N,N-dimethylacetamide (DMAC); 1-ethylpyrrolidin-2-one (NEP)

Response to comments on the SEAC draft opinion (ORCOM)

on an Annex XV dossier proposing restriction on

N,N-dimethylacetamide (DMAC); 1-ethylpyrrolidin-2-one (NEP)

30 May 2023

1. General comments and answers to specific information requests

1.1. Specific information requests

1. 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)?

1.2. Overview of the comments received

Total of three (3) comments were received during the SEAC Draft Opinion consultation – all from industry or trade association.

The following themes were identified in the comments and the ORCOM is structured accordingly, providing responses by theme rather than per individual comment:

- Support for the (higher) RAC proposed dermal DNEL vs the originally suggested dermal DNEL
    - Within reach
    - cost-wise practicable risk reduction measures expected to be found
- Transitional period
- Costs of improved Local exhaust ventilation (LEV)
- Current approach and proposal to decrease the biological limit value (BLV) and related DNEL (not direct concern of SEAC) is considered not to be sufficiently validated.

2. SEAC rapporteurs' responses to comments

The SEAC rapporteurs would like to thank the interested parties that contributed to the consultation on the SEAC draft opinion.

The SEAC rapporteurs note that the three comments received were similar in nature and concerned common topics. In line with the approach to respond to comments received during the Annex XV report consultation, the SEAC rapporteurs prepared general responses to these common topics. The general responses summarise the nature of the comments received and how the SEAC rapporteurs responded to them, e.g. by amending or complementing the SEAC opinion where considered justified and necessary.

To assist interested parties in understanding how their comments were assessed, the general responses include indicative lists of comment numbers that are associated with a specific topic.

None of the three comments received were marked to be "confidential" by their submitters, therefore, SEAC considers all the submitted information within the comments to be public.

2.1. Support for the (higher) RAC proposed DNEL vs the originally suggested dermal DNEL

Within reach

Cost-wise practicable risk reduction measures expected to be found

Comments submitted include comments #1195, #1219.

2.1.1. Summary of comments received

Higher dermal DNEL of 1.8 mg/kg/day (proposed by RAC) instead of DNEL of 0.53 mg/kg/day (proposed by Dossier Submitter) is supported.

2.1.2. SEAC rapporteurs' response

Thank you for the support.

2.2. Transitional periods

Comments submitted include comments #1195, #1220.

2.2.1. Summary of comments received

Based on the proposed DNELs, adaptation and expansion of existing LEVs is required because the DNELs are much lower than the existing national OELs for which the LEVs were developed and installed. Additional investment costs especially for adaption of LEV are expected. Therefore, European Man-Made Fibres Association (CIRFS) and The European Apparel and Textile Confederation (EURATEX) support a transition period of 4 years for Man-made fibre sector.

2.2.2. SEAC rapporteurs' response

Thank you for the comment. EURATEX refers to cost information provided by European Man-Made Fibres Association about LEV adaption costs. This information was already considered plausible by SEAC and already taken into account in the draft opinion. No new information is brought forward by comments from CIRFS and EURATEX on LEV costs.

2.3. Costs of improved Local exhaust ventilation (LEV) and of other RMMs

Comments submitted include comments #1195, 1219, 1220.

2.3.1. Summary of comments received

Costs of around €5-10 million are expected for improved ventilation for some companies and further costs from reduced DMAC recovery efficiency, potential additional heating costs, and increased emissions to the environment (Man-made fibre sector) and, for typical winding wire installations costs of around €25,000 per year for protective measures to be set up individually (Electrical wire winding sector).

2.3.2. SEAC rapporteurs' response

Thank you for the comment. EURATEX refers to cost information already provided by European Man-Made Fibres Association about LEV adaption costs. This information was

considered plausible by SEAC, and already taken into account in the draft opinion. The information from Electrical wire winding sector is considered new information and now also mentioned in cost section in Tab. 5, and in proportionality sector in Tab. 8.

2.4. Current approach and proposal to decrease the biological limit value (BLV) and related DNEL (not direct concern of SEAC) is considered not to be sufficiently validated (not direct concern of SEAC)

Comments submitted include comment #1195.

2.4.1. Summary of comments received

Current proposal to decrease the BLV might lead to an overestimation of the human health risk. In the restriction report, the proposed biological limit value (BLV) is based on the proposed inhalation DNEL of 13 mg/m3, which was derived from developmental toxicity in animal studies. However, the validity of this approach should be re-assessed as it does not reflect current principles for the derivation of limit values in biological materials.

2.4.1. SEAC rapporteurs' response

Thank you for the comment. This is a RAC issue but RAC Final opinion was already adopted in March" and this topic is already discussed in RAC opinion.