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European
Crop Protection

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Mr Martin Seychell
Deputy Director General
DG SANCO
European Commission
1049 Brussels
Belgium

Telephone : [redacted]
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Dear Mr Seychell

Further to our meeting on 4th March, I would like to take this opportunity to underline our concerns with the current proposal to identify endocrine disrupting substances (EDs) under development by DG Environment, and to highlight some key issues for our sector in the forthcoming discussions.

Any criteria to identify EDs must be based on reliable scientific methodology to ensure that risks are proportionately addressed to ensure measurable benefits for the protection of public health and the environment. There are no indications that the EU approach, which threatens to bias theoretical rather than proven risks, will benefit human health or the environment, rather it will weaken innovation in crop protection, decrease the competiveness of European farmers and food producing industry, and adversely impact international trade. A detailed impact analysis for the crop protection sector has already been shared with the European Commission and is attached for your convenience.

The European Crop Protection Association (ECPA) welcomes the European Food Safety Authority's (EFSA) opinion on EDs published in March 2013. Incorporating the scientific recommendations of EFSA will be a critical task for the European Commission in the further process of setting general ED criteria ahead of the forthcoming inter-service consultation.

As the European crop protection industry, we highlight several key elements from EFSA's scientific opinion which need further recognition in the work of DG Environment:

- reference to the WHO definition of EDs. The full meaning of this definition needs to be applied correctly, which is not currently the case (e.g. in the absence of an adverse effect a substance clearly should not be regarded as an ED);
- risk assessment taking into account hazard and exposure data makes best use of the available data and is a suitable approach for regulating EDs; and
- hazard characterisation is an essential part of hazard assessment and should be based on critical effect, severity, irreversibility of the effect and the potency of a substance. These elements should be used for hazard assessment as they inform about the intrinsic level of concern associated with an endocrine active substance.

It is also worth noting that the European Parliament's recent own initiative report supported these important elements highlighted in the EFSA report.

Under the European regulatory framework for plant protection products, assessing a substance's possible endocrine disrupting properties is undertaken via hazard assessment, thus detailed risk assessment approaches are excluded from product assessment. To avoid

the unnecessary banning of intrinsically safe substances, elements of hazard characterisation must be part of the overall hazard assessment of EDs. As more data on hazard identification and hazard characterisation are available for pesticides than for most other classes of chemicals, it is possible to fully identify and characterise the hazard from EDs for pesticides. It is fundamentally important that the full account of robust, scientific evidence is considered in a weight-of-evidence approach, as proposed by EFSA when identifying and regulating EDs.

Therefore, the DG Environment proposal should be revised to fully reflect core elements of hazard characterization according to EFSA's scientific opinion, to ensure the ED criteria can uphold human and environmental safety while also preserving food security and the competiveness of the food value chain.

We remain available to discuss the above with you or your staff at your convenience.

Yours sincerely

Cc:

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