Regulatory Management Option Analysis Conclusion Document

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

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

NMP, DMAC and DMF all have a harmonised classification as reprotoxic in category 1B.

Entry 30 of Annex XVII defines a restriction on the placing on the market and use for supply to the general public of each substances as such, as a constituent of other substances or in mixtures in a concentration above or equal to 0.3%.

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. The Netherlands submitted a restriction dossier on NMP in 2013. A restriction on NMP was adopted as Regulation (EU) 2018/588 on 18 April 2018.

On 5 October 2018 Italy submitted to ECHA an Annex XV dossier for the restriction of DMF.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	x
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	x
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Restriction under REACH

NMP, DMAC and DMF all have a harmonised classification as reprotoxic in category 1B. The three solvents appear to be used in the same sectors, namely as solvent for production of other chemicals (pharmaceuticals, agrochemicals, etc); in the production of man-made fibers, textiles and artificial leather; coatings; paint strippers and cleaners and in electronic.

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.

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. 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 available 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 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. For NMP, 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.

The NMP case is a good example of a case where there is an added value in applying REACH complementary to OSH 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.

In the particular case of DMAC and DMF, restriction appears 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 and Italy submitted an Annex XV restriction dossier to ECHA in 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.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Italy has submitted to ECHA an Annex XV dossier for the restriction of DMF on 5 October 2018. As regards DMAC, if no Member State expresses an interest to prepare a restriction dossier for this substance, the Commission will ask ECHA to do so, preferably in cooperation with a volunteering Member State. For a fourth, similar solvent, n-ethyl pyrrolidone (NEP), the Commission will consider whether a future update of this RMOA, to also include NEP, is necessary.