

Michael Carakostas, DVM, PhD, DACVP

SENIOR CONSULTANT

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Michael Carakostas is a Senior Consultant with ToxStrategies. He is a board-certified veterinary clinical pathologist with over 25 years of industry experience in the safety assessment of drugs, chemicals and food ingredients. Dr. Carakostas has also held faculty appointments on the veterinary school faculties of Kansas State University (KSU), Louisiana State University and Tufts University as well as adjunct appointments to the University of Pennsylvania and Georgia State University. Dr. Carakostas earned a Doctorate in Veterinary Medicine from Michigan State University. At Kansas State University he earned a PhD in laboratory medicine and comparative pathology from KSU's College of Veterinary Medicine. Dr. Carakostas is a diplomate in the American College of Veterinary Pathologists (ACVP).

Dr. Carakostas has experience in safety assessment through positions he held in the chemical, drug and food industries. He is widely known among veterinary pathologists for his expertise in the interpretation of clinical laboratory data in pre-clinical toxicity studies. He also has experience in the development of new veterinary drugs including target animal safety testing as well as the safety of residues in meat and milk from food producing animals.

Dr. Carakostas has extensive experience in food ingredient safety assessment, food regulatory affairs and the management of risk and communication issues related to food safety and product claims. He has held leadership roles in several major food trade associations, assisting those organizations through a number of crises that affected the food industry. He managed the corporate scientific and regulatory affairs department for a major global food company and led the department through a number of national and international scientific and regulatory crises. He has extensive experience with issues related to the safety and claim substantiation of functional and herbal ingredients and safety issues related to food biotechnology, caffeine, and sweeteners. He has managed a variety of GRAS evaluations, as well as several international ingredient approvals.

EDUCATION AND DEGREES EARNED

Ph.D., Comparative Pathology and Laboratory Medicine, 1980, Kansas State University

D.V.M., Doctor of Veterinary Medicine, 1975, Michigan State University

B.S., Veterinary Science (dual degree program), 1974, Michigan State University

CERTIFICATIONS

Diplomate, American College of Veterinary Pathologists, clinical pathology

PROFESSIONAL ASSOCIATIONS

American College of Veterinary Pathologists

Certification Examination Committee (member 1987–1991, chair 1991)

Federal Regulations Committee (1994–2003)

Society of Toxicology

Toxicology Forum

Program committee (2002–2008)

American Veterinary Medical Association

ORGANIZATION BOARD OF DIRECTOR AND LEADERSHIP POSITIONS

Calorie Control Council — Board and Executive Committee member, 2001–2008; Board Chairman, 2006–2007

International Food Information Council — Board member, 2003-2005; Executive Committee member, 2003–2005.

Toxicology Forum — Board member, 2002–2008

International Soft Drinks Council — Board member, 2001–2005

SCIENTIFIC COMMITTEES AND WORKGROUPS

AACC-DACC/ASVCP Joint Task Force on Clinical Pathology Testing for Non-Clinical Toxicity and Safety Studies.

Scientific and Regulatory Sub-committee, Animal Health Institute

American Beverage Association Scientific and Regulatory Affairs Committee

International Food Information Council — Caffeine Committee (co-chair), Food Sensitivities Committee

International Life Sciences Institute — Caffeine Committee, Biotechnology Working Group, Chronic/ Carcinogenicity Study Dose-Setting Working Group, Emerging Foodborne Pathogens Conference Working Group

Calorie Control Council — Aspartame Working Group (chair), Saccharin-Cyclamate Working Group

Grocery Manufacturers of America — Regulatory and Scientific Policy Committee (chair 2003-2004), Biotechnology Task Force,

Flavor and Extract Manufacturers Association — Safety Evaluation Coordination Committee

National Coffee Association — Scientific Advisory Group

Food Allergy Research and Resource Program (FARRP) — Industry Advisory Board

Joint Institute for Food Safety and Nutrition (JIFSAN) — Industry Advisory Board

Georgia State University — Institutional Bio-Safety Research Review Committee, (Expert Level Community member)

PROFESSIONAL EXPERIENCE

Food Safety

Managed a joint ingredient development project requiring several new toxicity, metabolism and human clinical studies leading to the successful establishment of a permanent ADI from JECFA and successful GRAS notification in less than 3 years, a first for an intense sweetener. An EU food additive petition also completed in the same timeframe is pending.

