



AUTHORISATION PROCESS NEEDS FURTHER FINE-TUNING NOT TO DISFAVOUR ALTERNATIVES PRODUCERS

ChemSec concerns regarding the socio-economic aspects considered in REACH Authorisation

► AUTHORISATION PROCESS IS WORKING AND MUST GAIN SPEED

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 substitution of Substances of Very High Concern (SVHCs) and to identify the specific uses where substitution is not yet possible. We have been pleased to hear the last weeks positive messages from ECHA, the Commission and applying industry, stating that authorisation is working. This important process must now gain speed, and therefore the extension of Annex XIV must not be further restrained.

ChemSec is also concerned about the outspoken message from the Commission that only the economic feasibility for the app-

licant is of importance when evaluating applications for authorisation. REACH and guidance from ECHA states that a broad range of socio-economic aspects should be considered.

We are also worried about some of ECHA's opinions where authorisation is proposed to be granted even though there appears to be available alternatives on the European market. We fear that granting these authorisations will cause an economic disadvantage to companies who have already invested substantial resources in substituting these SVHCs. Moreover, these opinions give an unclear message to companies on the legal intention that SVHCs should be substituted when possible.

► IMBALANCE BETWEEN THE INTEREST OF APPLICANTS AND THIRD PARTIES

We believe that one key issue is the current imbalance between taking into account the interest of the applicant and the interest of third parties, including alternatives producers and users. This imbalance is partly built into the process when it comes to incentives to provide information and the access to key background information. Unfortunately this has also been made obvious in how the supplied third party informa-

tion is assessed and weighted in the ECHA committees. This imbalance, or gap, particularly concerns the socioeconomic aspects of authorisation and the suitability of alternatives. At present, the applicant's perspective seems to be the only perspective considered for the opinions. Instead, the positive implications for the producers of alternatives and societal benefits need to be included in the evaluation more efficiently.

► SOCIOECONOMIC ASPECTS

REACH states that authorisation shall only be granted via the socio-economic route if it is shown that socio-economic benefits outweigh the risks and that no alternatives are available. REACH also states that when assessing whether feasible alternative substances or technologies are available, all relevant aspects shall be taken into account, including the technical and economic feasibility of alternatives for the applicant (art 60.5). This means that the assessment should cover these specific issues but also the broader perspective.

There is no definition in REACH for the term "feasible alternative". However, representatives for the Commission have repeatedly stated that it is only necessary to take the applicants perspective into account. It has also been said that anyone pro-

viding a "good business case" should be granted authorisation. This is also how it seems to currently work in practice, and we find very this problematic.

The Socioeconomic Committee (SEAC) states that their work is not to bring in any additional socioeconomic aspects into the evaluation than what has already been provided for by the applicant. We find this being of great concern. The socioeconomic aspects to be considered for an authorisation must also include society costs for continuous use of SVHCs as well as the market implications for producers of alternatives if continuous use of SVHCs is granted. If this information is not provided for by the applicant, SEAC must request it or find the information elsewhere.

We are also concerned about the Commission's suggestion to include socioeconomic aspects even earlier in the process – before listing on Annex XIV. We believe that this would further emphasize this imbalance. It is unclear what additional information the Commission is expecting to get from this, as aspects relating to the availability of alternatives and the consequences if authorisation is not granted are already being communicated through the current public consultation. Moreover, the prioritisation criteria for Annex XIV are clearly laid down in Article 58.3. This extra 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.

“Limiting our exposure to the most hazardous chemicals is likely to produce substantial economic benefit. The health costs of exposure to SVHCs need to be considered alongside the costs of safer alternatives and needs to be weighed in any socioeconomic analysis.”

Leonardo Trasande, Associate Professor in Pediatrics, Environmental Medicine and Health Policy at New York University and one of the authors behind the recent studies “Estimating Burden and Disease Costs of Exposure to Endocrine Disrupting Chemicals in the European Union”

► ALTERNATIVES ASSESSMENT

When alternatives are assessed, the applicant for authorisation and the producer of alternatives will most likely have different views regarding the technical feasibility of the alternatives. The applicant, however, having initiated the specific authorisation process is far more likely to contribute with extensive documentation supporting their case than the alternative producer.

The alternatives producer may also lack important information, such as specific uses, to contribute with relevant information. To make sure authorisations are not given when alternatives are available the ECHA committees need to be prepared to put effort into following up more in depth the information on alternatives provided through the public consultation.

FINE-TUNE THE PROCESS AND SHARPEN THE MESSAGE

The outcome of recent opinions for authorisation has added to the confusion around the authorisation process and around REACH and its intentions. Companies fear that investments in substitution made to comply with REACH may not have been necessary or may even turn to their disfavour.

Attached is a paper with quotes from companies expressing concerns with the current situation. These clearly show the need to address this confusion and to clarify the intention of REACH to drive substitution of *Substances of Very High Concern*. As a start, we suggest the following:

- The Commission needs to continue to add substances to Annex XIV, the “freeze” period must now be over.
- Socio-economic aspects should not be taken into account before Annex XIV listing.
- The message from the Commission and ECHA needs to be clear and in line with REACH: authorisation shall only be granted via the socio-economic route if it is shown that socio-economic benefits outweigh the risks and that no alternatives are available.
- Feasibility of alternatives must be investigated beyond the applicant’s perspective and opinions from alternatives producers and users should be carefully considered.
- The transparency in the process needs to increase. Unclear and limited information adds to the confusion and lack of faith in the process. This goes both for providing useful information on alternatives and for understanding the reasoning behind the committees’ opinions.

We ask for the members of CARACAL to take these aspects into consideration and welcome more in-depth discussions on how the authorisation process can be used to its full potential without disfavouring companies producing and using alternatives.



www.chemsec.org