Analysis of the most appropriate regulatory management option

Substance Name: N, N-Dimethylacetamide (DMAC); Dimethylformamide (DMF); N-methyl pyrrolidone (NMP).

EC Number: DMAC: 204-826-4

DMF: 200-679-5

NMP: 212-828-1

CAS Number: DMAC: 127-19-5

DMF: 68-12-2

NMP: 872-50-4

Authority: European Commission with the collaboration of ECHA

Date: 12 October 2018

Cover Note

NMP, DMAC and DMF were all included in the Candidate List between December 2011 and December 2012. DMAC and DMF were recommended by ECHA for prioritisation for Annex XIV (4th and 5th recommendation. NMP is included in ECHA's 8th recommendation. NL submitted a restriction dossier on NMP in 2013. The Commission postponed the inclusion of DMAC and DMF in Annex XIV while waiting for the outcome of NMP restriction and announced the intention to prepare a joint RMOA for the three aprotic solvents. NMP restriction was adopted as Regulation (EU) 2018/588 on 18 April 2018. In the REACH Committee meeting in which the NMP vote took place the Commission services committed to finalise the RMOA for the three aprotic solvents.

This is not a classical RMOA, but rather a policy analysis focusing on the possibile regulatory approaches and considering the processes that are already on-going.

Disclaimer: Please note that this RMOA was compiled on the basis of available information and may change in the light of new information or further assessment.
The main sources of information are the registration dossiers, the ECHA recomendation for Annex XIV, the Annex XV dossiers for restriction and the different EU legislative instruments.

1 IDENTITY OF THE SUBSTANCES

1.1 Other identifiers of the substances

Table 1: Other Substance identifiers for DMAC.

EC name (public):	N,N-dimethylacetamide,
IUPAC name (public):	N,N-dimethylacetamide
Index number in Annex VI of the CLP Regulation:	616-011-00-4
Molecular formula:	C_4H_9NO
Molecular weight or molecular weight range:	87.1 $g.mol^{-1}$
Synonyms:	Dimethyl amide acetate

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:

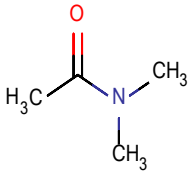


Table 2: Other Substance identifiers for DMF.

EC name (public):	N,N-dimethylformamide, dimethylformamide
IUPAC name (public):	N,N-dimethylformamide
Index number in Annex VI of the CLP Regulation:	616-001-00-X
Molecular formula:	C_3H_7NO
Molecular weight or molecular weight range:	73.09 $g.mol^{-1}$
Synonyms:	-

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:

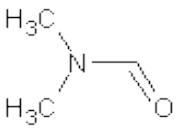
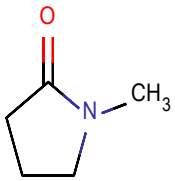


Table 3: Other Substance identifiers for NMP.

EC name (public):	1-Methyl-2-pyrrolidone
IUPAC name (public):	1-Methyl-2-pyrrolidone
Index number in Annex VI of the CLP Regulation:	606-021-00-7
Molecular formula:	C_5H_9NO
Molecular weight or molecular weight range:	99 $g.mol^{-1}$
Synonyms:	N-methyl-2-pyrrolidone

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



The three substances are polar aprotic solvents, meaning that they are molecules that cannot act as hydrogen bond donors (do not have O-H or N-H bonds) and have a high dielectric constant. These properties are very relevant to their use as solvents in organic chemistry and, because of their similarity, make them to a certain degree, interchangeable.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 4: Overview of other processes/EU legislation for DMAC, DMF and NMP.

	DMAC	DMF	NMP
REACH authorisation	December 2011 – included in the Candidate List. December 2013 – included in ECHA 4th recommendation for Annex XIV of REACH	December 2012 – included in the Candidate List. February 2014 – included in ECHA 5th recommendation for Annex XIV of REACH.	June 2011 - included in the Candidate List. February 2018 – included in ECHA 8th recommendation for Annex XIV of REACH.

REACH restriction	Entry 30 of Annex XVII restriction on placing on the market and use for supply to the general public of each substances as such, as constituent of other substances or in mixtures in a concentration above or equal to 0.3%.		
	No further restriction ongoing or listed in Annex XVII	Italy has submitted an Annex XV dossier in October 2018.	Regulation on the restriction of NMP as a substance on its own or in mixtures (published in the OJ as Regulation (EU) 2018/588 on 19 April 2018).
OSH legislation	Adopted SCOEL Recommendations on occupational exposure limits (OEL) for each substance. All include an additional notation for: "skin". National occupational exposure limits set in some Member States, some of which diverging from the EU OEL. For DMF and NMP, SCOEL also recommended biological limit values.		
	SEG/SUM/37, 1994 8 hour TWA: 10 ppm National values variation: 2 to 10 ppm Directive 2000/39/EC (1st list of IOELs)	SCOEL/SUM/121, 2006 8 hour TWA: 5 ppm National values variation: 5 to 10 ppm Directive 2009/161/EU (3rd list of IOELs)	SCOEL/SUM/119, 2007 8 hour TWA: 10 ppm National values variation: 5 to 25 ppm Directive 2009/161/EU (3rd list of IOELs)
EU vertical legislation	Restriction under the Toy Safety Directive (prohibited CMR under Annex II part 3, although exemptions may apply when the condition laid down in Annex II part 3 are met).		
	DMAC and DMF are listed in Annex II (list of substances prohibited in cosmetic products – entries 747 and 355, respectively) of the Cosmetic Products Regulation No1223/2009. DMAC, DMF, NMP are used in the production of medicinal products and are therefore subject to the provisions of directives 2001/83/EC on medicinal products for human use and 2001/82/EC on veterinary medicinal products, as well as those of Commission Delegated Regulation (EU) No 1252/2014 on principles and guidelines of good manufacturing practice for active substances for medicinal products for human use. Art. 68(2) restriction on CMRs in textiles and clothing (adoption pending, the measure received favourable vote from REACH Committee on 26 April 2018) sets a limit of 0.3% for these solvents in consumer articles.		

	-	-	Listed in table 1 of Annex I (entry 376) of the Regulation (EC) No 10/2011 on plastic materials. Authorised only when used as additive or polymer production aid.

Table 5: National OELs

	DMAC		DMF		NMP	
	Limit value – 8 h[1] (ppm)	Limit value – short term[2] (ppm)	Limit value – 8 h[1] (ppm)	Limit value – short term[2] (ppm)	Limit value – 8 h[1] (ppm)	Limit value – short term[2] (ppm)
EU[3,4]	**10**	**20**	**5**	**10**	**10**	**20**
Austria	10	20	5	10	10	20
Belgium	10	20	10	-	10	20
Denmark	10	20	10	20	5	10
Finland	10	20	5	10	10	20
France	2	10	5	10	10	20
Germany	10	20	5	10	20	40
Hungary	10	20	10	40	-	-
Ireland	10	20	5	10	10	20
Italy	10	20	5	10	10	20
Latvia	10	20	10	15	25	-
Poland	-	-	5	10	10	20
Portugal	10	20	5	10	10	20
Spain	10	20	5	10	25	75

[1] Measured or calculated in relation to a reference period of eight-hours time-weighted average.

[2] A limit value above which exposure should not occur and is related to a 15 minute period, unless otherwise specified.

[3] For DMAC – Commission Directive 2000/39/EU (OJ L 142, 16.6.2000, p. 47); for DMF and NMP – Commission Directive 2009/161/EU (OJ L 338, 19.12.2009, p. 87).

[4] All include an additional notation for: "skin".

Sweden	10	20	5	10	10	20
The Netherlands	10	20	5	10	10	20
United Kingdom	10	20	10	20	10	20

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table 6: Harmonised classification

	EC No	CAS No	Classification	Spec. Conc. Limits, M-factors	Notes
NMP	212-828-1	872-50-4	Repr. 1B STOT SE 3 Skin Irrit. 2 Eye Irrit. 2	STOT SE 3; H335: C ≥ 10 %	Commission Regulation (EU) 2016/1179 of 19 July 2016 (ATP 9 of CLP) removed the SCL of 5% for Repr. 1B.
DMF	200-679-5	68-12-2	Repr. 1B Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2		
DMAC	204-826-4	127-19-5	Repr. 1B Acute Tox. 4 Acute Tox. 4	Repr. 1B;	Commission Regulation (EU) 2016/1179 of 19 July 2016 (ATP 9 of CLP) removed the SCL of 5% for Repr. 1B.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[5]

4.1 Tonnage and registration status

Table 7: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☒ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