Managed the successful GRAS reviews for a number of beverage ingredients including herbals and functional ingredients.

Critically evaluated new products and ingredients, including a number of herbal and functional ingredients, in new products for M & A activities at a major food company.

Played a leading role in establishing the substantiation from existing research for a structure / function claim that led to the launch of a novel juice product. Veterinary and human clinical research was used in a novel way to establish the substantiation.

Provided leadership in the successful conduct of several caffeine effects studies performed at universities and contract clinical research organizations.

Risk and Scientific Communication Management

Developed strategy and draft white paper for trade association for their response to charges that certain ingredients cause adverse health effects.

Developed the regulatory submission for a new health claim for an intense sweetener.

Managed a number of media crises globally about the safety of a controversial intense sweetener using internal and external trade association and scientific expert resources. Led the only food industry committee responsible for managing attacks on a major intense sweetener.

Provided scientific leadership internally at a Fortune 100 food corporation through two anti-biotechnology proxy proposals requiring interaction with senior members of management and the board of directors.

Provided weekly and monthly scientific and regulatory updates to top-level North American and Corporate level management (President and CEO level, respectively) at Fortune 100 corporation.

Drug and Chemical Safety Evaluation

Provided a risk assessment of several polyol sweeteners that may be used in significant amounts in OTC drug products.

Provided scientific leadership on blood substitute / oxygen carrier compound development project at major chemical company.

Led the development of novel cholinesterase evaluation processes for carbamate insecticides (www.inchem.org/documents/jmpr/jmpmono/v89pr11.htm)

Led the submission of a complex phased safety-metabolism submission to the EU for a new (food) animal drug resulting in drug approval 23 months after the initial submission and only 6 months after the last carcinogenicity study was submitted.

Invited to present seminar on the interpretation of clinical laboratory data in safety assessment studies to FDA-CVM staff.

Participated the initiation of a global task force to formulate recommendations for clinical laboratory tests in pre-clinical safety studies leading to a number of changes to drug and chemical testing guidelines.

Placed and monitored more than two-dozen pre-clinical and target animal safety studies for the evaluation of new veterinary antibiotics, parasiticides, analgesics and growth promoters.

MANUSCRIPTS

Carakostas, M. 'Long-term feeding effects of stevioside sweetener on some toxicological parameters of growing rats'. Journal of Applied Toxicology. November 2, 2011. doi: 10.1002/jat.1756.

Maki KC, Curry LL, **Carakostas MC**, et al.: The hemodynamic effect of rebaudioside A in health adults with normal and low-normal blood pressure. Food Chem Toxicol 46:S40-S46, 2008.

Maki KC, Curry LL, Reeves MS, Toth PD, McKenny JM, Farmer MV, Schwartz SL, Lubin BC, Boileau AC, Dicklin MR, **Carakostas MC** and Tarka SM: Chronic consumption of rebaudioside A, a steviol glycoside, in men and women with type 2 diabetes mellitus. Food Chem Toxicol 46 Suppl 7:S47-S53, 2008.

Carakostas MC, Curry LL, Boileau AC and Brusick DJ: Overview: the history, technical function and safety of rebaudioside A, a naturally occurring steviol glycoside, for use in food and beverages. Food Chem Toxicol 46 Suppl 7:S1-S10, 2008.

Carakostas MC and Colaianne JJ: A Proposed Design for Conducting Target Animal Safety Studies for Developing New Veterinary Pharmaceuticals. Reg Pharm Toxicol 23:49-54, 1996.

Malley LA, **Carakostas MC**, Elliott GS, et al.: Subchronic Toxicity and Teratogenicity of 2-Chloro-1,1,1,2-tetrafluoroethane (HCFC-124). Fund Appl Toxicol 32:11-22, 1996.

