General Comments and answers to specific questions

## Specific Questions:

### What Risk management measures, including technical means, aiming at reduction of workplace exposure to NMP, are already implemented at your workplace / within your sector?

### What are workplace exposure levels, measured in the current conditions, with risk management measures listed in answer to question 1 in place?

### What measures are needed to achieve compliance with the proposed restriction, within the suggested time (5 years), including the expected cost of implementation of the change at your workplace / within your sector?

### What is the estimated, the most feasible, timeline for implementation of the restriction at your workplace / within your sector? What are the technical or socio-economic reasons for selecting this timeframe?

1. **NEW! 28/01/2014** **Do you have suggestions for changing the restriction proposal that would ensure the same risk reduction for lower costs? If possible, please specify the risk reduction potential and the differences in costs achieved by your proposal.**

|  |  |  |
| --- | --- | --- |
| **Ref.** | **Date/type/Org./**  **Related to section** | **Comments** |
| **282** | **Date:** 2013/10/11 15:01  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (H)  **Company name confidential:** **Yes** | **Comment:**  In one of our process, NMP is used as a solvent, actually replacing other chemicals with much higher toxicity. It is currently not possible to replace NMP with a chemical of lower toxicity. |
| **Answer 1:**  NMP is used in a closed system and it is not part of the final product.  Only for analytical purposes, samples are taken. |
| **Answer 2:**  The level of NMP in the air at sampling station for an NMP-containing solvent (50 wt% NMP) has been measured (conditions: temperature 20-24°C, less to no wind, sunny, 3 minutes).  The NMP concentration in the atmosphere was less than 1 mg/m3.  for a liquid with 50wt% NMP has been measured at 20 - 24°C air temperature |
| **Answer 3:**  No additional measurements necessary. |
| **Dossier submitter response**  The restriction proposal allows continued use of NMP if occupational exposure is below the DNEL.  **Answers 1-3:**  Thank you for this information. |
| **RAC Rapporteurs comments**  The problematic substitution is noted, but the information had been more valuable if knowing what sector this concerns.  **Answers 1-3:**  Thank you for this information. |
| **SEAC Rapporteurs comments**  It is noted that the proposed restriction will not entail further costs. |
| **283** | **Date:** 2013/10/24 00:06  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** United Kingdom  **Related to:** (D) (F)  **Company name confidential:** No | **Comment:**  I have been a General Manager in the Solvent Recovery industry for 40 years and have recovered NMP on many occasions. Over the period probably > 12,000 Tes. We were aware of the safety issues involved and took strong precautions to minimise the exposure of our staff, both in production and in the laboratories to NMP vapours and liquids. It is a solvent with valuable , almost unique, properties, of which ECHA will be well aware. It is not used in formulations marketed to the general public. If there were suggestions that it should be I would be opposed to that. However in its industrial use, with the right precautions, in exposure terms, I can see absolutely no reasons for any restrictions in its production or use. I would be happy to discuss these matters with any groups or organisation who may have concerns about this. |
| **Dossier submitter response**  We are aware of the properties of NMP. It is important to avoid exposure to NMP to a level at which it may result in a health effect (so above DNEL). Currently this is not guaranteed. The restriction proposal allows continued use of NMP if occupational exposure is below the DNEL. |
| **RAC Rapporteurs comments**  RAC supports further safe use of NMP. |
| **SEAC Rapporteurs comments**  No comments. |
| **284** | **Date:** 2013/11/14 16:48  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Turkey  **Related to:** (C)  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes (available from confidential version of RCOM table)**  **Privacy comment:** The document contains supplier information which is not public. | **Comment:**  1B reprotoxic chemical material should be eliminated in a plan, and an alternative chemical which is not dangerous for human health should be replaced. |
| **Answer 1:**  Personal protective equipment usage continue. It is a mask used for organic solvents. |
| **Answer 2:**  Exposure is not measured. |
| **Answer 3:**  Chemical material supplier will calculate the cost of alternative material. We do not know the exact expected cost of implementation at our workplace. |
| **Answer 4:**  As an end-user, we do not know when the material will be changed. Material will be changed by supplier. |
| **Dossier submitter response**  We agree that reprotoxic chemicals cat 1B should be replaced as much as possible. A proposal has been made to review harmonised classification, reducing the concentration cut-off point, which would result in the supply to the general public prohibited. For professional and industrial use of NMP, the restriction proposal allows continued use if occupational exposure is below the DNEL because there is a lack of less hazardous alternatives.  **Answers 1-4:**  Thank you for this information. |
| **RAC Rapporteurs comments**  RAC supports further safe use of chemicals, either by reducing exposure to safe levels or, if not possible, by substitution.  **Answers 1-4:**  Thank you for this information. |
| **SEAC Rapporteurs comments**  The comment is noted. |
| **285** | **Date:** 2013/11/26 16:01  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. country:** Austria  **Related to:** (A) (D) (H)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  see attachment  **Specific comment:**  information on existing national OEL |
| **Dossier submitter response**  Thank you for this information. In the Background Document the OEL for Austria has been adjusted (section B 5.10). |
| **RAC Rapporteurs comments**  The information is noted. |
| **SEAC Rapporteurs comments**  No further comments. |
| **287** | **Date:** 2013/11/27 11:47  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. country:** France  **Related to:** (C)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  - |
| **Dossier submitter response**  Thank you for this information with additional potential alternatives for several applications.  We are aware of the fact that many chemicals/solvents might be able to replace NMP. In the dossier we tried to give a comprehensive –but non-exhaustive- overview of these alternatives in Chapter C and in Annex 5. Priority was given to these alternatives which are already applied in practice and which are mentioned in the open literature. Dimethoxymethane is mentioned in the EMEA Impurity Guideline for residual solvents under Table 4: Solvents for which no adequate toxicological data was found. For methylenebis(oxy)dibutane a search on internet showed that it is used as a solvent in dry cleaning, but application as an alternative to NMP has not been found.  Based on the information provided in the comment, we don’t see enough evidence to change the conclusions in Table C.01 and therefore this information will not change the assessment in the restriction dossier. |
| **RAC Rapporteurs comments**  Thanks for the information, which is noted. |
| **SEAC Rapporteurs comments**  No further comments. |
| **290** | **Date:** 2013/11/27 13:30  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (A) (B) (C) (D) (F)  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes (available from confidential version of RCOM table)**  **Privacy comment:** The attached document discloses the identity of our company name. In Europe we have a very limited number of lithium ion battery producers. The name of our company should not be disclosed to the public in order to avoid unnecessary publication of our process details. | **Comment:**  According to TRGS 900 (List of Germanys national OELs) the time weighted average exposure limit (TWA) for 1-methyl-2-pyrrolidone (NMP) is 20 ppm (82 mg/m³). Commission Directive 2009/161/EU is setting a TWA of 10 ppm (40 mg/m³) and a short time (15 minutes) exposure limit (STEL) of 20 ppm (80 mg/m³) as indicative OEL (IOEL). The Dutch Member State Competent Authority has submitted a report proposing a restriction of the manufacturing and use of NMP, unless the TWA is below 5 mg/m³, the STEL remains lower than 10 mg/m³, and preventive measures are used for skin protection.  NMP is used by our company as a solvent for dispersions, which are used in the manufacturing process of electrodes for lithium ion batteries. The role of NMP in electrode manufacturing is closely related to the binder system that is feasible for lithium-ion technology. The specific polymeric binder system is the crucial technology necessary for manufacturing of lithium-ion cells.  For several reasons NMP has evolved as a state of the art solvent for lithium ion battery industry. NMP is one of the few solvents to dissolve polyvinylidene difluoride (PVDF), which is a well-established binder for electrodes in lithium ion batteries (other solvents like e.g. DMF and DMAC are able to dissolve PVDF as well, but are not suitable for the production of electrodes. It is also a preferred solvent, since it is available and recyclable on an industrial scale. Specific onsite recycling systems for electrochemical grade NMP are already established. NMP dissolves PVDF at room temperature whereas other solvents require elevated temperatures, resulting in higher energy cost and potentially higher emission rates. Due to a high boiling point and a comparable low vapour pressure it can be handled in a very safe way and with minimised environmental emissions. Nevertheless, the boiling point is low enough, to ensure an efficient drying process without damaging the cathode material.  Our company is always engaged in trying to continuously reduce any kind of chemical exposure to their workers. From our experience, a TWA of 20 mg/m³ with a STEL of 40 mg/m³ could be realised reliably and on a reasonable economic basis. We therefore propose to use these values in the restriction proposal for NMP rather than a limit value based on the most sensitive subpopulation, which is not relevant in our most critical production step.  Our company is open for a more in-depth discussion and may provide more details in a later comment. It was not possible to compile all our research data for our, now established, lithium-ion manufacturing process into an easily understandable summary within the suggested time frame of November 29th. |
| **Answer 1:**  Implications on electrode manufacturing processes of a proposed reduction of the TWA to 5 mg/m³  NMP is present in electrode production during two general process steps:  1) Preparation of NMP-based dispersions and  2) Coating of NMP-based dispersions on thin metal foils and subsequent drying and condensation of NMP.  1) Preparation of NMP-based dispersions  NMP enters the process from closed tanks and gets pumped through closed pipes into mixing or kneading machines, where NMP-based dispersions are being prepared. Under normal circumstances NMP does not get in contact with the environment during these process steps. Any NMP which evaporates during these processes is transferred to an exhaust gas treatment (RTO).  2) Coating of NMP-based dispersions on thin metal foils and subsequent drying and condensation of NMP  The coating and drying machinery (in total four production lines) are state-of-the-art technology. Three production lines have been set up in 2011 and are located in one building whereas the first production line, which is of the same type and was already set up in 2009, is located in a separate building. The lines consist of two parts, the coating head and the dryer. The coating head is capsuled by a PLEXIGLAS® containment and operated under slightly increased pressure. The dryer is operated under reduced pressure and is located outside the containment. The buildings itself are approx. 45 m long and well ventilated by general exhaust ventilation. For operational reasons only the operator in charge can open the PLEXIGLAS® containment in order to control the coating process or conduct any kind of corrective action.  The dispersion mentioned under subsection 1 is coated on a thin metal foil in reel-to-reel process. Unwinding of the foil and subsequent coating is carried out within contained sections, where the air pressure is slightly elevated in order to avoid product contamination. Directly after the application onto the foil and before entering the dryer, the freshly coated foil is transported for a distance of approx. 0.5 meter within the containment. The dryer itself is operated under slightly reduced pressure in order to avoid release of NMP loaded gas from the dryer.  Based on an internal risk assessment for this most critical step during the production process we only allow male workers as operators for the coating process. Additionally, in order to avoid any risks for pregnant women or women who plan to become pregnant, organizational measures are taken to restrict female workers also from the remaining work places in the production building. |
| **Answer 2:**  1) Preparation of NMP-based dispersions  Exposure to humans is limited to activities like sample preparation for quality control. The exposure time for these activities is very limited (one person, approx. 10 min. each, twice per shift). Therefore we do not see any constraints for these specific processes regarding the proposed reduction of the TWA. In order to proof this, personal monitoring was carried out during the above mentioned regular activities. The measured airborne concentration showed values below 5 mg/m³.  2) Coating of NMP-based dispersions on thin metal foils and subsequent drying and condensation of NMP  The highest NMP airborne concentrations of 5 – 20 mg/m³ are measured outside the containment in the area of the coating head. These values are two times lower than the EU OEL value of 40 mg/m³ and even four times below the German national OEL value of 82 mg/m³. Operators who are running and controlling the coating process are exposed permanently to these airborne concentrations which are regarded as safe by us, several Member State authorities and the SCOEL representing the European Commission.  It is worth stating at this point that due to national German occupational legislation an employer is obliged to stay always significantly below the TWA in the smoothly running process. Only ca. 70% of the TWA should be reached to have a safety buffer (otherwise additional measures are recommended). Additionally intervals for exposure measurement are connected to the exposure itself. If exposure is less than ca. 10% of the TWA exposure measurement intervals are longer which is saving permanent cost. Consequently in reality there is an additional burden to take.  More detailed information on measured concentrations might be submitted until March 18, 2014, if needed. |
| **Answer 3:**  1) Preparation of NMP-based dispersions  A restriction of the NMP use would have organisational implications for specific non-regular activities. Non regular activities are for example maintenance and repair work or irregular intensive cleaning processes, where it is necessary to open pipes, vessels and flanges. All these non-regular activities are conducted under wearing of full personal protective equipment like gas mask and chemical protective suit. This is due to the fact that it is not possible to pre-clean the facilities with another solvent, because of subsequent cross-contamination which then would have drawbacks on the product quality. For those activities additional risk assessments, precautions and organisational measures would be required if a TWA of 5 mg/m³ was set.  2) Coating of NMP-based dispersions on thin metal foils and subsequent drying and condensation of NMP  At this process step local exhaust ventilation cannot be established as it would severely affect the drying of the dispersion on the foil. Such change would have negative impact on the homogeneity of the electrode surface as well as on the complex air management system (over pressure at coating head and negative pressure in the dryer).  The production lines, which are state of the art, were installed according to German safety standards and hence are designed in a closed manner in order to fulfil TWA values safely below 82 mg/m³. If a restriction to 5 mg/m³ would be realised, fundamental modifications of dryers including their maintenance and/or the complex air management in the coating facility would be necessary. This would lead to disproportionate investments and significantly increasing running costs. In addition, these measures would not significantly contribute to a reduction of TWA values in the area of the coating head just before the wet dispersion on the thin metal foil enters the dryer. Operators frequently (>15 minutes) need to enter this area for process control and operation. For this specific environment further modifications associated with significant investment would be necessary. This includes additional measures for air tight containments and also a change in the complex air management at this certain environment. A change in the complex air management will affect the drying process, which in consequence requires fundamental evaluations regarding the quality of the manufactured electrodes associated with a new parameterising of the drying process. In summary the above mentioned measures would require a complete re-engineering of the coating process with related costs in a single-digit million Euro range.  In conclusion, from an electrode producers’ point of view a TWA of 5 mg/m³ would have significant cost impacts on electrode production. This includes re-engineering, investment costs as well as running costs caused by more extensive air management associated with higher energy consumption.  Potential alternatives to NMP in electrode manufacturing  The role of NMP or alternative solvents in electrode manufacturing is closely related to the binder system that is feasible for lithium-ion technology. Electrodes for lithium-ion cells are composed of particulate materials that are coated on both sides of thin metal foils. Adhesion of the particulate material to the foil as well as cohesion within the coating layer is enabled by specific polymeric binder systems. Anodes essentially consist of graphite powder coated onto copper foils, while cathodes mainly consist of lithium metal oxide powders coated onto aluminium foils. Since anodes and cathodes differ significantly in their material technology, they have to be discussed separately when it comes to possible alternatives to NMP.  Two types of binder systems are currently state-of-the art in lithium-ion technology:  • Polyvinylidene difluoride (PVDF) with the usage of NMP as solvent/dispersant  • Styrene butadiene rubber (SBR) with the usage of water as solvent/dispersant  The PVDF/NMP system can be used for both anodes and cathodes, while the SBR/water system can only be used for the anode, since the materials used in the cathode are not compatible with water. Besides this, the two technologies require different processing and machinery.  Consequently, the anodes and cathodes manufactured by our company have been developed based on the same PVDF/NMP base technology. These electrodes are currently in use in high-performance commercial cells in the automotive and industrial sector.  Potential replacement of NMP:  Only a limited number of solvents are known to be capable to a certain extent to dissolve PVDF, e.g. dimethyl formamide (DMF), dimethyl acetamide (DMAC), tetramethyl urea, dimethyl sulfoxide (DMSO), triethyl phosphate or N-ethly-2-pyrrolidone (NEP). We have considered and/or tested these and some other chemicals as potential candidates, but none of them are suitable: Either they were not suitable for technical reasons, and/or they have similar or even more severe toxicological hazard profiles. The use of DMSO which is from the toxicological properties the most interesting alternative cannot be used because the solubility of PVDF in DMSO is not sufficient for the manufacture of lithium-ion batteries. Also the high melting point of 18.5 °C and the degradation at the boiling point of 189 °C is a technical problem, especially the thermal instability is critical for the dryinig and recycling process. |
| **Answer 4:**  The most critical steps in the lithium-ion battery manufacture are the coating and the drying process. In order to comply with the proposed restrictions a complete re-engineering of the coating head and the dryer would be necessary (approx. 12 months). Then the new design would have to be realised, tested and parameterised (approx. 18 - 24 months). After the new parameterising the impact of the new parameters on the quality of the electrodes would have to be evaluated and optimised (approx. 12 months). After the optimisation a fully new qualification of the coating and drying step would be necessary according to automotive standards (18 – 24 months). The whole process would take approximately 60 to 72 months.  The above mentioned measures cannot be implemented in our existing production facilities due to capacity and space constraints. This would make at least a partial shut-down of the current production or additional investment into a new building necessary. As the reduction of current production capacities is not a viable option this could only be implemented as soon as a capacity expansion is required by increasing demands from the market.  Since the process steps coating and drying cannot be realized in a completely closed system for technical reasons it is uncertain if the envisioned process re-design will achieve the desired emission target level. It is also uncertain whether the envisioned re-design will have a negative impact on the quality of the final product. Changes in the electrode specification would lead to a different product which the automotive industry may reject. This would have a fatal impact on the competitiveness of the battery production in Europe.  The use of NMP in the current form is state-of-the-art technology. The above mentioned process re-design would create at least costs in the range of a single-digit million Euro number. Costs for the expansion of the existing production capacity which would require a new production building, will be significantly higher than the costs for the process re-design. These investments would be an additional burden in a very competitive environment and would risk the future of lithium-ion battery production in Europe. Lithium-ion battery technology, on the other hand, is critical for the implementation of electromobility in Europe. |
| **Dossier submitter response**  Thank you for this information. Part of this information was already included in the confidential version of the restriction dossier in an anonymized way. Based on provide socio-economic information the assessment in relation to the Battery industries was slightly adjusted in chapter F of the dossier.  **Answers 1-4:**  Thank you for this information. This information shows that exposure levels below 5 mg/m3 seems to be technical feasible. The comment on alternatives is already captured in the text on battery industry in section C: which conclude: “To conclude, the development on NMP free lithium ion and other hybrid batteries is ongoing, however, at this moment no alternatives have been proven on a commercial scale.” Thank you for the information in answer 4, this has been incorporated in the Background Document. |
| **RAC Rapporteurs comments**  Thanks for the information, which is noted.  **Answers 1-4:**  Thank you for this detailed information. |
| **SEAC Rapporteurs comments**  We note that you consider a TWA value of 5 mg/m3 to entail disproportionate investments and significant increasing cost and that a TWA of 20 mg/m3 with a STEL value of 40 mg/m3 could be realised reliably and on reasonable economic basis. There is no information on the situation if the TWA is established at 10 mg/m3. It is not quite clear whether PPE can be used and has been taken into consideration. |
| **291** | **Date:** 2013/11/28 10:40  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Italy  **Related to:** (F)  **Company name confidential:** No | **Comment:**  Comments to F 1.4.1 Pregnant and potentially pregnant workers (pp. 186 – 191)  Paragraph F.1.4.1 of the report acknowledges that protection for women with known pregnancy exists. However, it sounds as if this was still somewhat up to the industry to implement:  Paragraph F.1.4.1. Page 186:  “Personal communication with some of the NMP using industries indicated that there are indeed preventive measures in place to protect pregnant workers. In at least one industry, workers are informed about the potential hazardous effects of NMP before they enter the job and workers will temporary be replaced to a NMP free environment during the period of their pregnancy to avoid exposure to NMP (personal communication). Another industry notes that most plants have no female workers working at the jobs where they could potentially be exposed (personal communication).”  The situation is however strictly covered by EU and national laws and not at the liberty of the industry .In Germany for example the  Gesetz zum Schutze der erwerbstätigen Mutter (Mutterschutzgesetz – MuSchG) vom 20. Juni 2002, zuletzt geändert durch Artikel 6 des Gesetzes vom 23. Oktober 2012 (BGBl. I Nr. 51, S. 2261)  Section §4.1 of above law (Gesetz zum Schutze der erwerbstätigen Mutter) states that pregnant women are not allowed to do heavy physical work or work were they are exposed to dangers, such as those arising from harmful substances, radiation, dust, gases, vapors, heat, cold, humidity, commotions or noise. Pregnant women must therefore be transferred to other workplaces. In addition, work in production which operates in a shift system is impossible due to the restricted working hours §8.1. This law already protects every pregnant women with known pregnancies against working with NMP or other harmful chemicals.  Excerpt from the German national law:  § 4 Weitere Beschäftigungsverbote  (1)Werdende Mütter dürfen nicht mit schweren körperlichen Arbeiten und nicht mit Arbeiten beschäftigt werden, bei denen sie schädlichen Einwirkungen von gesundheitsgefährdenden Stoffen oder Strahlen, von Staub, Gasen oder Dämpfen, von Hitze, Kälte oder Nässe, von Erschütterungen oder Lärm ausgesetzt sind.  § 8 Mehrarbeit, Nacht- und Sonntagsarbeit  (1)Werdende und stillende Mütter dürfen nicht mit Mehrarbeit, nicht in der Nacht zwischen 20 und 6 Uhr und nicht an Sonn- und Feiertagen beschäftigt werden.  As conclusion it can be stated that as documented for Germany the existing laws already strongly protect pregnant women against the contact with NMP. Any additional regulation for women with known pregnancies is therefore not required.  The second argument of the restriction proposal addresses the fact that women might not know about an early pregnancy or not be aware of it and in this case the existing laws would not protect them from NMP:  Page: 187Paragraph F.1.4.1:  "The potential risk for pregnant workers might however remain, as women might not know that they are pregnant in the early days of their pregnancy, or, as women might not tell their employer before the 10th -week of their pregnancy. Because of this, it could be argued that all female workers during their reproductive period (20-45 years; CBS, 2007) should be included in the population at risk for this endpoint. As is calculated and explained in the text box 3 below, around 57% of the female worker population is at the reproductive age and on a yearly basis 3.5% of the female worker population becomes pregnant. These percentages give an indication of the female population potentially at risk,..”  The risk indicated in this paragraph is largely exaggerated. First, even in cases where a pregnancy is planned the employee is encouraged to inform their supervisor and she is normally moved to another area within the company. Secondly, and more importantly, the statistical figures are showing a much too large fraction for affected female workers. Only in production conditions exist which may lead to an extended exposure. Due to the physically taxing work, only a very small number if any of women in the affected industries work in production. At Elantas Italy the largest European wire enamel manufacturer for example out of more than 60 female employees no female works in the manufacturing department for wire enamels.  In summary, we believe that the risk for pregnant and potentially pregnant workers is in reality nearly nonexistent. |
| **Dossier submitter response**  We are aware of the current legislation that should protect the pregnant worker and the unborn child. It was not our intention to give the idea that the protection is up to the industry. However, especially in the first month of pregnancy the worker may be unaware of her being pregnant.  In paragraph F.1.4 we tried to describe the population potentially at risk. As explained this paragraph is aimed only to give an impression of the potential scale of the health risks (and the number of workers potentially affected by a restriction). We agree that this information is surrounded with large uncertainties.  We are of the opinion that a restriction on the use of NMP is still required based on the calculated RCR>1. |
| **RAC Rapporteurs comments**  Although female workers might be rare in some occupational settings, the DNEL applies to all workplaces and should also be protective for female workers that potentially may get pregnant. |
| **SEAC Rapporteurs comments**  The comment has been reflected in the draft opinion. |
