Outline of Draft Guidance Document for the Implementation of the Hazard-based Criteria to Identify Endocrine Disruptors

Update on time planning for finalisation and endorsement of the Guidance document

17 January 2018

European Food Safety Authority

European Chemicals Agency

Acknowledgements: EFSA and ECHA wish to thank the Joint Research Centre for the support and preparatory work for this outline to the Guidance Document for the Implementation of the Hazard-based Criteria to Identify Endocrine Disruptors.

Update on the procedure for finalisation and endorsement of the ED Guidance after public consultation

a. Public consultation.
The draft Guidance is subject to public consultation from 7 December 2017 to 31 January 2018. To this end, the draft Guidance is available on ECHA's website (https://comments.echa.europa.eu/comments_cms/PC_ED_Guidance.aspx).
Comments may be submitted using a webform that is available at the given link.

b. Workshop with MS ED risk assessors and stakeholders.
A workshop with MS experts in evaluating endocrine disruption in the regulatory context and with stakeholders will be organised by the European Commission in collaboration with EFSA and ECHA for assessing the applicability of the Guidance. The workshop will be held on 1/2 February 2018 in Brussels. The outcome of the workshop will be published in the form of a summary report.

c. Follow-up of the public consultation.
The drafting group will consider the comments from the public consultation and the feedback received from the workshop with MS ED assessors and stakeholders (see points a. and b. above) and will revise the draft Guidance as necessary.

d. Final consultation on ED guidance with risk assessors and risk managers of the Member States.
Before the finalisation of the ED Guidance by the drafting group there will be a final consultation of the relevant scientific risk assessment bodies (i.e. the ECHA Biocidal Products Committee, the EFSA Scientific Committee and PPR Panel, and the EFSA Pesticides Steering Network) and of the risk management bodies (the representatives of Member States Competent Authorities for the implementation of Regulation (EU) no 528/2012 and the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals - Plant Protection Products – Legislation). Comments received will be considered by the drafting team Agencies in the finalisation of the Guidance document.

e. Endorsement as technical Guidance.
The drafting group will submit the final Guidance document to EFSA and ECHA for approval. Thereafter, the document will be published as joint EFSA & ECHA guidance in the EFSA Scientific Journal and EFSA will inform DG SANTE that the guidance is ready for endorsement under Regulation (EC) 1107/2009 by the European Commission.

f. Publications.
The following documents will be prepared and published:
- Final Guidance document for ED identification.
- Report on the Public Consultation, containing the received comments and the ways the comments have been addressed during the finalization of the Guidance Document.
- Summary report on the workshop with MS risk assessors and stakeholders.
- Report summarising the consultation with the Consultation Group.

Updated time plan (part public consultation until publication of final guidance)

Year	2017				2018																										
Month	December				January					February				March				April				May					June				
Week	49	50	51	52	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
(07/12-31/01) Public consultation on draft guidance																														
(01-02/02) Workshop with MSCAs and stakeholders on the applicability of the draft guidance for ED identification																														
(05/02-13/04)* Evaluation of comments received in public consultation and revision of the guidance																														
(16-27/04) Consultation with risk assessors (competent EFSA & ECHA scientific bodies such as ECHA BPC; EFSA SC, PPR Panel and PSN)																														
(30/04-11/05) Consideration of final comments from risk assessors and update of ED guidance																														
(14-25/05) Consultation with risk managers (the representatives of Member States Competent Authorities for the implementation of Regulation (EU) no 528/2012 and the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals - Plant Protection Products – Legislation)																														
(28/05 – 01/06) Consideration of final comments of risk managers and finalisation of ED guidance																														
(04 - 07/06) Final endorsement by ECHA and publication of ED guidance (as joint EFSA & ECHA guidance in the EFSA Scientific Journal). *(ED-criteria for Biocides become applicable as of 7 June 2018)*																														