NMP

39 registrations, 7 DU reports, 8 SiA notifications

Total annual tonnage: 10,000 – 100,000

DMF

12 registrations, 0 DU reports, 0 SiA notifications

Total annual tonnage: 10,000 – 100,000

DMAC

15 registrations, 1 DU report, 1 SiA notification

Total annual tonnage: 10,000 – 100,000

[5] *Data retrieved on 15 January 2018.*

4.2 Overview of uses

Table 8: general overview of the 3 aprotic solvents main uses[6]

Use	DMAC	DMF	NMP
Solvent for production of other chemicals (pharmaceuticals, agrochemicals, etc)	70%	50%	40%
Man-made fibers/textiles/artificial leather	25%	25%	-
Coatings	5%	unknown	20%
Paint strippers/cleaners	<1%	unknown	20%
Electronics	unknown	unknown	20%

The three solvents appear to be used in the same sectors, as shown in table 8. The main uses are reported below, for the three solvents. The information sources are the Annex XV dossiers for SVHC identification and for restriction and the outcomes of the public consultations for the ECHA recommendations for inclusion in Annex XIV. The uses are mainly taking place under industrial or professional settings. The deletion in the 9th ATP of CLP of the previously applicable specific classification limit (SCL) of 5% for NMP and DMAC for the hazard class toxic for reproduction 1B has the consequence that now the generic limit of 0.3% applies and therefore any substances or mixtures for supply to the general public containing them above this amount will be banned.

NMP

In the chemical industry, NMP is used for the manufacturing process of up-stream base chemicals (including agrochemicals). Among these, it is used as a solvent for extraction and purification of benzene, 1,3-butadiene and acetylene.

In the Rubber & plastics industry, NMP is used in the production of certain specialty synthetic rubber products and as a solvent for the extraction and purification of butadiene. Butadiene is then used as a monomer for the manufacture of several synthetic rubbers. The synthetic rubber is used in the manufacture of many products such as tyres, automotive parts, medical industry, adhesives & sealants, rubber footwear, construction and lubricants.

In the pharma industry, NMP is used in the formulation of Active Pharmaceutical Ingredients (API). NMP is a solvent used to a great extent for the manufacturing of pharmaceuticals, peptides (chain of amino acids joined by peptide bonds) and small and large molecules. According to a very rough estimate from the European Pharmaceuticals association (EFPIA), NMP volumes used in 2016 for pharmaceutical production in the EU are in the range 5 000 - 10 000 tonnes per year.

Another use of NMP is as a solvent in the production of the positive electrode within Li-ion batteries used in electric vehicles and space launchers/vehicles.

[6] The information on this table is based on use-specific volume data available in the registration dossiers in 2015.

In production of semiconductors, NMP is used in two functions: as a manufacturing process aid for wafer stripping to remove organic residues and organic contamination and as a solvent in dedicated coating formulations. The volume of NMP used in semiconductor manufacturing (by ESIA members) in 2016 is up to 270 tonnes[7].

NMP is also used as solvent for wire coating. NMP is used in the production of special enamels (PAI – polyamide-imide enamels) used to coat copper wires to guarantee electrical insulation.

Another solvent use is in the production of polymer based membranes (for ultrafiltraton, microfiltration, nanofiltration), then used in various applications (drinking water, dialysis).

NMP is used as a laboratory reagent in nucleophilic substitution reactions. The reaction products are then used as reagent in biochemical analysis.

In the textile industry, NMP is used in the manufacturing process of para-aramid polymer. Para-aramid is then used in special textiles, such as anti-ballistic and stab resistant, heat and cut resistant clothing.

In the aeronautic and space industry, use of NMP include the already mentioned wire coating, coating of LCD panels and special coating to achieve anti-friction properties.

Finally, NMP is used as industrial cleaner and as a paint stripper.

DMF

In the chemicals industry, DMF has similar used to NMP, being used as solvent[8] in the synthesis of, e.g., Active Pharmaceutical Ingredients (APIs) and agrochemicals. It can apparently be used as an alternative to NMP as an extraction agent for butadiene and benzene.

In the pharma industry, DMF is also used as a solvent in the synthesis of peptides, then used in the production of in-vitro diagnostic devices (IVD). In some of these uses, it could be an alternative to NMP.

Similarly to NMP, DMF is used for wire and non-wire coating.

In the textile industry, DMF is widely used as solvent in the production of polyurethane coated textiles (such as artificial leather, rain and protection wear, footwear, medical mattress covers, surgical incise films etc) and of man-made fibers.

