Subject: Request for a scientific Opinion in accordance with Commission Decision 2014/113/EU: Chemical agent 1-methyl-2-pyrrolidone (NMP) and occupational exposure limit value

1. Background

In 2009 the Commission adopted (Directive 2009/161/EU) for the chemical substance 1-methyl-2-pyrrolidone (NMP) an indicative occupational exposure limit (OEL) value (IOELV) of 40 mg/m$^3$ 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/m$^3$) 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/m$^3$ 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 an OEL but with a lower numerical value than the existing IOELV.

In accordance with Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work\(^1\) (the Chemical Agents Directive, CAD) and/or Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work\(^2\) (the Carcinogens and Mutagens Directive, CMD) the

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Commission is to propose the establishment at EU level of occupational exposure limit values (OELs) for the protection of workers from chemical risks.

Through earlier discussions it had been established that SCOEL and the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC) would consider similar studies but they use different toxicological effects as points of departure and different assessment factors to derive the limit value. There was 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.

2. Terms of reference

(1) On the basis of the latest available scientific data the Commission services request to SCOEL in accordance with Commission Decision 2014/113/EU to:

   a) Review all available and specifically the latest scientific data regarding the chemical agent 1-methyl-2-pyrrolidone (NMP)

   b) By taking into account all available information, evaluate the health effects of NMP and the level of occupational exposure and develop Recommendation(s) for OEL(s), biological limit value(s)/biological guidance values and appropriate notations and/or scientific Opinion(s) which shall be supported and explained in detail by information on the basic data, a description and explanation of the critical effects and the extrapolation techniques used and any data on possible risks to human health.

   It is thereby of pivotal importance to describe the evaluation approach in a manner that allows the comparison of individual steps of it with comparable similar steps in the process applied by the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC), when forming a corresponding opinion on NMP.

   This should furthermore comprise explanation on the possible use of a weight of evidence approach and the use of appropriate assessment or uncertainty factors and their scientific relevance.

   c) Provide a view on how the methodological approach taken is based on and described by the Methodology of the Scientific Committee on Occupational Exposure Limits for Chemical Agents.


3 Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC
d) Identify any lack of specific scientific information, which may be necessary for the evaluation of risks associated to health hazards of 'NMP' and inform the Commission services accordingly.

e) Propose a process and list of action items regarding how to best cooperate with the members of the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC) to develop a joint opinion of the two Committees.

f) Cooperate with the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC) to develop a joint opinion of the two Committees.

(2) On the basis of the outcome from 1 above the Commission services further request SCOEL to, as appropriate:

a) Develop and provide a joint opinion together with the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC) on a recommendation for a limit value for worker protection for NMP related to inhalation exposure and/or

b) Develop and provide an opinion on the recommendation for a limit value for worker protection for NMP related to inhalation exposure highlighting all issues, for which a common view between SCOEL and RAC could not be presented including methodology.

3. Deadline
A reply is requested by 30 September 2015.

4. Supporting documents
None

Annex(es)
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Yours faithfully,

Maria Teresa Moitinho de Almeida
Head of Unit