Helsinki, 13 June 2019[1]

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 AND MUTAGENS 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*[2] " for candidate substances, which are listed under the Carcinogens and Mutagens at Work (CMD) Directive 2004/37/EC[3] and/or the Chemicals Agency Directive (CAD) 98/24/EC[4].

The 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 opinions in each case. 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 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

[1] Agreed at RAC 49 in June 2019
[2] Contribution Agreement between European Commission, DG Employment, Social Affairs and ECHA (February 2019).
[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC), OJ L 158, 30.4.2004.
[4]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.

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

The 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 a **background document** according to the conclusions and recommendations of the Committee.

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

a. a statement on substance identification;
b. an overview of regulatory status under relevant chemical and other legislation, e.g. REACH (authorisation and restriction), CLP, BPR and PPP; EU-OSH legislation;
c. a summary of the REACH registration status, specifying relevant tonnages;
d. an overview of current uses and where still relevant to human health, past uses;
e. a description of the relevant exposures in the workplace related to c) and d) above;
f. summaries of all human health endpoints, including human epidemiological data as well as animal data;
g. 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;
h. a comprehensive risk assessment of the endpoint(s) relevant to the derivation of limit values;
i. recommendations where possible and appropriate for OELs and notations, biological limit values (BLVs) or biological guidance values (BGV);
j. information on the remaining risk and the uncertainties related to any recommended safe limits;
k. a review of biomonitoring levels in exposed workers and the expected background concentrations among non-exposed workers;
l. a review of suitable analytical methods for implementation in the workplace covering air monitoring and biomonitoring.

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 opinions.

	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 Chairman appoints the RAC (co-) rapporteurs.	
c	The ECHA Secretariat starts preparing the draft scientific report.	
d	A call for evidence is initiated and an informal dialogue with industry and workers representative organisations is organised, if requested through ECHA Stakeholders.	Call for Evidence
e	The first dialogue[5] between the RAC (co-)rapporteurs and ECHA is convened for an initial exchange of views on the drafting of the ECHA scientific report.	First dialogue RAC-rapporteurs and ECHA
f	ECHA Secretariat delivers the draft scientific report.	
g	Launch of eight week Public Consultation	Public Consultation on ECHA - draft scientific report
h	In parallel with the Public Consultation, a RAC-consultation (4-weeks) is initiated allowing RAC members to submit comments on the ECHA-draft scientific report.	RAC-comments on **ECHA - draft scientific report**
i	Comments received from the Public Consultation are made available to RAC.	Compiled comments from Public Consultation
j	**At the first plenary meeting** key issues of the draft scientific report are presented by the RAC (co-) rapporteurs ECHA Secretariat presents compiled comments received during the Public Consultation on the ECHA - draft scientific report. At the plenary, the RAC (co-)rapporteurs are also expected to respond to members` comments submitted within the RAC-consultation round.	**Presentation of the key issues of the ECHA - draft scientific report**
k	The second dialogue between the RAC (co-)rapporteurs and ECHA is convened for the exchange of views on the first draft opinion, the draft ECHA scientific report and the comments received (PC and RAC-consultation).	Second dialogue RAC-rapporteurs and ECHA

[5] 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.

l	The RAC (co-)rapporteurs provide to the Secretariat the first draft RAC opinion.	
m	ECHA revises the draft scientific report into the draft background document, which is shared with the (co-) rapporteurs.	
n	A RAC-consultation is initiated, allowing RAC members to submit comments on the draft RAC opinion with the draft background document.	RAC-comments on **draft RAC-opinion** **draft background document**
o	**At the second plenary meeting** the discussion on the draft RAC opinion takes place, where the dossier submitter (ECHA) presents the draft background document and the rapporteur presents the first draft RAC opinion. At the plenary, the RAC (co-)rapporteurs are also expected to respond to members` comments submitted within the RAC-consultation round.	Second plenary discussion on first draft opinion and draft background document.
p	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 draft ECHA background document available to the (co-)rapporteurs.	
q	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 background document.	Third dialogue RAC rapporteurs and ECHA
r	The RAC (co-)rapporteurs provide to the Secretariat the revised draft RAC opinion.	
s	A RAC-consultation allows RAC members to submit comments on the revised draft RAC opinion and the revised draft background document.	RAC-comments on **revised draft RAC-opinion** **revised draft background document**

t	**The third plenary discussion**[6] takes place, where 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.	Third plenary discussion on draft final RAC opinion and draft final background document
u	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**
v	ECHA Secretariat and rapporteurs to edit final draft RAC opinion and final draft background document.	
w	(Short RAC consultation might be needed and follow-up editing).	**(RAC editorial comments on final draft RAC opinion)**
x	The adopted RAC opinion and the background document are sent to the Commission and published on the ECHA website.	**Final RAC opinion and supporting documents published: background document and RCOM**
y	**End of the procedure for RAC**	

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