

ECHA/PR/12/14

The Member State Committee agrees on identification of five SVHCs and finalises 41 dossier evaluation cases

Helsinki, 12 June 2012 – In its meeting from 6 to 8 June 2012, the Member State Committee (MSC) unanimously agreed on the identification of five substances of very high concern (SVHCs). These will be added to the Candidate List and may subsequently become subject to authorisation. The Committee also finalised 41 draft dossier evaluation decisions.

Candidate List

The MSC identified five new SVHCs: one, diborontrioxide, through written procedure and four dyes at its meeting. As a result of the discussions, it was agreed that the entry for the Candidate List will be made explicit so that it is evident that the dyes C.I. Basic Violet 3, C.I. Basic Blue 26, C.I. Solvent Blue 4 and 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol are identified as SVHCs only if the concentration of the impurities Michler's ketone or Michler's base is equal to or higher than 0,1%. These five SVHCs will be included in the Candidate List in its next update together with eight further substances that did not require the MSC's involvement. The updated Candidate List will be published in due course on ECHA's website.

Dossier Evaluation

The MSC also unanimously agreed on nine draft dossier evaluation decisions (eight testing proposal draft decisions and one compliance check draft decision).

No unanimous agreement was reached by the MSC in the meeting on one draft decision addressing a testing proposal for meeting the information requirements for a two-generation reproductive toxicity. In fact, though the majority of MSC members supported a draft decision giving the registrant the choice between a two-generation study (1) and an extended one generation reproductive toxicity study (2) (EOGRTS) with the second generation, a minority of MSC members considered that only an EOGRTS with extra cohorts on immunotoxicity and neurotoxicity and without the second generation should be requested.

In addition to the ten cases of dossier evaluation addressed at the meeting, the MSC agreed in written procedure on 23 draft dossier evaluation decisions. However, no unanimous agreement was reached in written procedure on eight draft decisions addressing testing proposals for meeting the information requirements for the two-generation reproductive toxicity where the EOGRTS was involved. The disagreement is mainly due to legal uncertainty regarding the status of the EOGRTS under REACH.

The cases where no unanimous agreement of the MSC was reached will be referred by ECHA to the Commission for decision making.

- (1) EU B.35 - OECD Test Guideline 416: Reproduction/Developmental Toxicity Screening Study
- (2) OECD Test Guideline 443: Extended One-Generation Reproductive Toxicity Study.

Further information

MSC – Member State Committee

<http://echa.europa.eu/about-us/who-we-are/member-state-committee>

Substances of Very High Concern identification

<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification>