DMF is used as industrial cleaner, in reactors or pipelines.

Other applications of DMF include as gas stabiliser in acetylene cylinders, as laboratory chemical, in paint strippers and in epoxy inks.

DMAC

Similarly to DMF and NMP, also DMAC is used in the manufacture of agrochemicals (fertilisers, pesticides etc.), pharmaceuticals (e.g. antibiotics and novel contrast media), and fine chemicals.

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[7] ESIA: European Semiconductors Association

[8] Use as solvent e.g. in purification, crystallisation, extraction operations or as reagent, catalyst or cross-linking agent.

In the textile industry, DMAC is used in the production of man-made fibres made of polymers such as acrylic, polyurethane-polyurea copolymer (elastane) and meta-aramid. It acts as the solvent in the polymerization reaction and helps transfer the polymer through the spinning process) to produce very fine fibres. The main part of the fibres is used for production of clothing. A part of fibres are used as technical textiles for other applications, for example:

- Fibreglass/meta-aramid nonwoven (felt) fabrics, used for aerospace composites
- Surface tissue made of polyacrylonitril used in fibre reinforced plastics (e.g. for truck cabins).
- Meta-aramid fibres used in different systems where properties typical of textiles should be adapted to high ambient temperatures. An example is filters for hot gas filtration.
- Paper made from synthetic meta-aramid polymer used for insulation for electrical equipment applications in liquid and dry transformers, motors, and generators and for structural composites

DMAC is also used as solvent in coatings for industrial use, including the use of the substance in polyamide-imide (PAI) enamels (varnishes) used for electrical wire insulation (use in common with NMP).

DMAC is used for polyimide resins used in film production and for the production of dialyser membranes. Polyimide films are used in a range of industries including consumer electronics, solar photovoltaic and wind energy, aerospace, automotive and industrial applications. Examples of applications include substrates for flexible printed circuits, transformer and capacitor insulation and bar code labels, wire and cable tapes, formed coil insulation, motor slot liners, magnet wire insulation.

DMAC is formulated into paint stripper products by producers of cleaning products for the industrial sector. These are used (by metal industry, but also professional users) in conjunction with other solvents (mainly dichloromethane[9]) for dissolvation and removal of paint/varnish.

Similarly with the textile fibres, residual DMAC from the production of the films is present in the films (from below 0.1% up to 1% depending on film thickness; DuPont (U.K.) in RCOM, 2011) and membranes used by downstream users.

The paint strippers are applied (depending on the type) either by dipping or by hand with a brush or bristle on the item (the paint is afterwards removed with a scraper) (Singoli, 2011 in ECHA, 2011).

[9] According to Commission Regulation No 276/2010, paint strippers containing dichloromethane in a concentration equal to or greater than 0.1 % by weight shall not be placed on the market for supply to the general public or to professionals after 6 December 2011 and not be used by professionals after 6 June 2012. By way of derogation from the general restriction, Member States may allow the use on their territories and for certain activities, by specifically trained professionals.

4.3 Additional information

4.3.1 Emission, exposure and/or risk(s) per use

Most of the uses of NMP, DMF and DMAC appear to take place in closed systems and in an industrial setting. However, the registration dossiers for the three solvents report uses such as spraying, mixing and blending with reactants in batch processes, transfer from containers, separation from products (by filtration or distillation), re-use (after purification by distillation), and equipment cleaning and disposal. Some coatings may be applied in industrial setting by spraying, roller application/brushing or dipping. Such uses might have a higher potential for emissions, with exposure of workers and man via the environment.

The Annex XV dossier for restriction for NMP and the previous draft Annex XV dossier for restriction for DMF prepared by IT identified risks for most of the uses, while in the respective registration dossiers all RCRs are below 1 for workplace exposure scenarios. This is due to the fact that the registrants use the IOELs as DNELs, while the restriction dossiers propose lower DNELs, calculated using the REACH methodology. In the case of the dossier for restriction of NMP, RAC concluded on a DNEL of 14.4 mg/m^3 (3.6 ppm) for inhalation exposure and of 4.8 mg/kg/day for dermal exposure. These are the values in the text of the restriction voted on 24 October 2017.

