10 May 2023

SUMMARY REPORT OF THE 25th ED EXPERT GROUP MEETING

The 25th ED EG meeting took place on 10 May 2023. In addition to providing scientific advice on ED assessments of one substance under REACH substance evaluation (SEv) and of one biocidal active substance the ED EG discussed the draft CLP guidance on new ED classification criteria.

The number of participants was the highest in the history of the ED EG, altogether 79 participants (online) 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 seven accredited stakeholder organisations (CHEM Trust, Cefic, Concawe, CropLife Europe, ECETOC, EEB, HEAL).

Main outcomes of the substance discussions

Open session

- Medetomidine (biocidal active substance): In their presentation the evaluating member state postulated three non-EATS MoAs (Mode of Action) for (i) suppression of sympathetic adrenomedullary axis, (ii) impaired insulin and glucose homeostasis, and (iii) suppression of glucocorticoid synthesis, as well as MoA for ED via S-modality (steroidogenesis). While the industry experts claimed that the assessment does not provide adequate evidence of adversity, the Member State experts agreed that considering the overall weight of evidence the substance meets the ED criteria for human health, and no further testing is needed.

Closed session

- Tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate (TOTM) (CoRAP 2012, follow-up evaluation): Based on the comments provided in an ED EG written procedure, the evaluating Member State considers that further testing in a ZEOGRTS or MEOGRTS (Zebrafish/Medaka Extended One-Generation Reproductive Toxicity Study) is needed to cover potential effects on both sexual development and reproduction. The ED EG discussed the most appropriate fish species to be used. Given the available data from an FSDT (Fish Sexual Development Test) on the substance, the experts preferred testing in zebrafish to testing in medaka.

General ED-related topics

Open session

- The ED EG had an *ad hoc* meeting on a draft update to the ECHA Guidance on the Application of the Classification, Labelling and Packaging (CLP) Regulation Criteria. The CLP Guidance is being updated to reflect the inclusion of new hazard classes in the Regulation including ED HH and ED ENV. ECHA gave presentations on the guidance update process and its work so far on the draft (with support from EFSA). The ED EG members provided comments which will be taken into consideration. Following further consultations with interested parties, the updated guidance is planned to be published in mid-2024[1].

[1] New hazard classes 2023 - ECHA (europa.eu)

The next ED EG meeting is scheduled for 3-4 October 2023.

Substances discussed at the 25th ED EG meeting:

MS	EC#	Substance name	Outcome of the discussion	Session	Notes
NO	CAS# 86347-14-0	Medetomidine	ED HH	Open	Biocidal active substance
AT	222-020-0	Tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate (TOTM)	More data needed	Closed	CoRAP 2012

Written procedures between 24th and 25th meeting

MS	EC#	Substance Name	Session	Notes
FR	214-946-9	Galaxolide	closed	CoRAP 2022
ES	200-143-0	Bronopol	closed	Biocidal active substance