Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

1-Methyl-2-pyrrolidone (NMP)

ECHA/RAC/RES-O-0000005316-76-01/F

ECHA/SEAC/RES-O-0000005316-76-02/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 5 June 2014) and SEAC's opinion (adopted 25 November 2014)

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5 June 2014

ECHA/RAC/RES-O-0000005316-76-01/F

25 November 2014

ECHA/SEAC/RES-O-0000005316-76-02/F

Opinion of the Committee for Risk Assessment

and

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 Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and 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 opinions adopted by RAC and 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 RAC

Rapporteur, appointed by RAC:	**Bert-Ove Lund**
Co-rapporteur, appointed by RAC:	**Thomasina Barron**

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The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***5 June 2014***.

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

The RAC opinion was adopted ***by consensus***.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: **Lars Fock**

Co-rapporteur, appointed by SEAC: **Åsa Thors**

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.

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation ***on 25 November 2014***.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by consensus***.

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OPINION

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***N-methylpyrrolidon*** is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the scope and conditions are modified.

The conditions of the restriction proposed by RAC are:

Substance	***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 long term Derived No Effect Level (DNEL) value for workers inhalation exposure of 10 mg/m^3 and a long term DNEL for workers dermal exposure of 4.8 mg/kg/day.

The Forum has noted the amended proposed text of the restriction, and suggested some refinements. However, as the RAC opinion presents only the conditions of the proposed restriction (see above), the suggested refinements were not introduced. Instead, the Forum advice will be made available to the Commission.

THE OPINION OF SEAC

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 ***N-methylpyrrolidon***, 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 socio-economic welfare to society.

The conditions of the restriction are the same as described in the opinion of RAC.

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

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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.

SEAC considers that for the use in wire coating lines it might be appropriate to allow longer implementation time of risk reduction measures (see discussion on *Impacts on the wire coating sector,* pages 25-27).

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JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD AND RISK

Justification for the opinion of RAC

Targeting of the information on hazard and exposure

According to the dossier submitter, the restriction proposal is focused on occupational health, as a harmonised classification proposal[1] (which was adopted by RAC at its 29th meeting[2]) is thought by the dossier submitter to result in the cessation of all consumer use because of the proposed lowering of the specific concentration limit to a level that would then make it a subject of entry 30 of Annex XVII of REACH.

Risk addressed by the proposed restriction

Information on hazard(s)

The toxicological data base for NMP is rather extensive even if focused on the two endpoints with relevance for this restriction proposal. There are twelve repeated dose toxicity studies described in the report (7 oral, 4 inhalation, and 1 dermal). For the assessment of developmental toxicity, the report describes four 2-generation studies (3 oral and 1 inhalation), as well as 7 developmental toxicity studies (3 oral, 2 inhalation, and 2 dermal). Most studies are conducted on rats, but there are a few on mice, rabbits, and dogs as well.

RAC agrees with the dossier submitter on the choice of the key studies, for which DNELs were derived. The overall conclusion based on the 17 rat studies is that the most sensitive effect of NMP concerns a decreased body weight gain, both in adults and offspring.

The key studies, for which the 'leading' DNELs were calculated, are described below, based on the summaries in the restriction proposal. These summaries are followed by the RAC assessment of the studies.

The 90 days inhalation study in rats as the basis for the worker inhalation DNEL (BASF AG 1994 (also referenced as Lee 1987 in the report)

RAC assessment: A NOAEC at 500 mg/m^3 was determined based on a statistically non-significant decrease in body weight gain of 4.8% in male rats at 1000 mg/m^3 at day 33 in a 90 days study (BASF, AG 1994). Although the decreased body weight gain was only statistically significant on day 33 (-9%) at 3000 mg/m^3, an apparent dose-response for the reduced growth rate was indicated at the time points studied (day 12, 33, 61 and 96). However, there were no signs of effects on the body weight gain of females, which perhaps could be interpreted as an inconsistency. However, also in the 2 year inhalation study (Lee et al, 1987), body weight was affected only in the males (a 6% reduction in body weight gain at 400 mg/m^3). There is no information given on body weight in the reporting of the 28 days inhalation study (Lee et al, 1987), but it is noted that excessive mortality was observed at 1000 mg/m^3. The effect on male body weight gain thus seems consistent and substance-related, although slight. Of these studies, the 90 days study is the most, and perhaps only, reliable study, as it used head-nose exposure, whereas the others used whole-body exposure, thus resulting also in oral exposure via grooming. The suggested NOAEC of 500 mg/m^3 is very conservative, and a more robust, alternative NOAEC from this

[1] Classification, Labelling & Packaging Regulation (EC) 1907/2006.
[2] Subject to a decision to implement by the Commission.

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study would be 1000 mg/m^3, based on the statistically significant 9% decrease in body weight at 3000 mg/m^3. It is noted that when the NOAEC of 500 mg/m^3 is not used a study with inhalation exposure of human volunteers (local irritation at 80 mg/m^3) would give a DNEL lower than the one calculated based on the 'new' NOAEC of 1000 mg/m^3. However, since the pregnant worker DNEL is the overall lowest DNEL and the one used in the RAC risk characterisation, other DNELs were not calculated.

The 28 days dermal study in rabbits as the basis for the worker dermal DNEL (GAF Corp. 1986)

RAC assessment: Based on the death of one of the four rabbits of the top dose (1653 mg/kg/day), the mid dose of 826 mg/kg/day was chosen as the NOAEL. There were no clinical signs of toxicity in the rabbits, which makes it difficult to know whether the death was substance related or not. Since a treatment relation cannot be excluded, the dossier submitter proposes the top dose as a LOAEL. RAC notes that some skeletal variations were observed at a dermal dose of 1000 mg/kg/day in a rabbit developmental toxicity study, and that NMP is known to be highly absorbed through the skin. There is some uncertainty regarding the cause of the death, as the substance-relationship can be questioned by the lack of other signs of toxicity on the three surviving animals (such as effects on body weight, clinical chemistry, haematology, histopathology or clinical signs). While noting this uncertainty, RAC agrees with a NOAEL of 826 mg/kg/day based on this study. RAC notes that a maternal LOAEL of 750 mg/kg/day was observed in a dermal developmental toxicity study in rats (Becci, 1992), where the maternal body weight gain was reduced by 28% during the gestation period (10 days exposure). The NOAEL was 237 mg/kg/day. The clear effect and clear substance relation make this study an alternative and more robust basis for a worker dermal NOAEL. However, the total data base for NMP indicates clearly lower LOAELs/LOAECs for pregnant than for non-pregnant animals, perhaps indicating that the apparent effect on maternal weight in pregnant dams also could be related to developmental toxicity i.e., reduced fetal weight. The rat developmental study is therefore not used as such for adult non-pregnant animals, but is considered to support the rabbit dermal NOAEL. Thus, RAC supports the (overall) NOAEL of 826 mg/kg/day.