Residuals of the three solvents might be present in some final articles (textiles, membranes, films, coated articles). There are uncertainties on the concentrations, but it appears that they could be above 0.1%. On 26 April 2018 a draft proposal by the Commisison to restrict CMRs in textiles and clothing under Article 68(2) of REACH establishing a limit value of 0.3% for the presence of these solvents in all consumer articles in scope, received a favourable vote in the REACH Committee. The measure was adopted 2018.

4.3.2 Information on alternatives, including on R&D

NMP, DMF and DMAC have similar hazard profiles and similar patterns of use. For some of the uses, they can be interchangeable, even if in most cases they cannot be considered as drop-in alternatives.

For example, even if DMAC, NMP and DMF are used for the production of special fibres, the final product is different, with different properties, if a different solvent is used.

In the pharmaceutical industry, in some processes both NMP and DMF could be used, but the more advanced the product development process is, the more difficult it is to substitute the solvent. Very often, the marketing and use authorisation of the medicinal product would need to be amended or requested again in case of a change of solvent. In the commercial scale production phase there are no examples of successful substitutions for these solvents, while some success is reported in previous phases.

According to industry, it is difficult to find a substitute outside of this family of solvents. 1-ethylpyrrolidin-2-one (NEP) was developed as a potential alternative, but its classification as toxic for reproduction makes its use as alternative to one of the other solvents unlikely. DMSO could be considered a safer alternative, but its physico-chemical properties do not allow its use in all processes. In the textile sector, alternative technologies are possible to produce DMF-free polyurethane (for example, water based PU coating), but it appears that the technical specifications are not always met. Annex 5 of the Annex XV dossier for restriction

of NMP[10] provides a complete overview of the potential alternatives, including the sectors where they could be or are used.
n-butylpyrrolidone (CAS 3470-98-2) has recently been proposed as an alternative to NMP for coating applications, paints, and chemical synthesis.

4.3.3 Preliminary socio-economic considerations

The three solvents are produced and used in high quantities. There is a high number of registrations and manufacturers and users appear to be widespread in EU. From the information summarised in chapter 4.2, the uses are very diversified. Regulatory management actions would then have consequences on a wide variety of sectors and on a high number companies.

The public consultation on the inclusion of the three solvents in ECHA recommendation for Annex XIV led to a high number of comments. On NMP, the Commission conducted a specific public consultation on socio-economic effects of authorisation and the results are available (document CA/73/2017 submitted to CARACAL 25). On DMF and DMAC such separate public consultation was not conducted, but many comments on socio-economic effects were submitted during the ECHA public consultation[11].

5 JUSTIFICATION FOR THE REGULATORY MANAGEMENT OPTION

5.1 Identification and assessment of regulatory management options

OSH legislation

As presented in chapter 2, the three solvents are covered by the Directive 98/24/EC on Chemical agents at work (CAD). The OSH process is based on three fundamental steps: a) identification of hazards, b) assessment of risks and c) control of the risks. OELs are a tool designed to assist the employer in steps b) and c).

The CAD sets out the minimum requirements on the protection of workers' health and safety from the risks related to chemical agents, including by setting indicative OELs, and it covers all workers and all activities at the workplace.

EU indicative OELs have been adopted for the three solvents. Indicative OELs are derived from the most recent scientific data available and taking into account the availability of measurement techniques. For any chemical agent for which an indicative OEL has been set at EU level, Member States are required to establish a national OEL. In doing so, they are required to take into account the EU OEL, determining the nature of the national OEL in accordance with national legislation and practice. In the case of NMP and DMF, some Member States have adopted

[10] https://echa.europa.eu/documents/10162/3f467af2-66e0-468d-8366-f650f63e27d7

[11] DMF: https://echa.europa.eu/previous-recommendations/-/substance-rev/1790/term

DMAC: https://echa.europa.eu/previous-recommendations/-/substance-rev/1784/term

values higher than the EU OEL. In the case of DMAC, all Member States have transposed the EU value as such (except FR, who has a value 5 times lower).

In the case of NMP, the Annex XV dossier for restriction put forward by the Netherlands pointed to risks in several uses despite the IOEL (used as the DNEL in the registration dossiers) were considered in the risk assessment. This was confirmed by RAC in its opinion. The risks associated to the uses of DMF will be analysed in the Annex XV dossier to be resubmitted by Italy in October 2018.

Additionally, the three solvents can also be adsorbed via the skin. Skin notations have been established for all the three solvents by the CAD, and RAC derived for NMP a DNEL for the dermal route.

