Enabling EU Market Access

REACH Registration and Authorisation

More than 22.000 chemicals have been registered to date in the European Union (EU) under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH; European Commission No. 1907/2006) by more than 15.000 companies. REACH aims to improve the protection of human health and the environment via better and earlier identification of the intrinsic properties of chemical substances. EU manufacturers, importers and downstream users have obligations under REACH and even companies established outside of the EU may be affected if they choose to take on the obligations of their EU customers.

Although the previous registration deadline (for substances produced or imported in the EU between 1 and 100 tonnes a year) passed in 2018, registration activities for new substances exceeding the tonnage threshold continue. Further, requirements related to maintaining the already-submitted dossiers (e.g., request for additional hazard information, changes in volumes, changes in uses, etc.) and the related tracking and sharing of costs between co-registrants requires the continued attention of the registrants. Lastly, the list of Substances of Very High Concern (SVHCs) that are subject to authorisation or restriction continues to grow.

Arcadis' extensive experience providing REACH registration and authorisation support to numerous clients can help you streamline your REACH compliance program with technically robust submissions and strategic compliance advice.

Proposed changes to REACH may remove the exemption for certain polymers. With approximately 400.000 polymers estimated to be on the market in the EU, Arcadis is proactively developing novel solutions to support affected clients should there be changes to the REACH polymer exemption.

Arcadis REACH Offerings

Strategic advice and training
- Compliance assessments
- Strategy development
- Legal obligation tracking

Registration Dossier
- Literature searches & data gap analysis
- Grouping & read-across strategies
- Testing strategies & study monitoring
- Hazard, exposure & risk assessment
- Dossier compilation and submission

Application for Authorisation
- Risk Management Option Analysis
- Chemical Safety Report
- Alternatives Analysis
- Socio-economic Analysis

Management Support
- Data management
- Data & cost sharing
- Letter of Access management
- Stakeholder & consortium management
- Safety Data Sheets & labeling
- Only representative & third-party representative

About Arcadis

Arcadis is the leading global design and consulting firm for natural and built assets. Applying our deep market sector insights and collective design, consultancy, engineering, project and management services we work in partnership with our clients to deliver exceptional and sustainable solutions. We are 27.000 people, active in more than 70 countries that generate €3.6 billion in revenue. We support UN-Habitat with knowledge and expertise to improve the quality of life in rapidly growing cities around the world.

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Select REACH Project Experience

Partnering with our Client to Meet Compliance and Operational Goals

As a strategic partner for a global pharmaceutical company, Arcadis submitted REACH registrations for more than 100 substances/intermediates by the 2018 deadline and continues to provide registration support as new products are marketed and meet tonnage thresholds. Providing full-spectrum registration support including both technical and management assistance, Arcadis tracks budget and progress status on a portfolio basis and per substance. We highlight which work stream processes need more attention and solve critical issues to provide continuous access to the EU market. As a study monitor, we support subject matter experts by managing the project through continuous status follow-up and communication with the contract research organization, review of study plans, evaluation of draft results and final reports. Lastly, we prepare and submit complete registration dossier packages in an efficient and timely manner.

Ensuring Business Continuity and Supply

Arcadis assisted several global manufacturing companies to compile applications for authorisation. Several dossiers were successfully submitted, receiving positive feedback from the European Chemicals Agency (ECHA). The submissions allow the companies to use substances that are critical to the production of pharmaceuticals and in-vitro diagnostics until the predicted substitution is completed. These authorisations thus ensure business continuity and supply of important products for health care. Support included use scoping, comprehensive data gathering and in-house preparation of the Alternatives Analysis, Socio-Economic Analysis and development of the Chemical Safety Report. Arcadis further provided overall project management support including stakeholder management, exemptions identification, and overall strategy development, e.g., joint or separate submissions. Post-submittal, Arcadis has provided support in responding to questions from the evaluating committees and communication with ECHA.

Providing Support to Maximize Impact through Consortia

Arcadis currently acts a consortium manager for several REACH registration consortia. We communicate with third parties (competent authorities, co-registrants, and data owners), taking the role of Trustee and handling business confidential information. We derive the cost for a Letter of Access (LoA) and prepare LoA agreements or data sharing agreements that meet the legal requirements as stipulated in the implementing regulation on data sharing (EU 2016/9). For more information on two consortia we manage, see: www.rare-earth-consortium.eu or www.mozoreach.eu.

Apart from the managerial tasks we perform, Arcadis also has prepared registration dossiers and supports alignment between the dossiers prepared for similar substances. As Consortium Manager, Arcadis participates in relevant meetings of sector associations where it represents the Consortia. We support the pro-active nature of companies and associations to invest in long-term solutions to meet the expectations of relevant Competent Authorities related to dossier quality. We provide strategic advice to the Consortia members and follow-up in case of substance or dossier evaluation.

Working in partnership with our clients, we provide a complete suite of services to meet registration and authorisation requirements, supporting compliance efforts and protecting human health and the environment. Contact us to learn more.

Arcadis. Improving quality of life