**General comments and answers to specific information requests**

**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.
	1. Could the risk management measures already in place at your site(s) ensure compliance with the agreed higher DNEL value?
	2. If not, what action(s) should be taken? What would be the costs of such action(s)?

|  |  |  |
| --- | --- | --- |
| Ref. | Date/Type/Org. | Comments |
| 1195 | Date/Time:2023/05/11 19:10Type:BehalfOfAnOrganisationOrg. type:Industry or trade associationOrg. name:CIRFS-European Man-made Fibres AssociationOrg. country:BelgiumAttachment:  | General Comments:CIRFS - European Man-Made Fibres Association (TR No: 401973428940-48), in agreement with IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (European transparency register no. 49913771894-86), provided comments to the DMAc restriction process first during the call for evidence and secondly to the Annex XV public consultation (comments number 3584, 3586, 3587, 3597, 3603, 3604, 3605, 3654 and 3667).These comments to the SEAC draft opinion do not include new information in addition to what was already shared during those previous consultation phases but are meant to highlight how critical is for the man-made fiber (MMF) industry sector to keep the proposed extended enforcement period in the final restriction conditions as included in the SEAC draft opinion.Current DMAc restriction proposal in the SEAC draft opinion:- Confirms the reduction from draft Annex XV restriction report in the long-term Inhalation DNEL to 13 mg/m3 (from current 23 mg/m3).Local exhaust ventilation and other engineering controls are already installed in MMF companies for fibre production with DMAC as shown to the Annex XV dossier submitter during online site visit and using similar production techniques as for wet-spinning DMF plants. Adaptation and extension of exhaust ventilation might be needed, within the technical limits possible, to maintain a safety margin to the proposed lower inhalation DNEL as these LEV were developed and installed for compliance with existing national OELs.In addition, task-based risk assessment review will be needed, including redefinition of PPE in order to adapt to the lower combination of inhalation+dermal DNELs.- Confirms the reduction in the long-term dermal DNEL to 1.8 mg/kg bw/day (higher than initial 0.53 mg/kg bw/day proposed in annex XV but still in the lower range discussed in the call for evidence).Detailed toxicological comments were given by CIRFS regarding the selection of the study and point of departure as well as on the use of the default assessment factors for the calculation of the dermal DNEL. (see attachment from comment #3584). Similar comments were given by other industry associations and companies (i.e. # 3588, #3602).The initially proposed dermal DNEL of 0.53 mg/kg bw/day is very problematic for all industries. An extremely low dermal DNEL leads to a substance ban in practice as even bulk charging/discharging operation of liquid DMAc in an industrial environment cannot be calculated to be safe when applying the highest dermal protection foreseen in the ECETOC TRA model (glove incl. specific training). Current dermal DNEL included in the SEAC draft opinion of 1.8 mg/kg bw/day for long-term dermal exposure is still a challenge in absence of a monitoring system where dermal risk assessment can only be done by modelling.Again, task-based risk assessment review will be needed, including redefinition of PPE in order to adapt to the lower combination of inhalation+dermal DNELs.- Refers to a reduction in biological limit value (BLV) from current 30 mg MMAc/g creatinine to 15 mg MMAc/g creatinine in urineDue to applicable BLV for DMAc under OHS legislation, biological monitoring programs are already established in the MMF industry.Detailed scientifical arguments were given jointly by Cefic BDO & derivatives sector group and CIRFS regarding the biomonitoring studies and biological limit values (see attachment from comment #3654). Similar comments were given by other stakeholders (i.e. #3602).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. An additional margin of safety was used, in order to avoid “misclassification of a large percentage of individuals as underexposed” and thus, the proposed value is lowered from the established average value, essentially following the recommendation by Spies et al., 1995. 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.- Includes an extended enforcement period for the man-made fiber industry of 4 years.In order to adapt to the lower DNELs proposed in this restriction, the MMF industry will need to enhance and expand existing LEVs as they were developed and installed for compliance with existing national OELs. Additional investments in the order of €5-10 million are expected for improved ventilation for some companies. In addition to the investment costs for adaptation, there would be further manufacturing costs from reduced DMAc recovery efficiency (due to lower concentration in the exhaust stream as a greater volume of air is drawn through the system), potential additional heating costs, and increased emissions to the environment.The MMF industry has already experienced implementation costs for the previous reductions in DNELs: inhalation long-term DNEL from 36 mg/m3 to 23 mg/m3 in 2016 and dermal long-term DNEL from 11 mg/kg bw/day to 5.6 mg/kg bw/day.In order to be able to cover these additional significant costs of adaptation and to avoid further closures of MMF plants in Europe, it is important that MMF companies are given a longer transition period in this DMAC restriction as already stressed during the annex XV public consultation and acknowledge by SEAC in its draft opinion.In addition to the cost for adaptation, current sociopolitical environment needs to be considered, as constrains in global supply chain may influence the timelines for implementation due to equipment availability.In conclusion:At the beginning of the restriction journey for DMAc, there were 6 companies in the MMF industry sector in EU using DMAc as process solvent. Four of them were included in the Antoniou et al., 2021 study (attached), but meanwhile three out of six companies have already closed the production in Europe.The transition period of 4 years (comparable to the period given for the adaptation of DMF-DNELs) is critical for the remaining MMF industry with operations in EU using DMAc to overcome the big socioeconomical impact that this restriction process will have on the sector. |
| Specific information 1:See under general comments |

|  |  |  |
| --- | --- | --- |
| 1219 | Date/Time:2023/05/19 08:04Type:BehalfOfAnOrganisationOrg. type:Industry or trade associationOrg. name:EWWAOrg. country:Belgium | General Comments:EWWA welcomes a higher than previously suggested dermal DNEL of 1.8 mg/kg/day.Please find ou specific information below |
| Specific information 1:EWWA welcomes a higher than previously suggested dermal DNEL of 1.8 mg/kg/day. In winding wire industry, biomonitoring is currently only used in rare exceptional cases. A DNEL of 0.53 mg/kg/day would only be verifiable by continuous biomonitoring. With the help of exposure calculations, we believe that practicable risk reduction means can be derived that can be coped with financially. We expect an additional financial burden of approx. 25,000 €/a for a typical winding wire installation (of which there are currently 18 in Europe) for protective measures to be set up individually, depending on the individual result of the exposure calculations and the occurrence of the known and confirmed PROC2, 8b and 10 scenarios (see NMP guidelines). |

|  |  |  |
| --- | --- | --- |
| 1220 | Date/Time:2023/05/21 15:57Type:BehalfOfAnOrganisationOrg. type:Industry or trade associationOrg. name:The European Apparel and Textile Confederation (EURATEX)Org. country:Belgium | General Comments: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.As additional investments 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, EURATEX supports the transition period of 4 years. This is comparable to the period given for implementation of DMF-DNEL and it is needed for the companies to ensure a proper transition.EURATEX also supports the data put forward by CIRFS - European Man-Made Fibres Association in their submissions to the ECHA consultations and their information regarding workplace exposure, alternatives and impact on the textile industry. |