

**Committee for Socio-economic Analysis (SEAC)**

**Response to comments on the SEAC draft**

**Opinion**

**on the Annex XV dossier proposing**

**restrictions on**

**1-methyl-2-pyrrolidone (NMP)**

**1-methyl-2-pyrrolidone (NMP)**

**EC number: 212-828-1**

**CAS number: 872-50-4**

**25 November 2014**

Comments on the SEAC draft opinion

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| **Ref.** | **Date/Type/Country** | **Comments** |
| 127 | **Date/Time:** 2014/11/07 18:20  **Type:** Industry or trade association  **Country:** Belgium  **Name confidential:** False | **Comment:**  1) NMP is critical for the semiconductor industry in Europe. The industry strongly depends on the availability of this chemical to manufacture semiconductor devices. Any disproportionate restriction or ban of the substance could jeopardise this manufacturing continuity in Europe. The industry uses NMP in safe and responsible manner as outlined in the draft restriction dossier. Any future potential demonstration of compliance should not add excessive or disproportionate burdens nor be outside of REACH and must be in line with current national worker protection legal requirements.  2) The continued manufacture and supply of NMP to European end industrial user sectors such as the semiconductor industry can be gravely affected if a disproportionately burdensome risk management option (RMO) for all parts of the manufacturing and supply chain is selected. Both the direct and indirect business impact of the RMO need to be considered adequately and carefully for the manufacture, formulation and end industrial use. The industry would feel that the RMO and final DNEL level chosen in the restriction should balance appropriately the broader socioeconomic issues of NMP with how the risk is managed. The semiconductor manufacturing sector cannot speak to the fact of whether the industry’s direct supply chain and its formulators can meet this restriction proposal with a potential subsequent disruption of the supply chain.  3) The industry strongly believes that the restriction route as modified by RAC is an effective way to manage the NMP substance under REACH. For clarity purposes the industry believes that the authorisation option should now not be taken forward for this substance as the overall risk is managed under the restriction annex XVII listing. We would like to express, that a disproportionately burdensome regulatory measure (i.e. authorisation) that would limit the semiconductor sector’s ability to use NMP, would lead to significant business consequences for the sector without any commensurate benefit for human health or the environment from the semiconductor use.  4) Under the current wording of the modified RAC proposal it should be noted that downstream user industries, as not being a registrant typically under REACH, will apply the exposure scenario annexed in the SDS by the actual registrant. The final conditions of restriction wording should include the wording - downstream users who are themselves registrants. The final restriction wording should also state that the DNEL shall be used in their chemical safety assessments documented in chemical safety reports and in safety data sheets. Semiconductor industry would propose following word modifications with the proposed conditions of restriction just to add more clarity:  Manufacturers, importers and downstream users (where DU are registrant of the substance also) of the substance on its own or in mixtures in a concentration equal or greater than 0.3% shall use in their chemical safety assessment documented in chemical safety reports and safety data sheets by [xx.yy.zzzz] a Derived No Effect Level (DNEL) value for workers inhalation of 10 mg/m3and a DNEL for workers dermal exposure of 4.8 mg/kg/day.  Restriction conditions foresee that no further enforcement activities are required due to the implementation of the restriction beyond the usual chemical safety reports, SDSs and ensuring that recommended risk management measures are implemented by downstream user.  5) The semiconductor sector would like to comment that any eventual demonstration of compliance with the restriction remains undefined. Any future potential demonstration of compliance should not add excessive or disproportionate burdens nor be outside of REACH and must be in line with current national worker protection legal requirements. Any future demonstration of compliance with the restriction and with relevant exposure scenarios should not induce more monitoring efforts than those currently performed under the EU workers protection legislation. In this regard the industry welcomes the view on page 15 of the SEAC draft opinion that no further enforcement activities are required “Should the restriction based on the RAC-modified proposal be included in the Annex XVII, the enforcement would follow the same procedures as is normally used with regard to development of CSRs, SDS’s and ensuring that the recommended risk management measures are implemented by the downstream user. Therefore no further enforcement activities are required due to the implementation of such restriction.”  6) The semiconductor manufacturing industry sector employs stringent risk management measures and safety practices to prevent NMP release at a manufacturing process level thus preventing worker exposure. The semiconductor sector uses NMP in a safe and highly controlled way. Stringent risk mitigation measures are in place as standard, such as closed systems. Uses of NMP take place in batch processes in dedicated process equipment tool in a controlled environment, i.e. the clean room. Potential risk is typically eliminated and controlled through the application of enclosed manufacturing equipment. Besides, automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment. Continuous local and equipment exhaust ventilation under alarm are also present.  7) The SEAC draft opinion does not include concerns relating to socioeconomic impacts of the measure at a global level. The European semiconductor industry like many affected sectors competes globally. The industry’s global competitors do not have comparable legislation on such an important material as NMP in their jurisdictions. ECHA Reach measures will not contribute to a level playing field globally and it is imperative that no disproportionate burdensome compliance measures are applied. | |
