



Toxicology Regulatory Services

January 2010

Curriculum Vitae

Andrey I. Nikiforov, Ph.D.

EXPERIENCE

President, Principal; 2005 to Present

Vice President; 1999 to 2005

Program Director; 1997 to 2005

Toxicology Regulatory Services, Inc.

Charlottesville, VA

Responsibilities include: 1) oversee TRS business organization and coordinate activities of scientific and technical staff; 2) managing toxicology and regulatory issues with the following types of activities: preparing chemical group safety evaluations and assessments for the flavor industry; preparing review/position papers and risk assessments; designing data development strategies and studies; scientific monitoring and managing of testing programs; interfacing with regulatory authorities; and participating in trade association technical groups; 3) providing regulatory expertise for PMNs or NONs, REACH, the EU Biocidal Products Directive, FDA GRAS Notices, and other approval or registration processes; and 4) providing support for product stewardship in areas such as the HPV chemicals, product safety assessments and in preparing documents for customer and worker communications. Basic Training: Good Laboratory Practice (September 2008), Society of Quality Assurance professional development seminar.

Group Head, Intermediates Toxicology; 1991 to 1996

Exxon Biomedical Sciences, Inc.

East Millstone, NJ

Responsibilities included supervising several toxicology advisors; managing approximately \$3.2M of consulting and testing budgets; developing and conducting projects in conjunction with business group environmental health contacts to assess product safety and health hazard; providing expertise as company technical contact on endocrine modulation issue, in particular, developing strategy and conducting research on phthalate ester products.

Provided leadership as Chairman of CMA Phthalate Esters Toxicology Research Task Group, CMA Phthalate Esters Endocrine Issues Work Group and CMA Phthalic Anhydride Toxicology Work Group; actively involved member of CMA Endocrine Issues Science Work Group, CMA Hazardous Air Pollutants Testing Technical Subgroup, CMA Hazard Characterization Work Group, AIHC Reproductive and Developmental Effects Subcommittee, and ECETOC Task Force on Environmental Estrogens.

EXPERIENCE (continued)

European Toxicology Advisor; 1988 to 1991

Exxon Chemical Europe, Inc.

Kraainem, Belgium

Responsibilities included serving as focal point for Exxon Chemical Europe on regional toxicology issues, such as implementation of EC health/environmental legislation, discussions with EC regulators, PMN coordination, toxicology testing recommendations; advising Exxon Food Advisory Panel and Labeling Task Force; serving as Chairman of the UK Chemical Industry Association Health and Environmental Risk Assessment Working Groups; serving as toxicologist member of CEFIC Plasticizer and Hydrocarbon Solvents Sector Groups, and member of several ECETOC Task Forces; creating a toxicology, environmental toxicology and risk assessment seminar series; and making presentations to Exxon Chemical Product Safety, Marketing and Technology network members.

Senior Toxicologist; 1987 to 1988

Exxon Biomedical Sciences, Inc.

East Millstone, New Jersey

Responsibilities included providing toxicology consulting for Exxon Chemical companies and affiliates in the areas of health hazard assessments and recommendations; advising on FDA, EPA and EEC regulatory issues; developing toxicity testing programs; formulating emergency planning guidelines; supporting product line marketing; and serving as project leader for determination of inhalation "no-effect-level" guidelines for Exxon's chemicals impacted by EPA Title III SARA 313.

Research Scientist; 1985 to 1987

Battelle Research Institute

Center for Toxicology and Biosciences

Geneva, Switzerland

Received basic training in OECD Good Laboratory Practices during April 1985.

Responsibilities included marketing and project management for acute and subchronic inhalation toxicology studies: protocol development, development of aerosol generation and exposure techniques, study direction, data analysis, and report writing.

Graduate Research Assistant; 1978 to 1985

New York University

Institute of Environmental Medicine

Laboratory for Aerosol and Inhalation Research

Tuxedo Park, New York

EDUCATION

New York University, Tuxedo Park, NY; Ph.D., Environmental Health Sciences; 1985

New York University, Tuxedo Park, NY; M.S., Environmental Health Sciences; 1981

University of Connecticut, Storrs, CT; B.S., Biology, Chemistry; 1974

PROFESSIONAL SOCIETIES

American College of Toxicology

EUROTOX

Society of Toxicology

National Capital Area Chapter Society of Toxicology

PROFESSIONAL HONORS

Session Moderator (1996). Endocrine Modulators in the Environment: Searching for Solutions. Mid-Atlantic Society of Toxicology Fall Symposium, East Windsor, NJ

Session Chairman (1986). Distribution of Particles Deposited in Lungs. Second International Aerosol Conference, Berlin.

