



Navigating the Global Regulatory Landscape

Our specialists closely track the latest developments in major regulatory initiatives such as REACH, GHS, ChAMP, Pollutant Release and Transfer Registries, chemical use inventories, and numerous others.

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ARCADIS' Global Product Stewardship Team includes a cadre of regulatory specialists with over 80 years of collective corporate experience in regulatory compliance and chemical management. Our technical mastery of the often-complex compliance procedures supports our clients' needs for sound and timely management of both routine and forthcoming regulatory issues and responsibilities around the world. Our regulatory services extend from local scales (covering state and provincial) to global scales.

We have experience in a wide range of chemical technologies, including petrochemicals, consumer products, pesticides, foods, pharmaceuticals, metals and mining products, agrochemicals and nanotechnology. Several of our major regulatory initiatives deal with REACH, GHS, and chemical product registrations in jurisdictions around the world. REACH will dramatically change the number of controlled chemicals and include existing as well as new chemicals. Our Team is engaged in REACH at virtually all levels, including consortium and SIEF management, IUCLID Robust Summary Development, corporate strategic planning, and Chemical Safety Assessments and Reports.

GHS has already been implemented in several jurisdictions in the Asia-Pacific region, such as Taiwan. Our Team has classified well over 1,000 organic and inorganic substances and mixtures to date. We have worked closely with leading companies and trade associations in the metals and mining industry and the consumer product industry to help shape data-based technical policies and practices. We frequently provide workshops and develop focused training tools for our clients to meet their GHS demands.

ARCADIS scientists and regulatory affairs experts are qualified to assist with every phase of product registration, including the development of a strategic plan; the review of toxicological, clinical, epidemiological, or environmental data; new study design; and field monitoring. We meet with regulatory authorities on behalf of our clients to discuss testing programs and risk assessment approaches, as well as to manage hazard classification issues.

In addition to REACH and GHS support, examples of our other regulatory services include:

- Preparation of test plans and robust summaries for EPA's High Production Volume (HPV) Challenge Program and Extended High Production Volume (EHPV) Challenge Program
- Preparation of FDA and EMEA-required environmental assessments for human drugs, veterinary products, and food additives
- Client assistance with direct and indirect food additive issues, GRAS self-affirmations, and "threshold of regulation" determinations
- Risk assessments to support the registration of new pesticides, re-registration of pesticides, and new uses of existing products under FIFRA
- Preparation of tolerance petitions for active and inert ingredients in pesticides
- Comparative risk assessments for reduced-risk petitions
- Global regulatory evaluations of products and ingredient requirements and timelines, particularly for MSDS and labeling changes under GHS
- Risk assessment for new and existing chemicals and chemical uses under TSCA (e.g., PMNs, Section 4), the EU and Canada