Malley LA, **Carakostas MC**, Hanson JF, et al., Two-Year Inhalation Toxicity Study in Rats with Hydrochlorofluorocarbon 123. Fund Appl Toxicol 25:101-114, 1995.

Theodorides VJ, **Carakostas MC**, Colaianne JJ, Freeman JF, Page SW: Developmental Safety of Albendazole in Cattle. Am J Vet Res 54:2171-2174, 1993.

Weingand K, Bloom J, **Carakostas M**, Hall R, et al.: Clinical Pathology Testing Recommendations for Nonclinical Toxicity and Safety Studies. Toxicol Pathol 20:539-543, 1993.

Carakostas MC: Interpreting Clinical Laboratory Data in Safety Assessment Studies. Toxicol Pathol 20: 480-483, 1993.

Carakostas MC: Interpreting Clinical Laboratory Data in Safety Assessment Studies. Toxicol Pathol 20: 480-483, 1993.

Frame SR, **Carakostas MC**, Warheit DB: Inhalation Toxicity of an Isomeric Mixture of Hydrochlorofluorocarbon (HCFC) 225 in Rats. Fund Appl Toxicol 18:590-595, 1992.

Warheit DB, **Carakostas MC**, Frame SR: A Two-Week Inhalation Toxicity Study with HCFC-122 in Rats. *Inhal Toxicol* 4:81-93, 1992.

Gavett SH, **Carakostas MC**, Belcher LA, Warheit DB: Role of Neutrophils in the Acute Inflammatory Response to Inhaled Silica Particles. *J Leuk Biol* 51:455-461, 1992.

Warheit DB, **Carakostas MC**, Bamberger JR, Hartsky MA: Complement Facilitates Macrophage Phagocytosis of Inhaled Iron Particles but Has Little Effect in Mediating Silica-Induced Lung Inflammatory and Clearance Responses. *Environ Res* 56:186-203, 1992.

Carakostas MC, Landis ML: Modification of an Automated Method for Determining Plasma and Erythrocyte Cholinesterase Activity in Laboratory Animals. *Vet Hum Toxicol* 33:450-456, 1991.

Carakostas MC, Green JW: Using Appropriate Statistical Methods for Comparing Two Analytical Techniques. *Vet Clin Pathol* 20:91-94, 1991.

Warheit DB, Moore KA, **Carakostas MC**, Hartsky MA: Acute Pulmonary Effects of Inhaled Wollastonite Fibers are Dependent on Fiber Dimensions and Aerosol Concentrations. *Proceeding of the NATO Advanced Research Workshop on Mechanisms of Fibre Carcinogenesis*, 1991.

Warheit DB, **Carakostas MC**, Kelly DP, Hartsky MA: Four-Week Inhalation Toxicity Study with Ludox Colloidal Silica in Rats: Pulmonary Cellular Responses. *Fundam Appl Toxicol* 16:590-601, 1991.

Warheit DB, Hartsky MA, **Carakostas MC**: Development of a Short-Term Bioassay to Assess Pulmonary Toxicity of Inhaled Particulates: Comparisons of Pulmonary Responses to Carbonyl Iron and Silica. *Tox Appl Pharmacol* 107:350-368, 1991.

Warheit DB, **Carakostas MC**, Hartsky MA: Assessments of Lung Toxicity to Acrawax C Following Acute Exposure. *Drug Chem Toxicol* 13:1-18, 1990.

Warheit DB, Seidel WC, **Carakostas MC**, Hartsky MA: Attenuation of Perfluoropolymer Fume Pulmonary Toxicity: Effect of Filters, Combustion Method and Aerosol Age. *Exp Mol Pathol* 52:309-329, 1990.

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Carakostas MC, Banerjee AK: Interpreting Rodent Clinical Laboratory Data in Safety Assessment Studies: Biological and Analytical Components of Variation. *Fundam Appl Toxicol* 15:744-753, 1990

Warheit DB, Kelly DP, **Carakostas MC**, Singer AW: A 90-Day Inhalation Toxicity Study with Benomyl in Rats. *Fundam Appl Toxicol* 12:333-345, 1989.

