

28 November 2022

SUMMARY REPORT OF THE 24th ED EXPERT GROUP MEETING

The 24th ED EG meeting took place on 15 November 2022. The EG provided scientific advice on ED assessments of one substance under REACH substance evaluation (SEv) and of three biocidal active substances.

The meeting was attended by 60 participants (online) representing 15 Member States and EEA countries (AT, BE DK, DE, ES, FI, FR, IE, IT, LT, NL, NO, PL, SE, SK), Switzerland, European Commission and 3 accredited stakeholder organisations (Cefic, ECETOC, EEB).

Main outcomes of the substance discussions*Closed session*

- Methyl 4-hydroxybenzoate (Methylparaben, MeP) (CoRAP 2014, follow-up evaluation): The ED assessment was carried out after submission of an EOGRTS (Extended One-Generation Reproductive Toxicity Study, OECD TG 443) under Compliance Check and an FSDT (Fish Sexual Development Test, OECD TG 234) under Substance Evaluation (SEv). The experts considered that the data provide evidence that MeP exhibits adverse effects relevant for human health (i.e. on sperm) which can be plausibly linked to its estrogenic activity. These effects can be considered population relevant for the environment. Various published studies provide evidence of adverse effects on fish including on sperm and testes. While the validity of the FSDT was questioned and further statistical analysis of the FSDT outcome was suggested, information from the study may be considered in a weight of evidence approach. Also, similar effects observed with other parabens should be considered in the assessment. Overall, based on the weight of evidence, the experts concluded that MeP is an ED for human health and the environment.
- Diuron (biocidal active substance, also earlier under SEv): The experts considered that the available evidence is not sufficient to conclude on a possible thyroid mode of action. Regarding a potential estrogenic/androgenic/steroidogenic (EAS) mode of action, effects seen in carcinogenicity studies were considered adverse but mechanistic investigation would be needed to support an ED mode of action (MoA). Further investigation with OECD level 2 or 3 studies before potentially conducting a level 5 study may be required. Regarding non-target organisms (NTOs), most experts agreed that a recently provided FSDT should not be considered reliable enough to conclude on the ED properties. Additional fish data trigger a concern for an EAS mode of action and this data, as well as the mammalian data from the human health assessment, should be considered in the overall weight of evidence for NTOs.

Open session

- Copper (biocidal active substance): The experts discussed whether a recently provided range finding study on the effects of copper on amphibians addressed concerns related to a potential thyroid mode of action of this substance. Member State experts considered that, due to limitations of the range finding study (e.g. in relation to dosing, length of study, incomplete histopathology, replicates), a LAGDA (Larval Amphibian Growth and Development Assay, OECD TG 241) was still needed to sufficiently address the concerns.

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- Geraniol (biocidal active substance): The ED EG considered the available dataset on this substance including, in particular, a newly provided EOGRT study. The experts agreed that there was no evidence that the substance had an EAS MoA. The experts considered that thyroid histopathology related observations could be considered adverse and that a thyroid disrupting MoA (other than secondary to liver toxicity) should be further investigated. The evaluating MS will consider additional information recently provided by industry before concluding on the most appropriate follow-up tests.

In a poll respondents expressed high satisfaction with the virtual meeting including their ability to contribute to the meeting effectively and the quality of the audio/video.

The provisional next ED EG meeting dates are 10-11 May 2023 (tbc).

Substances discussed at the 24th ED EG meeting:

MS	EC#	Substance name	Outcome of the discussion	Session	Notes
FR	202-785-7	Methyl 4-hydroxybenzoate (Methylparaben, MeP)	ED HH ED ENV	Closed	CoRAP 2014
DK	206-354-4	Diuron	Testing needed	Closed	Biocidal active substance
FR	231-159-6	Copper	Testing needed	Open	Biocidal active substance
FR	203-377-1	Geraniol	Testing needed	Open	Biocidal active substance