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

**Specific information requests:**

1. **Do you have information available regarding workplace exposure to DMAC/NEP and number of people exposed?**
2. 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.
3. 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.
4. 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.
5. 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”?
6. 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)?
7. 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).
8. **Experiences from NMP/DMF restrictions:**

Similar binding DNELs as now suggested for DMAC/NEP have been earlier derived for NMP and DMF in restrictions.

1. 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).
2. 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:**
4. 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?
5. 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?
6. **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).
7. Are you aware of further formulations or mixtures containing NEP which are expected to cease? Please, describe these formulations/mixtures
8. If the use of NEP for these formulations was to be substituted - what substances are considered suitable substitutes?
9. 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)?
10. 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).
11. **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?
12. **Costs of installing an LEV system (Local exhaust ventilation).**
13. 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?
14. Please, list the essential cost items and their value and/or share of the total costs of such a system.
15. 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).
16. **Effort and costs required for a training schemes.**
17. Do you foresee a need for a training program in your company due to the dermal DNEL as proposed in this restriction?
18. 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?
19. 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).
20. **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:
21. The main sectors of downstream users to be affected, and
22. any subsequent (indirect) impacts on costs for those down-stream users.
23. **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.

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| Ref. | Date/Type/Org. | Comments |
| 3584 | Date:  2022/07/13 17:48  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CIRFS: European Man-made Fibres Association  Org. country:  Belgium  Attachment: | 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), provide in this comment "CIRFS Toxicological comments on DNEL dermal and BLV" for RAC mainly. |
| Answer to specific info request 1:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Answer to specific info request 2:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Answer to specific info request 3:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Answer to specific info request 5:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Answer to specific info request 6:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Answer to specific info request 7:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Answer to specific info request 8:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Answer to specific info request 9:  1st deadline for comments on this point will be provided separately until July, 20th 2022 |
| Dossier submitter response:  Thank you for your comments on the derivation of the dermal DNEL of DMAC. We appreciate your critical review of the derivation of the dermal DNEL of DMAC in the Annex XV report; however, we don’t agree with your assessment and proposed Points of Departures (PoDs) or change of the Biological Limit Value (BLV). Since new information was provided and the derivation of the dermal DNEL in the Annex XV report clearly explained, no change has been made to the Background Document. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. This comment specifically helped in the derivation of the dermal DNEL of DMAC. With regards to the biomarker DNEL for DMAC RAC supports the Dossier Submitter proposal which is also targeted to protect from the developmental effects of DMAC. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |

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| 3585 | Date:  2022/07/14 10:58  Type:  MemberState  Country:  Germany | Answer to specific info request 1:  The German CA does not have original data on workplace exposure regarding DMAC/NEP. However, we would like to indicate that in addition to published data on DMAC (https://www.dguv.de/medien/ifa/de/fac/reach/mega\_auswertungen/dimethylacetamid.pdf) the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) holds measured inhalation exposure data for NEP which are stored in IFA's exposure database MEGA. We recommend to contact IFA in order to get access to these unpublished data. Measurements of DMAC/NEP were performed within the quality controlled measurement system for exposure assessment of the German Social Accident Insurance Institutions (MGU). Contact information can be found here: https://www.dguv.de/ifa/index-2.jsp |
| Dossier submitter response:  Thank you for your comment. We have contacted the relevant databases and updated the Background Document when information was provided. |
| RAC Rapporteurs comments:  This comment is in line with the RAC’s recommendation to the Dossier Submitter and was addressed also as a question for the Annex XV consultation for this restriction proposal. For most of the uses of DMAC and NEP still no relevant exposure measurement data are available for the exposure assessment of RAC. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |

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| 3586 | Date:  2022/07/14 13:30  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CIRFS: European Man-made Fibres Association  Org. country:  Belgium  Attachment:  <redacted> | 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 (TR No. 49913771894-86), provide in this comment CIRFS BM data from 2012-2019 as confidential information mainly for RAC. |
| Answer to specific info request 1:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Answer to specific info request 2:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Answer to specific info request 3:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Answer to specific info request 5:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Answer to specific info request 6:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Answer to specific info request 7:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Answer to specific info request 8:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Answer to specific info request 9:  1st deadline comments on this point will be provide before July, 20th 2022 separately |
| Dossier submitter response:  Thank you for your submitted information; this has been incorporated in the relevant updated Annex to the Background Document |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. This specific contribution supported the exposure assessment for DMAC in the man-made fibre sector. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |

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| 3587 | Date:  2022/07/14 17:06  Content:  Scope or restriction option analysis  Hazard or exposure  Description of analytical methods  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CIRFS: European Man-made Fibres Association  Org. country:  Belgium  Attachment:  <redacted>  Privacy statement:  confidential comments to question 6b as mentioned above | 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 (TR No. 49913771894-86), provide here CIRFS 1st deadline for comments on specific information requests in the information note on restriction report on DMAC and NEP.. |
| Answer to specific info request 1:  a) For the companies included in Antoniou et al., 2021 and the additional median analysis provided to the dossier submitter on January 07, 2022, including confidential raw data, shows that no worker was exposed to median values above 3.6 ppm (= 13 mg/m³) in this study. Due to maintenance operational conditions during production short term higher exposure can occur, which are reflected in only 2% of workers having 90%-values above 3.6 ppm (=13 mg/m³) in 2019 (average 4,6% of workers/year in years 2012-2019 with decreasing % in more recent years) for the same raw data set. Years 2012-2019 were chosen to reflect more recent and actual situations and because BM values were provided in this consultation as confidential values in reference 4626c010-582a-43ee-b37c-6226580fb442. Four out of six Man-made fibre (MMF) companies using DMAC as a process solvent were included in Antoniou et al., 2021, but meanwhile three out of six companies have already closed the production in Europe. The latest update on closure of two MMF companies were provided to the dossier submitter before finalization of the dossier. Despite following two quotes from the final DMF-RAC-SEAC opinion: • “…SEAC does not find it likely that the proposed restriction would result in the termination of the production of man-made fibres in the EU.” • “As no closing down of the production is expected, SEAC does not find it likely that the proposed restriction will have a great impact on the man-made fibres supply chain.” the closure of three MMF companies resulted in a total loss of min. 1100 working places in Europe. We are confident that these facts will be considered by SEAC in the discussions and decisions of the DMAc restriction process. b) The very low dermal DNEL of 0.53 mg/kg bw/day is very problematic for all industries. An extremely low dermal DNEL as proposed in this restriction, 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). This would lead to closure of plants as all industrial handling requires a charging/discharging operation of liquid DMAC at some stage. For other harmonized dermal DNEL (incl. DMF) exposure calculation results in a safe industrial use (PROC 8b) if max. dermal RMM are applied (dermal and combined RCR). Consequently, they do not cause a total substance ban (via PROC 8b). Toxicological comment by CIRFS on derivation of the dermal DNEL and the BLV has been provided (See reference 9a8f7847-afe8-4aaf-be8c-2853296f8133, July 13th, 2022). In practice MMF companies already monitor the total exposure via biomonitoring as a part of the dermal exposure is even given via air skin contact if direct skin contact with liquid DMAc is completely avoided due to use of PPE. Dermal exposure to liquid DMAc in MMF production may only occurs in a non-closed system and in these cases is prevented by use of Individual Protective Equipment. Biomonitoring values, representing the overall exposure of MMF workers to DMAC by inhalation and dermal exposure, is normally measured in areas of fiber production, the workplace with the highest exposures can occur and where compliance with OELs is controlled. Biomonitoring values for workers in the highest exposure work areas, also included in the publication by Antoniou et al., 2021, generally do not exceed 25 mg NMAC/g creatinine (confidential values given in this consultation in reference 4626c010-582a-43ee-b37c-6226580fb442). This proofs that potential dermal exposure to liquid DMAC is already well prevented in the man-made fiber industry as the total exposure is below the currently established biological limits value (BLV) of 25 mg NMAC/g creatinine and it is unnecessary to lower the BLV below this value. c) We refer to the confidential raw data for Antoniou et al., 2021 provided to the dossier submitter on January 07, 2022, including additional median evaluations. Additional information can also be found in company specific CSRs. d) All RMM required within OSH and hierarchy of controls (STOP principal) are in place in MMF companies using DMAC as a process solvent, as defined in Council Directive 89/391/EEC and amendments. Additional to the OSH limit values in some countries (Council Directive 98/24/EC and amendments), in general also actual and lower DNELs are considered for RMM at the workplace as advanced RMM. Typical RMM are: Containment, General ventilation, chemically resistant gloves required when handling liquid DMAc or solutions, eye protection when handling liquid DMAc. Masks in case of high exposure situations (non-routine activities, advanced measure). Training of workers. Biomonitoring. e) Yes, biomonitoring to measure total occupational exposure to DMAC is in place in MMF companies since long time. Further information and actual measured levels between 2012-2019 have been provided (confidential values given in this consultation in reference 4626c010-582a-43ee-b37c-6226580fb442) and might be extended later during the consultation period if needed. f) We are not aware of direct methods measuring only the dermal exposure and believe that biomonitoring to measure total occupational exposure to DMAC is sufficient and a well-established method. Actual all of the companies carry out biomonitoring on their workforce and have not identified problems. None of the companies are aware of adverse health effects for their work force. Therefore, very good experience exists with biomonitoring in MMF companies to measure total occupational exposure to DMAC at the workplace. This can also be used to identify additional training needs for workers if needed. |
| Answer to specific info request 2:  a) This answer is analogue to the one given in 1.b). Additional information may be provided later during the consultation period. b) There is no information on the implementation of binding DNELs for DMF because the transition period for man-made-fibres-industry is still going on. The outlook to the end of transition forces some EU-located companies to close their production at earlier time because of missing investments. |
| Answer to specific info request 3:  a) Information have been provided during the CfE by CIRFS and individual MMF-companies. Recent analysis of alternatives concluded that there are no potential alternatives for the fiber manufacturing process. Due to the specific physico-chemical properties needed from the solvent, critical for each of the manufacturing process steps, the toxicological properties of potential alternative solvents are also very similar. We are also not aware of the use of in industrial fiber production dialkylcarbonates (e.g. polyurethane fibres etc.). See also answers to Question 5 a). b) Following the actual point of view, we do not expect a significant increase. |
| Answer to specific info request 5:  a) See our comments provided on question 3 a). As we were unable to even identify a technically feasible alternative, there was no economic feasibility to be considered See also answers to Question 3 a). If in the future any alternative might be found, they need to be able to form stable solutions of the polymer, and during “extrusion” the alternative solution need to be able to form a uniform filament (which are some of the elements of the technical feasability). The Economic feasability is strongly depending among others aspects: • pricing and availability of industrial quantities of the alternative • boiling point/vapour pressure, determining the energy needed for evaporation • stability, rectification/distillation profile (for recovery) • compatibility with existing installations, materials, etc – prerequisite not needing reconstruction of sites Replacement of DMAc with a potential alternative solvent, if developed in the future, is likely not economically feasible because of R&D time/expense to develop new commercial processes, capital investment, product requalification in multiple applications and multi-year facility outages for installation of new equipment, process optimization and commercial prove-out. Total estimated cost and capital would have a huge economic impact of minimum ≥ € 500 Million. The alternative in such scenario would probably be to shut down EU manufacturing locations and keep manufacturing with current process solvent outside EU. With the same consequences a disproportionate dermal DNELs will only block production in the EU and provide competition advantage to non-EU-productions using DMAC as a process solvent. |
| Answer to specific info request 6:  a) Local exhaust ventilation is already installed in MMF companies for fibre production with DMAC as shown to the dossier submitter during online site visit and using similar production techniques as for wet-spinning DMF plants. Further information and figures were given in SEA comments for DMF restriction (e.g. DMF ref. 2029, 2030, 2031, 2032). Adaptation and extension of exhaust ventilation might be needed within the technical limits possible to maintain a safety margin to the proposed inhalation DNEL. b) This question is answered in the confidential comments c) The information is well known at the producer of this equipment (internal confidential calculation) but not told to their customer in the man-made-fibres industry. We are only aware about the total cost. |
| Answer to specific info request 7:  a) An extremely low dermal DNEL as proposed in this restriction, leads to a substance ban in practice as even bulk charging/discharging operation in an industrial environment cannot calculated to be safe when applying the highest dermal protection foreseen in the ECETOC TRA model (glove incl. specific training). This would lead to closure of plants as all industrial handling requires a charging/discharging operation of liquid DMAC at some stage. Variation of the proposed DNEL inhalation is not expected to have a significant impact on the cost of already existing training schemes. b) See answer to a) c) See answer to a) |
| Answer to specific info request 8:  a) Because the products created by using DMAC will be available from outside the EU the technical textile industry in their role as downstream users of MMF will buy these products from non-EU-producers by imports b) Maybe there might be cost-benefit in buying products from non-EU-producers but having in mind longer lead times, reduces offering and the danger of disturbed supply chains. |
| Answer to specific info request 9:  A transition period of 4 year (comparable to the period given for implementation of DMF-DNEL) would be helpful for the companies. Decisions leading to too conservatives DNEL will have impacts independent of any transition periods as we have seen in the DMF (or DMF and DMAC) cases were some companies have closed their production at earlier times than the transition period ends. |
| Dossier submitter response:  Thank you for your comments. The data from the Antoniou et al. study was already included in the Annex XV dossier and have been taken into account by the Dossier Submitter. We disagree that our proposed dermal DNEL for DMAC would lead to a substance ban as other Operational Conditions (OC) of Risk Management Measures (RMM) could be implemented to ensure safe use of the substance as indicated in the Annex XV report.  Cost information related to the adaption and extension of exhaust ventilation for the Man-made fibre industry in relation to the DMF-restriction is informative, however, they don’t allow for a quantitative estimate without further contextual data on the required increase in ventilation rates to comply with the DMF and DMAC/NEP restriction proposals.  No justification for the request for a transition period of 4-years is provided, therefore the Background Document has not been updated. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. |
| SEAC Rapporteurs comments:  Thank you very much for your contributions to the socioeconomic analysis of this restriction. We have considered this information in the assessment of the compliance costs, specifically concerning the LEV costs. Furthermore, the information provided on RMMs already implemented because of the OSH legislation and DMF restriction was helpful for assessment of the level of compliance already reached in the different sectors of use of DMAC.  The information provided on LEV costs was taken into account when assessing proportionality of the restriction proposal for the Man-made Fibres sector and when assessing the proposal for a transitional period of 4 years instead of the 1.5 years as proposed by dossier submitter. |

