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Professional Profile

Dr. Rulis has extensive experience in government, with nearly 30 years at the U.S. Food and Drug Administration, including nine as Director of the FDA's Office of Food Additive Safety (1995-2004). He served in the federal government's Senior Executive Service from 1996 to 2003, and as Senior Advisor for Special Projects in the FDA's Center for Food Safety and Applied Nutrition from 2004 until his retirement from federal service in June 2006. With a scientific background that spans both the physical and biological sciences, Dr. Rulis brings a broad perspective to a range of complex scientific, regulatory and policy issues in the public health arena.

As Director of the Office of Food Additive Safety, Dr. Rulis was responsible for FDA's premarket safety evaluation of new food and color additives, packaging materials used in contact with food, generally recognized as safe (GRAS) food ingredients, and the safety of foods developed through modern biotechnology. He has experience in all aspects of the safety evaluation of food chemicals, including toxicological testing requirements and guidelines; the chemistry, purity and specifications of permitted food ingredients; and the dietary intake estimation of new food ingredients, additives, and other food components.

Dr. Rulis is internationally recognized, having served as an advisor to the U.N. Food and Agriculture Organization/World Health Organization (FAO/WHO) Joint Expert Committee on Food Additives. For six consecutive years, he headed the U. S. Delegation to the FAO/WHO Codex Committee on Food Additives and Contaminants in The Hague. In that role, he worked with representatives from a number of countries to develop the General Standard for Food Additives, an international roster of food additives permitted in global food commerce.

Dr. Rulis was an original collaborator on FDA's carcinogenic impurities policy for food additives. Also he developed the scientific basis for FDA's Threshold of Regulation policy for addressing potential carcinogenic risks from food contact materials. He helped establish the agency's Priority-based Assessment of Food Additives, a continuously updated repository of chemical and toxicological information on food and color additives and other food chemicals permitted in the United States.

Dr. Rulis has received numerous awards including the Presidential Meritorious Executive Rank Award. He has published several book chapters as well as numerous articles in scientific and other scholarly journals. He represented FDA in numerous venues throughout his government career, and currently speaks and writes on a range of subjects.

Academic Credentials & Professional Honors

Ph.D., Chemistry, University of Wisconsin, Madison, 1972

Professional Affiliations

Board of Directors and Program Planning Committee, The Toxicology Forum, 1995-present

United States Senior Executive Service, Appointed, February 1996; served through July 2003

American Association for the Advancement of Science (member)

American Chemical Society (member)

Publications

Brock WJ, Rodricks JV, Rulis AM, Dellarco VL, Gray GM, Lane RW. Food safety: risk assessment methodology and decision making criteria. Int J Toxicol 2003; 22:435-451.

Rulis AM, Tarantino, LM. Food ingredient review at FDA: recent data and initiatives to improve the process. Regulatory Toxicology and Pharmacology 1996; 24:224-231.

Rulis AM, Tarantino LM. The food additive petition process: recent data. Food and Drug Law J. 1993; 48(1):137-151, May.

Machuga EJ, Pauli GH, Rulis AM. A threshold of regulation policy for food-contact articles. Food Control 1992; 3(4).

Rulis AM. The Food and Drug Administration's food additive petition review process. Food Drug Cosmetic Law Journal 1990; 45(5):533-544, September.

Rulis AM. Safety assurance margins for food additives currently in use. Regulatory Toxicology and Pharmacology 1987; 7:160-168.

Hattan DG, Rulis AM. FDA's Priority-based Assessment of Food Additives III: specific toxicity parameters. Regulatory Toxicology and Pharmacology 1986; 6:181-191.

Rulis AM, Hattan DG. FDA's Priority-based Assessment of Food Additives II: General toxicity parameters. Regulatory Toxicology and Pharmacology 1985; 5:152-174.

Rulis AM, Hattan DG, Morgenroth VH. FDA's priority-based Assessment of Food Additives I: Preliminary results. Regulatory Toxicology and Pharmacology 1984; 4:37-56.

Smith MV, Rulis AM. The GRAS Review Program and FDA's Priority-based Assessment of Food Additives. Food Technology 1981;71-74, December.

