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Members of SCOPAFF-phytopharmaceuticals

Criteria for endocrine disrupting properties, SCOPAFF meeting 18 November 2016

Dear Dr Flüh
Dear SCOPAFF members

Ahead of the SCOPAFF-Phytopharmaceuticals meeting on 18 November 2016 focussed on the Commission's proposal for the criteria for endocrine disrupting properties, ECPA would like to take this opportunity to provide our input on this important issue.

Absence of hazard characterisation and risk assessment
As per our previous letter of 30 September 2016, we would again underline the serious concerns we have with the Commission's proposal. Many substances, which present little or no concern to human health or the environment will be unnecessarily "identified" as endocrine disruptors by using the WHO/IPCS definition alone (option 2). For decision making under Regulation 1107/2009, regulators should be provided with the necessary tools to clearly separate out those substances which have the real potential to cause harm, from those that do not. To do this, we believe that the criteria should be based on option 4, and should incorporate all the elements of hazard characterisation, to allow full consideration of potency, irreversibility, severity and lead toxicity.

Hazard characterisation is a routine and essential second step in the assessment of the hazardous potential of any substance and can be built into the criteria for endocrine disrupting properties.

It remains our firm view that endocrine disruptors can and should be regulated like other substances of potential concern and be subject to risk assessment considering both hazard and exposure. A departure from this framework sets a precedent for regulation that neglects the consideration of all information potentially available to ensure the protection of human health and the environment.

Severe negative impact on agriculture, competitiveness and trade
We would highlight the conclusion of the Commission's Impact Assessment, that all policy options put forward in the roadmap document of June 2014 were evaluated as offering the same high level of protection for human health and the environment. However, the option proposed (option 2) is assessed as having the greatest negative impact on the availability of products for farmers, and the most severe and negative impact on sectorial competitiveness, agriculture and trade. We therefore question why this option has been selected which appears to contract Recital 8 of Regulation 1107/2009.

WHO/IPCS definition - adverse effect: certainty required not presumption
We are aware that some SCOPAFF members are requesting the word "presumed" (to cause an adverse effect) to be included as part of the application of the WHO/IPCS definition. In

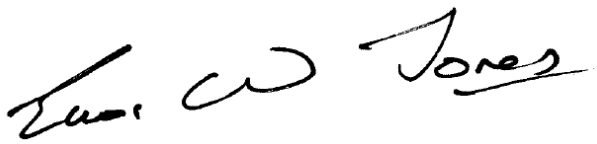
our view this request is confusing the requirement for an adverse effect (i.e. in laboratory animal studies) with the relevance of that adverse effect to humans. The WHO/IPCS definition is clear in that a substance **must** cause an adverse effect (i.e. "*An endocrine disruptor is an exogenous substance or mixture that …. **causes adverse health effects** in an intact organism, or its progeny, or (sub) populations*). In the current Commission proposal, the issue of whether an adverse effect is then considered relevant to humans is rightly managed as a second step; where the proposal reflects normal regulatory procedure in that adverse effects observed in laboratory animal studies are by default considered relevant for humans unless good quality data is provided to demonstrate otherwise.

Therefore, we do not believe that the word *"presumed"* should be included in the Commission proposal. The criteria for endocrine disrupting properties should reflect the certainty required by the WHO/IPCS definition in the need for adverse effects to be clearly observed and not presumed.

Workable, proportionate and science based criteria

We strongly urge the Commission together with Member States to amend the proposal to take into account our concerns above. We believe that the Commission should adopt workable, proportionate and science based criteria which ensure that regulators have the necessary tools to make informed decisions and which maintain the existing high levels of protection for human health and the environment, while also ensuring that European farmers have access to essential crop protection products.

Your sincerely



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