| **SEAC Rapporteurs response**  Thank you for your comment and support to the draft opinion. We note that it should be possible for the semiconductor industry to comply with the proposed restriction. With regard to the level of the derived DNEL, this is as a matter of principle not to be influenced by socio-economic considerations. In our opinion we assess the socio-economic consequences of ensuring that the exposure does not exceed the DNEL value. The comment on the specific wording of the restriction is forwarded to the Commission for further considerations as the wording of the Annex XVII entry is decided on by the Commission. With regard to the socio-economic impacts on global level, this is relevant for SEAC, and is also an important factor for not supporting a total ban (RMO1). The length of the transitional period of 5 years is reflecting that industry should have sufficient time to be able to adjust to international competition. | |
| 117 | **Date/Time:** 2014/11/12 17:01  **Type:** Company-Downstream user  **Country:** Germany  **Name confidential:** True | **Comment:**  Comments on the restriction proposal for 1-methyl-2-pyrrolidone (NMP) were already submitted by our company on November 27, 2013 (communication 02568d32-afdb-4d54-8cdb-f7b6d1bd73ca) and on March 18, 2014 (communication 22b0bd05-4fa5-4c8b-ba80-a80b444cd5cc).  SEAC considers the restriction proposal for NMP as modified by RAC as most appropriate EU wide measure. In general we would like to point out that we support the idea of using substance restriction instead of authorisation to address the identified risks for the industrial use of NMP.  The lead time needed for the implementation of the Derived No Effect Level (DNEL) value for workers inhalation of 10 mg/m³ for our use of NMP in the manufacturing process of electrodes for lithium ion batteries is estimated as approx. five years. This time frame is needed for a tiered approach in the adjustment of the technological process in order to find the best practicable and efficient solution for the reduction of the work place concentrations in the vicinity of the foil coating head. It is inevitable to assure that these changes will not negatively affect the drying of the dispersion on the foil. In particular the homogeneity of the electrode surface as well as the complex air management system play a decisive role in the battery production process. Therefore any change in this part of the production process needs to be carefully planned and implemented in order to avoid negative impact on the product quality of these state-of-the art electrodes for lithium ion batteries.  The costs for the required changes in this production process are estimated in the range of 2 – 5 Million €. We believe that an investment into the enduring reduction of the workplace concentration has a higher socio-economic benefit compared to an authorisation approach for limiting the identified risks for the industrial use of NMP. It also gives us a higher investment security in the high-tech production environment compared to the time limited authorisation approach.  Nevertheless we would like to point out that we would have preferred a higher DNEL value for the workers inhalation based on the highest DNEL that still excludes any health risk to the worker. The possibility of an organisational solution was not taken into account by the current. In our settings only male workers are allowed to work at the most exposure critical workplace which is the foil coating head, as described above. Therefore higher work place concentrations could be accepted without causing additional risks. | |
| **SEAC Rapporteurs response**  Thank you for the comment. SEAC is basing its consideration of what is considered to be as safe level (DNEL) on RAC's conclusion, and notes that according to REACH guidance and in line with CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION, art. 21, gender specific DNELs are not possible. | |
| 128 | **Date/Time:** 2014/11/13 15:03  **Type:** Industry or trade association  **Country:** Germany  **Name confidential:** True | **Comment:**  Page 7 of the draft SEAC opinion document (RMO Analysis, RMO4) contains the following section:  "In conclusion, SEAC considers that the authorisation route (RMO4) might be effective and practical for some sectors and giving a constant incentive to phase out the use of a CMR substance like NMP. This could especially apply for uses where the impacts of a general restriction on the most affected companies are considered not to be proportional. An option for risk management incentives could therefore be to combine a restriction with an authorisation approach for such uses."  We have the following comments:  This section on page 7 is generally in contradiction with the positive opinion on Restriction as the optimal RMO for NMP. In addition, the text is confusing, and it is not clear what is meant with “the most affected companies”, and how, why and/or in which cases Restriction would “not be proportional”.  This statement may very well create considerable confusion and debate with both users and (national) authorities, and it undermines the positive view of the SEAC for Restriction of NMP. Also, it may convey uncertainty among users about the future risk management strategies to be complied with.  We strongly suggest that this section will not be included in the final SEAC opinion. | |
| **SEAC Rapporteurs response**  SEAC does not consider authorisation always to be very burdensome, especially when the expected exposure is below what is considered to be a safe level (adequate control). Applications can be submitted by manufacturers. In the case where adequate control is not met, authorisation can be granted if the benefits exceed the costs. While for non-controlled substances exposure has to be below the adequate control level. | |
