Committee for Socio-economic Analysis (SEAC)

Opinion on an Annex XV dossier proposing restrictions on

1-Methyl-2-pyrrolidone (NMP)

ECHA/SEAC/[Opinion N°(same as opinion number)]

Draft

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Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**1-methyl-2-pyrrolidone**
EC No.:	212-828-1
CAS No.:	872-50-4

This document presents the opinion adopted by SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

The Netherlands has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***18 September 2013***. Interested parties were invited to submit comments and contributions by ***18 March 2014***.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***10 September 2014.***

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***16 September 2014***. Interested parties were invited to submit comments on the draft opinion by ***14 November 2014***.

The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by 90 days by the ECHA decision no I(2014)0192 of 12 June 2014.

OPINION

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information recorded in the Background Document. SEAC considers that the proposed restriction on ***NMP***, as modified by RAC, is the most appropriate EU wide measure to address the identified risks in terms of cost-effectiveness. SEAC is however unable to determine if the restriction is an appropriate EU wide measure to address the identified risks in terms of providing a net gain in socioeconomic welfare to society.

The RAC modified proposal is as follows:

Column 1. **Designation of substance**	***Column 2.*** **Conditions of restriction**
Substance name: N-methylpyrrolidone IUPAC name: 1-methylpyrrolidin-2-one EC number: 212-828-1 CAS number: 872-50-4	Manufacturers, importers and downstream users of the substance on its own or in mixtures in a concentration equal or greater than 0.3% shall use in their chemical safety assessment and safety data sheets by [xx.yy.zzzz] a Derived No Effect Level (DNEL) value for workers inhalation of 10 mg/m^3 and a DNEL for workers dermal exposure of 4.8 mg/kg/day.

The original restriction (proposed by the dossier submitter (DS)) is based on an inhalation exposure limit half the DNEL value derived by RAC. In addition, it is specified that dermal exposure shall be avoided by use of preventive measures. The higher inhalation DNEL value derived by RAC would according to SEAC result in significantly lower costs of compliance for the users that may have difficulties in reducing the exposure. RAC's introduction of a dermal DNEL could reduce these cost savings but SEAC has not received any information that indicates that this should be of any significance.

JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

SEAC acknowledges the justifications put forward by RAC stating that action is justified on an EU wide basis since the national Occupational Exposure Limit values (OELs) all are significantly higher than the DNEL proposed by RAC for inhalation and in some MSs are considerably higher than the existing indicative OEL established on EU level. SEAC therefore agrees that risk management activities on an EU wide basis are justified in order to ensure a common level of protection of human health across the EU, in relation to exposure resulting from manufacturing and use of NMP. The proposed restriction addresses manufacturing and use of the substance and would therefore prevent a possible trade and competition distortion and establish a common level playing field for manufacturers and users.

The RAC-modified proposal is following the general principles for managing chemicals under REACH, except for the fact that the DNEL, derived on a regulatory science basis, is defined in the restriction rather than by registrants.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

The restriction proposed by the DS is based on a harmonised inhalation exposure limit and a general requirement to protect against dermal exposure. The proposal required that NMP shall not be manufactured and used by professional or industrial workers unless the inhalation exposure remains below 5 mg/m^3 (Time–Weighted Average, TWA) and the 15 minutes peak exposure remains below 10 mg/m^3 (short-term exposure limit, STEL). Furthermore, dermal exposure shall be avoided by preventative measures. The TWA limit value was based on the derived no effect level (DNEL) proposed by the DS.

RAC has concluded that the inhalation DNEL should be 10 mg/m^3 rather than 5 mg/m^3. Furthermore, RAC has proposed to modify the restriction, whereby instead of a mandatory exposure limit for inhalation exposure the entry in Annex XVII should state, that the inhalation DNEL set by RAC shall be used in chemical safety assessments (CSA) documented in the Chemical Safety Reports (CSRs) and in the Safety Data Sheets (SDS). RAC also proposes to include the dermal DNEL in the restriction wording. The combined exposure from inhalation and skin shall be taken into account when defining the conditions of exposure.

The DNELs shall be used in the chemical safety assessments, by registrants and relevant downstream users. The resulting exposure scenarios would have to recommend concrete and use-specific operational conditions and risk management measures to ensure that the inhalation and dermal exposures on average over a day (8 hours) are below the DNEL values and the combined Risk Characterisation Ratios (RCR) are also below 1. Included in the RAC proposal for modification of the wording of the restriction is a requirement to include RAC-calculated DNEL values in Safety Data Sheets (SDSs) for the substance, to ensure that the SDSs developed by those manufacturers that do not have to develop CSA (below 10 t) and substance recyclers convey the correct DNEL values to the users.

