REACH – Authorisation
Information Sheet

March 2013

Authorisation is a process under REACH designed to manage the risks of hazardous substances. It is a licensing system of sorts, whereby certain substances may not be placed on the market for a use, or used, in the EU unless the company has been authorised to do so.

How are substances added to the Authorisation List ?

The authorisation list is contained in an Annex (Annex XIV) to the REACH Regulation. Before a substance can be added to the authorisation list, it must firstly be identified as a substance of very high concern (SVHC) (e.g CMRs, PBTs, 'substances of equivalent concern' e.g. endocrine disruptors) and included on ECHA's candidate list. Periodically the European Chemicals Agency (ECHA) examines substances on the candidate list and recommends some of them for inclusion on the authorisation list. This recommendation of ECHA is subject to a 3 month public consultation, during which stakeholders can submit comments. The final decision on addition of substances to the authorisation list is taken by the European Commission, in collaboration with the Member States. This means that the list is added to on a regular basis (currently yearly) and companies are recommended to check it regularly for updates. The up to date list can be found on ECHA's website.

Latest application dates and sunset dates

Within the authorisation list, there are 2 dates specified for each substance:

- The *sunset date* is the date after which the placing on the market and the use of a substance is prohibited unless an authorisation is granted to the user.
- The *latest application date* (LAD) is the date by which the authorisation application must be received by ECHA if the applicant wishes to continue to use the substance beyond the sunset date.

To ensure timely processing of the applications and to manage the workload, ECHA has established specific submission windows for substances with the same LADs and these submission dates can be found on ECHA's website.

Advice for suppliers

- ✓ Consider whether a substance on the authorisation list can be substituted with a less hazardous one
- ✓ If not, then consider whether to apply for an authorisation to cover your own use and uses in your supply chain

Advice for Downstream users

- ✓ Consider if you can use a different substance to the one that is on the authorisation list
- ✓ If this is not possible, then an authorisation must be in place for your specific use
- ✓ Speak to your supplier to find out if he intends to apply for an authorisation and if he will cover your use
- ✓ Provide information to your supplier so your use can be covered in his application
- ✓ If your current supplier does not intend to apply for an authorisation, or will not cover your specific use, then try to find an alternative supplier willing to do it
- ✓ Alternatively, consider submitting your own application which would allow a company immediately above you in the supply chain to supply you with the substance (without the supplier needing to have an authorisation in place himself)

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What needs to be included in the authorisation application?

An authorisation application is significant, and companies should refer to the ECHA website for details of what needs to be in it and how to prepare it. In brief, the application will need to specify:

- ✓ The use(s) for which authorisation is sought
- ✓ A chemical safety report (CSR) covering the risks related to the properties that led to identification as an SVHC (unless already submitted as part of a registration dossier by the applicant)
- ✓ An assessment of alternatives
- ✓ A substitution plan, if the conclusion is that there is a feasible alternative
- ✓ For the socio-economic route, a socio economic analysis, along with information that there are no alternatives available

What about cost?

There is a fee for each application for authorisation. The size of the fee will depend on a number of factors, including whether the submitting company is an SME (reduced fees) and the number of uses, substances and applicants covered by the application. Companies can use ECHA's Fee Calculator, which is available on ECHA's website, to estimate the fee before submission.

How will authorisation be granted?

Companies must submit their authorisation applications to ECHA. Decisions on whether to grant the authorisation or not will be taken by the European Commission, and agreed by Member States, and will take into account opinions from ECHA's Risk Assessment Committee (RAC) and Socio-Economic Committee (SEAC).

Further Information

The ECHA website contains a lot of information on applications for authorisation. There is a dedicated support section at **http://www.echa.europa.eu/web/guest/applying-for-authorisation**. In addition, companies intending to submit an application can request a pre-submission information session with an ECHA representative. Pre-submission information sessions should be held the latest about 6 months before the submission of the application.

Companies with specific questions or concerns should contact the HSA's Chemicals Helpdesk by email: **chemicals@hsa.ie** or by calling 1890 289 389.

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