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MEMORANDUM

13 September 2013

Re: **Request for exemption for use of DMF as an industrial process solvent in industrial installations (e.g. in chemical synthesis and in the industrial manufacture of fibres and membranes) further to the recommendation for the inclusion of DMF in Annex XIV of REACH**

The present memorandum contains the legal analysis of the relevant EU legislation supporting an exemption of specific uses of the substance N,NDimethylformamide ("DMF", CAS# 68-12-2) under Article 58.2 of REACH, in the context of ECHA's fifth Recommendation for the inclusion of DMF in Annex XIV of REACH[1].

1. Background

DMF 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 (PU skins; artificial leather). With the exemption of professional laboratory use there are only industrial uses of DMF. This professional laboratory use refers mainly to university research analytics which is exempted from authorization.

DMF 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 2012 (by ECHA Decision ED/169/2012). No environmental risks were identified.

On 24 June 2013, ECHA adopted its Draft 5th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation ("the ECHA Draft Recommendation"), in which it recommended DMF for inclusion in Annex XIV on the basis of the significant potential for workers exposure. Comments can be submitted on this draft by 23 September 2013.[2]

The following uses are identified in ECHA's draft background document of 24 June 2013:

- As a solvent in the synthesis of chemicals

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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 See also Draft background document for N,NDimethylformamide (DMF).

- As a solvent in the production of polyurethane coated textiles such as artificial leather, rain and protection wear, footwear, medical mattress covers, surgical incise films
- As solvent in the production of synthetic fibres
- As cleaning solvent in other applications, such as in the electronic industry.
- At industrial sites in solvent-based corrosion inhibitor products

ECHA's draft background document further indicates that there are uses in the aerospace industry in mixtures, such as strippers and epoxy inks, in the United States – and speculates that this may be relevant for the EU, but such a conclusion is not substantiated.

The background document acknowledges that *"[t]he majority of the uses takes place at industrial settings*", that "*there is no registered use for consumers"* and that *"DMF is not supposed to be a component of the final articles resulting from processes where it is used as a solvent*".

Further, the background document on DMF supporting the ECHA Draft Recommendation states, under section 2.4, that:

> *"There seems to be no specific Community legislation in force that would allow consideration of exemption(s) of (categories of) uses from the authorisation requirement on the basis of Article 58(2) of the REACH Regulation".*

Against this background, we were asked to analyse whether the use of DMF as an industrial process solvent, in chemical synthesis in industrial installations and in the industrial manufacture of fibres and membranes, should be exempted on the basis of Article 58.2 of REACH.

For the reasons explained below, we conclude that such uses of DMF should be exempted from authorization on the basis of Article 58.2 of REACH.

2. Legal Framework

A - Conditions for exemption under Article 58.2 of REACH

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*" (emphasis added).

It is recalled here that the risks to the environment are not the matter of concern according to ECHA's background document on DMF. Rather, it is the health of workers that is the endpoint of concern. As will be demonstrated below, this endpoint is sufficiently and adequately covered by existing legislation.

In its relevant guidance document[3], ECHA specifies that it will consider the following elements for the inclusion of 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 existing 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 in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper; additionally, it must provide that Member States can establish more stringent but not less stringent requirements.

- the existing legislation should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to, e.g. by referring to the classification criteria or the Annex XIII criteria.

- the legislation that does not clearly specify the actual type and effectiveness of measures to be implemented is not regarded as sufficient.

B - Interpretation of Article 58.2

In view of the above, it must be assessed how the specific wording of Article 58.2 of REACH is to be interpreted, in particular what is understood by "*specific Community legislation imposing minimum requirements"* for the use of a substance, and by the words "*the risk is properly controlled"*.

In EU law, specific superior principles and methods of interpretation endorsed by the EU courts should be followed for the correct and legal interpretation of EU provisions, such as this exemption to the authorization regime.

By way of introduction, it must be recalled that under EU law and further to consistent case law, a broad interpretation should be given to the basic rules of the Treaty (such as free movement of goods or of establishment), while exceptions to those rules must be given a strict interpretation. The same principle applies for secondary legislation[4], such as REACH.

Moreover, in order to make a correct interpretation of a legal provision, the historical background of this provision should not be ignored.[5] Neither should the preliminary considerations which have led to its adoption[6], nor analogy with other provisions.

