Dossier submitter's assessment of hazard classes and evaluation by RAC

Summary of the paper presented by ECHA to the 12th Meeting of Competent Authorities for REACH and CLP (CARACAL) on the 13-14 March 2013, and the response provided on the 23 September 2013.

One of the main objectives of harmonised classification and labelling (CLH) is to focus on substances and hazards of highest concern.

Since the carcinogenicity, mutagenicity, reproductive toxicity, respiratory sensitisation (CMR-RS) are the hazard classes of greatest concern, ECHA recommends - in line with Article 36(1) of the CLP Regulation - that dossier submitters assess systematically and for any type of substances all CMR-RS hazard classes and draw conclusions on whether or not the substance fulfils the CLP criteria for classification.

In the event that the dossier submitter does not assess all CMR-RS in the dossier, ECHA strongly recommends that they provide a brief reason why a particular CMR-RS hazard class was not assessed in the dossier.

Reasoning could be for instance that no data are available (i.e."no classification" due to lack of data) or that the hazard class in question was already assessed by the Committee for Risk Assessment (RAC) or the Technical Committee for Classification and Labelling (TC C&L) and there are no new data available.

Another reason could be that if there is an existing entry in Annex VI to CLP for a specific CMR-RS hazard class, the dossier submitter would not need to reassess such a hazard class unless the aim is to change the Annex VI entry. Also, if new data relevant for one hazard class becomes available e.g. through REACH dossier evaluation and no relevant new data are available for CMR-RS hazard classes, the dossier submitter should indicate this in their reasoning and conclude that no changes to C&L of the CMR-RS are foreseen.

The advantage of this approach is that the assessed CMR-RS hazard classes included in the CLH proposal will be subject to comments during public consultation, even if the dossier submitter did not conclude on classification (borderline cases). As a result, RAC will systematically develop an opinion on CMR-RS hazard classes that were open for comments during the public consultation.

Another advantage is that the process will start with a dossier that includes all available and relevant information for these hazard classes. When certain CMR-RS hazard classes are not assessed in the proposal, the reason will be communicated transparently to the public in the CLH report and will be traceable by future dossier submitters for any Annex VI update of the same substance.

This approach does not affect the current practice for plant protection products (PPPs)[1] and biocidal products[2] with no current entry in Annex VI, where it is already agreed that

[1] CLP refers to active substances in **plant protection products** in the meaning of Directive 91/414/EEC. This directive has been repealed by Regulation (EC) No 1107/2009 (hereinafter, the PPP Regulation).

[2] Active substances in **biocidal products** in the meaning of Directive 98/8/EC. This directive will be repealed with effect from 1 September 2013 by the Regulation (EU) No 528/2012 (hereinafter, the Biocidal Products Regulation).

the DSs should provide information on all hazard classes (including CMR-RS) on any proposals concerning new Annex VI entries.

Tasks for the main actors in the CLH process

The aim is to have a predictable, coherent and resource efficient CLH process where all parties involved would know which hazard classes were:
1) assessed and concluded by the dossier submitter;
2) open for public consultation comments; and
3) consequently evaluated by RAC.

1. Dossier submitter's tasks

All other substances than PPPs and biocidal products: a CLH proposal prepared by the dossier submitter should contain a comparison of the available information with the CLP criteria as set out in part 2 of Annex VI to CLP.

It should contain an assessment of the information provided and a conclusion on those hazard classes that were assessed. The dossier submitter is the initiator of the CLH process and it is in the DS's discretion[3] which hazard classes are considered for harmonisation. According to Article 36(1) of CLP, CLH proposals normally focus on CMR-RS hazard classes. ECHA **recommends** that the dossier submitter provides an assessment of all the CMR-RS hazard classes even if no classification for those is proposed or provides reasoning why certain CMR-RS hazard classes was not assessed in the dossier. For other hazard classes, a justification on community level is required.

PPPs and biocidal products: with reference to Article 36(2) of CLP, CLH proposals for active substances used in PPPs and biocidal products should normally cover all hazard classes[4]. Hence, it is expected that the dossier submitter draws conclusions on the classification for all hazards in their proposal. For hazard classes where the criteria for classification are not fulfilled, the conclusion in the proposal should state e.g. no classification is warranted due to "data conclusive but not sufficient for classification", "data lacking" or "inconclusive data".

The dossier submitter should always submit a CLH proposal for PPPs and biocidal products to ECHA, even if the conclusion of the assessment does not propose classification for any hazard class according to CLP.

Updates of Annex VI entries for all substances:
The dossiers proposing amendments to Annex VI entries only need to focus on the specific hazard classes that are proposed to be amended. In the event that CMR-RS hazard classes were not assessed in the harmonised classification process according to CLP or DSD in the past, then it is recommended, in line with Article 36(1), that these are included in the updated dossiers as well. Updating of Annex VI entries is the same for active substances used in PPPs and biocidal products as for other substances.

[3] However, for non CMR-RS hazard classes, a justification for action at the EU level must always be provided.

[4] Specifically for biocides, Regulation 528/2012 allows waiving of data relevant for some hazard classes (Article 21) and the data set may not always be complete for C&L.

2. *Hazard classes open for comments during the public consultation*

In the announcement of the public consultation, ECHA always indicates which hazard classes are open for comments by the parties concerned. A hazard class will be open for comments during the consultation if the dossier submitter has provided an appropriate information basis, assessment and conclusion. In addition, for other type of substances than PPPs and biocidal products only CMR-RS hazard classes and those hazard classes for which the dossier submitter has classes, a justification on the community level will be open, provided that the dossier submitter has given an appropriate information basis, assessment and conclusion.

This approach applies to both new Annex VI entries and to amendments of existing entries.

3. *RAC tasks*

RAC will assess all hazard classes open for public consultation. The committee can come to another conclusion, e.g. add specific concentration limits within the hazard class even if it was not proposed, but it cannot add another hazard class.

Table 1. Dossier submitter's assessment, public commenting and RAC evaluation of hazard classes in the CLH process.

Type of proposal and substance	DS's assessment	Commenting during PC	RAC evaluation
New entry in Annex VI:			
Active substance in PPP/biocidal product	All hazard classes	All hazard classes for which the dossier submitter has provided an appropriate information basis, assessment and conclusion including hazard classes for which classification is not proposed	All hazard classes which were open for comments during the PC
All other substances	At the dossier submitter's discretion, any hazard class meeting the CLP criteria for classification, and where needed accompanied by a justification for action at the EU level; the dossier submitter may include an assessment of CMR-RS hazard classes even if they conclude that classification is not warranted or provide reasoning[5] why certain CMR-RS hazard classes were not assessed in the dossier	All hazard classes for which the dossier submitter has proposed classification and provided appropriate an information basis, assessment and conclusion including those CMR-RS hazard classes for which classification is not proposed by the dossier submitter	All hazard classes which were open for comments during the PC
Update of an entry in Annex VI:			
All substances	Hazard classes for which the dossier submitter proposes an amendment; assessment of CMR-RS may also be included even if the dossier submitter concludes that classification is not warranted	Hazard classes for which an amendment is proposed by the dossier submitter; CMR-RS for which classification is not proposed if the dossier submitter has provided an appropriate information basis, assessment and conclusion	All hazard which were open for comments during the PC

[5] In the event that the dossier submitter does not want to disclose the reasoning during the PC, it can also be provided separately for ECHA only. However, at least a short statement as e.g. "hazard class not assessed in this dossier" or "data lacking and the hazard class not assessed in this dossier" should be given in the CLH report in all cases where the CMR-RS were not assessed.