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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 6 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 6

ANALYTICAL METHOD USED TO COMPARE AND RANK THE OPTIONS: THE MULTI-CRITERIA ANALYSIS

Contents

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

In order to compare and rank the options considered in the course of this impact assessment (IA), the methods presented in the Tool #55 of the Better Regulation Guidelines ("Useful analytical methods to compare options or assess performance") were analysed and compared with respect to the following dimensions: availability of evidence/data and appropriateness of each method for assessing the key impacts listed in the Tool #16 of the Better Regulation Guidelines ("Identification/screening of impacts") that are important for this IA.

2. SELECTION OF THE METHOD

1.1. Analysis of availability of evidence and data

The analysis of the data and evidence showed that the data were insufficient, partial or not sufficiently robust for assessing the impacts on agriculture, trade, human health and environment.

In particular:

- For agricultural/trade impacts, basic data are either not available, not ready, or not easy to use (e.g. information on uses of active substances per crop and per pest is patchy; yield decreases in crop production due to the absence of a plant protection product - crucial for any estimation of impacts - can only be based on significant assumptions; extrapolation from case studies based on few Member States to the whole EU will be difficult due to e.g. differences in climate conditions; extrapolation from the impacts related to the non-approval of one active substance to the non-approval of several active substances is technically complex and entails difficulties for the comparison of the options; some agronomic impacts cannot be quantified in any case for example due to resistance to target organisms).
- For health impacts, no active substance identified in the options can be linked directly to a disease due to general lack of scientific studies proving such links. Therefore, any quantification regarding health costs is controversial and any approach to estimate health impacts will differ from that chosen to calculate the agriculture/trade impacts creating a strong imbalance between the assessments of the areas. Further, due to the already high protection of health in the plant protection products (PPP) and biocidal products (BP) legislations (no use of substances that pose a serious health or environmental concern would be authorised), a comparison between Option A and Option B (approaches to regulatory decision making) would be difficult.

- For environmental impacts, assessing the impacts on biodiversity/ecosystems is even more difficult than impacts on human health (e.g. in the study of DG ENV[1] on benefits of chemical legislation, assessments can only be done based on a few case studies).

Also, a sufficient number of representative and reliable case studies to be used in assessing the impacts in all areas were not available.

1.2. Analysis of analytical methods

The selection of the analytical method started by considering the methods listed in the Better Regulation Guidelines' Tool #55: Cost Benefit Analysis (CBA), Least Cost Analysis (LCA), Multi-Criteria Analysis (MCA), Cost-Effectiveness Analysis (CEA), Counterfactual Analysis, and SWOT Analysis.

Cost-Benefit Analysis, Least Cost Analysis and Cost-Effectiveness Analysis were discarded as potential methods because robust assumptions for quantifying and monetizing the impacts were not available.

The Counterfactual analysis was also discarded as it is an analytical method that is more appropriate for evaluations as it looks at what would have happened in the absence of an intervention.

The SWOT analysis was also discarded as it is not an analytical method per se, but it is used to identify Strengths, Weaknesses, Opportunities and Threats in relation to a project/organisation.

In light of the availability of evidence/data and suitability of the methods presented in the Tool #55 of the Better Regulation Guidelines, the Multi-Criteria Analysis was considered the most appropriate method because:

- it is useful when impacts cannot be fully quantified or monetised;
- it allows impacts to be reconciled with policy objectives;
- it can capture distributional impacts (e.g. in terms of stakeholder types);
- it enables to judge the pros and cons of options along the MCA-criteria chosen for the comparison;
- it allows the selected MCA-criteria to determine the results obtained by assigning weights to them.

The Multi-Criteria Analysis has also many advantages over informal judgement unsupported by proper and robust analysis:

- the choice of objectives and MCA-criteria are open to analysis and to change if they are felt to be inappropriate. The objectives and MCA-criteria were discussed by the Impact Assessment Steering Group (IASG);

[1] RPA et al. 2015. Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment, Draft final report for DG Environment, December 2015, Loddon, Norfolk, UK

- performance scores and weights are explicit and are developed according to established techniques. They can easily be amended if necessary;
- a sensitivity analysis can be easily performed, highlighting how the weights assigned to MCA-criteria influence the final result;
- as scores and weights are used, it provides an audit trail.

3. THE MULTI-CRITERIA ANALYSIS

A key step in determining the MCA-methodology to be applied was to assess whether trade-offs between different MCA-criteria were acceptable, considering that some public decisions admit such trade-offs.

