

Helsinki, 24 October 2011

RAC/16/2011/11 (Agreed at RAC-16)

RAC FRAMEWORK FOR ACCORDANCE CHECK OF DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING

1 INTRODUCTION AND LEGAL BASIS

Proposals for harmonised classification and labelling of substances are governed by Article 37 of Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging (CLP Regulation). Member State Competent Authorities or manufacturers, importers and downstream users can submit a proposal(s) for harmonised classification and labelling of substances to ECHA as defined by CLP Art 37(1) and by Art 37(2), respectively. The CLH dossier submitted to ECHA shall follow the format set out in Part B of the Chemical Safety Report (CLP Annex VI, Part 2) and contain the relevant information provided for in Part 1 of the CLP Annex VI. This is further defined by the ECHA '*Guidance on the preparation of dossiers for harmonised classification and labelling'* and '*CLH report format'*.

An accordance check is introduced with the aim to ensure that a CLH dossier is prepared in accordance with the requirements as specified in the legal text and as defined in the relevant ECHA guidance and format. An additional aim is to check whether the dossier appears to have sufficient information and argumentation for RAC to formulate an opinion, and therefore a non-mandatory involvement of the RAC rapporteurs is described in this framework.

2 ACCORDANCE CHECK - RESPONSIBILITIES AND PROPOSED PROCESS FOR CLH DOSSIERS

The ECHA-Secretariat conducts the accordance check. The accordance check focuses on whether the format set out in Part B of the Chemical Safety Report (CLP Annex VI, Part 2) is followed and whether the CLH dossier contains the relevant information provided for in Part 1 of the CLP Annex VI.

The ECHA-Secretariat informs the (co-) rapporteurs of the reception of the CLH dossier at the start of the accordance check and provides (co-) rapporteurs with a template for inserting the comments. The (co-) rapporteurs are given the opportunity to provide their view on whether the dossier appears to have sufficient information and argumentation for RAC to formulate an opinion and/or specific comments and suggestions for improving the dossier within three weeks. The timeline can be extended by suggestion from the ECHA-Secretariat or by request from the rapporteurs.

If comments are submitted within the deadline, the ECHA-Secretariat will include the rapporteurs' comments as a complementary document to the ECHA's accordance check when sending the accordance check outcome to the dossier submitter.

In certain cases, the ECHA-Secretariat may also ask for (co-)rapporteur's views on the draft ECHA's accordance check before submitting the accordance check report to the dossier submitter.

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(Co-) rapporteurs are not involved in the accordance check process in case the CLH dossier is submitted by manufacturers, importers and/or downstream users.

The ECHA-Secretariat only processes the CLH dossier further when the CLH dossier is in accordance. The dossier is then distributed to RAC and the RAC is to be informed on the initialisation of the Public consultation on the CLH report and on the initiation of the procedure for opinion development.

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