# Authorisation vs restriction

## Why companies dealing with chemicals of concern should analyse the regulatory scenarios carefully

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Even though not foreseen in the REACH legal text, the Risk Management Option (RMO) analysis is becoming a standard tool, used by Echa and member states to determine which RMO is most appropriate to regulate risks related to chemicals qualifying as Substances of Very High Concern (SVHC). In the frame of such an RMO analysis, a key question is often whether candidate list inclusion and authorisation (Annex XIV), or a restriction (Annex XVII), should be proposed.

Under the European Commission's Roadmap on SVHCs for 2020, inclusion in the candidate list for authorisation is the baseline option for fully registered SVHCs containing non-exempted uses, which are not already regulated by specific EU legislation providing a pressure for substitution. The burden of proof for justifying continued use of an Annex XIV substance lies with the companies.

By contrast, restriction is understood as a "safety net" to manage risks that are not adequately controlled. It requires detailed information available to the authority on the uses to be restricted and possible alternatives. The burden of proof for justifying a restriction, hence, lies with the authority. Therefore, companies often see a restriction as the preferred tool – as far as they are able to avoid its limiting scope. So the question arises: Is restriction indeed always the more industry-friendly option?

### Restriction has 'losers and winners'

Restriction is a very flexible risk management instrument, in that it may impose any condition for, or prohibition of, the manufacture, use or placing on the market of a substance on its own, in a mixture or in an article (REACH Article 67(1)). There must be an unacceptable risk to human health or the environment, which needs to be addressed at EU level (REACH Article 68(1)).

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Restrictions require strict compliance by companies throughout the EEA; an authorisation for continued use is not possible. Furthermore, if major uses are subject to the ban, exempted niche uses may also suffer if the manufacturer loses interest in the market. Therefore, it is important to keep the big business picture in mind when pursuing a separate treatment for small volume uses. This being understood, companies may benefit from the limits set by the wording of a restriction or derogations from it. The case of cadmium (entry 23 of Annex XVII) is an illustrative example of such a limited restriction.

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### Authorisation: challenges and limitations

Authorisation is a lengthy, complex and costly process for most companies that have to go through it. Applicants for authorisation need to prepare a chemical safety report and analysis of alternatives. For non-threshold substances a socio-economic analysis is also required. Expertise from different company departments and consultants needs to be pooled to compile such a dossier. An authorisation is only granted for a limited period of time, resulting in added uncertainty – compared to a restriction and derogations from it - about the

possibility of continued use after the review period.
Yet authorisation only needs to be sought for uses of an Annex XIV substance, for which no exemption is foreseen in the REACH Regulation or included in Annex XIV. This can leave plenty of room for continued use of SVHCs without the need for an authorisation. Users of SVHCs as an intermediate (REACH Article 2(8)(b)), and importers of articles containing them do not need authorisation by virtue of the REACH legal text. The manufacture of SVHCs is also out of scope. Use for scientific research and development (REACH Article 3(23)) is exempted, both from authorisation and restriction.

Existing Union legislation imposing minimum requirements, relating to the protection of human health or the environment, for the use of the substance (REACH Article 58(2)) can justify the inclusion of a specific exemption in Annex XIV. In spite of numerous industry comments in previous public consultations on Echa Annex XIV draft recommendations, this has been accepted only in one case so far: uses of phthalates in the immediate packaging of medicinal products. However, industry bodies have been calling for a more comprehensive assessment of whether the clause can be applied. This could result in a more prominent use of REACH Article 58(2) in the near future.

Authorisation loopholes can – partly – be closed by initiating a restriction. As an example, for Annex XIV substances in articles, Echa shall consider after their respective sunset dates, whether the use in articles poses a risk to human health or the environment that is not adequately controlled. If so, Echa shall prepare a restriction proposal (REACH Article 69(2)). However, this mechanism does not always work, such as in the examples of chromates used for surface treatment, but no longer present in the imported article.

## Towards restriction of solvents?

The example of solvents illustrates well the increasing consideration of the restriction process for industrial settings and by professional users as well. The solvents 1-methyl-2-pyrrolidone (NMP) and dimethylacetamide (DMAC) were both included in the candidate list for authorisation in 2011, due to their harmonised classification as toxic for reproduction. However, a restriction proposal was submitted for NMP by the Netherlands in 2013. Due to this, Echa has postponed its recommendation of NMP for inclusion in Annex XIV, and the inclusion of DMAC was postponed by the European Commission.

The RMO analysis for NMP concluded that a restriction is most appropriate. It also appears most company-friendly. The proposed restriction does not foresee a direct ban, but an exposure limit in the form of a mandatory long-term derived no-effect level (Dnel) for workers' inhalation and dermal exposure, which is to be used in chemical safety assessments and safety data sheets. If the Commission would adopt the restriction as now proposed, this would be good news for companies able to comply with the proposed DNEL. But as the use is not fully banned, the door to authorisation is not closed.

A restriction may be good if you are able to be out of scope or comply with it while continuing your business, whereas an authorisation may – and will increasingly – be a manageable 'bridge' until you have found a safer substitute. This is especially true for threshold substances

## No black or white

Restriction is often a preferred option for industry in comparison to authorisation, but not always. Uses in the scope of the ban are to be phased out. No exception or authorisation is possible. For a manufacturer or user of the substance, this can mean shutdown of all or parts of the business or costly improvements of the technical equipment or safety measures. Therefore, it can be vital that affected industries use all means of consultation by the authorities in order to supply complete facts and protect their interests.

Restrictions can also potentially be implemented more quickly. Whereas the estimated time from an Annex XV SVHC dossier to an Annex XIV sunset date is - as a rule of thumb - a minimum of six years, a restriction proposal can be turned into an enforceable restriction within two to three years, normally however subject to transitional periods.

Authorisation is still a fairly burdensome process for downstream users, and their suppliers, and may not always be an appropriate instrument. But as experience with the process evolves, it is likely to become more and more "business as usual" to it apply until a substitute is found. The European Commission's initiative to work on rules for "simplified" authorisation could lead to further improvements.

## Be proactive

The best risk management tool for chemicals of concern, from a company perspective, may be either authorisation or restriction, depending on the case and the company.

A restriction may be good if you are able to be out of scope or comply with it while continuing your business, whereas an authorisation may – and will increasingly – be a manageable "bridge" until you have found a safer substitute. This is especially true for threshold substances. You may also analyse the grounds for an exemption from authorisation and discuss your conclusions with the authorities.

Hence, companies should not sit back and wait for the authorities to analyse their substances and uses, but be proactive in assessing by themselves what could be the most appropriate risk management tool – if any – for their case, and provide their input to the decision makers at the appropriate point of time.

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