| **292** | **Date:** 2013/11/28 11:00  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Italy  **Related to:** (C)  **Company name confidential:** No | **Comment:**  Comments concerning paragraph C.1 Wire Coaters (page 132)  Background on polyamide imide wire enamels  In the publication: “Poly(amide-imides)” : Wire Enamels with Excellent Thermal and Chemical Properties” , Macromolecular Materials and Engineering 2008, 293, 350–360, T.J. Murray reviewed the chemistry of polyamide imide wire enamels, their properties and also possible alternate solvents. The outstanding characteristics of a wire coated with a polyamide imide include high thermal performance, chemical and abrasion resistance, and low coefficient of friction. Typical for such a wire is a temperature index (long term thermal durability) of >220° (IEC 60216), a cut through of 390–420 °C (IEC 60851) and a heat shock of 240°C (IEC 60851). In addition coils of magnet wires were impregnated with unsaturated polyester resins, epoxy resins and various varnishes. The wire must resist chemically to these resins, their solvents or reactive diluents and also to the curing conditions (depending on the system used 1-6 hrs up to 160°C) (http://www.elantas.de/ and http://www.axaltacoatingsystems.com). According to Murray no alternatives to NMP as solvent have been identified, despite extensive research by many wire enamel companies in the past (common knowledge from Axalta Coating Systems (former DuPont Performance Coating Systems), Elantas and IVA). The main reason could be the suspected catalytic properties of NMP during oven cure, in addition to its role as an important solvent in the production of polyamide-imides.  Alternative polymers  On page 132 PVC, polyethylene and materials containing ethylene ethyl acrylate copolymer (EEA) and/or ethylene vinyl acetate copolymer (EVA) are listed as potential replacements for PAI. These materials are thermoplastic materials which do not have the thermal properties as needed for electrical devices. Such high thermal properties can only be achieved by using cured polyamide imide films. Polyester, polyurethane and epoxy-based enamels are used as basecoats, because they do not have the required abrasion resistance. Polyurethanes are solderable wire enamels that means the coating disintegrates at elevated temperatures and they cannot be thermally stable. Epoxy based enamels are used as self bonding, that means meltable materials. Polyvinyl acetates have a temperature index of 130, and are therefore inferior to a polyamide imide. Finally, fluorinated ethylene propylene and polytetrafluoro-ethylene cause major problems when the coated wires were recycled, because they generate hydrofluoric acid. In addition, they are not cost competitive compared to polyamide imides.  Finally, Murray clearly states that substitution of NMP by e.g. sulfolane, anisole, siloxane, butyl cellosolve acetate and lactone is technically not feasible.  Alternative solvents  The registration proposal lists a number of aprotic solvents as viable substitutes for NMR such as DMAC, DMF, and DMSO. We believe that they offer no true alternative:  DMF has a boiling point of 152°C and DMAC of 156°C both are below of that of NMP (203°C). A high boiling point for the solvent is needed in the enameling machines to obtain a smooth pinhole free polyamide imide film. In addition DMF and DMAC exhibit high toxicity as well. DMAC is already in the authorization process and DMF was subject to a public consultation from June to September for inclusion in the Authorization list (Annex XIV)  DMSO cannot be used as solvent for PAI because it violently decomposes at 180°C. Modern wire enameling machines have oven temperatures above 550°C (http://www.mag.at/). In addition solvents are catalytically oxidized in the enameling oven and the energy is used to heat the oven. DMSO will generate SO2, which will corrode the existing enameling machines and it cannot be released into the atmosphere (acid rain).  As conclusion it can be said that no alternative wire coating with properties anywhere near those of polyamide imide can be found. In addition, a huge R&D effort was undertaken by the wire enamel manufacturers for the last 20 years to find an alternative solvent to NMP for PAI enamels. No successful replacement could be identified.  It can therefore not be expected that in the near future alternatives will be found. |
| **Dossier submitter response**  Thank you for this information in relation to the difficulty in finding technical feasible alternatives. Overall, this comment supports the conclusion in Table C.01 that technical and economic feasibility of alternatives is not shown for all wire coaters. The restriction proposal allows continued use of NMP if occupational exposure is below the DNEL.  Although we believe that it will not be easy either to replace the high resistant polymers for a number of applications or to replace NMP as a solvent for these polymers, we do not think that the general remark at the end of this comment “It can therefore not be expected that in the near future alternatives will be found.“ is correct.  In the introduction Murray (2008) clearly summarises the devices in which poly(amide-imides) wire coatings are used: transformers, generators and electric motors. He also explains the reasons: the coating should be thin to obtain a maximum number of turns in each slot space, and it should have a high thermal performance, chemical and abrasion resistance and low coefficient of friction. Murray (2008) does not focus on wire coatings for all other applications. When consulting the product information and technical specifications of AKRON Coating and Adhesives Inc. or American Insulated Wire Corp., we learn that there are various coatings available for a range of different applications.  Murray (2008) states: “PAI resins used for electrical insulation are almost exclusively used as NMP containing solutions. Alternate solvents that are cost effective have limited solvency for PAI resins or the reaction cannot be carried out in this media. Many patents have been granted on achieving the high thermal and mechanical properties of PAI resins while using low cost solvents such as cresylic acid.” to end a little bit further with “Improvements are still needed in alternate solvent PAI resins to reduce applied costs yet maintain the high electrical, thermal, and mechanical properties.” At the end of the article Murray (2008) makes a few interesting statements: “Future Trends and Technical Limitations. Cost considerations are always critical in the development of coatings for the electrical insulation market. There will be continued efforts to achieve PAI coatings in alternate solvent systems to NMP.” and “Wire constructions have been optimized to achieve best mechanical and thermal properties while achieving the lowest possible cost.”  Murray (2008) does not make any statement on the technical feasibility of the substances mentioned in this comment such as sulfolane, anisole, siloxane.  From the above statements in Murray (2008) we conclude that alternatives are either available or on the way, but that cost considerations are important.  The present dossier already states at the end of the paragraph on wire coating: “Based on the literature, it is not clear if these alternatives are technically and economically feasible in practice and if they are applied on a commercial basis. During stakeholder consultation, wire coating industry indicated that no alternative for NMP was available, neither expected in the near future” Thus, the comments are already captured in the present dossier. |
| **RAC Rapporteurs comments**  Thanks for the very detailed information, which may be more relevant for SEAC than for RAC. However, from the dossier submitter response, we note that the Murray publication (2008) can be interpreted in different ways. |
| **SEAC Rapporteurs comments**  Agree with the DS response. We acknowledge that PAI seems to superior for some uses and that economically and technically substitutes does not seem to have been identified for this resin used for wire coating. |
| **293** | **Date:** 2013/11/28 11:09  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Italy  **Related to:** (F)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  Comments to F 4.4. Compliance Cost (218)  Polyamide imide wire enamels contain NMP as solvent. The outstanding characteristics of a wire coated with a polyamide imide include high thermal performance, chemical and abrasion resistance, and low coefficient of friction. Typical for such a wire is a temperature index (long term thermal durability) of >220° (IEC 60216), a cut through of 390–420 °C (IEC 60851) and a heat shock of 240°C (IEC 60851).  In table F.16 on page 218 for wire coaters and wire coating formulators it is stated that “According to industry, the uncertainties around authorisation are too high to continue production in case of an authorisation”. However, the situation is worse than written there and affects the whole electro technical industry in Western Europe:  An electrical motor is a complex construction that contains besides enameled wires, impregnating materials, sheet insulating components (laminates, films), tapes, the metal core, the housing, bearings, plastic parts, a.s.o.. Many of these are highly sophisticated components. e.g. for the slot wedges alone polyester and epoxy-glass laminates, NMN, DMD, phenolic paper laminates, and other materials can be used.  If polyamide imide coated magnet wires will not be produced any more in Western Europe the whole wire coating industry will collapse, because PAI is usually applied as a top-coat on top of other wire enamels. The motor manufacturers will most likely move outside Western Europe. The reason being that polyamide imide coated wires will be continued to be produced in the USA, China, India, Brazil, and other countries. The import of wire is expensive and laborious and co-development with European wire manufactures is no longer possible . In this case the motors will be produced in the countries where the wires are available. Jobs will be lost not only at the enamel and wire manufacturers but also the manufacturer of the motors, metal cores, laminates and films, tapes, housings a.s.o. will suffer. Similar things will happen to the manufacturer of generators (conventional (e.g. Nuclear, Hydro, etc.) and alternative energy as e.g. wind), transformers, relays a.s.o. Projects like electro mobility will go entirely too non-Western countries.  The socio economic assessment of the proposed restriction indicates unpredictable job losses down the value chain. On the other hand there are no benefits for the society. |
| **Dossier submitter response**  Thank you for this information. We have slightly adjusted the Background Document. The potential direct economic consequences as well as the wider socio-economic effects are already described in chapter F. |
| **RAC Rapporteurs comments**  The comment is noted. |
| **SEAC Rapporteurs comments**  No further comments. |
| **294** | **Date:** 2013/11/28 14:01  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. country:** Denmark  **Related to:** (E) (H)  **Company name confidential:** No | **Comment:**  The Danish Working Environment Authority (DWEA) has following comments on the REACH Annex XVII proposal for restriction on NMP:  DWEA has noted that Forum in advice on enforceability finds that Annex XVII restriction is not the preferred legal mechanism to set occupational exposure limits for NMP.  Forum has among other things stated that procedures to decide occupational exposure limits are set in Directive 98/24/EC. Occupational exposure limits under the Chemical Agents Directive are the result of consultation between employers, workers and the Commission. This is suggested as the appropriate route for setting occupational exposure limits for NMP.  DWEA supports that EU occupational exposure limits are set within the framework of OSH and Chemical Agents Directive. It is not appropriate that occupational exposure limits are set in two different EU set of legislation. There is a need for a clarification on OSH and REACH interface issues between DG Employment, DG Enterprise and DG Environment before the proposal is processed further. |
| **Dossier submitter response**  Thank you for your comment. We are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  RAC addresses the risks and discusses the RMOs, but the Commission decides on the legal measures. |
| **SEAC Rapporteurs comments**  The comment is related to the legal framework and not to risk reduction options. |
| **295** | **Date:** 2013/11/28 18:57  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (C) (F)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  Comment is contained in the "specific sections". For illustration, a picture is included as attachment.  **Specific comment:**  Comments concerning paragraph C.1 Wire Coaters (page 132)  Background on polyamide imide wire enamels  In the publication: “Poly(amide-imides)” : Wire Enamels with Excellent Thermal and Chemical Properties” , Macromolecular Materials and Engineering 2008, 293, 350–360, T.J. Murray reviewed the chemistry of polyamide imide wire enamels, their properties and also possible alternate solvents. The outstanding characteristics of a wire coated with a polyamide imide include high thermal performance, chemical and abrasion resistance, and low coefficient of friction. Typical for such a wire is a temperature index (long term thermal durability) of >220° (IEC 60216), a cut through of 390–420 °C (IEC 60851) and a heat shock of 240°C (IEC 60851). In addition coils of magnet wires were impregnated with unsaturated polyester resins, epoxy resins and various varnishes. The wire must resist chemically to these resins, their solvents or reactive diluents and also to the curing conditions (depending on the system used 1-6 hrs up to 160°C) (http://www.elantas.de/ and http://www.axaltacoatingsystems.com). According to Murray no alternatives to NMP as solvent have been identified, despite extensive research by many wire enamel companies in the past (common knowledge from Axalta Coating Systems (former DuPont Performance Coatings), Elantas and IVA). The main reason could be the suspected catalytic properties of NMP during oven cure, in addition to its role as an important solvent in the production of polyamide-imides.  Alternative polymers  On page 132 PVC, polyethylene and materials containing ethylene ethyl acrylate copolymer (EEA) and/or ethylene vinyl acetate copolymer (EVA) are listed as potential replacements for PAI. These materials are thermoplastic materials which do not have the thermal properties as needed for electrical devices. Such high thermal properties can only be achieved by using cured polyamide imide films. Polyester and epoxy-based enamels cannot be used as single coat, as they do not have the required abrasion resistance. Polyurethanes are solderable wire enamels. That means the coating disintegrates at elevated temperatures and they cannot be thermally stable. Epoxy based enamels are used as self bonding, that means meltable materials. Polyvinyl acetates have a temperature index of 130, and are therefore inferior to a polyamide imide. Finally, fluorinated ethylene propylene and polytetrafluoro-ethylene cause major problems when the coated wires were recycled, because they generate hydrofluoric acid. In addition, they are not cost competitive compared to polyamide imides.  Finally, Murray clearly states that substitution of NMP by e.g. sulfolane, anisole, siloxane, butyl cellosolve acetate and lactone is technically not feasible.  Alternative solvents  The registration proposal lists a number of aprotic solvents as viable substitutes for NMP such as DMAC, DMF, and DMSO. We believe that they offer no true alternative:  DMF has a boiling point of 152°C and DMAC of 156°C both are below of that of NMP (203°C). A high boiling point for the solvent is needed in the enameling machines to obtain a smooth pinhole free polyamide imide film. In addition DMF and DMAC exhibit high toxicity as well. DMAC is already in the authorization process and DMF was subject to a public consultation from June to September for inclusion in the Authorization list (Annex XIV)  DMSO cannot be used as solvent for PAI because it violently decomposes at 180°C. Modern wire enameling machines have oven temperatures above 550°C (http://www.mag.at/). In addition solvents are catalytically oxidized in the enameling oven and the energy is used to heat the oven. DMSO will generate SO2, which will corrode the existing enameling machines and it cannot be released into the atmosphere (acid rain).  As conclusion it can be said that no alternative wire coating with properties anywhere near those of polyamide imide can be found. In addition, a huge R&D effort was undertaken by the wire enamel manufacturers for the last 20 years to find an alternative solvent to NMP for PAI enamels. No successful replacement could be identified.  It can therefore not be expected that in the near future alternatives will be found.  Comments to F 4.4. Compliance Cost (218)  Polyamide imide wire enamels contain NMP as solvent. The outstanding characteristics of a wire coated with a polyamide imide include high thermal performance, chemical and abrasion resistance, and low coefficient of friction. Typical for such a wire is a temperature index (long term thermal durability) of >220° (IEC 60216), a cut through of 390–420 °C (IEC 60851) and a heat shock of 240°C (IEC 60851).  In table F.16 on page 218 for wire coaters and wire coating formulators it is stated that “According to industry, the uncertainties around authorisation are too high to continue production in case of an authorisation”. However, the situation is worse than written there and affects the whole electro technical industry in Western Europe:  An electrical motor is a complex construction that contains besides enameled wires, impregnating materials, sheet insulating components (laminates, films), tapes, the metal core, the housing, bearings, plastic parts, a.s.o.. Many of these are highly sophisticated components. e.g. for the slot wedges alone polyester and epoxy-glass laminates, NMN, DMD, phenolic paper laminates, and other materials can be used.  [For illustration please see the picture provided in the attachment]  If polyamide imide coated magnet wires will not be produced any more in Western Europe the whole wire coating industry will collapse, because PAI is usually applied as a top-coat on top of other wire enamels. The motor manufacturers will most likely move outside Western Europe. The reason being that polyamide imide coated wires will be continued to be produced in the USA, China, India, Brazil, and other countries. The import of wire is expensive and laborious and co-development with European wire manufactures is no longer possible. In this case the motors will be produced in the countries where the wires are available. Jobs will be lost not only at the enamel and wire manufacturers but also the manufacturer of the motors, metal cores, laminates and films, tapes, housings a.s.o. will suffer. Similar things will happen to the manufacturer of generators (conventional (e.g. Nuclear, Hydro, etc.) and alternative energy as e.g. wind), transformers, relays a.s.o. Projects like electro mobility will go entirely too non-Western countries.  The socio economic assessment of the proposed restriction indicates unpredictable job losses down the value chain. On the other hand there are no benefits for the society.  Comments to F 1.4.1 Pregnant and potentially pregnant workers (186 – 191)  Paragraph F.1.4.1 of the report acknowledges that protection for women with known pregnancy exists. However, it sounds as if this was still somewhat up to the industry to implement:  Paragraph F.1.4.1. Page 186:  “Personal communication with some of the NMP using industries indicated that there are indeed preventive measures in place to protect pregnant workers. In at least one industry, workers are informed about the potential hazardous effects of NMP before they enter the job and workers will temporary be replaced to a NMP free environment during the period of their pregnancy to avoid exposure to NMP (personal communication). Another industry notes that most plants have no female workers working at the jobs where they could potentially be exposed (personal communication).”  The situation is however strictly covered by EU and national laws and not at the liberty of the industry .In Germany for example the  Gesetz zum Schutze der erwerbstätigen Mutter (Mutterschutzgesetz – MuSchG) vom 20. Juni 2002, zuletzt geändert durch Artikel 6 des Gesetzes vom 23. Oktober 2012 (BGBl. I Nr. 51, S. 2261)  Section §4.1 of above law (Gesetz zum Schutze der erwerbstätigen Mutter) states that pregnant women are not allowed to do heavy physical work or work were they are exposed to dangers, such as those arising from harmful substances, radiation, dust, gases, vapors, heat, cold, humidity, commotions or noise. Pregnant women must therefore be transferred to other workplaces. In addition, work in production which operates in a shift system is impossible due to the restricted working hours §8.1. This law already protects every pregnant women with known pregnancies against working with NMP or other harmful chemicals.  Excerpt from the German national law:  § 4 Weitere Beschäftigungsverbote  (1)Werdende Mütter dürfen nicht mit schweren körperlichen Arbeiten und nicht mit Arbeiten beschäftigt werden, bei denen sie schädlichen Einwirkungen von gesundheitsgefährdenden Stoffen oder Strahlen, von Staub, Gasen oder Dämpfen, von Hitze, Kälte oder Nässe, von Erschütterungen oder Lärm ausgesetzt sind.  § 8 Mehrarbeit, Nacht- und Sonntagsarbeit  (1)Werdende und stillende Mütter dürfen nicht mit Mehrarbeit, nicht in der Nacht zwischen 20 und 6 Uhr und nicht an Sonn- und Feiertagen beschäftigt werden.  As conclusion it can be stated that as documented for Germany the existing laws already strongly protect pregnant women against the contact with NMP. Any additional regulation for women with known pregnancies is therefore not required.  The second argument of the restriction proposal addresses the fact that women might not know about an early pregnancy or not be aware of it and in this case the existing laws would not protect them from NMP:  Page: 187Paragraph F.1.4.1:  "The potential risk for pregnant workers might however remain, as women might not know that they are pregnant in the early days of their pregnancy, or, as women might not tell their employer before the 10th -week of their pregnancy. Because of this, it could be argued that all female workers during their reproductive period (20-45 years; CBS, 2007) should be included in the population at risk for this endpoint. As is calculated and explained in the text box 3 below, around 57% of the female worker population is at the reproductive age and on a yearly basis 3.5% of the female worker population becomes pregnant. These percentages give an indication of the female population potentially at risk,..”  The risk indicated in this paragraph is largely exaggerated. First, even in cases where a pregnancy is planned the employee is encouraged to inform their supervisor and she is normally moved to another area within the company. Secondly, and more importantly, the statistical figures are showing a much too large fraction for affected female workers. Only in production conditions exist which may lead to an extended exposure. Due to the physically taxing work, only a very small number if any of women in the affected industries work in production.  In summary, we believe that the risk for pregnant and potentially pregnant workers is in reality nearly nonexistent. |
| **Dossier submitter response**  Thank you for this information in relation to the difficulty in finding technical feasible alternatives.  For part C see response to comments 292.  Overall, this comment supports the conclusion in Table C.01 that technical and economic feasibility of alternatives is not shown for all wire coaters. The restriction proposal allows continued use of NMP if occupational exposure is below the DNEL.  In relation to the comments on pregnant worker:  We are aware of the current legislation that should protect the pregnant worker and the unborn child. It was not our intention to give the idea that the protection is up to the industry. However, especially in the first month of pregnancy the worker may be unaware of her being pregnant.  In paragraph F.1.4. we tried to describe the population potentially at risk. As explained this paragraph is aimed only to give an impression of the potential scale of the health risks (and the number of workers potentially affected by a restriction). We agree that this information is surrounded with large uncertainties  We are of the opinion that a restriction on the use of NMP is still required based on the calculated RCR>1. |
| **RAC Rapporteurs comments**  The difficulties for wire coaters to find alternatives are noted. However, if it is possible to reduce the exposure to below the DNELs, substitution will not be needed. |
| **SEAC Rapporteurs comments**  No further comments. |
| **296** | **Date:** 2013/11/28 19:02  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** Belgium  **Related to:**  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  Comments to the annex xv restriction report of:  SUBSTANCE NAME(S): N-METHYLPYRROLIDONE (NMP)  IUPAC NAME(S): 1-METHYLPYRROLIDIN-2-ONE  EC NUMBER(S): 212-828-1  CAS NUMBER(S): 872-50-4  Contact details of the dossier submitter: RIVM Bureau REACH,  Executive Summary  Cefic BDO & Derivatives sector group in principle supports restriction as the better risk management option to control possible risk from NMP exposure compared to authorization:  1. More practicable and understandable to downstream users in the non-chemical industry sectors and consequently in practice with a higher risk reduction potential.  2. More efficient and effective as grouping of application for authorization is practically impossible. NMP users are different (large, medium and small companies, chemical and non-chemical industry) Despite uses are similar in general (industrial process solvent use) they are very different in details (different technology, different alternatives to be discussed/evaluated).  The proposed 5mg/m³ 8h –TWA and 10 mg/m³ 15 min STEL is much too low. There is no justification for the requirement of such low OELs and consequently these values are disproportionate. Instead the IOEL (EU OEL) is supported by the Cefic BDO & Derivatives sector group:  1. SCOEL has the expertise and the mandate to derive EU OEL  2. IOEL can be used as DNEL according to ECHA Guidance.  3. There is no new information justifying a lower value. The restriction proposal is based on the same studies as the SCOEL value  The Cefic BDO & Derivatives sector group is of the opinion that restriction is necessary because:  1. Some member states are not compliant with the IOEL. The restriction can be seen as an appropriate action to enforce EU harmonization and IOEL in non-compliant member states.  2. The highest OEL of 200 mg/m³ that applies within a member state does not foresee any safety factor to the NOEC of the developmental key study, which may represent a risk to workers.  While supporting the IOEL, the Cefic BDO & Derivatives sector group, comments as follows on the DNEL derivation:  The dossier submitter states that there is no evidence of any remaining interspecies difference, consequently this factor can be and should be omitted on this weight of evidence.  1. Human studies with chemicals designed to find adverse systemic effects in humans are simply not allowed to conduct due to ethical reasons (These ethical reasons are fully supported by Cefic BDO & Derivatives sector group).  2. Studies in humans to elucidate metabolism and local irritation (designed to cause no adverse systemic effect) are in line with animal studies and thus proving evidence that NOAEL and NOAEC of animal do match and there is no other interspecies difference apart from algometric scaling to be considered.  3. Conducting non-human primate studies on NMP is not justified because the effect is not only visible in primates. Also there is no suspicion (from accident or any other experience) from >20 uses of NMP that the rat is not a proper model to estimate NMP effect in humans . (These ethical reasons are fully supported by Cefic BDO & Derivatives sector group.  The dossier submitter considers an intra-species factor of 10 for the pregnant worker. This is not supported by the Cefic BDO & Derivatives sector group:  1. There is no requirement to apply this factor according to the guidance. In fact applying a factor of 10 in this case would annul the factor of 5 for workers. As woman belong to the working population. The arguments used would apply to all substances at work. The risk that a pregnant women is using a chemical substance at work is much bigger for chemicals which are not reprotoxic as use of reprotoxic substances is forbidden during pregnancy.  2. An intra-species factor is used to cover variance between different sub populations and especially those not covered by the animal model (very young, very old and ill). However, possible effects on pregnant women including the unborn child are examined and evaluate directly by an animal model. This is done even in two different animal species (rat and rabbit). Consequently, there is no requirement to apply an additional safety factor to the working woman which may be pregnant but does not know.  3. In practice, the measure to be taken according to EU legislation is to exclude any exposure to reprotoxic substances during pregnancy irrespectively whether there is a safe level of exposure or not. As women and men are not equally distributed in the different workplaces in each industry sectors (office jobs, lab jobs, heavy duty shift work, logistics) it should be considered to include values for pregnant and non-pregnant workers in the restriction (part A and not only in the background document).  4. As the difference in the DNELs for pregnant and non-pregnant workers is only due to application of a theoretical factor which is overall questionable, it is questionable whether there is any requirement for a lower harmonized DNEL for pregnant woman.  Introduction  First, the members of the Cefic BDO& Derivatives sector group, which includes the Lead registrant BASF SE, would like to state that in principle they support the conclusion of the Netherlands in their RMO analysis that a restriction is the better RMO compared to an authorization procedure in the case of NMP.  Furthermore, the Cefic BDO& Derivatives sector group understands ECHA’s position to ask for early comments by the end of November, so that informed discussions can be had within the member states committee, the Commission and the Agency on the proposed restriction. The restriction describes an unacceptable risk as exposures exceeding a safe limit defined by a harmonized DNEL, 8h TWA and 15 min STEL value.  As a concession to the needs of ECHA these upfront general comments are made as complete as possible at this time. Additional comments requiring more time for data mining and data generation, will be sent under separate cover. We feel that these upfront general comments provide an opportunity for the member states, the Commission and the Agency to engage in an initial discussion and address additional questions to industry in case additional clarifying information is required. The Cefic BDO& Derivatives sector group is open for any question and indeed would welcome such a discussion.  These comments, provided on behalf of the Cefic BDO & Derivatives sector group, addresses specifically the derived inhalation DNEL, 8 hr TWA of 5 mg/m³, respectively. It is the need of industry to have the DNEL defined in a manner that substance risks are adequately protected while at the same time, unnecessary conservatism is avoided such that the value is as permissible as possible to be practical and proportionate to the risk.  There has been some information exchange and discussion between the Cefic BDO & Derivatives sector group, the Lead registrant BASF SE and the dossier submitter. The CEFIC BDO & Derivatives sector group and the Lead registrant BASF SE are of the opinion that their arguments to use the existing IOEL value of NMP (40 mg/m³), as published in directive 2009/161, have not been satisfactorily considered.  It was also the outcome of the 2nd Commission Workshop "Managing risks related to chemicals: REACH and sector specific legislation", 8 November 2013, Brussels that “ Harmonization of the methodologies to derive safe levels (DNELs / iOELs) should also be considered. This can be improved via better communication between SCOEL and Risk Assessment Committee (RAC) and possibly other parties. In particular it should be clarified, when the two values are not the same, which value should be applied for occupational exposure at industrial premises. The exchange of information between RAC and SCOEL, between the relevant Commission services and between the different MSCA should be intensified.  