 5299 Spring Grove Avenue, Cincinnati, Ohio 45217

W. Lamb Mobay Chemical Corporation, Chemagro Agricultural Division, Box 4913, Hawthorn Road, Kansas City, Missouri 64120

Roland A. Leimgruber CIBA-GEIGY Limited, CH-4002 Basle, Switzerland

Bill Brown Lerch & Co., Inc., 1030 15th Street, NW #840, Washington, D.C. 20005

Ruth R. Levine Boston University School of Medicine, 80 E. Concord Street, Boston, Massachusetts

William Lijinsky Chemical Carcinogenesis Program, Frederick Cancer Research Center, P.O. Box B, Frederick, Maryland 21701

Dale R. Lindsay University of Arizona, Department of Family & Community Medicine, 125 E. Canyon View Drive, Tucson, Arizona 85704

Janice Long Chemical & Engineering News, 1155 16th Street, NW, Washington, D.C.

Alvin J. Lorman Covington & Burling, 888 Sixteenth Street, NW, Washington, D.C.

Frank C. Lu Clinical Professor of Pharmacology, University of Miami, Research and Teaching Center of Toxicology, P.O. Box 248216, Coral Gables, Florida 33124

D. MacDougall Dow Pharmaceuticals, Dow Chemical of Canada, Ltd., 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada, L4C 5H2

R. C. Mallatt Standard Oil Company (Indiana), 200 E. Randolph Drive, Chicago, Illinois 60601

- James G. Martin The House of Representatives, Washington, D.C. 20515
- William F. Massmann Dr. Pepper Company, P.O. Box 5086, Dallas, Texas 75222
- Alex P. Mathers 1000 Frost Bridge Road, Matherville, Mississippi 39360
- David J. Matthews Australian Government, Embassy of Australia, 1601 Massachusetts Ave., NW, Washington, D.C. 20036
- R. M. McClain Hoffmann-LaRoche, Inc., Nutley, New Jersey 07110
- Donald D. McCollister Dow Chemical, Health and Environmental Research Department, P.O. Box 1706, Midland, Michigan 48640
- Bruce L. McDonald Kirkland & Ellis, 1776 K Street, NW, Washington, D.C. 20006
- M. A. Mehlman Mobil Oil Corporation, 150 E. 42nd Street, New York, New York 10017
- Thomas W. Mooney The Procter and Gamble Company, 5299 Spring Grove Avenue, Cincinnati, Ohio 45217
- Victor H. Morgenroth III Division of Toxicology, FDA, HFF-185, 200 C Street, SW, Washington, D.C. 20204
- Emil Mrak Chancellor Emeritus, University of California, Davis, California 95616
- Robert T. Murphy CIBA-GEIGY Corporation, P.O. Box 11422, Greensboro, North Carolina 27409
- Chris Murray Chemical & Engineering News, 1155 16th Street, NW, Washington, D.C. 20036
- A. W. Neff Agricultural Division, Upjohn Co., 301 Henrietta Street, Kalamazoo, Michigan 49001
- Charles A. O'Connor III Sellers, Conner & Cuneo, 1625 K. Street, NW, Washington, D.C. 20006
- A. C. Page Shell Development Company, P.O. Box 4248, Modesto, California 95352

Dennis V. Parke Department of Biochemistry, University of Surrey,
Guildford, Surrey GU2 5XH, England

Thomas M. Parkinson Dynapol, 1454 Page Mill Road, Palo Alto, California
94304

Dennis Poller Exxon Chemical Company, P.O. Box 45, Linden, New Jersey
07036

Vivian Prunier FDA, Washington, D.C. 20204

W. Quanstrom Standard Oil Company (Indiana), 200 East Randolph Drive,
Chicago, Illinois 60601

Charles E. Ross Shell Oil Company, P.O. Box 2463, Houston, Texas 77001

Louis Rothschild, Jr. Food Chemical News, 420 Colorado Building,
Washington, D.C. 20005

Randy Roth Diamond Shamrock, Box 348, Painesville, Ohio 44060

V. K. Rowe Dow Chemical, 1803 Bldg. - Dow Chemical, Midland, Michigan
48640

Ben C. Rusche E.I. Du Pont de Nemours & Co., Inc., Administrative Depart-
ment, 9058 Du Pont Building, Wilmington, Delaware 19898

Georgia Samuel Lever Brothers Company, 45 River Road, Edgewater, New
Jersey 07020

Neil L. Sass Division of Toxicology, Bureau of Foods, FDA, HFF-190, 200 C
Street, SW, Washington, D.C. 20204

F. Schmidt-Bleek Umweltbundesamt, 1000 Berlin 33, 1 Bismarckplatz,
West Germany

George C. Scott Smith Kline Animal Health Products, Applebrook Research
Center, 1600 Paoli Pike, West Chester, Pennsylvania 19380

