



Promoting the Science and Practice of Sustainable Crop Production

European Commission Public Consultation on Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation

Response from BCPC

[Text from the on-line consultation form is included in Italic font.]

Section 2. Options for criteria for determination of endocrine disrupting properties

The roadmap defines 4 different options for the establishment of criteria for determination of endocrine disrupting properties.

[The Roadmap on which this Consultation is based is available here:

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

2.1. Questions regarding option 1 (No policy change (baseline). The interim criteria set in the plant protection products and biocidal products regulations continue to apply. No other criteria are specified).

2.1.1 Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 1?

Yes.

If yes, please describe the methodology(ies):

BCPC has studied various reports including most recently -

1) The UK Arable and Horticulture Development Board (AHDB) report: "Endocrine disruptors – collation impacts across all sectors to give clear messages on impacts of changing availability on farmers and production" - See

<http://www.ahdb.org.uk/downloads/304064/304001/Endocrine%20Disruptors%20Report%20-%20Final%20181114.pdf>.

This report sets out the potential economic impacts of yield loss for the withdrawal of active substances on 51 horticultural, arable and forestry crops.

2) Andersons: "The Effect of the Loss of Plant Protection Products on UK Agriculture and Horticulture and the Wider Economy", which cites existing published reports on the potential loss of active substances which may be classified as endocrine disruptors, and notes fifty-eight out of eighty-seven active substances are at medium or high risk of being lost due to endocrine disruption classification.

If yes, please describe the outcome(s) of the assessment(s):

Thirty-nine active substances used in the UK are categorized as being at high risk of being lost, of which seventeen are due to the interim endocrine disruption classification as potential endocrine disruptors.

The Report concluded that the loss or restriction of active substances identified would result in yield decreases of up to 50% and the Gross Value Added (GVA) of UK agriculture would fall by around £1.6 billion a year (a reduction of 20% reduction compared with the 2009-13 average). The assessment shows that UK Total Income from Farming would drop by £1.73 billion,, and UK food processing and manufacturing sectors would suffer potential losses of £2.5 billion GVA with job losses of 35,000 to 40,000, and the UK would rely more on food imports.

2.1.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?

See 2.1.1

2.1.4. Please provide us with any other comments you may have regarding option 1:

There is absolutely no scientific justification for use of the interim criteria in Regulation 1107/2009 since these are based on different toxicological effects which are not relevant to an endocrine disruption mode of action. For this reason BCPC firmly believes that they should not be used.

2.2. Questions regarding option 2 (WHO/IPCS definition to identify endocrine disruptors (hazard identification))

2.2.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 2?

Yes

If yes, please describe the methodology(ies):

See the UK HSE-CRD WRC impact assessment of approved pesticide active substances which may trigger the endocrine disruption cut-off criteria in EU 1107/2009. Ref: <http://sciencesearch.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=18083>

2.2.4. Please, provide us with any other comments you may have regarding option 2.

The fundamental problem with the WHO/IPCS (2002) definition is that it does not include dose applied and exposure levels, and so is incapable of differentiating substances of high regulatory concern as Endocrine Disruptors from substances of little or no concern. Substances with negligible or no actual Endocrine Disruption effect, as a result of the dose applied, absorption, distribution, metabolism and excretion, and so target organ exposure levels, would be included. It is the dose that makes the poison. All substances, including oxygen and water, can cause adverse effects including death, if administered at sufficiently high doses.

2.3. Questions regarding option 3 (WHO/IPCS definition to identify endocrine disruptors and introduction of additional categories based on the different strength of evidence for fulfilling the WHO/IPCS definition) (Option 3)

Please, provide us with any other comments you may have regarding option 3.

As above, the problem with the WHO/IPCS (2002) definition is that it does not include dose applied and exposure levels of relevant organisms and their physiological systems. Option 3 does not address this issue. It is the adverse effects of impact on endocrine systems *per se* - as a function of the dose administered, and subsequent absorption, distribution, metabolism and excretion by the organism concerned - which require regulation. Regulation should not be applied to the mode of action or process which may, or may not, result in adverse effects without reference to the risk of such adverse effects actually occurring in practice (q.v. "Genetic Modification"; the process of genetic modification of crops is not *per se* a source of hazard or risk, yet "GM crops" are – wrongly – perceived by many to be dangerous).

