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Comments

To:	**ECHA**	
From:	**Field Fisher Waterhouse on behalf of the Alkylamines Sector Group of Cefic**	Date: **14 September 2012**

RE: Recommendation for the inclusion of DMAC in Annex XIV of REACH - Comments

The present document contains the legal analysis of ECHA's fourth Recommendation for the inclusion of the substance N,N-Dimethylacetamide ("DMAC") in Annex XIV of REACH[1], as well as arguments supporting the exemption of DMAC under Article 58.2 of REACH, which are submitted on behalf of the Cefic Alkylamines Sector Group.

1. Background

DMAC is a dipolar, aprotic solvent with high solving power for high molecular-weight polymers, which is used as industrial solvent in the production of pharmaceuticals, agrochemicals, fine chemicals, man-made fibres, industrial coatings, films and paint strippers.

DMAC was identified as a Substance of Very High Concern ("SVHC") because of its classification as toxic for reproduction 1B and included in the Candidate List for authorisation on 19 December 2011 (by ECHA Decision ED/77/2011).

On 20 June 2012, ECHA adopted its 4th Draft Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation ("the ECHA Draft Recommendation"), in which it recommended DMAC for inclusion in Annex XIV on the basis of the high volumes used and of the wide dispersive use (i.e. widespread uses with high likelihood for releases and exposure). Comments can be submitted on this draft by 19 September 2012.

In this regard, the Cefic Alkylamines Sector Group submits that the use of DMAC by workers at the workplace should be exempted on the basis of Article 58.2 of REACH for the reasons explained below.

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[1] REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396/1, 30.12.2006.

2. Legal Framework

Art. 58.2 of REACH provides that "*Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form*."

In its guidance document, ECHA specifies that it will consider the following elements when deciding whether to include an exemption of a use of a substance in its recommendation:

- there is existing Community legislation addressing the use that is proposed to be exempted;

- the existing Community legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance;

- the exiting Community legislation imposes minimum requirements for the control of risks of the use. The legislation must define the measures to be implemented by the actors and enforced by the authorities and it must provide that Member States can establish more stringent but not less stringent requirements.[2]

Regarding DMAC in particular and the control of risks linked to occupational exposure, Directive 2000/39[3] established a first list of indicative occupational exposure limit values ("IOELV") within the framework of Directive 98/24[4] on the protection of the health and safety of workers from the risks related to chemical agents at work ("Directive 98/24" or "the chemical agents at work Directive"). The IOELV for DMAC is set at 36mg/m³ and 10 ppm for eight hours of exposure and 72 mg/m³ and 20 ppm for short-term exposure (15-minute period), with possibility of significant uptake through the skin.[5]

Additionally, Directive 92/85[6] on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding also regulates occupational exposure to substances toxic to reproduction. It notably provides for necessary measures to be taken by the employer in case of risk or effect on the pregnancy or breastfeeding of a worker (see Article 5).

It should also be noted that in any event, EU legislation must comply with the general principle of proportionality.

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2 ECHA Guidance Document on "Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General Approach", 20 June 2012, page 6.

3 Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

4 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

5 See the Annex to Directive 2000/39.

6 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.

3. Exemption under Article 58.2 of REACH

As explained above, according to Article 58.2 of REACH, in order for a use of a substance to be exempted from the authorisation regime, there must be existing EU legislation addressing the use which is proposed to be exempted, which properly controls the risks from the use and which imposes minimum requirements for the control of the risks.

Regarding DMAC, the use which is proposed to be exempted is the use as industrial solvent, or more specifically, the "occupational use" or "contact at the work place", as defined in Article 2 of Directive 98/24 (see below).

Additionally, the inclusion of DMAC in Annex XIV of REACH should comply with the principles of proportionality.

3.1 Existing legislation addressing the use

Regarding the first condition, Directive 2000/39 is an existing EU legislation which provides Member States with indicative occupational exposure limit values (IOELV) for DMAC. It does not cover specific uses as such. However, it was adopted as an implementing measure within the framework of Directive 98/24 on chemical agents at work, which defines "*activity involving chemical agents*" as "*any work in which chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport or disposal and treatment, or which result from such work*".[7]

Therefore, read in combination, Directive 2000/39 and Directive 98/24 both address the occupational use of DMAC, or more specifically the "*contact at the workplace*" category of uses.