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| 3588 | Date:  2022/07/18 15:29  Content:  Hazard or exposure  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Cefic/ BDO & Derivatives Sector Group  Org. country:  Belgium  Attachment: | General Comments:  The input provided to this survey is the input of the BDO & Derivatives sector group of Cefic that represents the producers of BDO, GBL, NMP, NEP and THF In Europe. Two of the members are also producers of DMAC, hence the input given below concerns both DMAC and NEP.. For simplicity, the abbreviation BDO SG will be used to denote the opinion of the BDO & Derivatives Sector Group of Cefic. |
| Answer to specific info request 1:  Especially addressing sub question c) the BDO SG likes to point to the study of Antoniou et al., 2021. Antoniou, E. E., Gelbke, H. P., Ballach, J., Zeegers, M. P., & Schrage, A. (2021). The Association Between Dimethylacetamide Exposure and Liver Toxicity: A Large Retrospective Analysis in Workers From Four European Factories. J Occup Environ Med, 63(12), e893-e898. Some results are already included in the Dossier, however, much more information can be extracted from this study: • The study provides representative data for DMAC exposure from the low to the upper range in the textile industry. • Despite the study refers to inhalative data as only air concentrations were measured, workers were exposed to DMAC under real occupational conditions, which means that they had corresponding dermal exposure to their work as well - This Dermal exposure is expected to be low due to OSH “skin notation” requiring workers to minimize dermal exposure e.g. by gloves. • No liver effects were observed even in workers with the highest exposure. This is qualitative evidence that inhalative plus dermal exposure corresponding to the work under current RMM applied are safe use of DMAC. The other sub-questions require individual company data which are not available to the BDO SG. The BDO SG has forwarded this question to its member companies and may add further comments to this question later in this consultation. Alternatively, the individual companies will submit their data. |
| Answer to specific info request 2:  Members of the BDO SG do have experience with the harmonized DNEL set in the past. The BDO SG actively participated in the development of the ECHA Guidance Document: “How to comply with REACH Restriction 71, guideline for users of NMP (1-methyl- 2-pyrrolidone)” Any industrial handling of a chemical requires a charging /discharging operation (PROC 8a/b) at some stage. For other harmonized dermal DNEL (NEP, NMP, DMF) ECTOC TRA exposure calculation results in a safe industrial use exposure scenario (PROC 8b) if max. dermal RMM are applied (dermal and combined RCR). The inappropriately low dermal DNEL for DMAC would however suggest that charging /discharging operations (PROC 8a/b) involving DMAC are unsafe even if maximum dermal RMM are applied. This is problematic and hence the socio-economic impact of the DMAC restriction will be significant. If one sticks to ECTOC TRA as exposure assessment tool the socio impact will be equivalent to total substance ban. Consequently, derivation of the dermal DNEL should be done carefully, based on experimental dermal data, discriminating between adaptative and adverse effects and taking into account all existing human occupational data. Any Biomonitoring data are individual company data and not available to the BDO SG. Individual companies will submit their data. The BDO SG may add further comments to this question later in this consultation . Any Biomonitoring data are individual company data and not available to the BDO SG. Individual companies will submit their data. The BDO SG may add further comments to this question later in this consultation |
| Answer to specific info request 3:  Basically this is individual company data and not available to the BDO SG. The BDO SG nevertheless likes to point out that most obvious alternative NMP DMF are no real win because as the toxicological properties of these alternatives are similar. Moreover, the BDO SG is not aware of other obvious generally applicable alternatives. What alternatives are suitable depends on the application or the process that uses one of the aprotic polar solvents (NMP, NEP, DMF & DMAC ). Even exchange from DMAC to DMF, NMP, NEP is not a 1:1 replacement and requires process adaptation investments for changing the plant design or might have an impact on the application. These details are however part of the knowledge of downstream user and not available to the solvent producers. For NEP the harmonized DNEL are not easy to meet. This makes NEP use unattractive which is not a factor to promote increase of NEP use but for promoting volume decrease. We nevertheless like to point that basically it is possible to adjust RMM to safely use NEP under the new conditions set by the harmonize DNEL until a suitable alternative is found. However, when a DNEL does not lead to a safe exposure level at the max. RMM in the standard model, it is likely to act as total substance ban. As result, with the currently proposed DMAC dermal exposure value, which in our opinion is scientifically unrealistically low (scientific details see attached dermal DNEL comment), we rather expect a dramatic drop of DMAC use due to indirect substance ban. This, however, is an undesirable economic impact, as based on scientific evidence, the risks related to dermal exposure are much lower than based on the proposed dermal DNEL. The BDO SG would however like to stress that it supports the implementation of harmonized DNELs. Based on the BDO SG experience and active participation to the development of the ECHA Guidance Document: How to comply with REACH Restriction 71, guideline for users of NMP (1-methyl- 2-pyrrolidone), the BDO SG Is open to actively support a similar guidance in this case as well. |
| Answer to specific info request 4:  The BDO SG is not aware of suitable substitutes. |
| Answer to specific info request 5:  No Comment – the BDO SG expects fiber producers to comment here |
| Answer to specific info request 6:  This is individual company data and not available to the BDO SG. The BDO SG may add further consolidated comments to this question later in this consultation |
| Answer to specific info request 7:  Industry workers are generally trained to use gloves (95% dermal risk reduction). Additional training cannot change dermal exposure set by the standard exposure model to be used in the exposure assessment when max dermal RMM are applied. There is no further RMM you can take if glove use by a trained industrial worker is insufficient to assess dermal exposure as safe (RCR >1) at charging discharging operation in a dedicated filling line at work for mor than 4 h (proc 8b). The BDO SG does not consider applying LEV a realistic RMM to reduce dermal exposure. Additional training only makes sense if dermal DNEL goes up. Charging and discharging operations is done at any large scale industrial use at some stage. Consequently, a DNEL that does not lead to a safe exposure level at the max. RMM in the standard model is likely to act as total substance ban. As stated under question 3, The proposed harmonized dermal DMAC DNELis – from a scientifically point of view far too low (see attachment for scientific comment on the dermal DNEL). |
| Answer to specific info request 8:  No comment for now because no information available to the BDO SG. Charging and discharging operations is done at any large-scale industrial use at some stage. Consequently, a DNEL that does not lead to a safe exposure level at the max. RMM in the standard model is likely to act as total substance ban = affecting all sectors using DMAC with max impact. |
| Answer to specific info request 9:  No comment for now because no information available to the BDO SG. The BDO SG may add further comments to this question later in this consultation |
| Dossier submitter response:  Thank you for your comments on the derivation of the dermal DNEL of DMAC. We appreciate your critical review of the derivation of the dermal DNEL of DMAC in the Annex XV report; however, we don’t agree with your assessment and proposed Points of Departures (PoDs) or change of the Biologicial Limit Value (BLV). Since new information was provided and the derivation of the dermal DNEL in the Annex XV report clearly explained, no change has been made to the Background Document.  We disagree that our proposed dermal DNEL for DMAC would lead to a substance ban as other Operational Conditions (OC) of Risk Management Measures (RMM) could be implemented to ensure safe use of the substance as indicated in the Annex XV report. |
| RAC Rapporteurs comments:  Thank you for your contribution to the Annex XV consultation. The study of Antoniou et al. has been considered in the hazard assessment. The dermal DNEL proposed by the Dossier Submitter has been modified considering the comments provided. However, RAC supports the Dossier Submitter proposal for the biomarker-DNEL for DMAC which is also targeted to protect from the developmental effects of DMAC. |
| SEAC Rapporteurs comments:  Thank you very much for your contributions. We consider the information provided on RMMs already implemented (training, PPE) because of OSH legislation and DMF restriction especially helpful. It has been useful in assessment of the level of compliance already reached in the different sectors of use of DMAC. |

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| 3590 | Date:  2022/07/20 11:06  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Other socio economic analysis (SEA) issues  Transitional period  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United Kingdom  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  because disclosure of the information would undermine the protection of your commercial interests, including intellectual property in a very competitive market with only few actors. | General Comments:  Please see the confidential attachments for our comments to the sections below for which we have information |
| Answer to specific info request 1:  Please see the confidential attachments for our comments to the sections for which we have information |
| Answer to specific info request 3:  Please see the confidential attachments for our comments to the sections for which we have information |
| Answer to specific info request 5:  Please see the confidential attachments for our comments to the sections for which we have information |
| Answer to specific info request 6:  Please see the confidential attachments for our comments to the sections for which we have information |
| Answer to specific info request 7:  Please see the confidential attachments for our comments to the sections for which we have information |
| Answer to specific info request 8:  Please see the confidential attachments for our comments to the sections for which we have information |
| Answer to specific info request 9:  Please see the confidential attachments for our comments to the sections for which we have information |
| Dossier submitter response:  Thank you for your comments and submitted information. Where relevant, the relevant Annex to the Background Document has been updated. |
| RAC Rapporteurs comments:  Thank you very much for this confidential information to the Annex XV consultation. This contribution added to the development of the RAC opinion regarding DMAC. |
| SEAC Rapporteurs comments:  Thank you very much for this confidential information to the Annex XV consultation. This contribution has been useful for us as it adds to the information used in the assessment of alternatives to DMAC. |

