Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. The DMF draft opinion concludes that for uses where the risks cannot be sufficiently addressed by technical means alone it should be possible to address the risks by use of personal protection equipment and administrative measures (like job rotation or shorter working days) and that this could be done with relatively low costs (affordable means).

Please, submit detailed information on the technical and economic feasibility of adopting the risk reduction measures described above to reduce the combined exposure level of DMF to a safe level using the proposed DNEL values of 6 mg/m3 (inhalation) and 1.1 mg/kg bw/day (dermal). Furthermore, please submit information on costs and affordability of such risk reduction measures.

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 422 | **Date/Time:** 2019/10/16 11:25  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Industrievereinigung Chemiefaser e.V. (IVC)  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (European transparency register no. 49913771894-86), in agreement with CIRFS - European Man-Made Fibres Association, was present at the SEAC-44 meeting on September 16th 2019 in Helsinki and had prepared hand-outs for SEAC members. As it was not allowed to hand them out, they are now attached to this comment.  Our verbal comments at the SEAC-44 meeting on September 16th 2019 was stopped after only two minutes and the second time slot of one hour on DMF foreseen for September 18th 2019 was canceled. Also there were questions asked in the meeting and uncertainties still mentioned in the actual draft opinion. We believe that SEAC missed an opportunity to clarify these uncertainties with the industry stakeholders present in the SEAC-44 meeting.  Some data have been already provided in the former public consultation but were not considered yet by SEAC (see attachment). We will continue to participate in the public consultation process and are always open for further discussions to answer any questions. |
| **Specific information 1:**  See attachment and former PC ref. 2029-2032, 2245 |
| **SEAC Rapporteurs response:**  Thank you for the comment.  With regard to the nature of the products manufactured by the MMF companies SEAC has included a sentence appreciating the products.  With regard to attainability to the RAC agreed DNELs, SEAC refers to the response to comment #430.  With regard to the nature of the impacts of DMF, SEAC would like to note that a DNEL value is a scientifically based value based on agreed principles and it is not up to SEAC to question the RAC evaluation.  With regard to proportionality, SEAC agrees that the benefit estimation is quite uncertain. This is underlined in the opinion. See also response to comment 423. |
| 423 | **Date/Time:** 2019/10/16 13:13  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Industrievereinigung Chemiefaser e.V. (IVC)  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (European transparency register no. 49913771894-86), in agreement with CIRFS - European Man-Made Fibres Association, provide here detailed information on “Liver function and alcohol intolerance (AI) after exposure to DMF” as mentioned in our PC comment from October 16th 2019, 10:25 a.m. for SEAC as a basis for the recalculation of health benefits. |
| **Specific information 1:**  See PC comment from October 16th 2019, 10:25 a.m. and former PC ref. 2029-2032, 2245 |
| **SEAC Rapporteurs response:**  Thank you for the comment. SEAC's opinion underlines the uncertainties with regard to benefit estimation. SEAC notes that the relationship between exposure to DMF and alcohol intolerance is found in a number of studies, which are referred in the background document. SEAC agrees that alcohol intolerance is not a long term effect and has taken this into account when assessing the benefits. Please also see response to comment #430. |
| 424 | **Date/Time:** 2019/11/19 15:55  **Type:** Individual  **Country:**  Italy | **Comments on the SEAC draft opinion:**  We appreciate RAC and SEAC opinion that, due to the absence of suitable alternatives for a large number of uses, the total ban of DMF and the option to list the substance on Annex XIV to REACH and thereby only allow authorised uses were rejected.  In the PU-coating sector, the use of DMF for the different types of coatings strongly depends on the polymer used for coating, the material to be coated and the properties to be achieved. In some applications DMF as coating solvent may be substituted by water or organic substances. However, some specific coatings will still require DMF.  You quote DMSO as the most promising potential alternative, but it doesn’t have the same properties with regard to viscosity, tendency for coagulation, evaporation heat, operation temperature and distillation features. Particularly for coagulation (wet process) DMSO is not suitable, simply it doesn’t work.  We appreciate value for long-term inhalation exposure of 6 mg/m3 and long-term DNEL dermal exposure of 1.1 mg/kg bw/day instead of 3.2 mg/m3 and long-term DNEL dermal exposure of -0.79 mg/kg bw/day. We ask again a value closer than current OEL (15 mg/m3).  We have carefully read about benefits for human health, even if our company within 50 years of activity has never met health problems with our workers.  The coating industry is testing different options to improve the ventilation and decrease the diffuse emissions to further reduce the exposure to DMF in nearly future. Measures, like fully enclosing of the head of the coating line, cleaning with robots, increasing and improving the aspiration and ventilation efficiency. The subsequent costs reach millions Euro and our Company would find serious financial problems in order to face these costs.  