The inhalation developmental toxicity study in rats as the basis for the pregnant worker inhalation DNEL (Sallenfait 2001)

RAC assessment: A NOAEC of 247 mg/m^3 was set based on a statistically significant 5% decrease of the fetal body weight at the next highest dose (LOAEC 494 mg/m^3). The finding is supported by an apparent dose-response at lower dose levels, but the effects on body weights were very slight. The body weight gain of the dams was also affected, with a 19% decreased weight gain over the whole gestation period at 247 and 494 mg/m^3. The effect on the fetal body weight is rather small, but the treatment relationship is supported by finding decreased pup body weights of similar magnitude at the same exposure level in a rat 2-generation study (Solomon et al 1995). Furthermore, in the 2-generation study the effect on the body weight persisted up until weaning, supporting the adversity of the effect. The relevance of the finding is also supported by the observation that effects on body weight are characteristic of NMP toxicity in rats. It is noted that all developmental toxicity studies with inhalation exposure use whole body exposure, which makes the oral contribution to exposure via grooming somewhat unclear. However, mixed exposure via several routes is mainly a problem when droplets or aerosols are being formed, i.e., at concentrations exceeding the vapour saturation concentration, which for NMP is 480-640 mg/m^3. However, exposure through other routes cannot totally be ruled out at the LOAEC of 494 mg/m^3. Overall, RAC supports the proposed NOAEC of 247 mg/m^3.

The dermal developmental toxicity study in rats as the basis for the pregnant worker dermal DNEL (FDRL 1979)

RAC assessment: The rat dermal developmental toxicity study showed clear evidence of

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fetal toxicity and malformations at the top dose (750 mg/kg/day), as exemplified by lower (body weight -18%), fewer pups (litter size -17%) and missing sternebrae (63 fetuses affected vs 1 in controls). Although dams also were clearly affected (body weight gain -28%), the pup effects seem substance-related and not an indirect consequence of maternal toxicity. Thus, RAC supports the dermal NOAEL of 237 mg/kg/day.

Discussion of relevance of health effects observed

It is quite clear that one of the most sensitive endpoints of NMP in all species and all studies is a decreased body weight (of males, females, and pups). Therefore, it is difficult to assess the contribution of maternal toxicity in the evaluation of developmental toxicity. The maternal effect in the Saillenfait studies is described in the background document (BD) as a "transient decrease in body weight gain and food consumption". Body weight gain GD 6-21 minus gravid uterine weight is the most representative measure considering the decreased pup body weights, and although there is a decrease, it is not statistically significant. Thus, the rats weighed roughly 235 g at day 0, and whereas the controls gained 32 grams, the high dose dams gained 26 gram. It seems very unlikely that this small difference could explain the decreased pup body weights, and the pup effect is therefore not likely to be a secondary unspecific effect of maternal toxicity. In the second key inhalation study, Solomon et al 1995, a similar decrease in pup body weight (as in Saillenfait 2001) is observed at a similar exposure level. However, in this case without any effects on the maternal body weight, supporting that the effects on the pups are a direct effect and not a secondary unspecific effect of maternal toxicity. There is also one oral developmental study (TSCAT 1992a) with effects on pup body weights without statistically significant effects on the dams.

As regards the human relevance of the experimental animal data, it has to be assumed that the animal data is relevant for extrapolation to humans, and there is no data to contradict this assumption. Thus, an effect on fetal growth is expected to be the most sensitive endpoint in humans, and perhaps also the only relevant effect at the exposure values presented below. An average decreased birth weight of 5%, remaining at least until weaning, was observed in the rats at the LOAEC, which in general represents a distribution among the affected animals with some not affected at all and some affected more than 5 %. A low birth weight, defined as a weight <2.5 kg at birth, has in humans been correlated to impaired development (of e.g., the neurological or immune system) and with adult conditions such as type 2 diabetes and hypertension. However, it is generally difficult to draw firm casual links between a low birth weight and a subsequent condition. Thus, it is not possible to translate the decreased birth weight observed in the animal studies into an expected outcome in humans, but rather conclude that a decreased birth weight in general may be a disadvantage for the later development of the baby and/or adult health of the individual concerned. More severe effects can occur in animals at higher NMP exposure levels, but these exposure levels would likely represent rather unusual human exposure situations such as; oral ingestion of NMP; perhaps spraying 180 degree warm NMP (which is advised against in the registration); or by continually contaminating hands and arms with liquid NMP. Thus, at the observed exposure levels, the risk most likely concerns a decreased birth weight.

Calculation of DNELs

Based on the above NOAELs and NOAECs, long-term DNELS were calculated by the dossier submitter using the assessment factors for:

Interspecies differences – factors were set according to the REACH guidance (Guidance on information requirements and chemical safety assessment – Chapter R8: Characterisation of dose [concentration]-response for human health, 2012). A factor of 2.5 was used for remaining differences (toxicodynamics), both for the inhalation and dermal routes. A factor

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of 4 was used for allometric scaling (toxicokinetics) in the calculation of the dermal DNEL, whereas no allometric scaling is needed according to the guidance for the inhalation DNEL. However, if substance-specific data is available, the default assessment factors may be adjusted. Toxicokinetic studies indicate that humans do not show higher plasma NMP levels than rats following inhalation exposure. On the contrary, there are indications that the levels in humans would actually be lower than in rats, which potentially could justify a reduction in the inter-species factor for differences in kinetics. However, quantification of this difference is difficult, because of e.g., large individual differences among humans as well as rats, and that the plasma concentration in the low dose rat study represents NMP and metabolites whereas human plasma levels only represent NMP (and not metabolites). RAC supports the interpretation of the data made by the dossier submitter, and concludes that there might be an additional margin of safety for humans caused by differences in kinetics, but that this difference cannot be quantified and translated into an adjusted assessment factor.

Intraspecies differences – the factor for workers (5) was set in line with the REACH guidance. The guidance does not specifically mention pregnant workers, but the dossier submitter used a specific assessment factor for pregnant workers based on the argument that children whom the restriction is meant to protect belong to the general population rather than to the workers. Therefore, for pregnant workers the assessment factor normally used for the general population (i.e., 10), was used. As mentioned above, there is no specific guidance concerning pregnant workers, and although many RAC members were sympathetic towards the line of reasoning proposed by the dossier submitter, it was noted that a strict interpretation of the guidance would lead to using an assessment factor of 5 also for pregnant workers. Deviating from the guidance without having a scientific basis for doing so would not be justified and could lead to inconsistencies between opinions. For reference purposes, the DNELs and RCRs representing both the dossier submitter's and RAC's recommendation are presented in the opinion but only those of RAC are used.

