

GERMANY PROPOSES RESTRICTION ON DIISOCYANATES

Summary

Germany¹ is proposing a restriction on the placing on the market and the use of Diisocyanates as substances on their own, as a constituent in other substances or in mixtures in industrial and professional applications.

The public consultation on this proposed restriction will start on 22 March 2017 and ends on 22 September 2017. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome early comments, by 1 June 2017 to assist them in their opinion development.

SUGGESTED RESTRICTION

Scope

The proposal limits the use of diisocyanates in industrial and professional applications to those cases where a combination of technical and organisational measures as well as a minimum standardised training package have been implemented. Information how to get access to this package is communicated throughout the supply chain.

Exemptions are defined for cases where:

- (i) the content of diisocyanates in the substance or mixture placed on the market or used, is less than 0.1 % by weight, and
- (ii) mixtures containing diisocyanates at higher levels than 0.1 % by weight fulfil specified criteria that show that the potential risks of using such products are very low.

Reasons for action

Diisocyanates are known respiratory sensitisers and are widely used in many applications (foams, sealants, coatings) throughout the European Union. The total tonnage used is about 2.5 million tonnes/year.

The issue of occupational asthma caused by handling diisocyanates or formulations containing such substances has been known for decades. Occupational diseases caused by these products have been documented in each Member State. The annual number of new occupational diseases caused by diisocyanates (estimated to be more than 5000 cases) is considered to be unacceptably high.

An existing European wide regulation for Methylenediphenyl diisocyanate (entry #56 to Annex XVII to Regulation (EC) No. 1907/2006 (REACH)) focusses mainly on the risk of skin sensitisation for consumers and regulates the inclusion of protective gloves in packaging meant for the general public. This does, however, not solve the problem of occupational asthma described above.

¹ Specifically the German Federal Institute for Occupational Safety and Health (BAuA).

Consequences of the action

The proposed restriction is capable of significantly reducing the risks from workplace exposure to diisocyanates while keeping the safe use of diisocyanates a possible option.

The benefits of risk reduction are estimated to outweigh the costs of the proposal after a reasonable time (3 - 6 years). The reduction of risk in the EU as a result of the proposed restriction is estimated to avoid over 3 000 cases of occupational asthma per year after full implementation of the restriction measures. Benefits have been estimated growing to a range of € 5.4 – 7.6 billion.

A range of € 6 000 – 38 000 is derived for the costs of preventing one additional new asthma case. This range depends on the training option and the assumed effectiveness of training measures used and considers the initial risk for 6 500 cases/year.

It is expected that the effort to comply with the restriction is viable for all companies concerned. It is also anticipated that the restriction should have only a small impact on the prices of end-use services supplied.

SPECIFIC INFORMATION REQUESTED

A few specific elements have been addressed in the Public Consultation to gather relevant information, if available, from stakeholders:

1. What transition period do you consider to be appropriate to implement the measures specified in the restriction proposal and why? Please mention potential priorities in terms of application area or geographic regions.
2. What approaches (in addition to those already mentioned in the dossier) would you propose to communicate the requirements of the restriction through the supply chain, to effectively inform all levels of downstream users about their duties (including SMEs and self-employed practitioners)?
3. Could you give examples of training methods in the area of occupational health and safety which have proven to be particularly effective? Could you provide information on how the effectiveness of these methods has been assessed?
4. Do you have an information on a case(s) where respiratory or skin isocyanate-related symptoms were observed with a product containing less than 0.1% diisocyanates? Please provide as detailed case information as possible.
5. How would the proposed training program affect your company (we are particularly interested in how this affects SMEs or self-employed persons)?
 - a) What would be the most important cost to your company from the proposed training program – the €-cost of training, loss of employee time, else?
 - b) Would the training program benefit your company in other ways besides potential improvements in worker health, such as improved productivity/working methods?

Comments preferably by 1 June 2017

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 22 March 2017. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 22 September 2017, the rapporteurs of RAC and SEAC would appreciate receiving comments by 1 June 2017 to assist them in the early stages of the opinion development process .

The final opinions of both Committees are scheduled to be available by March 2018. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in the Public Consultation Guidance

http://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf