European Crop Protection

ECPA key messages on European Commission proposal for criteria for *endocrine disrupting properties* under Regulation 1107/2009

Background
Under the plant protection regulation (Reg 1107/2009) and biocidal products regulation (Reg 528/2012), substances considered to have "*endocrine disrupting properties"* will not be approved. The European Commission was required to develop by 14 December 2013 scientific criteria for the determination of these properties. In June 2014 the Commission published a roadmap document[1] with several policy options for the criteria. The Commission also initiated an impact assessment to evaluate the possible impacts of the different options put forward.

On 15 June 2016 the Commission published its final proposal for the criteria. Its impact assessment and overall Commission communication, all are available at the link below:
http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm

Included below are ECPA's key messages on the Commission proposal and impact assessment.

Key messages on Commission proposal for criteria for *endocrine disrupting properties*

- ECPA consider the current Commission proposal to be unacceptable as it is currently drafted. The proposal fails to allow all available and relevant scientific evidence, including potency, to be taken into account when evaluating a substance for its potential endocrine-disrupting properties.
- The proposal for the criteria is based almost solely on the WHO/IPCS definition which by itself does not constitute criteria suitable to support regulatory decision making. Many substances, both natural (e.g. caffeine, phytoestrogens) and synthetic, which present little or no risk to human health and the environment will be "identified" and labelled as endocrine disruptors by using the WHO/IPCS definition alone.
- We maintain that all elements of hazard characterisation, including potency, severity and lead toxicity, must be built into the criteria. Hazard characterisation is an essential step in the overall hazard assessment of a substance. These elements are essential to ensure that regulators have the necessary tools to clearly distinguish between those substances which pose a real danger to human health and the environment and those that do not.
- The Commission must adopt workable, proportionate and science based criteria for *endocrine disrupting properties* which maintain the existing high levels of protection for human health and the environment, while ensuring European farmers have access to essential crop protection products.
- 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 both hazard

[1] http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf

and exposure. This is the conclusion of the EFSA Scientific Committee[2], and the Scientific Committee on Consumer Safety (SCCS)[3].

- The Commission's Impact Assessment, concludes that all options under consideration offer the same high level of protection for human health and the environment. However, Option 2 and 3 are assessed as having the highest impact on sectorial competitiveness, agriculture and trade. We therefore fail to understand why the Commission has proposed Option 2, which fails to follow the Commission's own political commitment to better regulation and the principle of proportionality.
- In our view, this proposal will fail to meet the EU commitments with WTO, established under the SPS Agreement, which commits WTO members to ensure that their sanitary or phytosanitary measures are based on "risk assessment techniques" and are not more trade-restrictive than required to achieve the appropriate level of protection.[4]
- 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. This approach fails to provide a predictable regulatory framework and increases uncertainty for product development and stifles innovation.

Key messages on impact assessment: under-estimation of substances impacted

- We believe the Commission's impact assessment substantially under-estimates the number of substances actually meeting the proposed criteria. The results communicated also do not fully reflect the significant impact of confirmatory mode of action data, and do not accurately reflect how regulatory evaluations will be conducted by EFSA in practice.

Key messages on socio-economic impact assessment

- We cannot see why, after carrying out a socio-economic impact assessment, the Commission did not take it into account. This approach clearly goes against the principle of proportionality and the Commission's commitment to better regulation.
- The Commission's Impact Assessment, concludes that all options under consideration offer the same high level of protection for human health and the environment. However, Option 2 and 3 are assessed as having the highest impact on sectorial competitiveness, agriculture and trade. We therefore fail to understand why the Commission has proposed Option 2, the option that will have the greatest impact on the availability of products for farmers.[5]
- 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, and would further reduce the size of the farmer's toolbox.

[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.
[4] Article 5 of WTO SPS agreement
[5] 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.