Admitting trade-offs would imply that good performance on one MCA-criterion can, in principle, compensate for weaker performance on another; however there may be some circumstances, for example, where ethical, health or environmental issues are central, where trade-offs of this type are not acceptable. If it is not acceptable to consider trade-offs between MCA-criteria, then a non-compensatory MCA should be employed.

After assessing the appropriateness of a compensatory MCA-method vs. a non-compensatory MCA-method, it was concluded that the non-compensatory methods should be followed in the course of this IA in view of the following elements:

1. *Performance assessment of options based on relative performance.* The performance of the options was evaluated based on relative performance. In order to be able to compensate correctly it is necessary to determine the actual performance of an option, and then transpose it in a standardised measurement unit so that compensation can be performed. However, in the current situation it is not possible to determine actual performance; it is only possible to specify if one option is performing better or worse than another, without being able to determine with a sufficient accuracy the magnitude of the difference between the two options. Being in the impossibility to determine accurately how much better or how much worse an option is performing on a certain MCA-criterion; it is considered inappropriate in this case to compensate performance, as such compensation would be rather arbitrary.
2. *Unacceptable trade-offs between MCA-criteria.* It was determined that in the case of this IA it is not acceptable to allow trade-offs between MCA-criteria. For example, in the case of a compensatory method, if an option is performing weak on a certain MCA-criterion, this can be offset by a very strong performance on another MCA-criterion. As a concrete example, a weak performance on environment related MCA-criteria can be totally offset by an excellent performance on trade related MCA-criteria. However, the purpose of this IA is to determine the option that is performing well on the most MCA-criteria and not offset bad performance by excellent performance, especially when the actual performance of the option cannot be determined (as mentioned in the previous point).

Before carrying-out the MCA, it is fundamental to consider what the main purpose of the intervention and the options to be compared are.

The methodology was illustrated to the members of the IASG at the meetings on January 19 and February 1, 2016.

1.3. Main purpose of the intervention

As described in Section 3 of the main IA report, the comparison of the options should consider how each is contributing to the attainment of the main policy objectives:

- General objective within the Treaty, as they are the legal basis for both the PPP and BP Regulations:
    - ensuring a high level of protection to human health and the environment;
    - strengthening the functioning of the internal market

In addition, for the PPP Regulation the two objectives mentioned above should be considered while improving agricultural production (see Article 1 of Regulation (EC) No 1107/2009).

The compliance with international obligations, notably under the Sanitary and Phyto-sanitary (SPS) and Technical Barriers to Trade (TBT) Agreements in the World Trade Organisation are also important considerations.

- Specific objective for PPP and BP Regulations:
    - providing for legal clarity, predictability and coherence in the identification of endocrine disruptors (ED);
    - providing for scientific ED-criteria that are operational in terms of regulatory decision-making;
    - offering possibility to apply these ED-criteria across both the PPP and BP Regulations.

1.4. The options to be compared

As described in Section 4 of the IA report, the following options were compared:

Aspect I: Setting scientific criteria to identify EDs

- ***Option 1:*** *No policy change (baseline).* No criteria are specified and the interim criteria set in the PPP and BP Regulations continue to apply.
- ***Option 2****: WHO/IPCS definition to identify endocrine disruptors.*
- ***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 4****: WHO/IPCS definition to identify endocrine disruptors and inclusion of potency as element of hazard characterization.*

Aspect II: Implementation of the ED criteria / approach to regulatory decision making

- ***Option A****: No policy change (Baseline).* The regulatory consequences under the PPP and BP Regulations remain unchanged and therefore different between them.
- ***Option B****: Adjustment of the PPP derogations in light of current scientific knowledge*
- ***Option C****: Alignment of the PPP with the BP Regulation by introducing further socio-economic considerations.*

4. STEPS OF THE MULTI-CRITERIA ANALYSIS

The full application of multi-criteria analysis was based on the procedure described in the Tool #57 of the Better Regulation Guidelines ("Multi-Criteria Analysis") and followed several steps:

1. identify the "dimensions" where significant impact of the options is expected and define MCA criteria corresponding to the dimensions in order to compare key impacts of the options;
2. describe the expected performance of each option against the MCA-criteria and 'score' the options,
3. 'weighting': assign weights for each of the MCA-criteria to reflect their relative importance to the decision. The weighting was carried out through a sensitivity analysis, as explained in the following pages
4. combine the weights and scores for each of the options;
5. examining the results.