The risk reduction measures recommended by the registrants are communicated to the downstream users through exposure scenarios annexed to the Safety Data Sheets. Users are obliged to implement conditions described in the scenarios (unless they prepare their own CSR showing safe use). Therefore, as a consequence of implementation of the

restriction as proposed by RAC, safe use conditions, resulting in positive health impact, would be implemented.

A mandatory DNEL would be used by manufacturers, importers and downstream users that are required to develop a CSR. This concerns those companies manufacturing or importing 10 tonnes/year or more. This seems to apply to approximately 99% of the total volume of NMP based on the registrations submitted to ECHA.

As a result of SEAC's considerations below, SEAC supports the modified RMO proposed by RAC as it is seen to be the most cost-effective, effective, and monitorable of the options presented by the Dossier Submitter in the Risk Management Option (RMO) analysis carried out.

RMO analysis

The original proposal (RMO3) is based on an inhalation exposure limit and a specified requirement that dermal exposure shall be avoided by use of preventive measures.

In the RAC modified proposal, the limit value is replaced by a mandatory DNEL to be used in the Chemical Safety Report and a dermal DNEL is introduced.

Several other risk management options have been considered by the DS:

- RMO1 - A ban on manufacturing and use;
- RMO2A – A partial ban combined with a requirement of using best available techniques in the remaining sectors and uses;
- RMO2B - A partial ban combined with a mandatory DNEL to be used in the Chemical Safety Report;
- RMO2C - A partial ban for some uses alone;
- RMO4 – Authorisation;
- Establishing a binding OEL under the worker protection legislation.

In table 1 below the different components and main features of the considered RMOs are summarised.

Table 1 Content of different RMOs considered. DS indicates that the element is proposed by the DS. RAC indicates that it is proposed by RAC. An "X" in brackets indicates that the element could be incorporated in the RMO, if the approach is considered relevant.

Risk Management Option	RMO1	RMO2A	RMO2B	RMO2C	RM03	RMO4	Worker Protection
Mode of action	Ban	Ban for some uses + BAT for other uses	Ban for some uses + Exposure limit for others uses	Ban for some uses Only	Exposure limit	Authorisation	
Exposure limit value for inhalation					**DS**	(X)[1]	X
Ban (general or partial)	X	X	X	X			
Mandatory inhalation DNEL in the Chemical safety report (CSR)			X		**RAC**		
Restriction based on best available techniques		X					
Statement that dermal exposure shall be prevented		(X)	(X)		**DS**	(X)	X
Mandatory DNEL value on dermal exposure (in combination with mandatory inhalation DNEL) in CSR			(X)		**RAC**		

As stated above the RAC modified proposal is considered to be more appropriate than the original proposal. Below the other considered RMOs are assessed in order to ensure that they do not offer a more appropriate option than the one proposed by RAC.

Ban on manufacturing and use (RMO1)

RMO1 would constitute a ban on manufacture, placing on the market and use of NMP in concentrations above 0.3%.

This RMO would be the most effective measure in terms of reducing the exposure, ease of enforcement and monitoring.

SEAC agrees with the conclusion of the DS that due to the lack of feasible alternatives for a number of uses and considering that the risks can be sufficiently controlled by the proposed restriction, this option is least cost-effective.

Ban with derogations (RMO2)

The dossier discusses three different versions of RMO2.

In RMO2C, the DS has considered a ban of NMP for some uses where technical and economical alternatives have been identified, while remaining uses would be allowed. The

[1] Could be part of the conditions for authorisation on a case-by-case basis.

uses proposed to be banned are: non-wire coating, professional cleaning, agrochemical formulations and construction materials.

It is noted that EU Regulation 1107/2009 will ban the use of CMR substances categories 1A and 1B in plant protection products, meaning that the use of NMP as a co-solvent will be phased out in time. Information from industry indicates that the phase-out will be complete in 2015 [BD – B.2.2]. Therefore, the inclusion of these uses in a partial ban does not seem to have any impact on this sector.