Rulis AM, Ronk RJ. Cyclic Review — looking backward or looking forward? Food Drug Cosmetic Law Journal 1981; 36:156-165.

Esche BA, Kutina RE, Lang NC, Polanyi JC, Rulis AM. Energy transfer as a function of collision energy II. Chemical Physics 1979; 41:183-191.

Rulis AM, Scoles G. The isotropic part of the potential energy between two hydrogen molecules. Chemical Physics 1977; 25:183-188.

Smith KM, Rulis AM, Scoles G, Aziz RA, Nain V. Intermolecular forces in mixtures of He and the heavy noble gases. Journal of Chemical Physics 1977; 67:152.

Bickes RW, Duquette G, Van den Meijdenberg CJN, Rulis AM, Scoles G, Smith KM. Molecular beam

scattering experiments with polar molecules: Measurements of differential collision cross sections for H2O + H2, He, Ne, Ar, H2O and NH3. Journal of Physics B 1975; 8:3034.

Smith KM, Rulis AM, Scoles G, Aziz RA, Duquette G. Intermolecular forces in gaseous mixtures: He-Ar. J Chemical Physics 1975; 63:2250.

Van der Meulen A, Rulis AM, de Vries AE. Molecular beam study of the K + Br2 reaction in the electron-volt energy region. J Chemical Physics 1975; 7:1.

Rulis AM, Wilcomb BE, Bernstein RB. Molecular beam study of the K + CF3I reaction. Journal of Chemical Physics 1974; 60:2822.

Bernstein RB, Rulis AM. Translational energy dependence of product energy and angular distribution for the K + CH3I reaction. Faraday Discussions of the Chemical Society 1973; 55:293.

Rulis AM, Bernstein RB. Molecular beam study of the K + CH3I reaction. Journal of Chemical Physics 1972; 57:5497.

Gillen KT, Rulis AM, Bernstein RB. Molecular beam study of the K + I2 reaction. Journal of Chemical Physics 1971; 54:2831.

Book Chapters

Rulis AM, Tarantino LM. Food additives and other intentionally added substances. In: Food Safety Handbook. Rodricks J, Hulebak K, and Taylor M, (eds), Aspen Publishers 2002-2006.

Keefe D, Kuznesof P, Carberry S, Rulis AM. The Codex General Standard for food additives — A work in progress. In: International Standards for Food Safety. Rees and Watson (eds), Aspen Publishers, 2000.

Hattan DG, Rulis AM. Food toxicology: legal aspects. In: Toxicology. Marquardt H, Schafer S, McClellan R, Welsch F (eds), Academic Press, San Diego, CA., 1999.

Rulis AM, Pellicore LS, Thorsheim HR. Regulatory aspects of the introduction of new macronutrient substitutes. pp. 22-28. In: Annals of the New York Academy of Sciences. Harvey G, et al (eds), NYAS, Vol. 819, 1997.

Rulis AM. Threshold of regulation: options for handling minimal risk situations. In: American Chemical Society Symposium Series 484, Food Safety Assessment. Finley JW, Robinson SF, and Armstrong DJ (eds), ACS Press, Washington, DC, 1992.

Hall RL, Henry, Scheuplein RJ, Dull RJ, Rulis AM. Comparison of the carcinogenic risks of naturally occurring and adventitious substances in food: a perspective on the relative risk. pp. 205-224. In: Food Toxicology. Taylor and Scanlan (eds), Marcel Dekker, Inc., 1990.

Rulis AM, McLaughlin RJ, Salsbury PA, Pauli, GH. Carcinogenic impurities in food and color additives — an analysis of presumptive risk levels. pp. 485-493. In: Advances in Risk Analysis, Vol. 9: Analysis, Communication, and Perception of Risk. Garrick BJ and Gekler WC (eds), Plenum Press, New York, 1991.

Rulis AM. Establishing a threshold of regulation. pp. 271-278. In: Risk Assessment in Setting National Priorities. Bonin JJ and Stevenson DE (eds), Plenum Publishing Corp., 1989.

Rulis AM. De Minimis and the threshold of regulation. pp. 29-37. In: Food Protection Technology. Felix CW (ed), Lewis Publishers, 1987.

