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WORKING PROCEDURE FOR THE APPOINTMENT OF RAPORTEURS AND CO-RAPORTEURS BY RAC AND SEAC FOR APPLICATIONS FOR AUTHORISATION, AND RESTRICTIONS AND BY RAC FOR SCIENTIFIC EVALUATION OF PROPOSALS ON OCCUPATIONAL EXPOSURE LIMITS AND FOR PROPOSALS ON HARMONISED CLASSIFICATION AND LABELLING

1. INTRODUCTION AND LEGAL BASIS

This document lays down the principles, selection criteria and the detailed working procedure for the appointment of rapporteurs and co-rapporteurs by RAC and SEAC for a) authorisation applications submitted in the framework of Title VII of REACH, b) restriction dossiers submitted in the framework of Title VIII of REACH, c) for proposals for harmonised classification and labelling in accordance with Article 37 of the CLP Regulation and d) for Occupational Exposure Limits (OELs) at the workplace in accordance with a Service Level Agreement between the European Commission (DG EMPL) and ECHA².

The legal basis for the appointment of rapporteurs is Article 87(1) of the REACH Regulation. According to this Article, when a Committee is required to provide an opinion, *"...it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as a co-rapporteur."*

Article 17(2) of the Rules of Procedure for both of the Committees³ states: *"The Committee shall agree ... on details of the roles and tasks of the rapporteurs and possible co-rapporteurs, and on how they are appointed."*

2. PRINCIPLES TO BE APPLIED WHEN APPOINTING RAPORTEURS

2.1. General principles

¹ Agreed at RAC-31 and SEAC-25 in December 2014, editorial updates introduced in May 2019. At RAC-49 in March 2019 it was agreed for the working procedure for appointment of rapporteurs for the dossiers on OELs to agree on the pool of nominated rapporteurs, followed by appointment by the RAC-Chairman, a similar procedure as employed in the restriction process.

² The Service Level Agreement concerns provision of scientific evaluations by ECHA/RAC on proposals for occupational exposure limits (OELs), biological limit values, health surveillance measure and/or appropriate notations for candidate substances, which are listed under the Carcinogens and Mutagens at Work (CMD) Directive 2004/37/EC and/or the Chemicals Agency Directive (CAD) 98/24/EC.

³ Rules of Procedure for the Committee for Risk Assessment (MB/12/2019, part 1) and Rules of Procedure for the Committee for Socio-economic Analysis (MB/12/2019 part 2) both agreed by the Management Board of ECHA on 29 March 2019.

Throughout this document, the term 'rapporteurs' is used for both a rapporteur and a co-rapporteur. Even though the need for a co-rapporteur is considered on a case by case basis, a co-rapporteur is usually appointed to ensure appropriate expertise.

Over the course of the rapporteurship the membership of rapporteurs may expire. If the term of the members who have been appointed as rapporteurs is not renewed, the persons will be entitled to complete the pending rapporteurship.

The process for the appointment of rapporteurs in applications for authorisation, restrictions and scientific evaluation of OELs differs from that for harmonised classification and labelling.

2.1.1 Applications for Authorisation and Restrictions

The appointment process should start at an appropriate moment a) when the substance is included in Annex XIV of the REACH Regulation or b) when the intention to submit an Annex XV dossier is included in the Registry of Intentions (RoI). For each a) (group of) substance(s) in the Annex and/or for each b) intention of Annex XV dossier, RAC and SEAC members will be asked to express interest to become rapporteurs a) for an authorisation application and/or b) for a restriction dossier. Based on expressions of interest received, a pool of rapporteurs for each (group of) substance(s) and/or for each restriction dossier will be created by the Secretariat. After that, any RAC and SEAC member may apply for the rapporteurship at any time by sending a request to amend the pool of rapporteurs to the RAC/SEAC Secretariat.

The Secretariat will then seek agreement of RAC and SEAC on the pool by written procedure or, if applicable, at the next available plenary meeting. Agreement on the pool is considered as identification and appointment of its rapporteurs by the Committees. If no members express their interest in certain (group of) application(s) of authorisation and/or in certain restriction dossier, the Secretariat might consider taking appropriate action (e.g. sending a reminder to members, contact potential candidates).

When information is received that an application for authorisation will be submitted soon or that the expected submission date of a certain restriction dossier is approaching (at the latest when the application arrives to and/or the restriction dossier is received by ECHA), the Chairmen of RAC and SEAC will select the rapporteurs for a) this particular authorisation application and/or b) restriction dossier from the pool of rapporteurs so identified and appointed by the Committees.

