

3 December 2020

SUMMARY REPORT OF THE 18th ED EXPERT GROUP MEETING

The ED EG meeting took place on 17-18 November 2020 and it was the 2nd ED EG meeting hosted virtually by ECHA. Besides discussing generic issues such as pros and cons of AMA (amphibian metamorphosis assay) and LAGDA (larval amphibian growth and development assay) assays in ED assessment, ED related activities of the Commission, and recently funded EU research projects dealing with EDs under the Horizon 2020 program, the EG provided scientific advice on ED assessments of eight substances (see also the Table below).

The number of participants was the highest in the history of the ED EG, altogether 75 participants representing 16 Member States and EEA countries (AT, BE, CZ, DE, DK, EL, ES, FI, FR, IE, LT, NL, NO, PL, SE, SK), Switzerland, EFSA, European Commission and 6 accredited stakeholder organisations (CEFIC, CHEMTrust, ECETOC, EEB, Heal, HSI).

Main outcomes of the substance discussions

Closed session

- Tetraphenyl m-phenylene bis (phosphate) (RDP) (CoRAP 2020): Most ED EG members agreed that there is a potential ED HH concern that should be clarified with further data, but several experts expressed doubts that the repeated dose (28-day) toxicity study, as proposed by FR, would be the best way forward. While some experts suggested requesting an AMA, it was also discussed that ongoing activities in relation to the metabolites/impurities are relevant. It was agreed to follow-up the ED EG discussion with written comments to FR.
- Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkylchains from oligomerisation, covering any individual isomers and/or combinations thereof (PDDP) (SVHC intention): The ED EG had agreed in earlier meetings that there is sufficient evidence to conclude that the substances act as ED for HH. In this meeting, the group agreed that the reduced fertility in rodents linked to an estrogenic mode of action can be considered as population relevant thus supporting the ED ENV identification.

Open session

- 3-iodo-2-propynyl butylcarbamate (IPBC) (biocide): There was large support for the proposal by DK to request AMA and FSTRA (fish short term reproduction assay) to clarify the ED ENV properties. For ED HH, DK is refining the assessment after the discussion in the previous ED EG meeting and the subsequent written comments.
- (\pm)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one (4-MBC) (potential SVHC intention): While the ED EG provided a number of suggestions how to further refine the assessment, there was an agreement that 4-MBC is ED for HH acting via E and T modalities.
- Propyl 4-hydroxybenzoate (propylparaben) (CoRAP 2015 follow up): The ED EG agreed that the substance is ED for ENV acting via estrogen MoA. further refinement of the assessment is needed to clarify the concerns for ED HH.

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- Dicyclohexyl phthalate (DCHP) (CoRAP 2017 follow up): The substance is identified as ED HH and is under SEv for ED ENV. A FSDT (fish sexual development test) had been submitted as requested. However, the experts expressed concerns regarding the quality of the FSDT study because of water solubility issues in the test medium. All agreed the results are inconclusive. Suggestions from the experts are to further investigate the T modality and consider the potential population relevance of the ED HH properties using the available human health data.
- Copper (biocide): The experts from authorities supported the proposal by FR to request the LAGDA including measurements of vitellogenin and thyroid hormone levels. This was not supported by industry.
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Diethyl phthalate (REACH): The ED EG agreed that the available data do not allow a conclusion on the presence or absence of ED effects via EAS modalities. Whereas experts from authorities were of the opinion that carrying out a FSDT would be an appropriate way forward to clarify the ED concern, industry experts considered the substance of low priority for further testing.

General ED-related topics

The European Commission gave an update on their ED related activities. DG GROW reported on inclusion of ED hazard class in CLP/UNGHS, update of the REACH information requirements, update of Safety Data Sheets, update of data requirements under the BPR, ED assessment under the Cosmetics Regulation, and assessment of BPA in clothing by the Scientific Committee on Consumer Safety. DG ENV gave an overview of the EU Chemicals Strategy for Sustainability including strengthening the legislation on EDs.

DK gave an introduction to the ED related projects carried out under EURION cluster (European Cluster to Improve Identification of Endocrine Disruptors).

FR reported on the work carried out under SNPE-2 (The Second French National Strategy on Endocrine Disruptors) to define a method for prioritizing chemicals with suspected ED properties.

Following an introduction by DK the ED EG discussed pros and cons of AMA and LAGDA assays in the assessment of ED properties.

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 CCH or SEv.

Substances discussed at the 18th ED EG meeting:

MS	EC number	Substance name	Outcome of the discussion	Session	Notes
FR	260-830-6	Tetraphenyl m-phenylene bis (phosphate) (RDP)	HH: more data needed	closed	CoRAP 2020 ED HH assessment
DE	-	Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkylchains from oligomerisation,	HH: ED ENV: ED	closed	SVHC intention ED ENV+HH assessment

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		covering any individual isomers and/or combinations thereof (PDDP)			
DK	259-627-5	3-iodo-2-propynyl butylcarbamate (IPBC)	ENV: more data needed HH: refine assessment	open	Biocidal active substance ED ENV + HH assessment
DK	253-242-6	(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one (4-MBC)	HH: ED	open	Potential SVHC intention ED HH assessment
BE	202-307-7	Propyl 4-hydroxybenzoate (propylparaben)	ENV: ED HH: refine assessment	open	CoRAP 2015 ED ENV+HH assessment
SE	201-545-9	Dicyclohexyl phthalate (DCHP)	ENV: refine assessment	open	CoRAP 2017 ED ENV assessment
FR	231-159-6	Copper	ENV: more data needed	open	Biocidal active substance ED ENV assessment
EC HA	201-550-6	Diethyl phthalate (DEP)	ENV: more data needed	open	ED ENV assessment