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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E4/LF/od(2017)6351886

Dear Dr Url, Dear Mr Dancet, Dear Bernhard and Geert,

Subject: **Addendum to "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 (Ares(2016)5971523 – 17/10/2016)"**

On 17 October 2016 - with a view to ensure a harmonised implementation of the criteria to identify endocrine disruptors for biocides and plant protection products once they become applicable - DG SANTE sent a mandate to EFSA and ECHA with a request 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 (Ares(2016)5971523 – 17/10/2016).

EFSA and ECHA have accepted the mandate (Ares(2016)6834758-07/12/2016, D(2016)3874 GD/EK/HK). They have been working intensely on the development of the common guidance, which is now at an advanced stage. The draft guidance is now ready to be published for public consultation which you intend to start in December 2017.

The decision-making for the criteria to identify endocrine disruptors in the context of Regulation (EU) No 528/2012 on Biocidal Products has been completed. Commission Delegated Regulation (EU) 2017/2100[1] setting out the criteria to identify endocrine disruptors was published in the Official Journal on 17 November 2017, will enter into force in December 2017 and will be applicable from June 2018. For an appropriate implementation of the criteria it is important that the technical guidance will be available at the moment these criteria will be applicable.

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[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (Text with EEA relevance. *OJ L 301, 17.11.2017, p. 1–5.*

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The draft Regulation setting out criteria to identify endocrine disruptors in the context of Regulation (EC) No 1107/2009 on Plant Protection Products – equivalent in content to the criteria set in the context of Regulation (EU) No 528/2012 - was objected by the European Parliament on 4 October 2017 based on legal grounds related to the last paragraph which contained a special provision related to substances with an intended endocrine mode of action against target organisms. Therefore, the draft Regulation cannot be adopted.

The Commission maintains the view that the scientific criteria for plant protection products should not differ substantially from those adopted for biocides and thus, will submit a new draft Regulation to the competent Regulatory Committee that will be identical to the one that got support by qualified majority on 4 July 2017, except for the particular provision to which the European Parliament objected.

Thus, despite the still on-going decision making process as regards the criteria for plant protection products and considering the aim to maintain an harmonised approach for the criteria to identify endocrine disruptors in both the biocidal and plant protection product sectors, the guidance developed by ECHA and EFSA should remain a common one and should be ready to allow timely implementation of the criteria for biocides in June 2018. It is therefore necessary that both Agencies give the highest priority to the development of this common guidance.

Should there be any regulatory developments as regards the criteria to identify endocrine disruptors in the context of Regulation (EC) No 1107/2009 that lead to divergence from the criteria adopted for substances used in Biocidal Products, the Commission will consider how to address these after the public consultation on the draft guidance document and before its finalisation.

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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