The Chairmen will select rapporteurs from the pool against the selection criteria described in section 2.2, provided that the rapporteurs have not indicated any interest that might be prejudicial to the independent consideration of that case and after contacting the available member(s) to clarify their qualifications and any other relevant considerations. The selection will be made in an impartial manner with the aim of finding the most suitable rapporteurs for the application and/or the restriction dossier in question.

Once the decision has been taken by the Chairmen, the Secretariat will send a formal email to RAC and SEAC informing about the outcome. The rapporteurs will confirm absence of conflict of interest and submit the declarations of commitment.

If several applications are received for one and the same substance (or group of substances), close co-operation between rapporteurs of the authorisation applications on that substance is needed.

2.1.2 Occupational Exposure Limits

The appointment process should start when ECHA receives the Request for Service for a scientific evaluation of Health Based Exposure Limits at the workplace (OELs) for a (number of) substances within the Service Level Agreement of DG EMPL and ECHA. The Secretariat organises the calls for expression of interest **via a pool at the start of each plenary meeting** or by sending emails from the RAC functional mailbox as necessary.

Based on expressions of interest received, the pool of rapporteurs for each (group of) substance(s) will be created by the Secretariat. After that, any RAC member may apply for the rapporteurship at any time by sending a request to amend the pool of rapporteurs to the RAC Secretariat.

The Secretariat will then seek agreement of RAC on the pool **at the end of the respective plenary meeting** or by written procedure. Agreement on the pool is considered as identification and appointment of its rapporteurs by the Committees. If no members express their interest in certain (group of) substance(s) the Secretariat might consider taking appropriate action (e.g. sending a reminder to members, contact potential candidates).

The RAC Chairman will select rapporteurs from the pool against the selection criteria described in section 2.2, provided that the rapporteurs have not indicated any interest that might be prejudicial to the independent consideration of that case and after contacting the available member(s) to clarify their qualifications and any other relevant considerations.

Once the decision has been taken by the Chairman, the Secretariat will send a formal email to RAC informing about the outcome. The rapporteurs will confirm absence of conflict of interest and submit the declarations of commitment.

2.1.3 CLH

The appointment process should start when the dossier is submitted to ECHA, found in accordance and ready to be subject to a public consultation.

The Secretariat organises the calls for expression of interest **at the start of each plenary meeting** or by sending emails from the RAC functional mailbox as necessary.

The RAC Chairman will select rapporteurs against the selection criteria described in section 2.2.

Once a member has been appointed by agreement of RAC as the rapporteur **at the end of the respective plenary meeting** or via written procedure, the actual declaration of the absence of any conflicts of interest as well as the declaration of commitment is sought from the rapporteur. Based on the signed declarations, the letter of appointment is issued.

2.2 Considerations for selection of rapporteurs

According to Article 87(1) of the REACH Regulation, rapporteurs are appointed to facilitate the Committee to provide an opinion.

In cases where several members from the pool indicate their interest and availability to act as rapporteurs for a particular authorisation application, restriction dossier or

scientific evaluation of OEL proposals, and in case more than two members have expressed their interest in a CLH dossier (not via a pool) the Chairman will decide on the selection of the rapporteurs taking into account criteria (see below) which will allow the use of the best available expertise in the relevant scientific area and provided that there are no conflict of interests.

Members are appointed primarily on the basis of their scientific and technical qualifications. In addition, the expertise that the member has access to in his/her Member State as referred to in Article 85(6) of the REACH Regulation will be taken into account. The member in question must be able to assure the Committee of his/her suitability and commitment to maintain necessary timelines and to be able to produce a draft opinion that forms a good basis for the discussions with the intention of reaching consensus in RAC and SEAC.

The selection criteria to be considered for appointment of rapporteurs for all four processes are the following:

- Experience and expertise in the relevant industry sector and processes, uses, substance; alternative substances and techniques; relevant risk management measures and operational conditions.
- Experience or familiarity with e.g. a specific chemical substance group.
- Access of the member to appropriate expertise in the relevant field through the Member State supporting the member.
- The number of rapporteurships already allocated to the member concerned (to promote an even distribution of work across the Committee members and an efficient use of resources).
- Specifically for RAC members: environmental and human hazard and exposure assessment; environmental fate and behaviour; toxicological and/or ecotoxicological properties, occupational health and safety, epidemiology, exposure modeling etc.
- Specifically for SEAC members: methodologies of socio-economic analysis, assessing costs and benefits, economic and technical feasibility of alternatives, social and wider economic implications, etc.

The selection criteria listed above is not exhaustive and other aspects might be considered on a case by case basis.