Carakostas MC: 'Minding Our Own Business' Veterinary Clinical Pathologists in Research and Development. *Vet Clin Pathol* 18:4-6, 1989.

Warheit DB, Kinney LA, **Carakostas MC**, Ross PE: Inhalation Toxicity Study of Formamide in Rats. *Fundam Appl Toxicol* 13:702-713, 1989.

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Davenport DJ, Breitschwerdt EB, **Carakostas MC:** A Review of Platelet Disorders in the Dog and Cat. Part II: Diagnosis and Management. Comp Cont Educ Pract Vet 9:788-796, 1982.

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Carakostas MC, Moore WE, Smith JE, Johnson D: Effects of Etiocholanolone and Prednisolone on Intravascular Granulocyte Kinetics in Horses. Am J Vet Res 42:626-628, 1981.

Carakostas MC, Moore WE, Smith JE: Intravascular Neutrophilic Granulocyte Kinetics in Horses. Am J Vet Res 42: 623-625, 1981.

Carakostas MC, Moore WE, Smith JE: A Procedure for Granulokinetic Studies in the Horse with Chromium-51. Am J Vet Res 42:620-622, 1981.

Carakostas MC, Kennedy GA, Kittleson MD, Cook JE: A Malignant Foregut Carcinoid Tumor in a Domestic Cat. Vet Pathol 16:607-609, 1979.

BOOK CHAPTERS

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Loeb WF, **Carakostas MC**: Changes in Serum Biochemistry, in *Pathobiology of the Aging Rat*, Vol 1, U. Mohr, DL Dunworth, CC Capen, eds., ILSI Press, 1992, pg 7-13.

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ABSTRACTS AND PRESENTATIONS

Carakostas MC (session coordinator): Safety assessment of a new natural sweetener. *Toxicology Forum*, Summer, 2008.

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Carakostas MC: Biological vs. Statistical Significance of Clinical Pathology Data in Safety Assessment Studies, C.L. Davis Foundation for the Advancement of Veterinary and Comparative Pathology, Spring Meeting, 1994.

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Sykes GP, **Carakostas MC**, Alvarez L, Warheit DB: Subchronic Inhalation Toxicity Study with FC-C-51-12 in Rats. Presented at the Society of Toxicology Annual Meeting, 1992.

Valentine R, Warheit DB, **Carakostas MC**, Makovec GT: Ten-Day Inhalation Toxicity Study with Fiber Lubricant Aerosols. Presented at the Society of Toxicology Annual Meeting, 1992.

Frame SR, Valentine R, Hurtt ME, **Carakostas MC**: Ten-Day Inhalation Toxicity Study with Dimethylacetamide (DMAC) in Mice; Evidence for Age-Dependant Lethality and Testicular Toxicity. Presented at the Society of Toxicology Annual Meeting, 1992.

Weingand K, Bloom J, **Carakostas M**, Hall R, et al.: Recommendations for Hematology Testing in Nonclinical Safety Studies. Presented at the Society of Toxicologic Pathologists Annual Meeting, 1992.

Carakostas MC: Interpretation of Clinical Laboratory Data in Safety Assessment Studies. Presented at the Midwestern Section of the Society of Toxicologic Pathologists, 1992 (invited paper).

Weingand K, Bloom J, **Carakostas M**, Hall R, et al.: Recommendations for Clinical Laboratory Testing in Nonclinical Safety Studies. Presented at the Society for Veterinary Clinical Pathologists Annual Meeting, 1992.

Frame SR, **Carakostas MC**, Warheit DB: Subchronic Inhalation Toxicity Study with HCFC-132c in Rats. Presented at the Society of Toxicology Annual Meeting, 1991.

Gavett SH, Freund EA, Stanickyj LA, Hartsky MA, **Carakostas MC**, Warheit DB: Role of the Neutrophil in the Silica-Induced Increase in Lavaged Enzymes and Protein in the Lung. Presented at the Society of Toxicology Annual Meeting, 1991.

Warheit DB, **Carakostas MC**, Frame SR: Subchronic Inhalation Toxicity Study with HCFC-225 Isomer Mixture in Rats. Presented at the Society of Toxicology Annual Meeting, 1991.