Authorisation

DMF, DMAC and NMP have been recommended by ECHA for inclusion in Annex XIV. At the time when the restriction process for NMP started, the Commission decided not to include DMF and DMAC in Annex XIV, because it considered that, in terms of consistency, it made sense that the same approach would be followed for the 3 solvents, given their similar hazard properties, the similar uses and the potential interchangeability for some of those uses.

Should the three solvents be included in Annex XIV, this would probably lead to the need for applications for specific end-products in many different sectors concerning a high number companies. These applications, and possible subsequent re submission of authorisation applications in the absence of suitable alternatives[12] for all uses could potentially amount to many, given that the experience to date shows that specific applications are less controversial and are usually granted longer review periods, thereby demotivating the submission of large (joint) applications. This has been shown by the case of the solvent EDC, albeit with a relatively limited number of applications by the pharma industry, where the applicants opted to apply for very specific uses.

For many of the uses of the three aprotic solvents, there appears to be no alternatives readily available outside of the family of aprotic solvents. In a number of sectors where they are used, their substitution can take relatively long time also due to existing marketing and use authorisation systems (for example, pharmaceutical and IVD sectors).

A study[13] commissioned by the Commission on the impacts of authorisation shows that authorisation is providing a strong incentive for substitution and an improvement of Risk Management Measures at the workplace where substitution is not possible. Therefore, authorisation can be effective in improving the safety of use of substances in the workplace but its scope is limited to the specific uses and companies covered by it. Until substitution becomes possible, companies have to demonstrate that they are properly controlling the risk from the substances. Following the logic of REACH, the risk from uses should be adequately controlled in particular for substances for which a threshold can be established.

[12] A recent study by the University of Wageningen identied potential biobased alternatives to polar aprotic substances, however no assessment of the toxicological properties of the potential alternatives has been investigated. https://www.wur.nl/upload_mm/7/d/1/2556f9cf-490e-4782-af0f-c2d3087f45a8_WFBR%20report%201742%20RIVM%202017%20final%201.2.pdf

[13] http://ec.europa.eu/docsroom/documents/26847

Restriction

The identification of an unacceptable level of risk associated to the use of a chemical is the key driver of a proposal for a restriction at EU level.

Given the indications pointing to risks in several uses of NMP despite the existence of an EU wide IOEL, initiating a restriction process was the appropriate action to take. Such risks were subsequently confirmed by the ECHA's Risk Assessment Committee. The preliminary analysis carried out by Italy for DMF also pointed to possible risks in several uses. Concerning DMAC such analysis has not been carried out but in light of similarities with the other two solvents, the possibility that risks could be identified in some uses of DMAC cannot be excluded.

In such case, a restriction as one of possible regulatory management options should be considered.

A restriction for NMP was adopted on 18 April 2018[14]. The restriction requires that, when NMP is placed on the market, manufacturers, importers and downstream users include in the Chemical Safety Report (CSR) and in the Safety Data Sheet (SDS) two Derived no Effect Levels (DNELs):

- 14,4 mg/m^3 for inhalation exposure
- 4,8 mg/kg bw/d for dermal exposure.

The effect of introducing these two DNELs via a restriction is that, while allowing each manufacturer, importer and downstream user in a sector to decide how to best achieve the control of the substance, European wide harmonisation is achieved regarding the maximum level of exposure, and therefore of risk, associated to the use of the substance.

Manufacturers and users need to ensure that the two DNELs are complied with, by applying appropriate Risk Management Measures and by providing appropriate Operational Conditions. These measures are not specified in the restriction, giving each sector the freedom of chosing the most appropriate way to comply with the restriction. However, it is to be stressed that the risks management measures in the OSH Directives remain applicable.

It should be noted that the restriction does not regulate the placing on the market or use of articles containing NMP, as the risk from NMP in articles was not assessed in the Annex XV dossier. In workplaces handling articles that may potentially release NMP, the existing iOEL remains applicable in accordance with CAD. The restriction foresees a general deferral period of 2 years and a longer deferral period (6 years) for the wire coating industry.

5.2 Discussion on the most appropriate (combination of) regulatory management options

As explained in the previous chapter, NMP provides a good example of a case where there is an added value in applying REACH complementary to OSH

[14] Commission Regulation (EU) 2018/588. OJEU 19.4.2018. L99/3. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R0588

legislation, introducing DNELs, applicable throughout the EU, via a restriction. Concerning the other two solvents, the choice of the most appropriate regulatory management option should take into account the protection objective pursued, the already existing relevant legislation and should be in line with the better regulation guidelines avoiding, to the extent possible, double regulation and unnecessary administrative burdens.