PU-coating sector requested transition time of 10 years, but SEAC and RAC consider this request not sufficiently justified.  But costs for millions Euro deeply impact on our Company and it would not be possible to face such big investments in a short time period. We request again to have more than 2 years to be compliant with new rules.  In the public consultation several companies claimed that due to needs for quick interventions in the production process and frequent changes in the production it would not be possible for many of them to comply with the proposal limit. However, this appear to be based on the assumption that use of personal protection equipment shall not to be taken into account when estimating the exposure for inhalation.  For the above, we want to underline that our workers use PPEs whenever it is possible, but it needs to be clear that PPEs are neither practical nor comfortable since they should be worn continuously during eight-hour shift and we need to add that some of these PPEs are not allowed by laws to be worn for many hours.  SEAC has a view that PPE and job rotation may be used during adjustments periods when a company is adopting to new regulation and substitution or technical adjustments appear prohibitively costly in the short run.  Theoretically it is true, but some PPE (for example total mask and disposable clothes) are really uncomfortable and job rotation is very difficult: shifts shorter than 8 hours/day are unacceptable for our workers because of remunerative reduction that shorter shifts would involve. It is even more difficult thinking about a 4 hours job rotation in order to more exposed to DMF workers make actions which expose them just for a part of their working day, whereas other 4 hours they could work far from the production plant.  As a matter of facts many of our workers have physical limitations that forbid them to fulfil some specific tasks. They are tasks protected from heavy weights and/or chemical substances. These workers may be excluded from job rotation and their tasks are not available for an eventual rotation.  It’s also to be considered that our Company works on 3 shifts (24 hours a day): a job rotation becomes even more complicated. |
| **Specific information 1:**  we want to underline that our workers use PPEs whenever it is possible, but it needs to be clear that PPEs are neither practical nor comfortable since they should be worn continuously during eight-hour shift and we need to add that some of these PPEs are not allowed by laws to be worn for many hours.  SEAC has a view that PPE and job rotation may be used during adjustments periods when a company is adopting to new regulation and substitution or technical adjustments appear prohibitively costly in the short run.  Theoretically it is true, but some PPE (for example total mask and disposable clothes) are really uncomfortable and job rotation is very difficult: shifts shorter than 8 hours/day are unacceptable for our workers because of remunerative reduction that shorter shifts would involve. It is even more difficult thinking about a 4 hours job rotation in order to more exposed to DMF workers make actions which expose them just for a part of their working day, whereas other 4 hours they could work far from the production plant.  As a matter of facts many of our workers have physical limitations that forbid them to fulfil some specific tasks. They are tasks protected from heavy weights and/or chemical substances. These workers may be excluded from job rotation and their tasks are not available for an eventual rotation.  It’s also to be considered that our Company works on 3 shifts (24 hours a day): a job rotation becomes even more complicated. |
| **SEAC Rapporteurs response:**  Thank you for the comment.  SEAC would like to note that a DNEL value is a scientifically based value based on agreed principles and it is not up to SEAC to question the RAC evaluation.  SEAC agrees that costs for implementing major risk reduction measures might be substantial, and notes your comment that costs would reach millions of Euro and that your company would have serious financial problems in order to face these costs.  Furthermore SEAC agrees that use of PPEs is not possible for an 8-hour working day and notes your comments that job rotation is challenging in your company.  However, SEAC has no detailed information on the situation for your company and have to conclude on an aggregate level. SEAC finds it likely that a combination of risk reduction measures will make it possible to meet the proposed levels but has noted your considerations in the uncertainty section of the opinion. |
| 425 | **Date/Time:** 2019/11/22 00:10  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Italy  **Company name confidential: Yes**  **Privacy comment:**  Because we have done already an access to the previous public consultation as confidential and we want to maintain the same line.  Thank you. | **Comments on the SEAC draft opinion:**  Dear Sirs,  We would like to bring again to your attention our reasons and comments on the latest publication even if we have accessed already to previous consultation sharing documents and details supporting our request.  Sincerely, |
| **Specific information 1:**  We shared already all the info on previous consultation. |
