Non-confidential comments on the

„Draft background document for N,N-Dimethylacetamide (DMAC)[1]"

1) Comment to chapter 2.2.2.2 Uses and releases from uses

Agrochemicals, pharmaceuticals and fine chemicals (65-70% of tonnage)

a) General comments

1) Use descriptors

The uses description in the background document is misleading and we recommend it is corrected. Agrochemical, pharmaceutical and fine chemicals DMAC use is with very few exceptions exclusively "use for chemical synthesis in closed industrial installations". This large scale industry use is clearly a non-wide dispersive use as it is based on a very limited number of users consuming high DMAC volumes in closed industrial installations (see confidential part of this document).

DMAC as solvent for industrial chemical synthesis is used under controlled conditions in industrial installations. The evidence for this is as well the high recovery rate of DMAC in the existing processes used by industry given in ECHA's DMAC Background document on DMAC . While DMAC is handled under controlled conditions it is not an intermediate as it is not transformed into another substance. However, DMAC is removed for recovery from the final product after chemical synthesis. The removal of the solvent is very efficient (almost no residual amount is left in the final product) and all of the DMAC consumed ends up in chemical waste streams after being recycled several times. Chemical waste from industrial sites such as BASF SE in Ludwigshafen (Germany) is efficiently biodegraded in a sewage treatment plant or incinerated (see legal requirements on chemical waste management and CALC calculation for BASF sewage treatment plant presented to Echa via SVHC – Questionnaire). In other words, nearly all DMAC consumed will end up in waste streams influents which are subsequently treated. As a consequence, there are no environmental releases of DMAC and no relevant or uncontrolled substance releases in these processes. Off-gas incineration, elimination in sewage treatment plants below the limit of detection (= 5 µg/L) in the effluent and sites being built in a concrete trough in order to prevent direct soil exposure can be regarded as industrial standard for large scale industrial installations used for chemical synthesis.

Regarding the PROCs and ERCs used as use descriptors in the CSR, we wish to provide additional information.. PROC 5 was used to describe the formulation of preparations only because it was possible for this PROC to define a safe use by risk minimization requirements (goggles, gloves) being obligatory in any chemical plant at any time when handling a chemical substance. In practice there is neither significant contact to DMAC at any stage of use (PROC 5) nor a significant opportunity for such a contact at sampling or charging or discharging (PROC 8a/b). Beyond this, in the German translation of the use descriptor system PROC 8b is connected to a filling line for one product.

[1] Draft background document for N,N Dimethylacetamide (DMAC)
Document developed in the context of ECHA's fourth Recommendation for the inclusion of substances in Annex XIV (20 June 2012)

However very often there are dedicated filling lines that are used for more than one product (multi purpose). As PROC 8a is a safe use even with mandatory minimum risk minimization measures it was always included in the use description. DMAC exposure in a PROC 3, 4, 8a, 8b scenario has been measured at BASF SE to be below <0.07-<0.22 mg/m³ (= not detectable in 6 different measurement over a period of 2 years). Any significant dermal exposure can be excluded due to mandatory use of chemical resistant gloves (see information presented to Echa via SVHC –Questionnaire)

Automated filling and workers wearing gloves (butyl) and goggles can be regarded as common industry standard for large scale industrial installations. At maintenance a workers standard protection in the chemical industry includes gloves (butyl), face protection, chemical protection suit and respirator if there is a possibility of occupational exposure of the worker to the substance.

2) Authorization of DMAC use for chemical synthesis is disproportionate relative to the health and safety aims of the legislation

We believe that the authorization requirement for chemical synthesis is disproportionate relative to the goals of the legislation when existing risk management measures are taken into consideration. This is true in particular for the synthesis of agrochemicals and pharmaceutical active ingredients as route of synthesis is part of the registration of agrochemical and pharmaceutical registrations (Main use of DMAC). A change of solvent may therefore require repeated global registrations for these ingredients.

In addition, subjecting DMAC to Authorization is disproportionate due to the fact that use of DMAC in chemical synthesis is presently adequately controlled. The proposed inclusion of DMAC into Annex IV constitutes a significant burden for the applicant both on an organizational and on a financial level. The elaborate and costly authorisation process is accompanied by a substantial lack of planning reliability and asset protection leading to increased costs and market uncertainty which will significantly impact the competitivity of European producers. This is due to the fact that substance authorisations are subject to periodic reviews. Since no DMAC is present in the finished products, authorization for DMAC use for chemical synthesis is a burden only for an EU manufacturers using DMAC for synthesis of a chemical substance but not for an importer of such a substance. Furthermore by increasing costs of EU-based production of substances dependent on DMAC, authorization is:

1. a <u>disadvantage for EU-based production in export markets</u> when compared to non-EU production.
2. a <u>disadvantage for the EU-based production on the EU market</u> when compared to non-EU production and importing a chemical into the EU afterwards

This is a clear discrimination of an EU manufacturer and clearly in contradiction to article 1 (1) of the REACH regulation aiming at “enhancing competiveness and innovation”.

b) Fine chemical:

There is some small laboratory use for quality assurance of DMAC itself or laboratory research use (industrial) or at universities (professional). Nevertheless professional use in universities is DMAC use in a chemical laboratory where risk minimization measures like fume cupboard etc. can be expected.