Flamm WG, Lake LR, Lorentzen RJ, Rulis AM, Schwartz PS, Troxell TC. Carcinogenic potencies and establishment of a threshold of regulation for food contact substances. pp. 87-92. In: Contemporary Issues in Risk Analysis, Vol. 2, De Minimis Risk. Whipple C (ed) Plenum Press, NY, 1987.

Easterday OD, Hall RL, Ford RA, Rulis AM. A combined three-method safety/risk priority ranking system. In: 50th Anniversary Commemorative Book for Professor Rene Truhaut, School of Pharmaceutical and Biological Sciences, University Rene Descartes, Academy of Paris, Imprimerie Tardy Quercy (S.A.) 46001 Cahors; Depot legal: IV-1985.

Hattan DG, Henry SH, Montgomery SB, Bleiberg MJ, Rulis AM, Bolger PM. The role of the Food and Drug Administration in the regulation of neuroeffective food additives. In: Nutrition and the Brain, Vol. 6. Wurtman JJ and Wurtman JJ (eds), Raven Press, NY, 1983.

Invited Presentations

Rulis AM. Adulterants and contaminants in food ingredients. United States Pharmcopeia, Food Ingredients Stakeholders' Forum, Rockville, MD, February 20, 2008.

Rulis AM. Threshold of regulation: Perspectives from the food area. Cosmetic, Toiletry and Fragrance Association, Regulatory Science Summit, Washington, DC, September 6, 2007.

Rulis AM. Threshold of regulation: Perspectives from the food area. Cosmetic, Toiletry and Fragrance Association, Regulatory Science Summit, Washington, DC, September 6, 2007.

Rulis AM. FDA decisions on food additives: science, policy, and law. The David Bradford Seminars in Science, Technology and Environmental Policy, Woodrow Wilson School of Public and International Affairs, Princeton University, October 16, 2006.

Rulis AM. Contaminants in food: acrylamide and furan. Annual meeting of the International Life Sciences Institute, San Juan, Puerto Rico, January 17, 2006.

Rulis AM. Food safety resources and public health priority setting at FDA. Presentation to the Food Safety Research Consortium National Conference, Resources for the Future, Washington, DC, September 14, 2005.

Rulis AM. Furans in food: FDA update. Toxicology Forum, Aspen, CO, July 13, 2005.

Rulis AM. Acrylamide in food: A progress report. Introductory Remarks and Chair of Session, Toxicology Forum, Aspen, CO, July 11, 2005.

Rulis AM. Food safety and nutritional risk: bioactive food components; Olestra as a case study. UK Central Science Laboratory / Joint Institute for Food Safety and Applied Nutrition Joint Symposium on Bioactive Food Components, College Park, MD, June 29, 2005.

Rulis AM. FDA's obesity working group report and the keystone dialogue. Presentation to the CFSAN Obesity Lecture Series, College Park, MD, June 2, 2005.

Rulis AM. Opportunities for preventing weight gain and obesity. Presentation to the Keystone National Forum on Away-From-Home Foods, Washington, DC, April 26, 2005.

Rulis AM. CFSAN 2005 programmatic overview. National Restaurant Association Quality Assurance Executive Study Group, Washington, DC, March 16, 2005.

Rulis AM. The 'critical path' for FDA food and nutrition programs. Toxicology Forum Winter Meeting, Washington, DC, February 1, 2005.

Rulis AM. Food labeling; what is FDA's role? ECRI 12th Annual Conference on Private and Public Policy Making: "Preventing and Treating Overweight and Obesity: How Effective are the Interventions?" Plymouth Meeting, PA, October 27-28, 2004.

Rulis AM. Obesity: The problem, and responses by the government. Toxicology Forum Session presentation and Chair of session, Aspen, CO, July 19, 2004.

Rulis AM. Factors in food safety decision making. University of Wisconsin Food Research Institute and Department of Food Science Symposium on U.S. Food Law and Regulation, Madison, WI, June 8-9, 2004.

Rulis AM. Applied nutrition — optimizing consumer health. FDA 2004 Science Forum, Session Chair, Washington, DC Convention Center, May 18, 2004.

