Italy proposes a restriction on industrial and professional uses of N, N-DIMETHYLFORMAMIDE (DMF)[1]

Summary

Italy has submitted an Annex XV dossier under REACH proposing a restriction on the manufacturing, and industrial and professional uses of N, N-Dimethylformamide (DMF, EC No.: 200-679-5).

The basis for this restriction proposal is a concern for human health resulting from the exposure to DMF, due to its reprotoxic properties.

The public consultation on this proposed restriction will start on 19/12/2018 and end on 19/06/2019. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome early comments, by 01/03/2019, to assist them in their opinion development.

SUGGESTED RESTRICTION

Scope

The dossier proposes the restriction to apply to the manufacturing and all industrial and professional uses of N,N-dimethylformamide whatever its purity, in concentrations higher than 0.3%.

According to the restriction proposal, DMF may only be manufactured and used in industrial and professional settings in concentrations at or above 0.3% if under normal operating conditions the exposure will remain below the derived no effect levels (DNEL) calculated for workers for long-term inhalation exposure of 3.2 mg/m^3 and for dermal exposure of 0.79 mg/kg bw/day. Both DNEL values have been derived according to the relevant ECHA REACH Guidance.

Compliance with this requirement means that the users of the substance as such or in mixtures have to verify, whether their uses are included in the extended safety data sheets, and if their conditions of use are the same as those described in the relevant exposure scenarios. This means, that the substance shall not be used, as a substance on its own or in mixtures in a concentration equal to or greater than 0.3 % unless manufacturers and downstream users implement the risk management measures and provide the operational conditions to ensure that exposure of workers is below the DNELs specified in the restriction. The compliance can be demonstrated by the site-specific risk assessment, including exposure monitoring.

The exposure levels (inhalation and dermal) below the relevant DNEL values must be ensured by the use of preventative and protective measures (e.g. elimination, substitution, enclosure, local exhaust ventilation and general ventilation, administrative measures and if needed personal protective equipment) that are applied according to the "hierarchy of control" principle, which is an established concept referred to in the Chemical Agents Directive (Directive 98/24/EC).

The Dossier Submitter has identified two sectors, for which compliance with the provisions of this restriction may be difficult: man-made fibres and textile coating. Current proposal does not include any specific derogations or other special provisions for these sectors.

[1] The information note has been prepared based on the Annex XV report.

The transitional period of two years is recommended for the implementation of the restriction.

Reasons for action

The main reason for acting on a Union-wide basis is the protection of human health from the adverse effects of DMF due to its reprotoxic (Category 1B) properties. Based on information presented in the registration dossier and obtained through the stakeholders consultation, there is strong evidence that DMF is potentially used in all EU Member States. While there is an indicative Occupational Exposure Limit established at the EU level (with resulting exposure limits at national levels), it is higher than the DNEL level for inhalation calculated under the provisions of REACH, and there is no exposure level established for exposure through the skin under OSH legislation. The exposure estimations presented in the restriction dossier indicate that in some industrial settings occupational exposure may result in unacceptable risk.

DMF is an aprotic and medium polar organic solvent, with limited number of technically feasible alternatives; for the majority of uses adequate, less hazardous alternatives are not available. As it is possible to identify a no-effect level for DMF – safe exposure levels can be identified. Therefore, the dossier submitter concluded, that to achieve the uniform, adequate level of protection for workers across all sectors and in all member states a restriction based on the use of DNEL values for inhalation and skin exposure is needed.

Consequences of the action

The implementation of the proposed restriction would ensure that the risks resulting from inhalation and skin exposure to DMF would be adequately controlled. Therefore – there would be no ill health costs, should the restriction be implemented in all sectors.

The Dossier Submitter has evaluated, that the net present value of the health gains due to the restriction would be at least in the range of €567.1 – 1763.5 million considering a fifteen year time horizon. According to the Dossier Submitter the estimated health benefits are likely to be larger in practice, as results for some health points are not quantifiable.

According to the dossier, currently, the risk is not adequately controlled. Only in man-made fiber and textile coating sectors, employing about 4 500 to 5 800 workers, there is estimated to be about 1 300-2 500 employees potentially exposed to DMF.

However, the implementation of the changes needed to achieve the exposure levels below the level of DNEL – is linked to significant cost to the industry. The highest impact is expected by the man-made fiber and textile coating sectors.

The socio-economic costs of the proposed restriction are estimated to be in a range of €880 –1515 million in net present value over a 15-year period. These costs would be incurred due to measures that the companies may have to take to reduce the exposures to the workers.

While the restriction proposal foresees additional costs from enforcement activities of authorities, no major additional administrative burden on public authorities in terms of implementing the DNEL levels is expected.

SPECIFIC INFORMATION REQUESTED

A few specific issues have been identified to be addressed in the Public Consultation to gather relevant information, if available, from stakeholders:

Questions for the PC – DMF

1) Please provide measured data (personal as well as static sampling) from the workplace monitoring (for different uses and sectors) with contextual information:
   a) about the operational conditions,
   b) about the tasks performed (with potential exposure to DMF),
   c) the risk management measures in place (RMMs),
   d) personal protective equipment (PPE) worn, and
   e) on the sampling time

   Please state if the concentration provided is the time weight average for eight hours.

- Please provide an analysis of the biomonitoring data with sufficient contextual information on the sampling time related to the shifts (e.g. before or after), the tasks performed, the operational conditions, the risk management measures (RMMs) in place, including PPE worn.

2. Man-made fibres and textile coating are the two sectors identified as not being able to implement the provisions of the proposed restriction. Therefore, for these sectors, as well as for other uses/sectors in the same situation please provide information on:

   a. RMMs in place in workplaces and provide the information on the exposure levels achieved with these measures in place (TWA and STEL), preferably using measured data.

   b. The number of workers presently exposed to DMF in levels above the proposed DNEL values, on sector level if possible

   c. The tasks for which it is considered that the RMMs implemented are not sufficient to reduce the exposure level to below the proposed DNEL of 3.2 mg / m^3 for inhalation, and 0.79 mg / kg bw /day for skin exposure.

   d. What would need to be changed (e.g., introduction of robotics, production system, RMMs, procedures, PPE) to achieve compliance, and comment on the possibility to introduce the changes needed to achieve compliance with the restriction provisions (for both inhalation and skin exposure).

   e. What would be the costs of the changes needed to achieve compliance with the restriction, and when these changes could be implemented.

   f. In case the proposed reduction of exposure or substitution of DMF are not possible (at a company or sector level), please describe what exposure level would be achievable and how that reduction could be reached. Furthermore,

indicate, what would be the related costs and a required transitional period for the implementation.

g. Any company which i) has been able to implement the provisions of the proposed restriction, or ii) has been able to find less harmful substitutes to DMF.

3. Assuming upstream companies currently using DMF are not able to reduce the exposure to the proposed level or substitute it, and therefore would have to discontinue the use of DMF, please, describe subsequent (indirect) impacts on and costs for down-stream users in that supply chain. The question applies especially to man-made fibre and textile coating sectors.

Comments preferably by 01/03/2019

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 19/12/2018. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 19/06/2019, the rapporteurs of RAC and SEAC would appreciate receiving comments by 01/03/2019 to assist them in the early stages of the opinion development process.

The final opinions of both Committees are scheduled to be available by December 2019. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in the Public Consultation Guidance
http://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf