

Helsinki, 4 December 2015

Agreed at RAC-35 and SEAC-29

WORKING PROCEDURE FOR RAC AND SEAC ON CONFORMITY CHECK OF ANNEX XV RESTRICTION DOSSIERS

1. INTRODUCTION AND LEGAL BASIS

The purpose of this document is to outline the procedure for checking the conformity of Annex XV restriction dossiers submitted under the framework of Title VIII of the REACH Regulation. It describes the main roles and tasks of the Secretariat, (co-)rapporteurs and members of RAC and SEAC and gives the timelines for different tasks.

According to Article 69(4) of the REACH Regulation, RAC and SEAC shall check whether the dossier submitted conforms to the requirements of Annex XV. Within 30 days of receipt, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure shall be terminated.

This working procedure replaces the previous working procedure for RAC and SEAC on conformity check of Annex XV restriction dossiers agreed at RAC-27 and SEAC-21.

2. PROCEDURE FOR THE CONFORMITY CHECK

The table below outlines the main steps of conformity check from the receipt of an Annex XV restriction dossier by RAC and SEAC¹ until the agreement on the conformity of the dossier and informing the dossier submitter of the final outcome.

In case a Member State submits an Annex XV restriction dossier, the ECHA Secretariat prepares a preliminary draft conformity check outcome (consisting of a conformity report and recommendations to the dossier submitter), which is made available to the (co-) rapporteurs and which the (co-)rapporteurs can use as a basis for developing their views on conformity. If the dossier has been prepared by ECHA on request of the Commission, no preliminary draft conformity check outcome is provided to the (co-)rapporteurs.

¹ The Annex XV report is received by the (co-)rapporteurs around 1 month before the start of conformity check in RAC and SEAC.

	STEP	Timeline	Deliverables and milestones
a	The Annex XV dossier is made available to RAC and SEAC. Newsgroups are initiated allowing RAC and SEAC members to submit comments on the conformity of the dossier and the (co-)rapporteurs' draft conformity check outcome (within 12 days).	Day 1 (date of receipt of the dossier by the Committees)	Comments
b	The (co-)rapporteurs provide to the Secretariat their draft conformity check outcome, which is made available to RAC and SEAC ² .	By Day 5	Draft conformity check outcome
c	The (co-)rapporteurs consider comments received by other RAC and SEAC members and submit to the Secretariat the revised draft conformity check outcome. The Secretariat makes the documents available to RAC and SEAC.	By Day 20	Revised draft conformity check outcome
d	RAC and SEAC agree on their outcome of conformity check either by written procedure, according to Article 20 of the RAC and SEAC Rules of Procedure, or at the Committees' plenary meetings. Before the RAC/SEAC discussion, the dossier submitter is given an opportunity to introduce the dossier. If the dossier is considered in conformity by RAC/SEAC, the (co-)rapporteurs present the key issues they have identified in the dossier to the Committees (in order to facilitate the opinion development process).	By Day 30	RAC/SEAC agreement Introductory presentation by the dossier submitter Discussion on key issues
e	If the decision is taken by written procedure, the Secretariat informs RAC and SEAC of the outcome. If the Annex XV restriction dossier is found to be in conformity by both RAC and SEAC, the Secretariat informs the dossier submitter (Member State or ECHA) and initiates the public consultation. If the dossier is not found to be in conformity by one or both Committees, the dossier submitter is informed of this outcome.	By Day 30	Information to the dossier submitter
f	If the dossier is not found to be in conformity, detailed reasons for non-conformity are provided to the dossier submitter with a request to bring the dossier into conformity within 60 days of the day of receipt of the reasons from the Committees.	By Day 45	Information to the dossier submitter

² A teleconference meeting is normally arranged between the (co-)rapporteurs and the ECHA Secretariat to discuss any open issues.

3. INTERACTION BETWEEN RAC AND SEAC

The conformity check is a shared responsibility of RAC and SEAC. An Annex XV restriction dossier is in conformity only when both Committees conclude that it conforms to the requirements of Annex XV of the REACH Regulation. If either Committee fails to agree on the conformity of the dossier within 30 days, the Annex XV report is considered to be in conformity by that Committee. The template for the conformity report, provided as a separate document, indicates which questions are to be considered by RAC, which by SEAC and which questions both Committees have to scrutinise from their point of view.

For the conformity check, REACH stipulates a strict deadline of 30 days from the receipt of an Annex XV dossier by the Committees. The two Committees need to work in parallel during those 30 days. The Committees do not need to agree between themselves on the outcome of the conformity check, since the dossier can be in conformity on the aspects considered by one Committee, while not those of the other Committee.

However, co-operation between the (co-)rapporteurs during the conformity check is important to facilitate their further work on developing their opinions. Such interaction would make the (co-)rapporteurs aware of the crucial issues for the other Committee and help identify the possible links between the issues of the two Committees.