Rulis AM. FDA's initiatives on obesity. National Food Policy Conference 2004, National Press Club, Washington, DC, May 6-7, 2004.

Rulis AM. Role of FDA in the campaign against obesity. Kids and Nutrition Conference, Chicago, IL, April 27, 2004.

Rulis AM. FDA plans for a facilitated discussion on obesity in relation to restaurants and pediatric obesity. Meeting of the FDA Science Board, Rockville, MD, April 22, 2004.

Rulis AM. Obesity: strategies to combat the epidemic. National Health Policy Conference, Washington, DC, January 29, 2004.

Rulis AM. Obesity: legal and policy issues. Food and Drug Law Institute Conference on Obesity: Science, Policy and Regulations, Washington, DC, January 15-16, 2004.

Rulis AM. Food and nutrition in obesity prevention: Implications for research and education; federal agencies. National Agricultural Research, Extension, Education, and Economics Advisory Board, Washington, DC, October 28, 2003.

Rulis AM. Food additive safety and risk assessment. American College of Toxicology Annual Meeting, Hershey, PA, Nov 12, 2002.

Rulis AM. Precaution in the safety assessment of food additives. International Society of Regulatory Toxicology and Pharmacology Workshop on the Precautionary Principle, Washington, DC, June 20, 2002.

Rulis AM. Food additive safety evaluation. National Academy of Sciences, Committee on Ingredients New to Infant Formula, March 7, 2002.

Rulis AM. Periodic reassessment of regulatory safety decisions. Toxicology Forum, Washington, DC, February 5, 2002.

Rulis AM. Food additive safety evaluation. National Academy of Sciences, Committee on the Framework for Evaluating the Safety of Dietary Supplements, October 11, 2001.

Rulis AM. Food ingredient safety: New challenges, new tools. FDA Center for Food Safety and Applied Nutrition Break time Seminar, November 9, 2001.

Rulis AM. Chair of Sessions: Food irradiation initiatives; reorganization of Center For Food Safety And Applied Nutrition's Office of Premarket Approval; and update on CFSAN's standing advisory committee.

Toxicology Forum, Aspen, CO, July 12-13, 2001.

Rulis AM. Chair of Session: Assessing the effects of phytoestrogen consumption. Toxicology Forum, Washington, DC, February 12, 2001.

Rulis AM. Update on FDA's notification programs. Toxicology Forum, Aspen, CO, July 11, 2000.

Rulis AM. Update of FDA's food ingredient review program. Toxicology Forum, Washington, DC, February 8, 2000.

Rulis AM. Threshold of regulation. American College of Toxicology Workshop, McLean, VA, November 8, 1999.

Rulis AM. Threshold of toxicological concern. International Life Sciences Institute (ILSI) Europe; Workshop on the Threshold of Toxicological Concern, October 5-6, 1999, Paris, France.

Rulis AM. The safety standard and level of proof for establishing food additive safety; Current problems and limitations in the safety assessment of food additives; FDA's Olestra follow-up food advisory committee meeting of June 1998. Toxicology Forum, Given Biomedical Institute, Aspen, CO, July 13-14, 1998.

Rulis AM. Regulatory perspective on labeling and allergens; and Chair of the session on food allergies. Toxicology Forum, Given Biomedical Institute, Aspen, CO, July 7, 1997.

Rulis AM. Update on olestra. Toxicology Forum, Given Biomedical Institute, Aspen, Co., July 11, 1997.

Rulis AM. Chemistry, food safety and public policy. Department of Chemistry Seminar, University of California, Irvine, CA, May 31, 1997.

Rulis AM. Recent food additive petition process initiatives. Food and Drug Law Institute Food Regulatory Update '97, Washington, DC, June 3, 1997.

Rulis AM. Enhancing the regulatory approval process for food ingredient technologies. National Academy of Sciences, Institute of Medicine, Food Forum Symposium, May 6, 1997.

Rulis AM. International harmonization and Codex activities. International Hydrolyzed Protein Council, Board of Directors and Technical Committee meeting, Washington, DC, April 30, 1997.

Rulis AM. Update on olestra. Toxicology Forum, Washington, DC, February 25, 1997.