Additionally, it should be noted that the decision of ECHA to include DMAC in the Draft Recommendation was based solely on occupational health issues, because of its classification as toxic for reproduction (1B), thereby limiting the scope of the assessment to this specific use.[8]

In this regard, Directive 92/85 also covers the occupational use of DMAC regarding pregnant workers and workers who have recently given birth or are breastfeeding and could therefore be considered as relevant for the exemption.

3.2 Proper control of the risks

According to ECHA, under the legislation addressing the specific use of the substance, the risks to human health and/or the environment arising from the intrinsic properties of the substance that are specified in Annex XIV and specifically refer to the substance, should be properly controlled.

In this regard, Directive 2000/39 explicitly refers to DMAC and establishes specific IOELV for DMAC. The IOELV was based on an overall approach to occupational health and did not as such take into consideration the reproductive toxicity (category 1b) of DMAC. However, the Scientific Expert Group on Occupational Exposure Limits (SCOEL) considered the possibility of exposure-related irritations in the respiratory tract while taking into consideration possible reproductive toxicity effects. It notably stated that "reproductive toxicity has not been observed in inhalation studies at levels which do not cause maternal toxicity".[9]

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7 Article 2(c) of Directive 98/24.

8 See Chapter 3.1 of the ECHA Draft background document for N,N-Dimethylacetamide (DMAC), 20 June 2012.

9 Recommendation of the Scientific Expert Group on Occupational Exposure Limits for N,N-

Therefore, the intrinsic SVHC properties of DMAC (i.e. toxic for reproduction 1b) are properly controlled through Directive 2000/39, and Directive 98/24, since the IOELV covers exposure-related irritations in the respiratory tract as well as the reproductive toxicity endpoint. As specified above, ECHA based its recommendation for DMAC solely on occupational health issues. Therefore, the identified risks should be considered as properly controlled through the application of Directive 2009/39 and Directive 98/24. The Draft Recommendation itself shows that available assessments have confirmed that the IOELV is an effective limit value for adequate control of intrinsic risks.[10]

Additionally, occupational exposure to substances toxic to reproduction is also regulated by Directive 92/85. Article 5 notably provides that if the results of the assessment reveal a risk to the safety or health or an effect on the pregnancy or breastfeeding of a worker, the employer must take the measures necessary to ensure that the exposure of that worker to such risks are avoided.[11]

3.3 Minimum requirements imposed

According to the ECHA guidance, the legislation must impose minimum requirements for the control of risks of the use, which means that Member States can establish more stringent but not less stringent requirements when implementing the legislation and that it must define the measures to be implemented by the actors and enforced by the authorities.

According to Article 2 of Directive 2000/39, "*Member States shall establish national occupational exposure limit values for the chemical agents listed in the Annex, taking into account the Community values*". Therefore, Member States are under the obligation to implement mandatory limit values for concerned substances at a national level.

Although the precise level of the limit value is not mandatory, Member States are requested to take indicative values into consideration. Indeed, the IOELV must be taken into account by the Member States and must be included in the decision-making process. Additionally, Article 3.8 of Directive 98/24 provides that "*where a Member State introduces or revises a national occupational exposure limit value or a national biological limit value for a chemical agent, it shall inform the Commission and other Member States thereof together with the relevant scientific and technical data. The Commission shall undertake the appropriate action*."

Therefore, when a Member State wishes to introduce or change a national limit value, it has an obligation to report it to the Commission and it must supply the Commission with scientific and technical justification. As a result, the Member States cannot arbitrarily derogate from the IOELV. This is all the more true that all Member States have implemented national limit values identical to the IOELV or more stringent ones.[12] It is therefore an established practice for the Member States to implement the IOELV as a minimum requirement.

Dimethylacetamide, SEG/SUM/37, 1994.