T. Shellenberger National Center for Toxicological Research—FDA, Jeffer-
son, Arkansas 72077

George M. Sisson Mead Johnson Research Center, 2404 Pennsylvania
Street, Evansville, Indiana 47721

M. J. Sloan Shell Oil Company, 1025 Connecticut Avenue, NW,
Washington, D.C. 20015

M. B. Slomka Shell Oil Company, One Shell Plaza, P.O. Box 2463, Hous-
ton, Texas 77001

J. Smeets Service de L'Environnement et de la Protection des Consommateurs,
Commission of the European Communities, 200, Rue de la Loi, 1049 Bru-
xelles, Belgium

J. W. Stanley Pepsi Co., Inc., Purchase, New York 10577

Richard H. Stanton Velsicol Chemical, 340 E. Ohio, Chicago, Illinois 60611

Jean M. Taylor FDA, 200 C Street, SW, Washington, D.C. 20204

Andrew S. Tegeris Pharmacopathics Research Labs, Inc., 9705 N.
Washington Blvd., Laurel, Maryland 20810

J. P. Thorn Exxon Chemical Company, P.O. Box 3772, Houston, Texas

Cecil Timberlake, Jr. Phillips Petroleum Company, 1825 K Street, NW, Suite
1107, Washington, D.C. 20006

Edwin Traisman Food Research Institute, University of Wisconsin, 1925 Wil-
low Drive, Madison, Wisconsin 53706

William M. Upholt 525 East Indian Spring Drive, Silver Springs, Maryland
20901

Leslie M. vanHoose Schering Corporation—Animal Health Research, P.O.
Box 608, Allentown, New Jersey 08501

H. G. S. van Raalte Shell International Research Maatschappij B.V., Toxicol-
ogy Division, P.O. Box 162, The Hague, Netherlands

Leonard J. Vinson Lever Brothers Company, 45 River Road, Edgewater, New
Jersey 07020

Ralph C. Wands Cosmetics Ingredient Review, 1133 Fifteenth Street, NW,
Washington, D.C. 20418

Carol S. Weil Carnegie—Mellon University, 4400 Fifth Avenue, Pittsburgh,
Pennsylvania 15213

- K. W. Weinstein Sellers, Conner, & Cuneo, 1625 K Street, NW, Washington, D.C.
- Jack Winstead Cosmetic, Toiletry and Fragrance Association, 1133 15th Street, NW, Washington, D.C. 20005
- S. Jackson Wommack Amoco Chemicals Corporation, 200 E. Randolph Drive, Chicago, Illinois 60601
- Ernst L. Wynder American Health Foundation, 1370 Avenue of the Americas, New York, New York 10019
- Ralph E. Yodaiken National Institute for Occupational Safety & Health, 5600 Fishers Lane, Rockville, Maryland 20852
- J. Youngman Netherlands Embassy, 4200 Linneman Avenue, NW, Washington, D.C. 20008
- Ellen Zawel Zawel Associates Inc., 59 Giles Road, Harrington Park, New Jersey
- Robert G. Zimbelman The Upjohn Company, 301 Henrietta Street, Kalamazoo, Michigan 49001

FOREWORD

The Delaney Clause became a part of the Food and Drug Law in 1958. It was included as an added protection to the consumer from potentially carcinogenic additives. It was also considered by most scientists a statement of scientific principle rather than one of policy established by Congress. Unfortunately, this is still the interpretation of many, if not most, scientists.

The Delaney Clause states in part "that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found after tests which are appropriate for evaluation of safety of food additives to induce cancer in man or animal."

When the Clause was made a part of our food law, chemists were reporting analyses in terms of parts per million. The animal test was then, for all intents and purposes, considered infallible. The United States was about the only country to give serious consideration to the possible relationship of additives to carcinogenesis when the law was passed; others did consider the situation, but not as seriously. Other departments of our government were not intensely interested in safety from the standpoint of carcinogenesis. The Clause, when included in the law, therefore, was for all intents and purposes an instrument of the Food and Drug Administration.

Much has happened since 1958 when the Clause became a part of our food law. Analytical chemists are not only reporting in parts per million but parts per billion and, in some instances, even in parts per trillion. Furthermore, today many consider the animal tests, such as usually used, unreliable and at best indicative or useful only as screening tests.

New procedures, such as the Ames test for mutagenesis, have been developed. The question has arisen as to the possible relationship of mutagenesis to carcinogenesis. Some feel that there is a good relationship; others feel that the Ames test is not at all reliable and should at best be used for screening.

The Commission on Pesticides and Their Relationship to Environmental Health was concerned about protocols used in testing for safety and, accordingly, the National Center for Toxicological Research was established at Jefferson, Arkansas. At the time this facility was established, testing for the safety of additives involved feeding very large doses of the additive, a practice still considered by some to be reliable and the only procedure to follow, whereas