| **SEAC Rapporteurs response:**  SEAC would like to note that a DNEL value is a scientifically based value based on agreed principles and it is not up to SEAC to question the RAC evaluation.  SEAC has noted your comment in #2287 of the previous consultation, where you as a synthetic leather producer indicated that all equipment and machines are located in wide areas and the workers never stay more than 5 to 10 min. really close to the most potential exposure points, and that measured results show an average value of about 10 mg/m3.  Furthermore you informed ECHA that further decrease of exposure can only be achieved through a combination of measures such as increased ventilation, exhaustion and improved confinement of machines as well as adaptation of standard operating practices, creating a more specific proce­dures teaching workers. Considering the levels of enclosure and ventilation achieved in the factory, you also stated that this will be a huge challenge either in economic terms and production capacity which will return again as an further economical effort for the company. More close areas, more PPE and procedures obligating workers to have a continuous turn between different production areas will cause a less productivity.  Finally, you informed ECHA that it would be possible for your company to implement measures to achieve a 10 mg/cm limit in about 2-3 years.  SEAC does not have sufficient detailed information to assess which possibilities your company has to meet the 6 mg/m3 within a shorter time period. |
| 426 | **Date/Time:** 2019/11/22 14:00  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Industrievereinigung Chemiefaser e.V. (IVC)  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (European transparency register no. 49913771894-86), in agreement with CIRFS - European Man-Made Fibres Association, provide here detailed information on “Proportionality of a restriction based on the proposed RAC DNELs for the MMF industry”.  Additional to the Summary given below, following points are given in more detail in the attached document:  1. Introduction  2. Benefits  2.1. What is the correct DNEL?  2.2. Does the Kilo et al study provide a sound basis for quantifying alcohol intolerance?  2.3. Is cirrhosis a suitable proxy for alcohol intolerance?  2.4. How long do workers experience symptoms of alcohol intolerance for?  2.5. Risks to human reproduction  2.6. Qualitative review of effects in the Draft Background Document (Annex p. 414)  3. Costs  3.1. Can Job rotation reduce exposure to meet the proposed restriction?  3.2. Can PPE be used to reduce exposure to meet the proposed restriction?  3.3. Effects of forthcoming legislative changes  3.4. If other sectors can comply with the proposed restriction, why can’t the MMF sector?  3.5. Omission from the draft opinion  4. Annex 1 – International Occupational Exposure Limits (OEL)  Summary  Conclusions on benefits  The draft opinion notes that the main reason for the proposed restriction is concern over developmental effects; however, there is no information available in the literature about cases of reproductive or developmental effects in humans after exposure to DMF. (page 18 of the draft SEAC opinion). These specific requirements are already controlled for the EU’s MMF industry by Legislation (see footnote) (Germany) and company RMM policy (Germany, Austria, Hungary) that prevent female workers of reproductive age working in areas where DMF exposures are above 3 mg/m3, a figure below the DNELs proposed by both the Dossier Submitter and RAC.  We agree that the Kilo study is the most relevant to derive a DNEL for hepatic effects in humans also because it is the most recent study (the only cited that is less than 10 years old). However, it is not ideal for the purposes of quantification of health benefits based on alcohol intolerance (AI) (see also responses #422, #423 of this PC). The levels of alcohol intolerance forecast by the rapporteurs far exceed the experience of the industry at the present time. The companies are aware of alcohol intolerance from times prior to the adoption of the 15 mg/m3 indicative OEL, but have observed negligible levels since.  The valuation of alcohol intolerance is based on a lower bound QALY loss for cirrhosis of the liver. There is no scientific basis for equating the two, and from consideration of the characteristics of AI and cirrhosis of the liver, the assumptions followed will lead to substantial overestimation of the value of any incident case of AI. Also the sentence “Even if not a disease itself, the symptoms cause discomfort and may be an early sign of liver damage.” on page 18 of the draft opinion is not correct. That AI is not a pre-stage to liver toxicity can best be deduced from studies of exposure levels without liver toxicity in spite of AI still being reported. For example, the recent study of Kilo et al. (2016) showed that exposures not leading to elevated liver enzymes still elicit AI reaction (see also IVC response # 1597, p. 7-9 (15.02.19)). Page 24 ("workers... would be able to continue their work…”) implies that AI leads to workers taking time off for illness, which is not the case.  For these reasons, the quantified benefits of the proposed restriction in terms of reducing alcohol intolerance are far beyond actual experience in the MMF industry.  The qualitative argumentation on benefits, specifically in relation to a perception that the quantification provided is likely to lead to underestimation is flawed. Almost all of the evidence cited relates to studies undertaken over 20 years ago (and in some cases over 40 years ago) when controls were very limited and PPE not nearly so well advanced. The view that hepatic toxicity is linked to alcohol intolerance is not supported by experience, for example from Asian populations that have a naturally high level of AI because of genetic factors. Reference to reproductive effects does not account for the fact that legislation in Germany and company RMM policy at the German, Austrian and Hungarian factories (together covering all EU MMF facilities) prevents female works of reproductive age working in areas where the proposed DNELs would be exceeded.  