U.S. and European Patents for an Improved Rodent Plethysmographic Tube (Patent No. 87810763.0).

PUBLICATIONS

Nikiforov, A.I. and A.K. Eapen (2008). A 90-Day Oral (Dietary) Toxicity Study of Rebaudioside A in Sprague-Dawley Rats. *Int. J Toxicol.* 27(1):65-80.

Waterman, S. J., L. H. Keller, G. W. Trimmer, J. J. Freeman, A. I. Nikiforov, S. B. Harris, M. J. Nicolich and R. H. McKee (2000). Two-Generation Reproduction Study in Rats Given Di-Isononyl Phthalate in the Diet. *Reproductive Toxicol.* 14:21-36.

Waterman, S. J., J. L. Ambroso, L. H. Keller, G. W. Trimmer, A. I. Nikiforov and S. B. Harris (1999). Developmental Toxicity of Di-Isodecyl and Di-Isononyl Phthalates in Rats. *Reproductive Toxicol.* 13(2):131-136.

PUBLICATIONS (continued)

Carney, E. W., A. M. Hoberman, D. R. Farmer, R. W. Kapp, A. I. Nikiforov, M. Bernstein, M. Hurtt, W. J. Breslin, S. Z. Cagen, and G. P. Daston (1997). Estrogen Modulation: Tiered Testing for Hazard Evaluation. *Reproductive Toxicol.* 11(6):879-892.

Daston, G. P., J. W. Gooch, W. J. Breslin, D. L. Shuey, A. I. Nikiforov, T. A. Fico, and J. W. Gorsuch (1997). Environmental Estrogens and Reproductive Health: A Discussion of the Human and Environmental Data. *Reproductive Toxicol.* 11(4):465-81.

Lewis, S. C., J. R. Lynch, and A. I. Nikiforov (1990). A New Approach to Deriving Exposure Guidelines from "No-Observed-Adverse-Effect-Levels". *Reg. Toxicol. Pharmacol.* 11:314-330.

Suber, R. L., R. Deskin, A. I. Nikiforov, X. Fouillet, and C. Coggins (1989). Subchronic Nose-Only Inhalation Study of Propylene Glycol in Sprague-Dawley Rats. *Fd. Chem. Toxic.* 27(9):573-583.

Nikiforov, A. I., M. Lippmann, and E. D. Palmes (1988). Validation of an *In vivo* Aerosol Probe Technique by Measurements of Deposition and Morphometry in Excised Human Lungs. *Ann. Occup. Hyg.* 32:33-39.

Lippmann, M., A. I. Nikiforov, J. Esch, and D. Spektor (1988). Effects of Airway Branching Patterns on Particle Deposition in the Lungs. *Ann. Occup. Hyg.* 32:23-32.

Nikiforov, A. I. and R. B. Schlesinger (1985). Morphometric Variability of the Human Upper Bronchial Tree. *Respir. Physiol.* 59:289-299.

PUBLISHED REPORTS

Frazier, J. M., D. Dodd, and A. I. Nikiforov (2000). Data Development Strategy for Evaluation of Occupational Health Hazards of New Chemicals of Interest to the Air Force. United States Air Force Research Laboratory. 1-55.

Rose, F. G., S. Allen, P. Grasso, A. I. Nikiforov, J. L. Clark, and D. A. Stringer (1996). ECETOC Technical Report No. 70. Chronic Neurotoxicity of Solvents. European Centre for Ecotoxicology and Toxicology of Chemicals. 1-209.

Nikiforov, A. I. et al. (ECETOC Task Force). (1996). ECETOC Document No. 33. 'Environmental Oestrogens' A Compendium of Test Methods. European Centre for Ecotoxicology and Toxicology of Chemicals. 1-27.

Nikiforov, A. I. et al. (ECETOC Task Force). (1996). ECETOC Document No. 32. 'Environmental Oestrogens': Male Reproduction and Reproductive Development. European Centre for Ecotoxicology and Toxicology of Chemicals. 1-10.

PUBLISHED REPORTS (continued)

King, D. J., J. N. Bremmer, A. I. Nikiforov, R. Mueller, and W. Haebler (1991). ECETOC Joint Assessment of Commodity Chemicals (JAAC) Report No. 19: Dicyclopentadiene; CAS: 77-73-6. European Chemical Industry, Ecology & Toxicology Centre. 1-50.

ABSTRACTS/POSTERS/PRESENTATIONS

Nikiforov, A. I., G. P. Schoenig and N. Higley (2000). A Paradigm for Conducting Safety Assessments of Groups of Structurally Related Flavoring Ingredients for Occupational Hygiene Programs. American College of Toxicology Annual Meeting, San Diego.

