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Criteria for Endocrine Disruptors

Dear Commissioner

Thank you for your letter of 22 June 2016, addressing the issue of the criteria for Endocrine Disruptors. We recognise that in drafting the proposal you and your services will have had a difficult task in trying to balance the needs of many different constituencies and interest groups.

Unfortunately, however, from the point of view of the crop protection industry that balance has not been struck, and we consider the current proposal to be unacceptable as it is currently drafted. The proposal fails to take into account all available and relevant scientific information (including, in particular, potency) when evaluating a substance for its potential endocrine-disrupting properties; the proposal is based almost solely on the WHO/IPCS definition which by itself does not constitute criteria suitable to support regulatory decision making.

We highlight the conclusion of the Commission's Impact Assessment, that all options under consideration offer the same high level of protection for human health and the environment and **we support the strong focus on health and environmental protection**. We are however particularly **disappointed that the option put forward by the Commission** is assessed as having the **greatest impact on the availability of products for farmers¹, and the most severe and negative impact on sectorial competitiveness, agriculture and trade**. Furthermore, the impact assessment highlights the potential risk of resistance development in pests. The loss of some critical chemical classes due to these strict criteria would have many unintended and potentially dangerous consequences for food safety. The Commission has chosen a path that ignores its own impact assessment and is, by your own admission, not based on an assessment of the significant socio-economic impact that the proposal will have; and not only that, **it fails to follow the Commission's own political commitment to better regulation and the principle of proportionality**.

It is our firm view that endocrine disruptors can and must be regulated like most other substances of potential concern and be subject to risk assessment which considers

¹ While more substances are impacted by option 1, page 295 of the IA concludes that more commercial products would be impacted by the application of option 2.

both hazard and exposure. This is the conclusion of the EFSA Scientific Committee², and the Scientific Committee on Consumer Safety (SCCS)³.

The proposal fails to distinguish between substances of real concern from those posing little or no concern. Many substances, that present little or no risk to human health or the environment will be “identified” and labelled as endocrine disruptors by using the WHO/ICPS definition alone. We strongly believe that for the purposes of regulatory decision making regulators must be provided with the necessary tools to separate out those substances that pose a real concern, from those that don't.

The criteria must incorporate all elements of hazard characterisation, including potency, severity and lead toxicity. The strength of a substance (its **potency**) is a key determinant as to whether a substance will actually cause adverse effects and lead to harm. Hazard characterisation is an essential second step in the overall hazard assessment of a substance. Therefore consideration of these elements within the criteria to determine *endocrine disrupting properties* as described with Reg 1107/2009 is also essential.

The Commission has proposed certain derogations for substances triggering the hazard based approval criteria, by considering some elements of risk and exposure. Relying entirely on **regulation by derogation signals a fundamental flaw in the basic regulation.** Our first priority is to have in place the right criteria. The Commission's proposed approach fails to provide a predictable regulatory framework and increases uncertainty for product development and stifles innovation.

In conclusion, I would strongly urge the Commission to make significant amendments to the proposal to reflect our concerns. **The Commission must adopt workable, proportionate and science based criteria for endocrine disrupting properties which ensure regulators have the necessary tools to make informed regulatory decisions and maintain the existing high levels of protection for human health and the environment,** while ensuring European farmers have access to essential crop protection products. We acknowledge that there is public concern about crop protection products, however, rigorous and robust scientific testing ensure that products on the market meet the highest standards of safety, and that the food that arrives on the tables of Europe's 500 million consumers, is safe. We recognise there will be mounting pressure from some quarters to base a final decision on politics and emotion; we trust you will ensure that a final decision is indeed based on science.

Your sincerely



Jean-Charles Bocquet
Director General

² “Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment”, EFSA Journal 2013;11(3):3132, doi: 10.2903/j.efsa.2013.3132.

³ Scientific Committee on Consumer Safety (SCCS) Memorandum on Endocrine Disruptors. Retrieved from: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_009.pdf.