At the work place there is not only the requirement to be compliant with chemical regulations but with occupational legislation as well. Existing occupational legislation and the additional demands of occupational health legislation especially its interaction has to be considered completely in the restriction dossier. This is explained in the following in more detail as well.  Reasoning behind the NMP SCOEL value  In the attached document the NMP manufacturers tried to describe the reasoning behind the SCOEL value. Beyond this, it provides additional information why due to the phys-chem properties of NMP, even higher values like the German OEL are justifiable, as inhalative reprotoxic properties depend on phys-chem properties of NMP which are independent from the species exposed to NMP.  However, despite that the SCOEL value is plausible and justifiable and therefore transparent, it has to be stated that it is not the duty of the manufacturer to state how SCOEL reached its conclusion. The SCOEL has the mandate and the expertise to derive OELs in the EU and its decisions are science based. The SCOEL is an expert committee deciding on a safe value for a substance after intensive discussion. All the information required and considered for that decision is laid down in the SCOEL summary. By definition it is documented and transparent to the degree demanded by the EU Commission (see below).    IOEL (in general)  1) The Scientific Committee on Occupational Exposure Limit Values (SCOEL) was set up by a Commission Decision (95/320/EC) with the mandate to advise the European Commission on occupational exposure limits for chemicals in the workplace. The SCOEL shall be composed of members drawn from all Member States and reflecting the full range of scientific expertise which is necessary to fulfil its mandate in setting OELs (article3 (1) 95/320). The SCOEL shall in particular give advice on the setting of Occupational Exposure Limits (OELs) based on scientific data and where appropriate shall propose values (article2 (1) 95/320). Any recommendation shall be supported and explained by information on the basic data, a description of the critical effects, the extrapolation techniques used, and any data on possible risks to human health (article2 (2) 95/320). The feasibility of monitoring exposure at any proposed limit value(s) shall also be noted (article2 (3) 95/320). The Committee shall keep under review all relevant scientific factors relating to the setting of OELs and shall make recommendations to assist the Commission in setting out priorities (article3 (4) 95/320).  In short the SCOEL has the mandate and the expertise to derive OELs in the EU and its decisions are science based, documented and transparent to the degree demanded by the EU Commission.  2) The Commission, after first consulting the Advisory Committee on Safety, Hygiene and Health protection at Work, shall propose European objectives in the form of indicative occupational exposure limit values (IOEL) for the protection of workers from chemical risks, to be set at Community level (article3 (2) 98/24). For any chemical agent for which an indicative occupational exposure limit value is established at Community level, Member States shall establish a national occupational exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice (article3 (3) 98/24). Where a Member State introduces or revises a national occupational exposure limit value or a national biological limit value for a chemical agent, it shall inform the Commission and other Member States thereof together with the relevant scientific and technical data. The Commission shall undertake the appropriate action (article3 (8) 98/24). On the basis of the reports provided by the Member States under Article 15, the Commission shall carry out an assessment of the way in which Member States have taken account of Community indicative limit values when establishing the corresponding national occupational exposure limit values (article3 (9) 98/24).  Member States shall establish national occupational exposure limit values for the chemical agents listed in the Annex of the directives publishing a list of Community indicative occupational exposure limit values, taking into account the Community values (for NMP see article 2 and annex of directive 2009/161). Member States shall bring into force the necessary laws, regulations and administrative provisions to comply with this Directive by 18 December 2011 at the latest (for NMP see article 4 2009/161).  In short the IOEL values are existing specific Community legislation imposing minimum requirements relating to the protection of human health to ensure that the risk during occupational use is properly controlled. If the Commission sees the IOEL not properly implemented in the national legislation it should undertake appropriate action on the basis of article 3 of 98/24.  3) In their restriction proposal the Dutch competent authorities (dossier submitter) stated that in Europe, the following national OELs are used: 5 ppm (20 mg/m3) in Denmark and Norway; 10 ppm (40 mg/m3) in Finland, Belgium, Ireland and The Netherlands; 20 ppm (80 mg/m3) in Germany 25 ppm (100 mg/m3) in the United Kingdom and Spain; and 50 ppm (200 mg/m3) in Austria and Sweden. The lower values of Denmark and Norway are lower than the IOEL value. However, as they are lower they are in line with the minimum requirement set by the IOEL value for NMP as laid down in 2009/161. Currently non-compliant with the IOEL value are Germany, United Kingdom, Austria and Sweden.  Consequently one may see a restriction to introduce a harmonized 8h-TWA as an initiative by the Netherlands to reach harmonized acceptance of the IOEL value. If supported by the Commission, it can be seen as an appropriate action of the Commission after their assessment of the way in which Member States have taken account of Community indicative limit values when establishing the corresponding national occupational exposure limit values.  However, following EU procedures the member state is not the one who should advise the Commission with respect to the OEL value itself. This is the obligation and falls into the competence of the SCOEL (95/320).  In short the restriction proposal of the Netherlands can be seen as an appropriate action of the Commission, initiated by a member state to exclude possible risk arising from substance use with the exposure above the IOEL.  Despite this, it can be supposed that most industrial uses are likely to be in-line with the IOEL value already, however some national OELs (Germany, United Kingdom, Austria and Sweden) are still above the IOEL and consequently occupational exposure can result in excess risk.  However, it is the SCOEL who has the mandate and the expertise to derive OELs in the EU. SCOEL decisions regarding an IOEL are science based. There is no new scientific information to suggest that the the IOEL value should be lowered and consequently the Dutch restriction proposal should use the exisiting IOEL value.  Remark on ECHA Guidance  The ECHA Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (Version November 2012) states that “a registrant is allowed to use an IOEL as a DNEL for the same exposure route and duration, unless new scientific information that he has obtained in fulfilling his obligations under REACH does not support the use of the IOEL for this purpose.” (p. 137)  There is no new scientific information which suggests that the IOEL value should be lowered. In fact, , recent data is more suggestive for raising the IOEL (see reasoning for the German OEL as well as published kinetic modeling data). As stated above, the SCOEL has the mandate and the expertise to derive OELs in the EU and its decisions are science based.  In short, if there is no new scientific information suggesting the IOEL should be lowered, the value set by the Commission should be used in the restriction proposal as mutual acceptance of decisions within the Commission incl. EU-Directives is the basis for the functioning of the EU.    General remarks on the DNEL derivation in the NMP restriction Proposal:  1) Intra species variance  The intra species difference factor is for covering possible different susceptibilities of different population subgroups and the variance of individual susceptibilities within on grou . The in the intention of this factor is not to protect a non-worker more than a worker. This would be discrimination of the worker.  There is no requirement to apply a factor of 10 for intraspecies difference of workers according to the guidance. A factor of 10 is suggested for consideration in the case of reprotoxicants, however this is done without any further guidance. One has to consider that in fact applying a factor 10 in with respect to the endpoint of reprotoxicity is annulation of the factor 5 for workers as such. As woman belong to the working population. The arguments used would apply to all substances at work. The risk that a pregnant woman is using a chemical substance at work is much bigger for chemicals which are not reprotoxic as use of reprotoxic substances is in practice forbidden during pregnancy.  Intraspecies factor is used to cover variance between different sub populations and especially those not covered by the animal model (very young, very old and ill). However, possible effects on pregnant women including the unborn child are examined and evaluate directly by an animal model. This is done even in two different animal species (rat and rabbit). It is as well clear that a pregnant woman cannot be evaluated separately from the unborn child.  Consequently, scientifically there is no requirement to apply an additional safety factor to the working woman which may be pregnant but does not know. Because this exposure Scenario is tested in the animal study directly.  Additionally, occupational exposure to substances toxic to reproduction is also regulated by Directive 92/85 (COUNCIL DIRECTIVE 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).  Article 5 of Directive 92/85 notably provides that if the results of the assessment reveal a risk to the safety or health or an effect on the pregnancy or breastfeeding of a worker, the employer must take the measures necessary to ensure that the exposure of that worker to such risks are avoided. Mandatory means to achieve this are temporarily adjusting the working conditions and/or the working hours of the worker concerned, moving the worker to another job or granting leave for the period necessary to protect her safety or health (see Article 5 of Directive 92/85).  With-out doubt the pregnant workers, the unborn child, respectively are the working population to be protected against the reprotoxic properties of NMP. However, in practice the measure to be taken according to EU legislation is to exclude any exposure to reprotoxic substances during pregnancy irrespectively whether there is a safe level of exposure or not. Consequently, a inhalative TWA based on a DNEL for pregnant workers is an implied contradiction to Article 5 of Directive 92/85.  Furthermore women are trained at work to notify the employer if they are pregnant. In larger companies this can be done even if a woman is planning to get pregnant. Beyond this, as it is the duty of the employer to take care of his employees, women often do not work in areas dealing with teratogens. Finally, the IOEL already covers reprotoxic effects of NMP by cross checking of the final IOEL against possible reprotoxic effects – however this cannot be stated directly as it would be in contradiction to EU occupational legislation (= not any exposure of pregnant women to reprotoxic substances).  Consequently interspecies variance should be maintained at 5 for workers. Applying an intra-species 10 as for general population, again, is implying a contradiction to the restriction that general population should not be exposed to teratogenic substances at all. This is true as well for pregnant workers.  2) Remaining differences  Final conclusions on a DNEL should also take into account the entire and comprehensive set of toxicological information rather than focusing on individual studies. NMP is a well examined substance with a profound data base allowing weight of evidence considerations with respect to remaining differences extrapolation factor. Existing data demonstrates that there are no known species difference regarding NMP toxicity from animal studies with dogs, rats, mice and rabbits. Metabolism in rats and humans has been proven to be the same. These studies have been conducted with human volunteers on all three routes of exposure. Neither Human studies nor experience from work place exposure have given any hint for unknown remaining difference between rat and humans that is justifying the necessity to apply such an additional factor. In contrast to this kinetic modeling is even suggestive for that internal dose to NMP of the developing embryo is lower in humans than in the rat when the mother is exposed to the same concentration of NMP in the air.  The dossier submitter already states that there is no evidence of any remaining interspecies difference, consequently this factor can be and should be omitted on this weight of evidence.  Weight of evidence is the only possibility to draw conclusions on the remaining differences factor any way in a ethnical and politically correct manner in the NMP case. Human studies with chemicals designed to find adverse systemic effects in humans are simply not allowed to conduct due to ethical reasons. Consequently such information is only available from working accidents. In an accident situation exposure is often unknown and ofte via various routs of exposure at the same time. Available Studies in humans to elucidate metabolism and local irritation (designed to cause no adverse systemic effect) are in line with animal studies and thus proving evidence that NOAEL and NOAEC of animal do match and there is no other interspecies difference apart from algometric scaling to be considered. Beyond this, there is no hint (from accident or any other experience) from >20 use of NMP that the rat is not a proper model to estimate NMP effect in human. Consequently, there is no justification on a non-human primate study is this case as well. In conclusion there is as well no justification to conduct any non-human primate studies for NMP as the effect of concern is not effect visible in primates only.  Consequently remaining difference variance should be omitted based on scientific evidence.  Remark on the key studies:  It is supported that the study of Solomon et al. 1995 and Becci et al. should be selected as point of departure for DNEL derivation.  However some first comments can be made on the 90 Day inhalation Study BASF 1994 2 year inhalation study Lee et al. 1987  Conclusion of the SCOEL should be given more weight :”In a 2-year chronic toxicity/carcinogenicity study by the inhalation route in rats minimal inflammation of the lung and slight systemic toxicity was reported in male rats at 18 months, but not at 24 months, at the highest exposure level of 400 mg/m3 (Lee et al., 1987). The dose level of 400 mg/m3 in this study can be considered a borderline LOAEL/NOAEL. (ref. SCOEL SUM 119 2007)”  Possible explanation for the conclusion of SCOEL:  The 1000 mg/m³ dose group can be described as a systemic NOAEC/LOAEC or even as systemic NOAEC because the body weight retardation at day 33 only is small of no biological relevance. Beyond this, this effect is not confirmed by other effects in this dose group or the female. Furthermore body weight development within the next weighing period is the same (+ 42.2 g control vs. 43.0 g 1000 mg/m³). An in the last weighing period body weight development in the 1000 mg/m³ group is higher (23.6 g (control) vs. 28.9 g 1000 mg/m³). This clearly shows that this observation of different body weight development can also be seen as a natural variance body weight development instead of being a substance related effect at all.  The 90 Day inhalation Study (BASF 1994) is providing a LOEC/NOAEC of 1000 mg/m³ for systemic toxicity Time extrapolation (factor 2) provides a extrapolated chronic NOAEL of 500 mg/m³. Lee study provides a factor of LOAEC/NOAEC of 400 mg/m³ and consequently in the same range.  Consequently that leads to the conclusion that a LOAEC/ NOAEC extrapolation of 3 is over conservative. One may come to the conclusion that it a NOAEC/LOAEC extrapolation is not required.  Finally this supports the hypothesis that is an overall NOAEC 206 mg/m³ is a reliable overall NOAEC. This hypothesis is supported by Physico-chemical properties of NMP which is technical achievable vapor saturation concentration. Exposure of the lung tissue changes dramatically at vapour saturation concentration from diffuse low exposure of a vapour (exhalable) to a spotted concentrated exposure of droplets on the lung tissue: in a concentration range of 480 - 640 mg/m³ and consequently is supportive for that the IOELvalue is safe for all workers. |
| **Dossier submitter response**  Thank you for your comments. Based on the comments provided we did not change the background document, because the issues related to the DNEL derivation have been addressed already in the restriction dossier and now is for RAC to take further.  Further, we are aware of the political discussion on the relation between REACH and OSH legislation, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  RAC has to address the proposal and the DNEL-derivation independent of the setting of an iOEL by SCOEL. RAC notes that setting an AF of 10 for pregnant workers is not supported by the REACH guidance, and that the worker DNEL should cover all workers. Regarding the AF for dynamics (2.5), RAC is of the view that local effects and metabolic studies are not sufficient reasons for adjusting this assessment factor. |
| **SEAC Rapporteurs comments**  The comment is mainly a question for RAC. |
| **297** | **Date:** 2013/11/28 19:39  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (A)  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes (available from confidential version of RCOM table)**  **Privacy comment:** competition law: measured values at customers site at substance use including the company names. Information was generated under secressy agreement. This is comercial interest of supplier as well as of customer. | **Comment:**  see next sub section  **Specific comment:**  **[…]** likes RAC and SEAC to consider exposure measurement carried out in the pre submission phase of the Restriction dossier.  The marketed operations are essential steps in the corresponding manufacturing process. E.g. cleaning is required to maintain the wire-coating process running.  Process will not be compliant if one step is not compliant. Consequently despite most uses may manage the suggested TWA of 5 mg/m³ two applications Wire winding value chain as well as the lithium Ion batteries value chain mar lost completely according to the presented exposure values.  A domino effect on the connected manufacturing of electric motors and generators value chain is foreseen as there value chains are very closely connected and there is a big cost savings advantage to have electric motor and generator production near to the manufacturing if the coated wire. This value chain faces immense cost pressure.  The lithium ion battery production is connected to the automobile industry as well the manufacturing of electric motors. However it is unclear how big the impact on the automobile industry is in the end as this industry mostly produces conventional cars. However the fact that NMP is solvent for industrial coating at the manufacturing of the car. There may be additional impact from this side as well.  **[…]** as the lead registrant therefore ask to avoid an over conservative approach. A 8h TWA of 5 mg/m³ is likely to act like a total substance ban. This is as well likely to happen if a value of 10 mg/m³ is introduced. (see page 71 of the Amec report cost analysis )  More detailed comment may follow in the commenting period until March 2014.  (values see attachment) |
| **Answer 1:**  Will be done later |
| **Answer 2:**  Will be done later |
| **Answer 3:**  Will be done later |
| **Answer 4:**  Will be done later |
| **Dossier submitter response**  Thank you for your comments and information. The exposure related information is included in the confidential version of the restriction dossier in an anonimized way.  The potential direct economic consequences as well as the wider socio-economic effects are already described in chapter F. We have slightly adjusted the socio-economic information for wire coaters and battery industries in the Background Document. |
| **RAC Rapporteurs comments**  Thank you for this information. Exposure information is needed as complement to the modelling. |
| **SEAC Rapporteurs comments**  It is noted that the exposure in cleaning operations in a production of electric motors and generators would be higher than the proposed limits, even when using PPE. No information is presented on whether available alternative substances can be used as substitutes. |
| **298** | **Date:** 2013/11/29 12:35  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** France  **Related to:** (B) (C) (F)  **Company name confidential:** No | **Comment:**  IVA (company ESSEX SAS) is one of the 3 European enamel producers used for winding wire coatings  Restriction proposed appears as the most appropriate EU-wide measure but the harmonised DNEL for inhalation of 5 mg/m3 is too low and endanger the business continuity of our direct customers: the european winding wire industry.  The value chain would be interrupted then our activity would go the same way i.e the downstream users of the enamel producers (a part of them containing NMP)cannot stand this proposed OEL for a number of reasons developped further on these comments.  The existing SCOEL value at 40 mg/m3 appears as adequate on a scientific basis.  Extensive research to identify an alternative to NMP have taken place the last 20 years among the 3 enamel suppliers in Europe and have unfortunately not succeeded. An alternative is not likely to be identified in the next years.  **Specific comment:**  Comments on B.2 Manufacture and uses (p22)  Total European enamel market for the winding wire industry is estimated at 40 to 45 kT / year.  The main NMP-based enamel categories used in Europe are: PAI and PI, their share is estimated at 20% of the global enamel market: 8000 to 8500 T / year. Most of it is PAI.  NMP proportion in these enamels is approx. 50%.  Total consumption of NMP for the enameling European market is 4000 T to 4500 T.  The market trend for PAI & SB showed a growth of about 10% in the last 10 years.  Demand on high efficiency electrical motors for the next years should contribute to speed up this growth as the high thermal properties are a typical strength of PAI (Nota: this statement obviously not considering any ban of the substance).  Note winding wires are in most cases multi-layer coated, with different kinds of enamels, one or two layers being PAI (usually top-coat).  Comments concerning paragraph C.1 Wire Coaters (page 132)  Background on polyamide imide wire enamels  In the publication: “Poly(amide-imides)” : Wire Enamels with Excellent Thermal and Chemical Properties” , Macromolecular Materials and Engineering 2008, 293, 350–360, T.J. Murray reviewed the chemistry of polyamide imide wire enamels, their properties and also possible alternate solvents. The outstanding characteristics of a wire coated with a polyamide imide include high thermal performance, chemical and abrasion resistance, and low coefficient of friction. Typical for such a wire is a temperature index (long term thermal durability) of >220° (IEC 60216), a cut through of 390–420 °C (IEC 60851) and a heat shock of 240°C (IEC 60851). In addition coils of magnet wires were impregnated with unsaturated polyester resins, epoxy resins and various varnishes. The wire must resist chemically to these resins, their solvents or reactive diluents and also to the curing conditions (depending on the system used 1-6 hrs up to 160°C) (http://www.elantas.de/ and http://www.axaltacoatingsystems.com). According to Murray no alternatives to NMP as solvent have been identified, despite extensive research by many wire enamel companies in the past (common knowledge from Axalta Coating Systems (former DuPont Performance Coatings), Elantas and IVA). The main reason could be the suspected catalytic properties of NMP during oven cure, in addition to its role as an important solvent in the production of polyamide-imides.  Alternative polymers  On page 132 PVC, polyethylene and materials containing ethylene ethyl acrylate copolymer (EEA) and/or ethylene vinyl acetate copolymer (EVA) are listed as potential replacements for PAI. These materials are thermoplastic materials which do not have the thermal properties as needed for electrical devices. Such high thermal properties can only be achieved by using cured polyamide imide films. Polyester and epoxy-based enamels cannot be used as single coat, as they do not have the required abrasion resistance. Polyurethanes are solderable wire enamels. That means the coating disintegrates at elevated temperatures and they cannot be thermally stable. Epoxy based enamels are used as self bonding, that means meltable materials. Polyvinyl acetates have a temperature index of 130, and are therefore inferior to a polyamide imide. Finally, fluorinated ethylene propylene and polytetrafluoro-ethylene cause major problems when the coated wires were recycled, because they generate hydrofluoric acid. In addition, they are not cost competitive compared to polyamide imides.  Finally, Murray clearly states that substitution of NMP by e.g. sulfolane, anisole, siloxane, butyl cellosolve acetate and lactone is technically not feasible.  Alternative solvents  The registration proposal lists a number of aprotic solvents as viable substitutes for NMP such as DMAC, DMF, and DMSO. We believe that they offer no true alternative:  DMF has a boiling point of 152°C and DMAC of 156°C both are below of that of NMP (203°C). A high boiling point for the solvent is needed in the enameling machines to obtain a smooth pinhole free polyamide imide film. In addition DMF and DMAC exhibit high toxicity as well. DMAC is already in the authorization process and DMF was subject to a public consultation from June to September for inclusion in the Authorization list (Annex XIV)  DMSO cannot be used as solvent for PAI because it violently decomposes at 180°C. Modern wire enameling machines have oven temperatures above 550°C (http://www.mag.at/). In addition solvents are catalytically oxidized in the enameling oven and the energy is used to heat the oven. DMSO will generate SO2, which will corrode the existing enameling machines and it cannot be released into the atmosphere (acid rain).  As conclusion it can be said that no alternative wire coating with properties anywhere near those of polyamide imide can be found. In addition, a huge R&D effort was undertaken by the wire enamel manufacturers for the last 20 years to find an alternative solvent to NMP for PAI enamels. No successful replacement could be identified.  It can therefore not be expected that in the near future alternatives will be found.  Comments to F 1.4.1 Pregnant and potentially pregnant workers (p186 – 191)  Paragraph F.1.4.1 of the report acknowledges that protection for women with known pregnancy exists. However, it sounds as if this was still somewhat up to the industry to implement:  Paragraph F.1.4.1. Page 186:  “Personal communication with some of the NMP using industries indicated that there are indeed preventive measures in place to protect pregnant workers. In at least one industry, workers are informed about the potential hazardous effects of NMP before they enter the job and workers will temporary be replaced to a NMP free environment during the period of their pregnancy to avoid exposure to NMP (personal communication). Another industry notes that most plants have no female workers working at the jobs where they could potentially be exposed (personal communication).”  The situation is however strictly covered by EU and national laws and not at the liberty of the industry .  The existing laws in France already strongly protect pregnant women against the contact with NMP. Any additional regulation for women with known pregnancies is therefore not required.  The second argument of the restriction proposal addresses the fact that women might not know about an early pregnancy or not be aware of it and in this case the existing laws would not protect them from NMP:  Page: 187 Paragraph F.1.4.1:  "The potential risk for pregnant workers might however remain, as women might not know that they are pregnant in the early days of their pregnancy, or, as women might not tell their employer before the 10th -week of their pregnancy. Because of this, it could be argued that all female workers during their reproductive period (20-45 years; CBS, 2007) should be included in the population at risk for this endpoint. As is calculated and explained in the text box 3 below, around 57% of the female worker population is at the reproductive age and on a yearly basis 3.5% of the female worker population becomes pregnant. These percentages give an indication of the female population potentially at risk,..”  The risk indicated in this paragraph is largely exaggerated. First, even in cases where a pregnancy is planned the employee is encouraged to inform their supervisor and she is normally moved to another area within the company. Secondly, and more importantly, the statistical figures are showing a much too large fraction for affected female workers. Only in production conditions exist which may lead to an extended exposure. Due to the physically taxing work, only a very small number if any of women in the affected industries work in production. At IVA (Essex SAS)in France for example no women work in Production Department for wire enamels. Hiring women in Production is not allowed.  In summary, we believe that the risk for pregnant and potentially pregnant workers is in reality nearly nonexistent.  Comments to section F: Socio-economic effects for Winding Wire production incl. Lifetime issue  Enamelled wires are copper or aluminium wires with a very thin polymer layer, often of two different compositions to provide a continuous insulating layer. These wires are used in the transmission of electrical energy and the creation of magnetic fields in electrical or electronic devices in a wide variety of areas such as transformers, inductors, electromagnets, electrical motors and generators. The continued demand for enhancement of reliability and other performance characteristics of those devices has required the development and use of highly mechanical, chemical and heat resistant high end polymers like polyamide-imides (PAI) and polyimides (PI).  PAI is used as top layer on the most common class 200 °C magnet wires used in electrical motors, transformers or generators. This PAI top layer provides higher thermal performance, chemical and abrasion resistance to the enamel insulation.  