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IMPACT ASSESSMENT

Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation

Annex 7 out of 16

Accompanying the document

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND THE COUNCIL**

on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products

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ANNEX 7

THE MULTI-CRITERIA ANALYSIS: RESULTS

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This Annex focuses on the assessment of potential impacts, which build on the results of the screening study explained in Annexes 3 to 5. The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [Regulation (EC) No 1107/2009 on plant protection products and Regulation (EU) No 528/2012 on biocidal products] and in no way prejudge future decisions on active substances to be taken pursuant to these two Regulations. It would thus be erroneous to consider that the substances listed in Annex 5 are considered as endocrine disruptors within the meaning of the EU legislation. The methods and results presented in this Annex are to be interpreted as an estimation of the potential impacts.

The MCAs results are not concluding on any preferred option for setting scientific criteria to identify endocrine disruptors, but aim at providing additional information to decision makers with regards to the potential impacts

expected when implementing the criteria, after those would have been selected on the basis of science (two MCAs were performed: Options 1 to 4 under the current regulatory context, and Options A compared to Options B and C).

At a preliminary stage of the impact assessment it was anticipated that Option C should be discarded, nevertheless it was maintained for the analysis of the impacts for methodological reasons (see Section 4.2.3 of the main report and Annexes 6 and 7). Option C only applies to the PPP Regulation.

1. INTRODUCTION

As set out in Annex 6, a Multi Criteria Analysis (MCA) was performed to compare Options 1 to 4 (Aspect I, EU criteria to identify endocrine disruptors (EDs)) and Options A to C (Aspect II, Approaches to regulatory decision making).

The options were compared under different scenarios in order to ascertain how different weights could have affected the overall ordering of the options:

1. **SCENARIO 1 - HOMOGENITY:** equal weights were assigned to all dimensions. For the weights of the MCA-criteria within each dimension, two sub-scenarios were considered:
 - i) **1/A:** within each dimension, equal weights were assigned to each MCA-criterion;
 - ii) **1/B:** within each dimension, higher weights were assigned to those MCA-criteria for which the availability of data/evidence was considered to be higher, while equal weights were assigned to those MCA-criteria for which data/evidence available was thought to be insufficient to discriminate.
2. **SCENARIO 2 - PRIORITY TO EVIDENCE:** different weights were assigned to the dimensions depending on the overall availability of data/evidence. Within each dimension, higher weights were assigned to those MCA-criteria for which the availability of data/evidence was considered to be higher, while equal weights were assigned to those MCA-criteria for which data/evidence available was thought to be insufficient to discriminate.
3. **SCENARIO 3 – PRIORITY TO HEALTH AND ENVIRONMENT:** equal weights were assigned to the dimensions Health and Environment, in light of the precautionary principle set out in article 191 of the Treaty on the Functioning of the EU. Decreasing weights were assigned to the remaining dimensions depending on the overall availability of data/evidence. Within each dimension, higher weights were assigned to those MCA-criteria for which the availability of data/evidence was considered to be higher, while equal weights were assigned to those MCA-criteria for which data/evidence available was thought to be insufficient to discriminate.
4. **SCENARIO 4 - HEALTH FIRST:** the highest weight was assigned to the dimension Health. The remaining dimensions were assigned a weight dependent on the overall availability of data/evidence. Within each dimension, higher weights were assigned to those MCA-criteria for which the availability of data/evidence was considered to be higher, while equal weights were assigned to those MCA-criteria for which data/evidence available was thought to be insufficient to discriminate.
5. **SCENARIO 5 – AIM: EXPOSURE ZERO:** this scenario examines what would be the effect considering a regulatory decision making which aims at completely reducing exposure to chemicals and as a consequence is based on hazard and does not

consider risk assessment. Scenarios 3 (priority to health and environment) and 4 (Health first) were used as starting points. Additionally, sub scenarios were developed which increase the weight assigned to Health. The resulting 4 sub-scenarios are described as follows:

- i) **5/A:** as scenario 3 + Hazard based decision making;
- ii) **5/B:** as scenario 3 + Hazard based decision making + increase of the weight assigned to Health (from 0,20 to 0,40) at the expenses of the other dimensions excluding Environment. Further, 50% of the overall weight for Human Health (0,40) was assigned to the criterion "hormone related diseases and disorders" and the remaining 50% was split equally between the other two MCA-criteria of the dimension Human Health (in all other scenarios considered, equal weights were assigned to the Human Health MCA-criteria as data/evidence available was considered to be insufficient to discriminate among them). This scenario is consequently giving the highest weight to ED related issues on human health (20%) and environment (13.4%), amounting to 33.4 % of the total weight.
- iii) **5/C:** as scenario 4 + Hazard based decision making;
- iv) **5/D:** as scenario 4 + Hazard based decision making + an increase of the weight assigned to Health (from 0,25 to 0,40) at the expenses of the other dimensions.

For the purpose of the sensitivity analysis, additional simulations were run under Scenario 5/B (Aim: exposure zero) in order to evaluate when the policy ranking of the options would change.

