19 May 2020

Webinar on 30 April 2020

How to use ECHA's guideline for safe handling of NMP

QUESTIONS AND ANSWERS

Compiled by Petrochemicals Europe

Questions received via the chat during the webinar have been grouped by topic. Therefore, you may not find your exact question in this Q&A. However, the content of your question is covered. Some interesting questions from the webinar registration (webinar expectations entry) were also included in this document.

This public document only provides general answers, it cannot cover any company specific situations. Please do not hesitate to contact Philip de Smedt (pds@cefic.be) if you have questions about this document. For specific questions about your use of NMP, you may consider contacting your national helpdesk[1].

1. What is new & special about the NMP restriction?

The restriction entry 71 is the first time when authority set DNELs are used for regulatory risk management under REACH.

The use of DNELs is a modern way to restrict uses of a substance. All uses that generate an exposure above the harmonized DNELs are forbidden and all uses with an exposure below the harmonized DNEL are allowed.

Note: Usually DNELs are derived by REACH registrants of a chemical substance. EU-wide mandatory DNELs are reference values set by ECHA's Risk Assessment Committee and they are based on best available information.

2. What was the reason for a longer transition period for the wire winding sector?

ECHA's Committee for Socio-economic Analysis (SEAC) recommended a five-year general deferral of application of the restriction, in line with the period proposed in the Annex XV dossier, to allow stakeholders to take the necessary compliance measures. It also considered that a longer period might be appropriate for the wire coating sector, which was identified by The Netherlands as the sector on which the proposed restriction could have the greatest impact in relation to costs[2].

[1] https://echa.europa.eu/support/helpdesks

[2] Official Journal of the European Union, COMMISSION REGULATION (EU) 2018/588 of 18 April 2018, page 2

3. Is ECHA's NMP Guideline a blueprint for other substances undergoing restriction like DMF & DMAC?

There are a few other industrial process solvents (DMF, DMAC & NEP) in the restriction pipeline for which harmonized DNELs are foreseen to be used as the risk mitigation measure. All these solvents have similar phys.-chem properties and are used in similar applications. In addition, they are all reprotoxic solvents just like NMP. Therefore, the European Commission is considering to regulate them the same way as NMP. Due to the similarities in physical and chemical properties and uses, the guideline developed for NMP will also provide relevant information for DMF, DMAC & NEP users. Therefore, it is not currently envisaged to generate specific documents for these substances at EU level. However, industry webinars and seminars addressing DMF, DMAC & NEP specific questions are likely to be organized prior to companies need to comply with the corresponding restrictions.

4. What should I do if I do not get an up to date SDS with harmonized DNELs and related safe use information?

You should contact your supplier and insist on getting an up to date SDS and safe use information. It is the duty of your supplier to provide you with a REACH compliant SDS for NMP or a mixture containing NMP and safe use information relevant to the restriction.

If you import NMP or a mixture containing NMP and are supplied with NMP above 1t/year from a non-EU country, you may be an importer and have the same duties as a NMP manufacturer. Please check if your non-EU supplier has a REACH registration via an Only Representative (OR) for NMP. In this case the OR has to provide you with an EU compliant SDS. If your non-EU supplier has not nominated an OR for NMP then you are responsible for the registration of your imports and other related duties for NMP.

Finally, if you import a mixture and handle less than 1 t/year of NMP you are still required to follow OSH legislation as well as the REACH restriction. Consequently, do a safety assessment for the workplace. Use the information your supplier provides you with in the SDS; ensure that you are compliant with EU laws. The good practice examples and other information in the NMP Guideline may help you in this task. In addition, you may check your compliance with the legislation and the validity of your workplace safety assessment by carrying out monitoring as described in the Guideline.

For further advice please consult the importer's page on ECHA's website[3] or contact your national helpdesk[4].

5. What are the duties of suppliers of NMP-mixtures to ensure compliance with the restriction at the customers' sites?

The duties of suppliers of NMP mixtures are the same as those for a supplier of any other mixture. The supplier has to do a safety assessment of the mixture and provide the resulting advice to their customers in the SDS. Records of this safety assessment and information on the recommended RMMs should be kept available for any potential inspection for 10 years after the last delivery.