The top layer in self-bonding emanelled wires are also based on PAI polymers. The use of those wires allow manufacturers to eliminate the application of additional impregnation varnishes and therefore to reduce VOC.  PI-enamelled wires are preferably used in high end applications such as in the aerospace and nuclear industry due to the fact that PI enamels show outstanding thermal (up to 240 °C) and radiation resistance.  For the coating process the use of NMP is essential as it enables the use of PAI and PI polymers in a diluted (liquid) state due to the very good dissolving properties of NMP for high end polymers. During the wire coating process the wire is passed through an PAI or PI solution after which the solvent is evaporated off and the enamel layer is cured by passing through an oven. Such operation is made in high temperature ovens, typically with temperatures of 200 up to 500 °C where enamels are dried and cured onto the copper or aluminium wire at high speed. Inside the ovens all vapours of solvents incl. NMP are burnt at very high temperature through catalysts at typically 700 to 750 °C, so that no NMP is exhausted in the air. This process is operated a large number of times (up to 20 coats) with ultra thin coating layers until the targeted coating thickness (Grade 1, 2 or 3) is achieved.  A typical process for the coating of copper or aluminium wires is shown on page 2 (example for a 4-lines horizontal machine).  Such process is existing since many years and has been continuously optimized in such a way to improve product performance and productivity together with the reduction of the exposure for the workers and the environment. However enamelling machines in the winding wire industry have a long life time – typically of 20 - 30 years. The replacement of the machines requires substantial investment as a typical production plant has hundreds of such machines. Due to the low margins that are today earned in the winding wire industry the restriction of NMP - meaning very low exposure levels - would potentially result to a shut down of magnet wire manufacturing in Europe. The number of lost jobs is estimated to be of 8’000 considering 4’000 people involved in production, sales and distribution of magnet wire and an equivalent number of people working at subcontractors, machine producers, etc. This would also potentially affect the downstream users (transformer, motors or generator producers) which may decide to relocate their production outside Europe mainly for logistical reasons to be closer to the non-EU magnet wire producers. In addition, the loss of this industry in Europe would potentially lead to a lower quality of the enamelled wires which would be supplied from these non-EU countries.  Comments to F 4.4. Compliance Cost (218)  Polyamide imide wire enamels contain NMP as solvent. The outstanding characteristics of a wire coated with a polyamide imide include high thermal performance, chemical and abrasion resistance, and low coefficient of friction. Typical for such a wire is a temperature index (long term thermal durability) of >220° (IEC 60216), a cut through of 390–420 °C (IEC 60851) and a heat shock of 240°C (IEC 60851).  In table F.16 on page 218 for wire coaters and wire coating formulators it is stated that “According to industry, the uncertainties around authorisation are too high to continue production in case of an authorisation”. However, the situation is worse than written there and affects the whole electro technical industry in Western Europe:  An electrical motor is a complex construction that contains besides enameled wires, impregnating materials, sheet insulating components (laminates, films), tapes, the metal core, the housing, bearings, plastic parts, a.s.o.. Many of these are highly sophisticated components. e.g. for the slot wedges alone polyester and epoxy-glass laminates, NMN, DMD, phenolic paper laminates, and other materials can be used.  If polyamide imide coated magnet wires will not be produced any more in Western Europe the whole wire coating industry will collapse, because PAI is usually applied as a top-coat on top of other wire enamels. The motor manufacturers will most likely move outside Western Europe. The reason being that polyamide imide coated wires will be continued to be produced in the USA, China, India, Brazil, and other countries. The import of wire is expensive and laborious and co-development with European wire manufactures is no longer possible . In this case the motors will be produced in the countries where the wires are available. Jobs will be lost not only at the enamel and wire manufacturers but also the manufacturer of the motors, metal cores, laminates and films, tapes, housings a.s.o. will suffer. Similar things will happen to the manufacturer of generators (conventional (e.g. Nuclear, Hydro, etc.) and alternative energy as e.g. wind), transformers, relays a.s.o. Projects like electro mobility will go entirely too non-Western countries. |
| **Dossier submitter response**  For part C see response to comments 292.  From the comment it is not clear whether an alternative is not likely to be identified on the basis of technical feasibility or on cost considerations.  The comments made here are already captured in the text of the dossier: “Based on the literature, it is not clear if these alternatives are technically and economically feasible in practice and if they are applied on a commercial basis. During stakeholder consultation, wire coating industry indicated that no alternative for NMP was available, neither expected in the near future”  On specific comment:  Thank you for your comment. Information on the tonnage levels has be included in the Background Document.  Thank you for the information in relation to the difficulty in finding technical feasible alternatives. Overall, this comment support the conclusion in Table C.01 that technical and economic feasibility of alternatives are not shown for all wire coaters. The restriction proposal allows continued use of NMP if occupational exposure is below the DNEL.  In relation to the amount of female workers affected:  We are aware of the current legislation that should protect the pregnant worker and the unborn child. It was not our intention to give the idea that the protection is up to the industry. However, especially in the first month of pregnancy the worker may be unaware of her being pregnant.  In paragraph F.1.4. we tried to describe the population potentially at risk. As explained this paragraph is aimed only to give an impression of the potential scale of the health risks (and the number of workers potentially affected by a restriction). We agree that this information is surrounded with large uncertainties.  We are of the opinion that a restriction on the use of NMP is still required based on a calculated RCR>1.  Comments to section F: Thank you very much for this information. Especially the information of the typical life time of wire coating machinery is very helpful for the further discussions on this restriction proposal. The information has been incorporated in the Background Document. |
| **RAC Rapporteurs comments**  RAC appreciates the provided information. We understand that the use of NMP is considered crucial for the wire coater industry and that few viable alternatives are available. |
| **SEAC Rapporteurs comments**  Agree with the response by the Dossier submitter. |
| **300** | **Date:** 2013/11/29 15:28  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** United States  **Related to:**  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  See Attachment. |
| **Dossier submitter response**  Thank you for this comment. We are well aware of the importance of NMP to the wire coating sector and we think that is well reflected in the Dossier. The further statements in the document are very general and miss sufficient underpinning, so no further changes have been included in the Background Document based upon this information. |
| **RAC Rapporteurs comments**  The information is noted. |
| **SEAC Rapporteurs comments**  No further comment. |
| **301** | **Date:** 2013/11/29 17:37  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** France  **Related to:** (B) (C) (D)  **Company name confidential:** No  **Attachment confidential:** **Yes (available from confidential version of RCOM)** | **Comment:**  NMP is a critical solvent for the manufacturing of positive electrodes for Li-ion batteries. Saft dedicated over the last twenty years a lot of effort in R&D in alternatives for NMP. Saft succeeded in replacing NMP by water for the solvent of the negative electrode binder nearly 20 years ago but despite one patent detailed in confidential attachment, it was impossible to do the same for the positive electrode at industrial scale and NMP is currently used worldwide as a solvent for the PVDF binder of positive electrodes. In addition, NMP is used to clean all apparatus before coating.  As every CMR substance in Europe, the use of NMP at the workplace is already strictly regulated. Saft has ONLY AN INDUSTRIAL USE of NMP, solvent which is removed during drying of electrodes , recovered and thus:  • neither present in the final positive electrode,  • nor present in the final industrial Li-ion battery.  In general, only male workers are working with NMP, it seems over-protective to select the proposed restriction at the level of DNEL of pregnant women.  Even if the exposure values to NMP are already extremely low at Saft industrial sites, the French “arrêté du 15 décembre 2009 relatif aux contrôles techniques des valeurs limites d'exposition professionnelle sur les lieux de travail et aux conditions d'accréditation des organismes chargés des contrôles - NOR: MTST0924705A” imposes a very strict rule: in order to get a “non-exceedance diagnosis” in a given HGE (Homogeneous Group of Exposure), 3 different exposure measurements have to be below 1/10 of the binding OEL (meaning 0.5 mg/m3 according to the current restriction proposal of 5 mg/m3, to be compared to 4 mg/m3 being 1/10 of the current value of 40 mg/m3).  Saft is clearly in favor to stay with the current EU OEL (IOEL) of 40 mg/m3 which is implemented in France. Saft will have problems to be compliant with French downstream regulation (for non-exceedance diagnosis) if a TWA of 5 mg/m3 is introduced.  A 8h TWA of 5 mg/m3 will strongly encourage us (practically force us) not to exceed an exposure of 0.5 mg/m3. A 8h TWA of 20 mg/m3 is the utmost currently technically achievable, which means to stay below 2 mg/m3 in practice. Saft is also in favor of a harmonization among all the different MS for the methodology required to be able to control this OEL (non-exceedance diagnosis for 3 measurements below 1/10 of the OEL in France). |
| **Answer 1:**  The following PPE are compulsory for potential or proved exposure to NMP:  - Gloves TRIONIC 517  - 3M Jupiter™ Air Filter Unit with ABEKP3 filters+ hood  - Overall T65XP  In addition to the PPE, the following RMM are already implemented:  • Emergency/safety shower between ink manufacturing and ink coating  • Exhaust ventilation of the room where positive ink is manufactured  • The positive coating head is aspirated and protected.  • Sampling on workers according to legislation in force (external certified society) |
| **Answer 2:**  According to the French arrêté of “arrêté du 15 décembre 2009 relatif aux contrôles techniques des valeurs limites d'exposition professionnelle sur les lieux de travail et aux conditions d'accréditation des organismes chargés des contrôles - NOR: MTST0924705A”, we have in our French sites non-exceedance diagnosis in NMP HGE (Homogeneous Group of Exposure) and our workplace exposure levels are below 4 mg/m3, being 1/10 of the actual French indicative OEL of 40 mg/m3.  Detailed values are given in confidential attachment |
| **Answer 3:**  Not yet evaluated |
| **Answer 4:**  Not yet evaluated |
| **Dossier submitter response**  The text of the paragraph on Battery industries in chapter C of the dossier already states: “To conclude, the development on NMP free lithium ion and other hybrid batteries is ongoing, however, at this moment no alternatives have been proven on a commercial scale.”  Thus, the information does not add any to the conclusions made in the dossier.  It could be considered to add some of the technical details in relation to the use of NMP in the positive electrode to the Background Document. Also the information that NMP is used to clean all apparatus before coating is additional.  The current utmost technically feasible level of 2 mg/m3 – mentioned in the comment - is lower than the proposed DNEL of 5 mg/m3. By achieving this level one would adhere to the restriction proposal.  So far we estimated that the exposure in the battery industry is around 10 mg/m3, but we indicated that further exposure reduction is assumed to be possible. From the information in these comments one could conclude that the exposure is currently overestimated. And the estimated compliance costs for RMO3a this sector might be minimal (Table F.12). This signal is taken up in the BD in part F. Note however, that there are also signals from other parties in the public consultation that suggest that exposure levels in the battery sector are higher. These signals have also been included in the BD.  **Answers 1-2:**  Thank you for this information. |
| **RAC Rapporteurs comments**  RAC appreciates getting this exposure information that will complement the modelling.  **Answers 1-2:**  Thank you for this detailed information. |
| **SEAC Rapporteurs comments**  It is noted that an exposure level below 10 mg/m3 is already achieved. |
| **303** | **Date:** 2013/11/29 21:22  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** Belgium  **Related to:**  **Company name confidential:** No  **Attachment confidential:** **Yes (available from confidential version of RCOM)** | **Comment:**  Comments to Annex XV Restriction Report Version 2.0 dated 9 August 2013-11-12  This statement has been developed by the Technical Committee of the European Winding Wire Group (EWWG).  Our association is an independent section of the EuropaCable association. The members are “wire-coaters “in the definition of this Restriction Report. The member companies represent the whole enamelled wire industry in Europe. In terms of REACH “wire coaters” are downstream users of NMP which is contained in certain wire enamels (mixtures) used to coat high-temperature resistant wires for special applications in the automotive, aerospace and Electrical/Electronics industry. The finished wire is an ”article” as per definition of REACH.  NMP is used as a solvent in certain wire enamels because of its good solubility for the high-end polymers such as Polyamide-Imide and Polyimide. NMP and/or other aprotic solvents are used at percentages >5% in the wire enamels. For the description of our products and processes we have added a special diagram (see attachment).  Summary of our conclusions:  ---------------------------  We are not in agreement with the present proposal to define the TWA at 5mg/m³ and the STEL at 10 mg/m³ for inhalatory exposure. We are, however, in full agreement for the preventive measures against dermal exposition, which is already widely practice in our industry.  The proposal for the TWA is not justified in our opinion for the following facts and reasons:  ---------------------------------------------------------------------------------------------  • The DNEL submitted in the REACH registration dossier is 40 mg/m³. This value is the recommendation made by the Scientific Committee for Occupational Exposure levels (SCOEL) in the “Recommendation from the Scientific Committee on Occupational Exposure Limits for N-Methyl-2-Pyrrolidone” Summary of 2007. As a downstream user organisation we have no insight into the detailed calculation models and methodologies used. We have to rely on the data available to us from the Safety Data Sheets.  • Based on a decision made by the Commission and an EU Directive the SCOEL Committee acts as the advisory body to the EU Commission for setting indicative and binding OEL values. The methodology applied by SCOEL is described in the key documentation document version 7 from June 2013. Following the SCOEL recommendation of an OEL value the member states are obliged to review the national value in case that the national OEL is higher.  • SCOEL recommendation was implemented as EU OEL (IOEL) by EU Directive 2009/161  • The OEL level for NMP in Germany (AGW) is set at 82 mg/m³ as TWA and 164 mg/m³ as STEL. These values are based on the evaluation result that health effects observed were in the physical state of NMP as an aerosol only but not in the vapour state. The justification for the German OEL is describing this in detail in the justification document TRGS 900 (developed by AGS / BAuA). Furthermore German OEL justification for 82 mg/m³ already states (translation): “pregnancy category Y: If compliant with the OEL no harm to the unborn child is to be expected” (pregnancy category was confirmed in April 2011). Consequently, the EU OEL may be regarded as “more than safe” regarding the health risk during pregnancy for the unborn child. The justifications for the national OEL (such as the AGW in Germany) are partly publically available whereas the DNEL derived in the CSRs of the registration dossiers are only available to ECHA or Member States Competent Authorities.  • Section A 3.3. of the Restriction Report refers to a “REACH Methodology”. It has to be pointed out that the REACH Regulation only defines a number of evaluation steps, but does not define a certain methodology or calculation model in detail. The dossier submitter is obviously referring to ECHA Guidance documents and to certain tools such as ECETROC based on calculation models and assumptions. These guidance documents do allow the application of certain safety factors at the discretion of the user. As per definition the guidance documents published by ECHA do carry the disclaimer statements of being recommendations without legal power. On the other hand this document as well states that EU – OELs per se are valid to be used as DNEL. SCOEL, IOEL, respectively are EU competent authorities’ expert decisions.  • “In Europe, the following national OELs are used: 5 ppm (20 mg/m3) in Denmark and Norway; 10 ppm (40 mg/m3) in Finland, Belgium, Ireland and The Netherlands; 20 ppm (80 mg/m3) in Germany and Switzerland; 25 ppm (100 mg/m3) in the United Kingdom and Spain; and 50 ppm (200 mg/m3) in Austria and Sweden.” (See Restriction dossier page 77).  It is acknowledged that there are countries with OEL >40 mg/m³ (8h TWA), which is above the current EU. It is believed by the submitter of the comments that a TWA of 80 mg/m³ is scientifically justifiable despite being above the EU OEL. Higher values for a TWA may be considered as risk. For EU harmonization reason the EU OEL may be a value everybody can agree on.  It is worth mentioning that even Denmark and Norway concluded that a 8h-TWA of 20 mg/m³ is safe. This value is 4 times above the proposal of the Netherlands. So far as we understand the restriction dossier there is no new toxicity data available (see year of studies chosen for DNEL derivation).  Consequently we have serious doubt that a requirement for a 5 mg/m³ 8h TWA or a 10 mg/m³ STEL can be at all justified on existing risk.  We see no reason to have doubt in the expertise and the conclusion of SCOEL, or the German AGW. And furthermore we do not see a reason do have any doubt that the SCOEL has the mandate to advise on EU-OEL.  • Regarding the DNEL derived for workers and pregnant workers it has to be mentioned for the “wire coaters” that the machine operators and maintenance personnel are not physically present in the area of exposure during the whole 8 hours shift. This is due to the fact that they are also involved in e. g. logistical, testing and office tasks where they are not subject to exposure. The degree of automation at today`s machines does not require permanent attendance at the enamelling machines. The exposure during maintenance, set-up and cleaning of the machines is somewhat higher, but only during short periods.  • It is the declared target of our industry to limit the exposure of workers during routine operation. The highest exposure can be expected during technical problems, repair, cleaning or machine problems and/or failures. Consequently and definitely, a STEL well above 10 mg/m³ is required to keep the process running. Iit is to mention that we consider assessment of the German AGW and SCOEL as correct which means there is no health risk for workers (pregnant or non pregnant) at a concentration of 10 mg/m³ as STEL, since the according SCOEL value is 80 mg/m³ and 160 mg/m³ according to AGW)  • The issue of PREGNANCY at WIRE COATING:  Taking in account the number of people employed in the WW industry, which is 4000 people, the ECHA report page 190, table F0.5. shows that 30% are female, or 1200 women, from whom 57% are in reproductive age, which means 684 women who may be in risk if pregnant.  The reality is very different:  The wire coating industry is a continuous operating industry, due to high investment process and high curing temperature. Working in the production area 3 shifts, all the year long, is not proposed to women. So, it is assumed that no female is working in the production area, exposed to NMP occupation level, on the enamelling machines.  But this assumption may be questioned, and the association EWWG performed a new survey among all production sites in EU, with a specific questionnaire to the 20 production sites of Winding Wires in EU. All individual results are available for ECHA, with references and addresses.  This updated survey shows that among all 20 sites of production, with a rough number of 1000 workers, there is a unique woman employed as “foreman”. She is actually 50 years old. So, the assessment of 0 (=zero !) women at risk in production is checked. This situation is not foreseen to change according to the answers and the regulation.  There are also workers outside of production, dealing with production, such as quality, logistics, service, etc. These workers are not doing enamelling on the machines, but they are partially working in the production floor. A rough estimation of 1000 persons is given in our industry. Among these 1000 workers, 29 are female, mainly in the quality area, control, cleaning. Their working time in the production shops vary from just a few minutes to some hours, with maximum – in a single case – of 4 hours, never on enamelling machines with NMP environment. These female workers may become pregnant.  The same study inside the winding wire industry shows that any known pregnant woman is immediately moved to non-production, non-NMP and non solvent environment. This is not new. All companies follow national regulations (Last Directive 92/85 EEC)  This information of risk is also given to newly hired women, and information on pregnancy is highly required.  Finally, the remaining people employed in this industry, 2000, consists to a large portion of women working in non exposed environment at all. The risk to the unborn child is not an issue today in the Winding Wire industry (Wire coaters), and no change is likely.  • With respect to our situation (no women at wire coating production lines) we ask to include non-pregnant workers inhalative DNEL as 8h TWA into part A of the restriction dossier as well. The sub population at potential risk (women who might be pregnant without knowing) does not exist at winding wire production lines. Woman who know that they are pregnant are not allowed to work in these areas anyway even at safe levels due to heavy work and reprotoxic NMP.  • It has to be mentioned that the wire industry and the suppliers of the formulated wire coatings have been trying for more than 20 years to reduce or substitute any aprotic solvents such in the formulation of the coatings based on their high cost, however, without success.  Chapter B, Page 23 of 301, § Wire Coaters and Annexes, Page 271 of 301, § Wire coating:  ---------------------------------------------------------------------------------------  • Enamelled wires are copper or aluminium wires with a very thin polymer layer, often of two different compositions to provide a continuous insulating layer. These wires are used in the transmission of electrical energy and the creation of magnetic fields in electrical or electronic devices in a wide variety of areas such as transformers, inductors, electromagnets, electrical motors, power and wind turbine generators. The continued demand for enhancement of reliability and other performance characteristics of those devices has required the development and use of highly mechanical, chemical and heat resistant high end polymers like polyamide-imides (PAI) and polyimides (PI).  • PAI is used as top layer on the most common class 200 °C magnet wires used in electrical motors, transformers or generators. This PAI top layer provides higher thermal performance, chemical and abrasion resistance to the enamel insulation.  • The top layer in self-bonding enamelled wires are also based on PAI polymers. The use of those wires allow manufacturers to eliminate the application of additional impregnation varnishes and therefore to reduce VOC.  • PI-enamelled wires are preferably used in high end applications such as in the aerospace and nuclear industry due to the fact that PI enamels show outstanding thermal (up to 240 °C) and radiation resistance.  • All these typical properties are well described in typical standards which are widely used in the electro-technical industry (not only by wire manufacturers but also by downstream users) as IEC 60317-0-1, IEC 60317-0-2 (general specifications) and IEC 60317-13, IEC 60317-29, IEC 60317-38, IEC 60317-46 or IEC 60317-47 (more specific to a given enamel insulation).  • For the coating process the use of NMP is essential as it enables the use of PAI and PI polymers in a diluted (liquid) state due to the very good dissolving properties of NMP for high end polymers. During the wire coating process the wire is passed through a PAI or PI solution after which the solvent is evaporated off and the enamel layer is cured by passing through an oven. Such specific coating operation carried on wires cannot be run always in totally closed systems as different regular operations to set the machine or to enable the cleaning and maintenance require having direct access to the applicators. The curing of the enamel coating is made in high temperature ovens, typically with temperatures of 200 up to 500 °C where enamels are dried and cured onto the copper or aluminium wire at high speed. Inside the ovens all vapours of solvents incl. NMP are burnt at very high temperature through catalysts at typically 700 to 750 °C, so that no NMP is exhausted in the air. This process is operated a large number of times (up to 20 coats) with ultra thin coating layers until the targeted coating thickness (Grade 1, 2 or 3) is achieved.  • A typical process for the coating of copper or aluminium wires is shown in the attachment (example for a 4-lines horizontal machine).  Chapter C, Page 132 of 301, § Wire Coaters and Chapter C, Page 147 of 301, § Wire Coaters:  ------------------------------------------------------------------------------------------  • Alternatives to NMP have been tested several times in the last years in the typical wire coating process together with wire enamel producers and enamelling machine manufacturers but without success. DMSO cannot evaporate from the wire without breaking down (explosions in the oven). In addition sulphur oxides occurring with DMSO could lead to great troubles. Other alternatives are going to the same or similar authorisation process (NEP, DMAC) or are even worse in toxicology (DMF – higher vapour pressure but lower OEL than NMP equals higher risk at use).  Chapter F, Page 198 of 301, § Wider socio-economic effects; also p. 215 and p. 233ff:  -------------------------------------------------------------------------------------  • Wire coating processes exist since many years and has been continuously optimized in such a way to improve product performance and productivity together with the reduction of the exposure for the workers and the environment (low vapour pressure but high OEL; good recycling properties as no azeotrope formation; low VOC etc.).  Enamelling machines, however, are a special type of machine with lifetimes typically in the order of 20 - 30 years. For such a long life-time, several reasons ecist: The replacement of a singe line requires substantial investment, but in addition, a typical production plant has hundreds (!!!) of such lines. Let us give an example: The overall investment volume for the European winding wire industry to renew the whole of its production to the state of the art is in the order of 4.000 lines x Euro 120.000 (typical value), summing up to 480 Mio. Euros! Typical machines costs could easily be validated with one of the European machines manufacturers. In many of the European plants, machines of 20 years and older are a substantial part of the production.  Due to the low margins that are today earned in the winding wire industry shorter investment cycles are not profitable.  A harsh restriction of NMP - meaning very low exposure levels such as 5 or 10 mg/m³ 8h TWA consequently means high investment in a large number of new machines to be compliant. This scenariowould result in a shutdown of magnet wire manufacturing in Europe It has to be emphasised that due to these long machine lifetimes, the suggested transition period of 5 years to not in the same range and therefore not helpful in easing the compliance costs. Since the lifetime is about 5 times longer than the suggested transition period, normal investment costs are only in the range of 15-25% (1/5) of the overall costs for such a machine replacement program, the rest (75 – 85%) being specific compliance costs that would otherwise not occur.  • From a perspective of a SEA number of job losses is estimated to be 8’000 considering 4’000 people involved in production, sales and distribution of magnet wire and an equivalent number of people working at subcontractors, machine producers, etc. This would also likelyaffect the downstream users (transformer, electrical motor or generator producers) which may decide to relocate their production outside Europe mainly for logistical reasons to be closer to the non-EU magnet wire producers where as on the other hand there is no heath benefit for society as higher OEL such as the EU OEL can be considered as safe for pregnant and non-pregnant workers.  • EWWG for its member companies acknowledges that the 40mg/Nqm scenario could be achieved if some time is provided for the fulfillment without unbearable compliance costs. In some EU countries, in which the enameling industry is present, 40mg are already in place as a limit, however, in some others, e. g. Germany, a higher value is in place. 40mg are technically feasible and justifiably, therefore, given a transition period of 5 years, the industry is prepared to fulfill this limit as binding all over EU and is prepared to cover the necessary investment and running costs to achieve an important binding limit to protect people in the best way in terms of practical risk assessment.  Summary of our conclusions:  ---------------------------  For various reasons, which have been explained in detail, we are not in agreement with the present proposal to define the TWA at 5mg/m³ and the STEL at 10 mg/m³ for inhalatory exposure. We do not find a justification of such low limits in the face of any risk assessment and have shown, that investment costs solely necessary to comply with such a limit would result in immensely high costs which would mean the closure of the winding wire industry in the EU, which would negatively affect other important EU industries as well.  NB:  This document has been prepared to help any of the authorities/committees involved in the decision-making process to get a first overview. However, we reserve the right to submit further comments and supporting attachments until the official deadline of the consultation period. |