Study design versus human exposure situations – modification of the dose descriptors and corrections of study durations were done in line with the REACH guidance.

Inhalation exposure
The dossier submitter has proposed to use for derivation of DNEL a NOAEC of 500 mg/m^3 based on the 90 day inhalation study, with decreased body weight gain as a relevant effect. The resulting DNEL value would be 10 mg/m^3. RAC notes that this NOAEC is a very conservative one, because the effect at the next higher concentration (1000 mg/m^3) was very slight and not statistically significant.

RAC proposes that a more robust worker inhalation NOAEC based on this study would be 1000 mg/m^3 (based on a statistically significant effect on the body weight at the next higher concentration), resulting in a DNEL of 20 mg/m^3. This DNEL was used in calculating RCRs in table 2 below. It is noted that the local irritation observed at 80 mg/m^3 in human volunteers in the Bader et al (2007) inhalation study would give a DNEL (16 mg/m^3) similar to, although slightly lower than, the one calculated based on the selected NOAEC of 1000 mg/m^3. No RCR-calculations were, however, performed using this DNEL as RAC was of the view that the 'pregnant' worker DNEL should be used for all workers.

The NOAEC proposed for pregnant workers (247 mg/m^3), based on developmental toxicity study demonstrating decrease of the fetal body weight, is supported by RAC, but RAC has re-calculated the DNEL for pregnant workers based on an assessment factor of 5 for intraspecies differences (rather than 10 as proposed by the dossier submitter), resulting in an inhalation DNEL of 10 mg/m^3 rather than the proposed DNEL for pregnant workers of 5 mg/m^3.

Dermal exposure
The dossier submitter proposes a NOAEL on 826 mg/kg/day for workers based on a dermal

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4 weeks study in rabbits, where 1 out of four rabbits died at the next higher (i.e., the top) dose. For pregnant workers a NOAEL on 237 mg/kg/day (based on a dermal developmental toxicity study demonstrating fetal toxicity and malformations) is proposed based on a dermal developmental study in rats with clear toxic effects at the next higher (i.e., the top) dose. Based on these NOAELs, DNELs on 4.6 and 2.4 mg/kg/day were calculated.

RAC supports the NOAELs as such, but has re-calculated the DNEL for pregnant workers based on an assessment factor of 5 for intraspecies differences (rather than 10 as proposed by the dossier submitter), resulting in a dermal DNEL for pregnant workers of 4.8 mg/kg/day (using assessment factors of 2.5x4x5). It is noted that the dermal DNELs for workers and pregnant workers are almost identical, but considering the uncertainty concerning the rabbit study that is the basis for the worker DNEL (the substance-relationship for the single death can be questioned by the lack of signs of toxicity on the three surviving animals), RAC is of the opinion that the dermal DNEL of 4.8 mg/kg/day is the more robust DNEL.

In the opinion of RAC, the DNELs calculated for pregnant workers should be used for all workers. Thus, the alternative DNELs supported by RAC can be seen (in bold) in the right hand column in table 1 below, i.e., an inhalation DNEL of 10 mg/m^3 and a dermal DNEL of 4.8 mg/kg/day.

Table 1. Long term inhalation and dermal DNELs for workers and pregnant workers, as proposed by the dossier submitter and calculated by RAC, respectively

	Dossier proposal		DNEL based on AF=5	
	Workers (AF=5)	Pregnant workers (AF=10)	Workers	Pregnant workers
Inhalation DNEL (mg/m^3)	10	5.0	20	**10**
Dermal DNEL (mg/kg/day)	4.6	2.4	4.6	**4.8**

Considering that the leading health effect is related to reprotoxic properties of the substance, RAC did not consider it as necessary to develop DNELs for short-term exposure. In addition, even though the substance is volatile, it does not have significant acute toxicity that would justify such a short term value.

The equivalent DNELs used in the registration dossiers by industry were 40 mg/m^3 for inhalation (based on the iOEL recommended by the SCOEL, 2007) and 19.8 mg/kg/day for the dermal route.

The iOEL recommended by the SCOEL is set based on NOAECs for developmental toxicity in the range of 206-500 mg/m^3. The SCOEL applied an uncertainty (assessment) factor of 5 on the lowest NOAEC of 206 mg/m^3 (Solomon et al 1995), giving an iOEL of 40 mg/m^3. The reasons for choosing the factor 5 were not given. The inhalation DNEL proposed by RAC is based on the same studies, but using the Saillenfait study (2001) as the starting point (NOAEC 247 mg/m^3). Assessment factors (2.5x5) and dose corrections ((6/8)x(6.7/10)) as recommended by the REACH guidance have been applied. The assessment factors are for remaining differences in sensitivity (2.5) and for intraspecies differences (5). The NOAEC is corrected for the animal exposure being 6 hours per day in contrast to an 8 hour working day, and for different inhalation volumes for rats at rest (6.7 m^3) and humans at light work (10 m^3).

Under the provisions of worker protection legislation, dermal occupational exposure limits

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are not established. A skin notation is included with the OEL for NMP.

Information on emissions and exposures

There is a significant variety of uses of NMP, and the number of occupational settings where NMP is used is therefore very large, as is the number of workers potentially exposed to NMP.

Exposure was assessed for the following industrial uses: manufacture, importers and suppliers, chemical industry processes (generic use for synthesis processes), formulators (generic use for production of mixtures and articles), coaters, cleaners, laboratory use, functional fluids, and use in construction industry. Professional uses included importers and suppliers, formulators, coaters, laboratory use, agrochemical use and use in functional fluids. Charging and discharging of NMP is a generic process applied in both industrial and professional settings.

It is impossible to get detailed exposure information from all these, possibly, thousands of occupational settings, covering all workers. Therefore, the background document is based on the registration dossiers using modelled data, developed with the first tier assessment tool EasyTRA 3.5. The use of modelled data may better reflect the exposures resulting from the use of a substance in a wide variety of industrial and professional settings, in many countries. The registration dossiers demonstrate safe use in most scenarios with the 1st tier exposure modelling tool, and refinement using more detailed, higher tier models was pursued in very few cases (Table B.70 – non-wire coating and Table B.80 – agrochemicals). Some measured data is available and discussed in the restriction dossier, but it is difficult to know how representative measured data are for such a widely used substance.

