RESUMÉ

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Errol Zeiger Consulting
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Education:

1960	B.S.	City College of New York (Biology; minor credits: Chemistry; Philosophy)
1969	M.S.	George Washington University (Microbiology)
1973	Ph.D.	George Washington University (Microbiology)
1991	J.D.	North Carolina Central University (Admitted to the N.C. Bar, Sept., 1991; Transferred to inactive status, Oct., 2005)

My specific areas of scientific expertise are:

- Genetic toxicity research and testing, including the use of genetic toxicity systems in vitro and in vivo to study the mechanisms of carcinogenesis.
- Studies to assess the effectiveness of genetic toxicity, and other, test systems as predictors of cancer and other toxicological effects.
- Evaluation, interpretation, and integration of toxicology test data.
- Design, management, and evaluation of intra- and inter-laboratory validation studies to evaluate the reproducibility and effectiveness of toxicological tests, and to develop standardized test protocols.
- Development of toxicology test guidelines and guidance documents
- Development of toxicology and structure-activity relationship (SAR) databases
- Evaluation of laboratory capabilities and research programs.
- Procedures and practices for scientific publication and peer review.

Among my accomplishments and activities are:

- Designed, developed, and managed the US National Toxicology Program's genetic toxicity testing program, and was responsible for interpretation and publication of results from more than 2000 tests (1979 – 2000).
- Author or co-author of more than 200 scientific articles, book chapters, and published conference proceedings.
  Responsible for the direction and supervision of more than 40 governmental contracts and inter-agency agreements for genetic toxicity testing, test method development, preparation of summary toxicological reports, and development and maintenance of toxicology data bases.
- Organized, and directed national and international validation studies of in vitro genetic toxicity and in vivo endocrine disruptor tests, evaluated the results, and prepared, or participated in, the publication and presentation of the results.
- Invited lecturer at scientific conferences, universities, and organizations worldwide in the areas of genetic toxicology testing; prediction of carcinogenicity; development, evaluation, and validation of new test methods; evaluation of genetic toxicity data, and ethical issues in human (biomarker) monitoring studies.
- Lecturer on the topic of scientific publication and peer review at universities, organizations, and scientific conferences in US and abroad. Present short courses on topic.

- Recipient of performance and recognition awards from scientific societies and the U.S. Government.
- Serve as expert consultant and/or reviewer for U.S. and international scientific and regulatory organizations and scientific journals.

Some relevant professional activities are:

- Served as NIEHS representative to the EPA Toxic Substances Control Act (TSCA) Interagency Testing Committee; as vice-Chair (1994), and as Chair (1995).
- Chair of the (U.S. Congress) Office of Technology Assessment's Workshop on Screening and Testing Chemicals in Commerce (1995).
- Member of the federal Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (1996-2000), and Chair of its Method Validation Workgroup.
- Invited U.S. representative to the OECD workshop on Harmonization of Validation and Acceptance Criteria for Alternative Toxicological Test Methods (1996).
- Invited contributor to the OSTP document, "Interagency Assessment of Potential Health Risks Associated With Oxygenated Gasoline" (published, 1996).
- Co-Editor: "Handbook of Carcinogenic Potency and Genotoxicity Data Bases" (publ. 1996).
- Co-Editor: "Jet Fuel Toxicology" (publ. 2010)
- Consultant to the Test Guidelines program of the Organization for Economic Co-operation and Development (OECD), Paris, France; responsible for developing genetic toxicity, dermal, ocular, reproductive, and developmental toxicology test guidelines and guidance documents, and for directing and evaluating endocrine disruptor test validation studies (1999-2000; 2001-2002; 2007).
- Presented genetic toxicity course to the Brazilian regulatory authority (ANVISA) personnel and serve as an unofficial consultant for the evaluation of test protocols and test data evaluation. (2010 – present)

RELEVANT WORK EXPERIENCE

2001 – present: Errol Zeiger Consulting, Chapel Hill, NC.

Providing consulting services to chemical, pharmaceutical, and pesticide developers and manufacturers, government agencies, other consulting organizations, multinational organizations, and law firms in the areas of genetic toxicology, chemical carcinogenesis, general toxicology, test validation, preparation of summary toxicology reports, scientific review and evaluation, and litigation support.

2003 - 2005: Alpha-Gamma Technologies, Inc., Raleigh, NC. (part-time employee)

Project Manager and Senior Scientist for the EPA contract in support of the development of Integrated Risk Information System (IRIS) documents. Supervised document preparation team, prepared sections of documents, edited draft documents, and served as interface with EPA project managers.

2001 - 2002; 2007: Consultant, Environmental Health and Safety Division, Organization for Economic Co-operation and Development (OECD), Paris, France. [Work performed from home office.]

