

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

Ref: Request to the Committee for Risk Assessment to create a joint task force with the Scientific Committee on Occupational Exposure Limits (SCOEL) on scientific aspects and methodologies related to the exposure of chemicals at the workplace and to prepare a report on their scientific evaluation

Based on the request from the European Commission to ECHA of 6 July 2015, the purpose of this note is to give a mandate to RAC to create a joint task force with the Scientific Committee on Occupational Exposure Limits (SCOEL) for the comparative critical assessment of REACH DNEL and OEL methodologies a) for the inhalation route and b) for dermal route, including 'skin notation' and dermal DNEL.

1. Background

The processes for deriving REACH 'derived no effect levels' (DNELs) and occupational safety and health (OSH) 'occupational exposure limits' (OELs) are carried out separately and often result in different numerical values for exposure limit values and derived effect threshold levels for the same chemical, principally as a result of the different use of expert judgement and methodologies, which in turn reflect the different contexts in which each concept has been developed.

ECHA and SCOEL methodologies take different approaches to identifying risks associated with the dermal exposure route.

Under Article 95 of the REACH Regulation and Article 2(9) of Commission Decision 2014/113/EU¹ ECHA and SCOEL respectively are obliged to cooperate with each other as bodies established under EU law carrying out similar tasks in relation to issues of common concern.

Pursuant to Article 95(3) of the REACH Regulation, where there is a fundamental conflict between ECHA and SCOEL over scientific or technical points, they are obliged to work together to solve the conflict or to submit a joint document to the Commission clarifying the scientific and/or technical points of conflict.

ECHA and SCOEL are therefore requested to establish a joint Task Force composed of members drawn from each of the ECHA Risk Assessment Committee and SCOEL and including representatives from the Secretariats.

The Task Force will prepare a joint report detailing key aspects of the respective scientific approaches, methodologies, and concepts, identifying areas of convergence and divergence. The aim of this joint work will be to improve the mutual understanding of the different approaches and work towards agreed common scientific approaches including through the further development of existing and new concepts as necessary in relation to workers' exposure to chemicals. The overall objective is to enhance the quality of scientific

¹ Commission Decision of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC, OJ L 62, 04 03 2014 p.18

evaluations related to human health, to support delivery of policies and to improve standards of worker protection in Europe.

2. Terms of Reference

In order to allow the Commission, on the basis of the joint scientific report of RAC and SCOEL, to take action as regards exposure levels of NMP, the Executive Director of ECHA requests the ECHA Secretariat to make the necessary practical arrangements for RAC and SCOEL members respectively:

Task 1: Comparative critical assessment of REACH DNEL and OEL methodologies

- Outline the present methodologies adopted by SCOEL and ECHA for the derivation of exposure values relevant for worker protection via the inhalation route. Identify the key principles and present the main steps and assumptions on which these methodologies are based.
- Identify and explain differences between the ECHA and SCOEL methodologies and fundamental principles and assumptions, with reference to the scientific literature and in particular to aspects of the two methodologies which relate to:
 - selection of the critical and/or leading health effect/s;
 - selection of the studies;
 - use of dose descriptors and their modification;
 - dealing with uncertainty and the handling of inter- and intra-species differences, use of assessment and/or uncertainty factors and their scientific relevance; and
 - use of a weight of evidence approach, including the scope for discretion of the actor establishing values to depart from defaults.
- Identify and describe the extent to which SCOEL and ECHA methodologies represent the state-of-the-art in internationally agreed methodologies for use of test data in deriving exposure values associated with adverse effects of chemicals.
- As far as possible, and taking into account internationally agreed methodologies, make recommendations to adapt/improve the SCOEL and/or ECHA methodologies, guidance, or practice in order to align them. Justify any opinion that convergence of a given aspect of the methodologies is not scientifically appropriate.

Task 2: Comparative assessment of the ECHA and SCOEL methodologies for dermal route exposure, skin notation and dermal DNEL

- Outline and assess the approach used by SCOEL to identify the need for a 'skin' notation to be included in an OEL recommendation.
- Compare this approach in terms of scientific relevance and appropriateness for assessing workplace chemicals risks with the methodology for deriving dermal DNELs under REACH. Recommend areas for convergence.

In the preparation of the joint report the Task Force should:

- Identify any potential to engage with other EU scientific bodies to promote cross-system synergy (e.g. with EFSA, SCCP and/or SCHER) and collaborate in horizon-scanning supra-EU developments of relevant overarching methodologies.
- Where possible include summary case studies to illustrate practical examples of the key issues to be presented.

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- Take into consideration the joint opinion of the two Committees as regards exposure levels for 1-methyl-2-pyrrolidone (NMP).

3. Timescale for the joint RAC-SCOEL report on scientific evaluation

After the agreement of the parties involved on the terms of reference of the Task Force, ECHA and SCOEL should establish a common work programme with timelines for the fulfilment of each task.

The joint report on scientific evaluation of RAC-SCOEL should preferably be discussed in the respective RAC and SCOEL meetings through 2016.

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