**Discussions related to classification and labelling of active substances at Human Health WG meetings**

*Agreed 31 May 2017 at WG-III-2017*

**Introduction**

In active substance discussions at Human Health Working Group (WG) meetings, several open points in discussion tables have been related to classification and labelling (C&L). Harmonised classification is however discussed and agreed at the Committee for Risk Assessment (RAC), and normally, the WG should not discuss the C&L of the active substances. Some aspects related to C&L might however be relevant for the WG discussion.

The purpose of this document is to clarify how the WG should address discussion points related to C&L of active substances. This document does not concern C&L of biocidal products, where discussions may take place at the WG, as classification of products is not under the remit of RAC or harmonisation under CLP.

This document was first presented to WG-II-2017. A revised document, based on the WG discussion, was provided to the members and stakeholders for commenting. The current document addresses the comments made and is provided for discussion and agreement at WG-III-2017.

**WG discussions related to C&L**

RAC performs a hazard assessment and a comparison with the CLP criteria and adopts an opinion on harmonised classification and labelling independently from scientific opinions of any other committees or expert groups. RAC members are scientific experts who form an opinion in their own capacity, independent of their nominating Member State and any other party. For drafting an opinion on a harmonised C&L proposal, RAC takes into account all information submitted to ECHA by the dossier submitter, including the CLH report and Annexes, as well as all information that becomes available during the 45 days public consultation period. All parties concerned, including MSCAs, have the opportunity to comment on the CLH proposal of the dossier submitter during public consultation. The detailed study summaries needed for an independent and transparent assessment of the studies are made non-confidential in the CLH report.

According to CLP regulation No 1272/2008 Art 36 paragraph 2 “A substance that is an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC shall normally be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 37, paragraphs 1, 4, 5 and 6 shall apply.” According to CLP Art 37 “*a competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof.*” Thus, in principle, not only the eCA but any MSCA may at any time submit a new CLH proposal or a proposal to revise the current harmonised classification and labelling of a biocidal active substance on any hazard class. The other MSCAs might however not have sufficient information for submitting a proposal, as only the study summaries are normally available to them.

Information from the biocides WG discussion will be considered by RAC only if it is submitted during public consultation of the CLH report, or if it is part of the CLH report.

In order to avoid unnecessary work, C&L proposals should not be discussed at the WG. Any comments that the members would wish to make with regard to the C&L can be made during the public consultation of the CLH proposal. It has to be clarified however that this principle does not exclude a WG discussion on any toxicological effect or hazard property relevant for risk assessment.

Optimally, the RAC opinion should be available at the time of WG discussion. With this aim, the submission of CLH reports as early as possible is encouraged. The common CAR/CLH template facilitates providing the CLH parts as soon as the effects assessment is finalised, enabling the opinion forming process for CLH to start as early as possible. The full biocides CAR could be finalised subsequently and submitted to ECHA when the CLH process is already ongoing.

**Conclusion needed for local effects**

According to guidance for local risk characterisation[[1]](#footnote-2) (RC), information on C&L is necessary to conclude whether local risk characterisation is triggered. As indicated in the guidance, *“RC for local effects is triggered only when the biocidal product is classified for local effects. RC for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria*.”

The starting point is that the need to perform local RC is concluded on the basis of either an adopted opinion on harmonised C&L of the active substance, or if not available, the CLH proposal submitted by the eCA. The need to discuss at the WG would result from commenting MSCAs questioning the CLH proposal.

It would be unacceptable for other ECHA bodies than RAC to conclude on issues directly related to C&L, and it should therefore be made explicitly clear that the WG cannot conclude on meeting the criteria for C&L for an active substance. It is however suggested that the WG could conclude on the need to perform local RC. While it is recognised that classification and the need to perform local RC are linked, for practical reasons it is suggested to make this distinction.

**Principles for discussing issues related to C&L**

The following principles should be followed:

1. The WG will abstain from discussing C&L
2. The WG should discuss only the following aspects of risk assessment related to C&L of an active substance, if applicable:
3. Any toxicological effect or hazard property relevant for risk assessment
4. The relevant NOAEL/LOAEL or NOAEC/LOAEC
5. The need for additional assessment factors due to e.g. overall uncertainty, nature of the effect, duration extrapolation
6. Whether the effect has a threshold (e.g. genotoxicity, carcinogenicity)
7. The need to perform local RC
8. In order to conclude on the need to perform local RC, the following guiding principles should be followed in situations where the C&L proposal of the eCA has been questioned, leading to the discussion whether local RC should be performed:
9. While not concluding on C&L, the WG should conclude on the need to perform local RC. The conclusion should be made on the basis of meeting the C&L criteria for the hazard properties that would trigger local RC, while a conclusion is not made on the hazard category under CLP.
10. Where the eCA has proposed C&L that triggers local RC but the WG does not consider the local RC necessary, the proposed local RC would be moved to an annex of the CAR, clearly indicating that it is the eCA proposal[[2]](#footnote-3). Any consequences of the local RC, such as required RMMs, should be removed from the CAR.
11. Where the eCA has not performed local RC, the WG may request it to be performed.
12. If a RAC Opinion becomes available after the BPC Opinion is finalised, and based on this a more critical local RC would be triggered, this assessment should be requested at product authorisation. For the active substance an assessment should be requested only at the renewal stage.
13. The eCA will mark any comments concerning solely C&L in the RCOM as “*C&L – not for TOX WG discussion”* except for aspects described above in principles 2 and 3.
14. The SECR will include any open points concerning solely C&L as provisionally closed points in the discussion table.
15. If a comment has relevance to the aspects mentioned in points 2) and 3) above, the questions presented to the WG in the discussion table will accordingly concern the NOAEL/LOAEL, NOAEC/LOAEC, assessment factors, whether the effect has a threshold and whether local RC is triggered. For example, when it is commented that the substance may have mutagenic properties in somatic tissues, it would not need to be discussed whether this triggers Muta. 2, but instead, it should be discussed whether the hazard has implications on any of the points under 2) and 3) above.
1. Guidance on the Biocidal Products Regulation, Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 2.1, February 2017 [↑](#footnote-ref-2)
2. This annex could then be removed from the CAR if the RAC conclusion on C&L becomes available and it can be concluded that local RC is not necessary. [↑](#footnote-ref-3)