SUMMARY REPORT OF THE 16th ED EXPERT GROUP MEETING

The 16th meeting of the Endocrine Disruptor Expert Group (ED EG) was hosted by ECHA on 3 December 2019. The meeting was attended by 56 participants representing 16 Member States and EEA countries (AT, BE, CZ, DE, DK, EL, ES, FI, FR, LT, NL, NO, PL, SE, SK, SI), Switzerland, EFSA, European Commission, 5 accredited stakeholder organisations (CHEM Trust, Heal, HSI, ECETOC, CEFIC) and OECD.

Besides generic ED related issues such as grouping approach in ED identification and use of the new XETA test in ED assessment, the group discussed six substances in closed and open sessions (see also table below).

Main outcomes of the substance discussions

Closed session

- 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol (CoRAP 2019): The ED EG agreed that more testing will be needed to clarify the ED concern for human health and environment. There was large support for requesting EOGRTS (with modifications to assess liver effects) and LAGDA, and some experts advised additionally to consider FSDT. The evaluating CA was advised also to consider read across from other cresols.

- 1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (tonalide) (CoRAP 2020): The ED EG agreed that there is a concern for ENV ED, and supported requesting FSDT and LAGDA. Slides on the available data regarding ED properties for HH were provided, but not discussed further. Data from EOGRTS requested under dossier evaluation are yet to come, and may yield supplementary information on potential progestagenic effects.

- Triclosan (CoRAP 2012): While there is an ongoing legal process concerning data requested under SEv, all experts nominated by the Member States supported proposing triclosan as SVHC based on the available data regarding the ED properties for HH and ENV, but other experts were of the opinion that the data may not be sufficient.

- 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (propiconazole) (Biocide): The substance had been in written consultation in the ED EG, and in follow-up discussion in the plenary all the experts agreed that an ED mode of action for aromatase inhibition leading to reproductive dysfunction in fish can be postulated and thus the ED criteria for non-target organisms are met. The ED EG agreed that there is also enough data for ED identification with regard to human health, except for one expert who proposed requesting further information.

Open session

- Alphacloralose (Biocide): The evaluating CA looked for the ED EG advice on the ED testing strategy proposed by the applicant in relation to a forthcoming renewal application of this biocidal active substance. The experts did not agree with the proposal, but instead advised the eCA to check if the substance dataset, analysed in the renewal application, is compliant with the biocides information requirements and to consider following on this basis the tiered approach of the ED Guidance for identification and filling in the data gaps.

- Resorcinol (potential SVHC proposal): While there is an ongoing SEv process to clarify the ED concerns for environment, all the experts nominated by the member states, except for one, agreed that based on the available data resorcinol poses serious effects to human health via endocrine disruption. The one member state

expert said that they cannot give their opinion, because they have not yet evaluated all data. The expert invited by Cefic announced that they would submit a written statement on the case.

General ED-related topics

EFSA presented a proposal on how the new XETA assay (OECD TG 248) could be integrated into the assessment of thyroid mediated endocrine disruption. It is critical to have a consistent approach on how to apply the assay under different regulations, and EFSA asked the experts to provide written comments.

The Commission reported on their ED related activities including assessment of EDs under the Cosmetics Regulation, and implementation of actions regarding the Communication on EDs. With respect to EDs in cosmetics, the SCCS (Scientific Committee on Consumer Safety) will carry out risk assessments for several prioritised substances in 2020. COM also informed that the processes for updating data requirements under both BPR and REACH are ongoing; they have launched an ED web portal; and a user survey on the EASIS database will be launched in December 2019.

ECHA provided an overview on the implementation in practice of the integrated regulatory strategy and how grouping of substances and identification of EDs under the common screening approach is carried out.

ECHA gave a presentation on the support provided by the EDEG to the regulatory processes and possibilities to improve this support. Discussion on this topic will continue.

Tentative ED EG meeting dates in 2020 are April 7 - 8, September 29 - October 1 and November 17 - 19.

Substances discussed at the 16th ED EG meeting:

EC number	Substance Name	Outcome of the discussion	Submitted by	Remarks
201-618-5	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	Testing needed	FR	CoRAP 2019
216-133-4, EC 244-240-6	1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (tonalide)	Testing needed	DE	CoRAP 2020
222-182-2	Triclosan	Diverging views: ED / Refine assessment	DK	CoRAP 2012
262-104-4	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (propiconazole)	ENV ED. HH diverging views: ED/more data needed	FI	Biocidal active substance

240-016-7	Alphachloralose	Refine assessment	PL	Biocidal active substance
203-585-2	Resorcinol	HH ED	FR	Potential SVHC