The most reliable exposure estimates available are those from the registration dossier. According to the registration information referred to in the Annex XV restriction dossier, local exhaust ventilation (80, 90, or 95% efficiency) is used in some scenarios but not in others. The duration of exposure varies between 1 and 8 hours. The concentration (weight fraction) is normally set at 1, but in a few cases 0.5 or 0.25 was used (where mixtures would be used). Gloves with either 80 or 95% protection efficiency are used in some exposure scenarios, but there are also scenarios where gloves are not used. Respiratory protective equipment is not used in any of the scenarios. Overall, the impression is that the registrants have tried to describe the exposure scenarios reflecting current working practices as far as possible.

For industrial uses, the inhalation exposure levels ranged from 0.04 to 20.65 mg/m^3 and dermal exposure ranged from 0.03 to 5.49 mg/kg bw/day. For professional uses, the exposure levels ranged from 2.97 to 20.65 mg/m^3 for inhalation and from 0.14 to 5.38 mg/kg bw/day for dermal exposure.

Some information on exposure and working conditions has been provided during the public consultation, especially from a few companies in the wire coating and battery sectors, but the information does not in general contradict the current exposure assessment. However, some comments indicate routine use of respiratory protective equipment. It is noted that the wire coating sector is considered to use a very large share of the total volume of NMP in Europe. This sector claimed to have significant difficulties with reducing exposure to the DNEL levels.

RAC is of the opinion that the exposure estimates presented in the restriction dossier can be used as the basis for the risk characterisation, because the modelling seems sufficiently adequate and may acceptably represent the average conditions of a high number of occupational settings.

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The substance evaluation process may provide an opportunity to collect measured exposure data from a number of occupational settings. This data may provide a basis for a better risk assessment, but is not a risk management option as such.

Characterisation of risk(s)

Based on the DNELs presented above, calculated by the dossier submitter and RAC, respectively, and the exposure estimates from the registration dossier, RCRs are calculated and presented below in table 2. It is concluded that the RCR values for workers and pregnant workers are >1 for most scenarios. More specifically, using the DNELs calculated by RAC, 12 and 13 out of 15 scenarios for workers and pregnant workers, respectively, have RCRs>1. The contribution from the inhalation route is generally higher than that from the dermal route, and the combined exposure gives RCR that range between 0.3 and 2.6 for pregnant workers, with the majority of them above or around 2. For workers, and using the alternative inhalation DNEL proposed by RAC, the combined exposure gives RCR that range between 0.2 and 1.6, with 12 of 15 scenarios exceeding an RCR of 1.

The higher alternative RCRs (based on the standard AFs) for pregnant workers than for workers is a result of getting lower NOAELs/NOAECs in reproductive toxicity studies than in conventional long term studies. **In the opinion of RAC, the DNELs calculated for pregnant workers based on developmental toxicity studies should be used for all workers.** This is also the approach used by the SCOEL in setting their inhalation iOEL for NMP based on developmental toxicity studies.

Table 2. RCRs as calculated in the restriction proposal and RCRs calculated by RAC. In both cases, the RCRs represent combined exposure via inhalation and the dermal route.

	Combined RCRs in the proposal of the dossier submitter		**RAC derived RCRs**	
	Workers	**Pregnant workers**	**Workers**	**Pregnant workers**
Industrial uses				
Manufacturers	1.39	2.77	0.77	1.38
Charging and discharging	2.33	4.61	1.47	2.31
Chemical industry processes	2.22	4.42	1.18	2.21
Formulation	2.66	5.27	1.63	2.64
Coating processes	2.25	4.46	1.32	2.23
Cleaning processes	2.25	4.46	1.32	2.23
Laboratory use	0.28	0.56	0.17	0.28
Functional fluids	2.02	3.94	1.60	1.97
Construction chemicals	1.61	3.18	1.40	1.59
Professional uses				
Charging and discharging	2.33	4.61	1.47	2.31
Formulation	2.33	4.61	1.47	2.31
Coating process	1.74	3.46	1.02	1.73
Agricultural chemical industry	1.70	3.30	1.44	1.65
Laboratories	0.49	0.97	0.28	0.48
Functional fluids	2.44	4.84	1.40	2.43

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In some cases, according to the modelling being used, the RCRs could be reduced below 1 by considering additional RMMs (such as extraction ventilation or respiratory protective equipment), or change of duration of exposure (currently assumed to be 8 hours a day in most scenarios).

While it is noted that the modelling used is likely to be of a conservative nature (a first tier modelling tool is used) and may have overestimated the exposure, there is a significant number of occupational settings using NMP, therefore the exposure assessments are likely to be relevant for some, or even many, of these settings.

The DNELs for the pregnant workers are robust, and the concern for (pregnant) workers is hence supported by RAC.

It is therefore concluded that the risk characterisation shows that risks for (pregnant) workers are not sufficiently controlled, and that the risk assessment shows that further risk management measures (than those expressed to be used in the registration dossier) are needed.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Justification for the opinion of RAC

The large number of different uses of NMP, the large number of occupational settings in many different EU member states where NMP is used, and the large number of workers potentially exposed to NMP are reasons for EU wide action. Furthermore, it is noted that although there is an indicative occupational exposure limit (iOEL) proposed on the EU level, the national OELs vary greatly (10-fold) indicating varying levels of protection among workers in the EU, as described in the background document. Conditions as proposed in the restriction would be identical and applicable in all Member States, ensuring a uniform level of protection to the population at risk through the European Union.

Justification for the opinion of SEAC

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.

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

Justification for the opinion of RAC

The baseline

The baseline with which to compare the Risk Management Options (RMOs) below is that no restrictions on the use of NMP would be implemented. This would mean that the national OELs, implementing the EU iOEL of 40 mg/m^3, would remain as the main risk management measure. However, they vary between 20 and 200 mg/m^3, which can be compared with the DNEL of 10 mg/m^3 as proposed by RAC.

No additional enforcement or monitoring would be conducted and no further risk management measures would be introduced. When compared to the RAC DNEL, based on the REACH methodology, the current OELs set in Member States are not sufficient to protect workers.

The baseline situation is therefore that the existing legislative framework does not require further reduction of exposure of workers and considering that most RCRs are >1, the baseline situation will not be effective in reducing the risks (zero effectiveness). It is possible that some registrants would voluntarily introduce the RAC DNEL. However, as it would not be a mandatory requirement, this cannot be taken into account.

Risk Management Option (RMO) analysis

The Background Document discusses several different risk management options. A brief analysis of these options, presenting their effectiveness, enforceability and monitorability is given in Annex I.

