Helsinki, 20 February 2018

WORKING PROCEDURE FOR RAC ON SETTING OF RISK ESTIMATES SUCH AS DNELS AND DOSE-RESPONSE FUNCTIONS IN THE REACH APPLICATIONS FOR AUTHORISATION AND/OR ON REQUEST OF THE EUROPEAN COMMISSION

1. INTRODUCTION AND LEGAL BASIS

The purpose of this document is to outline the RAC working procedure on setting DNELs and dose-response functions in REACH.

The scope of the Working Procedure for RAC on the setting of risk estimates is limited to substances that have been or are very likely to be included in Annex XIV in accordance with Article 58(3), or for which the Commission has requested advice from ECHA regarding Risk Management[1].

Since 2012, RAC recommends DNELs and dose response relationships for Annex XIV substances prior to receiving applications for authorisation (AfAs)[2] [3]. The DNEL and dose response relationship so derived serve as non-legally binding 'reference values'. They provide applicants with a clear signal as to how RAC is likely to evaluate these key elements of the risk assessment of an application. Reference values in the form of DNELs for threshold substances and/or dose response relationship for non-threshold (mainly) carcinogens are published[4] in advance of applications for authorisation, so providing greater consistency and better use of the legally defined periods (e.g. the latest application date).

2. WORKING PROCEDURE

The main roles and tasks of ECHA, the (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 prepares i) a draft background report and ii) the RAC-note. RAC is responsible for evaluating and providing

[1] Related to restrictions, only one dose response relationship has been produced to assist with the European Commission deciding if any regulatory action is taken on a particular substance but this does not preclude this practice becoming more common in the future.

[2] https://echa.europa.eu/documents/10162/13579/setting_dnels_and_dose-response_curves_en.pdf/df747d00-c879-4983-ac0c-e32fa0af0b58

[3] . This was started by RAC as a trial exercise. However, At the Conference on "Lessons learnt on Applications for Authorisation" co-organised by ECHA and the European Commission that took place on 10-11 February, ECHA agreed to continue supporting the practice for all Annex XIV substances, recognising its value to the Authorisation process and its efficiency.

[4] https://echa.europa.eu/applying-for-authorisation/evaluating-applications

an advice on the risk estimates such as DNELs and dose-response functions in the RAC note and to agree the final version of the RAC note.

Once submitted, the draft background report and the draft RAC-note forms the basis for the evaluation and opinion forming of RAC. RAC's opinion contains an independent evaluation of the draft note.

The background report may be prepared with the support of external experts. Regardless, as ECHA is the Dossier Submitter it will ensure – through an internal review - that the quality of the proposal is up to the required standard**.**

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

- Review of published studies of recognised national and international organisations and authorities;
- Review of scientific literature;
- Identified approaches used in risk assessment;
- Review of methods for exposure monitoring;
- Overview of SVHC, including the reasoning for its inclusion in Annex XIV of the REACH Regulation;
- Risk assessment of each intrinsic property referred to in Article 57 of the REACH Regulation;
- Derivation of DNEL/DMEL, where possible, and/or establishing of the dose-response relationship, where derivation of DNEL/DMEL is not possible.

Table 1 outlines the main steps of the opinion development from receiving ECHA's request for setting DNELs and dose-response functions in the REACH applications for authorisation until the agreement of the RAC-note.

	STEP	**Timeline**	**Deliverables and milestones**
(0)	ECHA, or on request of ECHA the ECHA contractor prepares the **draft background report and the draft RAC-note**.		
1	ECHA informs the RAC about the request to set DNELs/DMELs and dose response relationships for substances on Annex XIV of the REACH Regulation prior to receiving applications for authorisation (AfAs). RAC Chairman appoints the RAC (co-) rapporteurs[5]	Week 1 (Week 1-5)	
2	A dialogue[6], if needed, between the RAC (co-)rapporteurs and ECHA, and, where applicable, the ECHA-contractor can be convened for an exchange of views and agreement on the outline of the draft background report and the key issues for discussion.	Week 8	Dialogue

5 For the selection of (co-)rapporteurs the Working Procedure for the Appointment of Rapporteurs and Co-rapporteurs by RAC and SEAC for Applications for Authorisation (agreed at RAC-33) applies.

6 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.

	ECHA/ECHA-contractor provides the agreed outline of the draft background report to the rapporteurs.		
3	ECHA/the ECHA contractor provides the revised draft background report and draft RAC note to the rapporteurs. The draft RAC note is revised according to rapporteur's views and possible diverging views of rapporteur's are reflected in the draft background report.	Week 9-10	
4	Newsgroups are initiated allowing RAC members to submit comments on the draft background report and draft note.	Week 11	**Draft RAC-note and draft background report** Comments
5	**The first plenary discussion** takes place, where the rapporteurs, ECHA or ECHA contractor may present the RAC note and (an outline of) the draft background report with the aim to discuss all the main components of the report and to agree on the draft RAC-note. At the plenary, the rapporteurs, ECHA or the ECHA contractor is also expected to respond to members` comments submitted within the written commenting round. If the RAC does not agree on the draft RAC-note, Step 2 – 5 apply again.	Week 15	First plenary discussion
6	ECHA provides **the edited agreed background report and the edited agreed RAC-note,** taking into account the comments received during the plenary meeting.	Week 17	**Final RAC note and background report**
	The RAC-note and the background report are published on the ECHA website.	Week 19	
	End of the opinion development on setting DNELs and dose-response curves prior to the application for authorisation phase.		