

26 April 2021

SUMMARY REPORT OF THE 19th ED EXPERT GROUP MEETING

The ED EG meeting took place on 13 April 2021 and it was the 3rd ED EG meeting hosted virtually by ECHA, and the 1st EG meeting where Interact Portal was used as the IT platform. Besides discussing generic issues such as use of the AMA (Amphibian Metamorphosis Assay) and LAGDA (Larval Amphibian Growth and Development Assay) assays in ED assessment, ED-related activities of the Commission, and ECHA's grouping approach in relation to endocrine disruptors, the EG provided scientific advice on ED assessments of three substances under REACH substance evaluation (see also the Table below).

The meeting was attended by 64 participants representing 18 Member States and EEA countries (AT, BE, CZ, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, NO, PL, SE, SK, SI), Switzerland, EFSA, European Commission and 5 accredited stakeholder organisations (CHEM Trust, Heal, HSI, EEB, CEFIC).

Main outcomes of the substance discussions

Closed session

- 2-ethylhexyl trans-4-methoxycinnamate (OMC) and isopentyl p-methoxycinnamate (IPMC) (CoRAP 2016, follow-up evaluation): The ED EG agreed that available information on OMC including recent literature data were not sufficient and more testing will be needed on IPMC to clarify the ED concern for both substances. The experts' preferences for the follow up in vivo (and possibly in vitro) testing strategy varied, including FSTRA (Fish Short Term Reproduction Assay) and FSDT (Fish Sexual Development Test) in combination, EOGRTS (extended one-generation reproductive toxicity study) with either medaka or zebrafish and/or XETA (Xenopus Eleutheroembryonic Thyroid Assay) potentially followed by LAGDA.

Open session

- 4,4'-sulphonyldiphenol (bisphenol S) (CoRAP 2014, follow-up evaluation): The experts nominated by the Member States agreed that there is sufficient evidence to conclude that the substance acts as ED for human health, and that the observed hazards (estrogenic mode of action linked to reduced fertility) are also population relevant for mammalian wildlife thus supporting identification as ED for environment. The group also discussed the results from a ZEOGRT (extended one-generation reproductive toxicity with zebrafish) study recently submitted under REACH substance evaluation as well as relevant fish studies from the scientific literature.

General ED-related topics

The European Commission gave an update on their ED related activities under REACH and CLP. DG ENV reported on the timelines foreseen for the update of REACH information requirements for ED, including impact assessment launch in 2021 and adoption in 2022. DG ENV also reported on the development of ED criteria under CLP, where the initial draft proposal includes separate hazard classes for ED human health and ED environment with categories 1 and 2 for both.

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In relation to the AMA and LAGDA assays, DK and ECHA clarified the information provided by the assays and their use in helping to identify EDs, including chemicals with thyroid disrupting modes of action, as recommended by the OECD.

ECHA provided a presentation on their approach to grouping of substances which is an important part of ECHA's integrated regulatory strategy. This included an overview of the significant progress made in 2020 in identifying substances for regulatory risk management including some potential EDs.

ECHA gave an introduction to the role and tasks of the Member State Committee and its' expectations from the expert groups. The presentation highlighted significant benefits from the EG discussions to the MSC, especially in clarifying the science of the cases before the MSC plenary. Advice was provided to EG members in relation to their potential interactions with the MSC.

As part of the Expert Groups Action Plan, ECHA introduced a draft presentation template for substance cases discussed in the ED EG. Several experts supported the initiative and provided some proposals for further improvement.

Substances discussed at the 19th ED EG meeting:

MS	EC#	Substance name	Outcome of the discussion	Session	Notes
DE	259-627-5	2-ethylhexyl trans-4-methoxycinnamate (OMC) and isopentyl p-methoxycinnamate (IPMC)	testing needed	closed	CoRAP 2016 ED ENV assessment
BE	201-250-5	4,4'-sulphonyldiphenol (bisphenol S)	HH: ED ENV: ED	open	CoRAP 2014 ED HH + ENV assessment