It should be noted that of all the options presented, RAC is of the view that the DNELs proposed by the dossier submitter should be replaced with an inhalation DNEL of 10 mg/m^3 and, where applicable, a dermal DNEL of 4.8 mg/kg/day should be used.

The following is therefore an analysis of the dossier submitter's proposal and the amended RMO 3, recommended by RAC.

The restriction proposed by the dossier submitter

The restriction proposed by the dossier submitter is based on imposing a harmonised inhalation exposure limit and a general requirement to protect against dermal exposure in the Annex XVII entry.

Advantages

The inhalation exposure limit should be applied in all sectors and for all uses, and is expected to be effective, although only after the proposed 5 years delay of entry into force. Enforcement will focus on compliance with the air concentration limit (as this is included in the wording of the proposed restriction) and is to be established by air monitoring. The obligation imposed by the restriction (to have exposure below the exposure limit) is on the users of NMP, not the registrants.

Article 31(9) of the REACH Regulation requires updating of safety data sheets (and their annexes containing exposure scenarios) once a restriction has been imposed by clearly

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stating the new exposure limit.

In addition, Annex I, paragraph 0.5, states that the registrants have to take into consideration 'where available and appropriate, an **assessment** carried out under EU legislation (…)', and reflect it in the CSR.

With reference to Annex I, the RAC opinion and the DNELs proposed therein can be considered to represent an assessment, and registrants therefore have to take the DNELs into consideration in their CSR. This may result in registrants amending the DNEL used in their CSRs (by choosing the RAC DNELs for inhalation and dermal effects), or providing a justification as to why they do not consider it appropriate to do so. If they would use the DNEL derived by RAC, it may lead to recommendation of enhanced (compared to currently used) risk management measures in the exposure scenarios annexed to the safety data sheets. This would not directly aid the enforcement of the restriction itself (an exposure level) but would likely assist the users to comply with the exposure level and lead to a human health benefits.

Disadvantages

The Forum has identified some issues concerning air monitoring and chemical analysis, both with regard to defining methods (different methods are available) and with regard to a perceived lack of experience in enforcement of OELs among REACH enforcers.

The dossier submitter proposed to include a general requirement to protect against dermal exposure, similar to the requirements under the chemical agents directive. Thus, dermal exposure should be avoided according to the proposal, but the Forum has pointed out that this may cause enforceability problems as it is unclear what avoidance means (using gloves, zero dermal exposure, or other limit values?).

In addition, it is noted that binding OEL values are developed under worker protection legislative framework, as discussed in Annex I, thus imposing effectively a REACH-equivalent to a binding OEL in contradiction to an existing OEL (under OSH legislation) could cause confusion amongst the users of the substance.

<u>The modified RMO 3 proposed by RAC</u>

RAC has modified the RMO3[3]. According to this modification, the entry in Annex XVII would state that the inhalation and dermal DNELs set by RAC shall be used by existing registrants (requiring updating of their CSRs), by new registrants, and by downstream users in their CSRs.

Advantages

In contrast to the restriction proposed by the dossier submitter and other RMOs proposing use of an inhalation DNEL (RMO2b and RMO3), RAC proposes to also include the dermal DNEL in the restriction wording. It would highlight the need to protect against dermal exposure and the exposure scenarios would then have to suggest concrete and use-specific risk management measures to reduce the dermal exposure (e.g., engineering controls or type and thickness of gloves limiting exposure potential). While the dermal risk

[3] Option 3 proposed by the dossier submitter (see also Annex 1) defines a mandatory inhalation DNEL, which in combination with protection measures for dermal exposure would have to be used by current registrants in updating the CSRs and by new registrants. The RMMs required to reduce the inhalatory exposure to below the DNEL level would be listed in the exposure scenarios (ESs) and passed on with safety data sheets to downstream users. This option would be applicable to all registered uses, irrespective of how they are defined.

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management measures recommended may not be different than those used when applying the chemical agents directive (or requiring avoiding dermal exposure), it is an advantage from a risk and enforcement point of view to assess the risk in a quantitative manner and have the dermal risk management measures specified in the exposure scenarios.

Additional advantages are that:

- the use of RAC-developed DNELs in updating of the CSRs should ensure that risk management measures, for inhalation and dermal exposure, defined on the basis of a quantitative assessment, are introduced / recommended for all uses until the RCR is below one,

- this option will not require other enforcement approaches than those currently in place for enforcing registration requirements related to CSRs and implementation of ESs in different member states, and

- that monitorability can be ensured by primarily, checking by ECHA and / or National Enforcement Authorities (NEA) that registration dossiers were updated, and checking of the Safety Data Sheets by the Member State National Enforcement Authorities.

Disadvantages

A disadvantage is that effective RMMs would be recommended only for import and manufacture requiring a CSR, i.e. ≥10 tonnes/year, so triggering the development of exposure scenarios. However, according to an analysis of information provided in registrations, the volume of substances manufactured or imported between 1 and 10 tonnes constitutes <1% of the total volume of NMP used in the EU. The SDSs issued by those registrants would have to include the DNEL value proposed in the restriction, even though exposure scenarios would not be included. It is expected that the lowest benchmark level is applied, in this case the DNEL. In the worst case - the workplaces where these volumes are handled would still have to apply the provisions of the current national worker protection legislation, including the national OEL.

Conclusion of the RMO analysis

All of the RMOs presented in Annex I and in the background document have their advantages and disadvantages. However, this analysis indicates that the RMO3 with the modifications proposed by RAC may be the best of the options considered.

Based on the assumption that the 'RAC's DNEL' will be used, the restriction proposed by the dossier submitter as well as RMO 3 could be good ways forward, as they apply to all uses. However, in the dossier submitter's proposal, the dermal exposure would not be meaningfully addressed, and there could be issues concerning enforceability. If it would be possible to clearly define which uses/sectors to include or exclude, option 2B could also be considered as a starting point for a restriction. A binding OEL has some advantages, but as it would be developed under a different legislative framework, it seems not realistic at present.

Of all the options considered it would seem to RAC, that the modified RMO 3 has the most advantages, as it is based on the normal REACH approaches.

RAC therefore recommends that the modified RMO 3 is an appropriate EU wide measure to be implemented in order to reduce the risk posed by NMP in the workplace. The modified RMO 3 requires use of DNEL for dermal and inhalatory exposure to be included in the chemical safety assessments and in the safety data sheets by all relevant actors

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(manufacturers, importers and downstream users). This restriction is expected to affect all uses and sectors where the RCR is currently above 1, by requiring introduction of additional risk management measures, communicated in exposure scenarios, until worker exposure is below the inhalation and dermal DNELs. Safety Data Sheets provided for users relaying on the suppliers not developing CSR (manufacture or import <10t), will include DNEL levels for both inhalation and dermal exposure. It is expected that they will be used in the evaluation of exposure.