The MCA was carried out in a step-wise approach, as there were two sets of options (for aspect I and aspect II):

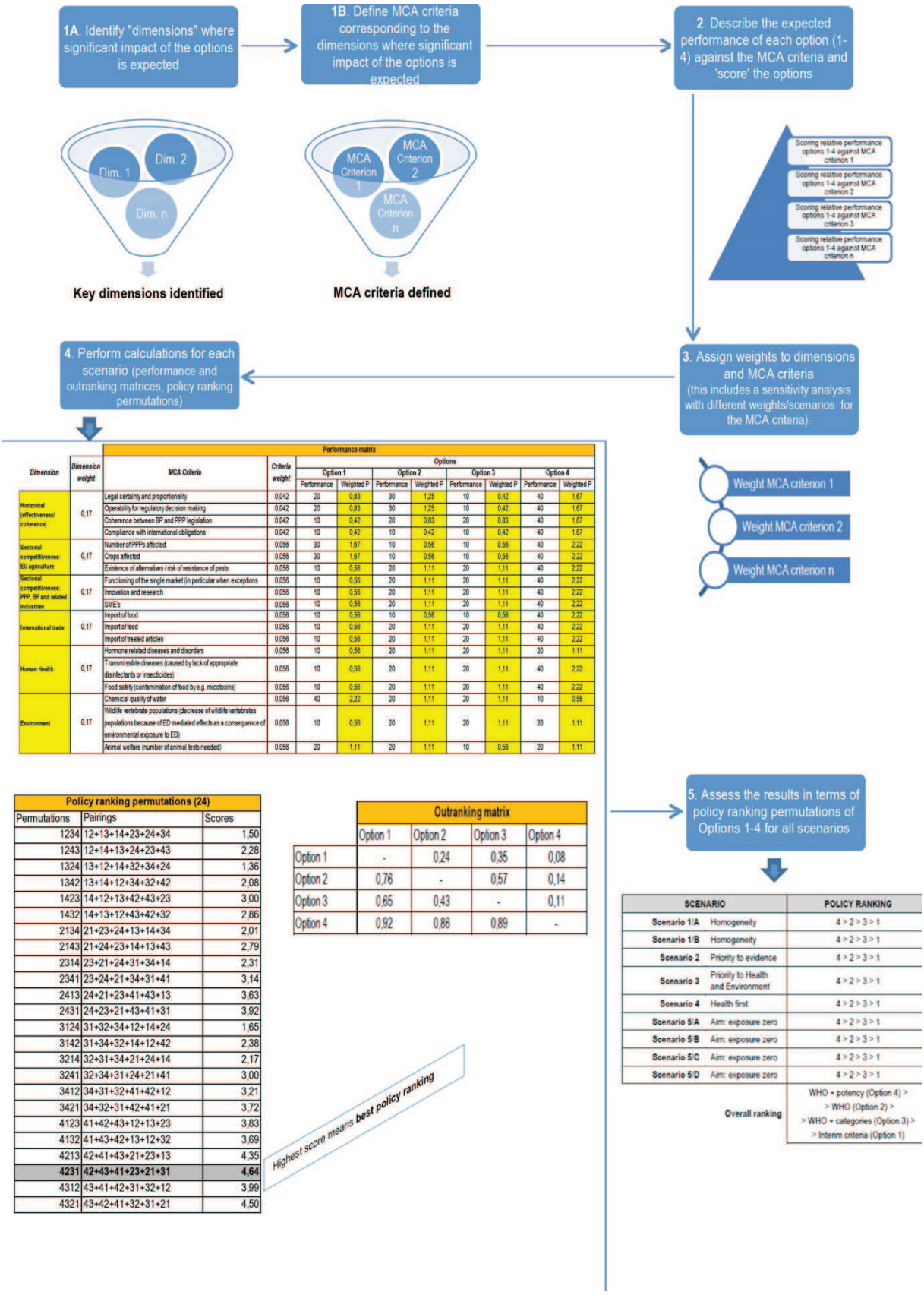
-Step 1: the MCA methodology will be applied to Options 1 to 4.

-Step 2: the MCA methodology will be applied to Options A to C.

The same MCA parameters (MCA-criteria, weights, performance assessment methods, etc.) were employed for both steps. The step-wise approach was selected rather than an approach comparing combined options for two major reasons:

1. The step-wise approach simplifies the already very complex analysis. Analysing the combined options would bring even more complexity into the analysis, increasing the difficulty level and potentially reducing the comprehensibility of the results to a larger audience.
2. The step-wise approach facilitates the ranking of the options for each MCA-criterion and enables for a clearer justification of the ranking order.

A graphical representation of the MCA-methodology applied is provided in Figure 1.