| **Dossier submitter response**  Thank you for your comments on the DNEL derivation. Based on the comments provided we did not change the background document, because the issues mentioned have been addressed already in the restriction dossier and now is for RAC to take further.  Thank you for this additional information on alternatives.  The limitations of the alternative solvents have already been mentioned either in the paragraph on Wire coaters in Chapter C (DMSO breakdown) or in the section Selection of alternatives for further consideration in chapter C. In the latter is stated: “When considering the harmonised classification in Table C.1 and the recommendations in Tables C.2 and C.3, the replacement of NMP by NEP, DMF, DMAC, DCM and HMPA is not recommended as these substances are classified or are in the process of being classified as reprotoxic or carcinogenic.”  Overall, this comment supports the conclusion in Table C.01 that technical and economic feasibility of alternatives are not shown for all wire coaters. This information will not change the assessment in the restriction dossier. The restriction proposal allows continued use of NMP if occupational exposure is below the DNEL.  Comments related to part F:  Thank you for the comment on machinery costs and lifetime. This information has been incorporated in the BD.  In paragraph F.1.4. we tried to describe the population potentially at risk. As explained this paragraph is aimed only to give an impression of the potential scale of the health risks (and the number of workers potentially affected by a restriction). We agree that this information is surrounded with large uncertainties.    We are of the opinion that a restriction on the use of NMP is still required based on a calculated RCR>1. |
| **RAC Rapporteurs comments**  Thank you for the information on e.g. unavailability of alternatives, possibilities to reduce exposure, and working conditions. Regarding the DNEL derivation, see response to comment no. 296. |
| **SEAC Rapporteurs comments**  The impacts on the wire coating sector is addressed in the draft opinion. We do not agree low exposure limit of 10 mg/m³ 8h TWA scenario would result in a shutdown of magnet wire manufacturing in Europe. According to other information from EWWG wire coating lines established after 1990 should be able to meet the limit for continuous operation of wire coating machines. For non continuous operations a limit value of 20 mg/m3 can not be met, nor is it always possible to conclude the operations within 15 minutes. |
| **304** | **Date:** 2013/11/30 01:35  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** France  **Related to:** (C)  **Company name confidential:** No | **Comment:**  Arkema strongly disagrees with the assessment of DMSO as an alternative to NMP as presented in the Report Proposal for a Restriction of NMP.  The commercial use of DMSO as an alternative for NMP is known in many applications, and Arkema is at the disposal of the ECHA and its consultants to demonstrate that DMSO is a technical feasible alternative for the manufacture of membranes, high performance polymers, active ingredients for the pharmaceutical and agrochemical industry, and as a key ingredient in agrochemical formulations, as well as in the electronic and semiconductor industry.  DMSO is able to dissolve and transport other substances trough skin and is used in pharmaceutical industry as a skin penetration enhancer because of its low toxicity. However, facilitation of the skin penetration of toxic substances is a common property of nearly all organic solvents, without being systematically correlated to a high skin permeation rate. “No data” does not mean “safe to use”, and end users and formulators could have a false sense of security when using alternative solvents than DMSO.  The main obstacles to substitution of NMP by DMSO in existing plants are not technical feasibility, but the R&D and regulatory costs associated with product development and re-approval at customers and/or authorities.  The Report Proposal for Restriction of NMP underestimates the risk of exposure for workers during maintenance operations. Even in a tightly controlled manufacturing environment – for instance in the semi conductor industry – it is extremely difficult to avoid high level of exposure during cleaning and maintenance of the production lines. This is the main reason for the inclusion of NMP in the “banned substance list” by a growing number of industry leaders.  One can also question the fate of NMP waste streams if the Restriction is implemented as proposed. DSMO can be regenerated with a quality suitable for cleaning and paint stripping applications. |
| **Dossier submitter response**  Thanks a lot for this information on the technical feasibility of DMSO in several applications  The comments of Arkema have already been captured in the dossier.  In a number of paragraphs in chapter C, DMSO has been mentioned as alternative, e.g. in the paragraphs on agricultural chemical industry and the pharmaceutical industry  Furthermore, DMSO has been extensively discussed in the section Selection of alternatives for further consideration in chapter C. As indicated there, DMSO cannot be considered as a drop in substitute for all applications as it degrades at temperatures above 150 oC. Thus, we cannot agree with the statement that DMSO cannot replace NMP on the basis of cost considerations only.  Most text in the sections on DMSO has been copied from the SIDS on DMSO (OECD, 2008) as indicated.  The comment does not lead to any changes in the dossier text.  We believe that the restriction proposal further promotes alternatives for NMP. |
| **RAC Rapporteurs comments**  Thanks for the information about DMSO. |
| **SEAC Rapporteurs comments**  No further comments. Further information from Arkema is listed under comment 314. |
| **305** | **Date:** 2013/12/13 11:02  **Type:** MemberState  **Org. type:**  **Org. country:**  **Related to:** (A) (B) (C) (F)  **Company name confidential:** No | **Comment:**  The substance NMP has been included in the Candidate List following a COM/ECHA proposal in 2011. Afterwards it was selected by ECHA for prioritisation for inclusion in Annex XIV of the REACH Regulation, i.e. for authorisation. However, the Dutch CA did not agree that authorisation was the best RMO for NMP and therefore initiated the restriction procedure in order to stop the authorisation process.  In this restriction proposal, the DNEL concept of REACH is used to establish an occupational exposure limit for all European countries. In principle the German CA supports any measures that improve occupational safety by reduction of exposure to solvents. However, the approach taken might not be consistent with other EU legislation and earlier conclusions by other scientific committees (e.g. SCOEL, 2009). The question therefore arises whether it is appropriate to use REACH Annex XVII to implement an OEL when at the same time other legislation exists for this purpose (e.g. CAD /CMD). This would be a precedent and needs careful consideration.  Furthermore, the restriction proposal has been targeted to occupational exposure while consumer uses have not been addressed. However, consumer use of NMP in inks has been registered and consumer health risks from uses in paints and cleaners cannot be excluded so far. In case the proposed reclassification of NMP is not successful, other risk management options would have to be considered in order to limit health risks from consumer uses of NMP. This could either be a restriction for consumer uses or authorisation for the remaining uses of NMP not yet covered by a restriction.  **Specific comment:**  A. In this restriction proposal, the DNEL concept as used under REACh is used to establish an occupational exposure limit for all European countries.  This approach may be not consistent with the clear distinction between European legislation on occupational conditions when handling chemicals (e.g. CAD /CMD) and the legislation regarding duties when marketing such chemicals (i..e. REACh), as indicated in REACH recital 5.  B. - The German CA considers the approach taken (defining the most conservative DNEL for pregnant women as obligatory for all workers) as contradictory to the reasoning on page 89, based on Directive 1992/85/EEC. According to the interpretation on that page, pregnant women should be removed from any exposure to NMP (if necessary by granting leave). So, introducing a DNEL of 5 µg/m3 as acceptable for pregnant women is less strict than the action derived from Directive 1992/85/EEC.  This is in contradiction with REACH recital 5.  - Page 90: In the assessment of gloves' effectiveness it should be taken into account, that the maximum wearing time of gloves should be maximum 4 hours.  - Page 112: The tables B.84 and B.85 contain estimated RCRs. For manufacture 2 and 3 estimated values are reported which are significantly higher than 1. Still, the conclusion is that risks are sufficiently controlled when taking into account protection factors of the defined RMMs. It would be more convincing if the resulting RCR (after implementing RMMs) were also shown.  C. - The discussion of DMSO as a potential alternative (pages 144ff), fails to mention the fact that use of DMSO instead of NMP as a process solvent for the production of some chemicals or polymers, leaves traces of sulphur in the final products. In discussions with industry on the use of aprotic solvents, it was mentioned that in most cases this is undesirable and will be another factor preventing use of DMSO as an alternative.  - Page 140: For some application fields where alternatives are already available substitution could be made an integral part of the restriction.  F. Page 201ff: The details of RMO2 remain unclear regarding the special conditions allowing derogation. Moreover, it is unclear for what reason derogation is not foreseen in cases (e.g. medical image and optical industry) where alternatives are not available. |
| **Dossier submitter response**  Thank you for this comment. It would be interesting to receive the information on consumer uses of NMP as this is clearly not supported by the registrant. We agree that if reclassification of NMP is not succesfull, other risk management measures for consumer use should be considered.  On specific comment:  The restriction proposal where an exposure limit of 5 mg/m3 is proposed should be protective for pregnant workers whom are unaware of their pregnancy, specifically in the first month of pregnancy. Indeed pregnant workers are to be removed from any exposure to reproductive toxicants according to legislation (that does not specify a OEL), which is not by any means in contradiction with the current proposal.  Concerning the calculated RCRs: they were based on the comparison between the derived DNEL by the DS and the exposure assessment by the registrant. A qualitative assessment of the resulting RCR was provided because if the registrant would have derived the same DNEL, they would have applied different RMMs were applicable to obtain lower RCRs. With the qualitative assessment we tried to determine for which processes there can be a realistic risk.  Thank you for the additional information on DMSO.  There is very limited scientific literature on trace amounts of sulphur present in final products, and it is not mentioned in the technical bulletin on the reaction solvent DMSO issued by Gaylord Chemical Company, 2003: http://chemistry-chemists.com/N3\_2011/U/DMSO-technical\_bulletin.pdf  In the EMEA 2009 guidance on residual solvents in pharmaceutical preparations DMSO is captured in class 3: Solvents in Class 3 may be regarded as less toxic and of lower risk to human health. Thus, the terminology ‘ in most cases this will be undesirable’ in the comment seems too generic to incorporate in the dossier. Quite some limitations of DMSO have already been mentioned in the dossier.  This information will not change the assessment in the restriction dossier. It can be considered to include the information sulphur traces to the Background Document.  Comment related to part E/F: No specific derogation for medical image and optical industry has been incorporated in the Dossier as only very limited information suggesting that alternatives might not be available was available to the Dossier Submitter. In our view, only a statement that alternatives are not available is not sufficient to underpin a derogation. Also the information given in this comment is not enough reason for us to include a derogation. |
| **RAC Rapporteurs comments**  RAC has to assess the proposal independent of iOELs, and it is then up to the Commission how to implement potential measures. Thanks for the information on DMSO. |
| **SEAC Rapporteurs comments**  We agree with the response by the DS. During the PC no further information in relation to medical images or optical industry has been submitted. |
| **307** | **Date:** 2013/12/19 14:04  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** Belgium  **Related to:** (A) (B) (C) (E) (F)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  -  **Specific comment:**  Chapter A  Page 11 A1.2 scope and conditions of use  The semiconductor manufacturing industry sector that manufactures semiconductor devices (microchips) believes it can meet the proposed restriction. The semiconductor sector would like to comment that eventual required demonstration of compliance with the restriction should not add excessive burdens.  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 distruption of the supply chain.  Chapter B Information on Hazard and Risk  Page 18 B 2.2 Uses  Table B.03  Table B.03: categorisation of users of NMP in this restriction dossier  8. Electronic and semi-conductor industries  The semiconductor sector manufactures semiconductor devices (microchips). This sector is not the same as the much larger electronics sector or the electronic equipment manufacturing sector and it is not possible to use the terms interchangeably. So technical data and information provided by the SC industry is representative of that sector only. Actually, the semiconductor can be regarded as a sub branch of the electronics industry.  Chapter B Information on Hazard and Risk  Page 25  Electronics and Semiconductor Industries  1991 (Beaulieu and Schmerber) This study is not currently relevant information to use or include in the dossier.  The semiconductor industry has submitted a table with relevant process categories for semiconductor. They are 1, 2, 8b and 9. On page 25 “NMP is used as a process aid for wafer cleaning. It is important to note that ‘cleaning’ is very much different from the typical understanding of cleaning in other industrial sectors. Wafer cleaning is done inside enclosed manufacturing equipment which is itself an inside controlled environment known as a clean room”.The industry is particularly concerned that the wafer cleaning process as has been classified the same as other industrial types of cleaning. This will lead to an inaccurate and invalid risk characterisation ratio. The use of the generic PROC 7 in table B 94 page 117 and in section B 11 Table B.116 page 125 for the cleaning process in the semiconductor industry is not coherent with the semiconductor industry practice, therefore PROC 1 must be taken into account and the relevant RCR should be considered.  The description of routine operations process (wafer cleaning and removing processes and solvent processes) is for semiconductor manufacturing in line with PROC 1. The production takes place batch wise in a closed tool. The semiconductor industry would like regulators to be clearly aware that PROC7 (industrial spraying cleaning agents) describes a completely different process, which is absolutely not representative and even not acceptable in semiconductor manufacture. The presence of aerosols, particles and chemical vapours in the clean room atmosphere are not acceptable. The semiconductor industry does everything possible to keep the air and environment clean. PROC 7 situations will never exist. Therefore the risk characterisation ratio leading from this can never be applied to the semiconductor industry. Semiconductor industry has submitted a table with relevant process categories for semiconductor. They are 1, 2, 8b and 9.  Chapter C page 135-137  Electronics and Semiconductor industries  The semiconductor industry believes that the potential risk from NMP is fully controlled with the current measures in place in the semiconductor manufacturing industry.  In the area of wafer cleaning there is no blanket replacement currently available that delivers the same required performance that nMP based cleaning solutions deliver today.  For NMP use as a solvent in dedicated formulations currently, as in the case of semiconductor wafer cleaning, there are no nMP-free alternatives for all semiconductor uses that yield the same performance as NMP based solutions. For the majority of semiconductor uses, NMP-free or NMP-light products, which deliver equal or at least acceptable performance as NMP based solutions, still need to be invented and subsequently qualified. Qualification itself for the semiconductor industry is a technical and mullti step process. It involves a lot of research and development activity, a significant lead-time for stringent material qualification, and then subsequent integration and verification of technical performance into individual company technologies. Only after these technical steps have been successful can the actual act of final introduction be attempted in volume manufacturing.  Chapter E. Justification why the proposed restriction is the most appropriate Community-wide measure  Page 158  Semiconductor industry see risk management option 3 as appropriate regulatory tool where the risk is managed within the industry and some certainty is provided for the industry using the critical substance.  Chapter F. Socio-economic assessment of the proposed restriction  Only 4 industry sectors were chosen to do a detailed socio economic analysis. The sectors chosen non-wire coatings, wire coatings, cleaning products and membranes are not suitable as a proxy for a cost analysis of the impact of a restriction of NMP on the semiconductor industry. It is hard to use membrane sector as a proxy for semiconductor with any accuracy. 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. |
| **Answer 1:**  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 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. Here the presence of uncontrolled particles, as well as chemical vapors and gases constitutes an unacceptable risk from a safety and health as well as from a production quality viewpoint. This risk is typically eliminated and controlled through the application of enclosed manufacturing equipment. Alongside this, 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. In addition although exposures are controlled and negligible, companies follow applicable regulations and have policies in place to not allow preganant women to work in any location where potential exposure to chemicals and other risks may occur.  Examples of technical methods in place by typical activity type are listed below.  - 1(a) wafer cleaning and photoresist removing processes / routine operations  - 1 (b) solvent processes / routine operations  o Process tools are located in the clean room where a stringent clean regime is maintained as a requirement for production which also ensures no chemical releases  o Closed systems (see Figure X01.2: picture on page 272 of Annex XV Restriction Report  o Continuous local exhaust ventilation under alarm  o Dermal personal protective equipment (PPE) is worn.  o PROC 1  - 2. maintenance  o Tool emptied and purged prior to invasive maintenance  o Maintenance occurs at room temperature under local exhaust ventilation.  o Wearing of proper PPE as determined at the local site level.  o Dermal exposure is controlled  - 3. chemical storage, dispensing, and handling  o Segregated Storage per local codes  o Automatic, ventilated, and fully enclosed supply and discharge systems  o Dermal exposure is controlled. Personal protective equipment is worn during drum, canister and bottle change out (chemical protective gloves, safety glasses, chemical resistant arm protection, and shoes)   Bottles are only used for small uses with PPE  o General ventilation and local exhaust ventilation  o PROC 8b/9  The description of routine operations process (wafer cleaning and photoresist removing processes and solvent processes) are for semiconductor manufacturing in line with PROC 1. The production takes place batch wise in a closed tool. The semiconductor industry would like to clearly state that PROC7 (industrial spraying /cleaning agents) describes a different process, which is absolutely not representative of semiconductor manufacturing in terms of exposure. The presence of aerosols, particles and chemical vapors in the clean room atmosphere are not acceptable. PROC 7 type situations do not exist in semiconductor manufacturing. Therefore the risk characterisation ratio leading from this cannot be applied to the semiconductor industry use of NMP. The semiconductor industry has submitted a table with relevant process categories for semiconductor. They are PROC 1, 2, 8b and 9.  Please see the table included as a relevant non confidential attachment to this submission on question 1 -  Semiconductor manufacturing industry and the EU REACH Use descriptor system table:  On page 25 the report notes that “NMP is used as a process aid for wafer cleaning. It is important to note that ‘cleaning’ is very much different from the typical understanding of cleaning in other industrial sectors. Wafer cleaning is done inside enclosed manufacturing equipment which is itself an inside controlled environment known as a clean room”. Semiconductor wafer cleaning process are not similar to other industrial types of cleaning and therefore should not inaccurately be classified as the same as other industrial types of cleaning. Thus, the use of the generic PROC 7 in sections B 10.1 and table B 94 on page 117 and in sections B 11 and Table B.116 on page 125 as a proxy for cleaning in the semiconductor industry will lead to an inaccurate and invalid risk characterisation ratio (RCRs) for the semiconductor manufacturing across the process uses particularly for pregnant worker. |
| **Answer 2:**  Please see the confidential table B.73 on page 101 of the Annex XV dossier for the relevant typical current workplace exposure levels for the semiconductor manufacturing industry.  Table B.73: Semiconductor Activity Types, Descriptions and Reported Exposure Measurement ranges (personal communication)  With these risk management measures in place (answer 1) , the exposure levels are below the proposed thresholds (TWA and STEL). TWA applies in case of exposure scenario 1 (routine operation), STEL applies in case of exposure scenarios (chemical handling) and (maintenance). |
| **Answer 3:**  The semiconductor manufacturing industry sector that manufactures semiconductor devices (microchips) believes it can meet the proposed restriction. The semiconductor sector would like to comment that eventual demonstration of compliance with the restriction should be clearly defined and in line with national legal requirements. It should not add excessive or disproportionate burdens (i.e. should not mandate continuous monitoring programmes).  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.  The industry strongly believes that the restriction route is the most 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 |
| **Answer 4:**  The semiconductor manufacturing industry sector that manufactures semiconductor devices believes it can meet the proposed restriction including the timeline that is proposed in the restriction dossier. |
| **Dossier submitter response**  Thank you for the comments related to the use and exposure of NMP in the semi conductor industry. The information has been added to the relevant sections of part B of the Background Document. We have not added separate exposure calculations to the dossier for the semi conductor industry, as the exposure description does not contain all the information required. A note has been made to reflect the comment that wafer cleaning occurs under different conditions as described under industrial cleaning.  Thank you for the comments related to the socio-economic analysis. The signals given are already recognized in the Background Document. |
| **RAC Rapporteurs comments**  Based on the description, we are pleased to note that NMP already is used in a safe way in the semiconductor industry. The RAC proposes a modified RMO3 as the best way forward. |
| **SEAC Rapporteurs comments**  The comment indicates that even the limit value originally proposed can be met. The revised proposal is using a limit value twice the original proposed. |
| **314** | **Date:** 2014/02/20 13:04  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** France  **Related to:** (C)  **Company name confidential:** No  **Attachment confidential:** **Yes (available from confidential version of RCOM)**  **Privacy comment:** Protection of commercial interest | **Comment:**  Additional information submitted in response to an ECHA’s request. |
| **Dossier submitter response**  Thanks a lot for this additional information on the technical feasibility of DMSO in several applications. The information has been added to the relevant sections of part C.2. We would however like to mention that in our view it will not change the overall conclusion and proposed risk management measure. |
| **RAC Rapporteurs comments**  Thanks for the additional information. |
| **SEAC Rapporteurs comments**  Although the information demonstrates that DMSO are used for several of the scrutinized uses we agree with the DS that the overall conclusion is not changed. |
| **316** | **Date:** 2014/02/21 12:29  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (C)  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes (available from confidential version of RCOM)**  **Privacy comment:** The information provided herein contains our confidential business information including our sales volume by each application, customer, and region. | **Comment:**  The information provided herein is submitted in response to an ECHA’s request on 31 January, 2014.  We, **[…]**, is the only representative appointed by **[…]**. who is a major manufacturer of DMSO (EC. No. 200-664-3 Dimethyl sulfoxide). We hereby provide with the intrinsic property and the market information of DMSO as a promising alternative of NMP. Although our downstream users’ name are undisclosed at this phase, we could unveil it to ECHA on the confidential basis if necessary. |
| **Answer 1:**  not applicable |
| **Answer 2:**  not applicable |
| **Answer 3:**  not applicable |
| **Answer 4:**  not applicable |
| **Answer 5:**  not applicable |
| **Dossier submitter response**  Thanks a lot for this additional information on DMSO. The information has been added to the relevant sections of part C.2. We would however like to mention that in our view it will not change the overall conclusion and proposed risk management measure. |
| **RAC Rapporteurs comments**  Thanks for the additional information. |
| **SEAC Rapporteurs comments**  Although the information demonstrates that DMSO are used for several of the scrutinized uses we agree with the DS that the overall conclusion is not changed. |
| **320** | **Date:** 2014/02/26 21:10  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. country:** Austria  **Related to:** (A) (C) (F)  **Company name confidential:** No | **Comment:**  Seitens der WKÖ wurde bereits eine ausführlicher Beitrag übermittelt, allerdings möchten wir auch auf die neue Frage Nr. 5 Stellung nehmen. |
| **Answer 5:**  Die Festlegung eines unionsweiten Grenzwertes (MAK oder TRK-Wert), der dem bereits bewährten österreichischen bzw. deutschen MAK entspricht, erachten wir als sinnvollste Maßnahme. Hierbei greift man auf eine Regelung zurück, die sich nachweislich und flächendeckend innerhalb der Industrie bewährt hat. Darüber hinaus ist auch davon auszugehen, dass andere MS vergleichbare Regelungen bereits implementiert haben. In diesen Mitgliedstaaten wäre die weitere sichere Verwendung von NMP damit mit keinen Kosten verbunden und der vorsorglich erhöhte ArbeitnehmerInnenschutz wäre fair belohnt.  Wiederholt möchten wir hervorheben, dass die Festlegung eines Arbeitsplatzgrenzwertes durch die ArbeitnehmerInnenschutzgesetzgebung statt finden sollte. Dies erachten wir als das adäquatere Regelungsinstrument, welches mit entsprechenden Expertengremien und Erfahrungsschatz ausgestattet ist. Was wiederum zu Kostenersparnissen in der Verwaltung führt. Auch Doppelgleisigkeiten und Intransparenz können so hinten angehalten werden. |
| **Dossier submitter response**  Question 5 asks for suggestions for another restriction proposal. The discussion on measures outside REACH is in our view outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The comment is noted. |
| **SEAC Rapporteurs comments**  The comment is related to the legal framework and not to risk reduction options. |
| **321** | **Date:** 2014/02/27 14:41  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Czech Republic  **Related to:** (A)  **Company name confidential:** **Yes** | **Comment:**  Our company, as a downstream user of NMP, will use this extraction solvent (NMP) in the production of lubricating base oils to remove aromatic hydrocarbons. This use of NMP is acknowledged in the Industrial Emission Directive (IED), Reference Documents on Best Available Techniques for Mineral Oils as a "best available technology". Therefore we are planning to modernize the technological process of lubricant base oil manufacturing by replacing the extraction solvent ( NMP instead of cresol).  It would be useful more deeply specify the uses that could be affected by the restriction. Anyhow, it can not be possible that a substance seen as a best available technique is up for restriction for industrial uses.  There is no sense to restrict any industrial uses because in general the pregnant women can not work in the workplace where they could be in the contact with the reprotoxic substances and where the unborn babies should be effected by the prenatal developmental toxicity.  Based on the information listed above we propose to remove the industrial uses from the restriction according to Annex XVII (of Regulation EC No. 1907/2006 REACH) |
| **Answer 1:**  The NMP will be used within the closed system (selective rafination of lubricating oils)and standard PPE will be applied. |
| **Answer 2:**  The use of NMP is planned (a future installation). The workplace exposure limits under planned RMM are not available so far. |
