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

Summary

ECHA has received a restriction proposal (Annex XV report) targeted to risks identified at European Union (EU) wide level due to use of the substances DMAC and NEP in industrial settings and by professionals. DMAC and NEP are used as solvents in the production of various formulations, e.g. in the production of agrochemicals, pharmaceuticals and fine chemicals.

Both substances are so-called dipolar aprotic solvents and are registered under REACH at substantial volumes. The substances have an EU harmonised classification in Annex VI of the CLP Regulation as reprotoxic category 1B based on developmental toxicity (Repro. 1B; H360D). Consumer applications are excluded from this proposal.

The restriction proposal concludes that human health risks are not adequately controlled for several industrial and professional uses of DMAC and NEP, especially when it concerns processes under elevated temperatures, open processes and processes that require manual activities. The restriction report proposes a restriction with binding DNELs for the inhalatory and dermal route to be the most appropriate risk management option.

The consultation on this proposed restriction will start on 20/06/2022 and ends on 20/12/2022.

When responding to the consultation, stakeholders should ensure that they are referring to the most recent version of the Annex XV report and any annexes (i.e. those published alongside the consultation).

Respondents are also encouraged to take into account when certain aspects of the proposal are planned to be discussed in the committee's plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation).

	Committee	
Plenary meeting of the Committee (timing)	**Risk Assessment Committee (RAC)**	**Socio-Economic Assessment Committee (SEAC)**
1 (2.5 months after PC starts)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on costs of the proposed restriction and hold preliminary discussions on its benefits.
2 (5.5 months after PC starts)	Conclude on exposure/risk and hold preliminary discussion derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.

[1] The information note has been prepared based on the Annex XV report prepared by ECHA.

3 (8.5 months after PC starts)	Finalise the derogations. Finalise the opinion plus justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion plus justification text and agree the draft opinion.
4	Not relevant.	Conclude on issues raised during the SEAC draft opinion consultation. Adopt the final opinion.

Information on the hazards of the substance(s) and the costs of the proposal would make the most impact if submitted by month two and exposure/risk, beneifts and derogations by month four of the consultation. This early submission would also allow the information to be considered at the appropriate time. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is published two weeks after submission or more than six weeks in advance of the start of the consultation.

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

How to submit a comment in the Consultation on the proposed restriction

Firstly please read the consultation guidance that describes the relevant information that should be submitted. It is available here:
https://www.echa.europa.eu/documents/10162/17233/restriction_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c

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 PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal - 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 Annex XV restriction proposal, including on issues related to socio-economic analysis.
- 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 several specific questions to gather information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

1. **Do you have information available regarding workplace exposure to DMAC/NEP and number of people exposed?**
   a) Please provide an estimate about the number and/or share of workers which are currently inhalation exposed to DMAC/NEP above the proposed DNEL values in your company, and on the sector level if possible.
   b) Please provide an estimate about the number and or share of workers dermally exposed to DMAC/NEP above the proposed DNEL values in your company, and on the sector level if possible.
   c) What are workplace exposure levels, measured under the current conditions at your workplace / within your sector? If available, please provide us also with contextual information and/or study reports of the workplace measurements.
   d) What risk management measures, including technical means (e.g. containment, LEV, technical general ventilation), workplace organisation (e.g. training of workers, certification systems) and personal measures (e.g. PPE, RPE) aiming at reduction of workplace exposure to DMAC and/or NEP are already implemented at your workplace / within your sector? Could you indicate which risk management measures are "typical" and what kind of risk management measures are "advanced"?
   e) Have you used biomonitoring to measure occupational exposure to DMAC and/or NEP? Could you provide us a summary of the methods used and the measured levels among workers (aggregated data)?
   f) What are your general experiences with regards to dermal exposure to DMAC and/or NEP at workplaces in your company/sector? Have you used yourself or are you aware of available methods to perform dermal monitoring to measure dermal exposure to DMAC and/or NEP? If yes, could you provide us more information on this including also a summary of the results (if available).