There is no likelihood of aerosol formation by spraying in chemical synthesis of fine chemicals as no such processes are used.

c) Pharmaceutical use:

The main use of DMAC in pharmaceutical industry is the use of DMAC as process solvent e.g. chemical synthesis of active ingredients. According to international pharmaceutical regulation DMAC is a class II solvent and residual DMAC in pharmaceuticals is regulated (ICH Q3C (r5) - International Conference On Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use). The maximal residual DMAC amount in active pharmaceutical ingredients is limited to 0.1% (exactly 1090 ppm).

Minor direct use of DMAC in veterinary and human pharmaceutical products is not regulated by REACH Annex XIV listing, authorization respectively. Adaption of the corresponding pharmaceutical EU regulation is the only way to regulate this use. Beyond this, Annex XV dossier on DMAC already concluded that use as excipient is “not widespread”. Such uses are already explicitly out of the scope of REACH and therefore should be removed from the document.

d) Agrochemical use

Agrochemical use of DMAC is exclusively chemical synthesis of active ingredients in industrial installations or small scale industrial laboratory use for quality assurance.

There is no use of DMAC in agrochemical formulation as DMAC is a CMR cat. 1b substance. DMAC use in agrochemical formulations is prohibited according to Regulation 1107/2009. Consequently there is no spraying of DMAC in pesticide uses as DMAC is no ingredient of such formulations.

<u>Man-made fibres (20-25% of DMAC tonnage)</u>

DMAC is used for production of m-aramid, elastane and acrylic fibres all having specific indispensible properties.

Addition to the description of Aramid fibres: Meta-aramid fibres are essential to society as they are the material used for fire protective clothing (firemen clothing) and military suits (Special Forces, pilots) or in industry to protect against electrical shock. These fibres are more commonly known by trade names such as, Nomex®.

As stated correctly, the solvent is recovered very efficiently in the production process of fibres (>99%), solvent losses in the recycling process are DMAC distillation by-products due to acid hydrolysis.

DMAC is used as a process solvent in an industrial installation. DMAc, due to its well understood properties, is used in the man-made fibre industry under conditions that allow for the adequate control of the risks associated with the substance properties. It is not an intermediate as it is not transformed into another substance. DMAC is removed from the final product during the converting processes following the fibre spinning process at the MMF producers. As removing of the solvent is very efficient (almost no residual amount in the final product), most DMAC consumed by the MMF industry end up in chemical waste streams. Chemical waste streams containing DMAC are well regulated and end up being incinerated or biodegraded in sewage treatment plants.

Raw fibre contains as an average over the production volume of the mentioned 3 fibre types 0.25 % residual DMAC. This is a concentration considered as non-reprotoxic even for mixtures according to Regulation 1272/2008 (limit concentration for C&L of reprotox. Substances 0.3%, though the CLP is using a substance specific threshold of 5% based on the results from studies considered during the global harmonized system process). A small volume of fibre does contain more residual DMAC up to maximum 1%.

In the discussion of a potential risk of exposure of workers by DMAC in the fibre and a potential uncontrolled release, the recommendation document focuses on the further processing (converting) of the fibre containing residual DMAC. The presence of residual DMAC in some fibres is not a use and is not regulated by REACH. Furthermore, adequate worker protection is achieved by compliance with the existing Occupational Exposure Limits (OELs). Published data however proves that this is not the case (CIRFS to provide references: Ex. IFA (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallvericherung, MEGA-Auswertungen zur Erstellung von REACH-Expositioinsszenarien für N,N-Dimethylacetamid in der Textilindustrie, 2011). Beyond this, the background document ignores the fact that the potential risk being described is not due to a handling or use of a chemical substance but to an article releasing this substance. The evidence shows there is no health risk based on controlled residual amounts of DMAC (manufactured or imported raw yarn). Should additional regulations be necessary to enhance an already adequate level of worker protection, the restriction route would be more appropriate, the only option to address this concern, respectively.

For more detailed information see the comment that CIRFS will to give to ECHA directly.

