EUROPEAN COMMISSION

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Mr Pietro GRASSO
President of the
Senato della Repubblica
Piazza Madama
IT-00186 ROMA

Dear President,

The Commission would like to thank the Senato della Repubblica for its Opinion concerning a Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for the determination of endocrine disrupting properties in the context of the EU legislation on plant protection products and biocidal products {COM(2016) 350 final}.

Following analysis of the comments received through various channels during the second half of 2016, the Commission put forward first in November and then in December 2016 two successive revised drafts for the criteria. Both these two revised drafts were published on the Commission's website in order to ensure maximum transparency.[1]

With respect to the first revision on which the Senato della Repubblica submitted its Opinion, the Commission has improved the drafting of the criteria in order to clarify the text to address concerns shown by Member States and other parties.

In particular, to address the concern that the criteria proposed by the Commission only considered substances 'known' and not substances 'presumed' to cause adverse effects in humans and were asking for a too high burden of proof, it is now indicated upfront that the identification of an endocrine disruptor can be based on animal studies and that there is no need to demonstrate evidence of adverse effects in humans.

The term "presumed" used in Regulation (EC) No 1272/2008 on classification, labelling and packaging[2] *is not included in the Commission proposal on the criteria to identify endocrine disruptors, because it is not part of the 2002 WHO definition of an endocrine*

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1 European Commission's thematic website on endocrine disruptors: http://ec.europa.eu/health/endocrine_disruptors/next_steps/index_en.htm.

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008on classification, labelling and packaging of substances and mixtures (OJ L353, 31.12.2008, p. 1).

disruptor[3]*, definition to which nearly all Member States, scientists and stakeholders ask the Commission to stick to as much as possible.*

It is also clarified in the revised criteria that there is no hierarchy in the type of scientific evidence that can be used in the identification of endocrine disruptors. The proposed criteria clarify that the information shall be gathered and analysed in a weight of evidence approach using all available in vivo and in vitro animal data, including studies submitted for an application of approval and those available in the public literature, plus human data whenever they are available. Moreover, data from animal studies are assumed to be relevant for humans unless proven otherwise. Finally, the revised criteria reintroduce the wording "may cause adverse effects". As indicated in the draft criteria, the biological plausibility of the link between the adverse effects and the endocrine mode of action will be considered.

The general approach followed by the Commission in the draft criteria presented in June 2016 is unchanged.

The revised drafts do not include potency as the Commission was asked to set criteria for the hazard identification of endocrine disruptors and potency is not an element that should be considered at the hazard identification stage.

No categories are foreseen as the Commission believes that it has no power to define the category "suspected endocrine disruptors" (endocrine disruptors category 2) in Regulation (EC) No 1107/2009 on plant protection products[4] *and in Regulation (EU) No 528/2012 on biocidal products*[5]*. No regulatory consequences are foreseen for this category under these two Regulations. Therefore, defining this category would bring legal uncertainty, because different Member States and stakeholders could interpret differently the regulatory consequences for this category. It could neither be envisaged that the Commission decides the regulatory consequences for this category because this would be beyond its legal powers. It should be noted that the exclusion criteria foreseen under the Regulations mentioned above are not applicable to substances classified as "suspected carcinogens", "suspected mutagens" or "suspected toxic for reproduction" (carcinogenic, mutagenic, toxic for reproduction ('CMR') category 2). It would therefore not be appropriate to apply the exclusion criteria to "suspected endocrine disruptors" when these criteria are not applicable to "suspected CMR".*

In the revised draft on Plant Protection Products, the original text has been split into two separate parts: one text containing the criteria and a second containing the technical amendment to the clause on negligible exposure. This offers Member States, and later on the European Parliament and the Council, the possibility to express their opinion on

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3 World Health Organisation International Program on Chemical Safety, Global assessment of the state-of-the-science of endocrine disruptors, 2002, WHO/PCS/EDC/02.2.

4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

5 Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

each draft separately. It is important to highlight that if the amendment to the clause on negligible exposure is adopted, the approval criteria on endocrine disruptors remain mainly hazard based like for carcinogens and substances toxic for reproduction, i.e. substances identified as such will not be approved unless clauses foreseen by the legislation apply. The Commission is aware that some Members of the European Parliament may believe that the Commission is exceeding its powers with the proposed amendments to Annex II to Regulation (EC) No 1107/2009 and they refer to the opinion of the Parliament's Legal Service. The Commission has already indicated that it has a different legal interpretation and published its views in the response to a letter from the chair of the Committee on Environment, Public Health and Food Safety, Mr Giovanni La Via[6].

The revised texts maintain the high level of protection of human health and the environment set in the plant protection and biocidal products Regulations.

The Commission hopes that these clarifications address the issues raised by the Senato della Repubblica and looks forward to continuing our political dialogue in the future.

Yours faithfully,

Frans Timmermans
First Vice-President

Vytenis Andriukaitis
Member of the Commission

6 http://ec.europa.eu/health/endocrine_disruptors/docs/andriukaitis_lavia_en.pdf.