Dimension	Dimension weight	MCA Criteria	Criteria weight	Performance matrix: Options							
				Option 1		Option 2		Option 3		Option 4	
				Performance	Weighted P	Performance	Weighted P	Performance	Weighted P	Performance	Weighted P
Horizontal (effectiveness/ coherence)	0,17	Legal certainty and proportionality	0,042	20	0,83	30	1,25	10	0,42	40	1,67
		Operability for regulatory decision making	0,042	20	0,83	30	1,25	10	0,42	40	1,67
		Coherence between BP and PPP legislation	0,042	10	0,42	20	0,83	20	0,83	40	1,67
		Compliance with international obligations	0,042	10	0,42	10	0,42	10	0,42	40	1,67
Sectorial competitiveness: EU agriculture	0,17	Number of PPPs affected	0,056	30	1,67	10	0,56	10	0,56	40	2,22
		Crops affected	0,056	30	1,67	10	0,56	10	0,56	40	2,22
		Existence of alternatives / risk of resistance of pests	0,056	10	0,56	20	1,11	20	1,11	40	2,22
Sectorial competitiveness: PPP, BP and related industries	0,17	Functioning of the single market (in particular when exceptions	0,056	10	0,56	20	1,11	20	1,11	40	2,22
		Innovation and research	0,056	10	0,56	20	1,11	20	1,11	40	2,22
		SME's	0,056	10	0,56	20	1,11	20	1,11	40	2,22
International trade	0,17	Import of food	0,056	10	0,56	10	0,56	10	0,56	40	2,22
		Import of feed	0,056	10	0,56	20	1,11	20	1,11	40	2,22
		Import of treated articles	0,056	10	0,56	20	1,11	20	1,11	40	2,22
Human Health	0,17	Hormone related diseases and disorders	0,056	10	0,56	20	1,11	20	1,11	20	1,11
		Transmissible diseases (caused by lack of appropriate disinfectants or insecticides)	0,056	10	0,56	20	1,11	20	1,11	40	2,22
		Food safety (contamination of food by e.g. micotoxins)	0,056	10	0,56	20	1,11	20	1,11	40	2,22
Environment	0,17	Chemical quality of water	0,056	40	2,22	20	1,11	20	1,11	10	0,56
		Wildlife vertebrate populations (decrease of wildlife vertebrates populations because of ED mediated effects as a consequence of environmental exposure to ED)	0,056	10	0,56	20	1,11	20	1,11	20	1,11
		Animal welfare (number of animal tests needed)	0,056	20	1,11	20	1,11	10	0,56	20	1,11

Policy ranking permutations (24)		
Permutations	Pairings	Scores
1234	12+13+14+23+24+34	1,50
1243	12+14+13+24+23+43	2,28
1324	13+12+14+32+34+24	1,36
1342	13+14+12+34+32+42	2,08
1423	14+12+13+42+43+23	3,00
1432	14+13+12+43+42+32	2,86
2134	21+23+24+13+14+34	2,01
2143	21+24+23+14+13+43	2,79
2314	23+21+24+31+34+14	2,31
2341	23+24+21+34+31+41	3,14
2413	24+21+23+41+43+13	3,63
2431	24+23+21+43+41+31	3,92
3124	31+32+34+12+14+24	1,65
3142	31+34+32+14+12+42	2,38
3214	32+31+34+21+24+14	2,17
3241	32+34+31+24+21+41	3,00
3412	34+31+32+41+42+12	3,21
3421	34+32+31+42+41+21	3,72
4123	41+42+43+12+13+23	3,83
4132	41+43+42+13+12+32	3,69
4213	42+41+43+21+23+13	4,35
4231	**42+43+41+23+21+31**	**4,64**
4312	43+41+42+31+32+12	3,99
4321	43+42+41+32+31+21	4,50

Outranking matrix				
	Option 1	Option 2	Option 3	Option 4
Option 1	-	0,24	0,35	0,08
Option 2	0,76	-	0,57	0,14
Option 3	0,65	0,43	-	0,11
Option 4	0,92	0,86	0,89	-

SCENARIO		POLICY RANKING
Scenario 1/A	Homogeneity	4 > 2 > 3 > 1
Scenario 1/B	Homogeneity	4 > 2 > 3 > 1
Scenario 2	Priority to evidence	4 > 2 > 3 > 1
Scenario 3	Priority to Health and Environment	4 > 2 > 3 > 1
Scenario 4	Health first	4 > 2 > 3 > 1
Scenario 5/A	Aim: exposure zero	4 > 2 > 3 > 1
Scenario 5/B	Aim: exposure zero	4 > 2 > 3 > 1
Scenario 5/C	Aim: exposure zero	4 > 2 > 3 > 1
Scenario 5/D	Aim: exposure zero	4 > 2 > 3 > 1
Overall ranking		WHO + potency (Option 4) > > WHO (Option 2) > > WHO + categories (Option 3) > > Interim criteria (Option 1)

Figure 1. Exemplary steps of the MCA applied in this IA for options 1 to 4. A similar process was followed for options A to C.

