

29 April 2022

SUMMARY REPORT OF THE 22nd ED EXPERT GROUP MEETING

The 22nd ED EG meeting took place on 11-12 April 2022. Besides discussing generic issues related to ED assessment, the EG provided scientific advice on ED assessments of four substances under REACH substance evaluation (SEv) and of one biocidal active substance.

The meeting was attended by 45 participants representing 15 Member States and EEA countries (AT, BE, CZ, DK, DE, ES, FI, FR, IE, IT, LT, NL, NO, SK, SI), Switzerland, European Commission and 5 accredited stakeholder organisations (CHEM Trust, Cefic, ECETOC, EEB, ETUC).

Main outcomes of the substance discussions

Closed session (authorities only)

- Benzotriazole (CoRAP 2016, follow-up evaluation): The ED assessment was carried out after an FSDT (fish sexual development test, OECD TG 234) had been submitted under SEv. The histological data indicated a shift in sex ratio towards less male and more undifferentiated fish, reaching statistical significance at the lowest concentration tested. The experts supported the conclusion that the FSDT results together with other available evidence are sufficient to conclude ED ENV.
- 6,6'-di-tert-butyl-4,4'-thiodi-m-cresol (CoRAP 2015, follow-up evaluation): The ED assessment was carried out after an FSDT (fish sexual development test, OECD TG 234) had been submitted under SEv. The experts agreed that the increase in weight may be considered adverse, and that the increase in gonadal stage in males is not linked to change in stock density. The experts agreed that the ED assessment requires further consideration once the results from the EOGRTS, also requested under SEv, become available.
- 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione (MMBI) and 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt (ZnMMBI) (CoRAP 2018, follow-up evaluation): The ED assessment was carried out after an AMA (amphibian metamorphosis assay, OECD TG 231) with MMBI had been submitted under SEv. The assay demonstrated effects on metamorphosis and thyroid histopathology providing clear evidence for thyroid antagonistic activity. The results fit the available *in vitro* and mammalian data on MMBI as well as to the effects observed in mammals and amphibians for structurally related substances. The experts agreed that there is sufficient evidence to conclude that MMBI and ZnMMBI cause adverse and population relevant effects, which are plausibly linked to an ED MoA, and both MMBI and ZnMMBI can be identified as ED ENV.

Open session

- Dinotefuran (biocidal active substance): Discussion was focused on potential thyroid modality for human health. There were diverging views expressed on the significance of the findings from existing studies. The experts recommended further assessment of existing data and consideration of the outcome of an AMA study which is expected shortly.

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General ED-related topics

ECHA provided a presentation on their workflow for screening of potential EDs. Based on the outcome from a pilot phase, the workflow can help evaluators to confirm or disregard potential ED concern and to check for consistency between available data and predicted ED properties for substance groups.

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

Tentative dates for the next ED EG meetings are 4-5 October and 15-16 November.

Substances discussed at the 22nd ED EG meeting:

MS	EC#	Substance name	Outcome of the discussion	Session	Notes
DE	202-394-1	Benzotriazole	ED ENV	Closed	CoRAP 2016 ED ENV assessment
AT	202-525-2	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	More details on available info/data needed	Closed	CoRAP 2015 ED HH+ENV assessment
DE	258-904-8 262-872-0	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione (MMBI) and 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt (ZnMMBI)	ED ENV	Closed	CoRAP 2018 ED ENV assessment
BE	CAS# 165252-70-0	Dinotefuran	More details on available info/data needed	Open	Biocidal active substance ED HH assessment