| **Answer 3:**  The use of NMP is planned (a future installation). The workplace exposure limits under planned RMM are not available so far. |
| **Answer 4:**  The use of NMP is planned (a future installation). |
| **Answer 5:**  The use of NMP is planned (a future installation). |
| **Dossier submitter response**  Thank you for your response.  The extraction techniques using NMP as described in the comment should be covered by chemical industry processes and may fall under the petrochemical industry description where also hydrocarbons are extracted. The Dossier Submitter is aware of NMP being part of a BAT. However, this does not preclude a substance of being subject to REACH restrictions.  Pregnant women may be unaware of their pregnancy, while being exposed to a reproduction toxic substance at the workplace in their first trimester. Therefore, the Dossier Submitter is of the opinion that pregnant workers and their offspring are at risk from being exposed to NMP. |
| **RAC Rapporteurs comments**  If NMP is used in a closed system, it should not be a problem to achieve exposure levels below the DNEL. The RAC supports having limit values covering the most sensitive subpopulation, including pregnant women. |
| **SEAC Rapporteurs comments**  We agree with the DS response and note that BAT at present does not address worker protection issues. |
| **323** | **Date:** 2014/02/28 22:26  **Type:** BehalfOfAnOrganisation  **Org. type:** International organisation  **Org. country:** Belgium  **Related to:** (C)(E)(F)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  The use of NMP is nearly limited to PAI enamel, which is an overcoat of Class 200 Winding  Wire, as described in IEC 60317-13. Class 200 WW is growing in EU, as the best performing  wire. This standard is becoming predominant, also worldwide.  The use of NMP has been limited by the proportion of PAI itself (typically 20% of total  insulation), and by the increase of dry content.  The WW industry is subject to NMP exposure, due to the type of process, the number of sites  and machines. For that reason, measures are possible and measures were made to completely  commit the SCOEL value, 40 mg/m3, and fulfil Health and Safety requirements. This  commitment is definitely agreed within the WW industry.  If a stronger requirement than SCOEL value is decided, the WW industry points out the  necessary costs, described in the preparatory documents. These costs are explained by the  invest situation of the industry. This is a low profit industry, and existing SME could not  survive to massive and rapid investment costs. |
| **Dossier submitter response**  Thank you for this very extensive description of the use of NMP in the wire coating industry. The Dossier Submitter is aware of the importance of NMP to the sector and reflected that in the restriction dossier.  The information on costs and socio-economic consequences to the sector presented, varies slightly from the figures currently presented in the Background Document. For example, the Dossier Submitter notes that this comment suggests that current exposure levels in the EU wire coating industry is already at the level of 40 mg/m3. Some other signals received from the sector indicated that current exposure levels are significantly higher (up to 80 mg/m3). If exposure indeed is lower than previously stated, that might lower the cost figures currently presented in the Background Document somewhat (although that would require taking new assumptions). Although it will not change the overall picture, some of the information has been added to the Background Document. |
| **RAC Rapporteurs comments**  Agree with the DS response. |
| **SEAC Rapporteurs comments**  Agree with the DS response. |
| **325** | **Date:** 2014/03/04 19:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Other contributor  **Org. country:** Germany  **Related to:** (A)  **Company name confidential:** No | **Comment:**  In the following comments, the restriction proposal submitted by the Dutch Competent Authority (RIVM) is solely discussed under formal and procedural aspects. Reasons are given why the proposal as it currently stands should be abandoned. Furthermore, it is suggested that either a restriction could be pursued entailing a different risk management option than currently chosen, or the authorisation pathway could be selected or, if a BOEL is to remain the risk management option of choice, this regulatory instrument should be included in the Chemical Agents Directive.  **Specific comment:**  Introduction  Core element of the restriction proposal is the introduction of a so-called “harmonised DNEL” for the workplace. Factually, this regulatory instrument is identical to a binding occupational exposure level (BOEL).  BOELs are already existing regulatory instruments within the framework of both the Chemical Agents Directive (CAD – Dir. 98/24/EC; cf. Art. 3, para. 4, and Annex I) and the Carcinogens and Mutagens Directive (CMD – Dir. 2004/37/EC; cf. Art. 16, and Annex III, section A).  Comments  (i) Against the background of the existence of the legal instrument “BOEL” in a regulatory framework different to REACH, there seems to be no necessity to incorporate the same instrument into another regulatory framework, i.e. Annex XVII of REACH, unless convincing legal arguments are presented. However, such arguments are completely absent from the restriction report.  (ii) The inclusion of the identical regulatory instrument “BOEL” in two structurally different legal frameworks, OSH directives and REACH regulation, respectively, would make the application of the instrument more complex as for each BOEL its respective legal environment would have to be taken into account.  (iii) Since the regulatory instrument “BOEL” is embedded in the OSH legal framework, it is not obvious how its additional inclusion in the REACH regulation could be accommodated with Art. 2 para 4 (a) of REACH, which refers explicitly to both the CAD and the CMD.  (iv) Irrespective of the legal framework chosen, the legal instrument “BOEL” falls within the scope of the Social Policy as addressed in Title X of the Treaty of the European Union (TEU). Thus, Art. 152 TEU applies and, therefore, the opinion of the Advisory Committee on Safety and Health (ACSH) has to be sought in the derivation process of any BOEL. Avoiding the opinion of the social partners constitutes an infringement on their participation rights and is, therefore, an affront to the social acquis of the Union. At the same time, the omission of an opinion of the ACSH contravenes Art. 110 para. 4 of REACH.  Principally, a stakeholder consultation as pursued in the development of the restriction report can, at best, inform but cannot replace an ACSH opinion. The derivation process of such an opinion offers workers’ representatives within the ACSH the possibility of scrutinising the arguments forwarded by industry, and of responding to them if deemed necessary. The same holds for Member States’ representatives within the ACSH.  Additionally, this specific stakeholder consultation was completely unbalanced, as out of the 26 stakeholders addressed, only a single one (ETUI) was representing workers’ interests. Furthermore, neither have the objections raised by ETUI against the specific RMO chosen been made public in the restriction report nor have any reasons been given for not taking them into account.  (v) The argument put forward by the Dossier submitter in section B.9.1.1. (p. 88) “whether the substitution of NMP of the basis of the workers’ protection Directive is to be considered ‘reasonable’ “ lacks any legal logic. According to the deliberation of the Dossier submitter, the substitution obligation of the CAD might only be enforceable for substances listed in Annex XIV or XVII of REACH. Both in view of the history of the CAD which came into force at a time when REACH was not even conceived, and of Art. 2 para. 4 (a) of REACH according to which the REACH regulation applies without prejudice to Directive 98/24/EC, this suggestion by the Dossier submitter is deemed absurd.  (vi) In the restriction report, the Dossier submitter does not address the regulatory instrument of a binding OEL within the framework of the CAD (cf. Art. 3, para. 4 of the CAD) comprehensively but in a rather misleading way.  Furthermore, the Dossier submitter confuses the roles of the different actors. Whereas it is the role of SCOEL to derive recommendations for health-based OELS or, under certain circumstances, to suggest the establishment of a binding OEL yet without proposing any numerical value for it unless based exclusively on health grounds, it is the prerogative of DG Employment (DG EMPL) as the Commission Service in charge to start the regulatory proceedings for establishing either an indicative OEL (IOEL) based on Art. 3, para 2 of the CAD or a binding OEL (BOEL) based on Art. 3, para. 4 of the CAD.  Thus, the allegation of the Dossier submitter in section A.3.3. (p. 14) that the “harmonised implementation on an indicative OEL by all Member States is … not guaranteed” is misleading. Should the Commission be of the opinion that a harmonised OEL is warranted, it could start the proceedings based on Art. 3 para 4. of the CAD.  The argument put forward by the Dossier submitter in section E.1.3.2 (p. 152) that “for only a few chemical agents … a binding OEL has been established at EU level” is insufficient for considering this regulatory option as “not realistic”. Were the Dossier submitter interested in this option, he should at least have contacted DG EMPL to receive reliable information and have presented it in this report, instead of including unfounded prejudice.  Given the information compiled in sections E and F of the Restriction Report, major preparatory work for the establishment of a binding OEL for NMP based on art. 3, para. 4 of the CAD has already been achieved. Thus, the implementation of such a value within the same timeframe of 60 months as suggested in the Restriction Report (cf. section E.2.3.2.1) should be feasible.  (vii) Regarding the derivation of a value for the BOEL, it is unacceptable that the Dossier submitter did not make any attempt to approach SCOEL as the Scientific Committee of the EU in charge of deriving OELs and to ask SCOEL to review its previous Recommendation on NMP (SCOEL/SUM/119) but, instead, derived such a value unilaterally.  By refraining from inviting SCOEL to comment on the OEL for NMP derived by itself, the Dossier submitter decided to ignore and to override the scientific competence of a Scientific Committee of the Union.  (viii) Additionally, for the derivation of the specific value of the BOEL, the Dossier submitter chose to deviate from both the methodology and the standard procedures applied by SCOEL when deriving proposals for health-based OELs.  With regard to the methodology, it is unacceptable that the Dossier submitter chose its own methodology different to that applied by SCOEL, without consulting with SCOEL and without giving SCOEL the opportunity to defend its own methodology.  With regard to the standard procedures, it is unacceptable that the Dossier submitter ignored the established consultation procedure pursued in the development of a SCOEL Recommendation on any health-based OEL, that is inviting scientific comments by sending the draft recommendation to the contact points in all Member States.  Conclusion  In view of the numerous procedural deficits and infringements on EU legal principles and EU legislation, the restriction proposal entailing the risk management option of a so-called “harmonised DNEL” should be abandoned immediately on formal grounds.  Since the risks from NMP for workers are deemed not to be adequately controlled as suggested by the Dossier submitter, a different approach should be proposed. One option could be a restriction proposal with a different RMO within the framework of REACH; a second one could be the authorisation of certain uses of NMP via Title VII of REACH; and a third option could be the derivation of a binding OEL within the framework of the CAD (by way of art. 3, para. 4). |
| **Dossier submitter response**  Thank you for your comment. We are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The comment is noted, but the arguments are not within the scope of RAC. |
| **SEAC Rapporteurs comments**  The comment is of more political nature and outside the scope of SEAC. |
| **327** | **Date:** 2014/03/05 15:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Trade union  **Org. country:** Belgium  **Related to:**  **Company name confidential:** No | **Comment:**  EU legislation under the Chemical Agents Directive (98/24/EC) and the Carcinogen and Mutagens Directive (2004/37/EC) defines limit values for occupational exposure to chemicals. Such limit values are set via a well-established process involving the Scientific Committee on Occupational Exposure Limits (SCOEL)and governmental, employers' and workers' representatives. In order to respect the consistency and coherence of EU legislation and taking note of REACH article 2.4 (a) which stipulates that REACH is without prejudice to EU workplace legislation, the European Trade Union Confederation (ETUC) is of the opinion that it is unacceptable for limit values that are relevant to occupational exposure to be established in the context of other EU legislation.  The EU's Occupational Safety and Health legislation foresees the involvement of expert scientific evaluation, following a defined methodology and including external consultation via national contact points and the social partners in line with article 152 of the Treaty on the Functioning of the EU.  The resultant SCOEL Recommendations are discussed in the tri-partite Advisory Committee on Safety & Health at Work which adopts Opinions on proposals for OELs. This procedure is scientifically based and follows an open and inclusive consultation and discussion with all relevant stakeholders. Thereafter, the Commission initiates the relevant legislative procedure.  Formal procedures under other legislative systems such as REACH should not seek to set official EU limit values for worker protection purposes which could present incoherence with limit values developed under OSH. However, it would be appropriate for such legislative systems to make reference to EU OSH existing limit values, and procedures for developing limit values for additional substances, for their policy development and implementation purposes. |
| **Dossier submitter response**  Thank you for your comment. We are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The RAC has analysed the different RMOs discussed in the proposal, and recommended a modified RMO3. With respect to the comment, it is up to the Commission to decide on the regulatory way forward. |
| **SEAC Rapporteurs comments**  Thank you for your comment which is of more political nature and outside the scope of SEAC. |
| **328** | **Date:** 2014/03/07 19:23  **Type:** Individual  **Org. type:**  **Org. country:**  **Related to:** (A)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  We are not in agreement with the present proposal to define the TWA at 5mg/m3 and the STEL at 10mg/m3 for inhalatory exposure. We are, however, in full agreement for the preventive measures against dermal exposition, which is already practice in our industry. |
| **Dossier submitter response**  Thank you for your comment. In relation to your remark on SCOEL: we are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. The information provided relevant to part B will not lead to changes in the Background Document. Please note, that health effects in animal developmental toxicity studies have been observed when exposed to vapours of NMP, and not aerosols, based upon which the DNEL has been set.  The information presented on socio-economic elements, is largely in line with the information already presented in part F of the Background Document. However, some additional information is presented when it comes to conditions of the current machinery stock in Europe and on typical investment cycles in the European wire coating sector. Thank you for this additional information. This information has been used to further refine the compliance costs estimates and to further underpin the estimation of reasonable investment time for the wire coaters in the Background Document. |
| **RAC Rapporteurs comments**  The RAC has proposed an inhalatory DNEL of 10 mg/m3. |
| **SEAC Rapporteurs comments**  We agree with the DS response. |
| **330** | **Date:** 2014/03/12 12:45  **Type:** Individual  **Org. type:**  **Org. country:**  **Related to:**  **Company name confidential:** No  **Attachment confidential:** No | **Comment**  **-** |
| **Dossier submitter response**  Thank you for your comment. In relation to your remark on SCOEL: we are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. The information provided relevant to part B will not lead to changes in the Background Document. Please note, that health effects in animal developmental toxicity studies have been observed when exposed to vapours of NMP, and not aerosols, based upon which the DNEL has been set.  The information presented on socio-economic elements, is largely in line with the information already presented in part F of the Background Document. However, some additional information is presented when it comes to conditions of the current machinery stock in Europe and on typical investment cycles in the European wire coating sector. Thank you for this additional information. This information has been used to further refine the compliance costs estimates and to further underpin the estimation of reasonable investment time for the wire coaters in the Background Document. |
| **RAC Rapporteurs comments**  The RAC has analysed the different RMOs discussed in the proposal, and recommended a modified RMO3 and an inhalatory DNEL of 10 mg/m3. With respect to the SCOEL, it is up to the Commission to decide on the regulatory way forward. |
| **SEAC Rapporteurs comments**  We agree with the DS response. |
| **332** | **Date:** 2014/03/12 15:43  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (A) (B) (C) (E) (F) (H)  **Company name confidential:** **Yes**  **Privacy comment:** Information is classified as confidential information. Reason is the protection of our commercial interests, including intellectual property. | **Comment:**  As a medical device manufacturer we support the restriction proposal. Further information is classified as confidential information and submitted separately. Reason is the protection of our commercial interests, including intellectual property.  **Specific comment:**  answers to specific questions |
| **Dossier submitter response**  Thank your for your support.  Confidential information provided by the company is presented in comment 337. |
| **RAC Rapporteurs comments**  The support for the restriction proposal is noted. |
| **SEAC Rapporteurs comments**  No comments. |
| **333** | **Date:** 2014/03/12 17:41  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** France  **Related to:** (A) (C)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  - |
| **Answer 1:**  Respiratory protection:  Ventilation and exhaust are our best solution to reduce our workplace exposure to NMP. Indeed, in clean rooms (semi-conductors development) and in labs or in anhydrous room (batteries development) we have local exhaust ventilation. Those local exhausts ventilations are either fume cupboard in labs, or they are integrated into equipment to capture NMP vapors at the source. In some cases, when local exhaust is temporary not possible for technical reasons (some maintenance operations), important ventilation is the key factor to reducing any possible exposure.  Skin protection:  Depending on the activities, we use gloves adapted to the risk: nitrile gloves for small projection risk and neoprene gloves if contact with NMP is likely to happen. |
| **Answer 2:**  Our workplace exposure levels are often below the limit of detection (<25 µg/solid sorbent tube containing activated charcoal) or between few µg.m-3 and 3 mg/m3. These measured levels depend on the amounts used (up to 12 liters of NMP by process) and conditions of use. |
| **Answer 3:**  We are not using as much NMP as many industrials in our research company. Achieving compliance with the proposed restriction seems to be possible without significant change in our installations and workplace procedures.  Specific case in France to monitor inhalation exposure:  In France, to ensure that 8-hour TWA exposure (called VLEP-8h) or 15 min peak exposure (called VLCT) are respected, we have to comply with a French order of 15th December 2009. This order specifies the methods to ensure compliance with the relevant exposure limit values. Following this regulation, exposure levels measured (at least 3 measures) must be below 10% of the exposure limit value (8h TWA or 15 min peak exposure). If one result is above 10%, six others measurements have to be carried on to ensure that the exposure limit value is respected (statistical theory).  Therefore, the main problem is to ensure compliance with the occupational exposure limit proposed in the restriction according to national method of measurement. It may be different in other countries, so it is difficult to say if additional measures are needed if we do not know the value we have to respect: 10% of the limit? 100% of the limit? |
| **Answer 4:**  As a R&D Institute, we have little equipment using the NMP. However, we permanently manage to upgrade them to reduce NMP exposure levels. |
| **Answer 5:**  As mentioned in the third question, the 8-hour TWA and the 15 min peak exposure limits proposed in the restriction will be difficult to respect, if it means respecting 10% of those limits (French order published in 2009). |
| **Dossier submitter response**  Thank you for your comment. The research and development branch is not seperately covered in the Background Document, but may fall under the mentioned industrial sectors of battery production and semi conductor production one the one hand and the laboratory use on the other. Since exposure levels are already below the proposed inhalation DNEL it would seem that the restriction proposal will not affect business as usual. Note that according to REACH article 67.1 scientific research and development is not in the scope of Title VIII (restrictions).  With respect to the enforcement situation in France where exposure levels must remain below 10% of the OEL to avoid additional measurements, we have no insight on how France will deal with the restriction proposal and whether or not France will impose additional requirements. |
| **RAC Rapporteurs comments**  Thanks for the exposure information. |
| **SEAC Rapporteurs comments**  We consider it reasonable to believe that the procedures under the worker protection legislation, in relation to higher frequency of monitoring if 10% of the limit value is measured, would be adapted also for similar restrictions under REACH. This is included in the draft opinion. |
| **336** | **Date:** 2014/03/14 12:55  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** Germany  **Related to:** (B)  **Company name confidential:** No | **Comment:**  BVMed is a German trade association representing 230 companies manufacturing a wide range of medical devices amongst which many devices based on different plastic materials and with live-saving or live-sustaining functions. Our answers regarding the specific questions below are given according to the best of our knowledge.  We notice that the dossier submitter sees need for further regulation of NMP and evaluates the option to set a binding OEL for NMP via SCOEL as not realistic. Taking into account these conditions the proposed approach for a partial restriction is appreciated in general.  Compared to an authorisation requirement under REACH (risk management option 4) this option will cause less administrative and formal burden for users. Anyhow the level of the proposed exposure limits is decisive for the overall assessment and the impacts on the European industry.  Exposure limits based on disproportionately strict DNELs might lead to a ban of safe and socio-economically beneficial uses. In contrast to an authorisation process, socio-economic aspects will not be taken into account in future enforcement of a restriction. So special care must be taken on the proportionately, feasibility and the socio-economic impact of any provision of a restriction.  In accordance with this the currently proposed exposure limits should be scrutinized.  **Specific comment:**  The derivation of the DNELs, included in the restriction proposal, is based on a conservative application of default assessment factors following ECHA Guidance R.8, a non-binding guidance on REACH (see legal notice in R.8). R.8 deviates significantly from the current derivation of OELs and its appropriateness and justification is also questioned by experts (see ECETOC, Technical Report 110: Guidance on Assessment Factors to Derive a DNEL, October 2010). An inappropriately low exposure limit is a serious burden for professional and industrial users and might jeopardize existing manufacturing in the European Union. So the derivation of the proposed binding DNELs should be scrutinized in detail. |
| **Answer 1:**  Adequate risk management measures are selected and implemented by our members following the applicable occupational health and safety legislation and under consideration of the individual circumstances and workplaces. |
| **Answer 2:**  Below the binding national OELs. |
| **Answer 3:**  -/- |
| **Answer 4:**  -/- |
| **Answer 5:**  Costs for implementation of additional measures are mostly linked to the future level of the inhalation DNEL and the binding exposure limits respectively. A less conservative application of assessment factors and thus a higher binding exposure limit could significantly reduce the costs. So the derivation of the proposed DNELs should be scrutinized (see above) to ensure a proportional and feasible regulation of NMP. |
| **Dossier submitter response**  Thank you for this comment. Up to now this specific use of NMP for the production of medical devices has not been mentioned explicitly in the restriction dossier. This specific use has been added to the Background Document (see also comment 337). |
| **RAC Rapporteurs comments**  The RAC has applied the Reach guidance and proposed an inhalatory DNEL of 10 mg/m3 and a dermal DNEL of 4.8 mg/kg/day. |
| **SEAC Rapporteurs comments**  We agree to your considerations in relation to scrutiny of socio-economic aspects with regard to proportionately, feasibility and the socio-economic impact of any provision of a restriction. If too many uncertainties, the authorisation route might be appropriate. |
| **337** | **Date:** 2014/03/14 16:16 (follow up to comment 332)  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (A) (B) (C) (E) (F)  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes (available from confidential version of RCOM)**  **Privacy comment:** protection of your commercial interests, including intellectual property | **Comment:**  see attachment |
| **Dossier submitter response**  Thank you for this comment. Up to now this specific use of NMP for the production of medical devices has not been mentioned explicitly in the restriction dossier. This specific use has been added to the Background Document. The Dossier Submitter, however, also recognizes that some of the statements made in this comment are not fully clear and are multi-interpretable. |
| **RAC Rapporteurs comments**  The comment and the updating of the background document are noted. |
| **SEAC Rapporteurs comments**  We note that you find an exposure level of 10 mg/m3 fully acceptable. |
| **338** | **Date:** 2014/03/14 16:42  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (C)  **Company name confidential:** **Yes**  **Attachment confidential:** No | **Comment:**  PPE / Excerpt from SDS  Engineering measures  Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.  Individual protection measures  Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.  Eye/Face protection: safety glasses  Hand protection  Full contact: Glove material butyl rubber, thickness 0.7 mm, breakthrough time > 480 min  Splash contact: Glove material latex, thickness 0.6 mm, breakthrough time > 60 min  The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN 374  Other protective equipment: protective clothing  Respiratory protection: required when vapours are generated, recommended filter type A-(P2), the entrepreneur has to ensure that maintenance; cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.  **Specific comment:**  During the assessment of DMSO strong emphasis is made of toxicologically and environmentally properties of DMSO demonstrating that DMSO is of low concern for the environment and the human health. Unfortunately, just a few general remarks were made on physical/chemical properties which might significantly influence worker’s safety.  It is well known in the literature (please refer to the attachments) that DMSO has some explosive potential in contact with special chemicals or at elevated temperatures. The temperature of decomposition processes may be reduced in the presence of substances with catalytic activity. Another issue regarding process safety is the high boiling point of DMSO which impedes the dissipation of heat. Based on this information a substitution of NMP by DMSO should be checked very carefully. Depending on the reactant the following severe effects are described:  • strong exothermic decomposition reactions  • danger of explosions  • danger of flammability respectively development of flammable gases or vapours  Additionally, the pure substance DMSO has no odour but it decomposes quite easily and due to the incorporated sulphur the decomposition products provide a quite distinct odour. Volatile and non-volatile decomposition products might influence the impurity profile/product quality of the newly synthesised product and might not be acceptable by every customer or downstream user (e.g. impact on smell or physic-chemical properties of the product, e.g. catalyst poison). |
| **Dossier submitter response**  Thanks a lot for this additional information on DMSO. The information has been added to the relevant sections of part C.2. |
| **RAC Rapporteurs comments**  Thanks for the information on DMSO. |
| **SEAC Rapporteurs comments**  No further comments. Other Alternatives might be available for some uses. The evaluation of alternatives is based on information regarding uses already going on. Therefore we do expect that your information will lead to identification of more uses than already covered where NMP cannot be substituted. |
