



EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
D(2016)

Opinion

Title **DG SANTE - Impact assessment on defining criteria for identifying endocrine disruptors (ED) in the context of the implementation of the Plant Protection Products Regulation and Biocidal Products Regulation**
(draft version of 13 April 2016)*

(A) Context

The Plant Protection Products Regulation (EC) 1107/2009 (PPPR) and the Biocidal Products Regulation (EU) 528/2012 (BPR) set the regulatory consequences in terms of market authorisation for substances considered as having endocrine-disrupting properties. The European Commission is legally required to establish scientific criteria in implementing legislation to identify substances with endocrine disrupting properties for these two pieces of legislation. The deadline to do so was December 2013. This impact assessment aims to inform this decision. It discusses two aspects surrounding the issue of endocrine disruptors (ED) in PPP and BP: I) options for setting scientific criteria to identify EDs and II) options for regulatory decision making for these EDs.

(B) Overall opinion: NEGATIVE

The Board gives a negative opinion due to a number of shortcomings in the report that limit its contribution to an informed policy decision. These shortcomings concern the following key aspects which need to be addressed:

- 1) The report should acknowledge the ECJ ruling of 16 December 2015 concerning the specification of scientific criteria for the determination of ED properties.**
- 2) The report should further clarify to what degree there is scientific consensus supporting the identified criteria, how this has developed over the past years, and whether there are outstanding issues. It should also better separate scientific elements from the regulatory aspects discussed in the report.**
- 3) The presentation of options should better distinguish between the sequential steps of a) identifying whether or not a substance is an ED, and b) whether or not a derogation can be applied for an ED. The report should also clearly explain the scope for introducing risk elements in the PPP regulation through an implementing act. Options that appear disproportionate or unfeasible should be discarded from the onset of the report.**

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

4) The assessment of impacts should be strengthened and in the absence of more evidence, the methodological bias favouring options banning fewer substances should be clearly described.

Once revised, the IA must be resubmitted to the Board, which will issue a new opinion on the revised draft.

(C) Main recommendations for improvements

(1) ECJ ruling. The report should acknowledge the recent ruling of the ECJ and consider the implications for the specification of scientific criteria for the determination of ED properties.

(2) Clarification of scientific and regulatory aspects. The report should clarify areas of scientific consensus surrounding endocrine disruptors and how they are reflected in the different options. Key elements of scientific dissent (e.g. low dose effects and non-monotonic dose responses of EDs) where there is no sound basis on which to base a decision should be further explained, summarising different stakeholders' arguments. The report should also provide the scientific rationale for the inclusion, as an option, of an element of potency in the definition of EDs and more systematically distinguish the steps that lead to the establishment of scientific criteria for the identification of EDs from their potential regulatory consequences.

(3) Presentation and sequencing of options. As a consequence from (2), the description of options should be changed from a matrix to a sequential presentation, whereby the definition of scientific criteria (i.e. "Aspect I" options) precedes a discussion on possible adjustments to their regulatory consequences (i.e. "Aspect II" options). In addition, the need and relevance of each option should be further substantiated and options that appear unfeasible or going beyond what is feasible in delegated or implementing acts (e.g. Option C) should be discarded upfront. The possibility to align the PPP to the BP regulation as regards elements of risk (Option B) through the proposed implementing act under the current legal framework should be described in more depth.

(4) Assessment of impacts and its limitations. The robustness of the multi criteria analysis should be further demonstrated and the scoring of the performance scores refined where feasible. The assumptions supporting the evaluation of the different criteria should be presented more explicitly, in light of the limited body of evidence. The limitations of the results should be more transparently acknowledged: in particular, the current methodological bias favouring options banning fewer substances should be clearly described. Where the level of uncertainty is high, a sensitivity analysis should be applied to the actual performance scores, rather than on the weights, to better reflect the level of confidence surrounding the scale of the impacts. Where no data is available, the addition of case studies for the most known substances would usefully illustrate the nature and magnitude of impacts that may be anticipated.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

As mentioned, the matrix presentation of options should be revised to reflect the sequential steps of identification of a substance as ED and its management as spelled out in the PPP and BP regulations.

(E) RSB scrutiny process	
Reference number	2015/SANTE/001 (PPP) and 2016/SANTE/045 (BP)
External expertise used	No
Date of RSB meeting	12 May 2016