



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E4/KN/np (2016) 6384691

Dear Mr Url, dear Mr Dancet,

Dear Bernhard and Geert,

Subject: Request to EFSA and ECHA for scientific and technical assistance in order to develop a common Guidance Document for the implementation of the hazard based criteria to identify endocrine disruptors

I refer to the letters from 15 June 2016, where we asked EFSA and ECHA to get prepared for the new tasks associated with the foreseen adoption of new criteria to identify endocrine disruptors under Regulations (EC) No 1107/2009 and (EU) No 528/2012. The draft legal acts^{1 2} setting these new criteria were published on the same day. Some bi- and tri-lateral technical discussions between our services were held during the last months as a follow up of these letters.

These draft acts propose hazard identification criteria which are based on the WHO definition and are identical for plant protection products and biocidal products. In addition, they specify principles regarding how the identification of an endocrine disruptor should be carried out: for example, using all available scientific evidence and applying a weight of evidence approach. The draft criteria maintain the high level of protection of human health and the environment set in the plant protection products and biocidal products legislations.

Once the criteria are adopted and enter into force, similar implementation procedures are crucial for a harmonised approach. Thus, it is important that a guidance document is available ensuring for an immediate, consistent and transparent implementation of the new criteria by the Agencies and competent authorities.

¹ http://ec.europa.eu/health/endocrine_disruptors/docs/2016_pppcriteria_en.pdf

² http://ec.europa.eu/health/endocrine_disruptors/docs/2016_bpccriteria_en.pdf

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The draft legal acts setting the criteria to identify endocrine disruptors are now following the foreseen procedures for their adoption. Discussions with Member States and experts are on-going. The need for a guidance document for the implementation of the criteria has been raised as an important point by several Member States, as well as the need for a harmonised approach in the different sectors (horizontality), i.e. the plant protection and biocidal products legislation. In addition, a guidance document needs to be available when the new criteria are adopted and enter into force because they are intended to be applied with no transitional periods for the approval/ renewal of active substances and the authorisation related to plant protection and biocidal products.

I would like to ask both Agencies to provide scientific and technical assistance to the Commission in order to issue a common guidance document for the implementation of the proposed scientific criteria concerning the hazard identification of endocrine disruptors in the context of Regulations (EC) No 1107/2009 and (EU) No 528/2012. This technical and scientific assistance is foreseen under Article 31 of Regulation (EC) No 178/2002 (for EFSA) and Article 76 (1) (d) of Regulation (EU) No 528/2012 (for ECHA). The scope of this request is limited to a guidance document on scientific hazard identification and does not cover other potential requests on issues potentially related to the assessment of substances identified as endocrine disruptors.

Due to the urgent need of this guidance document and the political sensitivity of the file, I would also like to ask you to give the highest priority to the development of this common guidance document. In particular, I would appreciate to have an outline of the guidance document ready by the end of December 2016. This outline should include a detailed plan of the drafting process, including timelines, responsibilities, as well as the foreseen consultations of all relevant parties. Moreover, it should detail how the respective endorsement procedures of the guidance by EFSA and ECHA are going to be co-ordinated and/or aligned.

According to preliminary discussions between the Commission and both agencies³, the drafting of the guidance document is expected to take 4 to 6 months (a 1st draft could be available between April and June 2017 at the earliest). The draft of the guidance document should undergo a consultation of Member States and stakeholders the moment the criteria are published⁴. I would appreciate if you would do the utmost to accelerate the issuance process of the guidance document, so that that the gap between publication of the criteria and initiation of the public consultation and availability of the final guidance is reduced to a minimum.

With this tight and ambitious timing, making best use of already existing experience, including consideration of available relevant documents/guidance and already developed tools in the context of endocrine disruptors and the associated impact assessment, seems to me relevant.

³ Meeting between the Commission, EFSA and ECHA on 4th October 2016.

⁴ Publication of the criteria can be done after their adoption and the conclusion of the scrutiny period of the European Parliament and the Council (3 months for Regulation (EC) No. 1107/2009 and 2 + 2 months for Regulation (EU) No. 528/2012). This time period is expected to allow ECHA and EFSA to align the draft guidance document to the agreed version of the criteria to identify endocrine disruptors.

In particular, a close collaboration with the Joint Research Centre, who was responsible during the last years for some of the preparatory work for the draft criteria including the screening methodology^{5 6 7}, is considered important and will contribute to the swift development of the guidance document.

I count on the co-operation of your agencies for delivering this important document in a timely manner, in order to support the implementation and application of the new criteria with no delays.

Yours sincerely,

Xavier Prats Monné

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⁵ Munn S., Goumenou M-P., Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disrupters Expert Advisory Group (ED EAG). JRC-IHCP 2013. [29 pp.]DOI: 10.2788/8659 (online).

⁶ Munn S., Goumenou M-P., Thresholds for Endocrine Disrupters and Related Uncertainties Report of the Endocrine Disrupters Expert Advisory Group (ED EAG). JRC-IHCP 2013. [19 pp.]DOI: 10.2788/8659 (online).

⁷ JRC, 2016. Screening methodology to identify potential endocrine disruptors according to different options in the context of an impact assessment. ISBN 978-92-79-58906-5, ISSN 1831-9424, doi:10.2788/73203