<u>Industrial coatings (3-5%)</u>

Use in industrial coatings as Polyamide-imide (PAI) enamel (varnishes) is a special coating application in a closed system and under controlled conditions. DMAC high solvating power for high molecular weight polymers is the reason for this special use. DMAC's low vapour pressure does not make it optimal for general coatings use, especially where drying of the coating under ambient temperature in open systems is applied. For drying of such coatings usually a high vapour pressure of the solvent is preferable. DMAC's vapour pressure (2 mbar @20°C) is lower than the vapour pressure of water (23 mbar @20°C) and much lower than usual solvents in paints such as n-hexane (126 mbar @ 20°C). In the PAI coating process DMAC is destroyed in this process at high temperature. The enamel production process is in a closed circuit with off-gas incineration resulting in emissions close to zero.

All operators wear solvent-resistant gloves, protective clothing and respiratory protection for filter sockets change operation.

Paint strippers (<1%)

This is a minor use not supported by industry (no use registered). In fact BASF SE is not aware of such use at our customers but we currently cannot exclude this use. Beyond this, as it can clearly be seen from the amounts used, this use has not been an issue up to now. Currently this use is not mentioned in the CSR chapter "Uses advised against" due to the lack of knowledge this use (existence and conditions), and as this measure is seen by industry as being too weak. Any downstream user who wishes to use DMAC as paint stripper can come up with his own risk assessment demonstrating safety of his "special" use. Any downstream user has an obligation to comply to information provided by the suppliers unless evidence of otherwise is provided. Paint strippers may be regulated efficiently by restriction. Restriction may be more appropriate to avoid DMAC being used in paint strippers.

Action by BASF SE:

An "advice against use" does not guarantee that DMAC is not used as paint stripper. However it may be a good tool if followed by a restriction. In expectation of a restriction BASF SE will update their DMAC CSR to include the paint striper application in the CSR chapter "uses advised against".

2) Comment to Chapter 2.3. Availability of information on alternatives

As already explained in the comment of the Annex XV dossier there is currently no general alternative for DMAC available.

DMSO cannot be considered as a general substitute for DMAC (solubilisation properties (polarity, hydrogen bonding), melting point, boiling point, glove and skin permeability thermal stability) etc. Aside from penetrant odour sulphur containing decomposition products such as methylmercaptan are toxic by inhalation and cause additional efforts in the off-gas treatment.

The use of acetone and acetonitrile, in place of DMAC is excluded due to very different properties (solubilisation properties (polarity, hydrogen bonding), boiling point etc.), especially due to their flammability. This property will prohibit large scale use in an industrial installation..

3) Comment to chapter 2.4 Existing specific Community legislation relevant for possible exemption

There is a specific Community legislation in force on which exemption of a category of uses from the authorisation requirement can be granted on the basis of Article 58(2) of the REACH Regulation (ref. DMAC - Annex XIV Recommendation - Cefic comments 140912.pdf handed in as comment to DMAC RCOM by Field Fisher Waterhouse on 14.09.2012). The conclusion of this legal opinion is:

"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."

4) Comments to chapter 3. Conclusions and justification

It has been concluded by ECHA that "*Exposures are believed to be within the IOELV and are likely to be a small fraction of the IOELV where processes are contained and effective ventilation is employed (ECHA, 2011)…..Transfer systems are designed to minimise environmental release, by trained personnel using appropriate protective equipment, and are thus contained within the process stream. In practice virtually all DMAC used will end/be handled in the waste streams",* which is incineration or biodegradation in sewage treatment plants.

There is practically no environmental release from these large scale uses such as solvent-use in chemical synthesis of agrochemicals, pharmaceuticals and fine chemicals.

A letter of legal opinion will be provided to Echa that clearly explains why an annex XIV listing of DMAC is disproportionate unless most of the current DMAC uses are excluded from authorization. As "*risks of DMAC 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 recommendation of DMAC prioritization for inclusion into Annex XIV is unnecessary."* (ref. DMAC - Annex XIV Recommendation - Cefic comments 140912.pdf handed in as comment to DMAC RCOM by Field Fisher Waterhouse on 14.09.2012)

<u>Prioritization (identified uses with high exposure)</u>

Batch formulation processes: as explained above batch formulation with opportunities of significant exposure does not exist for DMAC, therefore it has still to be regarded as safe. PROC 4 and 5 were just named as they are formulation PROCs and they are calculated to be safe. DMAC exposure in a PROC 3, 4, 8a, 8b scenario has been measured at BASF to be below <0.07-<0.22 mg/m³ (6 different measurements over a period of 2 years), which is far below the IOEL of 35 mg/m³.

The application of coatings containing DMAC is a special industrial process. DMAC is removed by evaporation and decomposition at high temperature. Applications are automated with no worker exposure at all which includes industrial spraying / roller / brushing and pouring (see as well confidential part of this document).