Angevine-Malley L, **Carakostas MC**, Hansen JF, Trochimowicz HJ, Rasch GM: Chronic Toxicity of Hydrochlorofluorocarbon HCFC-123 in Rats. Presented at the Society of Toxicology Annual Meeting, 1991.

Valentine R, Frame SR, **Carakostas MC**: Ten-Day Repeated Dose Inhalation Toxicity Study with 1,4-Hexadine. Presented at the Society of Toxicology Annual Meeting, 1991.

Valentine R, **Carakostas MC**, Hansen JF: Ten-Day Repeated Dose Inhalation Toxicity Study with Benzyltriphenylphosphonium chloride. Presented at the Society of Toxicology Annual Meeting, 1991.

Bogdanffy MS, Kee CR, Kelly DP, **Carakostas MC**, Sykes GP: Subchronic Inhalation Study with Vinyl Fluoride: Effects on Hepatic Cell Proliferation and Urinary Fluoride Excretion. Presented at the Society of Toxicology Annual Meeting, 1990.

Hartsky MA, Moore KA, **Carakostas MC**, Warheit DB: Acute Inhalation Effects of Crocidolite Asbestos and Wollastonite Fibers in Rats. Presented at the Society of Toxicology Annual Meeting, 1990.

Malley LA, **Carakostas MC**, Hansen JF, Trochimowicz HJ, Rusch GM: Subchronic Toxicity of Freon HCFC-123 in Rats. Presented at the Society of Toxicology Annual Meeting, 1990.

Stadler JC, Kelly DP, **Carakostas MC**, Makovec GT: Subchronic Inhalation Toxicity in Rats and Mice Exposed to Hexa-fluoropropene (HFP). Presented at the Society of Toxicology Annual Meeting, 1990.

Warheit DB, Achinko L, Hartsky MA, **Carakostas MC**: Assessments of Pulmonary Autoradiographic and Biochemical Responses in Rats Following a Subchronic Inhalation Exposure to Ludox Presented at the Society of Toxicology Annual Meeting, 1990.

Carakostas MC, Bannerjee AK: Biological and Analytical Components of Variation For Clinical Laboratory Tests in Rats. Presented at the Society for Veterinary Clinical Pathology Annual Meeting, 1989.

Landis MA, **Carakostas MC**: An Automated Method for the Determination of Plasma and Erythrocyte Cholinesterase in Laboratory Animals. Presented at the American Society for Veterinary Clinical Pathology Annual Meeting, 1989.

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Carakostas MC, Banerjee AK, Power RJ: A Procedure for Evaluating the Performance of Clinical Laboratory Methods Using a Newly Automated 5'Nucleotidase Technique as an Example. Presented at the Vth Symposium of the World Association of Veterinary Laboratory Diagnosticians, 1989.

Singer AW, Kelly DP, **Carakostas MC**, Warheit DB: Subchronic Inhalation Toxicity: 90-Day Study With Benomyl. Presented at the Society of Toxicology Annual Meeting, 1988.

Carakostas MC, Gossett KA, Watters JW, MacWilliams PS: Effects of Metrizamide Myelography on Cerebrospinal Fluid Analysis in the Dog. Presented at the American College of Veterinary Pathologists Annual Meeting, 1984.

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Carakostas MC, Gossett KA, Church GE, Cleghorn BL: The Predictive Value of Fourteen Serum Biochemical Tests for Evaluating Toxin-Induced Hepatic Lesions in Rats. Presented at the American Society for Veterinary Clinical Pathology Annual Meeting, 1984.

Carakostas MC: Evaluating Toxin-Induced Hepatic Injury in Rats by Laboratory Results and Discriminate Analysis. Presented at the New England Comparative Pathology Colloquy, Autumn Meeting, 1984.

Gossett KA, Adams R, **Carakostas MC**, Cleghorn BL, Hall P: Composition of the Anion Gap in the Horse. Presented at the Animal Research Workers in the Southern States Annual Meeting, 1983.

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