06 December 2023

SUMMARY REPORT OF THE 27th ED EXPERT GROUP MEETING

The 27th ED EG meeting took place online on 14 November 2023. The EG provided scientific advice on ED assessments of two REACH substances.

The meeting was attended remotely by 54 participants representing 17 Member States and EEA countries (AT, BE, CZ, DK, DE, ES, FI, FR, IE, IT, LT, NL, NO, PL, SE, SI, SK), Switzerland, European Commission and 7 accredited stakeholder organisations (CHEM Trust, Cefic, Concawe, CropLife Europe, ECETOC, EEB, PETA Science Consortium International e.V.).

Main outcomes of the substance discussions

Closed session

- 3-methylpyrazole (CoRAP 2018): Studies indicate that the substance is a potent alcohol dehydrogenase inhibitor (ADH). It is known that ADH is a key enzyme in the biosynthesis of retinoic acid, which is essential for reproduction and embryo development. The ED EG advised that the developmental effects induced by the substance in mammals (e.g. malformations of urogenital tract and the cardiovascular system) can be linked to the endocrine activity (ADH inhibition). Although fertility effects have not been tested and could potentially be triggered based on the proposed mechanism, the ED EG considered the adverse effects observed in developmental toxicity studies are already sufficient. Based on the evidence for adversity and endocrine activity and a plausible link between them, the ED EG advised that the substance may be a suitable candidate for ED HH classification (Cat 1). In addition, the EG advised that classification of the substance as ED ENV should be considered, as the adversity in mammals is considered population relevant. In a case ED ENV classification would not be warranted based on effects in mammals, then fish test(s) including developmental period and possibly also investigations on fertility effects could be considered.

Open session

- 4,4'methylenedi-2,6-xylenol (TMBPF): The presented ED assessment focussed on the environment. The ED EG agreed that the observed endocrine (in particular steroidogenic) activity of the substance in vitro can be linked to the observed adverse effects relevant at the population level on fecundity and fertility as well as to the histological findings in a short-term reproduction assay in fish (OECD TG 229). In addition, the ED EG agreed that TMBPF shows endocrine antagonistic activity via the thyroid pathway which can be linked to observed adverse effects on thyroid histopathology and on development and growth in the Amphibian Metamorphosis Assay (OECD TG 231), relevant at the population level. Therefore, the ED EG advised that the substance could be identified as ED for the environment.

General ED-related topics

ECHA provided an overview on their learnings from recent court and Board of Appeal (BoA) cases on EDs identified as SVHCs or potential EDs being assessed under Compliance Check or Substance Evaluation.

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Substances discussed at the 27th ED EG meeting:

MS	EC#	Substance name	Outcome of the discussion	Session	Notes
BE	215-925-7	3-methylpyrazole	ED HH, ED ENV	Closed	CoRAP 2018
DE	226-378-9	4,4'methylenedi-2,6-xylenol	ED ENV	Open	REACH

Written procedures between 26th and 27th meeting

MS	EC#	Substance Name	Notes
NL	200-712-3	Salicylic acid	Biocidal active substance
SE	300-340-2	Propenoic acid, methyl ester, reaction products with mixed O,O-bis(branched and linear pentyl and iso-Bu) phosphorodithioates	CoRAP, 2023