25th Meeting of Competent Authorities for REACH and CLP

15-16 November 2017

Concerns: Guidance document for identification of endocrine disruptors - status update on the drafting process

Agenda Point: Information Point 5

Action requested: For information
**Guidance document for identification of endocrine disruptors  
- status update on the drafting process**

The development of a Guidance document for the implementation of the criteria to identify endocrine disruptors (EDs) in the context of Regulations (EC) No 1107/2009 and (EU) No 528/2012 commenced in January 2017. After a first commenting round in April/May this year, the so-called ad-hoc ECHA-EFSA ED Consultation Group consisting of members of ECHA’s Endocrine Disruptor Expert Group and experts selected by EFSA was consulted a second time from mid-July to end of August on a revised and extended version of the draft guidance. The experts convened in the Consultation Group represent MSCAs for plant protection products (PPPs), biocidal products (BPs) and REACH as well as industry and public interest stakeholder organisations. They provided more than 1800 comments during the second consultation. The EFSA/ECHA drafting team with support by the JRC is currently considering these comments and preparing a revised version of the guidance for public consultation.

It is planned to submit the draft guidance for public consultation in the beginning of December. This is necessary to ensure that Guidance on identification of EDs is available by the time the ED criteria for BPs become applicable, which will presumably be in late spring 2018.

Public consultation will be open for 8 weeks. Thereafter a further revision of the draft Guidance, taking account of the comments received, is foreseen. This step will be followed by a final consultation of the competent ECHA scientific body (Biocidal Products Committee) and formal endorsement of the final Guidance document. The process for endorsement of the guidance regarding its applicability to PPPs will be clarified at a later stage, once a new draft Commission Regulation setting ED criteria for PPPs will be tabled by the European Commission.

The draft version for public consultation will provide an ED hazard assessment strategy for adverse effects potentially elicited by EATS 1 modalities in vertebrates (for both human health and non-target organisms). Further, it will give guidance on how to assess and follow-up indications of potential EATS-related adversity and endocrine activity but will also indicate which kind and level of information could be considered sufficient to allow a conclusion that the ED criteria are not met.

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1 EATS = estrogen, androgen, thyroid and steroidogenic