Rulis AM. FDA's perspective on reforming food ingredient review. Food and Drug Law Institute 40th Annual Educational Conference, Washington, DC, December 11, 1996.

Rulis AM. Food safety reform: pros and cons and the problems. Society of the Plastics Industry; Food Drug, Cosmetic Packaging Materials Committee Meeting, Washington, DC, June 20, 1996.

Rulis AM. FDA's views on the need for reform of the approval process for food ingredients. Toxicology Forum, Washington, DC, February 19, 1996.

Rulis AM. Optimizing the food additive safety review process. Conference of the International Society of Regulatory Toxicology and Pharmacology, Washington, DC, April 18, 1996.

Rulis AM. The FDA evaluation process for olestra. Toxicology Forum, Aspen, CO, July 8, 1996.

Rulis AM. Current FDA initiatives to improve the food ingredient evaluation process. Food and Drug Law

Institute, 39th Annual Educational Conference, Washington, DC, December 13, 1995.

Rulis AM. Current and future directions in food additive regulatory issues. Institute of Medicine, National Academy of Sciences, Food and Nutrition Board, December 13, 1995.

Rulis AM. Improving the food additive approval process. Grocery Manufacturers of America, Winter Technical Regulatory Affairs Conference, Washington, DC, December 6, 1995.

Rulis AM. FDA's views on macronutrient substitutes. International Life Sciences Institute Workshop on Safety and Regulatory Aspects of Macronutrient Substitutes, Washington, DC, August 25, 1994.

Rulis AM. Need for and advantages of a threshold of regulation. International Life Sciences Institute (Europe) Workshop on the Threshold of Regulation Concept, Brussels, Belgium, July 6, 1994.

Rulis AM. What's new in genetic engineering. Food and Drug Law Institute Food Update, Marco Island, FL, April 23-26, 1994.

Rulis AM. Derivation and interpretation of intake and exposure data and their integration into the safety evaluation process for flavors. European Union Scientific Committee for Food, Working Group on Flavouring Substances, National Food Agency of Denmark, Copenhagen, Denmark, March 23-25, 1994; and Institute of Toxicology, National Food Agency of Denmark, Soborg, Denmark, March 23, 1994.

Rulis AM. Threshold of regulation. Symposium on Synthetic Vitreous Fibers: Scientific and Public Policy Issues, Washington, DC, March 3, 1994.

Rulis AM. Making regulatory decisions across the food ingredient spectrum. Arkansas Toxicology Symposium Honoring John Doull, University of Arkansas for Medical Sciences, Little Rock, AR, November 10-11, 1994.

Rulis AM. Impact of FDA's Redbook on international regulatory programs. International Life Sciences Institute Conference on the FDA Redbook II, Washington, DC, December 16-17, 1993.

Rulis AM. Changes to the FDA food additive premarket approval system (including the Redbook). Grocery Manufacturers of America, Winter Technical Regulatory Affairs Conference, Washington, DC, December 1, 1993.

Rulis AM. Current issues in food law. Advanced Workshop on Current Issues in Food Law, Food and Drug Law Institute, Washington, DC, October 13-14, 1993.

Rulis AM. Mineral hydrocarbons: A regulatory update. 1993 Winter Toxicology Forum, Washington, DC, February 16, 1993.

Rulis AM. The food additive petition process: An FDA overview. National Meeting of the Calorie Control Council, La Jolla, CA, November 9, 1992.

Rulis AM. The food additive petition process: recent data. Annual Meeting of the Enzyme Technical Association, Washington, DC, July 9, 1992.

Rulis AM. Threshold of regulation: progress and implications. Packaging Materials Committee Meeting of the Society of the Plastics Industry, Washington, DC, June 23, 1992.

Rulis AM. Current activities in food additive approval. International Food Additives Council Meeting, Washington, DC, June 11, 1992.

Rulis AM. Applications of threshold of regulation to recycling of plastics for food packaging. Annual

Research Reporting Conference, National Center for Food Safety and Technology, Chicago, IL, January 14, 1992.

Rulis AM. Safety evaluation and regulation of flavors in the United States. Meeting of the European Scientific Committee on Food of the European Community (EC), Brussels, Belgium, December 9, 1991.