| **340** | **Date:** 2014/03/17 11:45  **Type:** MemberState  **Org. type:**  **Org. country:**  **Related to:**  **Company name confidential:** No | **Comment:**  We have added the following sentence at the end of the first paragraph of the general comments:  Nevertheless, the German CA could support this proposal as it might be a more efficient way to improve occupational safety and health.  The substance NMP has been included in the Candidate List following a COM/ECHA proposal in 2011. Afterwards it was selected by ECHA for prioritisation for inclusion in Annex XIV of the REACH Regulation, i.e. for authorisation. However, the Dutch CA did not agree that authorisation was the best RMO for NMP and therefore initiated the restriction procedure in order to stop the authorisation process.  In this restriction proposal, the DNEL concept of REACH is used to establish an occupational exposure limit for all European countries. In principle the German CA supports any measures that improve occupational safety by reduction of exposure to solvents. However, the approach taken might not be consistent with other EU legislation and earlier conclusions by other scientific committees (e.g. SCOEL, 2009). The question therefore arises whether it is appropriate to use REACH Annex XVII to implement an OEL when at the same time other legislation exists for this purpose (e.g. CAD /CMD). This would be a precedent and needs careful consideration. Nevertheless, the German CA could support this proposal as it might be a more efficient way to improve occupational safety and health.  Furthermore, the restriction proposal has been targeted to occupational exposure while consumer uses have not been addressed. However, consumer use of NMP in inks has been registered and consumer health risks from uses in paints and cleaners cannot be excluded so far. In case the proposed reclassification of NMP is not successful, other risk management options would have to be considered in order to limit health risks from consumer uses of NMP. This could either be a restriction for consumer uses or authorisation for the remaining uses of NMP not yet covered by a restriction. |
| **Dossier submitter response**  Thank your for your comment. we are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The RAC has analysed the different RMOs discussed in the proposal, and recommended a modified RMO3. With respect to the comment, it is up to the Commission to decide on the regulatory way forward. |
| **SEAC Rapporteurs comments**  No comments. |
| **341** | **Date:** 2014/03/17 12:12  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** France  **Related to:** (A)  **Company name confidential:** No | **Comment:**  NMP is a critical solvent for the manufacturing of positive electrodes for li-ion batteries. |
| **Answer 5:**  Protection of workers is already sufficiently covered by the existing TWA of 10 ppm (40 mg/m3) and a short time (15 minutes) exposure limit (STEL) of 20 ppm (80 mg/m3) as indicative OEL (IOEL). Therefore based on scientific rationales, we do not see the need to further reduce the existing limit values.  We would like to point out that the exposure limit (OEL of 5 mg/m3) proposed by the Dutch competent authority is to our mind overly conservative and not adequately addressing the real risk resulting from exposure to NMP. The most sensitive population regarding NMP toxicity are women with child bearing potential. The Dutch competent authority defined their new exposure limit valid for all individuals in industrial and/or professional settings, not taking into account that the risk cannot be applied to all male workers and women without child bearing potential.  To address the real risk in the battery production plant, Exposure-Measurements of all workplaces where exposure to NMP cannot be excluded have been conducted. Based on this the workplace with the highest measured NMP concentration is exclusively appointed to male workers. Therefore, the proposed low exposure limit of 5 mg/m³ would not lead to additional safety of workers. |
| **Dossier submitter response**  Thank you for your comment. Issues related to the DNEL derivation have been addressed already in the restriction dossier and now is for RAC to take further. Exposure measurements and specific information on the presence or absence of female workers at workplaces where NMP exposure can occur, have not been provided in the comments and therefore we cannot respond to that. |
| **RAC Rapporteurs comments**  The limit value should apply to all workers, irrespective of sex. |
| **SEAC Rapporteurs comments**  No comments. |
| **343** | **Date:** 2014/03/17 18:27  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Switzerland  **Related to:** (C)  **Company name confidential:** **Yes** | **Comment:**  The binders produced by the commenting party (downstream user supplying further downstream users in the EU) are used for special applications (e.g. food contact) and are characterized by a high temperature and chemical resistance. Such binders require highly polar aprotic solvents with specific Hansen solubility in order to be used as resin solution.  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) are known since a long time, the commenting party has searched for alternatives since more than five years (please see comments to section C).  In consequence, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in the last five years.  The production and application of coatings cannot always be done in closed systems. Thus, proper ventilation of workplaces is in these cases mandatory. The design of sophisticated ventilation systems ensuring concentration limits being at least 4-fold reduced than the existing one requires considerable financial investment for exposure reduction (millions of Euros). If technically not feasible, additional costs incurred are related to relocation and termination costs.  As a consequence, the production of the final article will be likely moved outside Europe to avoid such investments as the import of the article is not affected by this planned restriction (the final article is free of NMP).  **Specific comment:**  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) are known since a long time, the commenting party has searched for alternatives since more than five years.  Theoretically, potential solvents are NMP, N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), N,N-Dimethylformamid, DMF (CAS 68-12-2), and Dimethylsulfoxid, DMSO (CAS 67-68-5), Gamma Butyrolacton, GBL (CAS 96-48-0) and more. Practically, due to the known existing toxicological classification of NEP, DMAC, DMF and GBL these solvents are are no appropriate alternatives.  Also, another essential product criterion is the storage ability over a particular time and under certain conditions, which cannot be guaranteed with the above mentioned non-NMP solvents. The binders do not remain permanently resolved in these solvents.  One solvent whose hazardous properties are not as bad as NEP, DMAC, DMF and GBL is DMSO. But DMSO is due to technological requirements no appropriate alternative for the commenting party due to the dissolving problems. This leads in consequence to the fact that the application of the products (produced with DMSO) is from a state-of-the-art point of view not possible as DMSO is causing major technical/processing problems and even quality problems in the final product.  Using DMSO as a substitute solvent leads already after very short use to an unpleasant, strong smell during processing and storage (disproportionation to dimethyl sulfide). This odour nuisance is unacceptable over a longer period like during the required production time.  In consequence, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in the last five years. |
| **Dossier submitter response**  Although not specifically mentioned in the dossier, this use is in our view covered by the non-wire coatings. In the dossier it was concluded that alternatives are already available for non-wire coatings and no significant costs were expected for the proposed restriction measure. The information in this comment does not support this conclusion. Information on this specific use has been included in the Background Document.  In regard to DMSO, it is recognized in the restriction dossier that DMSO is not an alternative in all applications.  *Note: see also comments 345,347,348,349,355 and 365* |
| **RAC Rapporteurs comments**  It is noted that there seems to be conflicting experiences on the availability of alternatives for the non-wire coatings. |
| **SEAC Rapporteurs comments**  No further comments. |
| **344** | **Date:** 2014/03/17 18:37  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (C)  **Company name confidential:** **Yes** | **Comment:**  The planned NMP restrictions could lead to life-threatening of smaller, specialized paint shops with niche uses. Due to the known classification of NMP the commenting party carried out experiments on potential substitutes already years ago.  A planned restriction would lead to the fact that certain product groups can no longer be economically reasonable produced in the EU. As a result, this will lead to a further exodus of the affected industry from the EU to developing countries with lower safety and environmental standards as the import of NMP free articles into the EU will not be affected by the planned restriction.  **Specific comment:**  Due to the known classification of NMP the commenting party carried out experiments on potential substitutes already years ago.  N,N-Dimethylformamid, DMF (CAS 68-12-2), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), and N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4) have similar hazardous properties and are therefore not suitable as an alternative. Dimethylsulfoxid, DMSO (67-68-5), Gamma Butyrolacton GBL (96-48-0) or sulfolane (CAS 126-33-0) are - due to the inadequate dissolving capacity and due to the inadequate stability of the product – not a technically viable solution. The other alternatives mentioned in "ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION" are not solvents which are suitable for the use of highly resistant polymers in contact with food. Other possible substitutes with similar chemical structure and therefore similar properties also show a high probability for a similar hazard.  A planned restriction would lead to the fact that certain product groups can no longer be economically reasonable produced in the EU. As a result, this will lead to a further exodus of the affected industry from the EU to developing countries with lower safety and environmental standards as the import of NMP free articles into the EU will not be affected by the planned restriction. |
| **Answer 1:** |
| **Answer 2:** |
| **Answer 3:** |
| **Answer 4:** |
| **Answer 5:** |
| **Dossier submitter response**  Unfortunately, it is not very clear what specific use of NMP is referred to in this comment. The term ‘small paint shops’ suggests that it refers to a consumer or professional use, however, that is not made explicit. For that reason, the Dossier Submitter sees no possibility to add any potential new information to the Background Document based on this comment. As mentioned in chapter C, replacement of NMP is possible via reformulation of coatings in the automotive industry. |
| **RAC Rapporteurs comments**  Agree with the dossier submitter. |
| **SEAC Rapporteurs comments**  Agree with the Dossier submitter. |
| **345** | **Date:** 2014/03/17 19:09  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** United Kingdom  **Related to:** (C)  **Company name confidential:** **Yes** | **Comment:**  -  **Specific comment:**  The binders produced by the commenting party (downstream user) are used for special applications (e.g. food contact) and are characterized by a high temperature and chemical resistance. Such binders require highly polar aprotic solvents with specific Hansen solubility in order to be used as resin solution.  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) are known since a long time, the commenting party has searched for alternatives since more than five years.  Theoretically, potential solvents are NMP, N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), N,N-Dimethylformamid, DMF (CAS 68-12-2), and Dimethylsulfoxid, DMSO (CAS 67-68-5), Gamma Butyrolacton, GBL (CAS 96-48-0) and more. Practically, due to the known existing toxicological classification of NEP, DMAC, DMF and GBL these solvents are not appropriate alternatives.  Also, another essential product criterion, is the storage ability over a particular time and under certain conditions, which cannot be guaranteed with the above mentioned non-NMP solvents. The binders do not remain permanently dissolved in these solvents.  One solvent whose hazardous properties are not as bad as NEP, DMAC, DMF and GBL is DMSO. But DMSO is due to technological requirements not appropriate alternative for the commenting party due to the dissolving problems. This leads in consequence to the fact that the application of the products (produced with DMSO) is from a state-of-the-art point of view not possible as DMSO is causing major technical/processing problems and even quality problems in the final product.  Using DMSO as a substitute solvent leads already after very short use to an unpleasant, strong smell during processing and storage (disproportionate to dimethyl sulfide). This odour nuisance is unacceptable over a longer period like during the required production time.  In consequence, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in the last five years.  The production and application of coatings cannot always be done in closed systems. Thus, proper ventilation in these cases of workplaces is mandatory. The design of sophisticated ventilation systems ensuring concentration limits being at least 4-fold reduced than the existing one requires considerable financial investment for exposure reduction (millions of Euros). If technically not feasible, additional costs incurred are related to relocation and termination costs.  As a consequence, the production of the final article will be likely moved outside Europe to avoid such investments as the import of the article is not affected by this restriction (the final article is free of NMP). |
| **Dossier submitter response**  Although not specifically mentioned in the dossier, this use is in our view covered by the non-wire coatings. In the dossier it was concluded that alternatives are already available for non-wire coatings and no significant costs were expected for the proposed restriction measure. The information in this comment does not support this conclusion. Information on this specific use has been included in the Background Document.  *Note: see also comments 343,347,348,349,355 and 365* |
| **RAC Rapporteurs comments**  It is noted that there seems to be conflicting experiences on the availability of alternatives for the non-wire coatings. |
| **SEAC Rapporteurs comments**  We agree with the DS response. |
| **346** | **Date:** 2014/03/17 21:56  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** United States  **Related to:** (H)  **Company name confidential:** No | **Comment:**  The National Electrical Manufacturers Association (NEMA), representing manufacturers of electrical and medical imaging equipment, appreciates the opportunity to comment to EU authorities on behalf of its Magnet Wire Section on European Union (EU) proposals for tightening worker exposure limits for n-methyl pyrrolidone (NMP), plus EU further proposals to consider restricting manufacture and use of NMP in industry.    We politely reject the premise that there’s a need for radical changes in chemical safety in the magnet wire industry. The magnet wire industry in particular is accustomed to managing industrial solvents like NMP. Workspaces and work tasks in the magnet wire industry are arranged to minimize exposures to solvents present in enamels, thinners, and cleaners. Such arrangements include (but are not limited to) ventilation to reduce inhalation exposures, plus personal protective equipment (eg, resistant gloves and aprons) to reduce dermal exposures.    There is currently some limited interest in re-thinking NMP exposures in the United States. However, please note that all informal feedback arising from those USA reviews of NMP exposures suggests that industrial exposures are well-managed. Indeed, those same aforementioned instances of informal feedback suggest that USA regulators are concerned about NMP exposures from household NMP uses, not industrial use.    There’s some historic regulation of NMP exposures that might be worthy of consideration by ECHA. California Proposition 65 is acknowledged as one of the strictest toxics regulations in the world. Cal Prop 65 developed a Maximum Allowable Dose Level (MADL) for NMP. The basis for that Cal Prop 65 MADL for NMP was a US-EPA study that determined a No Observable Effect Level (NOEL) for NMP. US-EPA’s NOEL for NMP was based on animal testing at 50 parts per million airborne NMP. In other words, a US-EPA study reported no observable effects to laboratory animals when exposed to inhalation of NMP vapors at 50 ppm. That’s the equivalent of roughly 200 milligrams NMP per cubic meter of breathable air.    With this in mind, we do not grasp ECHA’s interest in tightening workplace inhalation exposures for NMP.    NEMA would like to provide EU authorities with a further consideration related to NMP: Magnet wire is absolutely integral to the efficient production, conversion, and management of electrical energy. Some of the most advanced insulations for magnet wire rely on use of NMP as a raw material input. Reducing accessibility of NMP could negatively impact magnet wire production, which would be entirely counterproductive to the ongoing worldwide drive for more intelligent management of energy.    Given the mechanisms already in place for controlling NMP exposures in the workplace, plus the low environmental persistence of NMP, the magnet wire industry sees no need for further regulation of NMP. Given that there is a growing need for high-performance magnet wire, for the efficient production, conversion, and management of electrical energy, the magnet wire industry must have continued access to NMP.    NEMA thanks the governing EU authorities for their consideration of this submittal. |
| **Answer 5:**  The National Electrical Manufacturers Association (NEMA), representing manufacturers of electrical and medical imaging equipment, appreciates the opportunity to comment to EU authorities on behalf of its Magnet Wire Section on European Union (EU) proposals for tightening worker exposure limits for n-methyl pyrrolidone (NMP), plus EU further proposals to consider restricting manufacture and use of NMP in industry.    We politely reject the premise that there’s a need for radical changes in chemical safety in the magnet wire industry. The magnet wire industry in particular is accustomed to managing industrial solvents like NMP. Workspaces and work tasks in the magnet wire industry are arranged to minimize exposures to solvents present in enamels, thinners, and cleaners. Such arrangements include (but are not limited to) ventilation to reduce inhalation exposures, plus personal protective equipment (eg, resistant gloves and aprons) to reduce dermal exposures.    There is currently some limited interest in re-thinking NMP exposures in the United States. However, please note that all informal feedback arising from those USA reviews of NMP exposures suggests that industrial exposures are well-managed. Indeed, those same aforementioned instances of informal feedback suggest that USA regulators are concerned about NMP exposures from household NMP uses, not industrial use.    There’s some historic regulation of NMP exposures that might be worthy of consideration by ECHA. California Proposition 65 is acknowledged as one of the strictest toxics regulations in the world. Cal Prop 65 developed a Maximum Allowable Dose Level (MADL) for NMP. The basis for that Cal Prop 65 MADL for NMP was a US-EPA study that determined a No Observable Effect Level (NOEL) for NMP. US-EPA’s NOEL for NMP was based on animal testing at 50 parts per million airborne NMP. In other words, a US-EPA study reported no observable effects to laboratory animals when exposed to inhalation of NMP vapors at 50 ppm. That’s the equivalent of roughly 200 milligrams NMP per cubic meter of breathable air.    With this in mind, we do not grasp ECHA’s interest in tightening workplace inhalation exposures for NMP.    NEMA would like to provide EU authorities with a further consideration related to NMP: Magnet wire is absolutely integral to the efficient production, conversion, and management of electrical energy. Some of the most advanced insulations for magnet wire rely on use of NMP as a raw material input. Reducing accessibility of NMP could negatively impact magnet wire production, which would be entirely counterproductive to the ongoing worldwide drive for more intelligent management of energy.    Given the mechanisms already in place for controlling NMP exposures in the workplace, plus the low environmental persistence of NMP, the magnet wire industry sees no need for further regulation of NMP. Given that there is a growing need for high-performance magnet wire, for the efficient production, conversion, and management of electrical energy, the magnet wire industry must have continued access to NMP.    NEMA thanks the governing EU authorities for their consideration of this submittal. |
| **Dossier submitter response**  Thank you for your comment. The exposure descriptions obtained from the wire coating industries indicate that elevated temperatures are used and wire coatings need to cure (dried in air), thus giving potential to high exposure levels. The exposure levels has to be viewed in relation to the toxicological reference value which has been extrapolated from the same point of departure as is referred to. In that respect, we have come to the conclusion that risks are not sufficiently controlled at this moment and actions are deemed necessary. |
| **RAC Rapporteurs comments**  Based on the Reach methodolofy, the RAC has recommended that the inhalation exposure should be below 10mg/m3, while also respecting the dermal DNEL of 4.8 mg/kg/day. |
| **SEAC Rapporteurs comments**  No comments. |
| **347** | **Date:** 2014/03/18 09:56  **Type:** Individual  **Org. type:**  **Org. country:**  **Related to:** (C)  **Company name confidential:** No | **Comment:**  -  **Specific comment:**  The binders produced by the commenting party (downstream user) are used for special applications (e.g. food contact) and are characterized by a high temperature and chemical resistance. Such binders require highly polar aprotic solvents with specific Hansen solubility in order to be used as resin solution.  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) are known since a long time, the commenting party has searched for alternatives since more than five years.  Theoretically, potential solvents are NMP, N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), N,N-Dimethylformamid, DMF (CAS 68-12-2), and Dimethylsulfoxid, DMSO (CAS 67-68-5), Gamma Butyrolacton, GBL (CAS 96-48-0) and more. Practically, due to the known existing toxicological classification of NEP, DMAC, DMF and GBL these solvents are are no appropriate alternatives.  Also, another essential product criterion, is the storage ability over a particular time and under certain conditions, which cannot be guaranteed with the above mentioned non-NMP solvents. The binders do not remain permanently resolved in these solvents.  One solvent whose hazardous properties are not as bad as NEP, DMAC, DMF and GBL is DMSO. But DMSO is due to technological requirements no appropriate alternative for the commenting party due to the dissolving problems. This leads in consequence to the fact that the application of the products (produced with DMSO) is from a state-of-the-art point of view not possible as DMSO is causing major technical/processing problems and even quality problems in the final product.  Using DMSO as a substitute solvent leads already after very short use to an unpleasant, strong smell during processing and storage (disproportionation to dimethyl sulfide). This odour nuisance is unacceptable over a longer period like during the required production time.  In consequence, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in the last five years.  The production and application of coatings cannot always be done in closed systems. Thus, proper ventilation in these cases of workplaces is mandatory. The design of sophisticated ventilation systems ensuring concentration limits being at least 4-fold reduced than the existing one requires considerable financial investment for exposure reduction (millions of Euros). If technically not feasible, additional costs incurred are related to relocation and termination costs.  As a consequence, the production of the final article will be likely moved outside Europe to avoid such investments as the import of the article is not affected by this restriction (the final article is free of NMP). |
| **Dossier submitter response**  Although not specifically mentioned in the dossier, this use is in our view covered by the non-wire coatings. In the dossier it was concluded that alternatives are already available for non-wire coatings and no significant costs were expected for the proposed restriction measure. The information in this comment does not support this conclusion. Information on this specific use has been included in the Background Document.  *Note: see also comments 343,345,348,349,355 and 365* |
| **RAC Rapporteurs comments**  It is noted that there seems to be conflicting experiences on the availability of alternatives for the non-wire coatings. |
| **SEAC Rapporteurs comments**  No comments |
| **348** | **Date:** 2014/03/18 10:18  **Type:** Individual  **Org. type:**  **Org. country:**  **Related to:**  **Company name confidential:** No | **Comment:**  -  **Specific comment:**  The binders produced by the commenting party (downstream user) are used for special applications (e.g. food contact) and are characterized by a high temperature and chemical resistance. Such binders require highly polar aprotic solvents with specific Hansen solubility in order to be used as resin solution.  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) are known since a long time, the commenting party has searched for alternatives since more than five years.  Theoretically, potential solvents are NMP, N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), N,N-Dimethylformamid, DMF (CAS 68-12-2), and Dimethylsulfoxid, DMSO (CAS 67-68-5), Gamma Butyrolacton, GBL (CAS 96-48-0) and more. Practically, due to the known existing toxicological classification of NEP, DMAC, DMF and GBL these solvents are no appropriate alternatives.  Also, another essential product criterion, is the storage ability over a particular time and under certain conditions, which cannot be guaranteed with the above mentioned non-NMP solvents. The binders do not remain permanently resolved in these solvents.  One solvent whose hazardous properties are not as bad as NEP, DMAC, DMF and GBL is DMSO. But DMSO is due to technological requirements no appropriate alternative for the commenting party due to the dissolving problems. This leads in consequence to the fact that the application of the products (produced with DMSO) is from a state-of-the-art point of view not possible as DMSO is causing major technical/processing problems and even quality problems in the final product.  Using DMSO as a substitute solvent leads already after very short use to an unpleasant, strong smell during processing and storage (disproportionation to dimethyl sulfide). This odour nuisance is unacceptable over a longer period like during the required production time.  In consequence, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in the last five years.  The production and application of coatings cannot always be done in closed systems. Thus, proper ventilation in these cases of workplaces is mandatory. The design of sophisticated ventilation systems ensuring concentration limits being at least 4-fold reduced than the existing one requires considerable financial investment for exposure reduction (millions of Euros). If technically not feasible, additional costs incurred are related to relocation and termination costs.  As a consequence, the production of the final article will be likely moved outside Europe to avoid such investments as the import of the article is not affected by this restriction (the final article is free of NMP). |
| **Dossier submitter response**  Although not specifically mentioned in the dossier, this use is in our view covered by the non-wire coatings. In the dossier it was concluded that alternatives are already available for non-wire coatings and no significant costs were expected for the proposed restriction measure. The information in this comment does not support this conclusion. Information on this specific use has been included in the Background Document.  *Note: see also comments 343,345,347,349,355 and 365* |
| **RAC Rapporteurs comments**  It is noted that there seems to be conflicting experiences on the availability of alternatives for the non-wire coatings. |
| **SEAC Rapporteurs comments**  No comments. |
| **349** | **Date:** 2014/03/18 10:53  **Type:** Individual  **Org. type:**  **Org. country:**  **Related to:** (C)  **Company name confidential:** No | **Comment:**  Comment to C.2.4:  The binders produced by the commenting party (downstream user) are used for special applications (e.g. food contact) and are characterized by a high temperature and chemical resistance. Such binders require highly polar aprotic solvents with specific Hansen solubility in order to be used as resin solution.  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) are known since a long time, the commenting party has searched for alternatives since more than five years.  Theoretically, potential solvents are NMP, N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), N,N-Dimethylformamid, DMF (CAS 68-12-2), and Dimethylsulfoxid, DMSO (CAS 67-68-5), Gamma Butyrolacton, GBL (CAS 96-48-0) and more. Practically, due to the known existing toxicological classification of NEP, DMAC, DMF and GBL these solvents are are no appropriate alternatives.  Also, another essential product criterion, is the storage ability over a particular time and under certain conditions, which cannot be guaranteed with the above mentioned non-NMP solvents. The binders do not remain permanently resolved in these solvents.  One solvent whose hazardous properties are not as bad as NEP, DMAC, DMF and GBL is DMSO. But DMSO is due to technological requirements no appropriate alternative for the commenting party due to the dissolving problems. This leads in consequence to the fact that the application of the products (produced with DMSO) is from a state-of-the-art point of view not possible as DMSO is causing major technical/processing problems and even quality problems in the final product.  Using DMSO as a substitute solvent leads already after very short use to an unpleasant, strong smell during processing and storage (disproportionation to dimethyl sulfide). This odour nuisance is unacceptable over a longer period like during the required production time.  In consequence, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in the last five years.  The production and application of coatings cannot always be done in closed systems. Thus, proper ventilation in these cases of workplaces is mandatory. The design of sophisticated ventilation systems ensuring concentration limits being at least 4-fold reduced than the existing one requires considerable financial investment for exposure reduction (millions of Euros). If technically not feasible, additional costs incurred are related to relocation and termination costs.  As a consequence, the production of the final article will be likely moved outside Europe to avoid such investments as the import of the article is not affected by this restriction (the final article is free of NMP). |