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| 3592 | Date:  2022/07/21 00:59  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  National Authority  Org. name:  Danish Working Environment Authority  Org. country:  Denmark | General Comments:  The proposed restriction on DMAC and NEP is setting a DNEL for workers and professional users. For DMAC the DNEL is supplementing the existing restriction by setting a maximum concentration limit in homogeneous materials (REACH annex XVII, restriction 72). No restriction exists for NEP. The proposal follows up on existing restrictions on dipolar aprotic solvents DMF, NEP and DMAP (REACH annex XVII no. 61, 71, 72). In the dossier, it is argued that since the substances have similar hazard profiles and use patterns the pro-posal offers legal consistency with these existing restrictions and further that it is complementary to existing OSH regulation. It is a general viewpoint of the Danish Working Environment Authority (DWEA) that the preferred way to regulate the risk of hazardous substances at work places should be done under the OSH regulation and that REACH or other regulations only are instruments that should be used exceptionally to complement OSH-regulation to further increase the protection of workers. In the case of DMAC and NEP we do not see that setting a DNEL value in a REACH-restriction is adding further to what can already be done under OSH regu-lation. The main reason is the recent amendment to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (the CMDR-directive). This amendment (di-rective 2022/431) entered into force in April 2022 and a consequence is that repro-toxic substances now are covered by strictest requirements for chemicals under OSH-regulation and hence also DMAC and NEP since they are classified as reprotoxic category 1B in Annex VI of CLP. A result of the change is that occupa-tional exposure limits (BOELs) now can be set for reprotoxic substances in this directive. This is as opposed to previously where the only option for this type of substances was to set indicative occupational exposure limits (IOELs) under the chemical agents directive. It is the view of DWEA that a DNEL set as a REACH-restriction does not add further to the protection of workers and professional users. Therefore these sub-stances should be regulated by setting a BOELV under CMDR. Further it should be stressed that setting a BOELV involves the tripartite dialogue in the Advisory Committee on Health and Safety at Work (ACSH) to address the feasibility of proposals and socioeconomic issues. By setting at DNEL for workers and profes-sionals under REACH, this dialogue is omitted. |
| Dossier submitter response:  Thank you for your comment. The merits of proposing a DNEL under REACH for both DMAC and NEP have been compared and assessed against the BOEL procedure under the CMDR-Directive in the Background Document. |
| RAC Rapporteurs comments:  Thank you for your comment.  The RAC opinion evaluated several options for addressing the identified risks for the use of DMAC and NEP. In the conclusion of RAC, the proposed restriction (setting workplace DNELs for DMAC and NEP and limiting the concentration of DMAC and NEP in mixtures) appeared to be the most balanced option compared to other options (full ban, occupational exposure limit values). This would also be in line with the restrictions of other similar aprotic solvents NMP and DMF.  However, RAC recommends to additionally derive corresponding BOELVs for DMAC and NEP in order to avoid confusion and address workplaces that might not be covered by this restriction. |
| SEAC Rapporteurs comments:  Thank you very much for your contribution related to alleged possible double regulation. We have taken this into account in the analysis and assessment of other regulatory options (“(Update of) OEL under OSH legislation)”. We consider setting a binding OEL (BOEL) under the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD, 2004/37/EC) as an acceptable risk management option, comparable to a harmonised DNEL. However, SEAC considers it likely that over the next 5 to 10 years, no update of the BOEL for DMAC or setting of a BOEL for NEP can be expected. Thus even if prioritised for BOEL setting, the implementation of the limit value is likely to be delayed, and consequently the identified unacceptable risks (in section 3.3) could persist. |

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| 3594 | Date:  2022/07/26 15:04  Content:  Scope or restriction option analysis  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Confederation of Danish Employers  Org. country:  Denmark | General Comments:  The proposed restriction in its parts, is not suited for REACH, but is solely a OSH matter. As reprotoxins are not included ind the CMD directive, binding limit values are now an option. In case these are set, the part of the proposal saying; "...downstream users are to implement appropriate risk management measures ensuring exposure of workers remains below the specified DNEL(s)" will be fully covered by the directive, which is already in place. It is therefore strongly suggested, to address this matter by way of the OSH legislation, following the established practice of involving the social partners in setting OEL's and BOEL's. At the same time, this would be more in line with articled 153 in the treaty, that states that EU-measures to protect workers health is by minimum directives. |
| Dossier submitter response:  Thank you for your comment. The merits of proposing a DNEL under REACH for both DMAC and NEP have been compared and assessed against the BOEL procedure under the CMDR-Directive in the Background Document. |
| RAC Rapporteurs comments:  Thank you for your comment.  The RAC opinion evaluated several options for addressing the identified risks for the use of DMAC and NEP. In the conclusion of RAC, the proposed restriction (setting workplace DNELs for DMAC and NEP and limiting the concentration of DMAC and NEP in mixtures) appeared to be the most balanced option compared to other options (full ban, occupational exposure limit values). This would be also in line with the restrictions of other similar aprotic solvents NMP and DMF.  However, RAC recommends to additionally derive corresponding BOELVs for DMAC and NEP in order to avoid confusion and address workplaces that might not be covered by this restriction. |
| SEAC Rapporteurs comments:  Thank you very much for your contribution concerning alleged possible double regulation. We have considered the matter and taken it into account in the analysis and assessment of other regulatory options (“(Update of) OEL under OSH legislation)”. We consider setting a binding OEL (BOEL) under the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD, 2004/37/EC) as an acceptable risk management option, comparable to a harmonised DNEL. However, SEAC considers it likely that over the next 5 to 10 years, no update of the BOEL for DMAC or setting of a BOEL for NEP is to be expected. Thus even if prioritised for BOEL setting, the implementation of the limit value is likely to be delayed, and consequently the identified unacceptable risks (in section 3.3) could persist. |

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| 3597 | Date:  2022/08/08 12:17  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CIRFS: European Man-made Fibres Association  Org. country:  Belgium  Attachment: | General Comments:  CIRFS European Man Made Fibres Association (TR No: 40197342894048), in agreement with IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (TR No. 49913771894-86), provide here CIRFS additional median analysis for Antoniou et al., 2021 mentioned in ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743, question 1 a) now as public available letter to editor for the restriction report on DMAC and NEP. |
| Answer to specific info request 1:  Please find attached additional median analysis for Antoniou et al., 2021 mentioned in ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743, question 1 a) which was now has been published in Journal of Occupational and Environmental Medicine in Vol. 64, No. 8, August 2022 as free public available letter to the editor under https://journals.lww.com/joem/Fulltext/2022/08000/The\_Association\_Between\_Dimethylacetamide\_Exposure.27.aspx |
| Answer to specific info request 2:  See ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743 for first comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 3:  See ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743 for first comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 6:  See ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743 for first comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 7:  See ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743 for first comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 8:  See ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743 for first comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 9:  See ref. 52f533a4-3ac6-40ff-a2cd-e6a4e4408743 for first comments. Additional information may be provided later during the consultation period. |
| Dossier submitter response:  Thank you for your comments. The data from the Antoniou et al. study and the additional median analysis was already included in the Annex XV dossier and have been taken into account by the Dossier Submitter. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. This additional evaluation of the Antoniou et al., 2021 data set is helpful for the evaluation of the DMAC exposure in the man-made fibre sector. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |

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| 3602 | Date:  2022/08/30 15:28  Content:  Hazard or exposure  Baseline  Information on alternatives  Information on benefits  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  We welcome the opportunity to provide input to a possible restriction of DMAC within this consultation. This statement is focused on the use of DMAC in the highly specialized manufacturing process of medical membranes. Such high-quality membranes are required for individuals undergoing hemodialysis because of chronic kidney failure, a condition that affects approx. 3 million individuals worldwide. Without a regular dialysis treatment, a chronic kidney failure will lead to death.  (A) Specific technical, regulatory and socio-economic situation of medical membranes:  One of the most crucial elements in hemodialysis (a treatment where the blood is filtered outside the body) is the filter (dialyzer) acting as an artificial kidney. Blood flows through as many as 20,000 extremely fine hollow fiber membranes clustered in a plastic tube. Pores in the membrane filter the life-threatening metabolic toxins and excess water from the blood. To prevent fatal complications, each patient undergoing hemodialysis needs around three new dialyzers per week. More than 100,000 patients in the European Union and more than 500,000 patients worldwide are regularly treated with dialyzers from DMAC-based production in the EU, depending on the performance and reliability of the treatment and the medical devices used. DMAC is an essential solvent used in the highly specialized, strictly controlled, and regulated manufacturing of the dialyzer membranes. The membranes must fulfill the strictest criteria with regards to safety, biocompatibility, treatment outcome and medical treatment costs worldwide. Highly specialized manufacturing processes transform selected polymers into the membranes with defined properties crucial for required medical performance and safety. Resulting intensive blood contact, needed safety, biocompatibility and treatment outcome (e.g., selectivity and medical performance) are very demanding and require highly specialized medical membranes. Consequently, the concerned manufacturing process and membranes are not at all comparable with non-hollow fiber spinning like garments. This applies on related technological details, the assessment of alternatives as well as the socioeconomic consequences.  This specific technical, regulatory, and socio-economic situation of medical membranes should be taken into account in the restriction process for DMAC. Data, examples and technology and theoretic substitution studies from other applications cannot be simply transferred to medical membranes. The dossier (Annexes to the Annex XV Restriction Report) also includes several misleading or incorrect claims which should be corrected, e.g.: Section B.9.8.1 (p. 121): Dialysis membranes are mentioned under “films” but hemodialyzer membranes are always hollow fiber membranes and not films. Section C.2.1.1. (p. 152): The relevant production technology (hollow fiber membrane spinning) is missing in the description of spinning. Section C.2.2.1. (p. 158): PP and PTFE cannot be dissolved in DMAC according to our data.  (B) Inconsistency between OHS and REACH – No uncontrolled risks:  The existing EU legislation on occupational safety and on medical devices already comprehensively regulates safety and risk control during manufacturing and use of the concerned medical devices and the materials used in manufacturing. Furthermore, occupational exposure to DMAC is already subject to strict national OHS legislation. Binding limit values are in place and already ensure that professional use of DMAC is safe, especially in France and Germany where major production sites for medical membranes are located. The limit values for inhalative exposure in Germany have been recently revised after review by the responsible expert committee (OEL: 18 mg/m³, BLV: 25 mg/l; see e.g., Walter D, Drexler H, Hartwig A, MAK Commission. N,N-Dimethylacetamide – Addendum for re-evaluation of the BAT value. Assessment Values in Biological Material – Translation of the German version from 2020. MAK Collect Occup Health Saf. 2020 Oct;5(3):Doc058. DOI: 10.34865/bb12719e5\_3ad). Consequently, we have no reason to believe that uncontrolled risks exist if current exposure to DMAC complies with such applicable OHS requirements and we assume that a further regulation of DMAC would not result in an improvement in safety and risk control.  EU occupational exposure limit values (IOELVs) have been based on the most sensitive toxicity endpoints, e.g., respiratory tract irritation, as such adverse effects are manifested at dose levels much lower than the levels that would trigger developmental effects. (see European Chemicals Agency: Background document for N,N-Dimethylacetamide (DMAC); 11/2012) Furthermore, available monitoring data show that existing uses of DMAC in medical membrane production are safe. Experience with real exposure and biological monitoring shows that the exposure tends to be significantly overestimated by REACH-based models, not at all underestimated as claimed in the dossier (see e.g., pages 44/45). The uncontrolled risks described in the dossier seem to be mostly based on old (no more representative) data, conservative modelling, and the usage of high safety factors. We are seriously concerned due to this overestimation of exposure in combination with derivation of too strict DNEL in the dossier. This impedes formally proving compliance via exposure scenarios / CSR and can cause serious organisational and technical burden - without really improving safety at work.  (C) Inhalative DNEL:  Regardless of these weaknesses and the inconsistency between OHS and REACH, it’s positive that the proposed air/inhalative limit is in the upper range (DNEL 13 mg/m3). Evaluating this value alone (without the combined impact of the dermal DNEL, see below), it is assumed to be feasible/already fulfilled according available air and biological monitoring and exposure modelling.  (D) Dermal DNEL too strict and with unclear basis:  The dermal limit (DNEL of 0.53 mg/kg bw/day) is significantly tightened and very low. The toxicological rationale for this reduction (and a possible even 5-times lower DNEL as discussed as in the dossier; see page 95) is not clear. The result of selected methodology, toxicological studies and safety factors is not conclusive from our point of view: The inhalative DNEL would allow a daily intake of 130 mg/day (13 mg/m3 x 10 m3/8h-workday) while the dermal DNEL equals only 29% (0.53 mg/kg bw/day x 70 kg). We ask to review the dermal DNEL to a come to a consistent and feasible, significantly higher level.  (E) Enforcement and derived BLV:  A combined RCR for inhalative and dermal exposure is a theoretical value and could not be measured in real-life. So, we highly appreciate that the dossier submitter took into account feasibility of monitoring. The derived biological limit value (BLV for the metabolite NMAC in urine) would allow monitoring compliance in reality. Due to applicable BLVs under OHS legislation such biological monitoring is established for many years. Nevertheless, the biological limit value as proposed in the dossier includes two weaknesses: a) The BLV is proposed to be part of the formally binding restriction, i.e., it’s status in case of enforcement is unclear. Legal certainty is needed and would require inclusion of the BLV and its status in DMAC’s Annex XVII entry (“Compliance with paragraph 2 and both binding DNELs is given if the BLV is met at the end of the exposure/shift.”). b) Due to additional safety factor applied, the value proposed (15 mg NMAC/g creatinine) is much lower than the value expected by us. The proposal equals an inhalative exposure of approx. 5 mg/m³ (safety factor 2.5 instead of 1.5-1.8) due to the non-linear relationship between exposure and NMAC: NMAC [mg/l urine] = (37.8 x 17 x DMAC [ml/m³]) / (37.8 + (17 x DMAC [ml/m³])) as e.g., described in the re-evaluation of the German BLV in 2020 (see: Walter D, Drexler H, Hartwig A, MAK Commission. N,N-Dimethylacetamide – Addendum for re-evaluation of the BAT value. Assessment Values in Biological Material – Translation of the German version from 2020. MAK Collect Occup Health Saf. 2020 Oct;5(3):Doc058. DOI: 10.34865/bb12719e5\_3ad) |
| Answer to specific info request 1:  The exposure to DMAC during work is very limited and in compliance with the currently applicable occupational health and safety requirements. Implemented risk management measures ensuring “adequate control” include technical, organizational, and personal measures. Measures for activities with the most relevant (potentially high) DMAC exposure include amongst others: \* closed plants with exhaust-air control and treatment in membrane production and regeneration during standard operation: DMAC-relevant workplaces are limited to maintenance and start-up processes in production when manual activities at open lids are required (representing a minor part of the total operations time). \* personal protection equipment (PPE) to prevent inhalation or dermal exposure: Used PPE depends on the possible exposure, is thoroughly selected, and complies with the legally binding requirements. Thus, for example, whole-body coveralls and respiratory protection are worn during maintenance and start-up processes. Possible dermal exposure is already adequately taken into account. Selection and usage time of gloves consider the specific resistance and penetration time of DMAC, ensuring very efficiency of the risk reduction measures. Our production is based on state-of-the-art technology and in compliance with the applicable occupational health and safety requirements and current exposure limits, as described above. We are also continuously working on further optimization whenever possible, e.g., when production lines are newly built or upgraded. Anyhow, options to introduce further technical or organizational reduction measures, exceeding the described concepts, are very limited. We are not in the position to categorize described measures as “typical” or “advanced”, as requested for this question. Obviously, significant efforts are taken to protect workers and to minimize exposure to DMAC. On the other hand, these measures are in line with applicable OHS regulations, i.e., the measures should be expected to be implemented (as applicable) by any industrial user of DMAC in the European Union. Compliance with current binding national exposure limits, derived in line with the European IOEL (Indicative Occupational Exposure Limits) for DMAC, is closely monitored in-house and supervised by the competent authorities and occupational insurance association. Applicable inhalative exposure limits include 8h-TWA of 5 ppm / 18 mg/m³ (Germany) and 2 ppm / 7.2 mg/m³ (France). In addition, short-term peak exposure (15 minutes) is limited at 10 ppm / 36 mg/m³ (Germany and France). Regularly conducted biomonitoring of employees (NMAC in urine) after most relevant DMAC activities (potentially high exposure) confirms that applicable limit values and existing DNEL for DMAC are safely fulfilled for all exposure routes. The real exposure data also indicates that exposure models applied for REACH over-estimate the (especially dermal) exposure. Models are very cautious and do not sufficiently take into account the actual effectiveness of applied safety concepts including use of personal protective equipment at real workplaces. Due to the weaknesses of the models (overestimating exposure) and the DNEL derivation (application of high safety factors, etc..), the uncontrolled risks and the need for further action as described in the restriction dossier for DMAC do not exist in reality in the production of medical membranes. We are not aware of methods to measure real dermal exposure. Consequently, the binding status and feasible level of the BLV (see general comments) for the indirect measurement (via biomonitoring) and a realistic exposure modelling are crucial for the production of medical membranes and for enforcement of the planned REACH restriction of DMAC. Please also refer to the information already provided by us in the call for evidence and previous consultations. |
| Answer to specific info request 2:  Our experience with NMP, from a regulatory perspective, has been that: a) The proposed DNELs showed a large variability in the course of the legislative process. The finally binding DNELs and their difference to applicable, existing OHS requirements have hardly been predictable in the process, especially for downstream users with limited toxicological expertise. b) The range of the binding DNELs for inhalative and dermal exposure seemed to be much more consistent than the current proposals for DMAC. c) Implementation and internal compliance control (as well as enforceability by authorities) of the restriction has been made more difficult because the related biological limit value (BLV) was only included in the non-binding guidance on NMP. In general, the future regulation of DMAC should not lead to discrimination of DMAC compared to other, comparable aprotic solvents. A restriction with mandatory DNELs might be consistent with the (proposed) restrictions of NMP and DMF. Nevertheless, the individual case needs to be taken into account because a de facto ban of DMAC (e.g., derivation of unfeasibly low binding DNELs) can pose a critical burden for concerned medical device production and can endanger supply of needed lifesaving devices, especially for end stage renal disease patients in the European Union and worldwide. |
| Answer to specific info request 3:  a) There is no alternative for DMAC used in production of concerned medical membranes. Possible future or existing options to substitute DMAC by other solvents in other applications or sectors are not at all meaningful for concerned medical membranes. “Drop-in” substitution in such medical technology is not possible for technical, regulatory and safety reasons. DMAC-based medical membranes must fulfill the strictest criteria with regards to safety, biocompatibility, treatment outcome and medical treatment costs worldwide. All these aspects are significantly influenced by the membrane material and structure. Only few polymers on an industrial scale meet the requirements for state-of-the-art membranes for the concerned medical devices. Highly specialized solvent-based manufacturing processes transform these polymers into the membranes with defined properties crucial for required medical performance and safety. Solubility of the polymers and the solvent’s influence on the membrane properties (e.g., pore structure, surface chemistry, permeability, selectivity) restrict the selection of solvents. Less hazardous solvents meeting the medical, technical and regulatory requirements for the concerned membranes are not available. This has been comprehensively tested by our R&D experts. Significant alternative membranes for the described applications are currently only produced using NMP (1-methyl-2-pyrrolidone). NMP is classified as reproductive toxic and subject to a REACH restriction. Due to the technical and regulatory conditions also NMP is not able to substitute existing use of DMAC in production of medical membranes. A time and cost intensive research, development, risk control, including clinical trials and technical modifications of equipment would be needed in case of substitution of DMAC in these highly specialized and customized production processes. Current state-of-the-art membrane technologies required approximately 20 years between first research and development and the broad use of the new technology. Even with such a long project timeline, there would not be a guarantee for the successful substitution of DMAC-based membrane technology, i.e. that results are comparable especially with regards to safety, biocompatibility and medical treatment outcome. Content of the dossier (see e.g., Annexes to the Annex XV Restriction Report, p. 164) should be corrected or specified accordingly to reflect the described lack of alternatives. b) DMAC will remain essential for production of medical membranes and we expect a constant slight increase of the related DMAC demand in the EU in the foreseeable future, based on market growth worldwide. |
| Answer to specific info request 5:  As mentioned above, there is no alternative for DMAC used in production of concerned medical membranes. Examples from other applications and theoretic substitution studies are misleading and do not take into account the technical and regulatory conditions and their criticality for medical performance and safety. In contrast to the claim in the Annex XV Restriction Report (see page 63), it is also highly questionable that substitution of DMAC in these applications would be economically feasible at today's margins, taking into account the needed investment in the transition (time and cost intensive research, development, risk control, including clinical trials), the following needed investment in the changed production processes/equipment (while safeguarding in parallel production and supply) and the regulatory risks. |
| Answer to specific info request 6:  Local exhaust ventilation systems (LEV) are already installed in DMAC-relevant workplaces. With regards to the currently proposed inhalation DNEL only, no need to install or adapt LEV is expected to meet this air/inhalation limit. Anyhow, due to the proposed extremely low dermal DNEL and the legal need to ensure a combined RCR below 1, impact on LEV systems cannot be fully excluded. NB: In case of an extreme reduction of the inhalative DNEL (lower part of range A as discussed in the CfE, 2020), this would also affect production areas and workplaces outside/without any DMAC use. There, exposure is limited to very low fugitive emissions. Complex, completely new technical solutions for climate control and ventilation would be required to reduce such minimal air concentrations in existing buildings and facilities, resulting in significant costs (several million EUR plus high interference with operations during installation). |
| Answer to specific info request 7:  At our concerned production sites for manufacturing of medical membranes with DMAC, adequate OHS training is already required and established in line with applicable OHS regulations on a regular basis. This also covers dermal exposure and use of required PPE. Experience with the restriction of MDI under REACH shows that the additional definition of extensive, inflexible OHS training requirements under REACH in parallel to already applicable OHS regulations can result in disproportionally high training efforts and constraints. Such efforts and possible inconsistencies between REACH and OHS training requirements would not increase safety and risk control for DMAC. Additional lengthy training sessions and duplicated training for DMAC, which are needed for formal reasons only, can even be counterproductive with regards to the training effectiveness. |
| Answer to specific info request 8:  High-quality medical membranes are required for individuals undergoing hemodialysis because of chronic kidney failure. Without a regular dialysis treatment, a chronic kidney failure will lead to death. More than 100,000 patients in the European Union and more than 500,000 patients worldwide are regularly treated with dialyzers from DMAC-based production in the EU, relying on the performance and reliability of the treatment and the medical devices used. More details with regards to lack of alternatives, possible no-use scenarios for DMAC and related serious socio-economic impacts have been shared in prior consultations/call for evidence. Besides this major, life-threatening impact on patients, further negative impacts on concerned medical devices manufacturers and healthcare institutions would be expected in case of discontinued use of DMAC. |
| Answer to specific info request 9:  The time needed to comply with the new restriction of DMAC and/or to avoid negative socioeconomic impacts (e.g., a possible interference with the life-saving treatment of patients) highly depends on the specific provisions of the future restriction (binding DNEL, possible additional conditions/exemptions etc.). Proposed standard transitional time of 18 months is expected to be too short if significant additional actions are needed. Considering current constraints in global supply chains and lack of technical staff, this especially applies if technical measures like additional LEV would be required. The “long period between the implementation of the NMP restriction, the Commission general RMOA on the polar aprotic solvents, the preparatory work for this restriction including several stakeholder consultations” (as stipulated in the Annex XV restriction report, p.87) do not justify short transitional periods for DMAC. We expect that many other concerned users of DMAC to monitor the substance’s regulation and to review the related OHS situation, like we do, for years. Anyhow, correct identification and implementation of required actions to ensure legal compliance with a new binding restriction (e.g., DU-CSR, investment in additional LEV, roll-out of training or changes in work organisation or exposure monitoring) require legal certainty, i.e., an effective amendment of REACH Annex XVII. Such measures cannot be just based on vague intentions, also considering the experience of NMP with significant changes of derived DNEL values within its dossier preparation and evaluation (see above). In addition, some needed actions by downstream users will also depend on upstream suppliers’ actions (especially update of CSR and SDS by manufacturers). Defined transitional periods for DMAC should also take into account the socio-economic consequences (see section 8) if a too short transitional period results in an interruption of supply of life-saving devices. |
| Dossier submitter response:  Thank you for your comments and your observations of incorrect information in the Annex XV dossier. These have been adjusted where relevant in the updated Annex to the Background Document.  Thank you for indicating the proposed inhalation DNEL for DMAC is feasible to comply with without the need to install or adapt local exhaust ventilation. We agree legal certainty is needed for the status of the proposed BLVs. The Dossier Submitter therefore recommends updating the NMP guideline to include the BLVs for DMAC and NEP in analogue with NMP.  The Annex to the Background Document has been updated to include the lack of alternatives for the medical membrane production. |
| RAC Rapporteurs comments:  Thank you for your detailed contribution to the Annex XV consultation.  The RAC opinion evaluated several options for addressing the identified risks for the use of DMAC and NEP. In the conclusion of RAC, the proposed restriction (setting workplace DNELs for DMAC and NEP and limiting the concentration of DMAC and NEP in mixtures) appeared to be the most balanced option compared to other options (full ban, occupational exposure limit values). This would be also in line with the restrictions of other similar aprotic solvents NMP and DMF.  However, RAC recommends to additionally derive corresponding BOELVs for DMAC and NEP in order to avoid confusion and address workplaces that might not be covered by this restriction.  RAC has noted the comments related to the derivation of dermal DNELs and considered those when preparing RAC proposal for dermal DNELs. With regards to biomarker DNELs, the value proposed by RAC for DMAC is only slightly lower than the value proposed by the German MAK-Commission (25 mg/L). Biomarker DNELs have not been included in the proposed conditions of the restriction. RAC has proposed ECHA to update NMP guidance on how to comply with the REACH restriction to include also these other aprotic solvents. This guidance will give more information on the status and use of different DNELs, including biomarker DNELs.  The planned restriction is not a full ban of all uses of DMAC. It offers a high level of flexibility for downstream users to implement appropriate risk management measures (RMM) where needed and adapt operational conditions (OC) to ensure exposure below the respective DNELs. RAC is of the opinion that the use of DMAC as solvent in the manufacturing process of medical membranes is not affected by the described restriction, as the provided data indicates that the RMM and OCs in place are already sufficient to comply with the obligations. |
| SEAC Rapporteurs comments:  Thank you very much for your contribution concerning alleged possible double regulation. We have considered the matter and taken it into account in the analysis and assessment of other regulatory options (“(Update of) OEL under OSH legislation)”. We consider setting a binding OEL (BOEL) under the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD, 2004/37/EC) as an acceptable risk management option, comparable to a harmonised DNEL. However, SEAC considers it likely that over the next 5 to 10 years, no update of the BOEL for DMAC or setting of a BOEL for NEP is to be expected. Thus even if prioritised for BOEL setting, the implementation of the limit value is likely to be delayed, and consequently the identified unacceptable risks (in section 3.3) could persist.  Furthermore, the information provided on RMMs already implemented because of OSH legislation was helpful for assessment of the level of compliance already reached in the Production of medical membranes sector. We have considered this information as indication that in this sector no further adaption of RMMs (especially LEV, training) would be necessary to comply especially with the proposed inhalation DNEL.  SEAC takes note of the benefits of medical membranes for individuals undergoing hemodialysis because of chronic kidney failure.  Based on the information provided an assessment whether a longer than 18 months transitional period would be needed to adapt to the conditions of the restriction was not possible.  Thank you also very much for your contributions to the alternatives assessment. |