- Managed OECD's in vivo endocrine disruptor test validation program, evaluated testing results, and prepared summary reports from studies of in vivo endocrine disruption assays.
- Responsible for preparation of the summary report of the Stockholm OECD Conference on Validation and Regulatory Acceptance of New and Updated Methods in Hazard Assessment.

- Managed the development and interim and final revisions of new OECD Test Guideline.

2001 – 2007: Consultant, NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), Integrated Laboratory Systems, Research Triangle Park, NC.

Provided technical support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). Evaluated in vitro endocrine disruption test data and prepared summary background review documents; prepared expert meeting report. Evaluated submissions for in vitro toxicity test methods that were offered for validation.

2001 – 2010: Consultant, Air Force Office for Scientific Research, Arlington, VA;
Consultant, Air Force Research Laboratory, Wright-Patterson Air Force Base

Provided scientific support for the AFOSR program on research in jet fuels toxicology. Participated in contractor workshops and other meetings as a scientific expert, and prepared formal workshop reports for AFOSR personnel and public distribution. Selected test protocols and evaluated submitted data for new synthetic fuel.

1999 –2000: Consultant, Environmental Health and Safety Division, Organization for Economic Co-operation and Development (OECD), Paris, France (on assignment from NIEHS).

- Responsible for developing or revising in vitro and in vivo health effects Test Guidelines, and Guidance Documents for animal toxicology testing, and for the validation and acceptance of alternative toxicology tests.
- Assisted in the management of the OECD's endocrine disrupter, test validation program including the design and management of validation studies for endocrine disrupting chemicals in rodents.
- Chaired or co-chaired expert committees to address specific toxicology testing issues.
- Managed the genetic toxicity testing component of the U.S. National Toxicology Program.

1994 –1998 (5-year appointment): Editor-in-Chief, *Environmental and Molecular Mutagenesis.*

This is the official journal of the Environmental Mutagen Society (now, Environmental Mutagenesis and Genomics Society). Solicited commentaries and articles for publication, and made all decisions regarding acceptability of submitted materials. This work was performed from a home office on evenings and weekends.

1992 –2000: Environmental Toxicology Program, NIEHS, Research Triangle Park, NC.

I had a number of titles and primary responsibilities during this period; most were in the following general areas:
- Nomination and selection of chemicals for testing, and identification of research issues to be addressed by the U.S. National Toxicology Program (NTP). This included development and implementation of the processes by which chemical nominations for carcinogenicity and toxicity testing were sought from within Government, public organizations, and the private sector.
- Managed a genetic toxicity contract testing program and evaluated the results. Responsible for development and direction of contracts to test chemicals for mutagenicity in vitro and in vivo, and the review, analysis, and dissemination of test data.
- Worked with the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods. Reviewed submissions of tests for consideration by the Center, participated in the planning and organization of peer-review meetings and workshops for proposed

methods, and developed background review documents for proposed methods. Served as expert in the design and interpretation of validation studies.

1976 - 1992: Head, Mutagenesis Group, Environmental Mutagenesis and Carcinogenesis Branch, NIEHS, Research Triangle Park, NC.

I held a number of titles primary program responsibilities during this period.
- Developed and directed a multi-faceted in-house laboratory research program on mechanisms of mutagenicity, metabolism of mutagens and carcinogens, development and refinement of in vitro genetic toxicology tests, and identifying chemical mutagens and carcinogens.
- Development and management of a contract program for test system development and validation, and for testing of chemicals for genetic toxicity in vitro and in vivo. Initiated programs and designed procedures for the development of standardized test protocols, and for the intra- and inter- laboratory validation of test procedures and performance.
- Performed and directed data analysis, the use of biological and chemical data and information to better understand mechanisms of chemical toxicity, and the design of test programs for understanding the relationships between mutagenicity and carcinogenicity.

1969 - 1976: Microbiologist, Division of Toxicology, FDA, Washington, DC.

Development and validation of in vitro and in vivo test systems for the detection of chemical mutagens. Performed research to provide baseline data for development of statistical models and computerized data systems for mutagenicity data. Developed and directed the first US Government testing contract programs to evaluate the mutagenicity of food additives.

OTHER RELEVANT EXPERIENCE

1972 - December 2000. Project officer or co-project officer on more than 40 U.S. Government research and development contracts and inter-agency agreements. The contracts and agreements were primarily for the development and validation of short-term genetic toxicity tests, for large-scale in vitro or in vivo testing of chemicals, identification and isolation of mutagens/carcinogens from chemical mixtures, support of databases, and preparation of toxicology literature searches and summaries for chemicals of interest. Responsible for pre-award site visits to evaluate candidate contractor capabilities, recommendations for award, and post-award laboratory site visits to monitor and evaluate performance, and trouble-shoot problems.