1.5. Identifying the MCA-criteria to compare key impacts of the options

The MCA-criteria are means of assessing the performance of the options; hence they need to be operational. A judgment needs to specify how well each option meets the objectives expressed by the MCA-criteria. In practice, a question that was borne in mind in developing the set of MCA-criteria was "Is it possible in practice to assess how well an option performs on these MCA-criteria?"

It is worth noting that the number of MCA-criteria should be kept as low as is consistent with making a well-founded decision. There is no 'rule' to guide this judgment and it certainly varies from application to application.

During the development of these MCA-criteria, the following principles were considered:

1. *Observing the Better Regulation Guidelines.* In designing the MCA-criteria, the requirements of Tool 8 of the Better Regulation Guidelines have been considered, meaning the aspects related to option effectiveness, efficiency and coherence.
   a. *Link with the objectives (effectiveness).* MCA-criteria were considered in relation to the objectives to be attained in order to facilitate the judgement on how the options will contribute to the achievement of the objectives set.
   b. *Areas with significant impacts (efficiency).* The MCA-criteria cover the areas that were considered to experience significant impacts in order to compare such effects between the various options and determine how efficiently the options are performing. In deciding which the key economic, social and environmental impacts are, Tool #16 – "Identification/screening of impacts" was employed.
   c. *Consistency with other EU legislation (coherence).* MCA-criteria give consideration to international treaties (like WTO and Codex Alimentarius) that the EU needs to observe or the coherence between PPP and BP legislation.
2. *Availability of evidence.* One of the most important considerations in the selection of MCA-criteria was the availability of quantifiable or qualitative information/data. It is acknowledged that the degree of granularity of available data would vary between the various areas, with some fields benefiting from more detailed statistics, while others being characterised by the prevalence of qualitative data.

Before finalising the choice of criteria of this MCA, they were assessed against a range of qualities:

1. completeness: this aspect considered whether all important criteria were included;
2. redundancy: this aspect considered whether there were criteria which were unnecessary. If in the process of fine-tuning it was discovered that MCA-criteria that mean the same thing have been defined in different ways, this represents a case of redundancy and one MCA-criterion will be discarded;
3. operationality: this aspect considered whether each option could have been judged against each MCA-criterion based on the available evidence;

4. mutual independence of preferences: this aspect considered whether preference scores for the options on one MCA-criterion could have been assigned without knowing what the options' preference scores were on any other criteria. If the answer is yes, then this MCA-criterion is preference independent of the others. If in the process of option ranking, it is discovered that MCA-criteria are dependent, they will be combined, to the extent possible, in order to eliminate dependence

Table 1. Potential impacts and the corresponding dimensions and criteria used in the MCA

Impacts		Dimensions and MCA-criteria	
EFFECTIVENESS & COHERENCE		**EFFECTIVENESS & COHERENCE**	
		Legal certainty and proportionality:	degree to which legal certainty is ensured
		Operability for regulatory decision making:	additional efforts required to public authorities and applicants resulting from implementing derogations and a revision of categories
		Coherence between BP and PPP legislation:	
		Compliance with international obligations of the EU:	compliance with international obligations of the EU (WTO and Codex Alimentarius)
EFFICIENCY	Economic	**SECTORIAL COMPETITIVENESS: EU AGRICULTURE**	
		Number of PPP affected:	number of PPP authorised at national level that will be affected as a consequence of the non-approval of active substances identified as EDs
		Crops affected:	number of crops affected by the non-approval of active substances identified as ED
		Existence of alternatives / risk of resistance of pests:	number of PPP alternatives existing for each crop, under consideration that the risk of appearance of resistance in pests is related to a lower number of available PPP
		SECTORIAL COMPETITIVENESS: PPP, BP AND RELATED INDUSTRIES	
		Functioning of the single market:	Functioning of the single market, in particular when exceptions apply
		Innovation and research:	increase of innovation, research, and technical development in PPP and BP industry, pesticide application industry, food industry, others
		SME's:	Burden to SMEs
		INTERNATIONAL TRADE	
		Import of food:	imports of food potentially affected by lowering the Maximum Residue Levels (MRLs) at the Limit of Quantification - LoQ (technical zero)
		Import of feed:	imports of feed potentially affected by lowering the Maximum Residue Levels (MRLs) at the Limit of Quantification - LoQ (technical zero)
		Import of treated articles:	imports of goods which may be affected as a consequence of implementing the BP Regulation in relation to treated articles
	Social	**HUMAN HEALTH**	
		Hormone related diseases and disorders:	health risks potentially related to hormonal modalities (EATS)
		Transmissible diseases caused by lack of appropriate disinfectants or insecticides:	Health risks caused by lack of appropriate disinfectants (e.g. in hospital settings) or insecticides (e.g. mosquito borne public health treats)
		Food safety:	risk of contamination of food (e.g. by mycotoxins)
	Environment	**ENVIRONMENT**	
		Chemical quality of water:	contamination of ground, surface, and drinking water with ED used as PPP or BP
		Wildlife vertebrate populations:	decrease of wildlife vertebrate populations because of ED mediated effects (e.g. reproduction, sex ratio) as a consequence of environmental exposure to ED
		Animal welfare:	number of animal tests needed

