

SUMMARY REPORT OF THE 11th ED EXPERT GROUP MEETING

The 11th meeting of the Endocrine Disruptor Expert Group was hosted by ECHA on 18-19 April 2018.

54 participants attended the meeting representing 15 Member States and EEA countries (AT, BE, DE, EL, FI, FR, IE, LT, NL, NO, PL, RO, SE, SK, UK), the European Commission (DG SANTE, DG JRC), Switzerland, EFSA, OECD and 5 accredited stakeholder organisations (Heal, CHEM Trust, Humane Society International, Ecetoc, Cefic). The number of attendees also includes scientific advisors invited by the ED EG members from industry or Member States.

The group discussed five substance cases, three of them on the CoRAP 2018 and two of them biocidal active substances (see table). This was the first time biocidal active substances were discussed in the ED EG meeting. In general, the substance discussions focused on the interpretation of available data and identification of potential needs for the generation of further information.

ECHA brought an MSC request for advice to the EDEG in relation to the questions

- (i) which kind of evidence should trigger requesting a fish sexual development test (FSDT, OECD TG 234) instead of a fish early life stage test (FELS, OECD TG 210) in the dossier evaluation process, and
- (ii) how to determine the appropriate concentration range, rendering the FSMT suitable for both investigation of the ED concern (as well as other apical endpoints) and risk assessment (i.e. determination of NOEC/EC10). The experts were asked to provide their views in writing by May 31.

ECHA gave a status report on ED guidance development. The public consultation on the guidance yielded over 2000 comments, which have been considered by the joint ECHA/EFSA/JRC drafting team for revision. The ECHA Biocidal Products Committee and the EFSA Scientific Bodies (Scientific Committee, Pesticides Peer Review Panel, Pesticides Steering Network) are currently consulted on the revised guidance, which will be followed by a final consultation of the MSCAs for biocides and PPPs. Endorsement and publication of the final ED guidance are foreseen by June 7, the date by which the ED criteria for biocides become applicable. The presentation triggered some discussion on potential intentions to apply the guidance also in the REACH context.

Both ECHA and DG SANTE gave presentations on the envisaged process for ED assessment of biocides and the role of the ED EG in this process. A substantial increase in the workload is anticipated for both the ED EG and the evaluating CAs.

In addition, OECD provided an overview on their ongoing and upcoming ED related activities (new and revised guidance documents and test guidelines) and ECHA on their learnings from court and Board of Appeal cases on EDs identified as SVHCs or being under substance evaluation.

| MS | EC# | Substance name | Notes |
|----|------------------|---|------------|
| DE | 258-904-8 | 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione | CoRAP 2018 |
| DE | 262-872-0 | 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt | CoRAP 2018 |
| DE | 310-154-3 | Phenol, dodecyl-, branched | CoRAP 2018 |
| SE | CAS# 130328-20-0 | Silver zinc zeolite | Biocide |
| SE | 422-570-3 | Silver sodium zirconium hydrogenphosphate | Biocide |