| 129 | **Date/Time:** 2014/11/13 16:27  **Type:** Industry or trade association  **Country:** Belgium  **Name confidential:** False | **Comment:**  13.11.2014  1-methyl-2-pyrrolidone (NMP) EC 212-828-1 CAS 872-50-4  Public consultation  Comment from the main European manufacturers on the draft opinion of SEAC  ---------------------------------------------------------------------------------------------------------------------------------  These comments on the draft SEAC opinion on the 1-METHYL-2-PYRROLIDONE restriction annex XVII dossier are made on behalf of the members of the Cefic 1,4-Butanediol & Derivatives Sector Group (Cefic BDO SG) representing the main European manufactures.  General comments  1. Cefic BDO SG generally supports the NMP restriction.  2. From a registrants perspective including a dermal DNEL into the conditions of the restriction does provide clarity. In practice we expect only a small additional economic impact as both DNELs are required for any exposure scenario in the MSDS.  3. Despite being generally supportive, Cefic BDO SG still sees some room for improvement for the NMP restriction for example:  a. Cefic BDO SG would like to point out that this restriction should define the highest DNEL that still excludes any health risk to the worker.  This should, in the view of SEAC represent the optimal NMP restriction as one can suppose an exponential cost/exposure reduction relationship. Defining a harmonized DNEL lower than needed to avoid risk and assure safe handling will produce additional exposure reduction costs without any health benefit. Furthermore a too low harmonized DNEL may restrict safe uses, which is not the purpose of a restriction.    b. The negative economic impact of the restriction is driven mostly by the proposed DNEL that is significantly lower than the IOEL currently in use in most EU countries (40 mg/m³ 8 h TWA). The IOEL value is equivalent to dermal uptake of 5.7 mg/kg, supposing light work and a 70 kg worker. Basically it is in line with ECHA guidance principle to use the IOEL value as inhalative DNEL. Furthermore this offers the chance to promote the required harmonization of occupational and chemical legislation and has the lowest economic impact.  c. It is acknowledged that SEAC cannot derive safe exposure levels and has to provide an opinion on the current proposal as it is. However, SEAC may consider explaining in the opinion that one can suppose in principle an exponential relationship between cost and exposure reduction and ask the commission to consider this aspect when transferring the restriction into the ATP amending annex XVII.  Detailed comments:  Apart from the general comments Cefic BDO SG would like to make detailed comments on some assumptions which we believe to be incorrect:  Page 7: “SEAC recognises that authorisation could be a good option in cases where requirements for implementation of risk reduction measures should reflect the individual circumstances, especially in the case where the socio-economic route is followed.”  Comment: Despite the fact that NMP authorization on the non-adequate control route (= exposure above the suggested harmonized DNEL) may provide some questionable relief to some individual companies, it will put a very significant cost burden on all the others.  Page 7: “An option for risk management incentives could therefore be to combine a restriction with an authorization approach for such uses.”  Comment: No authorization can be granted for restricted uses. The only way this offer might work as intended, would be that the restriction states that higher exposure requires authorisation. Basically this is the same as exemption for uses being compliant with the value provided in the restriction proposal, and authorisation for all other uses. | |
| **SEAC Rapporteurs response**  Thank you for the comment. We just note that socio-economic considerations are not part of the establishment of DNELs. If higher exposure levels are justified due to cost considerations this has to be accepted by higher mandatory values or as part of the authorization scheme. We agree that according to Art. 60.6 a use cannot be authorised if this would constitute a relaxation of a restriction. However there is a technical possibility from a broader risk management approach to combine a restriction with authorisation for exempted uses. However, this issue would have to be examined by the Commission, as SEAC does not give an opinion in terms of legal aspects. In the final opinion, the legal possibility for such a combined regulation is described. | |
| 121 | **Date/Time:** 2014/11/13 20:45  **Type:** National Authority  **Country:** Austria  **Name confidential:** False | **Comment:**  The proposal is as follows:  “Manufacturers, importers and downstream users of the substance on its own or in mixtures in a concentration equal or greater than 0.3% shall use in their chemical safety assessment and safety data sheets by [xx.yy.zzzz] a Derived No Effect Level (DNEL) value for workers inhalation of 10 mg/m3 and a DNEL for workers dermal exposure of 4.8 mg/kg/day.”  This proposal does not contain any provision for concentration below 0.3%. In particular in the case of dermal exposure low concentration can lead to high resorption through the skin. In the SCOEL Recommendation N-Methyl-2-Pyrrolidone explicitly is marked with “Skin” Notation.  A Safety data sheet has to be provided for concentration of reprotoxic substances if they are contained in a mixture above 0.1% (see Annex II part 2.10 footnote 1 to table 3.7.2 CLP-regulation). Therefore it is strongly misleading stating that a safety data sheet only “shall be used” from 0.3%.  Proposal: We strongly suggest to delete the denomination of any concentration range and to delete the words “in a concentration equal or greater than 0.3%”.  general comment (several pages):  There is a basic contradiction in the justification parts. The justification refers several times to exposure scenarios:  e.g.:  “The resulting exposure scenarios would have to recommend concrete and use-specific operational conditions and risk management measures to ensure that the inhalation and dermal exposures on average over a day are below the DNEL values and the combined RCR are also below 1.” (page 3)  “Users are obliged to implement conditions described in the scenarios” (page 3)  It must be emphasised that REACH guidance documents ONLY envisage exposure scenarios for substances and NOT for mixtures (which is the case for NMP)! The good looking justifications will get to nowhere. In most cases downstream users will get the DNEL in their “normal” SDS but no RMM because there is no need of providing an eSDS.  From the RAC Draft Opinion:  “It is therefore concluded that the risk characterisation shows that risks for (pregnant) workers are not sufficiently controlled, and that the risk assessment shows that FURTHER risk management measures (than those expressed to be used in the registration dossier) are needed.” (page 11)  There are no such “FURTHER risk management measures” that are necessary due to the opinion of the RAC in the proposed entry for Annex XVII.  