9 June 2016

Minority opinion of five MSC members on Annex XV proposal

to identify Dicyclohexyl phtalate (DCHP) as substance of very high concern (Art 57 (c) and 57 (f))

MSC members from ES, IT, DE, MT and CZ do not support the dossier submitter's proposal to identify dicyclohexyl phthalate as SVHC due to its endocrine activity with relevance to human health which gives rise to an equivalent level of concern to those of CMR.

Rationale:

Dicyclohexyl phthalate (DCHP) is included in the 9th ATP to CLP, which was agreed at the 44th meeting of the REACH Committee 3-4 February 2016, for classification as toxic for reproduction Repr. 1B, H360D ("May damage the unborn child.") based on the evidence of adverse effects on male rats exposed in utero. Thereby ES, IT, DE, MT and CZ agree that the requirements for SVHC identification following Art. 57 (c) are fulfilled.

The effects include early marker effects (e.g. on anogenital distance (AGD) and retained areola mammae) and morphological changes (e.g. on testes, prostate). Article 57 (f) requires "scientific evidence of probable serious effects to human or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e)" of REACH Art. 57 and substances "are identified on a case-by-case basis". The serious concern for DCHP relies on lowered prostate weight, reduced AGD and retained areola mammae in rats as pointed out in the Annex XV Dossier. All these effects can be subsumed under the endpoint "toxicity for reproduction". An independent consideration of the MoA is not possible as the endocrine activity of dicyclohexyl phthalate, namely the anti-androgenic MoA, would cause the adverse effects observed in the studies, namely developmental toxicity. Thus, no equivalent level of concern for the endocrine disrupting properties has been established as the serious effects referred to in Article 57 (f) are those of reproductive toxicity.

We fully agree that dicyclohexyl phthalate has an endocrine activity. However, we do not support SVHC identification based on this MoA as it is not, in this case, of an equivalent level of concern. In fact, it is the same concern (i.e. effect) which is already taken into account in the dossier for identification as SVHC in accordance with Article 57 (c) due to the adverse effects on development. We therefore are concerned about the approach of combined identification of DCHP as SVHC following Art. 57 (c) and (f) because a separate identification as SVHC under Art. 57 (c) would have allowed immediate inclusion of the substance into the Candidate List.

This position is in line with our position for DEHP, DBP, BBP and DIBP maintained in MSC and REACH Committee where no agreement has been found so far.