2. **Experiences from NMP/DMF restrictions:**
   Similar binding DNELs as now suggested for DMAC/NEP have been earlier derived for NMP and DMF in restrictions.
   a. Please, provide information on the practical implementation of the binding DNELs (for NMP and DMF) set under REACH in your country and/or in your industry field (if available)? Where possible, assess and compare this information with experience about other potential options of regulatory risk management (e.g. information/evidence on the effectiviness and possible challenges in implementing this kind of restriction at workplace compared to e.g. binding occupational exposure limit values).
   b. Please, describe any potential challenges related to the implementation of the binding DNELs at workplaces, based on the experiences from NMP/DMF.

Would you have experience in this regard that can be supported by data, e.g. workplace monitoring?.

3. Information on use and substitution of DMAC and NEP:

a. Do you have experience on substitution of DMAC and/or NEP at workplaces in your company/sector? Have you substituted these solvents lately by other solvents or processes? What have been the reasons for these substitutions? Which alternatives do you use now? What have been the major difficulties (if any) in this substitution process?
b. Are you aware of any applications using DMAC/NEP that are expected to see a significant increase in the amount of DMAC/NEP used in the future?

4. The professional use of formulations with high NEP concentrations are assumed to cease due to the proposed restriction (e.g. graffiti and paint remover, leather finishing agent and use as hardener for isocyanate-based sealers used on flooring).

a) Are you aware of further formulations or mixtures containing NEP which are expected to cease? Please, describe these formulations/mixtures.
b) If the use of NEP for these formulations was to be substituted - what substances are considered suitable substitutes?
c) If suitable alternatives are not available, how would you see the professional users to react to the non-availability of these formulations(e.g. shifting to less performing formulations, ceasing the use, other)?
d) Would this reaction represent a loss for the manufacturer of these formulations and the downstream user? Please, characterise the loss (profit loss, performance loss, job loss, other).

5. What is the economic feasibility of potential alternatives? There are already potential alternatives for some applications, but so far mainly at the technical level, e.g. dialkyl carbonates for DMAC use in fibre production and hydroxymethylfurfural for NEP use in binders. Would you be able to give an assessment of whether such alternative processes might also be economically feasible? Are you aware of other potential alternatives/processes not mentioned above?

6. Costs of installing an LEV system (Local exhaust ventilation).

a) Do you foresee a need to install or adapt an LEV system in your company due to the inhalation DNELs (DMAC, NEP) as proposed by this restriction?
b) Please, list the essential cost items and their value and/or share of the total costs of such a system.
c) Please provide an exemplary calculation of implementing and maintenance costs for Local exhaust ventilation system in the company (note that, LEV systems for other solvents like DMF, NMP may already be in place).

7. Effort and costs required for a training schemes.

a) Do you foresee a need for a training program in your company due to the dermal DNEL as proposed in this restriction?
b) Please provide an estimate about how many employees would need a training for adequate glove use and what is the share given the total number of the production/blue collar employees in your company?
c) Please provide a cost estimate for additional costs of training of your employees for adequate glove use to protect against skin contact with DMAC/NEP (note that there may be already training schemes in place for use of personal protective equipment).

8. Sectoral impacts and costs to downstream users: In case upstream companies

currently using DMAC or NEP would have to discontinue their use of DMAC or NEP what kind of impacts there would be, please, describe:

a) The main sectors of downstream users to be affected, and
b) any subsequent (indirect) impacts on costs for those down-stream users.

9. Transitional periods

Could negative socioeconomic impacts arising as a result of the proposed restriction be managed or avoided by means of specific transitional periods e.g. for specific sectors. Please describe the impacts that would occur under different lengths of transitional period. Please provide supporting information along with your comment.

The final opinions of both Committees are scheduled to be available by 09/06/2023. 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 Annex XVII of the REACH Regulation.

The Dossier Submitter and the Rapporteurs will respond to the issues raised in the consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion.