ECHA PROPOSES RESTRICTION ON N,N-DIMETHYLACETAMIDE (DMAC); 1-ETHYLPYRROLIDIN-2-ONE (NEP)[1]

Summary

DMAC and NEP are dipolar aprotic solvents used in industrial settings and by professionals[2]. Both substances are registered under REACH at substantial volumes and are, amongst others, classified in Annex VI of CLP as reprotoxic category 1B based on developmental toxicity (Repro. 1B; H360D).

Netherlands submitted a proposal to restrict the placing on the market, manufacturing and use of DMAC and NEP as a substance on its own, as a constituent of other substances, or in mixtures in a concentration equal to or greater than 0,3 %. The restriction report proposes DNELs and requires that exposure of workers has to stay below those DNELs. The original proposal did not include derogations or transitional periods.

The Socioeconomic Assessment Committee (SEAC) has agreed its draft opinion on the proposal, where SEAC notes that the Risk Assessment Committee (RAC), in its opinion, modified some of the originally proposed DNEL values. SEAC draft opinion proposes a 4-year transitional period for companies working on the Man-made-fibre sector.

The SEAC draft opinion is now subject to a 60-day consultation for interested parties. Comments received will be taken into account before SEAC adopts its final opinion.

SEAC draft opinion consultation

The consultation on the SEAC draft opinion for this proposed restriction will start on 15 March 2023 and end on 15 May 2023.

Interested parties can comment on the draft SEAC opinion using the relevant web form on the ECHA website.

When submitting comments, please keep in mind that:

- It is usually necessary to provide **supporting evidence** (i.e. in the form of references, data or other information) alongside comments. Without supporting evidence, it is usually not possible for SEAC to evaluate the credibility of the comment.

- Where respondents **request a derogation** from the proposed restriction the following supporting evidence should be provided:

    - A detailed description of the use of the substance, including the quantities used/released, technical function, sector of use, article category. etc;

    - Information on **alternatives**, including and assessment of their availability, technical feasibility and economic feasibility; if alternatives are available a

[1] The information note has been prepared based on the SEAC draft opinion prepared by ECHA.
[2] Consumer applications are excluded from this document because both substances are classified as reprotoxic category 1B based on developmental toxicity (Repro.1B; H360D) in Annex VI of the Classification, Labelling and Packaging (CLP) Regulation which prohibits the use in consumer products up to a level of 0.3% through listing in Appendix 6 of entry 30 of REACH Annex XVII.

detailed description of a substitution timeline;

- The **socio-economic impacts** to society in case a derogation is not included in the restriction. This includes, for example[3]:
  - Impacts to industry (e.g., manufactures, importers, downstream users), including related to alternatives providers;
  - Impacts on consumers (e.g., prices or product performance);
  - Impacts on society, (e.g. employment);
  - Wider implications on trade, competition and economic development, in particular for SMEs);
  - Benefits for human health or the environment (e.g. worker health)

- Information arriving after the closing date or via channels other than the web form will **not be taken into account**.

- It is your responsibility to remove **confidential information** from the comments and attachments submitted with non-confidential status.

- As far as possible, justifications based on non-confidential information are preferred to those based on confidential information. Should the submission of confidential information be considered to be fundamental to describe socio-economic impacts (i.e. in the case that a use is restricted), then a non-confidential form of the confidential information (i.e. generic use descriptions, a tonnage or concentration range or aggregated data from multiple sources to prevent back-calculation) should be submitted in addition to the confidential information. This is to allow for the most transparent discussion of the justification for a derogation in the SEAC opinion.

Further information can be found in the consultation guidance available at: https://echa.europa.eu/documents/10162/13641/restriction_consultation_guidance_en.pdf

When responding to the consultation, stakeholders should ensure that they are referring to the SEAC draft opinion and the most recent version of the Background Document and its annexes that are published on the ECHA website alongside the consultation.

How to submit a comment in the consultation on a SEAC draft opinion

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains five main parts:

- Introduction: containing some general information on the restriction and a link to this note and the consultation guidance.

- Section 1: personal information.

[3] Further relevant socio-economic impacts are described in Annex XVI of REACH

- Section 2: organisational information.

- Section 3: non-confidential comments on the SEAC draft opinion - both general comments and information on specific issues (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means. General comments can be on any aspect of the SEAC draft opinion.

- Section 4: Non-confidential attachments can be added here.

- Section 5: Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the webform.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail, and you should refer to this in any communication with ECHA on this issue. It is not possible for you to retrieve your submission so you may want to take a screen shot, or printed copy for your future reference.

Specific information requests

In addition to the general comments, outlined above, the consultation includes a specific question to gather information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

Question

RAC has agreed a higher long-term dermal DNEL value than originally proposed by the Dossier Submitter, i.e. 1.8 mg/kg bw/day instead of 0.53 mg/kg bw/day.

a) Could the risk management measures already in place at your site(s) ensure compliance with the agreed higher DNEL value?

b) If not, what action(s) should be taken? What would be the costs of such action(s)?

Next steps

The final SEAC opinion will be agreed in June 2023. ECHA will send the joint opinion of the RAC and SEAC Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.