

# CHEMSEC URGES THE COMMISSION NOT TO LOSE THE ESSENCE OF REACH WHILE SIMPLIFYING AND STREAMLINING THE AUTHORISATION PROCESS

The authorisation process constitutes the heart of REACH, in itself manifesting many of the principles that make REACH unique. The process is designed to drive the substitution of Substances of Very High Concern (SVHCs) and to identify the specific uses where substitution is not yet possible or feasible. As such, the burden of proof lies on authorities to verify the hazardous properties, while it lies on industry to make a case when substitution is not possible.

We recognise the need to make the authorisation process smooth and efficient and we see that temporary solutions may be necessary before establishing final procedures. We welcome suggestions to reduce and refine the information required in applications to only the essential information and to further simplify the application procedure for low-volume uses.

However, we urge the Commission, while aiming to make the process smoother, not to lose the important original intentions of REACH. We hope that a way forward can soon be established since the crucial work of addressing SVHCs for substitution by populating annex XIV must not be further restrained.

In particular, we are concerned about the following:

- ▶ **Increased focus on socio-economic analysis, steering REACH away from regulating chemicals based on intrinsic properties and towards regulation based on other, mainly economic, concerns**

Following the intentions of REACH, socio-economic information should not play a role in the inclusion of substances on the authorisation list. The availability of alternatives as well as socio-economic implications for companies are of course important but should only be taken into account first at the next stage, when companies apply for authorisation and for those specific uses. The proposal to add further socio-economic aspects into the early public consultation is in our view an attempt to steer REACH away from regulating chemicals based on their intrinsic properties and towards regulation based on other types of concerns, mainly economic.

We also find it unclear what extra information the Commission is expecting to get from this. Aspects relating to the availability of alternatives and the consequences if authorisation is not granted are already being communicated through the current public consultation. We are also deeply worried about the pro-

posal to make such information available only to the Commission and not to the public, nor to the member states or ECHA. What the Commission proposes here is in our interpretation a way for the Commission to be able to take independent decisions on what substances to add to annex IVX, since the final grounds for the inclusion of substances on the authorisation list would be hidden to all, except the Commission.

We also have concerns about the way the socio-economic analysis is currently being used in the process of granting authorisation. There are already examples of how producers of alternatives find themselves being disfavoured by the process. In addition there is a need to better consider the socio-economic costs resulting from continued use of SVHCs in society. These costs, which fall on the economy of governments rather than on private shareholders, have been demonstrated in several studies to be significant.

► Re-using risk-based exposure limits from national workers' protection regulations goes against the intention of REACH to protect the general public from hazardous chemicals

We find the proposal to use OELs (Occupational Exposure Limits), when available, as worrisome and problematic on several levels. First, the aims and legal grounds for REACH and the workers' protection regulations are different and the regulations were built up in different ways. In the case of Indicative OELs, Member States are free to use other limits, without much justification. In the case of Binding OELs, these incorporate socio-economic aspects and therefore clearly differ to DNELs. Binding OELs have also proved to be difficult to keep up to date with new scientific information and available alternatives. Many of the OELs that are in use are also very old and sometimes the background documentation is missing. OELs

are based on workplace-specific exposure and usually only take inhalation into account, not dermal or oral exposure. Moreover, OELs do not take into account the effects on the environment or the general public, including sensitive groups such as unborn babies or children. On top of this, the experience is that OELs and DNELs tend to differ significantly. Using OELs as a baseline to claim that a substance is adequately controlled is not scientifically robust. ChemSec is aware that it can be an educational challenge to clarify how a DNEL is relevant to a workplace that already complies with OELs, but incorporating OELs into the REACH Authorisation procedure is not the appropriate measure to solve this issue.

► Disfavouring companies that produce or use alternatives restricts EU innovation potential

Authorisation is about innovation and substitution, and many companies act accordingly, by initiating processes to search for alternatives once a substance is placed on the Candidate List. In a previous study by the Commission, the Candidate List has been identified as a main driver for innovation in the EU chemical industry. The Candidate List can only continue to be this driver if the use of recognised SVHCs, for which alternatives are available, is not granted authorisation. The proposal for simplifying and streamlining includes several measures that would make it easier to keep on using SVHCs, while there is no pro-

posal to encourage those companies that are now investing in substitution. There are already examples of companies that have invested heavily in the development or use of new alternatives, and have also contributed to the Public Consultation with very good arguments on why authorisation should not be granted. We find it very worrying if the Commission should propose not to support their work and their market. Please see the separate paper with related opinions from European industry.

► A smooth and efficient process that does not jeopardise the intentions of REACH is possible

Solutions on how to achieve a more effective process have already been presented by various stakeholders. We believe it is important to have clear guidelines for the applications and that applicants should only need to spend time on gathering the information that is important for the case. Information on uses should be specific, and information from ECHA to companies should be clear and focused.

Moreover, the most cost-effective application is the one that never needs to be written. We are glad that ECHA has initiated different initiatives to promote substitution. We hope that this work will be intensified and that companies will be able to find support and information on substitution easily, so that whenever possible SVHCs can be substituted instead of having to apply for authorisation.



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