Proposal: A mixture containing NMP must be provided with a safety data sheet including all relevant exposure scenarios. Thus the entry in Annex XVII must be supplemented by the following sentence:  “Chemical safety assessments and safety data sheets shall include all relevant exposure scenarios.”  Otherwise the opinion cannot be agreed. If the supply of ES is not granted, other RMO have to be faced (e.g. a total ban or a case by case authorisation).  page 10  It should be mentioned that NMP is used in many industrial fields (e.g. wire winding industry, battery, chemical synthesis, semiconductor production, etc.). These industries employ female workers. Excluding women from all these work places because of the use of NMP would be discriminatory and is contradictory to the aim of the Lisbon treaty (enhancement the number of employed people).  Date of enforcement:  A time scale of 60 months seems to be rather long taking into account the fact that the discussion on this restriction is ongoing for years. Additionally the final decision of the inclusion into Annex XVII will still take its time. Thus a shorter transmission period, no longer than 48 months, is suggested. | |
| **SEAC Rapporteurs response**  Thank you for the comment. According to the ECHA's website info on obligations of DUs – ‘Downstream users who supply hazardous substances, as such or in a mixture, have to communicate information regarding the safe use to their own customers. This should be in the form of a safety data sheet or otherwise, as required.’  The statement, that ESs and SDSs for mixtures are not reflected in REACH guidance is not quite correct. In fact, quite a lot of work has been and is being done by the industry and ECHA to develop a sustainable methodology for preparation of SDSs and ESs for mixtures.  Some of this work is reflected in the guidance for DUs: <http://echa.europa.eu/documents/10162/13634/du_en.pdf>  - section 7 describes legal obligations related to mixtures under REACH. The issue is also presented in the Guidance in a nutshell: <http://echa.europa.eu/documents/10162/13634/du_nutshell_guidance_en.pdf>  - in section 6.    Basically, SDS does not have to be prepared for a mixture only if none of the components can be considered as hazardous. For NMP – that will mean very low concentration - recently changed cut-off to 0.3%. Below this concentration – it is considered that there is no health effect, so no need for safe use instructions.  As we read the proposed entry, it is not said that SDSs only apply for concentrations above 0.3%. However, your comment on the specific wording of the restriction is forwarded to the Commission as the wording of the Annex XVII entry is decided on by the Commission.  SEAC has no information that would justify a shorter transitional period than 5 years, also taking the impacts in some sectors, e.g. the wire coating sector into consideration. | |
| 132 | **Date/Time:** 2014/11/14 09:54  **Type:** Industry or trade association  **Country:** Belgium  **Name confidential:** False | **Comment:**  EWWG Secretary  L Danel  Nov. 13th 2014  COMMENTS TO SEAC NOV.2014  Reference: ECHA report  Committee for Socio Economic Analysis on NMP  Draft from 10 Sept. 2014.    Thanks to the discussions between ECHA and EWWG, each member of this organisation is looking in details how to comply with the DNEL level defined in the current Restriction project. Restriction is indeed the only possibility for the Winding Wire industry, since Authorisation would be irreconcilable with long term investment needs of this industry.  We are mainly referring to the clause of the SEAC report called:” Impacts on the wire coating sector.”  As a preliminary remark, the meaning of the following wording from the SEAC report was not easily understood:  « A restriction would therefore mean advanced investment of total €276 M.  The advanced costs mean opportunity cost of €61,5M in total for the first 30 years which is the expected lifetime of wire coating lines.“  The total investment cost of €276 M is logical, but the meaning of opportunity cost is not understood; the total of such opportunity costs is also not related with a previous calculation.  The load of advanced expenditure and the relevant interest rates are also not considered.  Now, the crucial remark of the Winding Wire industry relates to the basis of calculation in the SEAC report, which shall be revised:  1 – TOTAL TURNOVER  The total production value of the wire coating sector is estimated by SEAC to be €3 billion per year. (This estimation was made by AMEC, in RIVM report, Aug 2013).  As stated in SEAC note 7, this is also including formulators’ turnover, not only the coating industry.  2 – ADDED VALUE OF THE WIRE COATING SECTOR  Special comments sent by EWWG to ECHA / RAC, 20 Feb 2014, were the following:  “First, the copper price has reached record levels on the London Metal Exchange, up to 5 or 7€/kg in the last decade, indicating record prices of WW for customers.  Unfortunately, record turnover does not mean record turnover for the WW industry, since the copper price is the same official price for the WW industry and for the final customer, this is just a transfer.  The profit is coming from the Added Value. As an example only, in this medium range of winding wire, the added value business to business is 10 to 20% of the material itself.”  3 – REVISED CALCULATION  Therefore, the base of calculation shall not be the total turnover of winding wires, since the copper value is by far the highest part of turnover. Copper is purchased worldwide through the London Metal Exchange, and invoiced to the Winding Wires customers, on LME basis. This is a pure transfer operation.  The base of calculation shall be the Added Value of the Winding Wires industry.  Based on 400 000 tons of copper usage (Information from the same document), the copper part is at least estimated 400 000 x 6€ = € 2billions and 400millions.  In the remaining € 600 million, the formulators’ turnover is also included inside the so-called “Wire coating sector”  The revenue of the Winding Wire industry in Europe, excluding copper, can be estimated now to be less than € 500 million.  