Rulis AM. How is FDA dealing with 'De Minimis? Environmental Protection Agency, Problem clinic on risk: Use of sub chronic data for carcinogen risk assessment, Washington, DC, July 8, 1991.

Rulis AM. FDA's current thinking on recycled polymers for food-contact use. Grocery Manufacturers' of America, Environmental Issues Conference on Solid Waste, Washington, DC, May 1, 1991.

Rulis AM. Flavor priority setting. International Regulatory Affairs Committee of the Flavor and Extract Manufacturers' Association, Washington, DC, April 6, 1991.

Rulis AM. Use of safety factors in food additive regulation. Workshop on Risk Assessment for Noncarcinogens, Health and Welfare Canada, Environmental Health Directorate, Ottawa, Canada, April 29, 1991.

Rulis AM. Safety evaluation and regulation of flavors in the United States. 81st Plenary meeting of the European Scientific Committee for Food; European Union, Brussels, Belgium, December 10, 1991.

Rulis AM. Threshold of regulation. The International Life Sciences Institute-Nutrition Foundation, Washington, DC, November 27, 1990.

Rulis AM. Perspectives on threshold of regulation. The International Society of Regulatory Toxicology and Pharmacology Annual Meeting, Arlington, VA, October 1-2, 1990.

Rulis AM. FDA review of what's new. USDA/FDA Journalists' Conference, National Press Club, Washington, DC, June 25-26, 1990.

Rulis AM. Some perspectives on threshold of regulation. Annual Meeting of the International Society of Regulatory Toxicology and Pharmacology, Alexandria, VA, October 2, 1990.

Rulis AM. Setting priorities among food-related risks. Toxicology Seminar for the Institute for Comparative and Environmental Toxicology, Cornell University, November 4, 1988.

Rulis AM. Setting priorities for the safety review of food flavouring ingredients. Ad hoc presentation to the 20th Session of the Codex Committee on Food Additives and Contaminants, Working Group on Flavors, The Hague, Netherlands, March 3, 1988.

Rulis AM. Priority setting of flavors. Joint Council of Europe/Commission of the European Communities Workshop on a Priority Ranking System for Flavourings, Strasbourg, France, December 3-4, 1987, and published as Partial Agreement in the Social and Public Health Field, COE publication No. P-SG(88)9, 1988.

Rulis AM. Establishing a threshold of regulation. 1987 Annual Conference of the Society for Risk Analysis, Houston, TX, November 1-4, 1987.

Rulis AM. Risk assessment for food additives - A regulatory viewpoint. Symposium on Chemistry and the Law, American Chemical Society National Meeting, New Orleans, LA, September 1, 1987.

Rulis AM. A threshold-of-regulation policy for food-contact materials. June Meeting of the Society of the Plastics Industry, Washington, DC, 1987.

Rulis AM. U.S. flavour regulation. Joint Council of Europe/Commission of the European Communities Meeting on Priority Ranking Chemically Defined Flavouring Substances, Strasbourg, France, December 3-4, 1987.

Rulis AM. Risks and regulatory issues associated with food additives. Cornell University, Institute for Comparative and Environmental Toxicology, Symposium: The American Food Supply — Are We At Risk?, October 23, 1985.

Rulis AM. Priority-based Assessment of Food Additives. Massachusetts Institute of Technology Department of Food Science and Nutrition, Summer School on Computer-aided Techniques in Food Technology, August 10, 1984.

Rulis AM. Selection and ranking of food additives for safety assessment. U.S. Interagency Toxic Substances Data Committee, Council for Environmental Quality, Executive Office of the President, March 6, 1984.

Rulis AM. Use of risk assessment in food-related issues. Center for Energy and Environmental Management, Conference of Environmental Risk Assessment, Washington, DC, November 2, 1984.

Rulis AM. Chemical structure classification in the setting of toxicity testing requirements for food additives. American Chemical Society Conference on Structure-Activity Relationships and Toxicity Assessment, National Bureau of Standards, June 8, 1984.

Rulis AM. The FDA Redbook - Toxicological Principles. American Oil Chemists Society annual meeting, Dallas, TX, April 30, 1984.

Rulis AM. BHA and other phenolic antioxidants. Toxicology Forum Summer Meeting, Given Institute for Pathobiology, Aspen, CO, July 16-20, 1984.

Rulis AM. Screening and priority selection of regulated food additives. National Library of Medicine, Toxicology Information Subcommittee and Chemical Substances Information Network Subcommittee Joint Meeting, National Library of Medicine, November 16, 1983.

Rulis AM. FDA's constituents policy for chemical carcinogens. Flexible Packaging Association Conference, Washington, DC October 12, 1983.

Rulis AM. FDA structure categorization process for food additives. Forum for Scientific Excellence, Washington, DC, November 10, 1983.

Rulis AM. FDA Redbook: Toxicological Principles. Food and Drug Law Institute Conference, March 9, 1983.

Rulis AM. FDA's toxicological principles for the safety assessment of direct food additives. Grocery Manufacturers of America Seminar, November 3, 1982.

Rulis AM. The role of structure-activity considerations in regulatory toxicology. Toxicology Forum Summer Meeting, Given Institute for Pathobiology, Aspen, CO, July 19-23, 1982.

Rulis AM. Development of safety regulations. New York Institute of Food Technologists - Society of Cosmetic Chemists, Joint Meeting, Saddlebrook, NJ, October 14, 1981.

Rulis AM. Priority ranking for food safety. Department of Health and Human Services, Committee to Coordinate Environmental and Related Problems, Washington, DC, May 27, 1981.

Rulis AM. FDA's cyclic review of food additives. Association of Official Analytical Chemists, Ottawa,

Canada, May 12-14, 1981.

Rulis AM. FDA's food additive priority-setting system. National Academy of Sciences Committee on Priority Mechanisms, Washington, DC, January 14-15, 1981.

Rulis AM. Cancer risk assessment and food safety policy. 14th Annual Middle Atlantic Regional Meeting of the American Chemical Society, April 24, 1980.

Rulis AM. Saccharin. Indiana Food Safety Debate for State High School Policy Symposium: Sen. Richard G. Lugar, 1978.

Rulis AM, Scoles G. The H2-H2 Intermolecular Potential. Annual Meeting of the Canadian Association of Physicists, Ottawa, Canada, October 30, 1976.

Project Experience

Formulated the design concepts for FDA's Cyclic Review of Food Additives and Priority-based Assessment of Food Additives (PAFA) programs. This work included analysis of existing and new operating procedures for the program and devising detailed Project Evaluation and Review Technique (PERT) task formulations for the review of food ingredient safety profiles.

Analyzed the aggregated data profiles of the PAFA program and published a series of four scientific papers documenting the chemical structure dependence, population exposure and toxicity distributions for hundreds of food and color additives. These papers advanced our comprehensive picture of safety margins for food chemicals currently approved in the United States.

Reorganized FDA's Office of Food Additive Safety, and reengineered its procedures for processing received applications. Major initiatives and achievements include the following:

- Finalizing the agency's Threshold of Regulation policy for exempting low-level food contact migrants from petition review
- Expediting the FDA's safety reviews of additives that provide food safety advantages; streamlining the review of selected food additive petitions based on exposure considerations; and defining generic classes of petitions that may be exempted from the requirement to file environmental assessments routinely
- Subjecting the agency's food additive review procedures to detailed programmatic analysis (both internally and with outside contractors) using PERT approaches and other tools to recommend new expectations and organizational structures for operating units within the program.
- Reorganizing the program from one based on academic disciplines to one based on programmatic functions
- Initiation of the premarket notification program for food contact materials under provisions of the FDA Modernization Act of 1997
- Initiation of a voluntary notification process for generally recognized as safe (GRAS) food ingredients under the agency's 1997 Federal Register proposal.

Chaired the report-writing committee for FDA's Qualified Health Claims Task Force Report. The report, "Consumer Health Information for Better Nutrition," released in July 2003, provides alternative pathways for agency exercise of enforcement discretion for qualified health claims on conventional foods and dietary supplements.

Chaired the report-writing committee for FDA's Obesity Task Force whose March 2004 report, "Calories Count," presented proposals within FDA's purview for addressing public health opportunities to curb overweight and obesity in the U.S.