For the construction industry, a shift to alternatives already has been carried out; therefore no impacts are expected for this sector. Although the amount of NMP used for the two remaining proposed banned uses (non-wire coating and professional cleaning) is estimated to be less than 3% of the identified total use of NMP, the risk reduction might be substantial as most of the identified potentially exposed workers are covered by the proposed scope[2]. However, the RCR values for these uses do not seem to be different from other uses [BD table B 177]. In terms of risks then there would seem to be no special reason for limiting the restriction to those uses/sectors.

It is difficult to properly define uses/sectors to be covered by the ban. For example, the definition of professional cleaning does not seem to be clear. It seems that in industrial cleaning processes NMP could be used directly as cleaner in the optical industry as well as cleaner (industrial) or as part of maintenance (could be professional). As the scope and applicability of the restriction to professional cleaning is not clear, further refinement of the scope would be required.

In RMO2A, the DS has introduced a condition that use of NMP in some specific sectors requires that best available techniques are adopted to reduce inhalation and dermal exposure of the substance. These sectors are: Petrochemical industries, Wire coating, Electronic and semiconductor industries, Battery industries, Filtration industries, High performance polymers, Agricultural chemicals for synthesis purposes and Pharmaceuticals. Other uses of NMP are banned.

However, SEAC notes that a specification of BAT in relation to worker protection is not given. It could be developed, but it is uncertain how fast and for which sectors they can be agreed on. In addition, technological progress would require periodical revisions of the BATs. Therefore, SEAC does not consider this a well-defined option that can be managed in practice.

In RMO2B, the DS has considered a ban of NMP for the same uses as in the RMO2A, while the exposure in remaining uses shall be managed by introducing a mandatory DNEL to be used in CSR, CSA and SDS. For these uses the restriction would be similar to the restriction proposed by RAC, but would be based on a lower DNEL value for inhalation and no DNEL value for dermal exposure.

For both RMO2A and RMO2B giving considerations to the possibly conservative nature of the exposure estimates and the limited specific data on exposure for the wider variety of uses for NMP, a ban for some uses or sectors may also be considered unnecessarily strict, and thereby costly if an introduction of additional risk management measures could reduce the RCRs below one.

In conclusion, for proposed banned uses this option would likely be more costly than necessary to address the risk adequately. For allowed uses, either the risk will not be controlled (RMO2C), not workable in practice (RMO2A) or similar to the RAC modified proposal assuming that the same DNELs were applied. Therefore, none of the RMO2 options

[2] More than 95% of those for which the DS has estimated the number total potentially exposed workers. However, the correct percentage may be lower as information for a number of sectors is not available.

seem to be more appropriate than the proposal modified by RAC.

Authorisation (RMO4)

The inclusion of NMP in Annex XIV would mean that unless a specific use has been authorised according to Article 60, the substance may not be used after the sunset date. By inclusion in Annex XIV the legislator would indicate that NMP progressively should be replaced by suitable alternative substances or technologies (Article 55). NMP is already included on the candidate list.

The authorisation approach includes the socio-economic route for cases where a risk cannot be controlled adequately. It is also an incentive to phase out the most hazardous substances, which is an aim of REACH.

Each sector (or even company) would have to evaluate its uses thoroughly, and either show safe use via a risk assessment (adequate control) or use socio-economic arguments for a continued use of a substance, the absence of technically and economically viable alternatives. All uses have to be approved and well described in the exposure scenarios, making it easy to enforce and monitor and use. The DNEL developed by RAC in the evaluation of the restriction proposal could be used as the reference DNEL for the substance.

If safe use is demonstrated, there would be no differences in the level of residual risk, compliance costs or monitoring of implementation whether an authorisation approach or a restriction route is used, as it would be possible to base the authorisation on the same conditions as in a restriction[3].

SEAC recognises that authorisation could be a good option in cases where requirements for implementation of risk reduction measures should reflect the individual circumstances, especially in the case where the socio-economic route is followed. In addition, authorisation would cover all tonnages placed on the market (as compared to the RAC modified proposal). However, authorisation does not cover the manufacture of the substance.

Due to more targeted evaluation approach the authorisations procedure is more costly, both for applicants and for the authorities. The authorisation system may seem to be resource intensive when there are very many varied uses that authorisation would have to be applied for.

EWWG[4] has indicated that especially for the new lines where safe use can be demonstrated, the authorisation approach would have a big impact on the financing of investments, in particular for an SME, as there is no guarantee that an authorisation is granted a second time. However, SEAC considers this to be a communication issue and a question when setting the length of the review period.

