The next step for REACH: Lessons learned and tips for success regarding authorisation

As all chemical companies doing business in the European Union (EU) should know, the "A" in REACH stands for Authorisation, the last of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) processes to be implemented since the regulation entered into force in 2008.

Authorisation aims to "assure that risks from substances of very high concern (SVHCs) are properly controlled and that they are progressively replaced by suitable alternatives." See the European Chemicals Agency's (ECHA) website at http://echa.europa.eu/regulations/reach/authorisation. On February 10-11, 2015, ECHA convened a "Lessons Learnt on Applications for Authorisation" conference with participation of industry, non-governmental organizations (NGO), the European Commission (EC), and Member States' competent authorities to share their experiences of the Authorisation process. To find out more about the ECHA conference, please visit **http://echa.europa.eu/view-article/-/journal_content/title/conference-on-lessons-learned-on-applications-for-authorisation.**

As the Authorisation process is still relatively new, and all parties involved are on a learning curve, a significant part of the conference objective was to allow for feedback on the current Authorisation process and receive recommendations for further improvement. The Acta Group (Acta®) assists many clients in developing effective business strategies around SVHC issues, and Acta's Pearl Németh, M.Sc., was among the 150 applicants selected to participate in the conference. This article reviews the path to Authorisation and reports on key developments shared during the ECHA conference.

Roadmap to Authorisation

The route to Authorisation begins when a Member State proposes that a substance be identified as an SVHC, and evaluated for placement on the SVHC Candidate List. Substances on the Candidate List are prioritized by ECHA to determine which should be placed on the Authorisation List (Annex XIV of REACH), and thus become subject to Authorisation. Substances requiring Authorisation cannot be used or placed on the market after a set date (sunset date) without an Authorisation or an exemption for that particular use. While only three Authorisations have been granted by the EC (DBP for Sasol-Huntsman, DEHP for Rolls-Royce, and both DBP and DEHB for Roxel), many more substances and applications are in the queue awaiting review and comment. According to ECHA's SVHC Roadmap to 2020 Implementation Plan, ECHA is committed to having "all relevant currently known SVHCs included in the Candidate List by 2020." This will mean significant work, costs, and commitment of resources from both industry and regulatory bodies.

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Preparing an Application for Authorisation (AfA) starts with considering if a safe threshold exists for the particular hazard for which the substance has been listed on the Authorisation List. If the answer is "yes," then the applicant must demonstrate the risks are adequately controlled in the submitted Chemical Safety Report (CSR), commonly referenced as following the "adequate control route" of Authorisation application. An Analysis of Alternatives (AoA) must also be submitted, and if that identifies a technically and economically feasible alternative, then a Substitution Plan must be submitted as well. If ECHA's Risk Assessment Committee (RAC) decides the risks are not adequately controlled, Authorisation might still be granted if the socio-economic benefits outweigh the risks of continued use that can be documented in the Socio-Economic Analysis (SEA), assessed by the Committee for Socioeconomic Analysis (SEAC).

If, however, no safe threshold is believed to exist, Authorisation may only be granted if the socio-economic benefits outweigh the risks and there is no suitable alternative (SEA-route). In this case, the application must include a CSR, AoA, and SEA. Persistent bioaccumulative and toxic (PBT) and genotoxic substances usually follow this route. For substances that are classified as endocrine disruptors (ED), it is up to the Applicant to demonstrate if a safe threshold exists and to then determine that threshold, which will be assessed or overruled by RAC. After submitting an AfA in a so-called "submission window," the road is still long before the EC will grant or refuse the Authorisation, taken into consideration of the RAC and SEAC opinions.

Notes from the February 10-11, 2015, ECHA "Lessons Learnt on Applications for Authorisation" Conference

Geert Dancet, Executive Director of ECHA, opened the Authorisation workshop with the message that, like the registration and evaluation processes, "the 'A' of REACH is equally working well." According to Thierry Nicot from the Risk Management Implementation Unit of ECHA, ECHA received no AfAs for about 50 percent of substances on the Authorisation List for which the Last Application Date (LAD) has past. This demonstrates to ECHA that companies are no longer using these substances. Furthermore, about 50 percent of the submitted AfAs are so-called "bridging Authorisations," which means companies have already identified a feasible alternative, but need time to transition to the alternative. From these numbers, ECHA drew the conclusion that the ultimate goal of Authorisation, which is substitution, works well.

The main message from industry emphasized the business uncertainty arising from the Authorisation process. Even with Authorisation granted, companies cannot be sure of the length of the review period (4-12 years), which hampers investments. Presenters from industry reiterated this message.

To ease this burden and uncertainty, a joint task force comprised of ECHA and EC members is working to streamline and make transparent the process, with emphasis on special cases subject to Authorisation such as low volume and legacy spare parts. Anna Borràs, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (Growth) of the EC, confirmed the aim of the joint task force is to avoid creating a system where economic imbalances are perpetuated to the detriment of any business sector.

With more experience being gained in industry and among consultants, the average cost of preparing an application for Authorisation has fallen by about 30 percent and is now below 200,000 Euros per applicant and use, as Geert Dancet said in his opening remarks. Björn Hansen, Deputy Head of the Chemicals Unit, Directorate-General Environment, EC, provided concluding remarks for the two-day event. Hansen's remarks emphasised the need for advocacy: "Companies that can demonstrate a well documented business case will (be strong candidates for receiving an) authorisation." Authorisation applicants were, however, advised to start the AfA process as early as possible, as the preparation of AfA is complex and time-consuming. It is also a one-shot process: companies have to get it right on the first try.

Regulatory consulting firm Acta, with offices in Manchester, Washington, D.C., and Beijing, as well as in Brussels through partner EPPA, offers comprehensive REACH services, including assistance in the strategic development and implementation of Authorisation applications.

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