

for their inclusion and by separating more clearly options relating to the definition of scientific criteria from their application).

However, the report should be adjusted in order to integrate the Board's recommendations with respect to the following key issues:

a) The report should be consistent throughout the text and make clear that, (i) in line with the ruling of the ECJ, the criteria for the identification of EDs should be specified only on the basis of the relevant scientific evidence and irrespective of the economic and social impacts resulting from their regulatory treatment and (ii) that the proposed analysis of impacts is provided only with a view to informing about the implications of the different options for the specification of EDs in a given regulatory context and not to influencing the selection of the preferred specification option.

b) In view of the emerging scientific consensus referred to in the report and according to which potency is not relevant for identification of a compound as an ED, Option 4 should be discarded from the outset on this basis.

c) The presentation of the regulatory option for derogations should clarify the criteria for derogations and establish a clear link between these criteria and the impact dimensions of the analysis.

d) The shortcomings of the impact analysis, in particular the current methodological bias of the proposed multi-criteria analysis favouring options banning fewer substances, should be acknowledged and supporting evidence for the regulatory aspects (aspect II) should be presented in a clearer way in the report.

The lead DG shall ensure that these recommendations are integrated in the report prior to launching the interservice consultation.

(C) Main recommendations for improvements

1) **Presentation and use of supporting evidence.** Areas of scientific consensus and outstanding issues are summarised in section 1.2.1. However, the inclusion criteria for the selected publications should be transparently presented. For instance, it is unclear why the added section on scientific developments does not mention the 2012 WHO review on the state of the science on ED (and its conclusions e.g. on the need for reducing exposures and expanding the list of chemicals currently examined, on the likelihood that harmful effects in humans and wildlife are being overlooked because of the absence of internationally agreed and validated test methods). An exhaustive list of references should be provided in Annex 1.2.

The consensus paper makes it clear that “potency is not relevant for identification”, the option 4 should be discarded and its impact not analysed.

The report should further clarify that the decision on the first aspect of the analysis (setting scientific criteria to identify endocrine disruptors based on hazard; options 1 to 4) should be exclusively based on scientific criteria, and not give the impression that the results of the multi-criteria analysis (MCA) are used for this (e.g. in sections 5.1, 6.1 and 6.3).

The report should also clarify option B on the introduction of derogations. It should specify on which grounds derogation will be considered and whether these criteria match the impact dimensions selected in the impact analysis.

On the second aspect of the analysis (implementation of the scientific criteria / approach to regulatory decision making; options A and B), the report should present the comparative

strengths of both options more clearly in section 6.2. The language used for the resulting "ranking" of options should more carefully reflect the uncertainties and assumptions made to perform this ranking. For instance, the conclusive statement whereby "*Option B performs better than Option A*" in terms of food safety (pp. 47-48) does not seem to entirely reflect the mixed supporting arguments for this conclusion (i.e. the risk of banning important fungicides to be weighed against remaining uncertainties as to their potential hazard).

2) Analysis of impacts. The report should better clarify the limits of the MCA undertaken in relation to the comparison of options. In particular, the dominant effect of the number of banned substances on the results of the MCA should be put clearly in evidence and presented as the main caveat for the MCA. Due to the dominance of the number of substances, the sensitivity analysis on the MCA is bringing limited additional insights and could be presented much more concisely or only presented in the annex. Moreover the annexes have not been updated to reflect the sequential approach on the definition of criteria in a first step and the regulatory treatment in a second step and are therefore not consistent with the main report.

(D) Procedure and presentation:

Following its extensive revision, the entire report should be proof-read, consistently formatted and edited (e.g. formatting of footnote 1 added in Box 1, under paragraph 22 of the extract from the BfR consensus statement; p.50 clarify the sentence "(...) impact on agriculture (...) varies *from* the option chosen" – could be replaced with "varies depending on the option chosen"; ref to "Options 4" on p55). The insertion of a bibliography as well as a table of tables & figures would further enhance the readability of the report. The nature and the magnitude/direction (i.e. positive/negative) of specific impacts should be explicitly stated and, if unclear, should be clearly presented as such (e.g. ambiguous on innovation, p.50).

(E) RSB scrutiny process

Reference number	2015/SANTE/001 and 2016/SANTE/045
External expertise used	No
Date of RSB meeting	Written procedure (an earlier version of this report was discussed by the Board on 13 April 2016, for which an opinion was issued on 13 May 2016).