Note: It is the responsibility of users of NMP to demonstrate that they comply with the NMP restriction at their sites.

[3] https://echa.europa.eu/support/getting-started/importer

[4] https://echa.europa.eu/support/helpdesks

6. Why was a harmonized DNEL established instead of setting a BOEL?

DNEL and OEL values (incl. BOEL: Binding Occupational Exposure Limit) are derived under different pieces of EU legislation. REACH uses DNELs and OELs are used under the OSH legislation[5]. The EU authorities' decision to manage the risks of NMP under REACH led to the selection of DNELs as the most appropriate way to limit the exposure at the workplace.

7. Is there a measurement requirement to demonstrate compliance with the harmonized DNELs?

The restriction does not include a requirement to carry out measurements, but the employer is required to ensure that the workers' exposure is below the harmonized DNELs. The employer must be able to demonstrate compliance according to the national requirements (mainly through monitoring the exposure; some Member States may accept modelling). Enforcement of the compliance with the NMP restriction may be carried out by national labour inspectors and/or REACH enforcement authorities depending on the Member State. Users of NMP should contact their national authorities for advice on local requirements.

8. Is ECETOC-TRA a suitable modelling tool as NMP is a CMR?

ECETOC-TRA provides an exposure estimation towards a chemical substance under certain conditions of use. It is based on physical and chemical properties of the substance and on exposure measurement data of model compounds. Consequently, ECETOC-TRA model generally applies to any substance in the application domain of that model. There are other exposure calculation models e.g. "Stoffenmanager"® available. Finally, there is also the possibility for workplace measurement if a more precise exposure assessment under the condition of substance use is required.

The important step of the chemical safety assessment, however, comes after exposure estimation. It is the comparison of the exposure with the DNEL to conclude whether there is a health risk under the conditions of use. NMP is a CMR, but as reprotoxic substance it has a threshold level which is defined under REACH by the NMP harmonized DNEL (restriction 71). Only exposure of the worker below the harmonized DNEL is allowed.

You should consult ECHA's Guidance document on Information Requirements and Chemical Safety Assessment Chapter R.14: Occupational exposure assessment[6]. ECTOC TRA and other models including their applicability domain to assess occupational exposure are briefly introduced in the appendix. For a better understanding of Chapter R.14, reading of Chapter R.12: use description[7], will be helpful.

9. How to measure dermal exposure to NMP?

Please consult the NMP Guideline[8], Appendix 2 on Potential Analytical Methods.

[5] General principles of EU OSH legislation
[6] https://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf
[7] https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf
[8] https://echa.europa.eu/documents/10162/13641/entry_71_exp_note_biomonitoring_en.pdf

10. Does dermal exposure occur when you are exposed to vapour?

That is possible due to NMP's high skin penetration potential.

11. What to do if air concentration is above DNEL but below OEL?

The exposure to NMP at the workplace must be below both the DNELs specified in the restriction[9] and any national OEL in your country. Please consult your national list of OELs for values relevant to you.

12. What is the time reference for the restriction DNELs?

The harmonized DNELs for NMP refers to repeated exposure. For comparison with hazards after repeated or continuous exposure (chronic effects), a reference period of a full shift (normally 8 hours) is generally used. Exposures that are typically longer or shorter than the 8-hour reference period can be adjusted in magnitude to provide an 8-hour time-weighted average estimate so they can be compared with chronic DNELs.

See ECHA's Guidance document on Information Requirements and Chemical Safety Assessment Chapter R.14: Occupational exposure assessment[10].

13. Can DNELs or OEL be set for different subpopulations with different heath risk (e.g. pregnant women)?

Theoretically this is possible, but for NMP the same DNEL applies to all worker populations.

14. Are the OSH requirements (CAD - Chemical Agent Directive) part of the restriction?

No, the restriction requires employer to ensure that the employees use NMP in compliance with the harmonized DNELs. In addition, the employer needs to comply with the duties under the OSH legislation. The NMP guideline aims at helping companies using NMP to understand and be compliant with both REACH and OSH requirements.

[9] https://echa.europa.eu/documents/10162/e7598958-eae7-1661-0636-02778b427efc
[10] https://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf