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Agreed at RAC-62

WORKING PROCEDURE FOR RAC ON THE SCIENTIFIC EVALUATION OF OCCUPATIONAL EXPOSURE LIMITS AND OTHER VALUES IN SUPPORT OF THE CHEMICAL AGENTS DIRECTIVE AND THE CARCINOGENS, MUTAGENS AND REPROTOXICANTS DIRECTIVE

1. INTRODUCTION AND LEGAL BASIS

The purpose of this document is to document RAC's working procedure for the scientific evaluation of occupational exposure limits and other values.

ECHA/RAC may be requested by the Commission *"to evaluate proposals for occupational exposure limits (OELs), biological limit values, health surveillance measures and/or appropriate notations"*[1] for candidate substances, listed under the Carcinogens, Mutagens and Reprotoxic substances at Work (CMRD) Directive 2004/37/EC[2] and/or the Chemicals Agents Directive (CAD) 98/24/EC[3].

ECHA's work is to evaluate the information generally already available in relevant international and national reviews as well as assess the most recent scientific information, providing a report which is then evaluated by RAC which provides the opinion of the Agency.

The opinions include a recommendation to the Commission to enable them to inform the Advisory Committee on Safety and Health at Work (ACSH) in line with the OSH legislative procedures.

2. WORKING PROCEDURE

The main roles and tasks of the ECHA Secretariat, (co-)rapporteurs and members of RAC are described below and the timelines for different tasks are listed in Table 1.

The roles and tasks of ECHA and RAC are separate:

- ECHA as Dossier Submitter is responsible for the provision of an evaluation of the available data presented in a scientific report. When complete but prior to submission, ECHA shall ensure that the scientific report is subjected to a robust internal peer review.

- The (co-)rapporteur is responsible for drafting, co-ordinating and presenting their opinion on the scientific report to RAC. Exchange of views between the (co-)rapporteur and ECHA is

[1] Contribution Agreement between European Commission, DG Employment, Social Affairs and ECHA (February 2019).

[2] Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work at work (Sixth individual Directive within the meaning of Article 16(1) Directive 89/391/EEC) of 9.03.2022" available at EUR-Lex - 02004L0037-20220405 - EN - EUR-Lex (europa.eu).

[3] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 131, 5.5.1998.

expected to take place during the opinion development. An initial exchange of views may take place before the scientific report is launched for consultation.

- RAC is responsible for reviewing the scientific report and for providing the Commission with an **opinion** recommending health-based exposure limit values (or not) at the workplace, as appropriate. RAC's opinion contains an independent assessment of the scientific report and provides the Committee's conclusions and recommendations to the Commission.

The ECHA Secretariat then revises the scientific report into an annex to the opinion according to the conclusions and recommendations of the Committee.

The ECHA scientific report contains *inter alia* the following elements for RAC to evaluate:

- a statement on substance identification;
- an overview of regulatory status under relevant chemical and other legislation, e.g. REACH (authorisation and restriction), CLP, BPR and PPP, EU-OSH legislation;
- a summary of the REACH registration status, specifying relevant tonnages;
- an overview of current uses and where still relevant to human health, past uses;
- a description of the relevant exposures in the workplace related to the two points above;
- reviews and summaries of all human health endpoints, including human epidemiological data as well as animal data;
- special consideration of relevant acute effects (even if non-adverse, e.g. sensory irritation) among workers in order to support an appropriate level of protection;
- a review of biomonitoring levels in exposed workers and the expected background concentrations among non-exposed workers;
- a discussion of suitable analytical methods for implementation in the workplace covering air monitoring and biomonitoring;
- a comprehensive risk assessment of the endpoint(s) relevant to the derivation of limit values;
- recommendations where possible and appropriate for OELs and notations, biological limit values (BLVs) or biological guidance values (BGV);
- information on the remaining risk and the uncertainties related to any recommended safe limits.

Table 1 outlines the main steps of the opinion development from receiving the request from the Commission to evaluate the scientific relevance of OELs for a substance until the adoption of the RAC opinion.

