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CONTRIBUTION

From: General Secretariat of the Council
To: Ad hoc Working Party on the ECHA Basic Regulation

N° prev. doc.: WK 14447/2025
WK 14088/2025

Subject: ECHA Basic Regulation: comments from a delegation

Following the call for comments on the above set out with WK 14447/2025, delegations will find attached comments from MT.

MT

Comments on the Proposal for a Regulation of the European Parliament and of the Council on the European Chemicals Agency (ECHA) and amending Regulations (EC) No 1907/2006, (EU) No 528/2012, (EU) No 649/2012 and (EU) 2019/1021, as per last Presidency compromise text WK 14088/2025

Round 1: Articles 4, 5, 6, 10, 12, 14, 15, 17, 18, 27, 29, 45, 54.

Article 5(1c)

“(c) a Committee for Risk Assessment (‘RAC’), which shall be responsible for preparing opinions of the Agency relating to risks and hazards of chemicals to human health or the environment;”

MT is of the opinion that the word “*hazards*” should not be included in the text due to the following points:

- (1) Under the EU chemicals legislation, hazard and risk are intentionally separated concepts - hazard identification and classification are handled under the CLP Regulation, while risk assessment and management are handled mainly under REACH. If RAC started formally dealing with hazards as well, it would blur the line between hazard classification and risk assessment.
- (2) ECHA already has established processes for hazard classification (via CLH dossiers). If RAC took on formal hazard assessment too, would this duplicate work already done by Member State competent authorities or ECHA’s classification teams? This could slow down process due to repeated evaluations of the same data from a hazard standpoint and then a risk standpoint.

Amendment to Recital 19 & Article 14

“Member States should continue to be able to nominate persons from any nationality as members of RAC and SEAC. There is no requirement of nationality, or employment as public servants. The nominees should meet the requirements to membership of RAC and SEAC. Upon request from a Member State, the Agency should facilitate finding suitable candidates for RAC and SEAC. The nominees should meet the requirements to membership of RAC and SEAC.”

MT appreciates the efforts taken by the Presidency to safeguard smaller Member States due to their (potential) inability to appoint relevant experts to the RAC and SEAC and that flexibility is allowed to nominate experts independent from their nationality. MT certainly feels this amendment is a step in the right direction and supports its inclusion. MT would however strongly suggest that the amendments introduced in Recital 19 are also included in the operative part of the text (i.e., Article 14(2a)).

Nevertheless, MT continues to reiterate its previous position on the mandatory appointment of experts to the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC). MT continues to show a strong preference towards the original EE proposal whereby a centralised EU-level pool of experts is formed and experts (meeting the RAC and SEAC membership requirements) can be selected from that pool. Priority could be given to experts nominated from the respective Member States; however, this pool of experts would be used in case vacant seats persist.

Alternatively, MT suggests that the appointment of experts to the RAC and SEAC is conducted using the same procedure as for the appointment of experts to the Scientific Committee on Consumer Safety (SCCS), i.e., a similar Article 14(5) is applied to Article 14(1) and Article 14(2).

New Article 14(2a) & Recital 19

“In case the Member States request the Agency's assistance, the Agency shall facilitate the identification of possible candidates for nomination referred to in paragraphs 1 and 2.”

It is not clear how the Agency shall facilitate this. Will it assist the Member State by selecting candidates/experts from a centralised EU-level pool of experts? MT would like to kindly ask the PRES/ECHA to provide further clarification on this.

New Recital 11a & New Article 14(5a)

“5a. Member States shall not nominate or appoint, and the Management Board shall not appoint members of the Committees where there are reasonable grounds to believe that there is a conflict of interest.”

In line with our previous comments, MT would urge caution on the term “*conflict of interest*” as this could potentially significantly increase the risk of limiting the (already limited) number of experts eligible for nomination to the RAC, SEAC and SCCS.