Annex 4

Helsinki, 1 April 2022

BACKGROUND PAPER

Committee for Risk Assessment

Summary: The Committee for Risk Assessment (RAC) is currently looking for specialists to be nominated in particular in the fields of:

- epidemiology (worker/consumer)
- toxicology and human health risk assessment
- human and environmental risk assessment
- biodegradation and ecotoxicology
- occupational hygiene and medicine

1 Introduction

The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) is responsible for providing opinions to the Commission on Restrictions and Applications for Authorisation under the REACH[1] regulation as well as on harmonised classifications under Classification, Labelling and Packaging CLP[2] and Occupational Exposure Limits (OELs) under the Carcinogens and Mutagens Directive (CMD[3]). All of these processes require an in-depth scientific knowledge and expertise from the Committee's members in a variety of specific disciplines.

This document has been developed to support the Member States (MSs) in nominating, the best candidates to RAC. It provides details on the tasks and expected workload of the members and the level of support required from their nominating members state. Finally, the paper concludes with an overview of the fields of expertise needed by the members of RAC.

2 Composition, role and tasks of the Committee for Risk Assessment

RAC is composed of members nominated by the EU Member States and EEA-EFTA countries but appointed by the Management Board of ECHA in their personal capacity as scientists. It has a nominal capacity of 60 members, two each from the 27 EU and 3 EEA-EFTA countries. At the moment there are 45[4] members (excluding the full complement of 5 co-opted members), thus 15 places are free.

In addition, RAC can co-opt up to five additional members – all five places were filled in 2021.

RAC formulates its opinion in relation to the following:

- **Applications for Authorisation** – Assessing the risk from the use(s) of a substance to workers and the environment arising from those uses for which authorisation is being sought. This includes an assessment of the operational conditions and risk management measures and the related exposures described in the application (Article 64(4) of the REACH Regulation);

[1] Regulation (EC) No 1907/2006, OJ L 396, 30.12.2006 p.1, corrected version in OJ L 136, 29.5.2007, p. 3
[2] Regulation (EC) No 1272/2008, OJ L 353, 31.12.2008
[3] DIRECTIVE 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
[4] After the MB-65 meeting on 29-30 March 2022

- **Restrictions -** Evaluating whether the restrictions proposed by a Member State or ECHA for a substance are appropriate in reducing the risk to human health and/or the environment;
- **Harmonised Classification and Labelling -** Evaluating proposals from Member States or manufacturers, importers or downstream users for harmonised classification and labelling of a substance under the CLP Regulation.
- **Occupational Exposure Limits –** RAC is requested by the European Commission to provide scientific evaluations on occupational exposure limits for carcinogens and chemical agents at the workplace.

3 Working procedures

As described above, RAC covers several types of dossiers and processes. Moreover, there are fixed, tight deadlines for the delivery of opinions.

RAC is chaired by Dr Tim Bowmer, with Ms Johanna Peltola-Thies as Deputy Chair; both are ECHA staff members and are supported by a committee secretariat provided by ECHA.

4 Expectations of expertise for the RAC members

The REACH Regulation makes it clear that members must possess the necessary qualifications in order to allow the Committees to meet the high expectations placed on them. RAC members require a knowledge of regulatory science and its use under the REACH, CLP and OSH Regulations, related to chemicals. To provide independent scientific advice, the Committee requires expertise from both regulatory scientists and from academics.

Key areas of expertise required
The key areas of specialised expertise required by the Committee are presented below.

Applications for Authorisations and Occupation Health and safety
- Epidemiology and occupational medicine
- Human health risk assessment in particular carcinogenicity
- Occupational hygiene and workplace exposure assessment
- Risk Management Measures and operational conditions
- Indirect exposure (humans via the environment); emissions to air, water, soil/sediment

Classification Labelling and Packaging (CLP)
- Regulatory toxicology: carcinogenicity, mutagenicity, toxicity to reproduction Specific Target Organ Toxicity, Sensitization, acute toxicity
- Ecotoxicology and biodegradation
- Test Guideline development
- Understanding of the CLP criteria

Restrictions
- Human health and environmental health risk assessment
- Technical aspects of restrictions: effectiveness, monitorability, etc
- Risk management measures
- PBT, vPvB

Occupational exposure limits
- Occupational medicine
- Epidemiology

- Carcinogenicity, Mutagenicity, including Mode of Action

Support for member's activities
Member State Competent Authorities are obliged to provide support to enable RAC members to accomplish their activities in RAC in accordance with Art. 85(6), keeping in mind the scientific independence of the members as established under Article 85(7) of the REACH Regulation. To this end, RAC members should be entitled to dedicate a major part of their working time to RAC activities - **at least 50% of their time (See Annex III)** - which requires specific arrangements with the members and their institutions/employers. With responsibilities as rapporteur, this can rise to 70-80% of the member's time.

This support could include the provision of regular advisers depending on the topic and ad-hoc specialists plus administrative support.

Rapporteurships
Most of the work of RAC is conducted between meetings and consists of drafting by Rapporteurs and consultation of the Committee's opinions with the membership. According to Article 87(1) of the REACH Regulation, **the members of RAC are expected to serve as (co-) rapporteurs for preparing the opinions of the Committee**. Each member is expected to act as a rapporteurs or co-rapporteur for several dossiers per year during his/her 3-year membership depending on the scale of individual dossiers, this may be lower or higher. It should be noted that the scale and scoep of dossiers can vary considerably.

Written commenting rounds on opinions
All RAC members are expected to provide their comments and views on the different draft proposals during written consultations and should be fully involved in the opinion-making process.

Reimbursement
ECHA reimburses the travel and accommodation expenses and pays subsistence allowance to the members and, where relevant, remunerates the rapporteur and co-rapporteur for the work undertaken in line with the rules adopted by the Management Board (MB/41/2020). As no remuneration is considered for the rapporteurs of CLH dossiers, ECHA has implemented a mechanism for supporting them and thus contributing to the costs. The participation of one adviser supporting the CLH rapporteur in RAC meetings where the substance is discussed is reimbursed. Advisers not employed in the public service of the Member State can also receive an expert remuneration for their contribution to the meeting.

5 Further considerations

RAC meetings are held four times a year, at present this usually consists of a single week meetings; the provisional dates are published on the Committee pages of the ECHA website at least a year in advance.

Please note that RAC has established three working groups for Authorisations, Restrictions and Classification and Labelling; these meet between plenary meetings and pre-assess all dossiers ahead of the next plenary, making recommendatiosn to RAC. Members and/or their advisors are expected to be active in the Working Groups of RAC.

Note: For 2022, a mixture of remote and face-to-face meetings are expected.