	Step	Deliverables and Milestones for RAC
a	RAC members are informed about the request from the Commission to evaluate the scientific relevance of OELs and other health based values at the workplace for the respective substances.	Information
b	The RAC Chair appoints the RAC (co-)rapporteurs.	
c	The ECHA Secretariat starts preparing the draft scientific report.	
d	The ECHA Secretariat initiates a call for evidence and an informal dialogue with industry and workers representative organisations may be organised, if requested through ECHA Stakeholders.	Call for Evidence
e	The RAC (co-)rapporteurs and ECHA convene for an initial exchange of views on the drafting of the ECHA scientific report.	First dialogue[4] between RAC rapporteurs and ECHA

[4] Dialogue could take the form of a tele-, videoconference or face-to-face meeting as decided by the (co-)rapporteurs on a case-by-case basis.

f	The ECHA Secretariat delivers the draft scientific report.	
g	Launch of 60-day consultation on the ECHA website.	Consultation on ECHA scientific report
h	In parallel to the consultation on the ECHA website, a RAC consultation (4-weeks) is initiated allowing RAC members to submit comments on the ECHA scientific report.	RAC **comments** on ECHA scientific report
i	Comments received from the consultation are made available to RAC.	Compiled comments from consultation
j	The second dialogue between the RAC (co-)rapporteurs and ECHA is convened for an exchange of views on the first draft opinion, the draft ECHA scientific report and the comments received (Consultation and RAC-consultation).	Second dialogue between RAC rapporteurs and ECHA
k	The RAC (co-)rapporteurs provide to the Secretariat the first draft RAC opinion.	Draft RAC opinion
l	ECHA prepares the annex to the opinion based on the scientific report, which is shared with the (co-)rapporteurs.	Annex to draft opinion
m	A RAC consultation is initiated, allowing RAC members to submit comments on the draft RAC opinion and the annex to the opinion.	RAC comments on **draft RAC opinion** and **annex to the opinion**
n	**At the first plenary meeting** the discussion on the draft RAC opinion takes place. At the plenary, the RAC (co-)rapporteurs are also expected to respond to members` comments submitted within the RAC consultation round.	First plenary discussion on first draft opinion and annex to the opinion.
o	The RAC (co-)rapporteurs provide to the Secretariat the revised draft RAC opinion, taking into account the comments by other members. ECHA makes the revised annex to the opinion available to the (co-)rapporteurs.	Revised draft opinion Revised Annex to the opinion
p	The third dialogue is convened between the RAC (co-)rapporteurs and ECHA for discussion of issues related to further work on the opinion as well as on the annex to the opinion.	Third dialogue between RAC rapporteurs and ECHA
q	The RAC (co-)rapporteurs provide to the Secretariat the revised draft RAC opinion.	Revised draft opinion

r	A RAC consultation allows RAC members to submit comments on the revised draft RAC opinion and the annex to the opinion.	RAC comments on revised draft RAC opinion and annex to the opinion
s	**At the second plenary discussion[5]** the draft final RAC opinion is discussed with the aim of being adopted. At the plenary, the RAC (co-)rapporteurs are also expected to respond to members` comments submitted within the written commenting round.	Second plenary discussion on draft final RAC opinion and annex to the opinion
t	ECHA Secretariat prepares the final RCOM, taking into account the conclusions of the opinion development. The final RCOM is made available to RAC.	**Final RCOM**
u	ECHA Secretariat and (co-)rapporteurs finalise the draft RAC opinion and annex to the opinion.	Final draft opinion
v	(Short RAC consultation may be needed and follow-up editing).	**(RAC editorial comments on final RAC opinion)**
w	The adopted RAC opinion and its annex (ECHA scientific report) are sent to the Commission and published on the ECHA website.	**Final RAC opinion and supporting documents published: Annex to the opinion and RCOM**
x	**End of the procedure for RAC**	

[5] A third plenary discussion is possible, but preferably the discussion can be finalised at the second plenary meeting.