Advice for Joint Registrants on Exposure Scenarios, DNELs and the CSR

Introduction

REACHReady's aim is to help our subscribers help themselves achieve compliance. A plethora of guidance and articles about REACH and CLP can make it all seem more complicated and difficult than it is, so much of what we do is to remove some of the mystery and fear. We want our customers to feel reassured through the advice and positive action plans we offer to those attending our training events, reading our technical guidance, using our helpdesk and benefiting from our consultancy services.

However, this short report issues a warning that is intended to make the reader sufficiently concerned to invest some time in the technical issues around the Chemical Safety Report (CSR), as wrong conclusions can have a potentially major impact on uses of chemicals later. There are technical issues relating to joint registrations that you do perhaps need to worry about...

Joint registration is encouraged by ECHA and allows considerable benefits to share costs, share work and to reach common technical endpoints including agreed classification. Data is being shared and joint registrants will be sharing the Derived No Effect Levels (DNELs) for workers and consumers and Predictive No Effect Concentrations (PNECs) for the environment.

Sharing exposure scenarios and the CSR as part of the joint submission will also allow cost and time savings, and registrants may choose to include their identified uses in a joint CSR. The decision to be part of a joint CSR may be based on commercial considerations – it has the short term potential to save time and money and perhaps improve the chances of having a compliant dossier. However, the technical implications of sharing the CSR may be far-reaching and costly in the longer term.

Due to the available guidance erring on the side of caution, there is actually a significant chance of excessive risk management measures being recommended that may also be too expensive for companies to implement.

DNELs and PNECs

The output for toxicological and environmental effects testing needs to be expressed in the lead registration as DNELs and PNECs. These data are difficult to estimate and guidance from ECHA is complex; in the absence of large amounts of data, following the guidance is about all that is possible to do. However, following the guidance has the potential to add many unnecessary safety factors; for example, if the cause of mortality in oral toxicity tests is damage to the stomach due to local effects, the factors to give chronic DNELs may not apply.

Submitting a registration dossier with incorrect or inappropriate DNELs and PNECs may leave manufacturers and users of the substance impossibly low targets to meet for exposure levels; it is easy to end up with a chronic inhalation DNEL of micrograms per cubic metre and then finding no

way to monitor exposure at these levels. In this case, risk management measures may need to be imposed that include expensive ventilation and filtering, specialist equipment for users or perhaps a decision not to supply certain markets where exposure control is poor.

Check with your lead registrant / consultants that the DNELs and PNECs are 'realistic' in terms of expected exposure. In many cases, it is possible to use existing workplace exposure limits (WELs) as a basis for DNELs and in most examples examined to date, WELs provide a higher limit for exposure than the DNELs.

Note that the Derived Minimal Effect Level (DMEL) is different as this is used where there is no predicted no-effect level, such as for carcinogens, mutagens and reprotoxic substances (CMRs); in these cases, very low exposure levels may actually be needed.

Exposure scenarios and the CSR

The level of data requirements and exposure estimates for the CSR and Exposure Scenarios is based on tonnage manufactured or imported. Higher tonnages are associated with higher exposure and all the risk assessment models need a precise tonnage figure to estimate exposure to workers, consumers and the environment. The tonnage will impact on the risk management measures and using an inappropriate figure may result in either too much or too little in the way of risk management.

IUCLID 6 does not accept the "greater than" symbol, >, to be used when recording tonnage and in Section 3.2 the maximum tonnage needs entering; for example if registering 20,000 tonnes per year, you may wish to enter 25,000 tonnes to provide flexibility, but if the lead registrant has based the CSR on 100,000 tonnes, the figure used in exposure models for production could be inappropriate for your own registration so some assessment of exposure specific to the tonnage you include in Section 3.2 may be required. For low hazard materials, overestimation of exposure based on maximum tonnages is less of an issue, but for hazardous materials, an exposure estimate that is much too high may be problematic.

An example is if applying a default loss of 2% to waste water; this may be manageable if annual production is 1500 tonnes (100 kg / day lost to waste water, for production over 300 days). However, if the CSR was prepared for a maximum annual production of 20,000 tonnes, the default loss climbs to 1,300 kg per day and risk management required for registrants of the higher tonnage may be unnecessary for lower annual production or use figures.

ECHA's guidance on joint CSRs[1] is clear that, whilst a joint CSR could address potential risks based on total tonnage of the substance, the report should contain all relevant types of risk management measures appropriate to the manufacturing and use sites for each registrant covered by the shared CSR. For environmental assessment, a joint CSR should include local and regional release estimates based on consideration of the amount of the substance for each set of conditions under which the substance is manufactured and used.

Risk Characterisation Ratio

The output of the CSR is the risk characterisation ratio (RCR) and if this figure is >1, then exposure needs to be managed through risk management measures. For example, if the exposure to workers is 1 mg/m^3 by inhalation and the chronic DNEL is estimated as 0.1 mg/m^3, the RCR is 10 and risk management must be implemented to keep exposure to <0.1 mg/m^3 (RCR <1).

The true value of the RCR needs to be questioned in that the hazard values (DNEL or PNEC) and the exposure estimates (worker contact, consumer use or environmental concentrations) are all based on assumptions, models and 'worst case' scenarios. Getting any of these assumptions wrong can impact heavily on the risk management; getting it wrong one way can endanger life or the environment, but overestimating can lead to expensive risk management measures.

Risk Management Measures

Part A of the CSR includes three parts; the first is a summary of risk management measures, the second is a declaration that you are implementing these and thirdly is a declaration that you have communicated them on the safety data sheet. Whilst it is possible for the lead registrant to submit a joint declaration for all registrants covered, the ECHA guidance is clear that it is preferable for each registrant to submit individually their own declaration of implementation and communication of appropriate risk management measures. Doing so should help resolve questions of liability and ensure transparency for both the registrants and the authorities.

Conclusions

Despite the best intentions, in considering the need to share as much work as possible to save time and money and acknowledging the desire to follow standard guidance and models, it is essential to take a reality check on the outputs of the registration dossier. The hazard outputs are the DNEL, DMEL and PNEC and these need comparing to the exposure estimates to calculate the RCR. Exposure estimates are based on tonnages and, unless tonnages relevant to your production or use are used, they may not apply to you.

Getting it wrong now may be very difficult to change later; applying to ECHA to raise the DNEL, for example, will need a lot of explaining!

Need further help?

If you need help understanding the impact of REACH on your business, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.

If your customers or suppliers need help, get them to sign up to REACHReady's Gold service at http://www.reachready.co.uk/ and let us help them too!

References

[1] How to prepare registrations and PPORD dossiers
https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf/891754cb-a6b6-4bb6-8538-52ccde74070e