ARCADIS Design & Consultancy for natural and built assets

REGULATORY PHASE-OUT OF SUBSTANCES OF VERY HIGH CONCERN

SERVICE SHEET REGULATORY PHASE-OUT OF SUBSTANCES OF VERY HIGH CONCERN

Both authorities and NGOs are committed to phase out the use of selected substances of very high concern (SVHCs) in the EU. This might impact your business today or in the future.
Arcadis has a team of experts in place in Belgium and Switzerland that can support you when substances are (likely to be) included in the Candidate List in the EU and/or Switzerland. Our in-house experts have the required skills and experience to support you in the road to Authorisation in case you need to use the substances beyond the sunset date:

- our technical experts support the analysis of alternatives,
- our risk assessors compare the impacts of different substances on the environment and human health,
- our environmental economists develop socio-economic assessments and monetise impacts,
- our consortium managers install and manage consortia to align strategies and minimise costs per company,
- our project managers make sure the deliverables are available on time and within budget.

BEFORE INCLUSION IN THE CANDIDATE LIST

Understand which substances are or might become under scrutiny in the future. Set up a proactive approach to be prepared for the latest EU REACH challenges and other regulatory regimes. Start gathering data which are needed to be prepared.
Companies with a focus on sustainability know which substances are considered as substances of very high concern (SVHCs) on the basis of their hazard properties (CMR, PBT, vPvB, endocrine disruptors, respiratory sensitisers, etc.). These companies review the existing but living Candidate List, and initiate the search for alternatives in time.

Arcadis has prepared several risk management option analyses (RMOAs) in which a high-level evaluation is performed:
- what are the hazardous properties of the substance?
- how is the substance used (in which sector, in which process, what routes of exposure are most critical)?
- what are potential alternatives to the substance?
- what are the regulatory options to address the substance (within or outside of REACH) and what would be the most appropriate option?

The result of such an analysis is a guidance on how the remaining concerns that are linked to the use of a hazardous substance, can be controlled in the most appropriate way. It aims to define the type of policy action needed to address the remaining concern. This process is usually performed by authorities, but often prepared by industry as well to provide their own perspective. The result can help you as a company to focus on the best way forward for your portfolio.

Proactivity has been demonstrated to be rewarded: it lowers your business risk, gives you more control over your business, helps you to contribute to the discussion with policy makers to find the most effective and acceptable risk management measure. Trade associations or consortia can play a key role to support and coordinate such a type of exercise. That way you can spread resources and budget over time and your company actively contributes to a more sustainable industry.

YOUR SUBSTANCE ON THE CANDIDATE LIST

Inform management, install a project team and develop a plan.
When substances are included in the Candidate list, the project reaches a next level of urgency.
This is – for many companies – the moment to screen their full portfolio to check whether and where the substances are used and to identify the impact of the potential phase-out of these substances on their business.
This is when management is informed, business cases are developed and project teams are installed. Also, this is when the search for alternatives should be further intensified: project teams start to gather relevant information to avoid or limit business risks. Further, it is suggested to initiate discussions with your suppliers / downstream users related to alternatives, uses and exposure scenarios, and their strategy related to Authorisation. Arcadis can assist you on these topics.

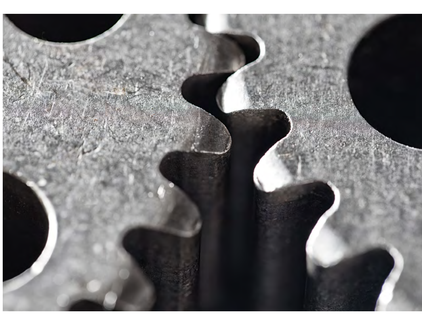
In parallel, alignment between different players of an industry sector can be considered and (individual or joint) position papers can be written and submitted during a public consultation round. In addition, you are encouraged to think about the type of dossier you might need to submit (DU single application, upstream application, or something in between). If you decide to join forces with other companies, Arcadis can act as a Trustee to gather and manage confidential information.

YOUR SUBSTANCE ON THE AUTHORISATION LIST

Your last call to avoid rupture of your business, you are forced to find alternatives and demonstrate your efforts to do so.
When your substance is included in the Authorisation list (Annex XIV of EU REACH), the timelines are fixed. With the publication of the list, the latest application date for submitting your application for Authorisation and the sunset date are set (i.e. the date after which the use and placing on the market is prohibited unless an Authorisation has been granted or your specific use is mentioned in the exemptions).

An application for Authorisation should contain very specific information:
- a Chemical Safety Report (CSR) focusing on the use applied for,
- an Analysis of Alternatives (AoA), considering their hazard profile/potential risks and the technical and economic feasibility of substitution,
- a substitution plan and timetable of proposed actions, in case suitable alternatives are available,
- a Socio-Economic Analysis (SEA) is not always mandatory but recommended to be included in any case. It should merge all elements of the application dossier into an evaluation of costs and benefits. As a company, you need to think about the non-use scenario: what if the Authorisation is rejected and you are no longer allowed to continue the use of the substance in Europe. That is the focus you should keep at all times. When the SEA is mandatory, it should demonstrate that the impacts to human health and/or the environment from the continued use of the substance are outweighed by the socio-economic benefits,
- justifications for not considering certain risks, if applicable, and
- a sensitivity analysis to evaluate the impact of certain assumptions.

Arcadis has the specific knowledge and experience to build a "fit for purpose" application. Finally, Arcadis can help you through the regulatory landscape and take care of strategy, communications and advocacy in the EU and offer similar support on the corresponding process in Switzerland.



YOUR APPLICATION FOR AUTHORISATION IS SUBMITTED

It ain't over … till it's substituted.
Once an application is submitted, the (non-confidential part of the) dossier will be shared with the public and third parties are requested to comment. Also, the risk assessment committee (RAC) and the committee for socio-economic analysis (SEAC) of the ECHA will initiate their reviews. We will assist you to reply to comments and questions against challenging timelines.
As Arcadis, we are proud to be a real partner of industry in the search for the best way forward related to substances of very high concern. We focus on long-term, sustainable solutions in an evolving regulatory climate.

ABOUT ARCADIS

Arcadis is the leading global Design & Consultancy 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 withour clients to deliver exceptional and sustainable outcomes throughout the lifecycle of their natural and built assets. We are 27,000 people active in over 70 countries that generate more than €3.3 billion in revenues.

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