Nikiforov, A. I., G. W. Trimmer, L. H. Keller, and S. B. Harris (1997). Lack of Transgenerational Reproductive Effects Following Treatment with Di-Isodecyl Phthalate. *Toxicologist*. 36(1):1827.

Carney, E., A. Hoberman, D. Farmer, R. Kapp Jr., A. Nikiforov, M. Bernstein, M. Hurtt, W. Breslin, S. Cagen, and G. Daston (1997). Estrogen Modulation: Tiered Testing for Hazard Evaluation. *Toxicologist*. 36(1):65.

Keller, L. H., A. I. Nikiforov, G. W. Trimmer, and S. B. Harris (1997). Lack of Selective Developmental Toxicity in Rats Treated with Cekanonic C8 Acid. *Toxicologist*. 36(1): 1312.

Baker, T.K., G. H. Kalimi, A. W. Lington, J. S. Isenberg, J. E. Klaunig, and A. I. Nikiforov (1996). Species Differences Observed in Gap Junctional Intercellular Communication (GJIC) Studies on Five Phthalate Monoesters: Implications for Risk Assessment. *Toxicology Letters*. 88(1):P1C-127.

Lington, A. W., G. H. Kalimi, J. E. Klaunig, and A. I. Nikiforov (1996). Value of Tissue Dosimetry Data to Design and Interpret *In vitro* (Hepatocyte) Gap Junction Studies with Peroxisome Proliferating Agents. *Toxicology Letters*. 88(1):P1C-128.

Medeiros, A. M. and A. I. Nikiforov (1996). Lack of Human Skin Sensitization Response of Dialkyl (C6-C13) Phthalate Esters. *Toxicology Letters*. 88(1):P1F-172.

Nikiforov, A. I., G. W. Trimmer, L. H. Keller, and S. B. Harris (1996). Two Generation Reproduction Study in Rats with Di-Isodecyl Phthalate. *Toxicology Letters*. 88(1):P2I-230.

Keller, L. H., A. I. Nikiforov, G. W. Trimmer, and S. B. Harris (1996). Lack of Selective Developmental Toxicity in Rats Treated with Cekanonic C8 Acid. *Toxicology Letters*. 88(1):P2I-231.

Nikiforov, A. I., L. H. Keller, and S. B. Harris (1996). Lack of Transgenerational Reproductive Effects Following Treatment with Di-isononyl Phthalate (DINP). *Toxicologist*. 30(1):608.

Keller, L. H., G. W. Trimmer, F. T. Whitman, and A. I. Nikiforov (1996). Repeated Exposure of Rats to NP-439 Does Not Produce Developmental Toxicity or Neurotoxicity. *Toxicologist*. 30(1):988.

ABSTRACTS/POSTERS/PRESENTATIONS (continued)

Baker, T. K., G. H. Kalimi, A. W. Lington, J. S. Isenberg, J. E. Klaunig, and A. I. Nikiforov (1996). Gap Junction Intercellular Communication (GJIC) Studies on 5 Phthalate Monoesters in Hepatocytes of Four Species: Implications for Cancer Risk Assessment. *Toxicologist*. 30(1):1063.

Isenberg, J. S., T. K. Baker, G. H. Kalimi, A. W. Lington, J. E. Klaunig, and A. I. Nikiforov (1996). Gap Junction Intercellular Communication (GJIC) Studies on Mono-2-Ethylhexyl Phthalate in Rat Hepatocytes: Effects of Modulators on Oxidative Stress, Signal Transduction, Peroxisomal Beta Oxidation and P450 Pathways. *Toxicologist*. 30(1):1064.

Lington, A. W., G. H. Kalimi, J. E. Klaunig, and A. I. Nikiforov (1996). Value of Liver Tissue Dosimetry Data to Design and Interpret In Vitro (Hepatocyte) Gap Junction Studies with Peroxisomal Proliferating Agents. *Toxicologist*. 30(1):1068.

Nikiforov, A. I., L. H. Keller, and S. B. Harris (1995). Two Generation Reproduction Study in Rats with Di-Isononyl Phthalate (DINP). EUROTOX'95, Prague, Czech Republic.

Keller, L. H., A. I. Nikiforov, and S. B. Harris (1995). Developmental Toxicity Study in Rats with Exxal 8N Alcohol. EUROTOX'95, Prague, Czech Republic.

Kalimi, G. H., A. W. Lington, A. I. Nikiforov, and J. E. Klaunig (1995). Gap Junction Assay in Rodent Hepatocytes: A Good Predictor for Liver Cancer in Rodents for Phthalate Esters. *Toxicologist*. 15(1):1469.