| **Dossier submitter response**  Although not specifically mentioned in the dossier, this use is in our view covered by the non-wire coatings. In the dossier it was concluded that alternatives are already available for non-wire coatings and no significant costs were expected for the proposed restriction measure. The information in this comment does not support this conclusion. Information on this specific use has been included in the Background Document.  *Note: see also comments 343,345,347,348,355 and 365* |
| **RAC Rapporteurs comments**  It is noted that there seems to be conflicting experiences on the availability of alternatives for the non-wire coatings. |
| **SEAC Rapporteurs comments**  No comments |
| **351** | **Date:** 2014/03/18 12:31  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. country:** Sweden  **Related to:**  **Company name confidential:** No | **Comment:**  Exposure to NMP – Input from the Swedish Work Environment Authority  The proposal is that a REACH restriction shall prohibit the use of NMP if the exposure by inhalation exceeds 5 mg/m3. Our position is that REACH should not in this way affect the application of health and safety legislation. This would be in contrary to Article 2.4 of the REACH Regulation. Directive 98/24/EC lays down the procedure for establishment of occupational exposure limit values for workplaces. Unless the Council and Parliament decide to change this procedure REACH should not be used to set such limits.  The proposal questions whether the indicative limit value recommended by SCOEL provides adequate security for pregnant workers. The Swedish Work Environment Authority suggests that SCOEL consider if their recommendation should be changed and justify their choice of uncertainty factor transparently. Each member state must in that case then determine their national limit value in accordance with article 3.3 of 98/24/EC.  We suggest that restrictions under REACH are used to prohibit prioritized unwanted chemical products used by workers. An investigation must first state that there are technical and economic possibilities to use products containing other substances that are less likely to damage health. Substitution of hazardous products is usually a more effective way to reduce the risk than measures that reduce exposure. In cases where a respirator is the only reasonable measure it is especially justified to substitute.  The proposal includes a review of the various uses of NMP and when suitable substitutes are available. The Swedish Work Environment Authority recommends that NMP is prohibited in products where less hazardous reasonable alternatives exist. In particular we wish to prohibit chemical products widely used in non- industrial environments, such as graffiti removal and cleaning. |
| **Dossier submitter response**  Thank your for your comment. we are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The RAC has had to analyse the different RMOs proposed in the proposal, and while the RAC has recommended a modified RMO3, it is now up to the Commission to decide on the legal way forward. |
| **SEAC Rapporteurs comments**  The comment is related to the legal framework and not to risk reduction options. |
| **352** | **Date:** 2014/03/18 13:00  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** United States  **Related to:** (G)  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  SEMI would like to support the contribution of the European Semiconductor Industry Association (ESIA) to this consultation. Please find attached SEMI's message outlining key issues for our industry. |
| **Dossier submitter response**  SEMI would like to support the contribution of the European Semiconductor Industry Association (ESIA) (ref 307) to this consultation. Please find attached SEMI's message outlining key issues for our industry. |
| **RAC Rapporteurs comments**  Thanks for the information. |
| **SEAC Rapporteurs comments**  We note that even the limit value originally proposed can be met. The revised proposal is using a limit value twice the original proposed. |
| **354** | **Date:** 2014/03/18 14:05  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. country:** Austria  **Related to:**  **Company name confidential:** No | **Comment:**  Obviously, the Derived No-Effect Level (DNEL) provided in the draft restriction report are different from the Indicative Occupational Exposure Levels (IOEL) derived by the Scientific Committee on Occupational Exposure Limits (SCOEL) in 2007.  The DNEL values provided in the draft restriction report seem to be more accurate than the SCOEL deriviation. Nevertheless, binding Occupational Exposure Levels should be set according to the EU occupational safety and health directives.  It is therefor necessary that ECHA committees ask SCOEL to reevaluate und to revise the current IOEL in a close cooperation with ECHA Risk Assessement Committee. In particular, it is not acceptable to make any difference with regard to developmental toxicity whether a (potential) pregant woman is „part of general population“ or is a „worker“. |
| **Dossier submitter response**  Thank you for your comments. We decided to discriminate between female workers in the childbearing age and the general worker in order to be able to make impact assessments for the worker population as there are different critical effects. By taking the lowest DNEL automatically other workers would be protected too. However, if there are derogations (see RMO2) it may mean that risks remain for both worker population having risks for different effects. In the wording of the proposed restriction there is no discrimination.  Further, we are aware of the political discussion on the relation between REACH and OSH legislation, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The RAC supports having one limit value, based on the most sensitive sub-population. |
| **SEAC Rapporteurs comments**  The comment is related to the legal framework and not to risk reduction options. |
| **356** | **Date:** 2014/03/18 14:32  **Type:** MemberState  **Org. type:**  **Org. country:**  **Related to:**  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  We have consulted the The Swedish Work Environment Authority that advice against including occupational exposure limits in REACH. There is a procedure in place for setting EU-wide exposure limits in Council Directive 98/24/EC article 3. That procedure should be adhered to until the directive is amended. It is in our view inadvisable to set occupational exposure limits in several different legislations.  Furthermore:  The report (ANNEX XV PROPOSAL FOR A RESTICTION – NMP, section A.1.2, 2nd line) says that the limit values should not be exceeded “under normal operating conditions” this is not our interpretation of the proposed wording of the restriction which can be read that exposure should be below limit values in all circumstances and at all times. In the same report (section A.1.2, paragraph 5) it says that “Manufacturers and industrial and professional users of NMP must be able to demonstrate at the request of the local authorities that they comply with the above restrictions.” This also is not clear from the wording of the restriction, it may well be possible to require this based on other legislation e.g. worker protection legislation, but this is not clear.  We realise that the definition of TWA and the limit values (how they should be measured etc) refer to definitions in the worker protection legislation, but is this clear in legal terms when no reference is made in the proposed restriction? |
| **Dossier submitter response**  The definitions of TWA and analytical methods to measure limit values has been added to the Background Document. In the dossier the text “under normal operating conditions” was used to exclude accidents, but the Dossier Submitter has no problem in deleting or improving this text. |
| **RAC Rapporteurs comments**  The RAC has proposed DNEL values (inhalation and dermal) which represent 8 hours working days, thus being equivalent to the TWA. |
| **SEAC Rapporteurs comments**  We read the “under normal operating conditions” as an explanation of the TWA value concept. |
| **355** | **Date:** 2014/03/18 14:33  **Type:** Individual  **Org. type:**  **Org. country:**  **Related to:** (C)  **Company name confidential:** No | **Comment:**  -  **Specific comment:**  The binders produced by the commenting party (downstream user) are used for special applications (e.g. food contact) and are characterized by a high temperature and chemical resistance. Such binders require highly polar aprotic solvents with specific Hansen solubility in order to be used as resin solution.  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) are known since a long time, the commenting party has searched for alternatives since more than five years.  Theoretically, potential solvents are NMP, N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), N,N-Dimethylformamid, DMF (CAS 68-12-2), and Dimethylsulfoxid, DMSO (CAS 67-68-5), Gamma Butyrolacton, GBL (CAS 96-48-0) and more. Practically, due to the known existing toxicological classification of NEP, DMAC, DMF and GBL these solvents are are no appropriate alternatives.  Also, another essential product criterion, is the storage ability over a particular time and under certain conditions, which cannot be guaranteed with the above mentioned non-NMP solvents. The binders do not remain permanently resolved in these solvents.  One solvent whose hazardous properties are not as bad as NEP, DMAC, DMF and GBL is DMSO. But DMSO is due to technological requirements no appropriate alternative for the commenting party due to the dissolving problems. This leads in consequence to the fact that the application of the products (produced with DMSO) is from a state-of-the-art point of view not possible as DMSO is causing major technical/processing problems and even quality problems in the final product.  Using DMSO as a substitute solvent leads already after very short use to an unpleasant, strong smell during processing and storage (disproportionation to dimethyl sulfide). This odour nuisance is unacceptable over a longer period like during the required production time.  In consequence, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in the last five years.  The production and application of coatings cannot always be done in closed systems. Thus, proper ventilation in these cases of workplaces is mandatory. The design of sophisticated ventilation systems ensuring concentration limits being at least 4-fold reduced than the existing one requires considerable financial investment for exposure reduction (millions of Euros). If technically not feasible, additional costs incurred are related to relocation and termination costs.  As a consequence, the production of the final article will be likely moved outside Europe to avoid such investments as the import of the article is not affected by this restriction (the final article is free of NMP). |
| **Dossier submitter response**  Although not specifically mentioned in the dossier, this use is in our view covered by the non-wire coatings. In the dossier it was concluded that alternatives are already available for non-wire coatings and no significant costs were expected for the proposed restriction measure. The information in this comment does not support this conclusion. Information on this specific use has been included in the Background Document.  *Note: see also comments 343,345,347,348,349 and 365* |
| **RAC Rapporteurs comments**  It is noted that there seems to be conflicting experiences on the availability of alternatives for the non-wire coatings. |
| **SEAC Rapporteurs comments**  No comments. |
| **357** | **Date:** 2014/03/18 14:42 (follow up to comment 290)  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Germany  **Related to:** (A) (B) (C) (D) (F)  **Company name confidential:** **Yes** | **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). The original comments submitted under this communication are not repeated in this document. This new comment refers to the request of the Committee for Socio-economic Analysis (SEAC) for additional information from stakeholders to assist with its opinion development for the 1-methyl-2-pyrrolidone (NMP) restriction proposal.  Please note that the request for additional comments was only published via the ECHA e-News from January 29, 2014 and no additional information can be found on ECHA’s restriction proposal website (only by opening the “give comment” web form). We would very much appreciate, if ECHA could for the future contact stakeholders directly via the contact details given in the previously submitted web form and make such requests clearly visible on the restriction proposal website. |
| **Dossier submitter response**  Response from ECHA.  ECHA: Thank you very much for the comment provided in the Public consultation and those related to the improvement of the ECHA website. They will be taken into consideration, to improve communication with the stakeholders. |
| **RAC Rapporteurs comments**  The advice to ECHA is noted. |
| **SEAC Rapporteurs comments** |
| **358** | **Date:** 2014/03/18 14:57  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** United Kingdom  **Related to:** (A) (C)  **Company name confidential:** **Yes** | **Comment:**  Previously we moved away from DMF, DMAc etc but NMP is the last of the commercially available solvents that dissolve many of the engineering polymers we use in our coatings. Without NMP the stability / cost of the coating we provide will be adversely affected. We also believe that many of the solvents, which might work, but are not commercially available will end up be classified similar to NMP. As such it puts our business at risk |
| **Answer 1:**  In most applications NMP is sprayed in vented are and coatings is cured in oven with extraction so personnel are not subject to fumes. |
| **Answer 2:**  Difficult to measure for just NMP as it is used in conjunction with other solvents but total solvent is <10 ppm except when adding solvent when 400ppm can be measured |
| **Answer 3:**  Although not an issue at our site I do many of our customers could easily or without excessive cost measure or reduce the amount of NMP in the air. |
| **Answer 4:**  At the moment we do not have a viable alternative for 50% of our business. The shelf of the products we currently make which is >12 months drops to four weeks with any solvent we try. So unless "new" commercially viable solvents become available half our business is at risk if NMP's use is restricted. |
| **Answer 5:**  Restrict to professional use where companies have extraction systems which meets minimum limits. |
| **Dossier submitter response**  Thank you for this comment. Unfortunately, it is not made explicit in the comment what specific coating use is covered here (that what is called ‘general coating’ in the restriction dossier, or one of the specific coatings, for example car coatings). This makes it very difficult to use the presented information for improving the Background Document. As mentioned in chapter C, replacement of NMP is possible via reformulation of coatings in the automotive industry. |
| **RAC Rapporteurs comments**  The response from the dossier submitter is supported. |
| **SEAC Rapporteurs comments**  We agree with the dossier submitter**.** |
| **360** | **Date:** 2014/03/18 15:34  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. country:** Belgium  **Related to:**  **Company name confidential:** No  **Attachment confidential:** No | **Comment:**  Please find our comments within the attached documents... |
| **Answer 5:**  Please find our comments within the attached documents... |
| **Dossier submitter response**  Thank you for your comments. With respect to the comments related to the DNEL derivation. We are of the opinion that RAC should decide what extrapolation factors to consider as the Dossier Submitter already indicated why we have chosen the extrapolation factors as they are presented in the dossier. The Dossier Submitter evaluated kinetics data in rat and humans to see if the remaining uncertainties factor could be reduced. However, though the data provided some indications that human plasma levels of NMP may be lower than those in the rats after comparable external exposure, the data were not sufficiently robust to conclude that there are no remaining differences. Moreover, the remaining differences also include possible toxicodynamic differences for which we did not find comparable data in rats and humans. The Dossier Submitter therefore decided to keep the factor at 2.5. See also annex 4 of the Background Document. |
| **RAC Rapporteurs comments**  The RAC view on the kinetic data and the assessment factors is described in the opinion. |
| **SEAC Rapporteurs comments**  No comments. |
| **363** | **Date:** 2014/03/18 17:12  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** Ireland  **Related to:** (C)  **Company name confidential:** **Yes**  **Attachment confidential:** No | **Comment:**  Engineering measures  Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.  Individual protection measures  Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.  Eye/Face protection: safety glasses  Hand protection  Full contact: Glove material butyl rubber, thickness 0.7 mm, breakthrough time > 480 min  Splash contact: Glove material latex, thickness 0.6 mm, breakthrough time > 60 min  The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN 374  Other protective equipment: protective clothing  Respiratory protection: required when vapours are generated, recommended filter type A-(P2), the entrepreneur has to ensure that maintenance; cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.  **Specific comment:**  During the assessment of DMSO strong emphasis is made of toxicologically and environmentally properties of DMSO demonstrating that DMSO is of low concern for the environment and the human health. Unfortunately, just a few general remarks were made on physical/chemical properties which might significantly influence worker’s safety.  It is well known in the literature (please refer to the attachments) that DMSO has some explosive potential in contact with special chemicals or at elevated temperatures. The temperature of decomposition processes may be reduced in the presence of substances with catalytic activity. Another issue regarding process safety is the high boiling point of DMSO which impedes the dissipation of heat. Based on this information a substitution of NMP by DMSO should be checked very carefully. Depending on the reactant the following severe effects are described:  • strong exothermic decomposition reactions  • danger of explosions  • danger of flammability respectively development of flammable gases or vapours  Additionally, the pure substance DMSO has no odour but it decomposes quite easily and due to the incorporated sulphur the decomposition products provide a quite distinct odour. Volatile and non-volatile decomposition products might influence the impurity profile/product quality of the newly synthesised product and might not be acceptable by every customer or downstream user (e.g. impact on smell or physic-chemical properties of the product, catalyst poison). |
| **Dossier submitter response**  Thanks a lot for this additional information on DMSO. The information has been added to the relevant sections of part C.2. |
| **RAC Rapporteurs comments**  The additional information on DMSO is noted. |
| **SEAC Rapporteurs comments**  No further comments. Other Alternatives might be available for some uses. The evaluation of alternatives is based on information regarding uses already going on. Therefore we do expect that your information will lead to identification of more uses than already covered where NMP cannot be substituted. |
| **364** | **Date:** 2014/03/18 17:15  **Type:** MemberState  **Org. type:**  **Org. country:**  **Related to:**  **Company name confidential:** No | **Comment:**  Slovenia believes that measures for managing workers exposures to chemicals, especially those setting the exposure levels for working place should be considered within the scope of EU working legislation, namely directives 98/24/EC and 2004/37/EC. |
| **Dossier submitter response**  Thank your for your comment. We are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The RAC has analysed the different RMOs, and while proposeing a modified RMO3, it is up to the Commission to decide on the legal way forward. |
| **SEAC Rapporteurs comments**  The comment is related to the legal framework and not to risk reduction options. |
| **365** | **Date:** 2014/03/18 17:15  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. country:** United Kingdom  **Related to:** (C)  **Company name confidential:** **Yes** | **Comment:**  The commenting party operates a continuous coil coating line involved in the application of high temperature non stick coatings to metallic substrates for the intended use of domestic bakeware. The total market throughout Europe is estimated to be in excess of 20,000 tonnes per annum of which the commenting party supplies approximately half. The total market for bakeware products per annum is in excess of 60 million euros and supports in excess of 1000 European based jobs  The primary solvent used in these non stick coatings has traditionally been NMP at levels between 25% and 50% of coating formulation. Currently the pre coating industry purchase an estimated volume between 800 and 1000 tonnes of coatings containing this solvent.  The commenting party has been aware for a number of years of the status of NMP and has worked with its suppliers of these coatings to substitute this solvent from the formulations. This evaluation to date has proved to be unsuccessful due to application and shelf life issues with the coatings. Work on substitution of NMP will continue.  **Specific comment:**  The binders used by the commenting party (downstream user) are used for special applications (e.g. food contact) and are characterized by a high temperature and chemical resistance. Such binders require highly polar aprotic solvents with specific Hansen solubility in order to be used as resin solution.  As the hazardous properties of N-Methylpyrrolidone, NMP (CAS 872-50-4) have been known since a long time, the commenting party has searched for alternatives dating back more than five years.  Theoretically, potential solvents are NMP, N-ethyl-2-pyrrolidone, NEP (CAS 2687-91-4), N,N-Dimethylacetamid, DMAC (CAS 127-19-5), N,N-Dimethylformamid, DMF (CAS 68-12-2), and Dimethylsulfoxid, DMSO (CAS 67-68-5), Gamma Butyrolacton, GBL (CAS 96-48-0) and more. However practically, due to the known existing toxicological classification of NEP, DMAC, DMF and GBL these solvents are not appropriate alternatives.  Also, another essential product criterion, is the storage ability over a particular time and under certain conditions, which cannot be guaranteed with the above mentioned non-NMP solvents. The binders do not remain permanently resolved in these solvents.  One solvent whose hazardous properties are not at a level of NEP, DMAC, DMF and GBL is Dimethylsulfoxid, DMSO. But due to technological requirements DMSO is no longer an appropriate alternative for the commenting party due to the dissolving problems. This leads in consequence to the fact that the application of the products (produced with DMSO) is from a state-of-the-art point of view not possible as DMSO causes major technical/processing problems and even quality problems in the final product.  Using DMSO as a substitute solvent leads after very short use to an unpleasant, strong smell during processing and storage (disproportionate to dimethyl sulfide). This odour nuisance is unacceptable over a longer period such as during the required production time.  In conclusion, all research and substitution efforts invested to find an acceptable alternative for NMP meeting the required non/less hazardous and technological requirements were not successful in recent years.  The production and application of coatings cannot always be done in closed systems. Thus, proper ventilation in these cases of workplaces is mandatory. The design of sophisticated extraction systems ensuring concentration limits being at least 4-fold lower than the existing UK OEL’s requires considerable financial investment for exposure reduction (potentially millions of Euros across the industry as a whole). If technically not feasible, additional costs incurred are related to relocation and termination costs.  As a consequence, the production of the final article will be likely moved outside Europe to avoid such investments as the import of the article is not affected by this restriction (the final article is free of NMP). |
| **Answer 1:**  At the commenting party site local exhaust extraction, yearly solvent monitoring, and personal protective equipment. |
| **Answer 2:**  The commenting party current yearly solvent monitoring program of operators, gives personal airborne concentrations of between 1 and 6 mg/m3 average 3mg/m3 in standard processing conditions and airborne concentrations of between 12 and 20 mg/m3 at cleandown periods. The current long term exposure limit is 103 mg/m3 and short term exposure limit 309 mg/m3 in the UK. |
| **Answer 3:**  Improved or revised extraction system for cleandown periods, improved or revised personal protective equipment, substitution of solvent used in cleandown from NMP to alternative this may however render the residue coating scrap |
| **Dossier submitter response**  Although not specifically mentioned in the dossier, this use is in our view covered by the non-wire coatings. In the dossier it was concluded that alternatives are already available for non-wire coatings and no significant costs were expected for the proposed restriction measure. The information in this comment does not support this conclusion. Information on this specific use has been included in the Background Document.  *Note: see also comments 343,345,347,348,349 and 355* |
| **RAC Rapporteurs comments**  It is noted that there seems to be conflicting experiences on the availability of alternatives for the non-wire coatings. |
| **SEAC Rapporteurs comments**  It seems that a restriction based on the RAC derived DNEL of 10 mg/m3 can be respected. However, it is not clear whether the clean down periods exceed 15 minutes where an exposure level of 20 mg/m3 would be acceptable. |
| **367** | **Date:** 2014/03/18 17:23  **Type:** MemberState  **Org. type:**  **Org. country:**  **Related to:**  **Company name confidential:** No | **Comment:**  Slovenia believes that measures for managing workers exposures to chemicals, especially those setting the exposure levels for working place should be considered within the scope of EU working legislation, namely directives 98/24/EC and 2004/37/EC. |
| **Dossier submitter response**  Thank you for your comment. we are aware of this (important) discussion, but in our view this is outside the scope of the RAC and SEAC opinion development. |
| **RAC Rapporteurs comments**  The RAC has analysed the different RMOs, and while proposeing a modified RMO3, it is up to the Commission to decide on the legal way forward. |
| **SEAC Rapporteurs comments**  The comment is related to the legal framework and not to risk reduction options. |
| **369** | **Date:** 2014/03/18 19:30  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. country:** United Kingdom  **Related to:** (E)  **Company name confidential:** No | **Comment:**  The dossier submitter does not demonstrate that the proposed restriction is the most appropriate EU-wide measure as authorisation seems to be preferable both from a risk control measure and from the point of view of the overall risk management options foreseen in REACH.  **Specific comment:**  The dossier submitter does not justify how restriction is the best EU wide measure. It claims (page 14) that “[t]he main disadvantage of the authorisation process is that it is costly and time-consuming both for industry as for authorities. Besides that, it gives large uncertainty to industry regarding the continuation of their business because an authorisation request will only be given for a limited period of time.” However this is a general sweeping statement that could be claimed for any authorisation process and it is not at all corroborated by a thorough socio economic in the proposal. Further it is disputed that a mandatory harmonised DNEL could be properly monitored on all workplaces in which NMP is used.  The dossier submitter also claims in relation to the proposed restriction that “There are no specific concerns with regard to the monitorability . This can be done through enforcement.” However it is also noted in the dossier that there is uncertainty about the number of workers exposed to NMP in levels above the proposed DNEL, thus the monitorability of the restriction could not be deemed as effective as claimed by the dossier submitter.  In relation to RMO4 (Authorisation) it should be noted that a risk management option analysis was already carried out by the Netherlands and for transparency reasons it should be included in the dossier or referenced in the final opinion or background document. Although not available to the public, it is understood that the conclusion of that analysis was that authorisation is the best risk management option. Thus a comparison of the analysis made at that stage and the opposite decision to propose a restriction with similar characteristics of an authorisation would increase clarity on the political, rather that socio-economic reasons that have motivated the Netherlands to submit this proposal. Indeed, the dossier makes further sweeping statements such as that “[r]equesting for authorisation is costly and time-consuming, both for industry as for authorities especially given the widespread use of the substance. Besides, it gives large uncertainty to industry regarding the continuation of their business.” It is actually not clear how authorisation is more costly for authorities given that the nature of authorisation is to place the burden to prove the safety of use or the socio-economic benefits of continued use on the applicant for authorisation. Calculations have not been made about these costs. Further, no realistic estimation is given about the actual possibility that companies may relocate or terminate their activities in the EU. All figures provided in Table F.25 are confidential, thus cannot be commented thoroughly. |
| **Dossier submitter response**  Thank you for your comment. In our view, based on the REACH legal text, both authorisation and restriction can apply for substances fulfilling the criteria of article 57 of REACH. No guidance is given on the most preferred option. As explained in the dossier, in our view in the case of NMP restriction is the most appropriate one. Indeed the Compentent Authority of the Netherlands in advance of preparing the restriction dossier, made an RMO analysis. This RMO analysis has not been published but the outcome of this RMO analysis was that a restriction is the most appropriate risk management measure (and not authorisation as mentioned in the comment). The text in section E of the dossier, is for a large extent copied from the RMO analysis. |
| **RAC Rapporteurs comments**  The RAC has analysed the different RMOs, and while proposeing a modified RMO3, it is up to the Commission to decide on the legal way forward. |
| **SEAC Rapporteurs comments**  Pros and Cons of the various RMOs are described in the BD and opinion. |