

SUMMARY REPORT OF THE 15th ED EXPERT GROUP MEETING

The 15th meeting of the Endocrine Disruptor Expert Group (ED EG) was hosted by ECHA on 7 October 2019. The meeting was attended by 49 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, European Commission, EFSA, JRC and 2 accredited stakeholder organisations (Heal, CEFIC).

Besides generic ED related issues such as the French Second National Endocrine Disruptor Programme SNPE2 and a meta-analysis of the sources of data available for the impact assessment in the context of development of the scientific criteria for ED assessment of biocides and pesticides, the group discussed six substances in closed and open sessions (see also table below).

Main outcomes of the substance discussions

Closed session

- Resorcinol (CoRAP 2019): The ED EG agreed that more testing will be needed to clarify the ED concern for environment, and there was large support for requesting a LAGDA with thyroid hormone measurements included in the parameters to investigate. In open session Cefic presented their view that all ED related concerns had already been addressed in the previous SEv carried out by FI. Further, Cefic raised concerns regarding the feasibility of carrying out the LAGDA. The ED experts from regulatory bodies conceded that there might be some difficulties associated with testing the substance, however they did not consider these as insurmountable.
- Propargite (CoRAP 2019): The substance is used as a pesticide and produced but not authorised in the EU. Discussion was around difficulties in the interpretation of available data and whether these data would be sufficient to conclude. With regard to ED environmental assessment, experts were of the opinion that weight of evidence analysis of the existing data might be sufficient to enable ED identification but there was also a view that LAGDA may be required to demonstrate thyroid-mediated adversity. The HH part was not open for extensive discussion, the only question posed to the group was whether the pubertal assay is adequate to conclude on the ED properties of the substance. In view of experimental issues the results of the study in isolation were not considered adequate to conclude on the ED properties.
- Peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate and hydrogen peroxide (Biocide): The ED EG acknowledged that according to the ED Guidance the data set for ED assessment is not complete for assessment of this in situ generated biocidal active substance and its precursors/ reaction by-product. There was however agreement that the assessment could be focused on the reactive substances peracetic acid and hydrogen peroxide, and several members also supported the view of the evaluating authority that further testing doesn't seem scientifically justified. However the justification for waiving further testing should be refined.

Open session

- 4,4'-propane-2,2-diyldiphenol, polymer with 2-methyloxirane (CoRAP 2013): The thyroid-modality was seen by several experts as not yet fully clarified and further explanation would be beneficial. The evaluating authority will consider further clarification to improve the future SEv conclusion and report document. The deadline for requesting further data has passed for this SEv case.

- Phenol, styrenated (CoRAP 2014): The expert group unanimously agreed that the available information is sufficient to identify the substance as endocrine disruptor for the environment.
- Butyl 4-hydroxybenzoate: There was broad agreement by the experts from Member States that the information available seems to be sufficient to identify the substance as ED for human health. However, refinement of the mode of action analysis should be considered to strengthen documentation of the plausible link between observed endocrine activity and adverse effects.

General ED-related topics

France introduced their Second National Endocrine Disruptor Programme SNPE2. The initiatives in SNPE2 were appreciated by the group, but coordination among Member States, the Commission and the Agencies is necessary to avoid duplication of work and to ensure effective information and communication with stakeholders and the general public on the identification and regulation of endocrine disruptors. France is planning to discuss their Programme also in RiME+ and CARACAL.

The Greek Benaki Institute presented their meta-analysis on the results of the screening study, carried out under contract by DG Sante, in the context of an Impact Assessment on 4 optional sets of criteria for ED identification among biocides and pesticides. The analysis revealed that regulatory guideline studies had been the predominant source of data for adverse effects, but for endocrine mechanistic information it was open scientific literature. The EDEG members broadly supported the conclusion that further work on development and validation of assays providing mechanistic information for ED assessment is necessary.

The next ED EG meeting will take place on December 3, 2019. Tentative dates for the year 2020 are April 7-9, September 29-October 1 and November 17-19.

Substances discussed at the 15th ED EG meeting:

EC number	Substance Name	Outcome of the discussion	Submitted by	Remarks
-	Peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate and hydrogen peroxide	Refine the assessment	AT	Biocidal active substance
500-097-4	4,4'-propane-2,2-diylidiphenol, polymer with 2-methyloxirane (BPAPO)	Refine the assessment	DK	CoRAP 2013
202-318-7	Butyl 4-hydroxybenzoate	Refine the assessment / ED	DK	Potential SVHC
219-006-1	Propargite	Testing needed	NL	CoRAP 2019
262-975-0	Phenol, styrenated	ED	UK	CoRAP 2014
203-585-2	Resorcinol	Testing needed	FR	CoRAP 2019