Helsinki, 22 September 2023

Note for the attention of Mr Roberto Scazzola, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment to review the RAC opinion in relation to the harmonised classification of Methyl methacrylate (MMA)

The Committee for Risk Assessment (RAC) is requested to review the respiratory sensitisation classification as adopted by RAC in its opinion of 18 March 2021.

1. Background

On 18 March 2021, RAC adopted an opinion on Methyl methacrylate (MMA, EC Number 201-297-1).

The dossier submitter (France) had proposed an additional classification for Respiratory Sensitisation 1 (Resp. Sens. 1; H334), based on case reports on diagnosed occupational asthma cases and epidemiological studies on human respiratory sensitisation from the scientific literature and national occupational disease databases.

RAC, taking into account additional studies (Walters et al, 2017 and Suojalehto et al, 2020) as well as supplementary information from the authors of the study by Suojalehto et al, 2020 on six cases, where MMA could be determined as the predominant exposure at the workplace, who had positive responses to MMA in the Specific Inhalation Challenge test, and applying a weight of evidence approach, confirmed the additional classification for respiratory sensitisation 1 (Resp. Sens. 1, H334).

During an additional ad hoc consultation held in February 2020 on the Suojalehto et al. 2020 study, stakeholders had expressed their concerns related to the lack of data available to assign causality to specific substances, uncertainty on potential co-exposure and irritating peak exposures, as well as inconsistencies in the methodological approach. In addition, several comments concerned the lack of MMA-induced asthma cases in selected companies or use sectors.

Following the adoption and publication of the RAC opinion, manufacturers of the substance provided additional evidence, namely a comprehensive review of the available data following the ECHA weight of evidence guidance, as well as a summary of information on the actual exposures of the sensitised individuals whose case reports formed the basis of the RAC conclusions, which could challenge the causality of the association between MMA exposure and occupational asthma.

The information contained in the submitted information package, which was not considered in the RAC opinion, may have an impact on the classification of MMA for Respiratory Sensitisation 1.

2. Terms of Reference

Therefore, in accordance with Article 77(3)(c) of REACH, RAC is requested to review the submitted information and, if appropriate, to amend the opinion of 18 March 2021 in relation to the classification for Respiratory Sensitisation 1.

3. Timescale for the RAC opinion

Considering the limited scope of the request, it is considered that the opinion be prepared in a shorter time than usually required for an opinion on harmonised classification. The European Commission is also requesting ECHA to conduct a consultation, for which the duration could be reduced compared to normal harmonised classification-related consultations given the limited amount of information that is new compared to the information considered in the original CLH dossier.

Within 12 months after the receipt of this request (1 September 2023), ECHA should finalise the analysis with a view to confirming or amending the opinion of 18 March 2021 in relation to the additional classification of Methyl methacrylate for Respiratory Sensitisation 1.

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.

(e-signed)[1]

Dr Sharon McGuinness
Executive Director

Cc: Mike Rasenberg, Peter van der Zandt

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.