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3 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.

4 See *Mrozek* case (C-335/94), 21 March 1996, para. 9, [1996] ECR I-1573

5 See e.g. *Stauder* case (29/69), 12 Nov. 1969, para. 5, [1969] ECR 425.

6 See e.g. CFI judgment of 10 March 1992 in the *Flat Glass* Cases T-68/89, T-77/89, and T-78/89, [1992] ECR II-1403; ECJ judgment of 20 March 1980 in Case 118/79, *Knauf*, para. 5, [1980] ECR 1190.

It must be recalled that the former versions of the text of Article 58.2 referred to the need for an authorisation decision to "*take into account of the application of other EU legislation to the use in question and whether the use is sufficiently controlled so ensuring that the risks to human health and the environment are adequately controlled. This would allow the authorisation process to concentrate on the uses of substances that are likely to pose the greatest risk rather than devoting resources to considering uses that are known to be adequately controlled and corresponds to the principle of proportionality*".[7] This version of the text cited as possible examples of such legislation being capable of justifying an exemption and listed "*binding occupational exposure limits, emission limits and so forth*".[8]

The final version of the text was adopted without this list of examples. However, the legislature's preliminary considerations shows that occupational exposure limits, which are essentially minimum requirements and by nature binding (see below), qualified as the type of legislation covered by Article 58.2. Therefore, disregarding existing exposure limits or emission limits for the purposes of authorisation would not be consistent with the appropriate interpretation of this provision.

Further, the ECJ has indicated that *"[i]t must in addition be considered whether such cases are also covered by the intention of the Community legislature*" and that "*it is necessary to interpret it by reference mainly to its structure and objectives in order to make it fully effective*"[9], or in order to prevent unacceptable results: "*the effect of such an exemption would therefore be to open a considerable breach in the effectiveness of the provision of the regulation*"[10].

If the only existing occupational health directives were to be in principle disregarded for the application of the Article 58.2 exemption, this whole provision would be devoid of any purpose or effectiveness. A correct interpretation of Article 58.2, therefore, cannot lead to the exclusion of existing occupational health, emissions and OEL secondary legislation imposing minimum requirements.

Further, in light of these principles, the phrase "the risk is properly controlled" should be interpreted as applying to the exposure and endpoint under consideration for exemption.

C - <u>Existing specific legislation providing the basis for the exemption of uses of DMF from authorization under Article 58.2</u>

Below we analyse several EU laws which, collectively and individually, meet the conditions imposed for the exemption under Article 58.2 of REACH, and namely:

- DMF is covered by EU legislation imposing "minimum requirements" on Member States
- The legislation relates to the protection of human health for the use of the substance
- Such legislation refers specifically, by name, to DMF

7 See COM(2003)644 final.

8 Ibid, under Article 55. This version survived until the European Parliament's environmental committee second reading A6-0352/2006 of 13.10.2006.

9 ECJ judgment of 14 July 1983 in Case 201/82, *Gerling*, para. 11 [1983] ECR 2515.

10 *Derycke* Case (65/76), 25 Jan. 1977, para. 20, [1977] ECR 35.

- Such legislation ensures that the risks to human health related to the use of DMF as an industrial process solvent (in chemical synthesis in industrial installations and in the industrial manufacture of fibres and membranes) are properly controlled
- Risks related to life-cycle stages resulting from such use of DMF are also covered by such legislation.

1. *Existing EU legislation on minimum requirements for the protection of workers (the Chemicals Agents Directive and Occupational Exposure Limits for DMF)*

Directive 98/24[11] 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" or "CAD") is based on Article 118a of the EC Treaty (now Article 153 under the Treaty on the Functioning of the European Union).

Article 118a EC read as follows:

> "1. *Member States shall pay particular attention to encouraging improvements, especially in the working environment, as regards the health and safety of workers, and shall set as their objective the harmonisation of conditions in this area, while maintaining the improvements made.*
>
> *2. In order to help achieve the objective laid down in the first paragraph, the Council, acting in accordance with the procedure referred to in Article 189c and after consulting the Economic and Social Committee, shall adopt, by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States.*
>
> *[…]*
>
> *3. The provisions adopted pursuant to this Article shall not prevent any Member State from maintaining or introducing more stringent measures for the protection of working conditions compatible with this Treaty*."