2.3 Considerations for exclusion of certain members to act as rapporteurs

According to Article 87(1) of the REACH Regulation, for each authorisation application as well as for each restriction dossier, OEL evaluations or CLH dossier the appointed rapporteurs shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing by signing and sending the relevant declarations to the Secretariat. They shall not be appointed as rapporteurs for a particular case if they indicate any interest that might be prejudicial to the independent consideration of that case. In order to maintain a clear separation of interests, it is preferable that the rapporteur for a restriction dossier or a CLH dossier is from a different country from that in which the dossier was prepared. A RAC/SEAC member who is employed by the Member State Competent Authority (MSCA) which is submitting an Annex XV dossier cannot be a rapporteur for that dossier.

2.4 Replacement of rapporteurs

Replacement of rapporteurs should be avoided to the extent possible so as not to hamper the opinion development process. However, pursuant to Article 17(4) of RAC RoPs and

Article 17(4) of SEAC RoPs, the Committees may replace the rapporteur by another one of its members at any time, if, for example, the rapporteur is unable to fulfil his/her duties within the prescribed time limits, or if a potentially prejudicial interest comes to light. When the substitution of a rapporteur is needed, the co-rapporteur may be the most suitable to act as a rapporteur, or alternatively, a new rapporteur will be selected by the Chairman of the respective Committee.

2.5 Co-rapporteurs

The procedure for appointing co-rapporteurs should be the same as for appointing rapporteurs. Co-rapporteurs should be co-workers with either the same or a different field of expertise as the rapporteur, and they could provide, for example, either an initial review of the proposed opinion or provide support to the review of complex cases.

If a co-rapporteur is appointed at a later stage than the rapporteur, the co-rapporteur will be selected from the pool of rapporteurs appointed by the Committee. If no such member is available, the appointment procedure will have to re-start. Due to time constraints the timeline described in section 3 might have to be shortened.

3. WORKING PROCEDURE

Step		Deliverables and Milestones
a	RAC and/or SEAC members are informed about the start of the call for expression of interest to become rapporteurs for a) an authorisation application per each (group of) substance(s), b) a restriction dossier, c) OEL evaluations or d) a CLH dossier.	Information
b	RAC and/or SEAC members express their interest and declare absence of any conflict of interest. If they wish, they may provide documentation to support their nomination.	Expressions of interest
c	<p>The Secretariat verifies whether there are any considerations that might exclude the member(s) to act as rapporteur. Based on expressions of interest received, for Applications for authorisation, Restrictions and OEL evaluations the Secretariat creates the pool of rapporteurs per each (group of) substance(s) or restriction dossier and seeks agreement of RAC and/or SEAC on the pool of rapporteurs by written procedure or, if applicable, at the (next) available plenary meeting.</p> <p>For CLH the Secretariat seeks agreement of RAC on the rapporteurs at the (next) available plenary meeting or, if applicable, by written procedure. The Secretariat contacts the rapporteur to request the submission of a confirmation of absence of any conflict of interest.</p>	Agreement by RAC and/or SEAC on the pool of rapporteurs (considered as identification and appointment)
	Information is received that application for authorisation, restriction dossier or ECHA dossier on OEL will be submitted soon	
d	The Secretariat contacts the rapporteurs from the pool	Information

	for this particular a) (group of) substance(s) b) restriction dossier or c) OEL evaluations and asks to clarify their availability to become rapporteurs for the application/restriction dossier and to submit a confirmation on absence of any conflict of interest.	
e	Members clarify their availability to become rapporteurs for this particular authorisation application/restriction proposal/OEL evaluation, and submit a declaration of absence of any conflict of interests.	Confirmation of availability and submitting a declaration of absence of any conflict of interests
f	The Secretariat verifies whether there are any considerations that might exclude the member(s) to act as rapporteurs. If yes and there are no other members who confirmed their availability, start again from step c.	
g	The Chairmen select the rapporteurs and inform the Committees thereof.	Information
	After an authorisation application has formally been received by ECHA (i.e. the fee has been received from the applicant)⁴/ After a submission of a restriction proposal or OEL dossier	
h	The Secretariat sends the appointing email to the selected rapporteurs, together with the service contract (applicable to AfA, restrictions and OELs). The rapporteurs return the declarations of absence of conflict of interest and commitment to the Secretariat.	Formal appointment of the rapporteurs

⁴ Step h can also take place already before an application is formally received by ECHA (before the fee is received from the applicant). In such case, it should be mentioned in the letter of appointment that the appointment is effective from the date of the formal receipt of the application (i.e. receipt of the fee from the applicant) and only if it is actually received.