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| 3603 | Date:  2022/09/01 14:16  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CIRFS: European Man-made Fibres Association  Org. country:  Belgium | General Comments:  CIRFS European ManMade Fibres Association (TR No: 40197342894048), in agreement with IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (TR No. 49913771894-86) and together with STO expert of Cefic/ BDO & Derivatives Sector Group provide follow-up comments after RAC-62\_REST\_WG on the proposed biological limit value. |
| Answer to specific info request 1:  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. Additionally, the number of available biomonitoring studies in 1995 was very limited and a careful recommendation with a bias to lower limit value concentrations was reasonable. In the meantime, more studies on occupational DMAC exposure are available and should be used in an overall evaluation of biomarker levels and effects: The determination of airborne DMAC as well as NMAC analyses in urine have been carried out routinely for many years using the limit values then in force (5-10 ppm and 25-30 mg/g creatinine); e.g. confidential biomonitoring data were submitted prior to the first deadline for commenting this Annex XVII report. In 2019 the MAK value was set to 18 mg/m3 (Hartwig and MAK commission, 2019). Prenatal effects are still unlikely when the limit value is observed (Pregnancy Risk Group C), as long as skin contact is avoided. The BAT value was re-evaluated in 2020 and set to 25 mg NMAC + HMMAC/L urine (Walter et al., 2020; restriction dossier p. 35). With the correction factor of 1.2 for a mixed group, this is similar to the former BAT value of 30 mg NMAC + HMMAC/g creatinine in the postshift urine (DFG, 2010: MAK collection Part VI: BAT Value Documentation, Vol. 5). From our point of view, the question whether systemic toxicity occurs at doses equivalent to urinary NMAC levels below 25-30 mg/g creatinine remains to be elucidated and should be addressed in a thorough review of the existing data. A further decrease of the BLV might lead to an overestimation of the human health risk. |
| Dossier submitter response:  Thank you for your comments. The submitted biomonitoring data (#3586) did not allow an assessment of the relation between external exposure and biomonitoring values for DMAC. Therefore, our derivation of the BLV for DMAC did not change. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. We have noted the available data on the biomonitoring levels and also MAK Commission recommendation on the BAT value. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |

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| 3604 | Date:  2022/09/01 14:25  Content:  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CIRFS: European Man-made Fibres Association  Org. country:  Belgium  Attachment:  <redacted>  Privacy statement:  Please see Antoniou et al, 2021 and summary given in PC ref. 3587 as well as published letter to the editor with median analysis provided in in this PC on 08.08.2022, with ref. d386f6fb-f2d0-4da7-bb90-7ef20e818504) for the raw data provided here. Short summary from PC ref. 3587: "For the companies included in Antoniou et al., 2021 and the additional median analysis provided to the dossier submitter on January 07, 2022, including confidential raw data, shows that no worker was exposed to median values above 3.6 ppm (= 13 mg/m³) in this study. Due to maintenance operational conditions during production short term higher exposure can occur, which are reflected in only 2% of workers having 90%-values above 3.6 ppm (=13 mg/m³) in 2019 (average 4,6% of workers/year in years 2012-2019 with decreasing % in more recent years) for the same raw data set." | General Comments:  CIRFS European ManMade Fibres Association (TR No: 40197342894048), in agreement with IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (TR No. 49913771894-86), provide here confidential raw data for the epidemiological study on exposure and health effects of Antoniou et al., 2021 and the additional public available median analysis provided in this PC under ref. d386f6fb-f2d0-4da7-bb90-7ef20e818504 . |
| Answer to specific info request 1:  Confidential raw data and supporting “Codebook for all variables” were provided to the DS already on 24.03.2021 also to forward to RAC. An additional median analysis for the for 8h-TWA exposure measurements were provided to the DS on January 07, 2022 which is now published and was provided in in this PC on 08.08.2022, with ref. d386f6fb-f2d0-4da7-bb90-7ef20e818504). To be fully transparent we submit this confidential data and “Codebook for all variables” again in this PC comment. |
| Answer to specific info request 2:  See former PC comment by CIRFS. Additional information may be provided later during the consultation period. |
| Answer to specific info request 3:  See former PC comment by CIRFS. Additional information may be provided later during the consultation period. |
| Answer to specific info request 5:  See former PC comment by CIRFS. Additional information may be provided later during the consultation period. |
| Answer to specific info request 6:  See former PC comment by CIRFS. Additional information may be provided later during the consultation period. |
| Answer to specific info request 7:  See former PC comment by CIRFS. Additional information may be provided later during the consultation period. |
| Answer to specific info request 8:  See former PC comment by CIRFS. Additional information may be provided later during the consultation period. |
| Answer to specific info request 9:  See former PC comment by CIRFS. Additional information may be provided later during the consultation period. |
| Dossier submitter response:  Thank you for your comments. The data from the Antoniou et al. study and the additional median analysis was already included in the Annex XV dossier and have been taken into account by the Dossier Submitter. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |

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| **3605** | **Date:**  2022/09/02 13:07  **Content:**  Hazard or exposure  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  CIRFS: European Man-made Fibres Association  **Org. country:**  Belgium  **Attachment:**    <redacted>  **Privacy statement:**  The summary is given in a non-confidential attachment. | **General Comments:**  CIRFS European ManMade Fibres Association (TR No: 40197342894048), in agreement with IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (TR No. 49913771894-86), provide here confidential CSR information as a first example of tier 2 and tier 3 exposure and risk assessments in the Man-made fibre industry using DMAc as a process solvent. The summary is given as non-confidential attachment. All information in this PC comment complements the PC comments already contributed by CIRFS/IVC on exposure and risk considerations under Reach and OSH. |
| **Answer to specific info request 1:**  See non-confidential summary and confidential attachments |
| **Answer to specific info request 2:**  See former PC comment by CIRFS. Additional information may be provided later during the consultation period |
| **Answer to specific info request 3:**  See former PC comment by CIRFS. Additional information may be provided later during the consultation period |
| **Answer to specific info request 5:**  See former PC comment by CIRFS. Additional information may be provided later during the consultation period |
| **Answer to specific info request 6:**  See former PC comment by CIRFS. Additional information may be provided later during the consultation period |
| **Answer to specific info request 7:**  See former PC comment by CIRFS. Additional information may be provided later during the consultation period |
| **Answer to specific info request 8:**  See former PC comment by CIRFS. Additional information may be provided later during the consultation period |
| **Answer to specific info request 9:**  See former PC comment by CIRFS. Additional information may be provided later during the consultation period |
| **Dossier submitter response:**  Thank you for your comments and information. The data from Chemical Safety Report was already included in the Annex XV dossier and have been taken into account by the Dossier Submitter. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. the contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. |
| **SEAC Rapporteurs comments:**  No comment since this contribution addresses RAC issues. |

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| **3609** | **Date:**  2022/09/12 12:34  **Content:**  Hazard or exposure  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  EWWA  **Org. country:**  Belgium  **Attachment:**  <redacted> | **General Comments:**  EWWA is the european winding wire association. A european organisation, representing 80 % of the european winding wire producers https://www.ewwa.be  1.) All data , details and comments refer exclusively to DMAC since NEP is not used in winding wire enamels 2.) DMAC as a part of the solvent system in the varnish receipt can only be replaced with NMP and vice versa. Solvents are mandatory for the production of winding wires |
| **Answer to specific info request 1:**  a.) 3375 employees based on EWWA members are inhalation exposed, we have to add estimated 1045 inhalation exposed of none EWWA members-> 4220 employees b.) 3798 of employees could have a dermal exposure c.) We have deposited information on this in the confidential section. d.) based on the risk management measures after NMP restriction process - measures against NMP guideline are valid, (e.g. closed production system, PSA, ventilation, air flow, respiratory equipment) e.) Biomonitoring is a very sensitive topic in occupational safety. Biomonitoring is currently not used in daily practice in the winding wire industry. It is used for some very use very specific laboratory chemicals. Here, for example, the German Occupational Medicine Ordinance provides for the use of biomonitoring to monitor exposure to hazardous substances from people who regularly come into contact with this substance. However, this requires the consent of the person concerned. These measuring results are strictly confidential! We cannot see that biomonitoring is a useful instrument to ensure adequate control on exposure. |
| **Answer to specific info request 2:**  we refer to the NMP restriction process. EWWA was heavely involved. Experiences should be known, we refer to to ECHA document “How to comply with REACH Restriction 71, guideline for users of NMP”. The transition is ongoing. Measures to implement the NMP Directive have been initiated in all factories |
| **Answer to specific info request 3:**  a.) DMAC can only be replaced by NMP. Increasing the NMP content in the solvent formulation would make compliance with the new NMP limits impossible. b.) DMAC is part of the solvent system in high performance enamels for high performance applications (e.g. e-drives in e-cars) - This big technical trend will lead to an increase in wire volumes with this insulation type and thus also to an increased consumption of the corresponding DMAC-containing wire enamels. |
| **Answer to specific info request 5:**  There is currently no known economically feasible alternative for non-solvent based insulation for winding wires. There are currently no known alternatives for DMAC other than replacing it with NMP |
| **Answer to specific info request 6:**  We refer to the measures for the implementation of the NMP Directive. All necessary measures to comply with the NMP limits are also effective for the DMAC emissions. The adaptation of the conditions in the process, infrastructure and individual protective measures are being implemented or have already been carried out. |
| **Answer to specific info request 8:**  Varnish suppliers have to replace DMAC by NMP. This leads to a change in the solvent system. This means that the insulation system loses its approval. New varnish systems would have to be tested at great expense and validated by our customers - OEMs! Especially for safety-relevant components such as ABS and electric drives, this means years of approval procedures with immense costs. |
| **Answer to specific info request 9:**  It is vital that no considerable costs (connected with a lower limit value for DMAC) would be imposed on the industry for reasons lying in the economically bad situation, even before Covid-19 but in particular now. We would like to point out that two winding wire installations in the EU have closed in 2020! There is also a great danger that winding wire productions will be moved to non-EU countries due to cost pressures and environmental requirements. |
| **Dossier submitter response:**  Thank you for your comments and information. The information on the number of workers potentially exposed has been incorporated in the updated Background Document and relevant Annexes. |
| **RAC Rapporteurs comments:**  Thank you for your contribution to the Annex XV consultation. We are aware of the ethical issues related to the use of biomonitoring data. However, these challenges can be overcome. We consider it useful method to support the exposure assessment and inhalation measurements. Biomonitoring DNELs (or obligation for biomonitoring) are not included in the conditions of the restriction. |
| **SEAC Rapporteurs comments:**  Thank you very much for your contributions to the alternatives assessment, and to the discussion about biomonitoring. We have reflected on legal requirements of biomonitoring in chapter on the analysis and assessment of other regulatory options (“(Update of) OEL under OSH legislation)”.  The information provided on RMMs already implemented because of the NMP restriction and NMP guidance document was helpful for assessment of the level of compliance already reached in the electrical wire coating sector. We considered this information as an indication that in this sector no significant further adaption of RMMs (especially LEV, training) would be necessary to comply given the proposed inhalation DNEL. |

