European Commission

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Mr Paul Whaley
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Dear Mr Whaley,

I would like to thank you for the open letter of scientists, dated 16 November 2016, and for your interest in the issue of endocrine disruptors.

Following a thorough analysis of the comments received through various channels over the summer the Commission recently put forward revised drafts for the criteria to identify endocrine disruptors. These revised drafts were published on the Commission's website in order to ensure maximum transparency[1]. In your letter you referred to these revised drafts. I would like to emphasise that the Commission has made all possible efforts to improve the drafting of the criteria in order to clarify the text to address the concerns raised by various parties.

In particular, to address the concern that the criteria proposed by the Commission only considered the "known effects" of endocrine disruptors in humans and not the "presumed effects" and that they were asking for an excessively 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. Furthermore, the word "primarily" has been removed to clarify that there is no ranking for the evidence to be assessed.

[1] http://ec.europa.eu/health/endocrine_disruptors/next_steps/index_en.htm

I note your preference for having a category-based approach. The general approach followed by the Commission in the draft criteria presented in June 2016 has not changed and therefore the revised drafts do not include categories. This point was discussed in detail in the meetings with experts and Member States. For more information regarding the reason for not having categories, please see the minutes of those meetings which have been published on the Commission`s website[1].

You suggest that best practices should be followed in evidence gathering, appraisal and integration. Under the proposed revised criteria, information must be gathered and analysed using a weight-of-evidence approach and according to systematic review methods. I would like to point out that the weight-of-evidence approach is not a new concept as it is included in the EU legislation for biocidal products and for plant protection products.

Concerning your comments on the proposed change to the concept of "negligible risk from exposure", as outlined in the amendment to the Plant Protection Products derogation, please see my letter of reply to MEP La Via which has also been published on the Commission's website[1]. I would like to underline that the amendment has not changed the general approach on the approval of active substances, as any substance identified as an endocrine disruptor will continue to be banned unless the conditions for an exception are met.

I would like to emphasise that the Commission highly appreciates your comments and your suggested rewording of certain parts of the revised drafts. It is important for the Commission to be fully aware of all relevant comments, views and opinions as this will allow us to take an informed decision.

Let me conclude by saying that as the Commissioner for Health, I am fully committed to ensuring a high level of protection for human health and the environment and that this commitment has guided me in my decision on the revised criteria that have been put forward.

Yours sincerely,