Finally, the MCA-criteria defined were then cross-checked with the Public Consultation Report to ensure that important areas mentioned by stakeholders have not been missed. Furthermore, the MCA-criteria were discussed with the members of the IASG at the meeting of 1st February 2016.

In addition to the MCA-criteria included in the table, serious consideration has been given also to other potential MCA-criteria. Nevertheless, following an analysis of the evidence available it was decided that the quantitative and qualitative findings are not sufficiently robust in order to provide a solid basis for properly ranking the options' performance.

The final result of considering the different aspects mentioned before is illustrated in Table 1.

1.6. Describing the expected performance of each option against the MCA-criteria and scoring the options

Considering the limitations encountered in obtaining fully quantifiable data that would allow the determination of the absolute performance of each option, the options are assessed based on their relative performance. More precisely, it is specified how each option is performing in relation to the other options. In consequence, the options are ranked on a scale. The ranking only indicates if an option has a stronger or a weaker performance than another option, but it does not represent the extent to which an option is performing better/worse than another. Strongest performance means the highest positive impact or the lowest negative impact. Lowest performance means the lowest positive impact or the highest negative impact.

The r*elative performance* of the policy option was evaluated with respect to each MCA-criterion based on the results of the screening, illustrated in Annex 5, and further available specific evidence. The evaluation of the options (indicated as, e.g. B>A>C, meaning B performing better than A, which is performing better than C) and the consideration of the respective additional evidence is detailed in the respective Annexes:

- Achievement of effectiveness and coherence (Annex 8)
- Human Health-Hormone related diseases and disorders (Annex 9)
- Human Health-Transmissible diseases and food safety (Annex 10)
- Environment (Annex 11)
- Sectorial competitiveness: EU agriculture (Annex 12 and 13)
- Sectorial competitiveness: Plant Protection Products, Biocidal Products and related industries (Annex 14)
- International Trade (Annex 15)

For the MCA-calculations, the ranking of the options was entered as an *ordinal scale*. Each value on the ordinal scale has an ordered relationship to every other value on the scale. The values assigned to options performance have no inherent numerical value with respect to magnitude. The least performing option will be assigned a value of 10, with the next options being assigned values in intervals of 10. The size of the interval was selected at 10 only to facilitate calculations. It has no impact on the results. For example, B>A>C, which means that B performs better than A which performs better than C was coded in the MCA-calculations as follows: Option B performs the best and receives a score of 30, Option A is second best and receives a score of 20, and Option C is the worst performing and receives a score of 10.

The differences in values on the scale do not represent differences in strengths of performance. It cannot be inferred that an option scored with 30 is 3 times better than an

option scored with 10. The only inference that can be made is that one option performs better than another on that particular MCA-criterion. Therefore, only a relative judgement can be made, comparing differences in consequences between options, without determining the exact magnitude of those differences.

