

Toxicology Services

ARCADIS optimizes toxicological support to maximize its real-world relevancy and effectiveness. Our success demands that we deploy our full spectrum of toxicology expertise to help our industrial, consortia, legal and trade association clients find appropriate, reliable and cost-effective solutions for regulatory- and safety-related issues.



Sound Science to Support Quality Products

ARCADIS toxicologists and industrial hygienists, are well versed in federal, as well as established and emerging global regulatory requirements. They have worked with pesticides, biocides, and antimicrobials; commodity and specialty chemicals; metals and metal-containing compounds; consumer products; process intermediates; and industrial wastes. Our technical disciplines encompass physical and chemical hazards, acute toxicity (ingestion, skin and eye irritation), and chronic toxicity (reproductive and developmental, carcinogenic, endocrine and neurotoxicological effects). We have extensive experience with bioassay design and interpretation, including mechanistic studies to establish thresholds for carcinogenicity, where supportable. We have also designed protocols for more specialized toxicity studies, such as evaluations of dermal penetration, specialized human sensitization assays, and studies designed to look for specific biochemical effects, such as effects on hormones or neurotransmitters.

We have a working familiarity with the full range of environmental, occupational, consumer and residential exposure scenarios and have conducted toxicology studies that involve different routes of exposure (e.g., respiratory, oral and dermal). Our toxicology work has supported the successful registration and/or notification of novel pesticides, industrial chemicals, polymers, micro-electronic materials and petrochemicals. We optimize the design of toxicological studies (sample selection, dosing, route of exposure) to maximize the real-world relevancy of the results.

ARCADIS' Toxicology Services Effective Risk Assessment

The appropriate development of a risk assessment is a cornerstone of good product stewardship and the successful registration, marketing and defense of chemicals and products. The ARCADIS team of highly experienced toxicologists employs a tiered approach — based on the reliable use of clinical and non-clinical (e.g., mammalian, in vitro, QSAR) toxicology data — to meet the

needs of innovative producers of chemical products and registrants in the chemical and chemical-dependent industries.

Identification of Data Needs

We help determine the data necessary to meet regulatory requirements, review existing data and work with the client to evaluate the possible use of surrogate data and/or alternative testing procedures. Where appropriate, we develop requests for waivers of study requirements for registration or notification schemes. Finally, we leverage our experience, as well as our relationships with regulators, to determine the best combination of data and alternatives to best balance cost and schedule requirements.

Design, Monitoring and Management of Toxicology Studies

ARCADIS' broad practical experience with the Organization for Economical Cooperation and Development (OECD) and Office for Pollution Prevention and Toxic Substances (OPPTS) testing guidelines and novel protocol development allows us to

provide high-quality services in these areas. We develop protocols for specialized testing, assess laboratory capabilities and select the best laboratory for the work, monitor the critical phases of testing in progress and evaluate the results.

Compilation, Review and Analysis of Existing Toxicology Data and Literature

Fulfilling registration requirements or defending a product's use does not usually require reinventing the scientific wheel in terms of toxicology. ARCADIS provides valuable assistance in extracting the best possible toxicological information out of existing, often published, data. We will track down existing toxicological studies; obtain translations, as necessary; review the information for quality/reliability; interpret the data that prove to be reliable; prepare concise reviews; and identify data gaps, if any.

Coordination with Regulatory Agencies

ARCADIS professionals enhance the value of their scientific work and expertise by coordinating and leading communications with government agencies. Our scientists frequently interact with the United States Food and Drug Administration (FDA), the United States Environmental Protection Agency (USEPA) and other national regulatory agencies. We have assisted clients with the completion and submission of dossiers for the Canadian Pest Management Regulatory Agency (PMRA); USEPA Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Japanese Ministry of International Trade and Industry (MITI) and Ministry of Health, Labor and Welfare (MHLW); and the European Union (EU), as well as Toxic Substances Control Act (TSCA) Pre-Manufacture Notifications (PMNs), Low-Volume Exemptions (LVEs), and Test Market Exemptions (TMEs).

Peer-Reviewed Publication and Technical External Relations

The establishment of long-term credibility in the field of chemical safety and toxicology requires strong documentation of key test

results and conclusions in the peer-reviewed literature. Our scientists are widely published in their technical disciplines and frequently assist corporate clients in synthesizing test results and summarizing conclusions in manuscript format for submission to peer-reviewed journals or for presentation at professional conferences. Because many of us had years of experience at corporations before becoming consultants to industry, we're adept at developing effective communication strategies, as well as materials (e.g., brochures, website text and position papers), for diverse audiences in support of the safety of chemical ingredients and formulations.

Relevant Experience Defending the Safety of Polycarbonate Plastics

A key project that was awarded to us based on our reproductive and developmental toxicology expertise is the ongoing work on Bisphenol-A, a chemical that has been in use for 40 years, especially as a component of polycarbonate plastics. While ARCADIS' contribution to this effort has been expanded into an active involvement in proving and communicating the safety of these products, its foundation was our initial analysis of the toxicology of Bisphenol-A. We performed a comprehensive analysis of the extensive toxicological data for Bisphenol-A on a spectrum of endpoints. Where data gaps were identified concerning reproductive toxicity, we helped identify solutions.

EU Risk Assessment Support

Our team of toxicologists has several years of experience with EU chemicals regulations, including conducting and supporting the risk assessments of New and Existing Chemicals Commission Directive Regulation No. 1488/94. We have supported both the exposure and effects assessments for environmental and human health sections of these risk assessments.

OECD and USEPA HPV and REACH Data Gap Analysis, Robust Summary

Development, and Test Plan Development and Implementation

For the past 10 years, our team has been involved in international and national voluntary chemical data-gathering programs, such as the OECD's High Production Volume (HPV) Chemicals program and the USEPA's HPV Chemical Challenge program, by coordinating the efforts of consortia and corporations. The challenge that many companies are now facing is the implementation of REACH in the EU. Thanks to our past experience, current level of understanding, and active participation in the development of REACH guidance for inorganic metal compounds, we are helping our clients prepare for, and manage the consequences of, REACH for their businesses. Since before the June 2007 implementation of REACH, we have been providing training to our clients (REACH 101), helping them design and implement the tools and systems necessary to operationalize REACH in their businesses, and providing consulting services on an as needed basis, as we will continue to do throughout the process.