This revised basis has been put into ECHA´s calculation of “Opportunity costs” as follows:      ECHA CORRECTED  2020 2021 2022 2023 2024 2025 2026 2027 2028 Total    Production value 500 500 500 500 500 500 500 500 500    Opportunity cost 61,5 48,5 37,5 27,5 19,4 12,8 7,6 3,7 1,2 219,7  Interest 0,0 0,0 0,0 0,0 0,0 0,0 0,0 0,0 0,0    Total opport. costs 61,5 48,5 37,5 27,5 19,4 12,8 7,6 3,7 1,2 219,7  12,3% 9,7% 7,5% 5,5% 3,9% 2,6% 1,5% 0,7% 0,2%      LIQUIDITY OUTFLOW  2020 2021 2022 2023 2024 2025 2026 2027 2028 Total    Production value 500 500 500 500 500 500 500 500 500    Investments 276,0 276,0    Liquidity outflow 276,0 0,0 0,0 0,0 0,0 0,0 0,0 0,0 0,0 276,0  55,2% 0,0% 0,0% 0,0% 0,0% 0,0% 0,0% 0,0% 0,0%  As can be seen from the corrected table, in the years 2020 / 2021 and 2022, the ”Opportunity costs” because of the new limit for NMP are amounting to 12%, 10% and 7,5%, respectively. Together with « normal » investment activities, about 10 – 15% of the turnover would have to be invested in those years.  Such a level of investment ratio is impossible for the winding wire sector, which has to live with small margins. A longer transition time is absolutely necessary for the whole industry.  Looking at another financial aspect, the flow of liquidity is drastically negative in first years; as can be seen in the following table, such liquidity flows will be impossible to handle.  5 - CONCLUSION  EWWG asks ECHA to consider the new ratios, 6 times higher than described in ECHA original table.  These costs are not bearable in the Winding Wires industry for the following reasons:  This industry is exclusively made of SME, since big groups and companies have left this industry. It is a low-profit industry, because of investment costs.  The global trend of this business is not increasing, when OEM are relocating in lower cost countries; production sites have closed in EU.  EWWG companies survive between profit and loss; they need sufficient time to adapt.   The transition period is preferred to be 15 years; it is not acceptable and not possible in 5 or 6 years. A longer transition period is essential.   SEAC is kindly asked to propose in the report a more realistic transition period, which is economically bearable. | |
| **SEAC Rapporteurs response**  Thank you for your remarks.  We do not agree that authorisation per se is irreconcilable with long term investments. This can be managed through the length of the review period. Furthermore, if after the investment the risk is adequately controlled, application for authorisation will be granted.  The opportunity costs should not be aggregated as done in your comment. For all wire lines of more than 20 years (as those established in this century already are able to comply with the proposed level for exposure) the relevant factor is the advanced investments. Lines of 29 years age would in average only have 1 year left, while lines of the age of 21 years would have 9 years left. Hence the following opportunity cost (what the money could have been used for instead) is estimated as follows (cf. table 15a in the background document).   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Number of remaining years | Part of investment | Projection factor | Interest m€ | Number of years postponed | Opportunity costs total, m€ | | 1 | 30,67 | 1,04 | 1,2 | 8 years | 1,2 | | 2 | 30,67 | 1,08 | 2,5 | 7 years | 3,7 | | 3 | 30,67 | 1,12 | 3,8 | 6 years | 7,6 | | 4 | 30,67 | 1,17 | 5,2 | 5 years | 12,8 | | 5 | 30,67 | 1,22 | 6,6 | 4 years | 19,4 | | 6 | 30,67 | 1,27 | 8,1 | 3 years | 27,5 | | 7 | 30,67 | 1,32 | 9,7 | 2 years | 37,2 | | 8 | 30,67 | 1,37 | 11,3 | 1 year | 48,5 | | 9 | 30,67 | 1,42 | 13,0 |  | 61,5 |     We think the opportunity cost approach is valid for the socio-economic view as it also reflects that the new lines will last 30 years.  However, we acknowledge that for the individual companies, the financial costs might imply difficulties in the case where profit margin is very low or negative.  The comparison with the turnover gives some indications of the scale of the challenge. In the final opinion, it is mentioned that a large part of the turnover is directly linked to the copper price and that the metal value constitute 80% of the turnover (which is a turnover anyway to be financed). In the final opinion, the opportunity costs are compared with the total discounted production value for 15 years, showing a OC/PV ratio around 1%.  However, due to the uncertainty with regard to the economic feasibility SEAC considers that for us in wire coating lines it might be justified to prolong the transition time for implementation of risk reduction measures needed.  In the BD the concept of opportunity cost is described. | |
| 122 | **Date/Time:** 2014/11/14 10:09  **Type:** Company-Manufacturer  **Country:** France  **Name confidential:** False | **Comment:**  Public Comments submitted by Arkema France, on behalf of the DMSO Consortium, in the frame of the Public Consultation on the Background document to the RAC and SEAC Opinion on the Annex XV dossier proposing restrictions on 1-methyl–2–pyrrolidone (NMP)  DMSO Consortium would like to submit comments on some of the statements contained in this document. The members of the Consortium are:  • Arkema France, manufacturer of DMSO in Europe.  • Gaylord Chemical Company, L.L.C. manufacturer of DMSO in USA.  • Toray Fine Chemicals Co., Ltd. manufacturer of DMSO in Japan and China.  All members of the Consortium have significant technical, toxicological, ecotoxicological and commercial expertise on DMSO.  General statement  The RAC and SEAC Opinion lists a number of criteria which have to be considered in a responsible substitution plan of NMP by DMSO (reactivity and incompatible mixtures, temperature stability range, skin permeability and choice of skin protective gloves). The technical competences to assess and manage these criteria are available and the cases of successful substitutions and experiences of NMP by DMSO are increasing.  The RAC and SEC Opinion lists 13 uses and concludes that the use of DMSO as alternative for NMP has been described for a limited number of uses. Herein, and in confidential submissions, the DMSO Consortium indicates that there are 10 uses for which commercial activity already exists and the number of uses where development is ongoing to organise the substitution of NMP by DMSO is increasing in Europe.  