In conclusion, SEAC considers that the authorisation route (RMO4) might be effective and practical for some sectors and giving a constant incentive to phase out the use of a CMR substance like NMP. This could especially apply for uses where the impacts of a general restriction on the most affected companies are considered not to be proportional. An option for risk management incentives could therefore be to combine a restriction with an authorisation approach for such uses.

[3] Formally both manufacturing and use are included in the proposed restriction while authorisation only applies on uses.
[4] Answer from Eurocable winding wires group of 23 July 2014.

Application of Worker protection legislation

The proposed restriction only targets the protection of workers. Under the worker protection legalisation (WPL), an indicative OEL is already established at the EU level, at a 4 times higher level than the DNEL for exposure via inhalation proposed by RAC. Under the WPL it is also possible to establish a binding OEL.

Revising the current indicative OEL to the same value as proposed by RAC would be an option. Member States would have to reconsider their national OELs and it is reasonable to believe that most of the national OELs would be adjusted. However, it cannot be ensured that all workers would be sufficiently protected and that the same level playing field between companies would be achieved.

Setting a binding OEL under the worker protection legislation could be a risk management option, comparable to the restriction as proposed by the Dossier Submitter.

So far, only five binding OELs have been established at the EU level. The original restriction proposal is quite similar to introduction of a binding OEL.

The enforcement of a binding OEL would be well known to enforcement authorities of WPL-related legislation. An advantage is that a new binding OEL would be used and enforced in the same way as other OELs under the WPL. This option would also avoid a potential overlap in tools used between REACH and the WPL. Binding OEL-values take account of socio-economic and technical feasibility factors as well as the hazard and risk - similarly to restriction options.

There are no exposure levels for dermal exposure under the WPL. But similar to the original proposal, the Chemical Agents Directive implies that dermal exposure of NMP shall be avoided.

In conclusion, two legal instruments, REACH and the WPL, could establish similar obligations for users and manufacturers to protect against the unacceptable exposure from NMP.

Similar to the conclusion between the restriction proposed by the DS and the RAC modified proposal neither the indicative nor the binding OEL seems to offer a more appropriate RMO than the RAC-modified proposal.

Conclusion on the RMO assessment and justification for the most appropriate EU wide measure

The RAC-modified proposal follows the normal way for managing the risk from chemical substances under Title II – V of REACH ensuring safe use of chemicals once a safe level has been defined. No special enforcement activities are required.

SEAC concludes that the RAC proposal seems to be the most appropriate risk management option. It would ensure a safe use of NMP once safe exposure conditions have been identified and implemented. SEAC notes that the higher DNEL value derived by RAC implies that the restriction is significantly less costly than the proposed restriction. SEAC considers the original RMO3 as proposed by the DS to be the second best RMO, provided that exposure limit is adjusted to be in line with the DNEL value proposed by RAC.

None of the other considered RMOs are considered to be more appropriate due to the following reasons:

- RMO1 (Total ban on the manufacturing and use): Lack of feasible alternatives and considering that the risks can be sufficiently controlled by application of the RAC-modified proposal.

- RMO2 (Ban with derogations under specific conditions): For proposed banned uses the ban would be more costly than necessary to address the risk adequately. For non-banned uses, either the risk will not be controlled (RMO2c), not workable in practice (RMO2A) or similar to the RAC modified proposal (RMO 2b?) assuming that the same DNELs were applied. The partial ban of NMP is not well defined and no justification for this RMO is presented.
- RMO4 (Authorisation): If safe use is demonstrated by the applicants, there would be no differences in the level of residual risk. More costly procedures could be balanced with the aim of REACH to phase out CMR substances. However, if a restriction is considered to have major negative impacts on some part of a sector or use, the authorisation scheme may offer the socio-economic route on a case by case basis to ensure a regulation of use adapted to the possibilities for individual companies.
- Establishing a binding OEL under the worker protection legislation: Similar to the conclusion between the restrictions proposed by the DS and the RAC-modified proposal: neither the indicative nor the binding OEL seems to offer a more appropriate RMO than the RAC-modified proposal.

Proportionality to the risk

NMP is a high tonnage substance: more than 40,000-60,000 tonnes are used per year in EU. NMP is used primarily as a solvent in: petrochemical industries, non-wire coating, wire coating, in cleaners, in electronics and semiconductor industry, in production of batteries, membranes, high performance polymer producers, agricultural chemical industries, pharmaceutical industries, construction industry, in functional fluids and in laboratories. According to the BD the overall use seems to be increasing, although a decline is expected in some sectors even without further regulatory actions being taken.