For ranking the options, the following elements were considered:

1. *"Direction" is not looked at separately*. In Tool #57 of the Better Regulation Guidelines – Multi-Criteria Analysis, it is foreseen that for each MCA-criterion a "direction" will be indicated, whereas "option performance" is only looking at the magnitude of the performance, without considering if it is a negative or a positive impact. Considering that the IA is looking at relative and not absolute performance, the ranking of the options already takes into account the direction of the MCA-criteria. Therefore "direction" will not be considered separately, but only in connection with performance in order to allow for proper ranking of the options. An option that indicates a lower negative impact or a higher positive impact will always rank better than another option that indicates a higher negative impact or a lower positive impact.
2. *Equal performance.* For options that score equally on a certain MCA-criterion, the lower end of the range will be selected to show their performance. This does not exert any influence in the ordering of the options or in the MCA calculations considering that the values do not represent magnitude, they only represent the order. For example, assuming that the four options perform in this order: Option 1 is the best, Option 2 and Option 3 follow, and Option 4 is the worst, the values on the ranking scale would be the following: 40 for Option 1; 20 each for Option 2 and Option 3; 10 for Option 4. Different methods of ranking equal options were also considered – taking the middle point (assigning 25 each to Option 2 and Option 3) or taking the higher value (assigning 30 each to Option 2 and Option 3). However, this does not influence the results in any way because this is an ordinal scale where the values only indicate the order and not the magnitude. Therefore, no matter which method would have been selected, the final result would have remained unchanged.
3. *Dominating and dominated options*. If one of the options has a consistently strong performance (ranks equally to other options on certain MCA-criteria, but performs better than all other options on the rest of the MCA-criteria) or a consistently low performance (ranks equally to a specific option on certain MCA-criteria and on the rest of the MCA-criteria it ranks consistently worse), it will be maintained in the analysis as the purpose of the assessment is not to determine which is the best or worst option, but to consider all options in the analysis and understand how they perform in relation to each other.

1.7. Weighting and sensitivity analysis

According to Tool 57 of the Better Regulation Toolbox, the standard approach in applying the MCA methodology would require first to assign weights to each MCA-criteria, then perform the analysis, obtain the results, and finally carry out a sensitivity analysis.

In fact, it is a recommendation of Tool 57 to complement this type of MCA with sensitivity analysis to determine the robustness of the final ranking to the assumption about the weights given to each MCA-criterion. The Better Regulation Guidelines document supports this approach in section 2.5.3 – "Assessment of most significant impacts" where it recommends that when an assumption is particularly important or uncertain, sensitivity analysis should be used to check whether changing it would lead to significantly different results.

However, a slightly modified approach was followed in the course of this MCA to consider the particularities of this IA. Therefore, the methodology was adapted in order to take into account that, unless making a value judgement e, it was not possible to establish the relative importance of each MCA-criterion/dimension (i.e. horizontal, health, environment, agriculture, trade, etc.) with respect to the other MCA-criteria/dimension.

For this reason, the weighting was carried out through a sensitivity analysis; after identifying the MCA-criteria for each area of impacts (i.e. dimension), the options were compared under four main scenarios (with 2 sub-scenarios being also considered) in order to ascertain how different weights could have affected the overall ordering of the options (sensitivity analysis). A 5th scenario was included in addition, based on two of the previously described scenarios. This scenario 5 includes 4 sub-scenarios which consider a more protective analysis of the options (performance) based on hazard regulatory decision making instead of risk, and also a higher weight on the dimensions of human health and environment.

The following elements were considered in assigning the weights to the different MCA-criteria:

1. *Evidence robustness*. If the available evidence used to assess option performance for the respective MCA-criterion is not considered sufficient or robust enough, the weight of the respective MCA-criterion could be lowered
2. *Equal performance.* If the options have very similar performance levels for a certain MCA-criterion (for example several options register equal performance), the weight of the respective MCA-criterion could be lowered as the MCA-criterion is not instrumental in analysing differences between the options. Nevertheless, if the respective MCA-criterion was considered to be very important, its weight was not adjusted based on this principle.

   If for a certain MCA-criterion all options of aspect I receive equal scores, then the respective MCA-criterion will be maintained if options of aspect II rank differently. The reverse is also valid.
3. *Fulfilment of legal obligations.* If a certain MCA-criterion is very important to the fulfilment of legal obligations (for example obligations assumed in the Treaties or other legal acts, such as the protection of health by application of the precautionary principle), the weight of the respective MCA-criterion could be increased.

The scenarios considered are summarised as follows:

- **SCENARIO 1 - HOMOGENITY:** under this scenario, equal weights were assigned to all dimensions (i.e. impacts) considered: achievement of effectiveness and coherence; sectorial competitiveness: EU agriculture; sectorial competitiveness: PPP, BP and related industries; international trade; human health; environment. For the weights of the MCA-criteria within each dimension, two sub-scenarios were considered:
  - 1/A: within each dimension, equal weights were assigned to each MCA-criterion;
  - 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. The overall availability of evidence was expressed as a value which resulted from the analysis included in the respective annexes.
- **SCENARIO 2 - PRIORITY TO EVIDENCE:** under this scenario, different weights were assigned to the dimensions depending on the overall availability of data/evidence for the respective dimensions. 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. The overall availability of evidence was expressed as a value which resulted from the analysis included in the respective annexes.
- **SCENARIO 3 – PRIORITY TO HEALTH AND ENVIRONMENT:** under this scenario, 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[2]. 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. The overall availability of evidence was expressed as a value which resulted from the analysis included in the respective annexes.
- **SCENARIO 4 - HEALTH FIRST:** under this scenario, 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. The overall availability of evidence was expressed as a value which resulted from the analysis included in the respective annexes.

[2] Retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al32042

- **SCENARIO 5 – AIM: EXPOSURE ZERO:** this scenario considers scenarios 3 (priority to health and environment) and 4 (Health first) as a starting point to examine what would be the effect for the policy ranking of the options considering a regulatory decision making which aims at reducing exposure to chemicals as completely as possible and as a consequence is based on hazard and does not consider risk assessment[3]. It then examines what would be the effect for the policy ranking of the options considered if the initial weight assigned to Health is increased. The resulting 4 sub-scenarios are described as follows:
  - 5/A: as scenario 3 + Hazard based decision making;
  - 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 MCA-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.
  - 5/C: as scenario 4 + Hazard based decision making;
  - 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.

Table 2 provides an overview of the weights corresponding to each scenario, as well as the assessment of the overall availability of data/evidence.

[3] Taking into account hazard based regulatory decision making for the approval of chemicals translates into a change of the relative performance for the following MCA criteria linked directly to ED effects: Hormone related diseases and disorders; Wildlife vertebrate populations and Chemical quality of water.

Table 2. Overview of weights assigned to the MCA criteria according to the different scenarios (sensitivity analysis).

			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	
IMPACTS		Dimensions and MCA-criteria[4]	Weight	Weight	Weight	Weight	Weight	Weight	Weight	Weight	Weight	
EFFECTIVENESS & COHERENCE		**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 PPPs 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 [5]
		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

[4] Note that some criteria names have been abbreviated. See table 1 for complete titles for the criteria.

[5] 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%).

1.8. Combining the weights and the scores for each of the options

Multiplication of the performance and weight gives a weighted performance which allows each policy option to be compared and ranked with respect to each MCA-criterion.

An outranking matrix[6], summarising how one option compares against another for all possible pairs of policy options, was built.

For a given pair of options (say Option A and Option B), the weightings for each MCA-criterion are summed but only for those MCA-criteria where the first option is determined to be better than the second. This sum provides an element (A-B) of the outranking matrix. Only the weightings are added. It makes no difference how much better each option is in respect to another.

In case of equally performing options, two methods were considered for the calculation of the outranking matrix:

- *discarding the ties.* The sum of the element (A-B) of the outranking matrix will include only the weights where Option A is better than Option B. In case they performing equally on a certain MCA-criterion, the weight of the respective MCA-criterion is not added to the sum. This prevents the outranking matrix from being perfectly symmetrical; however this has no impact on the final result.
- *divide the MCA-criterion weight equally between the pairs of options.* The sum of the element (A-B) of the outranking matrix will include the weights where Option A is better than Option B, and only half of the weights for the MCA-criteria on which Option A and Option B are equally performing. This results in the outranking matrix being perfectly symmetrical.

Both methods were discussed and tested with JRC and the final result remains unchanged, no matter which method is used. For the purpose of this IA the second method was used.

For scoring the pairs of ordered options, numerous[7] ways to rank the policy options which must be "scored" using the outranking matrix are available. For example, in the case of three policy options A, B, and C, there are 3! (i.e. 6) different possible rankings (ABC, ACB, BAC, BCA, CAB, and CBA). These are scored by summing the elements from the outranking matrix for each policy pair which make up a given ranking of the policy options (i.e. for the ranking ABC, the policy pairs are AB, AC and BC).

1.9. Analysis of the results

The analyses of the results obtained through the MCA are illustrated in Annex 7.

[6] The outranking matrix is a square 4 x 4 matrix for step 1 when options 1-4 are compared and it is a square 3 x 3 matrix for step 2 when options A-C are compared.

[7] There are 4! (factorial) = 24 possible combinations for step 1 when options 1-4 are compared and 3! (factorial) = 6 possible combinations for step 2 when options A-C are compared.