The RAC and SEAC Opinion indicates that due to economic and toxic considerations, industry would have replaced NMP by DMSO if possible. Herein, the DMSO Consortium explains the evolution of the price of the two solvents demonstrating that the economic interest of DMSO is very recent. It is also explained that the toxicological and ecotoxicological data base of DMSO has been completed only recently and the absence of hazards confirmed by an independent OECD experts panel in 2010. As a result, it is considered that the sustainable use conditions of DMSO have been established only recently; these are prerequisite for the industry to consider substitution of NMP by DMSO.  Separate confidential and more detailed submissions by the individual members of the consortium will address:  C.2.2.9 Hazards from physico-chemical properties of DMSO  C.2.3 Environmental risks related to DMSO  C.2.4.1 Technical feasibility  Commercial uses are confirmed in Petrochemical industries, Non-wire coaters, Wire coaters, Cleaners, Electronics and semiconductor industries and Battery industries, Membrane manufacturers, High performance polymer producers, Agricultural chemical industries (synthesis, formulation), Pharmaceutical industry and biotechnology.  C.2.4.2 Economic feasibility  C.2.5.Conclusion on DMSO  The statement that “due to both economic and toxic considerations industry would have replaced NMP by DMSO if possible” is perceived as biased based on the fact that DMSO is already used commercially at industrial scale in 10 uses out of the 13 presented and further developments are ongoing.  On the economic aspect, the evolution of the price of the two solvents is favourable to DMSO only in the last 4 years, hence limiting the consideration of DMSO as an economically feasible alternative to NMP before 2010.  On the “toxic” aspect, it is important to understand that the toxicological and ecotoxicological database confirming the absence of hazards for DMSO is complete and available since 2007 only. The confirmation by independent OECD experts of the absence of hazards for DMSO started in 2008 and was completed in 2010 with the publication of the OECD SIDS.  There have been numerous historical cases of hasty substitutions from a dangerous substance to a substance perceived as not dangerous until the toxicological and ecotoxicological results performed on the latter proved the opposite. In the industry using polar aprotic solvents in particular, this happened when a non-negligible number of actors switched from DMF to NMP.  Based on the amount of fine tailoring development, financial and time investment required to substitute a aprotic solvent by another, the industry has therefore been careful to have all the elements related to the absence of hazards before deciding to consider DMSO for sustainable developments.  The consideration of DMSO as a valid economical and safe alternative to NMP is therefore recent. Industrial actors have now started and in some cases completed substitution plans that demonstrate the technical feasibility in carefully tailored conditions. | |
| **SEAC Rapporteurs response**  Thank you very much for your comment. We agree that the description of DMSO in the BD could be considered as biased, especially with regard to the economic feasibility. However, for some uses, especially for wire coating, European experience on the use of DMSO seems to be lacking. In a footnote in the background document we have reflected that information has been submitted by manufacturers of DMSO with reference to downstream users which demonstrates that DMSO seems to be suitable alternative in a number of uses, and that there is no basis for stating that it is believed that due to [both toxic and] economic considerations industry would have replaced NMP if possible. | |
| 124 | **Date/Time:** 2014/11/14 10:49  **Type:** Industry or trade association  **Country:** Belgium  **Name confidential:** False  **Attachment confidential:** False | **Comment:**  EWWG Secretary  L.Danel  November 14th,2014  Reference: ECHA Report  Committee for Socio Economic Analysis on NMP  Draft from 10 Septe. 2014  Addendum to comments of EWWG  Due to the limitations of the comment-website (6000 characters maximum, no tables) a Word document has been sent separately to ECHA by e-mail.One table,which is already available from previous documents, had to be deleted from the transmission to the ECHA website to stay within the limits.  The Word document submitted to ECHA is public and does not contain any confidential information. | |
| **SEAC Rapporteurs response**  See #129 | |
| 123 | **Date/Time:** 2014/11/14 12:44  **Type:** National Authority  **Country:** Denmark  **Name confidential:** False | **Comment:**  Comments on the SEAC draft opinion from Danish Working Environment Authority (DWEA)  Hereby the The Danish Working Environment Authority (DWEA) has following final comments on the REACH Annex XVII proposal for restriction on NMP:  The Danish Working Environment Authority (DWEA) supports that the wording in the proposal is changed from concepts/terms based on The Occupational Safety and Health legislation (OSH)(worker protection legislation(WPL) )to the concepts/terms that belongs in REACH Regulation. […] call attention to that REACH Regulation shall apply without prejudice to the OHS legislation in accordance with Article 2 (4.a) of REACH.  Working environmental regulations for work places are regulated in (OSH) in accordance with Frame Directive 89/391, Chemical Agents Directive (CAD) 98/24 and Carcinogens and Mutagens Directive (CMD) 2004/37.  WPL (Worker Protection Legislation) is based on precautionary principle and that exposure at workplaces for hazardous substances should be kept as low as possible.  DWEA supports, that RACs modified proposal in the restriction are directed at registrants and downstream users, especially formulators who need to perform a chemical safety report (CSR) and complete a chemical safety assessment according to REACH article 14 and 37.  DWEA wishes to call attention to that the derivation of DNEL according to ECHA guidance on how to set DNEL values is mainly based on use of human data and based on health effects. Furthermore also according to REACH Annex I, the DNELs are health based.  Furthermore, DWEA wiches to call attention to NMP already seems to be covered by Annex XVII (552/2009) point 30 because of the harmonized classification Repr. 1B (Reproductive toxicant category 1B), which would mean that NMP shall not be placed on the market for supply to the general public | |
| **SEAC Rapporteurs response**  Thank you for the comment. | |