Hence, in the very wording of Article 118a, any EU legislation adopted on this basis, such as CAD, imposes "minimum requirements" for Member States and as a result qualifies, formally, as legislation "imposing minimum requirements" capable of being the basis of an exemption under Article 58.2 of REACH.

Recital (1) of CAD indicates that its purpose is to lay down requirements in order to "*guarantee a better level of protection of the safety and health of workers*". These requirements are minimum requirements in that they oblige Member States to adopt limit values.

The scope of CAD is defined to be "*protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents*" (Article 1.1 of

[11] 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.

CAD).

Chemical agents are defined as "*any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market*" (Article 2(a) of CAD).

Activity involving chemical agents is defined 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*" (Article 2(c) of CAD).

CAD foresees the adoption by the Commission of occupational exposure limit values ("OELV"), defined as "*the limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker over a specified reference period*" whether binding or indicative, and of biological limit values. The main difference between binding and indicative OELV is that indicative OELV ("IOELV") are "*European objectives*" (see Article 3(2) CAD) based on the evaluation of "*the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment of the latest available scientific data*" (emphasis added).

The binding OELV, by contrast, in addition to the (scientific) factors considered when establishing IOELV, "*shall reflect feasibility factors while maintaining the aim of ensuring the health of workers at work*" (emphasis added). In other words, the socio-economic impact of those OELV is taken into consideration when they are made binding. Article 3(5) CAD further states that *"[f]or any chemical agent for which a binding occupational exposure limit value is established. Member States shall establish a corresponding national binding occupational exposure limit value based on, but not exceeding, the Community limit value*". So far, binding OELV only exist for one substance, inorganic lead and its compounds, while several chemical agents have been the subject of IOELV through Commission directives.

Regarding DMF in particular and the control of risks linked to occupational exposure, Directive 2009/161[12] established a list of IOELV within the framework of CAD.

The IOELV for DMF is set at 15 mg/m³ and 5 ppm for eight hours of exposure and 30 mg/m³ and 10 ppm for short-term exposure (15-minute period), with possibility of significant uptake through the skin.[13]

Additionally, Directive 92/85[14] 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).

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12 Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

13 See the Annex to Directive 2009/161.

14 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.

2. Existing EU legislation on minimum requirements in the field of industrial emissions (the VOC and IPPC Directives)

Potential DMF emissions are covered by Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations ("VOC") [15], on the one hand, and by Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control ("IPPC") as amended.[16] Both pieces of legislation will be repealed and replaced by Directive 2010/75/EU on industrial emissions ("IED"), effective on 7 January 2014. Thus, the three pieces of legislation are to be considered relevant for the present analysis.

The currently in force VOC and IPPC Directives were based on Article 130s under the Maastricht Treaty, which became Article 192 TFEU.

Article 193 TFEU indicates that protective measures adopted on the basis of Article 192 do not prevent any Member State from maintaining or introducing more stringent protective measures – hence, per the rules of the TFEU, VOC and IPPC qualify as EU legislation imposing *minimum requirements*.

Moreover, the IED, replacing the VOC and IPPC Directives, is also based on Article 192(1) TFEU, meaning that it will continue providing minimum requirements to be adopted by Member States, which are however entitled to enact more stringent measures.

The IED lays down rules on integrated prevention and control of pollution arising from industrial activities. It subjects the pursuance of certain industrial activities to the issuance of permits granted by the competent authorities of Member States on the basis of Best Available Techniques reference documents determined at EU level. Pollution is defined in the IED as the "*introduction, as a result of human activity, of substances […] into air, water or land which may be harmful to human health or the quality of the environment, result in damage to material property, or impair or interfere with amenities and other legitimate uses of the environment*" (emphasis added).

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 DMF, the use which is proposed to be exempted is the use as industrial process

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15 Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations, to be repealed by Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) as of 07/01/2014.

16 Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, codified and replaced by Directive 2008/1/EC, which in turn is to be repealed by Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) as of 07/01/2014.

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 DMF in Annex XIV of REACH should comply with the principles of proportionality.

A. - Existing legislation addressing the use ("specific")

As a preliminary remark, the phrase "existing legislation" does not necessarily refer to a single piece of law, but can as well refer to a combination of legislative measures, or a framework of regulations and directives (leading to national laws), resulting in defining EU-wide minimum requirements.