As it is not possible to derive an analogous link between the developmental effects in animals and any health consequences in humans, it has not been possible to quantify the current health effects of exposure to NMP in humans, or what the effects / benefits would be following a restriction. SEAC therefore acknowledges that it is not possible to assess the change in health impacts, and that the only information available is to consider changes in exposure (risk reduction capacity) as a proxy of potential health effect changes. However, as a result it will not be possible to compare the impact on health with the costs on a commensurate basis. A cost effectiveness approach has thus been used to assess the relative merits of the different options.

The DS has selected a number of sectors for more detailed assessment and scrutiny (coating, cleaners and membranes). These account for at least 50% of the volume used, and cover sectors where a restriction could imply major costs or wider economic consequences. More than 400,000 workers potentially exposed to NMP are covered in this analysis. The number of workers is very uncertain. On the one hand an estimate of the number of workers is not available for 2/3 of the uses identified by the DS, while on the other hand it is highly uncertain how many of the 400,000 identified workers in reality are exposed to NMP in a concentration above the proposed DNEL.

SEAC considers that the RAC-modified proposal could reduce the costs of compliance for industry compared to the original proposal. Generally, the costs would be lower in cases where NMP would still be used while no change in costs would apply in cases where NMP is substituted by other substances. The lower costs are primarily a consequence of the higher DNEL value to be respected, as well as the lack of a peak exposure limit.

In this context, the DNEL value is calculated as the level where the average exposure over 8 hours would not result in any health effects. As it is an average it might be acceptable if a worker is exposed to a higher level of a substance for a part of the day, if compensated by lower exposure in the remaining part of the shift. This gives more flexibility (and thereby

potentially lower compliance costs) compared to original proposal which contained a limit for the exposure during 15 minutes at a level twice the DNEL. According to RAC there is no specific reason for setting a peak value for a substance like NMP that is proposed for restriction on the basis of repro toxicity.

In relation to the introduction of a dermal DNEL, SEAC notes that in some exposure scenarios in the already submitted registrations, the exposure is above the dermal DNEL proposed by RAC[5]. Introduction of the dermal DNEL also means that the combined risk characterisation ratio (RCR), calculated for dermal and inhalatory exposure, has to be below 1. The modelled data in the BD was developed with no respiratory protection and (for some scenarios) not the best level of skin protection. Therefore, it seems likely that use of additional affordable RMMs, including reduction of duration of exposure, may result in a satisfactory outcome. However, SEAC has not been presented with any information on the costs related to implementation of RMMs needed to bring the exposure to a level below the dermal DNEL as proposed by RAC, or related to reduction of exposure via both inhalation and dermal routes needed to achieve RCR <1.

Impacts on the wire coating sector

The wire coating sector has been identified by the DS as the sector where the proposed restriction could have the greatest impacts in relation to cost and possible wider economic impacts.

NMP is used as a solvent and also as a reactant in a specific type of enamel (Polyamide-imide – PAI[6]) used in the coating process for wires. PAI represents 2/3 of the EU market of 400,000 tons of enamelled winding wires. The use is growing (REF PC COM323). According to industry the users are SMEs. The consumption of NMP for enamelling in the EU is 4,000 – 4,500 tons per year. According to industry and available literature, no technically and economically feasible alternatives, having less hazardous properties, are available for this use.

The DS estimates that several thousands jobs are considered to be associated with coating (half involved in production, sales and distribution of magnet wire, and half associated with subcontractors, machine producers, etc).

According to the European Winding Wire Group (EWWG) representing more than 95% of the industry (REF PC COM 371) in all 20 production sites, employing about 1000 workers, only 1 woman is employed in the processes which involve exposure to NMP. However, no women are working on the wire coating machines. Therefore at present, NMP due to its reprotoxic properties does not seem to constitute a risk in this sector.

Nevertheless, implementing the DNEL values proposed by RAC may provide additional protection in relation to other health risks identified in the Background Document, such asreduced body weight (gain), reduced food consumption, general loss of wellbeing, effects on organs, eye, skin, respiratory irritation for all workers. In addition, the employment structure in the industry may change in the future, resulting in female workers employed in currently predominantly male positions.