Nikiforov, A. I., G. D. Koehler, and S. B. Harris (1994). Developmental Toxicity Studies in Rats on Di-Isononyl Phthalate (DINP) and Di-Isodecyl Phthalate (DIDP). *Toxicology Letters*. 74(1):57.

Lington, A. W., G. H. Kalimi, A. I. Nikiforov, and J. E. Klaunig (1994). Gap Junction Intercellular Communication Studies on DEHP and Metabolites: Impact on Understanding Mechanisms. *Toxicology Letters*. 74(1):48.

Lington, A. W., G. H. Kalimi, A. I. Nikiforov, and J. E. Klaunig (1994). Effects of Di-2-ethylhexyl Phthalate and Four Metabolites on Rodent Hepatocyte Gap Junction Intercellular Communication. *Toxicologist*. 14(1):136.

Nikiforov, A. I. and M. D. McIntyre (1994). Potassium Amino Isobutyric Acid (K-AIBA) - 4 Week Rat Oral Toxicity Study. *Toxicologist*. 14(1):802.

Howie, L. E., A. I. Nikiforov, and F. T. Whitman (1994). Respiratory Sensory Irritation Potential of Iso-Alcohols and Iso-Alkyl Acetates in Male Mice. *Toxicologist*. 14(1):1204.

Przygoda, R. T., L. E. Howie, and A. I. Nikiforov (1994). Results of *In vivo* Mouse Micronucleus Tests Following Oral or Inhalation Exposure to Olefins. *Toxicologist*. 14(1):1277.

ABSTRACTS/POSTERS/PRESENTATIONS (continued)

Lington, A. W., and A. I. Nikiforov (1993). Critical Review of Rodent Liver Tumor Promotion Data for DEHP. *Pharmacol. Toxicol.* 73(2):50.

Nikiforov, A. I., W. C. Daughtrey, and S. C. Lewis (1989). Formulation of an Emergency Planning Guideline for Cobalt Hydrocarbonyl. Assessment of Inhalation Hazards: Integration and Extrapolation Using Diverse Data, Hannover, Germany.

Lewis, S. C., J. R. Lynch, A. I. Nikiforov, and R. A. Scala (1989). A New Approach to Deriving Exposure Guidelines. *Toxicologist.* 9(1):196.

Nikiforov, A. I., S. C. Lewis, J. Lynch, and G. F. Egan (1989). Community Exposure Guidelines. *Toxicologist.* 9(1):451.

Nikiforov, A. I., W. C. Daughtrey, J. P. Hinz, E. A. Mount, F. T. Whitman, and J. Signorin (1989). Acute Inhalation Toxicity of Cobalt Hydrocarbonyl. *Toxicologist.* 9(1):573.

Suber, R. L., A. I. Nikiforov, X. Fouillet, R. Deskin, and C. Coggins (1987). Subchronic Inhalation Study of Propylene Glycol. *Toxicologist.* 7(1):758.

Nikiforov, A. I. and G. Allgower (1987). The Effect of Restraint in Nose-Only Exposure Tubes During Pregnancy on Teratogenic Endpoints in Sprague-Dawley Rats. *Inhalation Toxicology: The Design and Interpretation of Inhalation Studies and Their Use in Risk Assessment*, Hannover, Germany.

Bernstein, D. M. and A. I. Nikiforov (1986). The Importance of Rat Respirable Aerosols in Performing Quantitative Inhalation Toxicology. *Toxicologist.* 6(1):134.

Nikiforov, A. I. and D. M. Bernstein (1986). Comparative Aerosol Deposition in Rat and Man as Related to Quantitative Inhalation Toxicology. *Cong. of the Europ. Soc. of Toxicol.*, Harrogate, England.

Nikiforov, A. I. and R. Ventrone (1986). Measurements of Respiratory Parameters in Rats to Evaluate the Sensory Irritation Potential of Aerosols. *Second International Aerosol Conference*, Berlin, Germany.

Nikiforov, A. I. and M. Lippmann (1986). Patterns of Aerosol Deposition During Breath Holding in Excised Human Lungs and *In vivo*. *Second International Symposium on Deposition and Clearance of Aerosols in the Human Respiratory Tract*, Salzburg, Austria.

Nikiforov, A. I., E. D. Palmes, and M. Lippmann (1982). Estimation of Mean Effective Airspace Diameters *In vivo* and in Excised Lungs Using an Aerosol Probe Technique. *Amer. Ind. Hyg. Assoc. Annual Meeting*, Cincinnati.