Conclusions on estimated costs and response to restriction  The position of the companies, that closure is a likely response to the proposed restriction, is unchanged. This position is not taken lightly: For reasons given here and in earlier submissions, the companies have not identified solutions to meeting the proposed limits that are technically, operationally, or economically feasible. We note here that under the hierarchy of controls for the long term that job rotation and use of PPE would not be considered acceptable and hence that additional technical controls would be needed. Page 16 of the draft opinion reports data submitted previously by IVC indicating costs for further technical controls that only go part way to meeting the RAC DNEL of €150 million for one small MMF producer. This cost for one producer is far greater than the benefits as quantified in the draft opinion for workers in the MMF and PU coating sectors combined.  The companies have considered the potential for job rotation and enhanced use of PPE. In both cases there are substantial barriers to implementation at the scale needed to ensure compliance with the proposed restriction.  The threat of closure in the sector is real, as the following information covering the last 20 years shows:  • UK: 120.000 tons capacity closed  • France: 100.000 tons capacity closed (factory dismantled and moved to South Africa)  • Spain: >100.000 tons closed  • Romania: 60.000 tons capacity closed  • Italy: 3 factories totalling 250.000 tons closed  • Bulgaria: factory closed  • Ireland: factory closed  • Hungary: Capacity moved from commodity fibre production to the production of carbon fibre precursor  Only a few highly-specialized companies have been able to continue operating in the EU. We make no claims as to the role of legislation in these closures, but simply note that they are indicative of a sector where margins are tight, the opportunity to increase prices to account for new legislative demands is small, and the threat of closure cannot be lightly dismissed. The potential for further closures in the event that companies have difficulties meeting new legislation should not be ignored.  Conclusions on proportionality  For the reasons given above, and in more detail below, the benefits of the proposed restriction are substantially overestimated, and the costs underestimated. Levels of alcohol intolerance in the MMF industry are negligible. Developmental/reproductive risks are controlled already. Job rotation and increased use of PPE do not resolve the issue of excess exposure beyond the proposed DNELs. An inability to meet the requirements of the restriction poses a serious threat of closure to the 4 remaining manufacturers in Europe.  For these reasons, we do not believe that the SEAC opinion and background documentation demonstrate that the restriction as now proposed is proportional when costs and benefits are accounted for. |
| **Specific information 1:**  See details in attached pdf-document “IVC\_Proportionality of a restriction based on the proposed RAC DNELs for the MMF industry\_SEA PC\_20191122.pdf” |
| **SEAC Rapporteurs response:**  See response to updated comment from the comment submitter (#430). |
| 427 | **Date/Time:** 2019/11/22 16:38  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  BASF SE  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  BASF SE welcomes the overall conclusions of RAC and SEAC and the support of the DMF restriction proposal.    As being one of the DMF registrants, however, BASF SE asks RAC and SEAC to consider checking their opinion on DMF for “consistent regulatory approach” with NMP restriction, meaning to consider an extended transition period for industry sectors having difficulties to quickly adopt to the harmonized DNELs proposed (namely PU-coatings/membranes sector and man-made fiber sector). The NMP restriction granted the wire winding sector a 5 years transition period for adoption to the harmonized DNELs while the rest of the industry has to adopt within 2 years.    In the preamble of Regulation 2017/999/EU\* the EU commission acknowledged similarities of NMP, DMF and DMAC with respect to toxicological properties as well as uses and basically concluded that NMP, DMF and DMAC should be treated in the same way for the sake of regulatory consistency. Consequently, it is valid to ask for checking DMF restriction proposal against NMP restriction for regulatory consistency.    “SEAC finds the overall cost estimate developed by the Dossier Submitter to have short cummings and to be very uncertain…” (1st § p.12). This may be true, but it is questionable whether this only can lead to over estimation of implementation cost and that argument brought up be the affected sector are invalid. Granting an extended transition period, however, will significantly reduce yearly economic burden for SMEs of these sectors with-out giving away high European safety standards and socio-economic benefit of the DMF restriction proposal.    BASF SE does not know the details of the arguments brought forward be these industry sectors and trusts competence of RAC and SEAC to check and to conclude whether a 5 years transition period should be granted to these sectors.      \* Preamble of regulation 2017/999 states the following:  (21) ….. DMF has similar intrinsic properties to those of N,N-dimethylacetamide (DMAC) and N-methyl-2-pyrrolidone (NMP) and the three substances may be considered as potential alternatives for some of their major uses. NMP is the subject of an on-going restriction procedure in accordance with Article 69 of Regulation (EC) No 1907/2006. In view of the similarities of the three substances, both regarding their intrinsic properties and their industrial applications, and in order to ensure a consistent regulatory approach, the Commission considers it appropriate to postpone the decision on the inclusion of DMF in Annex XIV as has already been done for DMAC when the Commission considered the Agency's recommendation of 17 January 2013. |