The following sections (effectiveness, practicability and monitorability) reflect that recommendation.

In addition, RAC would suggest that ECHA, 1 year after entry into force of the restriction, initiate a targeted compliance check to verify that the DNELs introduced in the Annex XVII entry were used in development of the Exposure Scenarios in the registration dossiers of NMP, as due to the implementation of RMO 3 (modified), registrants will have to update and resubmit their registrations for the substance under Article 22 of REACH.

Justification for the opinion of SEAC

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 the 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 (or in some cases directly through 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

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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. However, SEAC considers that for the use of NMP in wire coating lines it might be justified to extend the deadline for implementation of risk reduction measures due to the impacts an earlier implementation date could have on this sector.

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 3 below the different components and main features of the considered RMOs are summarised.

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Table 3. 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	Only	Exposure limit	Authorisation	
Exposure limit value for inhalation					**DS**	(X)[4]	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

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

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economical alternatives have been identified, while remaining uses would be allowed. The 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[5]. 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

[5] 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.

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proposal assuming that the same DNELs were applied. Therefore, none of the RMO2 options 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 the 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[6].

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[7] 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 following a review. This was repeated in the consultation on the draft opinion. However, SEAC considers this to be a communication issue and a question when setting the length of the review period.

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

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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 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.

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 Titles 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

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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.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

The proposed restriction defines mandatory inhalation and dermal DNELs, which would have to be used by current registrants in updating the CSRs, by new registrants and downstream users developing own CSRs. The operational conditions and RMMs required to reduce the inhalatory and dermal exposure to levels below the DNEL would be listed in the exposure scenarios (ESs) and passed on with safety data sheets to downstream users. This option would be applicable to all uses, irrespective of how they are defined. The proposed wording of the restriction also requires use of the RAC–proposed DNELs for inhalation and dermal exposure in safety data sheets by those, who do not have an obligation to develop CSRs.

The registrants have an obligation to provide updates to their registrations when the CSR is changed (Article 22(g) of REACH). As a result of the incorporation of the DNEL values in the CSR, safe use (RCR<1) will have to be described for all uses presented in the CSR. The risk reduction measures proposed by the registrants to protect against inhalation and dermal exposure are communicated in the exposure scenarios annexed to the safety data sheets - communication tools already being used for this purpose. While implementation of the recommended RMMs is not a requirement of the proposed restriction, it would be a result of it, and would bring along a desired risk reduction.

This option applies to manufacture, placing on the market (including import) and use of the substance (as in the option proposed by the dossier submitter).

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The Forum has noted that the enforcement of this restriction proposal would lead to compliance with an update of the registration documentation related to the use of substance as such and in mixtures. However, as also noted by RAC, the risk reduction will not be directly achieved through compliance with the restriction. As pointed out by RAC, the identified risks will be reduced through the implementation of the conditions of use described in the updated exposure scenarios by downstream users.

Proportionality to the risk

Justification for the opinion of SEAC

NMP is a high tonnage substance: more than 40,000-60,000 tonnes are used per year in the 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 the 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.

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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[8]. 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[9]) 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 as reduced body weight (gain), reduced food consumption, general loss of wellbeing, effects on organs, eyes, 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 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.

[8] 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.

[9] A small fraction of NMP used for wire coating is used in other polyamide overcoatings.

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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[10] 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.

According to information submitted by EWWG in the consultation on the draft opinion the total yearly production value (PV) of the wire coating sector is estimated to be €3 billion, of which €2.4 billion is directly linked to the cost of copper, which is said to be transferred directly to customers. Assuming a constant production value, the total discounted production value of following 15 years (half of expected lifetime of wire coating lines) would be €33 billion and the discounted PV not counting copper would be €6.7 billion. [11]

The ratio between the opportunity costs[12] and the discounted $PV_{15\ years}$ is 0.2% and 0.9% respectively.

[10] Cf BD, table 15a.
[11] Information to SEAC members. Discounted total PV of 15 years production value of €600M per year, using an interest rate of 4%.
[12] Without taking co-benefits into consideration.

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In evaluating this ratio it should be taken into consideration that the opportunity costs are attributable to the wire coating lines established before 2000 that represent about 1/3 of the total number. SEAC has no information on how much these old lines contribute to in terms of the production value, but for these lines the opportunity cost/production value ratio will be higher than the calculated 0.2% and 0.9%.

According to EWWG the sector is a low profit industry, making it difficult for individual companies to bear high costs.

This was the reason for the DS to propose 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 supported by specific information presented in the dossier. In the public consultation on the submitted Annex XV report, the wire coating sector has stated that a period of 60 months is not sufficient and EWWG has proposed a prolonged derogation period for this sector (15 years). In the consultation of the draft opinion, EWWG has indicated again that a longer transition period is essential.

SEAC has estimated the opportunity cost for the advanced investments in case extension of the deadline for implementation of risk reduction measures should be considered.

Table 4: Opportunity costs per year

Year where lines have to comply	2020	2021	2022	2023	2024	2025	2026	2026	2027
Opportunity Costs[13], million €	61.5	48.5	37.5	27.5	19.4	12.8	7.6	3.7	1.2

Due to the uncertainty with regard to the economic feasibility it is not possible for SEAC to conclude on whether the costs are bearable or not for the whole wire coating industry and in particular for the individual companies of concern. SEAC therefore considers that for this use it might be justified to extend the deadline for implemention of required risk reduction measures (see Table 4 above[14]).

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[15] 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

[13] Not taking into account other non-quantified benefits of renewal of machinery.
[14] To refine the exemption further it could be considered only to let the postponement apply for wire coating lines established after e.g. 1995, thereby the oldest lines with the less remaining value would have to be renewed anyway.
[15] Costs accumulated over 15 years, discounted by 4% p.a.

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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[16]. 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 limits proposed by the DS are already complied with (REF PC COM301).

SEAC therefore concludes that for the battery sector 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[17]. However, 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[18] [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.

[16] No detailed information on the cost was submitted.
[17] More than 95% of those for which the DS has estimated the total number of potentially exposed workers. However, the correct percentage is lower as information for a number of sectors is not available.
[18] In the survey the costs were estimated to be incurred over two years.

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

For the following uses/sectors[19] 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.

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[20] 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 the RMO analysis above, SEAC does not find any of the 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 socio-economic welfare to society.