Regarding the first condition, Directive 2009/161 is existing EU legislation which provides Member States with indicative occupational exposure limit values (IOELV) for DMF. It does not cover specific uses as such. However, it was adopted as an implementing measure within the framework of CAD, 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*".[17]

Therefore, read in combination Directives 2009/161 and CAD both address the occupational use of DMF, or more specifically the "*contact at the workplace*" category of uses.

Additionally, it should be noted that the decision to include DMF in the ECHA Draft Recommendation was justified solely by occupational health issues, because of its classification as toxic for reproduction (Cat. 1b), thereby limiting the scope of the assessment to this specific use.

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

The IED also addresses the use of DMF as a solvent in industrial installations described under Annex VII (installations and activities using organic solvents), Part 4 (Emission limit values relating to volatile organic compounds with specific risk phrases).

The activities in which DMF are used are listed in Annex I to the IED, specifically point 4 (chemical industry) and more specifically sections 4.1 (production of organic compounds), 4.4 (production of plant protection products or biocides), and 4.5 (production of pharmaceutical products including pharmaceuticals).

B.- Proper control of the risks

In order to benefit from the Article 58(2) exemption, ECHA's guidance[18] provides that 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

[17] Article 2(c) of Directive 98/24.
[18] See above.

Annex XIV and specifically refer to the substance, should be properly controlled.

In this regard, Directive 2009/161 explicitly refers to DMF and establishes specific IOELV for DMF. The IOELV was based on an overall approach to occupational health and was not as such justified on the reproductive toxicity (category 1b) of DMF. However, the Scientific Expert Group on Occupational Exposure Limits (SCOEL) considered the possibility of exposure through inhalation and dermal uptake while taking into consideration possible developmental toxicity effects.[19] Consultation of the SCOEL is a requisite for the establishment of IOELV since IOLV are set on scientific grounds exclusively.

Therefore, the intrinsic SVHC properties of DMF (i.e. toxic for reproduction 1b) are properly controlled through Directive 2009/161, and Directive 98/24, since the IOELV covers the reproductive toxicity endpoint. As specified above, ECHA based its recommendation for DMF solely on occupational health issues. Therefore, the identified risks should be considered as properly controlled through the application of Directive 2009/161 and Directive 98/24.

Directive 98/24 sets obligations and acknowledges the responsibilities for the employer to ensure that, where the nature of the activity does not permit the risk to be eliminated by substitution, the risk is reduced to a minimum by application of protection and prevention measures, consistent with the assessment of the risk. Accordingly, the determination of whether a chemical agent poses a risk relies on the employer's judgement. Indeed, if an analogy is drawn from the adequate control of risks, as understood in REACH for the exemptions benefitting intermediates such as the authorisation exemption[20], this also relies on the employer's determination that the chemical substance (or agent) must be handled under strictly controlled conditions. Therefore, REACH accepts that both the nature and scope of the strictly controlled conditions, as well as the time when they need to be applied, are determined by the employer (or registrant). Similarly, Directive 98/24 relies on the principle that risks are minimised for the workers and thus, minimum requirements for proper control of the risks are set by existing legislation, in accordance with Article 58.2 of REACH.

Finally, occupational exposure to substances toxic to reproduction is additionally 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 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.[21]

The industrial emissions Directive (IED) also contains provisions on installations using organic solvents such as DMF – hence DMF is addressed by this legislation not by name, but by class of chemicals – requiring such installation, when specific consumption thresholds are reached, to operate only if they hold a permit or are registered.

The IED encourages substitution of organic solvents and, more importantly, sets down

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19 Recommendation of the Scientific Expert Group on Occupational Exposure Limits for N,N-Dimethylformamide, SCOEL/SUM/121, 2006 p. 22: "The OEL of 5 ppm also protects from developmental toxicity for which the NOEL was 50 ppm."

20 See Article 2.8 of REACH.

21 See Article 5 of Directive 92/85.

emission limit values for particular activities involving volatile organic compounds such as DMF and contains, in Article 59(5), a requirement that the use of such substances be controlled "*as far as technically and economically feasible to safeguard public health and the environment and shall not exceed the relevant emission limit values in […]*"set out in Part 4 of Annex VII.