Spinning of fibres is a highly automated industrial use with no worker exposure. Residual amounts in the fibre (= article) are in average < 0.3 % which is considered as not relevant even for mixtures. In a

measurement initiative conducted in the year 2000 inhalative exposure at such processes were determined to be below 0.03 mg/m³ or below 3.5 mg/m³ in 116 measurements in 16 different plants.

The presence of residual DMAC in some fibres is not a use and is not regulated as such by REACH – annex XIV inclusion.

Scoring

There are several comments to the scoring regarding the volume and wide dispersive use.

Volume: As there is a specific community legislation on DMAC in place which is defining minimum requirements relating to the protection of human health, the main uses like chemical synthesis of agrochemicals, active pharmaceutical ingredients and fine chemicals that represent 65 -70 % of total DMAC use in the EU can be exempted from authorization based on article 58.2.

Concerning the use of DMAC in the production of man-made fibre (aramid, acrylic and elastane), fibre spinning is an industrial process under controlled conditions. The recommendation considers the possible release of residual DMAC from the fibre as well. Fibres however are articles which may be regulated by a restriction, but cannot be regulated by authorization. Nevertheless it is clear that the amount of residual DMAC and possible maximal release is clearly adequately controlled and at not posing an occupational risk .

Thus, only a very low amount of total DMAC-use (about less than 3% for paint strippers and other applications as mentioned above) is left as potential subject to an authorisation requirement.

Conclusion: Volume score should be 7 or even 5 instead of 9 because only volumes that are subject to authorization should be considered in the scoring for prioritization.

Wide dispersive use: The Scoring of wide dispersive use is split up into two factors:

> **Number of sites**: As shown in the confidential part of this document the main use of DMAC takes place at a very limited number of industrial sites. Processing of fibres containing residual DMAC at concentrations not relevant to health is processing of an article that cannot be regulated by authorization. Consequently the number of sites treating fibres (finishing of the article) should therefore not be included in the scoring procedure.
>
> **Release**: Release score is rather 1 instead of 3 because as described above DMAC is used in closed systems or at controlled conditions with occasional controlled exposure only. Systems to recycle DMAC within the process of chemical synthesis are in place. As a solvent for chemical synthesis, DMAC ends up in industrial waste streams which results in incineration or biodegradation in sewage treatment plants.

Conclusion: Site score should be 2 instead of 3 because at toxicological relevant concentrations DMAC is handled at a very limited number of sites only. Release score should be 1 instead of 3 because DMAC is only used in closed systems or under controlled conditions and waste streams of the chemical use are controlled as well.

Overall conclusion on prioritization score

Consequently the overall score for prioritization of DMAC should be 10 or even less (IP = 0; V = 5-7, WDU = 2 x 1): IP + V + WDU = 8-10

The major potential health risk described in the recommendation-document may arise from the paint stripper use.

5) Summary: Authorization is not the appropriate risk measurement option as:

There are only large scale industrial uses for DMAC for which no risk is identified for all DMAC uses.

The use of DMAC is already adequately controlled on an EU community level (application of Directive 2000/39, Directive 98/24 and Directive 92/85) what qualifies such uses for exemption from authorisation according to 58.2

The authorization requirement for use of DMAC in chemical synthesis is disproportionate. This is true in particular for the synthesis of agrochemicals and pharmaceutical active ingredients as route of synthesis is part of the registration of agrochemical and pharmaceutical registrations (Main use of DMAC). A change of solvent may therefore require repeated global registrations for these ingredients.

For other industrial uses as described above authorization is disproportionate as well due to the fact that use of DMAC is adequately controlled. The solvent DMAC is removed from the substance synthesised after chemical synthesis. Consequently, authorization for DMAC use for chemical synthesis is a burden only for an EU manufacturer of a chemical substance using DMAC for synthesis but not for an importer of such a substance. Furthermore authorization is not only puts an EU manufacturer at a competitive disadvantage on the non-EU market, but as well a disadvantage for the EU manufacturer on the EU Market in comparison to a non-EU manufacturer importing a chemical substance into the EU. This is a discrimination of an EU manufacturer and clearly contradicts article 1 (1) of the REACH regulation aiming at “enhancing competiveness and innovation”

Any potential risk identified in the recommendation is either a defined use (paint stripper) or a postulated risk from an article containing toxicological non relevant amounts of residual DMAC that may be released during further processing of the article. But articles potentially releasing a Substance of Very High Concern (SVHC) may be regulated by restriction, which is the only regulatory option for articles according to REACH.

This demonstrates that authorization is an ineffective RMO and thus is disproportionate.

If you have any further questions, please do not hesitate to contact:

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