Equally importantly, we note that the Commission is required under Regulation 1107/2009 to develop a single set of criteria for the determination of endocrine disrupting properties, not a series of Categories, as is being proposed in Option 3.

2.4. Questions regarding option 4 (WHO/IPCS definition to identify endocrine disruptors and inclusion of potency as element of hazard characterisation (hazard identification and characterisation))

2.4.4. Please provide us with any other comments you may have regarding option 4.

Option 4 has the benefit of being properly scientifically-based unlike the other Options, in that it recognises the importance of dose applied and exposure levels of organisms and their physiological systems in determining whether a substance may cause adverse effects. That is, it enables assessment of whether the substance is likely to be administered at concentrations which will be toxicologically relevant. As part of this, additional elements of characterisation which relate to severity and reversibility of effect, resulting from rates of absorption, distribution, metabolism, and excretion, should also be included in this assessment. Otherwise, substances may still be classified as Endocrine Disruptors despite having no significant impact on human health or the environment. The pharmaceutical industry operates entirely under such a risk-based assessment, including that of overdose and side-effects. If it did not use risk-assessment procedures, we would have no drugs at all given their intrinsic hazards.

Section 3. Options for approaches to regulatory decision making

3.1 Have you conducted or are you aware of an assessment applying any of the 3 different options for regulatory approaches to decision making (option A-C) to substances identified as endocrine disruptors by any of the options for defining criteria (option 1-4)?

No

Section 4. Other information

4.1. Please provide any other data or information that could help the Commission to conduct its impact assessment.

A full risk assessment option, which takes account of all the available information on the mode of action, adverse effects and exposure, is the approach preferred by BCPC. Using

cut-off criteria, based simply on hazard, does not provide a suitable basis for regulatory decision making, unlike a full risk assessment, which includes both hazard and exposure. As concluded by the EFSA Scientific Committee in their Scientific Opinion (March 2013), Endocrine Disruption should be assessed with through a risk assessment process. This would minimise the unnecessary loss of essential plant protection products on the basis of the scientifically unsound basis of hazard classification, without consideration of risk.

The effects, which could include banning key grass weed herbicides and triazole fungicides, would soon be even greater than the already large figures quoted e.g. in the Andersons report, due to the far greater pressure put on the few remaining products rapidly hastening resistance development. Loss of this capability to maintain or improve plant health would significantly reduce the ability of farmers to control critical crop pests, weeds and diseases, with major impact on agricultural productivity in the EU, without any proven benefit to human health or the environment.

Importantly, potentially safe and effective new products will cease to be available as innovative research is increasingly focusing on opportunities in outside the EU, due to its regulatory environment; regulating on hazard rather than risk is a prime component of this. The continued use of unscientific criteria provides hugely restrictive barriers to innovation of new and improved products for EU agriculture. It will continue to drive innovative industry to focus on crop production and protection targets in particularly the Americas and Asia Pacific. Here, a science-based, more ordered and objective regulatory environment provides a much more innovation-conducive environment for the crop production industry. This has major impact in innovation, competitiveness and growth of the economies and employment in the EU.

BCPC will be pleased to discuss any of the comments made in this response and to provide additional information where this would be helpful.

BCPC will be pleased for this response to be made public without restriction.

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Annex

BCPC - Promoting the Science and Practice of Sustainable Crop Production

BCPC (The British Crop Production Council) is an independent body which promotes the use of good science and technology in the understanding and application of effective and sustainable crop production. It represents the interests of Government departments, the agrochemical industry, farmers' organisations, advisory services and independent consultants, distributors, research councils, agricultural engineers, environment interests, consumer opinion, training and development.

BCPC derives its opinions from a network of experts in a wide range of organisations involved in crop production, and from its Expert Working Groups.

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