For emissions of the volatile organic compounds referred to in Article 58 where the mass flow of the sum of the compounds causing the labeling referred to in that Article is greater than, or equal to, 10 g/h, an emission limit value of 2 mg/Nm3 shall be complied with. The emission limit value refers to the mass sum of the individual compounds.

Last but not least, DMF when used as an industrial process solvent is either recycled to be used as an industrial process solvent again or incinerated after use (the incineration process is covered by occupational health legislation, by emissions-related legislation, by Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and by Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste).

It is therefore demonstrated that the risks potentially posed to human health by the use of DMF as an industrial process solvent are under regulatory control at all stages of the DMF life cycle of this particular use, since

- Potential risks to human health arising during the manufacturing of DMF are adequately controlled by the occupational health legislation described above, and by the emissions control legislation described above;

- Potential risks to human health arising during the use of DMF as an industrial process solvent are adequately controlled by the occupational health legislation described above, and by the emissions control legislation described above, and

- Potential risks to human health arising during the disposal phase of DMF after use as an industrial process solvent are controlled under Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and by Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste, as well as under the emissions control legislation described above.

- Furthermore, IED foresees substitution where and as soon as possible (art. 58). Consequently, IED provides a more proportionate way of substitution through the implementation of BAT (Best Available Technique) in BREF (BAT Reference documents) defined at EU level. Substitution can be attained by IED and not necessarily through the REACH authorisation process, which would be redundant.

C. - <u>Minimum requirements imposed</u>

According to the ECHA guidance, the legislation must impose <u>minimum requirements</u> 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 2009/161, "*Member States shall establish national occupational exposure limit values for the chemical agents listed in the Annex, taking into account the Community values*". This reflects the wording of CAD which imposes, at Article 3(3) , that *"[f]or any chemical agent for which an indicative occupational exposure limit value is established at Community level, Member States shall establish a national occupational exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice*". Therefore, Member States were under the obligation to implement mandatory limit values for concerned substances at a national level by 18 December 2011 at the latest. Member States that have failed to timely comply with this obligation are exposed to court proceedings, as provided under Article 260 TFEU. The binding nature of the minimum requirements imposed by Directive 2009/161 cannot be contested.

Although the exact level of the limit value is not mandatory Member States are requested to (1) positively establish exposure limit values and (2) take the Directive's IOELV 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*".

As a result, the Member States cannot arbitrarily or unjustifiably derogate from the IOELV. The Annex XV dossier submitted by Sweden for DMF in August 2012 states that "*National occupational exposure limits (OEL) already exist for DMF*" and that "*the implementation of the Directive 2009/161/EU should lead to establishment of OEL in remaining Member States*". (see Annex XV report, page 13)[22]. This result has materialised with the IOELV having been adopted as is by all Member States, with a few exceptions due to late transposition and not from a different national OEL. It is therefore an established practice for the Member States to implement the IOELV as a minimum requirement.[23]

Therefore, through the application of Directive 2009/161 and CAD imposing the obligation for Member States to establish national limit values for DMF taking into account the IOELV, and 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.

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

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[22] Annex XV report (2012): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. N,N-dimethylformamide. Submitted by Sweden, August 2012.

[23] Incidentally, the fact that, to date, four Member States may not have yet transposed the IOELV into their respective national legislations – and that the Commission has apparently not launched Article 260 TFEU proceedings in that regard - is entirely irrelevant to the question of whether existing EU legislation meets the conditions for exemption under Article 58.2 REACH.

Lastly, it should be emphasized that it is the mandatory nature of the Member States' obligation to impose an OEL for DMF that constitutes, first and foremost, the minimum requirements ensuring the proper control of risks posed by the use of DMF as an industrial solvent. The fact that, in addition to respecting binding DMF OELs imposed by Member States, the employer using DMF in industrial settings is also obliged to apply a series of risk management measures reinforces the arguments related to the proper control of such uses, but does not replace them.

With regard to IED, the annexes and the relevant BREF impose minimum requirements which the Member States may make more stringent but to which they cannot derogate to grant permits.

D. - Proportionality

The inclusion of DMF in Annex XIV without the requested exemption would be disproportionate.

