

Note for the attention of Dr Tim Bowmer, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment for a joint opinion of the Committee for Risk Assessment (RAC) and the Scientific Committee on Occupational Exposure Limits (SCOEL) to resolve the differences in scientific opinion as regards exposure levels for NMP

Based on the request from the European Commission to ECHA on 24 June 2015, the purpose of this note is to give a mandate to RAC to draw up a joint opinion with SCOEL on differences between the Derived No Effect Level (DNEL) and the Occupational Exposure Limit (OEL) for the aprotic solvent n-methylpyrrolidone (NMP).

1. Background

In 2009, the Commission adopted¹ for the chemical substance 1-methyl-2-pyrrolidone (NMP) an indicative occupational exposure limit (OEL) value (IOELV) of 40 mg/m³ for inhalation exposure (over 8 hours, time weighted average) with a notation indicating the possibility of significant uptake through the skin, based on a 2007 recommendation by the Scientific Committee on Occupational Exposure Limits (SCOEL). In December 2014, SCOEL confirmed their recommendation for an OEL of 10 ppm (40 mg/m³) with a skin notation.

On 5 June 2014, the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC) adopted their opinion, on a proposal from the Netherlands, to restrict the marketing and use of NMP. In the opinion of RAC those conducting a REACH chemical safety assessment should be obliged to use long term 'derived no effect levels' (DNELs) of 10 mg/m³ for inhalation exposure and 4.8 mg/kg/day for dermal exposure for workers as the basis for their risk characterisation.

In practice, the inhalation DNEL in particular could be seen as being equivalent to an OEL but with a lower numerical value than the existing IOELV.

Through earlier discussions it has been established that both Committees consider the same studies but use different toxicological effects as points of departure, and different assessment factors to derive the limit value. There is therefore a difference of opinion between RAC and SCOEL regarding which critical adverse health effect should be used as the basis to derive an exposure value or recommendation for a limit value for worker protection for NMP related to inhalation exposure.

Consequently, in accordance with the obligations of ECHA and SCOEL under Article 95(3) of REACH as implemented through ECHA Management Board Decision 22/2013 and Article 2(9) of Commission Decision 2014/113/EU, the Commission services request that the two committees address this issue and work together to resolve this difference in view.

¹ Directive 2009/161/EU

2. Terms of Reference

In order to allow the Commission, on the basis of the joint scientific opinion of RAC and SCOEL, to take action as regards exposure levels of NMP, the Executive Director of ECHA requests ECHA Secretariat to make the necessary practical arrangements for RAC and SCOEL members respectively to work together to discuss the application of their differing methodologies in the case of NMP and in particular:

- the choice of critical adverse health effect(s),
- the use of a weight of evidence approach,
- the appropriate use of assessment factors and their scientific relevance,

with the objective to agree, if possible, on these parameters for the specific case in order to recommend a common health-based reference value.

Any identified differences of approach should be duly justified.

3. Timescale for the joint RAC-SCOEL opinion

The joint opinion of RAC-SCOEL should preferably be discussed in the respective RAC and SCOEL meetings in November/December 2015 and to be adopted by February 2016. I wish to be informed if the adoption of the opinion is not feasible by the indicated target date.

4. Remuneration

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

[Signed]

Geert Dancet
Executive Director

Cc: Jukka Malm, Jack de Bruijn