In this annex, the tabular results are presented:

- overview of weights assigned to the MCA criteria and dimensions according to the different scenarios considered (sensitivity analysis, Table 1);
- performance of the options 1,2,3 and 4, and options A, B, and C.
- weighted performance matrices (multiplication of the performance and weights), giving composite quantities which allow each policy option to be compared and ranked for each criterion (Sections 2 and 3);
- outranking matrices and policy ranking permutations. Outranking matrices summarise how each option compared against another for all possible pairs of policy options. Policy ranking permutations allow selecting the policy options which maximise pair-wise agreement - and minimise disagreement (Sections 4 and 5);
- summary overview of the results (Section 6).

Table 1. Overview of weights assigned to the MCA criteria according to the different scenarios (sensitivity analysis)

IMPACTS		SCENARIO 1 HOMOGENITY		SCENARIO 2 PRIORITY TO EVIDENCE	SCENARIO 3 PRIORITY TO HEALTH AND ENVIRONMENT	SCENARIO 4 HEALTH FIRST	SCENARIO 5 AIM: EXPOSURE ZERO				Qualitative assessment of evidence	
		A	B				A	B	C	D		
EFFECTIVENESS & COHERENCE	Dimensions and criteria¹	Weight	Weight	Weight	Weight	Weight	Weight	Weight	Weight	Weight		
	Effectiveness & coherence	0,167	0,167	0,18	0,16	0,16	0,16	0,11	0,16	0,13		
	Legal certainty and proportionality	0,042	0,033	0,036	0,032	0,032	0,032	0,022	0,032	0,026	0,20	
	Operability for regulatory decision making	0,042	0,033	0,036	0,032	0,032	0,032	0,022	0,032	0,026	0,20	
	Coherence between BP and PPP legislation	0,042	0,050	0,054	0,048	0,048	0,048	0,033	0,048	0,039	0,30	
Compliance with international obligations of the EU	0,042	0,050	0,054	0,048	0,048	0,048	0,033	0,048	0,039	0,30		
EFFICIENCY	Economic	Sectorial competitiveness: EU agriculture	0,167	0,167	0,21	0,17	0,19	0,17	0,12	0,19	0,16	
		Number of PPP affected	0,056	0,083	0,105	0,085	0,095	0,085	0,060	0,095	0,080	0,50
		Crops affected	0,056	0,050	0,063	0,051	0,057	0,051	0,036	0,057	0,048	0,30
		Existence of alternatives / risk of resistance of pests	0,056	0,033	0,042	0,034	0,038	0,034	0,024	0,038	0,032	0,20
		Sectorial competitiveness: PPP, BP and related industries	0,167	0,167	0,12	0,09	0,08	0,09	0,04	0,08	0,05	
		Functioning of the single market	0,056	0,056	0,040	0,030	0,027	0,030	0,013	0,027	0,017	0,33
		Innovation and research	0,056	0,056	0,040	0,030	0,027	0,030	0,013	0,027	0,017	0,33
		SME's	0,056	0,056	0,040	0,030	0,027	0,030	0,013	0,027	0,017	0,33
		International trade	0,167	0,167	0,22	0,180	0,20	0,180	0,13	0,20	0,17	
	Import of food	0,056	0,058	0,077	0,063	0,070	0,063	0,046	0,070	0,060	0,35	
	Import of feed	0,056	0,058	0,077	0,063	0,070	0,063	0,046	0,070	0,060	0,35	
	Import of treated articles	0,056	0,050	0,066	0,054	0,060	0,054	0,039	0,060	0,051	0,30	
	Social	Human Health	0,167	0,167	0,13	0,20	0,25	0,20	0,40	0,25	0,40	
		Hormone related diseases and disorders	0,056	0,056	0,043	0,067	0,083	0,067	0,20	0,083	0,133	0,33 ²
		Food safety	0,056	0,056	0,043	0,067	0,083	0,067	0,10	0,083	0,133	0,33
		Transmissible diseases caused by lack of appropriate disinfectants or insecticides	0,056	0,056	0,043	0,067	0,083	0,067	0,10	0,083	0,133	0,33
	Environment	Environment	0,167	0,167	0,14	0,20	0,12	0,20	0,20	0,12	0,09	
Chemical quality of water		0,056	0,056	0,047	0,067	0,040	0,067	0,067	0,040	0,030	0,33	
Wildlife vertebrate populations		0,056	0,056	0,047	0,067	0,040	0,067	0,067	0,040	0,030	0,33	
Animal welfare		0,056	0,056	0,047	0,067	0,040	0,067	0,067	0,040	0,030	0,33	

¹ Note that some criteria names have been abbreviated. See Table 1 in Annex 6 or Table 3 in the main report for complete titles for the criteria.

² Scenario 5/B, assigns 50% of the overall weight for Human Health (0,40) to "hormone related diseases and disorders" and split the remaining 50% equally between the other two MCA-criteria of Human Health. In all other scenarios, equal weights are assigned to these 3 MCA-criteria as data/evidence available was considered insufficient to discriminate among them. This scenario is thus giving the highest weight to ED related issues on human health (20%) and environment (13.4%).

Table 2. Performance of Option 1, 2, 3 and 4.

PERFORMANCE OF OPTION 1, 2, 3, AND 4