As explained above and as recognised in the ECHA Draft background document, DMF is used as an industrial solvent in a multitude of production and manufacturing processes (with the exception of professional laboratory use only industrial uses registered). However, it cannot be considered as an intermediate, according to the ECHA definition, because it does not participate in the chemical reaction. It is removed at the end of the process. DMF 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 DMF authorisation requirement. As a consequence, the authorisation requirement, potential authorisation review and related costs would lead to a permanent competitive disadvantage for EU manufacturers.

Indeed, the industrial uses and workers exposure can only be regulated through REACH if they take place within the EU. Accordingly, only the EU industry will be affected by the authorisation regime. This seems an unwanted and undesirable objective, especially when legislation imposing minimum requirements for the control of risks to worker's safety already exists in the EU, as has been shown above.

Furthermore, the manufacture of intermediates in the EU, which is generally exempt from authorisation (article 2(8) REACH), would indirectly be made subject to authorisation as the solvent used for the synthesis of these intermediates would need to be authorised. This is an unwanted consequence which can be addressed by an exemption.

On the other hand, there is no additional risk-mitigation benefit in making DMF subject to authorisation. Indeed, as explained above, the decision to recommend DMF 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 the above described existing legislation. Moreover, there are no suitable substitution substances. Therefore, there would be no effective added value for human health or environment considerations brought about by the inclusion of DMF in Annex XIV, and in any event if it was included without the requested exemption.

It is noteworthy that, so far, the EU has made little use of the Article 58.2 exemption. A

circumstance where it may have been used was the exemption from authorisation granted to use of DEHP in blood bags, when three substances were considered for inclusion in Annex XIV of REACH. This exemption relied on the basis that medicinal devices are exempt from authorisation under Article 60(2) and 62(6) of REACH, and that the "immediate packaging" of medicinal products "covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC"[24] using DEHP, BBP or DBP, such as blood bags, should benefit from the same exemption. Without prejudice to the merits of the justification of this exemption, it seems to be the sole occurrence where an exemption has been granted for a use relying on the appropriate control of risks and minimum requirements. Also, based on this sole example, it seems that the application of Article 58.2 is limited to situations where REACH does not apply, which would be contrary to the spirit and provisions of REACH, and render Article 58.2 devoid of sense and effect.

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 DMF in Annex XIV, which would therefore be disproportionate and contrary to general EU principles.

E. - Appropriate legal basis

Because DMF is proposed for inclusion in Annex XIV of REACH on the admission that all its uses (except from laboratory uses that are exempt from authorisation) are industrial uses, there are grounds to argue that regulation of DMF is purely a social measure, taken for the "*improvement in particular of the working environment to protect workers' health and safety*" as per the wording of Article 153 of the Treaty on the Functioning of the European Union ("TFEU"). Measures adopted by the Union in this field must be based on Article 153 TFEU in order to support and complement the activities of the Member States. They may take the form of either "*measures designed to encourage cooperation between Member States through initiatives aimed at improving knowledge, developing exchanges of information and best practices*" or of, "*by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. Such directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings*".[25]

However, the contemplated inclusion of DMF into Annex XIV of REACH would not qualify as either of the above measures. REACH is not based on Article 153 TFEU. Implementing measures resulting on inclusion into Annex XIV would no more meet the criteria of Article 153 TFEU. Therefore, subjecting DMF to authorisation where the only uses of the substance are either industrial or exempt, would be infringing the rules of the Treaty on the competency of the Union institutions in the field of workers' health and safety.

[24] See Annex XIV of REACH, entries No. 4, 5 and 6, and Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to REACH.

[25] See Article 153(2) TFEU.

4. Conclusion

Since the decision to recommend DMF for inclusion in Annex XIV was based solely on occupational health risks (because of the classification of DMF as toxic for reproduction category 1b), those risks are already properly controlled by the application of Directive 2009/161, Directive 98/24, Directive 92/85 and Directive 2010/75, which impose minimum requirements which must be implemented by the Member States.

Therefore, the occupational use of DMF as an industrial process solvent in industrial installations (i.e. the use of DMF with contact at the workplace), can be exempted from the authorisation requirements, in accordance with Article 58.2 of REACH.

In view of the significant burden for applicants, the resulting competitive disadvantage for the EU industry, and the limited added value, the inclusion of DMF in Annex XIV would be disproportionate if it did not include the requested **exemption for use of DMF as an industrial process solvent in industrial installations (e.g. in chemical synthesis and in the industrial manufacture of fibres and membranes).**

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