EWWG indicated that production lines established after the 1990's are able to meet the DNEL value derived by RAC (REF PC COM 371) under normal operational conditions. However, they also indicated that in non-continuous conditions (repair of break, filling enamel tanks, cleaning operations and maintenance) the exposure limit value (5 or 10

[5] It should be recalled that in the Chemical Safety Assessment RMMs are only required to the extent that it is possible to ensure exposure below a DNEL level. As the outset for the registrants was a higher DNEL value not all RMMs that would be relevant for a lower DNEL were included. Once incorporated in the exposure scenarios the RMMs would be mandatory for most downstream users.
[6] A small fraction of NMP used for wire coating is used in other polyamide overcoatings.

mg/m^3) proposed by the DS (amended or not by the RAC decision on the DNEL) can not be met. For SEAC it is not clear whether it would be possible in these situtations to meet a limit of 10 mg/m^3 by using additional personal protection equipment or changing operational conditions.

Furthermore, EWWG indicates that it is not always possible to use adequate risk management measures, 8 hours long, for certain part of non-continuous operations, and that exposure to NMP is far above the average. Therefore, EWWG proposes that it is accepted that individual workers 10 times per year may be exposed to inhalation levels above the 10 mg/m^3 for a maximum of 8 hours. However, the industry did not provide SEAC any indication what the possible exposure levels for non-continuous operations might be. They also did not consider other methods of exposure reduction, for example job rotation / shortening of exposure duration. As the industry did not specify what would be an exposure in these exempted episodes of exposure – it is not possible to assess the proposal.

The EWWG technical group has indicated that a restriction on NMP that imposed exposure levels of 10 mg/m³ averaged over 8h, would require a high level of investment in a large number of new machines, in order to be compliant (REF PC COM303). EWWG indicates that enamelling machines using NMP typically have lifetimes of 20-30 years and that during the suggested transition period of 5 years it would only be possible to incorporate the replacement for 15-25% without exceeding the normal investment cycle costs. All new lines are state of art and able to meet the proposed requirement, so all costs are related to advanced investments.

EWWG estimates that about 50% of existing 4,000 wire coating lines already comply with the limit of 10 mg/m^3 (although there might be problems for non-continuous operations taking place up to 10 times per year for the invidual worker), implying that 2,000 lines would have to be renewed.

Within the next 6 years, which is the expected period before the restriction is implemented, imply phasing-out of non-compliant wire coating lines, further 800 lines would be replaced due to normal business cycle. Hence, 1,200 lines would have to be replaced before the normal business cycle replacement.

EWWG considers 50% of these lines to be horizontal lines, where replacement is expected to cost €150,000 € per line, and 50% to be vertical lines where replacement is expected to cost €250,000 per line. In addition, EWWG estimates installation costs to be 30,000 € per line. In 2014 prices the average replacement cost per line would then be €230,000.

A restriction would therefore mean advanced investment of total €276 M.

The advanced costs mean opportunity cost of €61,5M in total for the first 30 years which is the expected lifetime of wire coating lines.

However, investment in new production lines is considered to imply other co-benefits of buying new machines in terms of more efficient production that would off-set the costs further (capacity, running costs, etc.). As there is no information on comparative efficiency of the new production lines – it is not possible to quantify the off-set.

The DS has proposed a relatively long period of entry into force of 60 months after the inclusion into Annex XVII. The length of the proposed period is not based on specific information presented in the dossier. In the public consultation on the submitted Annex XV report, the wiring coating sector has stated that a period of 60 months is not sufficient. In consequence the DS, supported by EWWG, has proposed a prolonged derogation period for this sector (15 years).

SEAC has estimated the opportunity cost for the advanced investments in the case the restriction implies that all wire coating lines should apply with the DNEL value proposed by

RAC in specific years.

Year where lines have to comply	2020	2021	2022	2023	2024	2025	2026	2026	2027
Opportunity Costs, million €	61.5	48.5	37.5	27.5	19.4	12.8	7.6	3.7	1.2
yearly production value	2,1 %	1,6%	1,2%	0,9%	0,6%	0,4%	0,3%	0,1%	0,0%

The total production value of the wire coating sector is estimated to be €3 billion per year[7].

Therefore, SEAC considers that a prolonged implementation is not necessary, taking into account that the additional costs of advancing investments is very small compared to the production value of the sector as indicated in the table above[8]. In case later implementation should be considered, the opportunity cost for different implementation years can be found in the table above.

Impacts on the membranes sector

NMP is used as a processing aid in the production of polymer based membranes. According to the BD data gathered from literature suggest that alternatives for NMP are available even for the more solvent resistant polymers, but their technical and economic feasibility on production scale in most of the sector has not yet been shown.