| **SEAC Rapporteurs response:**  Thank you for the comment. SEAC agrees that the overall regulation of the three aprotic solvents should be same. However, the necessary time for implementation depends on the actual uses. SEAC also agrees that longer transitional period would ease the implementation of technical risk reduction measures. However, also further use of PPEs, job rotation and other management options could be used in order to reduce the exposure. |
| 428 | **Date/Time:** 2019/11/25 17:15  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Mabel srl  **Org. country:**  Italy | **Comments on the SEAC draft opinion:**  DMF is a very important solvent for the PU coating industry, which we belong to. As it is true that, only for specific coatings, alternative to DMF as a solvent already exist and is already used by the majority of the industry, for other specific technical coatings there is no viable alternative as of today. Furthermore, the Dossier submitter, and both SEAC and RAC, have never taken the coagulation industry into account. Coagulation is a form a textile coating where no viable alternative to the use of DMF exist. We do have invested into researching alternative solvents for this specific application, but a viable alternative in terms of costs and performance is still far to be found. Also in this sense, the proposed transition time of 2 years is too short. We’d like to underline that the coagulation industry within EU borders only exists in Italy (around 10 companies) and in Holland (1 company), while there are many coagulation companies in Turkey and in the far east in general.  We agree with the comment submitted by IVC (Ref #422 of 2019/10/16), in particular with points #2-3-4.  The PU coating industry has requested a higher DNEL value of 10mg/m3, which seems to be possible by implementing the use of PPE and ventilation inside the factory. As the actual possible compliance with this limit is nevertheless to be demonstrated, and the level of investments for such implementation are extremely high considering the current market stagnation and fierce competition from non EU countries, we require a longer transition time of 10 years.  We would like to underline that the proposed solution of job rotation is not economically feasible. As the SEAC opinion already reports, there is fierce competition in the PU coating market, coming from outside EU borders, where competing companies can profit of lower loan costs and milder limits of environmental and working security compliance. Adding costs to the EU based manufacturing would result in an even less competitive price and thus to closure of the plants within EU borders.  According to the published opinion, SEAC does not find it likely that 50% of the PU coating and membrane sector as well as the complete man-made fiber industry would close down due to the restriction. In our opinion, and this is only related to the PU coating industry, all companies producing with coagulation plants will close down as there is no possible alternative to this kind of manufacturing and 2 years’ time is too short in order to find a possible alternative to DMF. |
| **Specific information 1:**  The use of PPE can be further enforced, but it must be taken into account that many of them are not practical for the workers to be worn for long period of times and for some specific operations on the machines. Temperature and humidity in working areas increase the discomfort for prolonged periods of wearing invasive PPEs.  Administrative measures are not economically feasible, especially in sectors like the PU coating industry, where the market is stagnating and there is fierce competition from outside EU borders. Increasing manufacturing costs is not an option, as non EU manufacturers profit from lower wages and less strict regulaments on workers and environment protection. |
| **SEAC Rapporteurs response:**  Thank you for the comment.  SEAC would like to note that a DNEL value is a scientifically based value based on agreed principles and it is not up to SEAC to question the RAC evaluation. SEAC notes your view that 2 years will not give sufficient time to switch to alternatives. However, despite of practicalities SEAC has not been presented for evidence that it should not be possible to reduce the exposure to below the proposed DNEL values using a combination of different means as PPEs and management measures. |
| 429 | **Date/Time:** 2019/11/25 17:24  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Fedustria  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  Fedustria attended the SEAC-44 meeting on September 16th 2019 in Helsinki, in order to provide information and clarifications on questions/uncertainties raised during the opinion making process. Even at the meeting, some SEAC members, raised further questions. However is was regrettable that SEAC did not take the opportunity of the attendance of the industry experts to give additional information and clarifcations on these items.  Fedustria remains available for any further clarifications in order to have a final restriction that takes into account the real situation of the textile PU coating. |
