Procedure for redefinition of an active substance according to Article 13 of Regulation (EU) No 1062/2014

Date of document: 1 December 2016	Agreed at BPC-17

1. Introduction and objectives

This document describes the procedure for redefining an active substance according to Article 13 of Regulation (EU) No 1062/2014.

A proposal was drafted by the SECR and was first discussed at the APCP Working Group and agreed at BPC-17.

2. Redefinition of an active substance according to Article 13 of Regulation (EU) No 1062/2014

Article 13 of the Regulation (EU) No 1062/2014 defines the responsibilities for redefining an active substance:

1. *Where the evaluation of an existing active substance does not allow for conclusions to be drawn relating to the substance as identified in Annex II, the evaluating competent authority shall, after consultation with the participant concerned, establish a new substance identity. The evaluating competent authority shall inform the Agency thereof.*
2. *The Agency shall update the information in the Register with respect to the identity of the substance.*

In this context, it is apparent that the redefinition of an existing active substance needs solely to be agreed between the eCA and the applicant. No involvement of other Member State CAs or ECHA is intended. ECHA is only required to update the information in R4BP and publish an invitation to take over the role of participant for "*any substance covered by the existing identity in Annex II, but not by the new substance identity*" according to Article 14(1)(b) of Regulation (EU) No 1062/2014.

However, Member State CAs and ECHA have the possibility to comment on the substance identification during the commenting of the CAR. In the worst case, comments might be received which do not support the redefinition of the active substance and require either a further redefinition or a return to the original name of the active substance. It is therefore suggested to consult the APCP Working Group via an early working group discussion, so before the CAR is submitted to ECHA for the peer review process.

Consequently, ECHA proposes the following procedure:

1. The eCA and applicant discuss and agree, as far as possible, on the redefinition of the substance.
2. The eCA initiates an early working group discussion in the APCP Working Group on the redefinition. The applicant is invited to the early APCP Working Group discussion.
3. During the early APCP Working Group discussion members, the applicant and ECHA can exchange their views on the redefinition of the active substance.
4. After the consultation of the APCP Working Group the eCA informs ECHA via R4BP about the redefinition (template attached).
5. ECHA updates the R4BP.
6. ECHA publishes an invitation to take over the role of participant according to Article 14(1)(b).

It is noted that an active substance may also be redefined during the peer review process. In this however a discussion at the APCP Working Group will take place. Following this discussion the steps 4 to 6 given above should be followed.

o0o

Sent via R4BP to ECHA

Redefinition of an active substance according to Article 13 of Regulation (EU) No 1062/2014

After consultation with the applicant we would like to inform ECHA about the redefinition of the active substance **XXXX** as listed in Annex II to Regulation (EU) No 1062/2014 (entry number **XX**) into **XX**.

The redefinition of the active substance was discussed and agreed at the Working Group meeting for analytical methods and physico-chemical properties (APCP WG **XX** in 20**XX**).

Name of eCA:

Date: