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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

IMPACT ASSESSMENT

DEFINING CRITERIA FOR IDENTIFYING ENDOCRINE DISRUPTORS IN THE CONTEXT OF THE IMPLEMENTATION OF THE PLANT PROTECTION PRODUCTS REGULATION AND BIOCIDAL PRODUCTS REGULATION

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Executive Summary Sheet

Impact assessment (IA) on defining criteria for identifying Endocrine Disruptors (ED) in the context of the implementation of the Plant Protection Products Regulation and Biocidal Products Regulation

A. Need for action

Why? What is the problem being addressed? Maximum 11 lines

The Plant Protection Products Regulation (EC) 1107/2009 (PPPR) and the Biocidal Products Regulation (EU) 528/2012 (BPR) set the regulatory consequences for substances considered as having endocrine-disrupting properties. The European Commission is legally required to establish scientific criteria to identify substances with endocrine disrupting properties for these two pieces of legislation. The deadline to do so was December 2013.
The regulatory consequences for substances identified as EDs are already set under the PPPR and BPR. They differ as – contrary to the PPR – in the BP limited derogations based on risk and socio-economic considerations apply.

What are these initiatives expected to achieve? Maximum 8 lines

Scientific criteria to identify EDs shall be presented. The ***general objectives*** within the Treaty which are the legal basis for both the PPPR and BPR were guiding the IA: 1) ensuring a high level of protection of human health, animal health, and the environment and 2) strengthening the functioning of the internal market. These objectives should be considered while improving agricultural production (additional objective of the PPPR). Compliance with international obligations is also an important consideration. In addition the following ***specific objectives*** were considered: 1) legal clarity, predictability and coherence in the identification of ED, 2) scientific criteria that are operational in terms of regulatory decision-making, and 3) the possibility to apply these criteria in the PPPR and BPR.

What is the value added of action at the EU level? Maximum 7 lines

Defining scientific criteria for the identification of EDs is a legal obligation for the Commission, set out in the PPPR and BPR, which were both adopted through the ordinary legislative procedure. The objectives can therefore not be met through Member State action and an EU action is needed.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why? Maximum 14 lines

Four options of scientific criteria to identify substances with endocrine disrupting properties under the PPP and BP Regulations have been assessed:

- ***Option 1:*** No policy change: interim criteria (baseline);
- ***Option 2:*** WHO/IPCS definition to identify EDs;
- ***Option 3:*** WHO/IPCS definition to identify EDs and introduction of additional categories based on the different strength of evidence;
- ***Option 4:*** WHO/IPCS definition to identify EDs and inclusion of potency as an element of hazard characterization

The regulatory consequences of the criteria to identify EDs are already set under the PPP and BP Regulations and differ in terms of scope and implementation, adding complexity to the impact assessment. In order to address this complexity, a second set of options for regulatory consequences was developed (Aspect II):

- ***Option A:*** No policy change (Baseline);
- ***Option B:*** Adjustment of the PPP derogations in light of current scientific knowledge;
- ***Option C:*** Alignment of the PPPR with the BPR by introducing further socio-economic considerations,.

Option C was discarded at a preliminary stage of the impact assessment because it was considered as going beyond the mandate of the Commission but it was maintained in the assessment for analytical purposes.
The IA report does not identify a preferred option of scientific criteria leaving the political choice to the decision makers.

Who supports which option? Maximum 7 lines

The majority of the respondents to the public consultation did not support Option 1 (interim ED criteria set in the PPPR and BPR). There is scientific consensus on the WHO definition for the identification of endocrine disruptors (Option 2). Health, environmental and consumer NGOs call for EU criteria based on hazard (Option A) that would also include additional categories based on the different strength of evidence for fulfilling the WHO/IPCS definition (Option 3). Third countries support an option that will identify EDs and takes regulatory decisions under consideration of risk elements (Option B). This is also the position of the chemical industry and farmers who support Option 4 (WHO definition and inclusion of potency). EU MS are divided: some argue in

favour of Option A in combination with categories (Option 3), while others argue in favour of Option B and/or including potency (Option 4). Recent scientific consensus made evident that Option 4 could no longer be pursued from a scientific point of view, although it is supported by some stakeholders and MS.

C. Impacts of the best performing combination of options

What are the benefits of the best performing combination of options (if any, otherwise main ones)? Maximum 12 lines

All options offer the same high level of protection of human health and environment under the current PPPR and BPR because they are all based on the WHO definition (currently recognised by most scientists) and because the Regulations are based on a prior approval system, a high level of data requirements and a regulatory decision making based on thorough risk assessments.
The options which could be selected to define scientific criteria to identify EDs are Option 2 (WHO definition), Option 3 (WHO definition + categories), and Option 4 (WHO definition + potency). In addition, Option B (adjustment of the PPP derogations in light of current scientific knowledge) could be considered for the implementation of the criteria.
There is scientific consensus regarding the appropriateness of the WHO definition. Since very recently there is also scientific consensus that potency should not be used for identifying endocrine disruptors, and that the assessment of risks from endocrine disruptors to human health and environment should consider hazard characterisation (including potency) and exposure.

What are the costs of the best performing combination of options (if any, otherwise main ones)? Maximum 12 lines

Options 2, 3, 4, and B are expected to offer the same high level of protection to human health regarding EDs under the current PPP and BP Regulations. All options are expected to affect the number of substances approved for PPP and BP at EU level. This will impact to a different extent human health, environment, sectorial competitiveness including agriculture, and trade.
Regarding Options 2 and 3, Member States, scientists and stakeholders agree that they would correctly identify EDs. If they are implemented under the current PPP and BP Regulations, these options will have the highest impacts on sectorial competitiveness, agriculture, and trade. The implementation of Option 3 may in addition be challenging in the context of the PPPR and BPR which are not designed for "categories", may impose additional burden to economic sectors, and may reduce harmonisation in the single market.
Option 4 is contested by some stakeholders, including scientists. The regulatory consequences under the PPP derogations would not be in line with current scientific knowledge. Option 4 will affect the same areas as Options 2 and 3 but to a lesser extent because of a prioritisation of substances based on potency.
Option B, in combination with any of the other options, would be based on science because the derogations would be adjusted to current scientific knowledge and applied on a case-by-case basis, while the general hazard based approach in the PPP Regulation is maintained. Moreover option B would be in line with international obligations.

How will businesses, SMEs and micro-enterprises be affected? Maximum 8 lines

SMEs are affected under all options to a different extent (farmers are mainly SMEs and the biocidal industry is represented mainly by SMEs): it was assumed in the IA that a decrease of availability of PPP or BP would negatively affect SMEs. No derogations or special regimes for SMEs are foreseen in the PPPR and BPR. Options 4 and B (in combination with 2 or 4) would lead to the smallest impacts on SMEs.

Will there be significant impacts on national budgets and administrations? Maximum 4 lines

The criteria to identify EDs will be applied in the framework of the PPPR and BPR and will thus not impact national budgets and administrations beyond what is already foreseen in the Regulations mentioned above.

Will there be other significant impacts? Max 6 lines

No other impacts than those mentioned under the "costs" section.

D. Follow up

When will the policy be reviewed? Maximum 4 lines

The legal acts will be presented under Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012. Any review should be done in the context of the reviews of these Regulations. Sufficient time should be allowed after the implementation of the ED criteria, in order to be able to evaluate the regulatory consequences.