[19] Table F.12.
[20] Or lower as indicated by AMEC (BD, app B).

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Practicality, including enforceability

Justification for the opinion of RAC

The modified RMO 3 is similar to the restriction wording proposed by the dossier submitter, but with the important difference that it would require enforcers to enforce the provisions related to CSRs and verify implementation of conditions presented in exposure scenarios rather than focusing on enforcing compliance with an air concentration limit (as presented in the proposed wording of the restriction), to be established by air monitoring. In addition, dermal exposure would be evaluated quantatively in the CSR and specific RMMs would be proposed in the ESs. It seems to be an advantage from an enforcement point of view.

The compliance with the proposed restriction could be verified at two levels. The registration dossiers and CSRs would have to be amended, to include proposed DNEL levels (a requirement under Article 22(g) of the REACH Regulation). This requirement would also apply to downstream users developing own CSRs (Art 37 of REACH). Therefore, exposure scenarios will have to be modified to describe conditions of safe use (RCR<1). Then, the conditions described in the exposure scenarios would have to be communicated to and implemented at the use sites. The manufacturers and importers that do not have to develop CSR will have to include relevant DNELs in their SDSs.

The compliance with the restriction requirement could be assessed by checking of the registration dossiers (ECHA and NEA), and by checking that the DNELs are stated in the SDS.

The enforcement of exposure scenarios (attached to the SDS), based on the implementation of set DNELs, by Member State National Enforcement Authority would not differ from enforcement of general provisions of REACH related to implementation of conditions presented in the exposure scenarios, and would not be a part of the enforcement of the restriction. Nevertheless, the implementation of RMMs presented in the Exposure Scenarios is essential to achieve the risk reduction by this restriction.

Including a dermal DNEL in the restriction proposal removes for the user and enforcement agency any ambiguities related to the type of RMMs needed to establish safe level of dermal exposure (compared to the option proposed by the dossier submitter).

The Forum did not raise any issues with practicability or enforcement of this restriction proposal.

Justification for the opinion of SEAC

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 the 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 a general REACH requirement related to downstream users. (In addition, to comply with the

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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 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, SDSs 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 by 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

Justification for the opinion of RAC

Registrants should provide updates to their registrations when the CSR is changed (Article 22.g of REACH); it would be relatively easy to identify if this has been done by current registrants. The DNEL levels used in the new registrations could also be easily checked.

Downstream users developing own CSRs have an obligation to notify ECHA that their use is not covered by the CSR of the registrant. Therefore, they are known, and their CSR can also be examined by the NEA.

The compliance with the requirement to include relevant DNEL values in the SDSs could be verified by the Member State National Enforcement Authorities.

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It is noted that there is currently limited experience on how well enforcement of registrations and exposure scenarios works in practice. It is therefore suggested to have an EU-wide enforcement project on NMP 3 years after entry into force, focusing on verification of the DNEL values used in SDSs and implementation of exposure scenario conditions by users of the substance.

Justification for the opinion of SEAC

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 ensures 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 out and monitoring of exposure levels is already carried out under the worker protection legislation.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

The main changes introduced in the restriction as suggested in this opinion compared to the restrictions proposed in the Annex XV restriction dossier submitted by the Netherlands are:

- The proposed inhalation DNEL has been revised (10 rather than 5 mg/m^3).
- A dermal DNEL has been introduced to the restriction text proposal.
- Rather than stating an air concentration limit to be established by air monitoring (analogous the iOEL), the proposed restriction defines mandatory DNELs, which would have to be used by current registrants in updating the CSRs and by new registrants, as well as by downstream users, preparing their own CSRs. The RMMs required reducing the inhalatory and dermal exposure to below the DNEL levels would be listed in the exposure scenarios (ESs) and passed on with safety data sheets to downstream users.
- A requirement to include the proposed RAC DNEL values for inhalation and dermal exposure to Safety Data Sheets prepared by all relevant actors (manufacturers, importers and downstream users) is added.

The basis for these changes is:

- That RAC has chosen to use assessment factors as proposed in the REACH guidance.
- A dermal DNEL is already used in the current CSR and its inclusion in the restriction would highlight the need to protect against dermal exposure; the exposure scenarios would then have to suggest concrete and use-specific risk management measures to reduce the dermal exposure, removing the ambiguities present in the original proposal.

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- The approach for producing the CSR and ESs is well known; risks have to be dealt with when encountered (such as when RCRs >1) by introducing further risk management measures or adjusting operational conditions. The risk reduction measures proposed are easy to communicate to the users in the supply chain as they have to be included in the exposure scenarios annexed to the safety data sheets, which are communication tools already being used currently for this purpose.

- To ensure that even when there is no requirement to prepare a CSR, proposed in the restriction DNEL values are included in the SDSs (e.g.: registrations <10t, substance recycling).

Basis for the opinion of SEAC

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.

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Annex I: Risk Management Option Analysis for 'other' RMOs

RMO 1

This RMO proposes a total ban on the use of NMP (option 1).

Advantages

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

Disadvantages

The calculated RCR values would indicate that less severe measures could adequately address the concern. There are some uses and occupational settings that can already use NMP in a safe way (that is, RCR is <1). A total ban would not differentiate between workplaces on the basis of risk and so is unlikely to be proportionate related to the risks.

RMO 2

The dossier discusses three different versions of this RMO proposing restriction of some uses/sectors where alternatives seem to be available (options 2A, 2B, and 2C), while derogating other uses.

In options 2A and 2B, the derogated uses/sectors are listed. These derogated uses are allowed only if they occur in controlled closed systems or with best available techniques (BAT) implemented (option 2A) or if a CSR based on the proposed inhalation DNEL can demonstrate safe use (option 2B). Uses/sectors not derogated are banned, which includes six applications discussed in the dossier (non-wire coating, professional cleaning, agrochemical formulation, construction materials, functional fluids, and laboratory uses) as well as uses/sectors which were not identified by the dossier submitter in their analysis or 'new' uses that could become desirable in the future. It is noted that the risk assessment indicates no concern for laboratory settings (RCR<1), so it may be a mistake in the dossier not to include laboratory uses among derogated uses.

Option 2C is a targeted restriction on four specified uses/sectors where alternatives are thought to be available (non-wire coating, professional cleaning, agrochemical formulation, and construction materials), with all other uses allowed irrespective of RCRs (including those with RCR>1). Based on volume, the allowed uses would make up the majority of the total tonnage.

Advantages

Partial bans in options 2A-2C would be efficient measures, assuming that the banned and derogated uses/sectors could be properly defined.