| 126 | **Date/Time:** 2014/11/14 14:39  **Name confidential:** False | **Comment:**  The proposed restriction is insufficient for creating a harmonized level of protection for workers’ health across EU MS as it is lacking two indispensable elements:  (i) a specification for duty-holders under the restriction on how to validate that the DNELs prescribed in the restriction will actually be achieved by means of the RMMs derived by them in their CSA and communicated in the SDS, including a specification on the documentation of the validation procedure and of the results achieved by it;  (ii) a specification for DUs as applicants of the RMMs on how to review the effectiveness of the implemented RMMs communicated to them in the SDS, including a specification on the documentation of the review procedure and of the results achieved by it.  Furthermore, it will be indicated that a DNEL for workers’ dermal exposure can be neither controlled by the DU nor enforced by the authorities.  In addition, it will be highlighted that certain RMMs for dermal exposure might result in additional health risks and, thus, might contradict OSH obligations, unless those RMMs are accompanied by specific organisational RMMs.  Validation of RMMs  In order to secure that the derived RMMs are appropriate to achieve the DNELs prescribed in the restriction, they would have to be validated. Such a validation step is not obligatory as part of the CSA. Thus, a safeguard is missing that by the resulting RMMs, derived under the sole responsibility of the duty-holders under the restriction, the DNELs will actually be achieved. As a consequence of this gap, the DU, that is the recipient of the SDS, cannot be sure that the RMMs communicated in the SDS are appropriate to achieve the DNEL.  This situation is not different to the situation in which RMMs are derived as part of the CSA under the registration obligation in order to achieve a DNEL derived by the M/I. However, as the DNEL used in the restriction has been derived by a legal entity and not by a private company, since it is intended to serve a different legal function, an improved quality control of the corresponding RMMs by prescribing a validation procedure is deemed necessary in view of the aim of the restriction to secure a harmonized level of protection for workers’ health across EU Member States.  Review of effectiveness of implemented RMMs  In addition to the validation of the RMMs by the duty-holders under the restriction, there is also the necessity on the part of the applicants of the RMMs (DUs under REACH, employers under OSH) to review the effectiveness of the RMMs after their implementation, as the actual situations at the workplaces in question might be different to the assumptions under which the RMMs were derived up the supply chain.  Although such a review of effectiveness is a standard procedure under OSH legislation as part of the risk assessment process under the responsibility of the employer, it is by no means a harmonized procedure, as in the CAD (Dir. 98/24/EC) only a general framework is prescribed as a minimum standard which was transposed into national legislation by the MS at their discretion.  It should also be taken into account that legal instruments under REACH, such as DNELs, are not necessarily incorporated into national OSH legislation by MS. Thus, it is not predictable whether, and if so in what way, a DNEL under REACH would have to be observed under national OSH legislation in the risk assessment process under the responsibility of the employer.  As it is the aim of the restriction to secure a harmonized level of protection for workers’ health across MS, it is not sufficient to rely in the restriction implicitly on the non-harmonized obligations of the OSH legislation. Instead, as part of the restriction, it would be necessary to specify to DUs, as applicants of the RMMs communicated to them in the SDS, how to review the effectiveness of the RMMs implemented by them, including a specification on the documentation of that review procedure and of the results achieved by it.  Only based on such specifications, is it conceivable that the mechanism according to art. 34 (b) of REACH might facilitate a harmonized level of protection for workers’ health across EU MS.  DNEL for dermal exposure  As there are no methods available for determining dermal exposure by ambient monitoring (in contrast to exposure by inhalation), biological monitoring is the only monitoring method available for controlling a DNEL for dermal exposure.  However, as there is no legal obligation for workers neither under REACH nor under OSH legislation to provide blood or urine samples for biological monitoring, the DU / employer has no legal basis for performing biological monitoring and, thus, is not in a position to fulfil his legal duty of checking the DNEL for dermal exposure. As a consequence, the mechanism prescribed in art. 34 (b) of REACH cannot work, as input from down the supply chain cannot be generated.  RMMs for dermal exposure  When RMMs for dermal exposure comprise the use of protective gloves, as can be expected for a number of uses of NMP, it has to be taken into account that the measure “protective gloves” constitutes a health hazard in itself by giving rise to “wet work”, so that the prolonged use of protective gloves can result in skin damage. In some MS, the continuous use of protective gloves for more than two hours is considered a health risk which has to be remedied by additional measures (such as an obligatory skin protection programme, and rotation of work tasks between those with and without use of protective gloves).  Should the RMMs for dermal exposure derived by duty-holders under the restriction comprise the use of protective gloves, such RMMs might clash with obligations under national OSH legislation, unless additional, primarily organisational, RMMs are communicated aiming at the health risks caused by the prolonged use of protective gloves. | |
| **SEAC Rapporteurs response**  Thank you for the comment, which is mostly related to national enforcement and monitoring activities.  We do not see any need to change / develop new approach to monitoring of implementation of legislative provisions related to controlling the risk, just because the DNEL is established by a legal entity than – as in normal case under REACH – by industry. | |