The compliance cost in the membrane sector of the RAC-modified proposal is estimated to be minimal [BD, App. B]. For the initial DS proposal the compliance cost would be €20 M[9] over 15 years, including costs for extra exposure measurements.

Impacts on the battery sector

In the battery sector, NMP is used for production of electrodes for lithium batteries. Information from one company suggests that the originally proposed limit of 5 mg/m3 for inhalation is not proportional, as fundamental modifications of dryers are said to be necessary. Costs related to re-engineering of the process are said to be €1-9 M , and even then the comment (REF PC COM290) indicates that it is uncertain if the desired emission target is achieved. The comment indicated that an inhalation value limit of 20 mg/m³ with a short term exposure level (STEL) of 40 mg/m³ could be realised reliably and on a reasonable economic basis[10]. There is no information on the need to modify the machines if the inhalation exposure limit value is established at 10 mg/m³.

Another comment from this industry suggested that the proposed by the DS limits are already complied with (REF PC COM301).

SEAC therefore concludes that for the battery sectors the cost impacts of the proposed restriction are limited.

Impacts on the non-wire coating sector

NMP is used in the non-wire coating sector, especially the automotive sector, both for industrial processes (manufacturing) and by professionals (repairs). This sector comprises most of the potentially exposed workers identified as possibly exposed to NMP[11]. However,

[7] Acc. to BD, app. A. also including formulators.
[8] Note that the depreciated costs are one time costs, while the production value is yearly.
[9] Costs accumulated over 15 years, discounted by 4% p.a.
[10] No detailed information on the cost was submitted.
[11] More than 95% of those for which the DS has estimated the number total potentially exposed workers. However the correct percentage is lower as information for a number of sectors is not available.

the share of NMP used in this sector is quite low – approximately 5% of the total tonnage [BD, Annex 3]. There is no information from the public consultation on the number of workers actually exposed in this sector.

Information from industry suggests that the compliance cost in the automotive coating would be less than €20-30 M[12] [App B, 3.3.5]. SEAC has no possibility to assess the information included in the BD that a subsequent study carried out by the same consultant company indicated that the costs would be lower. No information was submitted from the sector during the public consultation.

With a restriction based on the DNELs values derived by RAC, the costs in the non-wire coating remain unchanged, as the likely response is considered to be to change to an alternative substance, irrespective of which DNEL value would be used.

Impacts for the use as cleaners

NMP is used in the optical industry as a cleaner in the production of specific equipment. One industry comment has claimed that the compliance with the DNEL value proposed by RAC would still involve unsolvable problems for the industry [BD App. B]. However, this statement has not been supported or justified during the public consultation. Information submitted by the producer of alternatives during the public consultation shows that an alternative substance has been used as optical cleaners (REF PC COM314).

NMP is also used for cleaning of spray guns in the automotive sector. For these uses NMP can be substituted with other substances / solvents used for coatings.

The DS has considered possible impacts on the production of coating in the films and medical images. However, only very limited information suggesting that alternatives might not be available was submitted to the DS. No information was submitted during the public consultation.

Impacts on uses/sectors where costs are considered to be zero or minimal

For the following uses/sectors[13] the costs are estimated to be zero or minimal: manufactures, petrochemical industries, formulators of coatings, electronic and semiconductor industries, agricultural chemical industries (formulation, synthesis), pharmaceutical industries and construction industries.

The sector manufacturing semiconductor devices (microchips) believes it can meet the proposed restriction (the DS limit value)(REF PC COM307).

Uses and sectors where no information is available

For the remaining uses and sectors, like medical images, functional fluids and laboratories, no information on cost is available.

[12] In survey costs were estimated to be incurred over two years.
[13] Table F.12.

SEAC notes that the DS has identified functional fluids as an application where there is a potential lack of alternatives, but no information was received in the PC.

The laboratory uses related to product and process orientated research and development is exempted by Article 67(1). Furthermore, the laboratory use is the only use where risk characterisation ratio is below 1.

Conclusion on proportionality

Summarising, the identified additional cost of the restriction proposed by RAC compared to the baseline is €61.5 M in the wire coating sector and €20-30 M[14] in the non-wire coating sector, while no major costs are expected in other sectors.