Option 2B would be easy to implement as enforcement of the CSR would rely on approaches currently being used to enforce REACH registrations (see also option 3 below) and the introduction of additional risk management measures will be risk based, i.e., only needed when RCRs are >1.

Disadvantages

The main drawback with option 2A is that the "BATs to reduce inhalation and dermal exposure" are not defined, which is likely to affect enforceability. Also, since BATs are not defined, it is difficult to assess the effectiveness of the control of the risk in the allowed uses, although banning the other uses is clearly an effective measure. BATs could be

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developed, but it is not clear how fast and for which sectors they can be agreed on. Technological progress would require periodical revisions of the BATs.

Option 2B only focuses on limiting the inhalation exposure (just as the iOEL) and as dermal exposure can contribute significantly to the exposure to NMP, this is a disadvantage from an effectiveness perspective; the need for risk management measures would be quantitatively assessed only for inhalation exposure. In addition, only import and manufacture requiring a CSR, i.e. ≥10 tonnes/year, would be affected by the restriction. However, according to an analysis of information provided in registrations, the volume of substances manufactured or imported between 1 and 10 tonnes constitutes <1% of the total volume of NMP used in the EU. The SDSs issued by those registrants would have to include the DNEL value proposed in the restriction (REACH, Article 31, 9c), even though exposure scenarios would still not need to be included. It is expected that the lowest benchmark value would be used for exposure assessment by the user. In the worst case scenario, the provisions of the current national worker protection legislation, including the national OEL would be used.

It is difficult to properly define the uses/sectors to be included in the ban or derogated as proposed in RMO2c. For example, a restricted use such as professional cleaning may occur in all different sectors, including allowed sectors, making enforcement difficult unless the banned uses can be defined very clearly. This uncertainty makes it difficult to estimate the effectiveness, both with regard to volumes affected and number of workers affected. Professional cleaning on the one hand represents a very small part of the total volume of NMP (approx. 5%, BD, Annex III), but on the other hand a very significant proportion (more than 50%, BD, Table F.05A) of workers potentially exposed to NMP belong to the use category 'professional cleaning', especially if cleaning in the automotive sector is also included. The efficiency of this RMO will depend on the extent to which cleaning is included in the ban, which at present is unclear as it occurs also in allowed sectors.

Therefore, the main problem with these three options (2A-C) is that it is difficult to clearly define the uses/sectors to be included or derogated, and as mentioned above, a use such as professional cleaning may occur in many different sectors. This will affect both the enforceability and the monitorability. These three alternative options may result in risk reduction in some uses/sectors, and not in others, but the reduction will depend on the availability of alternatives and not on whether there is a concern or not for a particular use/sector (e.g. 2C). The effectiveness in reducing the identified risks could, therefore, be challenged. Giving consideration to the possibly conservative nature of the exposure estimates and the limited specific data on exposure for the wide variety of uses of NMP, a total ban for some uses/sectors may also be considered unnecessarily strict, if instead introduction of additional risk management measures could reduce the RCRs below one.

RMO 3

Option 3 proposes to define an inhalation DNEL, which in combination with protection measures for dermal exposure would have to be used by the registrants in updating the CSRs and by new registrants. The RMMs required to reduce the inhalatory exposure to below the DNEL level would be listed in the exposure scenarios (ESs) and passed on with safety data sheets to downstream users. This option would be applicable to all registered uses, irrespective of how they are defined.

Advantages

Option 3 is the basis of the restriction wording proposed by the dossier submitter, as discussed in the opinion. However, the important difference is that in this option it would be required to enforce the provisions related to CSRs and conditions presented in exposure scenarios rather than focusing on enforcing compliance with an air concentration limit (as presented in the proposed wording of the restriction), to be established by air monitoring.

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The approach for producing the CSR and ESs is well known. Registrants are obliged to provide updates to their registrations when the CSR is changed (Article 22.g of REACH); it would be relatively easy to identify if this has been done for current registrants, thus easing enforcement. The risk reduction measures proposed have to be included in the exposure scenarios annexed to the safety data sheets that are communication tools already being used currently for this purpose. The enforcement of the application of conditions of exposure scenarios generated due to restriction process would be the same as for any other registration.

Another advantage is that this option covers manufacture, placing on the market (including import) and use of the substance (as in the option selected by the dossier submitter).

Disadvantages

A drawback of option 3 is that only import and manufacture requiring a CSR, i.e.>10 tonnes/year, would be affected by the restriction. The possible ramifications of this limitation are already described in presentation of negative aspects related to RMO2B.

It is noted that there is currently limited experience on enforcement of registrations and exposure scenarios, however, experience will be gained over the next 5 years (the expected transition period for the measure). Another limitation of this RMO is that it deals with the issue of dermal exposure only in qualitative way, as the DS proposes to include a general requirement to protect against dermal exposure. However, the Forum has pointed out that it is unclear what avoidance means (using gloves, zero dermal exposure, other limit values?) which may cause enforceability problems.

RMO 4

Risk management option 4 is authorisation. NMP is on the candidate list. For the substance to be subject to authorisation, this would require that NMP is prioritised (by ECHA in the future), and that it would gain approval of the MSs and Commission. If this was the case - the substance would be included in Annex XIV.

Advantages

Advantages are that each sector (or even company) has 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 the substance, in 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 the use. The DNEL developed by RAC in the evaluation of the restriction proposal could be used as the reference DNEL for the substance.

In addition, authorisation would cover all tonnages placed on the market (as compared to option 3 and uses covered by the restriction in 2B).

Disadvantages

One of the disadvantages of the authorisation system is that it may seem a resource intensive process: there are very many varied uses for which authorisation would have to be applied and considered for.

While authorisation covers the use of the substance it does not cover the manufacture of the substance (as specified in the original dossier submitter's proposal).

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Other potential measures based on RMOs discussed in the DS proposal

A binding OEL

The proposed by the dossier submitter restriction could be seen as a harmonised, binding "OEL", even though it would reflect the DNEL, and so setting a binding OEL (BOELV) under the worker protection legislation could be an option to consider.

Advantages

An advantage of this option is that a new binding OEL would be used and enforced in the same way as other binding OELs under the worker protection legislation.

This option would also avoid perceived conflict between REACH and the worker protection legislation.

BOELVs take account of socio-economic and technical feasibility factors as well as the hazard and risk – similarly to restricition opinions.

Disadvantages

Binding OELs are developed under the worker protection legislative framework. It is a difficult and lengthy process initiated when policy considerations require it; there are only binding OELs for 5 substances so far. It also should be considered that it cannot be predicted what would be the numerical value of such binding OEL.

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