| 119 | **Date/Time:** 2014/11/14 16:13  **Type:** Company-Manufacturer  **Country:** France  **Name confidential:** False  **Attachment confidential:** True (available from confidential table) | **Comment:**  In addition to the public comment submitted by Arkema France on behalf of the DMSO consortium, Arkema France wishes to submit additional confidential comments on the SEAC draft opinion dated 10th September 2014.  These have been transmitted via an email to the ECHA dossier manager in charge on the 14th November 2014.  Arkema France wishes a good receipt for this contribution. | |
| **SEAC Rapporteurs response**  See #122 | |
| 125 | **Date/Time:** 2014/11/14 16:14  **Type:** Company-Downstream user  **Country:** Italy  **Name confidential:** False | **Comment:**  Dear Sirs,  with reference to SEAC draft opinion of 10th September 2014 on 1-methyl-2-pyrrolidone (NMP) restriction proposal, we would like to point out that application of the DNEL values proposed by RAC would have a great impact in several sectors (especially in wire coating sector) since till now the workers DNEL for inhalation route reported on the currently available e-SDS for NMP is 40 mg/m3 (TWA) - which is equivalent to the EU OEL for this substance - and the workers DNEL for dermal route is 19.8 mg/kg bw/day with the exposure scenarios setting OC/RMM to be below these limits.  The new DNEL values proposed by RAC (10 mg/m3 for workers inhalation route and 4.8 mg/kg bw/day for workers dermal route) would impose relevant changes in the set of OC/RMM to be applied by downstream users. In fact it should be highlighted that when this restriction will become legally binding, also the exposure scenarios (and exposure estimation) attached to the SDS will have to be updated to guarantee the safe use with RCR < 1. In this situation the updated exposure scenarios and related exposure estimation from TIER 1 tools (typical approach used by REACH registrants for their CSR) set to obtain RCR < 1 (when comparing the exposure estimation with these DNEL values proposed) could be over-conservative and unrealistic to apply for DU of several sectors, with unsustainable costs for new RMM implementation especially for SME. Also following the approach stated on ECHA Guideline for DU (in case of “dismatching” between the set of OC/RMM for the exposure scenario and the real OC/RMM of the DU), with the starting request to the registrant above in the supply chain for an update of these exposure scenarios and for a more realistic exposure estimation (i.e. using more complex TIER 2 tools), in many cases will not obtain a positive result, since in EU only a few EU based companies are able to modify a “standard CSR” purchased by co-registrants of a joint submission via a letter of access. So in many situations there will be a relevant waste of time and effort only to obtain a negative feedback by the registrant above in the supply chain.  For the same reason also the following step with research of an alternative supplier, which could guarantee the creation of realistic exposure scenarios and exposure estimation (which give an RCR < 1 with these new DNEL values), would be very difficult and would be very long due to commercial and practical issues.  In this hypothetical situation also the possibility of a DU CSR is not technically and economically sustainable for most of EU downstream users (especially SMEs).  For this reason many companies, operating in sectors where NMP is used and where no realistic technical/economical alternative is available (especially in wire enameling sector), realistically will not be able to be compliant with these new DNEL values and could also decide to drop out of their business with relevant consequences for loss of many people job and related socio-economic consequences, in particular for countries with high number of SMEs.  Since no alternative RMO is acceptable (because the alternatives would even have a deeper socio-economic impact on EU companies using NMP), in our opinion at least an appropriate time lapse should be provided so that the EU DU (in particular SMEs) will be able to invest money to modify their RMM to be lower these new limits. Considering the current historical moment and the deep economic crisis ongoing in most of EU countries, in our opinion this time lapse should be longer than 60 months after the inclusion into Annex XVII of REACH proposed by DS for the above mentioned elements.  Another relevant point is related to the fact the new DNEL values proposed by RAC was set to protect pregnant women due to reprotoxic properties of NMP. As stated by EWWG, in wire enameling sector for sites employing about 1000 workers, only 1 woman is employed in the process. On the basis of this analysis it seems more appropriate/proportional to asks EU companies to set and apply specific standard operative procedure to guarantee women are not exposed for process where NMP is used (in compliance with national worker protection legislation), instead of modifying deeply the process with the related economic impact especially for SME.  With best regards,  ELANTAS Italia S.r.l. | |
| **SEAC Rapporteurs response**  Thank you for the comment. We do not follow your argumentation that REACH registrants should be over-conservative in their recommendations for risk reduction measures. Objectively, registrants should be most interested in making their substance/mixture as favourable as possible for the downstream users. In addition, we refer to our response to #132. | |
| 134 | **Date/Time:** 2014/11/17 10:55  **Type:** Company-Manufacturer  **Country:** Japan  **Name confidential:** False  **Attachment confidential:** True (available from confidential table) | **Comment:**  Confidential comments have been submitted via email on 14 November. These supplement the public statement made on behalf of the DMSO consortium on the same day. | |
| **SEAC Rapporteurs response**  Thank you for the comment. We agree that the description of DMSO in the BD could be considered as biased, especially with regard to the economic feasibility. However, for some uses, especially for wire coating, European experience on the use of DMSO seems to be lacking. In a footnote in the background document we have reflected that information has been submitted by manufacturers of DMSO with reference to downstream users which demonstrates that DMSO seems to be suitable alternative in a number of uses, and that there is no basis for stating that it is believed that due to [both toxic and] economic considerations industry would have replaced NMP if possible. | |