18 November 2021

SUMMARY REPORT OF THE 21st ED EXPERT GROUP MEETING

The 21st ED EG meeting took place on 16 November 2021. The group reached a noteworthy milestone, as since February 2014 the ED EG has provided scientific advice on assessments of 100 potential ED substances. In this meeting the ED experts addressed four substances under REACH substance evaluation and a group of biocidal active substances.

The meeting was attended by 68 participants representing 17 Member States and EEA countries (AT, BE, CZ, DE, EL, ES, FI, FR, IE, IT, LT, NL, NO, PL, SE, SK, SI), Switzerland, European Commission and 6 accredited stakeholder organisations (CHEM Trust, Cefic, ECETOC, EEB, ETUC, Heal).

Main outcomes of the substance discussions

Closed session

- 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2-FTMA) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (6:2-FTA) (CoRAP 2016, follow-up evaluation): The ED assessment was carried out after FSDT (fish sexual development test, OECD TG 234) on the degradation product 6:2 FTOH (6:2 fluorotelomer alcohol), and AMA (amphibian metamorphosis assay, OECD TG 231) on the degradation product PFHxA (perfluorohexanoic acid) had been submitted under substance evaluation process. The ED EG supported the conclusion that considering all data available, there is sufficient evidence on E modality to identify FTOH as ED for ENV. The ED EG was of the opinion that LAGDA (larval amphibian growth and development assay, OECD TG 241) could be in principle justified to clarify the T-mediated adversity of PFHxA, but it was deemed not necessary considering the available data for FTOH. Furthermore, the view was expressed that the T mediated adversity could already be concluded based on the effects observed in the submitted AMA study.

Open and closed session

- 2,6-di-tert-butyl-p-cresol (BHT) (CoRAP 2016): LAGDA will be requested under substance evaluation to clarify interaction on HPT axis. The available neurodevelopmental data shows adversity, but a mechanistic study would be needed to clarify MoA (mode of action). There was some support for the US-EPA thyroid assessment assay to clarify the concern.

Open session

- Tert-butyl methyl ether (MTBE) (CoRAP 2014, evaluation in the conclusion stage): Some of the experts thought that the available data on atherosclerosis, adipogenesis and reduced insulin sensitivity are sufficient to postulate a non-EATS endocrine disrupting MoA, and to potentially proceed to ED identification. Some other experts had reservations and thought that further information may be needed. At this stage of the process, further data cannot be requested under substance evaluation.

- Group of in-situ generated monochloramines (biocidal active substances): The ED EG agreed that further data will be needed to conclude the ED HH assessment. For EAS modalities, there was some support for the EOGRTS (extended one-generation reproductive toxicity study, OECD TG 443), especially if a data gap on reproductive toxicity is identified. *In vitro* studies were not considered scientifically justified due

to the nature of the substances, since possibility for false negatives may not be excluded. Altogether these studies would not provide sufficient information for substances of this type to conclusively rule out the ED property. For T modality, some experts thought that the available data is enough to conclude that the substances do not meet the ED criteria for T-modality, while others proposed to include parameters related to T-modality if a EOGRTS is performed.

Tentative ED EG meeting dates in 2022 are 11-12 April, 4-5 October, and 15-16 November.

Substances discussed at the 21st ED EG meeting:

MS	EC#	Substance name	Outcome of the discussion	Session	Notes
DE	218-407-9 241-527-8	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2-FTMA) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (6:2-FTA)	ED ENV	Closed	CoRAP 2016 ED ENV assessment
FR	204-881-4	2,6-di-tert-butyl-p-cresol (BHT)	Testing needed	Open and Closed	CoRAP 2016 ED ENV assessment
FR	216-653-1	Tert-butyl methyl ether (MTBE)	Refine assessment	Open	CoRAP 2014 ED ENV + HH assessment
AT ES FR SE	-	Group of in-situ generated monochloramines: - Monochloramine generated from sodium hypochlorite and an ammonium source - Monochloramine generated from ammonium hydroxide and a chlorine source - Monochloramine generated from ammonia and a chlorine source - Monochloramine generated from ammonium sulphate and a chlorine source - Monochloramine generated from ammonium chloride and a chlorine source - Monochloramine generated from ammonium carbamate and a chlorine source	Testing needed	Open	Biocidal active substances ED HH assessment