The DNELs for NMP will be applied in all companies in all Member States, thereby creating a level playing field for EU companies and ensuring appropriate protection of workers.

It is uncertain if a restriction introducing a harmonised DNEL is providing the same incentive to substitution as authorisation under REACH or in terms of substitution under the CAD, but it can address the main concern (exposure of workers) more quickly.

Two options could be considered. Reassessing the existing iOELs and the possibility to lower them or setting DNELs at a lower level than the current iOELs. Both options would lead to improvements of Risk Management Measures and Operational Conditions at the workplace as these must ensure that the exposure is maintained below these more protective limits. The setting of a DNEL would imply a binding harmonised limit while the iOEL allows Member States on basis of justified reasons to depart from it. The existance of a DNEL will not affect the application of the relevant OSH RMM, nor of the iOEL for uses in certain situations not covered by the restriction. Such solution would therefore provide appropriate protection for workers and is workable in a shorter period of time than the reassessment of the iOEL.

Although the approach chosen in the restriction dossier for NMP already defines a possible way forward for the other solvents, this should not impede the assessment of other possible solutions (e.g., restricting the placing of the market for some uses) different from setting a harmonised DNEL, in order to identify the most effective, practical and monitorable option. Additional RMO coming from the public consultation, including the setting or revision of iOELs under CAD should be evaluated by RAC and SEAC during the opinion making process.

In the particular case of DMAC and DMF, restriction appear to be the most appropriate risk management option under REACH, given the potential burden to industry and public administrations that would result for multiple applications (and foreseeable reapplications) that result from the combination of a lack of suitable alternatives and multiple sectors of use. Furthermore a restriction would also cover intermediate uses of the solvent, whereas authorisation would not.

As regards the option of using a REACH restriction, versus that of establishing iOELs for DMAC and DMF, beyond considerations regarding the level of harmonisation that could be achieved with each of these instruments, it is important to seek regulatory consistency in the approach used with these very similar substances. A restriction for NMP is already in place since April 2018 and for DMF, Italy has submitted an Annex XV restriction dossier to ECHA on 5 October 2018 where a DNEL is also proposed. It is expected that this dossier will be discussed in RAC and SEAC in the first half of 2019.

Taking into account all of these elements, and for regulatory consistency, a restriction appears to be the best regulatory option for the other two aprotic solvents considered DMF and DMAC, when a risk is identified which is not adequately controlled. If no Member State expresses an interest to prepare a restriction dossier for DMAC, the Commission will ask ECHA to do so, preferably in cooperation with a volunteering MS.

For a fourth, similar solvent (NEP), preparatory work on an RMOA had been initiated by Austrian authorities, but this work has been discontinued. The Commission will consider whether a future update of this RMOA, to also include NEP, is necessary.

It could be appropriate and more efficient to ensure that the restriction dossiers for these aprotic solvents are discussed as a group in RAC and SEAC in particular given the similarities in terms of risks, analysis of alternatives and socio economic aspects.

If it is confirmed that a harmonised DNEL is the most relevant RMO, and given the novelty of this type of restriction, the Commission believes that there is a need to develop guidance for downstream users and for enforcers (REACH and Labour Inspectors) about the best way to communicate and apply the provisions arising from the two complementary regulatory regimes (REACH and OSH). The Commission will ask ECHA and the Forum to work on this matter, also by collaborating with SLIC[15], once the restrictions have been adopted (this has already happened for NMP). Finally, the Commission believes that there is a need to check if such restrictions setting harmonised DNELs are working as intended. Two years after the entry into force of the individual restrictions, the Commission will ask ECHA to:

- Collect data on occupational exposures in the different sectors and compare these with the established DNEL values.
- Ask users of the three solvents which measures were put in place to comply with the DNELs (RMMs, technological changes, substitution).
- Based on this information, conclude on whether the restrictions have achieved the expected results in terms of improved risk management.

If the restrictions have not achieved the expected results in terms of reduction of the risks, or if information available is insufficient to derive a conclusion, the Commission will re-evaluate the need for additional regulatory actions, including authorisation.

5.3 References

N/A

[15] Senior Labour Inspectors' Committee