The health impact of NMP on workers and their new-borns cannot be quantified but RAC has identified a risk in those cases where the exposure would exceed the proposed DNEL values. Reductions in health impact from the proposed restriction cannot be calculated; only reduction of exposure can be assessed as a proxy.

Therefore, a proportionality assessment comparing costs and benefits is not possible. However, SEAC has evaluated the proposal from a cost-effectiveness point of view. SEAC considers the RAC-modified proposal to be more cost-effective than the original proposal, primarily as it is based on a higher DNEL value for inhalation and the limit for short term exposure (STEL) is deleted.

In addition, it follows the normal route for managing substances under REACH through a Chemical Safety Assessment.

As described in RMO analysis above, SEAC does not find any of other considered RMOs to be more cost effective than the RAC-modified proposal. However, this does not imply that the RAC modified proposal provides a net gain in socioeconomic welfare to society.

Practicality, incl. enforceability

For professional uses in most cases substitution with other substances is considered to be the only way in which the restriction requirement can be met, but some users may be able to afford additional safety measures and develop safe use conditions (BD, App B). For industrial and some professional uses, enclosure, local exhaust ventilation and personal protective equipment can be used in addition to substitution. Laboratory use, as presented in the BD, already fulfils the criteria of 'safe use' (RCR<1).

While the requirement to comply with RAC-modified proposal would be limited to the registrants, the users of NMP would have to implement the recommendations presented in the exposure scenarios as regards RMMs and operational conditions, in order to fulfil general REACH requirement related to downstream users. (In addition, to comply with the requirements of the worker protection legislation, inhalation exposure should be monitored at plant level.) Where the user has information that calls into question the appropriateness of the communicated RMM, such as exposure measurements above DNEL value even if the proposed RMMs are applied, the user has to inform the person responsible for the CSR (normally the supplier) thereof. The supplier might then have to update the CSR introducing further RMM (or to advise against the use). This procedure allows some flexibility in the

[14] Or lower as indicated by the AMEC (BD, app B).

implementation actions to reduce risks. In contrast to this, the proposal by the DS to specify an exposure limit in Annex XVII, would make the requirement directly applicable to the user, who in order to be in compliance would need to take immediate action to reduce exposure imposing additional costs compared to the DNEL/CSR approach. Thereby, the RAC modified proposal seems to be more flexible than the original proposal and similar to the way other similar substances are treated. SEAC does not see any justification for treating NMP differently from other similar substances.

Should the restriction based on the RAC-modified proposal be included in the Annex XVII, the enforcement would follow the same procedures as is normally used with regard to development of CSRs, SDS's and ensuring that the recommended risk management measures are implemented by the downstream user. Therefore no further enforcement activities are required due to the implementation of such restriction.

In contrast to the original proposal, costs for monitoring of exposure would not increase, as no specific value in the individual workplace would be imposed. Under the workers protection legislation it is common practice due to an EN standard that the frequency of measurements increases if the measured values are more than 1/10 of the limit value, the proposed limit values could be expected to result in higher frequency of air monitoring and thereby increased costs for monitoring.

With regard to original proposal the enforcement procedures focusing on CSR, SDS and RMM could be used as well. However, this is up to the national enforcement regimes.

In relation to the dermal protection measures under the DS proposal, the Forum has pointed out that it is unclear what "avoidance" means and indicated that this may cause enforceability problems. SEAC considers this to be a question of guidance, since worker protection legislation has similar requirements. Furthermore, most likely this can be done checking whether the recommended RMMs included in the CSR have been implemented.

In conclusion, SEAC considers that the RAC-modified proposal is fully enforceable and would not entail further enforcement activities.

Monitorability

ECHA and Members State National Enforcement Agencies (NEA) could verify if the submitted registration CSRs will be updated to include new DNEL values and updated exposure scenarios in the legislatively prescribed time, and NEAs may conduct a campaign to verify SDSs, and implementation of the amended exposure scenarios. CSRs developed by downstream users may also be verified by the NEAs. Information from the enforcement activities can be collected in order to evaluate whether the restriction as such ensure sufficient control of the exposure. Therefore, the proposal modified by RAC would be possible to monitor. SEAC also agrees with the DS that monitorability of the original proposal would not raise major concerns, as similar activities can be carried and monitoring of exposure levels already are carried out under worker protection legislation.

BASIS FOR THE OPINION

The Background Document (BD) has been reviewed in order to provide support and form a basis for this opinion. The BD has also been updated in relation to the further information presented during the public consultation and the advice given by the Forum.