10 See Annex XV dossier prepared by ECHA for DMAC, August 2011, page 15, which notably states that "*worker exposure to DMAC in the EU should be controlled to levels below the Indicative Occupational Exposure Limit Values (IOELVs), which are intended to protect workers from the development of respiratory irritation*", and ECHA Draft Background document for DMAC, section 2.2.2.2 (pages 5-8).

11 By temporarily adjusting the working conditions and/or the working hours of the worker concerned, moving the worker to another job or granting leave for the period necessary to protect her safety or health (see Article 5 of Directive 92/85).

12 See footnote 7 of the ECHA Draft background document for DMAC, which states that "*the IOELV has been adopted by most EU Member States, but France has set OELs at lower levels*".

Therefore, through the application of Directive 2000/39 and Directive 98/24 and the obligation for Member States to establish national limit values for DMAC taking into account the IOELV, as well as the strict conditions applicable for introducing or revising them, minimum requirements are imposed to the Member States for the control of risks of occupational uses.

In any case, the exemption from the authorisation requirements could be linked to the continued existence of the current legal situation. In this case, if a Member State would decide to change its national limit value for DMAC, it would have to inform the Commission and the other Member States and provide scientific and technical justification. According to Article 3.8 of Directive 98/24, the Commission could then react by undertaking appropriate action. Such appropriate action could consist in modifying the entry in Annex XIV for DMAC and revoking the exemption from the authorisation requirement.

A sufficient level of risk control is therefore ensured and should support the exemption.

3.4 Proportionality

The implementation of an authorisation requirement for DMAC would be disproportionate and therefore illegal, at least if DMAC would be included in Annex XIV without the requested exemption.

Indeed, the authorisation process is considered as elaborate and costly, which can therefore constitute a significant burden for the applicant, both on organisational and financial level. Additionally, as a new procedure, there is no predictability regarding ECHA's decisions on applications for authorisation since there is no established administrative practice yet in this field. Furthermore, since the substance authorisations are subject to periodic reviews, the applicant must face a lack of certainty, planning reliability and asset protection.

As explained above and in the ECHA Draft background document, DMAC is primarily used as an industrial solvent in a multitude of production and manufacturing processes. However, it cannot be considered as an intermediate, according to the ECHA definition, because it does not participate in the chemical reaction and it is removed at the end of the process. DMAC therefore does not remain in the final product, which means that downstream users do not come into contact with the substance and are not exposed. As a result, manufacturers located outside the EU which import manufactured products in the EU will not be affected by a DMAC authorisation requirement. As a consequence, the authorisation requirement and related costs would lead to a permanent competitive disadvantage for EU manufacturers.

Further, there is no effective added value in making DMAC subject to authorisation. Indeed, as explained above, the decision to recommend DMAC for inclusion in Annex XIV was based solely on occupational health risks. In this regard, those risks are already properly controlled by the application of Directive 2000/39, Directive 98/24 and Directive 92/85. Moreover, there are no suitable substitution substances. Therefore, there would be no effective added value by the inclusion of DMAC in Annex XIV, and in any event if it was included without the requested exemption.

Therefore, because of the significant burden for EU manufacturers and the competitive disadvantage compared to non EU manufacturers importing final products, and because of the lack of effective added value, there would be a considerable disparity between the costs and benefits of a possible inclusion of DMAC in Annex XIV, which would therefore be disproportionate and contrary to general EU principles.

4. Conclusion

Since the decision to recommend DMAC for inclusion in Annex XIV was based solely on occupational health risks (because of the classification of DMAC as toxic for reproduction category 1b), those risks are already properly controlled by the application of Directive 2000/39, Directive 98/24 and Directive 92/85, which impose minimum requirements which must be implemented by the Member States.

Therefore, the occupational use of DMAC (i.e. the use of DMAC with contact at the workplace), should be exempted from the authorisation requirements, in accordance with Article 58.2 of REACH.

In any event, in view of the significant burden for applicants, the competitive disadvantage and the limited added value, the inclusion of DMAC in Annex XIV would be disproportionate and in any event if such inclusion did not include the requested exemption for occupational use.

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