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| 3654 | Date:  2022/10/28 18:44  Content:  Scope or restriction option analysis  Hazard or exposure  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  CIRFS: European Man-made Fibres Association  Org. country:  Belgium  Attachment: | General Comments:  Cefic BDO & Derivatives Sector Group and CIRFS: European Man-made Fibres Association provide a joint follow up comment on toxicological considerations to the biomarker DNEL for DMAC in attached documents based on additional scientific arguments and additional scientific literature, which complements earlier comments in the PC supplied by the BDO&Derivatives Sector Group of Cefic with the reference 3588, by CIRFS with reference 3584 and a joint Cefic/CIRFS comment with reference 3603 after the RAC-62\_REST\_WG. |
| Answer to specific info request 1:  The American BEI committee (ACGIH) and the German MAK commission (DFG) preferably use human biomonitoring studies for setting limit values in biological materials, essentially in the same way as proposed in the restriction report. Limit values in biological materials are usually either health-based (if systemic effects are reported in the studies) or they relate to the respective health-based limit value of a substance in workplace air (e.g., “BAT values are based on a relationship between external and systemic exposure or between the systemic exposure and the resulting effect of the substance.”). Both expert groups follow the average value concept in the derivation of the biological limit values (with few exceptions); the MAK commission changed its former approach from using the upper limits of the confidence interval of the biomarker concentration at a given concentration of a substance in air to the average value concept only some years ago (“The derivation of the BAT value is based on the average of systemic exposures.”). The reason for this adaptation was the fact that limit values in biological material do not allow for a strict differentiation between critical and non-critical biomarker concentrations on an individual level. The former German BAT values were ‘maximum values’, not to be exceeded. Now the BAT value “is exceeded when, following several individual examinations, the average concentration of the parameter is greater than the BAT value; measured values greater than the BAT value must be evaluated in relation to occupational‐medical and toxicological data. Adverse effects on health can not necessarily be deduced from one single excursion above the BAT value.”. This approach is basically the same as that of the ACGIH BEI committee. In the restriction report, the derivation of the so called “biological limit value (BLV)” differs compared to these established procedures: 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. Additionally, the number of available biomonitoring studies in 1995 was very limited and a careful recommendation with a bias to lower limit value concentrations was reasonable. In the meantime, more studies on occupational DMAC exposure are available and should be used in an overall evaluation of biomarker levels and effects, e.g. Antoniou et al. 2021/2022, Qian et al. 2012. The restriction report summarizes only few studies on DMAC exposure as well as the conclusion of the MAK commission. In view of the apparently different study designs of the DMAC reports in the literature (time of sampling, repeated sampling over a workweek, broad differences in the concentrations of airborne DMAC, different personal protective equipment, etc.), a thorough review of the existing data is necessary in order to derive a biological limit value. Additionally, the determination of airborne DMAC as well as NMAC analyses in urine have been carried out routinely for many years using the limit values then in force (36 mg/m3 with 30 NMAC/g CREA or 18 mg/m3 with 25 NMAC/L urine, respectively). From our point of view, no systemic toxicity is to be expected below 25 mg NMAC/L urine (or 20 mg/g CREA, respectively). • The available animal data for DMAC show, that liver toxicity occurs at lower doses than the developmental toxicity (see restriction report). Thus, the liver toxicity is the most sensitive endpoint. • Human data concerning liver toxicity resulted in human NOAEC of 22 mg/m3 (Antoniou et al., 2021/2022, see also restriction report). • Supportingly, a Chinese study on the biological limit of NMAC in urine of DMAC exposed workers (Qian et al., 2012) recommends a DMAC upper exposure limit based on workweek, end-of-shift urinary NMAC of 20 mg/g CREA. Thus, a further decrease of the BLV might lead to an overestimation of the human health risk. Additional further important remark: The use of the term biological limit value should be restricted to OSH legislation. The biological monitoring value corresponding to the harmonized DNEL of 13 mg/m³ should be called biological monitoring value, only. Otherwise, the restriction leads to an undesirable further mixing up of OSH and REACH. The ECHA Guidance on NMP restriction (No 71) refers to the BLV-Method to determine NMP in biological samples, however, the purpose always was and is to have a method to check compliance with hDNELs, nothing else. (References and Literature in attached documents) |
| Answer to specific info request 2:  See former PC comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 3:  See former PC comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 5:  See former PC comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 6:  See former PC comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 7:  See former PC comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 8:  See former PC comments. Additional information may be provided later during the consultation period. |
| Answer to specific info request 9:  See former PC comments. Additional information may be provided later during the consultation period. |
| Dossier submitter response:  Thank you for your comments and provided translation of the Qian study. The Background Dossier has been updated to incorporate the study results of Qian et al. The data provided in this study further supports the proposed BLV of 15 mg NMAC/g creatinine corresponding to the DNEL of 13 mg/m3. The submitted biomonitoring data (#3586) corresponding to the Antoniou et al., study did not allow an assessment of the relation between external exposure and biomonitoring values for DMAC. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly.  Thank you also for your considerations on biomonitoring which have been noted. In the RAC opinion, the name biomarker DNEL is used instead of BLVs. These biomarker DNEL values are meant to support industry to ensure compliance with inhalation and dermal DNELs. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |

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| **3667** | **Date:**  2022/12/07 12:04  **Content:**  Other socio economic analysis (SEA) issues  Transitional period  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  CIRFS: European Man-made Fibres Association  **Org. country:**  Belgium | **General Comments:**  CIRFS European Man Made Fibres Association (TR No: 40197342894048), in agreement with IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (TR No. 49913771894-86), provide here CIRFS comments for a longer transition period for the MMF industry in Europe in this DMAC restriction in regulatory consistency with former NMP and DMF restrictions as also discussed in the SEAC-57 meeting on December 01st, 2022. |
| **Answer to specific info request 1:**  See former CIRFS comments with ref. #3584, #3586, #3587, #3597, #3603, #3604, #3605 and #3654 |
| **Answer to specific info request 2:**  See former CIRFS comments with ref. #3584, #3586, #3587, #3597, #3603, #3604, #3605 and #3654 |
| **Answer to specific info request 3:**  See former CIRFS comments with ref. #3584, #3586, #3587, #3597, #3603, #3604, #3605 and #3654 |
| **Answer to specific info request 5:**  See former CIRFS comments with ref. #3584, #3586, #3587, #3597, #3603, #3604, #3605 and #3654 |
| **Answer to specific info request 6:**  As noted in Comment #3587 (Response to Inquiry 6) of the current PC, the LEV situation at the three remaining MMF companies using DMAC as a process solvent is much more comparable to the DMF restriction (CIRFS DMF SEAC comments cited in #3587) than to the NMP restriction. Based on RAC's 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 investments in the order of €5-10 million are expected for improved ventilation for some companies. In addition to the investment costs, there would be further 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. To be able to cover these significant costs (the cost per year is crucial, even if the total amount does not change) 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, which is also in regulatory consistency with the NMP and DMF restrictions. IVC/CIRFS already requested this longer transition period of 4 years in Ref #3587 (response to Question 9). |
| **Answer to specific info request 7:**  See former CIRFS comments with ref. #3584, #3586, #3587, #3597, #3603, #3604, #3605 and #3654 |
| **Answer to specific info request 8:**  See former CIRFS comments with ref. #3584, #3586, #3587, #3597, #3603, #3604, #3605 and #3654 |
| **Answer to specific info request 9:**  see answer to request 6 above: As noted in Comment #3587 (Response to Inquiry 6) of the current PC, the LEV situation at the three remaining MMF companies using DMAC as a process solvent is much more comparable to the DMF restriction (CIRFS DMF SEAC comments cited in #3587) than to the NMP restriction. Based on RAC's 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 investments in the order of €5-10 million are expected for improved ventilation for some companies. In addition to the investment costs, there would be further 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. To be able to cover these significant costs (the cost per year is crucial, even if the total amount does not change) 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, which is also in regulatory consistency with the NMP and DMF restrictions. IVC/CIRFS already requested this longer transition period of 4 years in Ref #3587 (response to Question 9). |
| **Dossier submitter response:**  Thank you for your comments. Cost information related to the adaption and extension of exhaust ventilation for the man-made fibre industry in relation to the DMF-restriction is informative, however, they don’t allow for a quantitative estimate without further contextual data on the required increase in ventilation rates to comply with the DMF and DMAC/NEP restriction proposals.  No detailed justification for the request for a transition period of 4-years is provided, therefore the Background Document has not been updated. |
| RAC Rapporteurs comments:  Thank you very much for your contributions to this Annex XV consultation. The contributions by CIRFS: European Man-made Fibres Association have been especially helpful with regard to the hazard, exposure and risk assessment for DMAC and NEP. These contributions assisted the development of the RAC opinion significantly. This specific comment was more relevant for the SEAC evaluation. |
| **SEAC Rapporteurs comments:**  Thank you very much for your contributions to the socioeconomic analysis. We have considered this information in the assessment of compliance costs, especially the LEV costs. Furthermore, the information provided on RMMs already implemented because of OSH legislation and DMF restriction was helpful for assessment of the level of compliance already reached in the different sectors of use of DMAC.  The information provided on LEV costs (including investment costs as well as use costs) was taken into account when assessing proportionality of the restriction proposal for the Man-made Fibres sector. The information was also useful when assessing the proposed transitional period of 4 years (instead of the 1.5 years as proposed by dossier submitter) and its potential impact on the proportionality. |

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| **3668** | **Date:**  2022/12/12 08:30  **Content:**  Hazard or exposure  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  EWWA  **Org. country:**  Belgium | **General Comments:**  Dear DMAC/NEP restriction team, We have prepared the requested additional information within our EWWA DMAC team. We have included this information directly with your questions  1. Is the level of exposure clearly connected to a workplace or task? Yes! The ranges of measured exposures are directly and clearly connected with the three PROCs (known from the NMP procedure) which are relevant for the winding wire production process. We have specified for DMAC exposure as representative values for winding wire production across EWWA: PROC2 (between 0,4 and 4,1 mg/m³), PROC 8b (between 4,8 and 9,3 mg/m³), PROC 10 (between 31,5 and 44,4 mg/m³). This is the result of comprehensive data collecting across companies in our sector.  2. Please describe this workplace or task, e.g.: o Which activities are performed? frequency and duration, operational conditions (e.g. open handling, closed system, number of workers that are performing the tasks  a.) Winding wire serial production is a continuously running process in a 24/7 operation, it includes the enameling itself (together with cooling) and includes a fully automated encapsulated enamel supply, PROC 2: For illustration, here is an example of a typical type of enameling machine for serial production of wire winding (Source: MAG Maschinen- und Apparatebau AG). Enamelling machines differ in size, some of them are built vertically, but the principle in particular in respect to possible exposures, is exactly the same, also between the limited number of European machine producers. The serial production is well described by PROC 2 (no difference for DMAC in comparison to NMP).  b.) Manual filling, PROC 8b In case of small special batches or sample production (not even serial production!), which remains a rare activity, varnish is (re-)filled manually. In this case, the operator is typically equipped with additional occupational safety equipment that is used to comply with the applicable limits, such as protective glasses, chemical-resistant gloves and respiratory masks   c.) Cleaning of enameling side tank , PROC 10 In rare cases, manual cleaning of tools and machine is carried out with cleaners containing DMAC. The operator is then typically equipped with occupational safety equipment that is used to comply with the applicable limits, such as protective glasses, chemical-resistant gloves and respiratory masks   o What risk management measures are in place (LEV, PPE, training of workers on e.g. PPE or glove use…)? Each EWWA member company is due to the NMP process and extensive coaching from the project team within EWWA aware of suitable, appropriate or necessary RMMs. It is, however, up to each company to choose the suitable or necessary means. EWWA cannot state which RMMs are used in which installation, but the Techncial Committee has some knowledge about the RMMs most often in place, which are:: PPE (personal protection equipment): gloves, work clothes, eye protection glasses LEV (local exhaust ventilation): e. g. air exchange in the production area Shift management to reduce the exposition time Training: training on e.g. yearly base (often compulsory), special training for new workers or due to special events or changes in the process  o A description of the OSH system in place (frequency and content of OSH relevant training, supervision at the workplace…). Regular training on yearly base, special training for new workers or due to special events or changes in the process Monitoring of compliance with safety-related regulations by direct supervisors and in various internal audits.  3. Please, also describe the monitoring method and its parameters (which standard, LOQ, monitoring time, monitoring duration…). Several measurement data related to the exposure in a work shift have been determined over various companies. The values therefore reflect the total exposure of a worker. They have all been carried out and analysed by external expert service companies. Measurements were often done at different locations relating to the different PROCS. They are not just point measurements.  4. Are there monitoring data included that are reflecting “unexposed” situations, e.g. background level? For clarification: workers at enameling machines typically work in a larger area with several / many machines and they are actually responsible for a larger number of machines. Therefore, in this area they move and walk from one machine to another and follow their work program / work load, which typically also includes work a little bit away from the enameling unit, e.g. the winder. With the above values, the exposure is complete described, no additional unexposed values  5. Could you also describe/justify the representativeness of the data regarding o Technologies used by others in your sector – is the technology you use the main production method? The technology to produce magnet wire is in all installations very much comparable. The “new” machine generation, which was one of the main reasons for the longer transition period for NMP, are now typically in place, more or less everywhere, without knowing all details from all companies. o All other EU Member States – are there other technologies in broad use? No, there is one state of the art, used in comparable way in all European (and in fact worldwide!) installations, EWWA is covering all EU member states with winding wire production o Different scales of enterprises – is this a common technology in companies of all sizes? The production of winding wire is carried out in the European winding wire industry at comparable plants with identical processes. Only the number of machines and lines are variating, but not the processes and therefore there is no dependence of exposure data vs. installation size. |
| **Dossier submitter response:**  Thank you for your comments and provided information related to the exposure situation. The provided exposure information was already included in the Annex XV dossier and have been taken into account by the Dossier Submitter. |
| **RAC Rapporteurs comments:**  Thank you for your contribution to the Annex XV consultation. The provided data was considered during exposure and risk assessment. |
| **SEAC Rapporteurs comments:**  Thank you very much for your contributions to the socioeconomic analysis.  The information provided on RMMs already implemented because of NMP restriction and NMP guidance document was helpful for assessment of the level of compliance already reached in the electrical wire coating sector. We have considered this information as indication that in this sector no significant further adaption of RMMs (especially LEV, training) would be necessary. |

