# Biocides assessment and RAC opinion on harmonised classification (CLH)

Date: 26 February 2019

**Agreed at BPC-29**

## 1. Introduction

The Human Health WG agreed at the WG-III-2017 meeting[1] on principles for discussing issues related to harmonised classification & labelling (CLH) in the context of biocidal active substance approval. On this basis, the HH WG will abstain from discussing CLH, but the WG should discuss the following aspects of risk assessment related to CLH of an active substance, if applicable:

a) Any toxicological effect or hazard property relevant for risk assessment

b) The relevant NOAEL/LOAEL or NOAEC/LOAEC

c) The need for additional assessment factors due to e.g. overall uncertainty, nature of the effect, duration extrapolation

d) Whether the effect has a threshold (e.g. genotoxicity, carcinogenicity)

e) The need to perform local risk characterisation

In particular, it was agreed that when it is commented that the substance may have mutagenic properties in somatic tissues, it would not need to be discussed whether this triggers classification as Muta. 2, but instead, it should be discussed whether the hazard has implications on any of the points above.

The following principles need to be considered as established in the *Working procedure for active substance approval*[2]:

> *"If the substitution criteria are met because of CMR properties, it is highly preferable and therefore strongly recommended that the RAC opinion on harmonised C&L is available at the time of submitting the CAR[3]. In any case a CLH dossier needs to have been submitted by the time of submitting the CAR."*
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> *"Substances not considered to meet the exclusion or substitution criteria: If changes are proposed to an already existing harmonised classification, or no harmonised classification is available for the active substance, a CLH dossier needs to have been submitted by the time of submitting the CAR."*

In addition to these principles, which are based on CA meeting agreements[4], SECR recommends the eCAs to submit the CLH dossier as early as possible during the evaluation of a biocidal active, i.e. during the hazard assessment. This will reduce the problems that may be encountered due to the timing of the CLH process and the consequences of the CLH on performing the risk characterisation. A combined CAR-CLH report template is available[5] to facilitate this work and collaboration between the MSCA authorities for biocides and CLP is encouraged.

The purpose of this document is to clarify the interdependence of CLH and biocides assessments.

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[1] https://echa.europa.eu/documents/10162/4221979/discussions_on_c_l_final_en.docx
[2] https://echa.europa.eu/documents/10162/4221979/bpc_working_procedure_active_substance_en.pdf
[3] Competent Authority Report
[4] CA-Nov14-Doc.4.5 – Final. https://circabc.europa.eu/d/a/workspace/SpacesStore/eaae0dc2-1715-4906-a5d5-af3932fcd7c9/CA-Nov14-Doc.4.5%20-%20Final%20-%20Processus%20Art%205(1)%26(2).doc
[5] https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

## 2. Context of decision making

The contexts of decision-making are different in the CLH process and biocides assessment.

- RAC compares the available information with the CLP criteria and concludes whether CLH is warranted. Where the data provided are insufficient, inconclusive or unreliable, RAC may conclude that the information is insufficient/inconclusive for classification. This may occur if, for example, appropriate mutagenicity *in vivo* follow-up studies have not been performed.
- The BPC concludes whether the conditions set out in BPR Article 4(1) are complied with, referring among others to Article 19(1) whereby it has to be established that *"the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans (…)"*. This is done according to specified data requirements where further information requirements may be triggered by the results of the core information requirements.

Where concern on a hazard endpoint is identified for an active substance that would trigger the need for further testing, but the testing cannot be required anymore, the biocides assessment would have to be based on the available information.

From a procedural point of view, the BPC shall provide its opinion on the approval or non-approval of an active substance based on the available information and this opinion cannot be dependent on a future RAC opinion. Furthermore, agreed assessments would in principle not be re-opened should RAC decide not to follow the CLH proposal of the eCA. Re-evaluation of the substance may however take place in the context of BPR Article 15 (Review of approval of an active substance), or at the active substance renewal.

The genotoxicity endpoint requires specific considerations because it is generally considered that the effects would not have a threshold, and accordingly, the risk characterisation may be very restrictive as exposure would need to be minimised without an identifiable threshold of safety. It is therefore considered that for substances for which the eCA proposes classification as mutagenic (any category), the RAC opinion would need to be available at the time of submitting the CAR for peer review.

## 3. Proposals

SECR proposes an amendment in Chapter 5.1.2 of the Working procedure for active substance approval, regarding the criteria for the accordance check for AS/PT combinations in the Review Programme. The following point is proposed to be included under "*Substances not considered to meet the exclusion or substitution criteria*" (p. 20 in Version 6.0):

- "If the eCA proposes Muta. 2 classification, the RAC opinion on CLH needs to be available at the time of submitting the CAR, because the risk characterisation may be very restrictive as exposure would need to be minimised without an identifiable threshold of safety."

Furthermore, SECR proposes the following principles:

a) A decision taken by RAC not to classify a substance for a certain hazard property should not be taken as a confirmation that the substance does not have that hazard property. For instance, RAC may decide not to classify due to insufficient/inconclusive information when there are indications but not sufficient evidence that the criteria for classification are met – it may however not be possible or appropriate to disregard such indications in the biocides assessment. The same will apply if critical information is available in the biocides assessment that was not included in concluding on the CLH dossier at RAC.

   This principle is targeted for a situation where no RAC opinion is available and it is necessary to conclude in the biocides process, but it also enables concluding in a biocides assessment on either the presence or the absence of a certain hazard in a case where RAC has considered the information insufficient for classification. Furthermore, a decision by RAC not to classify

due to insufficient information may help the eCA to identify a data gap during the evaluation stage. In any event, the BPC and WGs will not conclude or establish CLH as this is to be done by RAC, but the conclusions of the BPC and WGs will concern the risk assessment.

b) In the absence of harmonised classification, the biocides risk assessment will rely on the CLH proposal included in the CAR by the eCA. While the CLH proposal is the responsibility of the eCA, the WG may discuss the underlying information used in preparing the CLH proposal and this may have consequences on the CLH proposal itself. The decision on which CLH is proposed is however still the responsibility of the eCA.

As a general note, SECR highly recommends the eCAs to submit a CLH proposal as early as possible during the evaluation phase.

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