Call for evidence and information on the use of N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP)

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Background document

Introduction

Following the Commission's Regulatory Management Option Analysis (RMOA) Conclusion Document on DMAC, DMF and NMP (https://echa.europa.eu/documents/10162/12a07361-9d62-65cf-48e9-5cd6b461cc9a), Bureau REACH of the Netherlands is preparing an Annex XV restriction dossier on the use of N,N-dimethylacetamide (DMAC, CAS 127-19-5, EC 204-826-4) and 1-ethylpyrrolidin-2-one (NEP, CAS 2687-91-4, EC 220-250-6).

DMAC and NEP are REACH registered aprotic solvents, both with a EU harmonised classification in Annex VI of CLP as Repro Cat 1B, that appear to be used by the same sectors, namely as solvent for production of other chemicals (pharmaceuticals, agrochemicals and fine chemicals); for production of synthetic fibres, textiles and artificial leather; industrial coatings; films, paint strippers and cleaners. Since December 2011 DMAC is listed as a Substance of Very High Concern (SVHC) on the Candidate list for Annex XIV.

Elements of an Annex XV assessment

The elements that need to be considered during the preparation of a restriction proposal are set out in Annex XV of REACH and further elaboration in ECHA Guidance documents[1].
These can be summarised, as follows:

- A characterisation of exposure and resulting risks to human health from a use of a substance, including via food and water;
- A characterisation of exposure and resulting risks to the environment and wildlife from a use of a substance;
- A justification that risks are not adequately controlled and occur on a Union-wide basis;
- An analysis of the availability and technical performance of alternatives;
- A socio-economic analysis (e.g. costs and benefits to society) that would arise from a restriction.

Objective

The objective of this call for evidence is to gather (updated) information from relevant stakeholders for the preparation of an Annex XV restriction dossier on DMAC and NEP. In 2011, ECHA prepared an Annex XV SVHC dossier for identification of DMAC as SVHC and industry provided input in consultations. The results of this previous consultation will be used in conjunction with the registration information (the comments received are

[1] https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions

summarised in https://www.echa.europa.eu/documents/10162/95105cf0-affb-4fd7-b9bb-c6923e793dd8).

For DMAC, this call for evidence invites stakeholders to indicate any changes in uses, quantities, expected trends and worker exposure measurements or, where appropriate, to reaffirm the information provided in the registration dossiers and in the ECHA background document referenced above.

For NEP, information will be taken from the registration dossiers, and the call for evidence invites stakeholders to update (where appropriate) their registration dossiers and/or provide information on uses, quantities, expected trends and worker exposure measurements.

In addition, information is requested on additional exposure reduction measures and their effectiveness and costs; estimates of the number of workers involved in the different sectors and information on alternatives to the use of DMAC and NEP (hazard and risk profile of alternatives, their technical characteristics and substitutability for the restricted substances and their costs).

Stakeholders are also invited to point out any specific areas of interest/concern in case of a restriction e.g. possibilities to curtail exposure via technical measures, potential for additional use of PPEs (Personal Protective Equipment) and/or organisational/administrative measures.

Evidence and information to be collected

The objective of this call is to gather information or comments on:

1. For DMAC and/or NEP, information on the (company and/or sector level) quantities in use for the different sectors of activity and the trends in the last ten years as well as the foreseen future market demands expected for these substances.

2. For DMAC and/or NEP, information on the number of companies working with DMAC and/or NEP, the number of workers employed potentially exposed to DMAC and/or NEP, and worker exposure measurements for your specific sector and, where possible, indicate if the numbers are likely to increase or decrease in the near future.

3. The option for mandatory DNELs, similar to the (proposed) restrictions of NMP and DMF, is currently being explored. Acknowledging that the DNELs proposed by the Netherlands may be modified by the RAC as part of the opinion forming on any submitted proposal, we provide two indicative ranges of possible mandatory DNELs for DMAC and NEP, both for inhalation and dermal effects:

DMAC	*Indicative DNEL range A*	*Indicative DNEL range B*	*Current DNELs*[*]
Inhalation Systemic effects - Long-term	1-5 mg/m3 TWA	10-15 mg/m3 TWA	23-36 mg/m3 TWA
Dermal Systemic effects - Long-term	1-5 mg/kg bw/day	5-10 mg/kg bw/day	11-13.6 mg/kg bw/day

[*]Based on the registration dossiers of DMAC

NEP	*Indicative DNEL range A*	*Indicative DNEL range B*	*Current DNELs*[*]
Inhalation Systemic effects - Long-term	0.5-2 mg/m3 TWA	4-7 mg/m3 TWA	16.75 mg/m3 TWA
Dermal Systemic effects - Long-term	0.3-1.2 mg/kg bw/day	2-3 mg/kg bw/day	4 mg/kg bw/day

[*]Based on the registration dossiers of NEP

In case of a mandatory DNEL in either range A or B, do you consider the introduction of additional engineering or organisational measures to reduce exposures such as closed systems, increased automation, etc. as technically and economically feasible? Do you consider a need for any other additional measure(s) to manage the proper use of the solvents?

Additionally, provide specific information on the economic impacts of the introduction of such engineering measures or any other measures you may have in your specific sector of activity. You may also provide reasons why certain measures would not be applicable for your sector of activity.

4. In case you consider that exposure reduction is practically non-feasible for your specific sector of activity, what would be your anticipated response to a proposed restriction? Furthermore, what would be the economic impact for your own business and other actors in your sector and supply chain if DMAC and/or NEP is restricted as proposed in the EU?

5. Information on the suitability and availabilities of alternatives (including other substances or other technologies) for any industrial and professional use of DMAC or NEP. In case there are no available alternatives, it would be useful to receive information on the possible technical or economic difficulties for substitution (e.g. related to qualification of alternatives for safety critical uses), prices of alternative substances or technologies and other relevant information on substitution costs.

6. In case you are aware of other administrative or regulatory changes (national or other) affecting the use of DMAC and/or NEP in the near future e.g. introduction of new Best Available Technique reference documents (BREFs) under the IPPC Directive (1996/61/EC), please provide that information.

Additional relevant information for the preparation of an Annex XV restriction dossier is also welcome. General information on the exposure for these two substances will be taken from the available registration dossiers. Therefore, if outdated and particularly on OCs (Operational Conditions) or RMMs (Risk Management Measures) currently in place in the different sectors, these should also be updated.

Who should participate in the call for evidence?

This call for evidence is intended for interested parties such as companies (manufacturers, suppliers, distributors, importers etc.), trade associations, scientific bodies and any other stakeholders or Member States holding relevant information. Information can be submitted confidentially and will be treated as such by ECHA and the Dossier Submitter.

The information provided will be used to determine if any derogations would be necessary in the event that a restriction was proposed. However, derogations cannot be proposed without adequate information on risk and socio-economic information,

including alternatives. If a derogation is not proposed in the initial restriction proposal then it will be incumbent on relevant stakeholders to provide a full justification based on a comprehensive information on risk, socio-economic elements and alternatives, during the opinion-making process.

ECHA invites interested parties to respond to the call for evidence by 13 March 2020.

The questionnaire can be completed using this URL: https://comments.echa.europa.eu/comments_cms/CallForEvidence.aspx?RObjectId=0b0236e184507af3

For any clarifications or more information regarding the specifics of this call for evidence, please, contact Bureau Reach of the Netherlands: bureau-reach@rivm.nl