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| 3682 | Date:  2022/12/15 16:25  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  The European Apparel and Textile Confederation (EURATEX)  Org. country:  Belgium | Answer to specific info request 1:  EURATEX would like to refer to a study: Antoniou et al., 2021. Antoniou, E. E., Gelbke, H. P., Ballach, J., Zeegers, M. P., & Schrage, A. (2021). The Association Between Dimethylacetamide Exposure and Liver Toxicity: A Large Retrospective Analysis in Workers From Four European Factories. J Occup Environ Med, 63(12), e893-e898. The study concluded that no association between DMAC exposure and hepatoxicity amongst European workers was found. Furthermore, the prevalence of elevated liver values was lower compared to the general population without occupational exposure. EURATEX also supports the data put forward by CIRFS - European Man-Made Fibres Association in their submissions to the ECHA consultation and their information regarding workplace exposure, alternatives and impact on the textile industry. |
| Answer to specific info request 2:  EURATEX is concerned of the double regulation on DMAC. Workplace specific limits should no longer be part of a REACH restriction procedure if a BOELV is already in place. If the authorities were of the opinion that the BOELV would have to be adapted for certain reasons, this adaptation should have to happen under the OSH procedure and not under a REACH restriction procedure. |
| Answer to specific info request 3:  Currently there are not any suitable alternatives for the fiber manufacturing process. Due to the specific physico-chemical properties needed from the solvent, critical for each of the manufacturing process steps, the toxicological properties of potential alternative solvents are also very similar. |
| Answer to specific info request 8:  In general, by further restriction of irreplaceable chemicals/raw materials and related productions in the EU downstream user industries, the EU risks losing the independence and security in supply. The products created by using DMAC will be available from outside the EU, the technical textile industry in their role as downstream users will buy these products from non-EU-producers by imports. |
| Answer to specific info request 9:  EURATEX supports a transition period of 4 years (comparable to the period given for implementation of DMF-DNEL) as it would be helpful for the companies to ensure a proper transition. |
| Dossier submitter response:  Thank you for your comments. The data from the Antoniou et al. study was already included in the Annex XV dossier and have been taken into account by the Dossier Submitter. The merits of proposing a DNEL under REACH for both DMAC and NEP have been compared and assessed against the BOEL procedure under the CMDR-Directive in the Background Document. No justification for the request for a transition period of 4-years is provided, therefore the Background Document has not been updated. |
| RAC Rapporteurs comments:  Thank you for contribution to the Annex XV consultation. The study of Antoniou et al. was considered during risk assessment. |
| SEAC Rapporteurs comments:  Thank you very much for your contribution related to alleged possible double regulation. We have taken this into account in analysis and assessment of other regulatory options (“(Update of) OEL under OSH legislation)”. We consider setting a binding OEL (BOEL) under the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD, 2004/37/EC) as an acceptable risk management option, comparable to a harmonised DNEL. However, SEAC considers it likely that over the next 5 to 10 years, no update of the BOEL for DMAC or setting of a BOEL for NEP can be expected. Thus even if prioritised for BOEL setting, the implementation of the limit value is likely to be delayed, and consequently the identified unacceptable risks (in section 3.3) could persist.  Thank you also very much for your contributions to the alternatives assessment.  We acknowledge your support on the (general) 4-year transition period, however, noting that no specific justification was provided on the matter. No specific action is taken as a result of this comment. |

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| 3688 | Date:  2022/12/16 14:11  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | Answer to specific info request 4:  we are not able to produce hollow fiber membran without DMAC-this will cause of a shortage of dialyzers worldwide. |
| Answer to specific info request 5:  there is no alternative available to substitute dmac in our manufacturing process for holoow fiber membran |
| Answer to specific info request 8:  without dmac where will be no production of dialyzers for clinical applications. In the end people will be die |
| Dossier submitter response:  Thank you for your comment. The proposed restriction allows for (conditional but) continued use of DMAC and NEP in processes where substitution is difficult to achieve whilst effectively reduces worker risks because of inhalation and dermal exposure. The Dossier Submitter foresees no obstacles in the production of dialyzers due to the proposed restriction. |
| RAC Rapporteurs comments:  The planned restriction is not a full ban of all uses of DMAC. It offers a high level of flexibility for downstream users to implement appropriate risk management measures (RMM) where needed and adapt operational conditions (OC) to ensure exposure below the respective DNELs. RAC is of the opinion that the use of DMAC as solvent in the manufacturing process of medical membranes is not affected by the described restriction because this sector already seems to fulfil the conditions of the restriction proposal. |
| SEAC Rapporteurs comments:  Thank you very much for your contributions to the alternatives assessment.  SEAC takes note of the mentioned benefits of medical membranes for individuals undergoing hemodialysis because of chronic kidney failure. SEAC considers that the comment does not contradict the proposed restriction. |

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| 3708 | Date:  2022/12/19 20:11  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  Bracco Imaging SPA  Org. country:  Italy | Answer to specific info request 1:  a) According to the results of Personal Exposure Measurements, no one of the workers is currently exposed via inhalation to DMAC above the proposed DNEL values. b) We haven't got any certain results yet. However, relying on the fact that the inhalation exposure measurements have shown values extremely under the proposed DNEL limit (0,2 mg/m3), we do not expect a dermal exposure above the proposed DNEL. c) In our productive sites the measurements have shown inhalation exposure values equal to 0,2 mg/m3. Still, there's no data about the dermal exposure. d) Workers while handling the DMAC are wearing protective gloves, goggles and protective work clothing. e) No, we have never used Biomonitoring to measure occupational exposure to DMAC. However, we have recenlty started a series of measurements based on the Urine Analysis in order to evaluate the presence of the metabolite. f) We have no experience due to a lack of measurements. |
| Answer to specific info request 3:  a) DMAC is used as a solvent throughout an intermediate production process. We have never faced a substitution to replace the DMAC. b) We are not aware of any application using DMAC of this kind. |
| Answer to specific info request 5:  As the substitution is not needed, we are not able to provide an economic feasibility of potential alternatives. |
| Answer to specific info request 6:  a) According to the results of the inhalation exposure measurements, we do not expect the future necessity of an LEV system. |
| Answer to specific info request 7:  a) According to the results of the inhalation exposure measurements, we do not expect the future necessity of considering a training program. |
| Answer to specific info request 9:  Even if the proposed restriction (DMAC) is not supposed to affect our business at all, considering the extremely restrictive proposed DNEL values and the negative socio-economic impact, we suggest a transitional period of at least 72 months. |
| Dossier submitter response:  Thank you for your comments and information that indicates the proposed DNEL would be achievable. No detailed justification for the request for a transition period of 6 years is provided, therefore the Background Document has not been updated |
| RAC Rapporteurs comments:  Thank you for your contribution to this Annex XV consultation. The provided data indicates that the RMMs and OCs at your production site are already sufficient to comply with the proposed restriction. |
| SEAC Rapporteurs comments:  Thank you very much for your contributions to the alternatives assessment.  The information provided on RMMs already implemented was helpful for assessment of the level of compliance already reached. We have considered this information as indication that in this sector no further adaption of RMMs (especially LEV would be necessary to comply especially with the proposed DNELs.  Concerning your point on the alleged “extremely restrictive proposed DNEL values” SEAC notes that RAC has proposed modifications to the originally proposed DNEL values. As this relates to transition period, SEAC thanks for your suggestion for the 72 months transition period. SEAC, however, does not consider the proposed transition period necessary at this point observing your statement that “the proposed restriction (DMAC) is not supposed to affect our business at all”. |

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| 3714 | Date:  2022/12/20 11:17  Content:  Other socio economic analysis (SEA) issues  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  United Kingdom  Company name confidential:  Yes | General Comments:  Comments related to cost mentioned in table 33 on page 81 of Annex XV restriction report:  Actual costs for drafting a DU CSR (building on a lead registrant CSR, replacing Chapters 9 and 10): Drafting the first CSR in 2010 needed 14 days and cost was 14000 € (excl VAT). Update in 2019 needed 11 days and cost was 13000 € (excl VAT).  The cost mentioned in table 33 on page 81 of Annex XV restriction report of 2700 € appears far too low. Even for a less complex exposure situation and less monitoring data than in our case. That is likely due to the underestimation of the cost per hour charged by service providers and the time needed. Depending on the country, one day of consultancy can cost 1000€/d or more.  The professional expertise needed to perform such a complex assessment following the detailed guidance documents and to use Chesar is typically not available in DU companies. Therefore, the expected situation will be that DU companies will have to contract such work to a specialized consulting company and cannot make use of internal resources. |
| Answer to specific info request 1:  see previously submitted CSR |
| Answer to specific info request 5:  We are not aware of the use of dialkylcarbonates in industrial polyurethane fiber production. Provided the alternative can form stable solutions of the polymer, and during “extrusion” the alternative solution can form a uniform filament (which are some of the elements of the technical feasability), the economic feasability is strongly depending amongst others on: - pricing and availability of industrial quantities of the alternative - boiling point/vapour pressure - determining the energy needed for evaporation - stability, rectification/distillation profile – determining the rate of recovery - compatibility with existing installations, materials, etc – determining the need for reconstruction of sites, replacing equipment. - Qualifying of products made with the alternative solvent by our customer base. Re-certification requirements can take significant time and effort. |
| Answer to specific info request 6:  to b) Installing new or additional LEV would require significant captial and would add operational cost expense (ventilation, additional heating/cooling). Such a project requires extensive scoping study for design and installation. |
| Answer to specific info request 7:  see earlier submission |
| Answer to specific info request 8:  a) Downstream users affected: the Textile supply chain (yarn covering, fabric and garment production). In addition to the loss of employment at the upstream site, any contracted work or supporting work would also be lost. b) As all spandex/elastane fibers would need to be imported from non-EU production sites due to the loss of EU spandex production, significantly higher cost for fibers, longer lead times, complex logistics, reduced offering would be expected impacts on downstream users. |
| Answer to specific info request 9:  In case the newly proposed DNELs or BLV would be too difficult to respect site closure could be one consequence. A longer transition period would not change such an outcome. Regarding the identification of alternative solvents, long transition times would certainly be needed due to the ongoing lack of alternatives, but there is no guarantee that research will be successful in that time window. On top of that, time would then be needed to adapt existing equipment or install new equipment. In case a realistic chance is seen to achieve more stringent requirements and financing is supported by the profitability of a site, long transitional periods would be needed to allow for proper decision making regarding the necessary technical upgrades and their implementation. |
| Dossier submitter response:  Thank you for your comments and information. The hourly rate for consultancy in the Annex XV report is based on Eurostat turnover data for the EU-27 and is considered a valid estimate for the average hourly rate of the indicated sectors, although differences exist within Europe. The Dossier Submitter estimated the amount of time needed to update a DU CSR as six days. The Background Document is updated with your information and the time needed to update a DU CSR is changed to 11 days. |
| RAC Rapporteurs comments:  Thank you for the information you provided. |
| SEAC Rapporteurs comments:  Thank you very much to your contribution to the socioeconomic analysis. We find especially the information regarding costs for CSR-updates very useful for assessing the costs of the proposed restriction. |