| **Specific information 1:**  A detailed argumentation why Fedustria, representing the Belgian textile PU coating companies, can not agree with this SEAC draft opinion, is elaborated in the attached document. |
| **SEAC Rapporteurs response:**  Thank you for the remarks. SEAC again acknowledge the information submitted in the public consultation of the Annex XV report. As mentioned at page 21 in the draft opinion: However, Fedustria does not consider this practical nor comfortable since RPE should be worn continuously during eight-hour shifts, and mentions PPEs in many cases are not allowed to be worn for many hours. SEAC has a view that PPE and e.g. job rotations may be used during adjustment periods when a company is adapting to new regulation and e.g. substitution or technical adjustments appear prohibitively costly in the short run. The information in #1986 describes the situation for 10 companies specifically relating to the original proposed DNELs and does not contain information which makes it possible to etaimate the magnitude of the impact, as SEAC considered that it should be possible to combine different risk management measures in order to reduce the workers exposure. With regard to impact of the new BREF on surface treatment, SEAC just referred the informatoion submitted in the attachment to #1986 It is expected that these developments will bring down the exposure of DMD in the textile coating companies to below or at least the proposed DNEL of 3.2" This paragraph referred to the BREF work as well as to other adaptions which will be implemented of DMF in the workplace". SEAC notes that the stated reduction of a factor 4 times lower of the present emission level was not related to the direct worker exposure and has amended the opinion accordingly. |
| 430 | **Date/Time:** 2019/11/25 17:45  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Industrievereinigung Chemiefaser e.V. (IVC)  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  IVC as the Association of the German, Austrian and Swiss Man-Made Fibres Industries (European transparency register no. 49913771894-86), in agreement with CIRFS - European Man-Made Fibres Association, provide here detailed information on “Proportionality of a restriction based on the proposed RAC DNELs for the MMF industry”.  This version replaces ref. nr. 5e8919de-d5e1-4b7b-acdf-8c99c2923f8a uploaded 22nd November 2019, 13:00, as clarification of wrong cited MMF technical control cost in the SEAC draft opinion were added. Please use this version instead of the version from 22nd November 2019.  Additional to the Summary given below, following points are given in more detail in the attached document:  1. Introduction  2. Benefits  2.1. What is the correct DNEL?  2.2. Does the Kilo et al study provide a sound basis for quantifying alcohol intolerance?  2.3. Is cirrhosis a suitable proxy for alcohol intolerance?  2.4. How long do workers experience symptoms of alcohol intolerance for?  2.5. Risks to human reproduction  2.6. Qualitative review of effects in the Draft Background Document (Annex p. 414)  3. Costs  3.1. Can Job rotation reduce exposure to meet the proposed restriction?  3.2. Can PPE be used to reduce exposure to meet the proposed restriction?  3.3. Effects of forthcoming legislative changes  3.4. If other sectors can comply with the proposed restriction, why can’t the MMF sector?  3.5. Omission from the draft opinion  4. Annex 1 – International Occupational Exposure Limits (OEL)  Summary  Conclusions on benefits  The draft opinion notes that the main reason for the proposed restriction is concern over developmental effects; however, there is no information available in the literature about cases of reproductive or developmental effects in humans after exposure to DMF. (page 18 of the draft SEAC opinion). This risk is already controlled for the EU’s MMF industry by legislation (Germany) and company RMM policy (Germany, Austria, Hungary) that prevent female workers of reproductive age working in areas where DMF exposures are above 3 mg/m3, a figure below the DNELs proposed by both the Dossier Submitter and RAC. The proposed restriction would therefore generate no additional benefit for developmental effects.  We agree that the Kilo study is the most relevant to derive a DNEL for hepatic effects in humans also because it is the most recent study (the only cited that is less than 10 years old). However, it is not ideal for the purposes of quantification of health benefits based on alcohol intolerance (AI) (see also responses #422, #423 of this PC). The levels of alcohol intolerance forecast by the rapporteurs far exceed the experience of the industry at the present time. The companies are aware of alcohol intolerance from times prior to the adoption of the 15 mg/m3 indicative OEL, but have observed negligible levels since.  The valuation of alcohol intolerance is based on a lower bound QALY loss for cirrhosis of the liver. There is no scientific basis for equating the two, and from consideration of the characteristics of AI and cirrhosis of the liver, the assumptions followed will lead to substantial overestimation of the value of any incident case of AI. Also the sentence “Even if not a disease itself, the symptoms cause discomfort and may be an early sign of liver damage.” on page 18 of the draft opinion is not correct. That AI is not a pre-stage to liver toxicity can best be deduced from studies of exposure levels without liver toxicity in spite of AI still being reported. For example, the recent study of Kilo et al. (2016) showed that exposures not leading to elevated liver enzymes still elicit AI reaction (see also IVC response # 1597, p. 7-9 (15.02.19)). Page 24 ("workers... would be able to continue their work…”) implies that AI leads to workers taking time off for illness, which is not the case.  For these reasons, the quantified benefits of the proposed restriction in terms of reducing alcohol intolerance are far beyond actual experience in the MMF industry.  The qualitative argumentation on benefits, specifically in relation to a perception that the quantification provided is likely to lead to underestimation is flawed. Almost all of the evidence cited relates to studies undertaken over 20 years ago (and in some cases over 40 years ago) when controls were very limited and PPE not nearly so well advanced. The view that hepatic toxicity is linked to alcohol intolerance is not supported by experience, for example from Asian populations that have a naturally high level of AI because of genetic factors. Reference to reproductive effects does not account for the fact that legislation in Germany and company RMM policy at the German, Austrian and Hungarian factories (together covering all EU MMF facilities) prevents female works of reproductive age working in areas where the proposed DNELs would be exceeded.  Conclusions on estimated costs and response to restriction  The position of the companies, that closure is a likely response to the proposed restriction, is unchanged. This position is not taken lightly: For reasons given here and in earlier submissions, the companies have not identified solutions to meeting the proposed limits that are technically, operationally, or economically feasible. We note here that under the hierarchy of controls for the long term that job rotation and use of PPE would not be considered acceptable and hence that additional technical controls would be needed. Page 16 of the draft opinion reports data submitted previously by IVC (#2245, p. 27) indicating costs for further technical controls that only go part way to meeting the RAC DNEL of €150 million for the MMF sector (not only one small MMF producer as written in the SEAC draft opinion). This cost is far greater than the benefits as quantified in the draft opinion for workers in the MMF and PU coating sectors combined.  The companies have considered the potential for job rotation and enhanced use of PPE. In both cases there are substantial barriers to implementation at the scale needed to ensure compliance with the proposed restriction.  The threat of closure in the sector is real, as the following information covering the last 20 years shows:  • UK: 120.000 tons capacity closed  • France: 100.000 tons capacity closed (factory dismantled and moved to South Africa)  • Spain: >100.000 tons closed  • Romania: 60.000 tons capacity closed  • Italy: 3 factories totalling 250.000 tons closed  • Bulgaria: factory closed  • Ireland: factory closed  • Hungary: Capacity moved from commodity fibre production to the production of carbon fibre precursor  Only a few highly-specialized companies have been able to continue operating in the EU. We make no claims as to the role of legislation in these closures, but simply note that they are indicative of a sector where margins are tight, the opportunity to increase prices to account for new legislative demands is small, and the threat of closure cannot be lightly dismissed. The potential for further closures in the event that companies have difficulties meeting new legislation should not be ignored.  Conclusions on proportionality  For the reasons given above, and in more detail below, the benefits of the proposed restriction are substantially overestimated, and the costs underestimated. Levels of alcohol intolerance in the MMF industry are negligible. Developmental/reproductive risks are controlled already. Job rotation and increased use of PPE do not resolve the issue of excess exposure beyond the proposed DNELs. An inability to meet the requirements of the restriction poses a serious threat of closure to the 4 remaining manufacturers in Europe.  For these reasons, we do not believe that the SEAC opinion and background documentation demonstrate that the restriction as now proposed is proportional when costs and benefits are accounted for. |
| **Specific information 1:**  See details in attached pdf-document “IVC\_Proportionality of a restriction based on the proposed RAC DNELs for the MMF industry\_SEA PC\_20191125.pdf” |
| **SEAC Rapporteurs response:**  Thank you for the comment. SEAC notes your concern on the possibilities for the four man-made fibre companies to reduce the exposure of DMF to the proposed DNEL values. However, SEAC also notes that the companies reiterate their view that a restriction is a preferred option compared to regulation under the authorisation scheme even if the authorisation scheme would make it possible to take individual circumstances into consideration under the socio-economic route. This again questions the validity of the statement that at least 2 companies will terminate the production within the EU.  SEAC would like to note that a DNEL value is a scientifically based value based on agreed principles and it is not up to SEAC to question the RAC evaluation. However, SEAC notes that DNEL values according to guidance are protective in order to protect to reflect differences between individuals and uncertainties in data. Hence, it is not likely that exposures slightly above the DNEL would result in major impacts.  SEAC notes the information that in four companies no female workers is exposed to DMF and that that the use of DMF therefore does not present a risk with regard to developmental effects. SEAC notes that it is up to the decision makers to decide on whether gender specific DNELs may be used in the risk assessment.  SEAC notes your information that the quantified benefits of the proposed restriction in terms of reducing alcohol intolerance are far beyond the actual experience in the man-made fibre industry and that you find this to be in contrast the opinion indication that roughly 40 % of staff working in areas with DMF exposure experiences alcohol intolerance. SEAC agrees that such high prevalence would most likely easily be detected and that it is very likely that the 40 % prevalence rate is a significant overestimation. The value is based on average values for a number of studies which found alcohol intolerance between 3.5 % and 74 %, and that the actual exposure was not always very clear. E.g. Fioritto et al., 1997, referred to in the Appendix to the Background Document, found 74 % to have alcohol intolerance while Wang et al (1991) found that 21 % had alcohol intolerance.  SEAC notes that the estimation is based on available studies but noted that the dose-response relationship is uncertain. In the final opinion this uncertainty is underlined and it is said that the quantified benefit estimated must likely is significantly overestimated.  With regard to the comments on the used QALY weight of 0.08 used for the liver effect, SEAC notes that the value is the lowest of the considered range. It should further be noted that a QALY measures the discomfort etc. during one year of the disease. The loss of a lifelong disease is therefore calculated by multiplying the loss of one year with the number years where a person is expected to suffer of the disease. Furthermore, the medicinal costs and the cost in the health sector is not part of the QALY loss. Points 1 to 4 of the difference between alcohol intolerance and cirrhosis in your comment are therefore not relevant. The important point is whether the dis­com­fort of the two diseases in a certain year can be considered to be the same. For compen­sated cirrhosis (cirrhosis without symptoms) the QALY weight in some studies have been found to be 0.16 while the QALY for decompensated cirrhosis has been found to be 0.48. As the number of the symptoms are the same, SEAC does find a QALY weight of 0.8 as unjustified, but acknowledge the uncertainties. More reflections on the QALY weight can be found in https://echa.europa.eu/­documents/10162/13639/report\_qualy\_daly\_en.pdf/f8c20060-8e7d-4b87-9e0c-64ba2999e63d, Annex 3.  With regard to risk reduction measures, your comment refers to the "hierarchy of control" principle and states that in the long run PPEs and job rotation would not be considered acceptable and that additional technical controls therefore would be needed. However, according to SEACs understan­ding the principle is not an automatic process leading to substitution or enclosure in all cases. It is always a case-by-case assessment and only if economically are feasible there is an obligation to ensure the higher levels of risk management measures (enclosure, substitution) are used.  In the background document SEAC has given its opinion on the principles of calculating costs in case the production is terminated, but has not included it in the opinion as it is not considered to be a likely response.  SEAC acknowledges the importance of the products produced using man-made fibres. However, this has not been assessed in detail, as SEAC's conclude that it should be possible to reduce the exposure to the proposed level. As the companies do not agree to that conclusion there is still uncertainty related to this, and SEAC has therefore added a paragraph related to the importance of the production.  With regard to how SEAC has considered comments on the public consultation of the Annex XV report (#2287,#2320 and #2323), SEAC notes that the artificial leather sector is part of the coating PU-sector. Comment #425 above is from that sector.  With regard to comments (£2295, #2299, #2300, #2303 and #2325, SEAC notes that the comment, SEAC notes that the pharmaceutical sector did not find it possible to do without DMF and they stated the original proposed DNEL's will represent an additional effort to ensure compliance with them. The sector has not submitted comments to the SEAC opinion. |
| **x** | **Date/Time:** 2019/11/25 21:54  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:** Vetex nv  **Org. country:**  Belgium  **Attachment:**  <redacted> | **Comments on the SEAC draft opinion:**  **-** |
| **SEAC Rapporteurs response:**  The confidential comment is submitted by the PU-coating company The main argument is that workers cannot work eight hours with full-face gasmasks; there will be a lot of opposition towards this proposed solution, and that job rotation would not solve the problem as all workers work in the production hall, where exposure takes place.  The company indicates that compartmentation (full or partly) of the coating line and a manufacturing line that is fully automated (sensors, robots, automated dosing, etc.) is possible given acceptable transition time. The company submitted information on investment costs and yearly operational costs.  SEAC thanks for the information on costs, which are within the level described in the opinion and background document.  Furthermore, SEAC agrees that the use of PPEs is not possible for an 8-hour working day and notes the comment that job rotation is challenging in this company. |