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| 3718 | Date:  2022/12/20 16:07  Content:  Scope or restriction option analysis  Hazard or exposure  Description of analytical methods  Information on benefits  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  BASF intermediates  Org. country:  Germany  Attachment: | General Comments:  1) BASF SE (Lead registrant for DMAC) welcomes and supports the harmonized DNELs as agreed by the RAC. Especially, the new dermal DNEL for DMAC suggested by the Rapporteur follows a scientifically sound argumentation line taking available human biomonitoring data into account. Agreed DNELs for DMAC and NEP as published in the Minutes of RAC-62 and RAC 63 are • DMAC: Systemic long-term inhalation DNEL of 13 mg/m³ (agreed RAC-62) • DMAC: Systemic long-term dermal DNEL of 1.8 mg/kg bw/day (agreed RAC-63) • Corresponding to a Biomarker DNEL of 15 mg NMAC/g creatinine (agreed RAC-63)  • NEP: Systemic long-term inhalation DNEL of 4 mg/m³ (agreed RAC-62) • NEP: Systemic long-term dermal DNEL of 2.4 mg/kg bw/day (agreed RAC-62) • Corresponding to a Biomarker DNEL of 20 mg 5-HNEP+2-HESI/L urine (agreed RAC-62) Source: Minutes RAC 63 plenary: https://echa.europa.eu/documents/10162/2166371/rac\_63\_minutes\_en.pdf/e6693dc7-da07-391a-eced-c8f9ac0cb1fd?t=1671454220196 Minutes RAC 62 plenary: https://echa.europa.eu/documents/10162/2200976/rac62\_minutes\_en.pdf/850ae7ed-90d8-358d-e90b-2bd893ce8e86?t=1664886031664  2) In the light of the RAC- agreed DNELs BASF SE fully supports the conclusions of the dossier submitter: “A restriction with binding DNELs for the inhalatory and dermal route for DMAC and NEP is the most appropriate risk management option i) because it effectively reduces worker risks as a consequence of inhalation and dermal exposure, ii) applies equally to all sectors and users in supply chains and iii) allows for (conditional but) continued use of DMAC and NEP in processes where substitution is difficult to achieve. In addition, the proposed restriction offers a high level of flexibility for downstream users to implement appropriate risk management measures where needed and adapt operational conditions to ensure exposure below the respective DNELs.” Source: ANNEX XV RESTRICTION REPORT (Conclusion chapter p96 bottom). https://echa.europa.eu/de/restrictions-under-consideration/-/substance-rev/70602/term?\_viewsubstances\_WAR\_echarevsubstanceportlet\_SEARCH\_CRITERIA\_NAME=N%2CN-dimethylacetamide+%28DMAC%29%3B+1-ethylpyrrolidin-2-one+%28NEP%29&\_viewsubstances\_WAR\_echarevsubstanceportlet\_SEARCH\_CRITERIA\_EC\_NUMBER=-   3) In support to the above cited conclusion of the dossier submitter BASF SE likes to add the following points: • The harmonized DNELs set for DMAC and NEP is providing free trade and a level playing field  • The harmonized DNELs set for DMAC and NEP are mandatory for and applicable to all -manufactures, importers and downstream users in all member states of the EU • Downstream users are only workers (almost exclusively industrial for DMAC) as restriction No. 30 already forbids to place any consumer product on the market containing DMAC or NEP higher than an impurity level of 0.3% (general classification limit as set by CLP regulation 1272/2008 for all reprotoxic substances)  • DMAC uses significantly contribute to EU resilience with respect to medicinal independency, civil protection and e mobility and therefor can be seen as essential to EU society. The restriction allows continuous use of DMAC and NMP in industrial processes where substitution is difficult to achieve, practically impossible due to maximal product quality requires in the production such as e.g. DMAC in the production dialysis membranes for medicinal machines to treat kidney insufficiency (p. 64)or the use of DMAC in the production of fire protective clothing (meta aramid fiber - p.62 ) or carbon fiber production for light weight cars (p. 62) and wire coating for e-engines and electric generators (p.62).  Source: ANNEX XV RESTRICTION REPORT (Conclusion chapter p96 bottom).  • The harmonized DNEL for DMAC and NEP furthermore support regulatory consistency, as harmonized DNELs are set as well for potential alternatives NMP and DMF. This measure avoids regrettable substitution as well as level playing field for all users of this class of aprotic polar process solvents. The EU Commission sees the harmonized DNEL a case where there is an added value in applying REACH complementary to OSH legislation The DNELs will be applied in all companies in all Member States, thereby creating a level playing field for EU companies and ensuring appropriate protection of workers and t it can address the main concern (exposure of workers) more quickly independently from level of OSH legislation in the different EU MS.  Source: RMOA of the EU Commission in 2018 https://echa.europa.eu/documents/10162/c5eb4d65-5692-024d-bdff-522f1854b02f)  • OSH legislation and REACH can work together complementary and are not a contradiction if handled responsibly by all stake holders. Support for setting a harmonized DNEL this time is for the sake of regulatory consistency with NMP and DMF. A huge overlap between REACH and OSH legislation is a legislative fact: o Any exposure scenario in a SDS is defining RMM for workers for a safe use meaning an exposure below the derived DNEL by the registrants. Consumers rarely receive any SDS. Consequently, the exposure scenarios in the eSDS consequently almost exclusively address workers already covered by OSH legislation, employers or industrial hygienists translating the data provided in to a company’s operating procedure). o A reference DNEL/DMEL in an up-stream authorization is a de-facto harmonized DNEL/DMEL to the downstream users covered by this authorization (eg. chrome plating authorization granted for 2µg/m³ while 2004/37/EC currently sets a BOEL of 5 mg/m³).  • It is BASF’s experience from the NMP restriction that a restriction setting a harmonized DNEL is generally technically feasible, and manageable.  • Despite there is no CSR requirement for smaller importers or manufactures ( below 10t/y) There is no tonnage limit on providing an SDS especially for substance triggering a product classification as reprotoxic cat 1b in concentration above 0.3 %. NEP ad DMAC have been originally registered above 1000 t/year in 2010 meaning that there is information on a full data set available on the ECHA web page.  • The value 0.3% is not a specific value but applies to any rep1b substance according to CLP regulation (labelling requirement if above 0.3 %) and as well for restriction No 30. Forbidding to pace a consumer product on the EU market containing more than 0.3 % of a reprotoxic substance cat 1b  • Setting a harmonized DNEL facilitates eSDS creation in this case as no individual DNEL derivation requiring expert knowledge is required as DNEL derivation was conducted by RAC experts. Exposure scenarios can be calculated with Tier 1 tools that are publicly available for free.  • Like for NMP and DMF validated methods for bio monitoring and determining NEP and DMAC in biological samples (Urine) are available:  For example o Koch, H. M., Bader, M., Weiss, T., Koslitz, S., Schütze, A., Käfferlein, H. U., & Brüning, T. (2014). Metabolism and elimination of N-ethyl-2-pyrrolidone (NEP) in human males after oral dosage. Archives of Toxicology, 88(4), 893-899. 10.1007/s00204-013-1150-1 o Spies, G. J., Rhyne Jr, R. H., Evans, R. A., Wetzel, K. E., Ragland, D. T., Turney, H. G., Leet, T. L., & Oglesby, J. L. (1995a). Monitoring acrylic fiber workers for liver toxicity and exposure to dimethylacetamide 1. Assessing exposure to dimethylacetamide by air and biological monitoring. Journal of Occupational and Environmental Medicine, 37(9), 1093-1101. http://dx.doi.org/10.1097/00043764-199509000-00010 o Spies, G. J., Rhyne Jr, R. H., Evans, R. A., Wetzel, K. E., Ragland, D. T., Turney, H. G., Leet, T. L., & Oglesby, J. L. (1995b). Monitoring acrylic fiber workers for liver toxicity and exposure to dimethylacetamide 2. Serum clinical chemistry results of dimethylacetamide- exposed workers. Journal of Occupational and Environmental Medicine, 37(9), 1102-1107. http://dx.doi.org/10.1097/00043764-199509000-00011 Source: ANNEX XV RESTRICTION REPORT (references).  • BASF as lead registrant has been actively contributing to the development of Echa’s NMP guidance and can offer to contribute to the inclusion of NEP and DMAC in that guidance or in the development of a similar guidance document. Source: acknowledgement of Echa’s NMP guidance https://echa.europa.eu/documents/10162/17233/entry\_71\_how\_to\_comply\_en.pdf/c6e09198-c0b1-44e3-abae-6b3d0bc909a8 |
| Answer to specific info request 1:  BASF SE has used biomonitoring to measure occupational exposure and has used the methods referenced in the Restriction Report to determine DMAC and NEP metabolites in biological samples to finally determining DMAC or NEP exposure. Biomonitoring to measure occupational exposure consists of sample biological sample collection which is addressed as well in the ECHA's NMP Guidance: How to comply with REACH Restriction 71, guideline for users of NMP. How to comply with REACH Restriction 71, guideline for users of NMP. Available surveillance methodologies include the EN-68921 or national equivalent, which provides a methodological framework for monitoring exposure by inhalation. Others include the BOHS / NVvA guidance22 , the French (INRS NMP M-1523) and German (TRGS 40224) methodologies. The analysis of the biological samples. reference to methods is already provided in the restriction report: o Koch, H. M., Bader, M., Weiss, T., Koslitz, S., Schütze, A., Käfferlein, H. U., & Brüning, T. (2014). Metabolism and elimination of N-ethyl-2-pyrrolidone (NEP) in human males after oral dosage. Archives of Toxicology, 88(4), 893-899. 10.1007/s00204-013-1150-1 o Spies, G. J., Rhyne Jr, R. H., Evans, R. A., Wetzel, K. E., Ragland, D. T., Turney, H. G., Leet, T. L., & Oglesby, J. L. (1995a). Monitoring acrylic fiber workers for liver toxicity and exposure to dimethylacetamide 1. Assessing exposure to dimethylacetamide by air and biological monitoring. Journal of Occupational and Environmental Medicine, 37(9), 1093-1101. http://dx.doi.org/10.1097/00043764-199509000-00010 o Spies, G. J., Rhyne Jr, R. H., Evans, R. A., Wetzel, K. E., Ragland, D. T., Turney, H. G., Leet, T. L., & Oglesby, J. L. (1995b). Monitoring acrylic fiber workers for liver toxicity and exposure to dimethylacetamide 2. Serum clinical chemistry results of dimethylacetamide- exposed workers. Journal of Occupational and Environmental Medicine, 37(9), 1102-1107. http://dx.doi.org/10.1097/00043764-199509000-00011 |
| Answer to specific info request 2:  It is BASF's experience from the NMP restriction that a restriction setting a harmonized DNEL is generally technically feasible, and manageable. BASF as lead registrant for NMP has been actively contributing to the development of Echa’s NMP guidance and can offer to contribute to the inclusion of NEP and DMAC in that guidance or in the development of a similar guidance document. Source: acknowledgement of Echa’s NMP guidance https://echa.europa.eu/documents/10162/17233/entry\_71\_how\_to\_comply\_en.pdf/c6e09198-c0b1-44e3-abae-6b3d0bc909a8 |
| Dossier submitter response:  Thank you for your comments and support of the proposed restriction. |
| RAC Rapporteurs comments:  Thank you for your contribution to the Annex XV consultation. The explicit support for the proposed restriction and the confirmation of its feasibility are very valuable. RAC appreciates your offer to contribute to the inclusion of NEP and DMAC in the NMP guidance. |
| SEAC Rapporteurs comments:  No comment since this contribution addresses RAC issues. |