Council of the European Union

Brussels, 17 June 2016
(OR. en)

10442/16
ADD 9

ENV 440
AGRI 357
SAN 272
MI 464
CHIMIE 41
IA 43

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	16 June 2016
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2016) 211 final - PART 9/16
Subject:	COMMISSION STAFF WORKING 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 Annex 8 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

Delegations will find attached document SWD(2016) 211 final - PART 9/16.

Encl.: SWD(2016) 211 final - PART 9/16

EUROPEAN
COMMISSION

Brussels, 15.6.2016
SWD(2016) 211 final

PART 9/16

COMMISSION STAFF WORKING 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

Annex 8 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

{COM(2016) 350 final}
{SWD(2016) 212 final}

ANNEX 8

ACHIEVEMENT OF EFFECTIVENESS AND COHERENCE

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.

Annexes 8 to 15 describe the impacts expected when implementing the criteria to identify EDs (Options 1 to 4) under the current regulatory framework (Option A). In addition, it was assessed whether these expected impacts would remain the same or not under consideration of different regulatory implementations (Options B and C, only applicable to the PPP Regulation). The analyses of the impacts described in these Annexes translate into the "performance" of the options, which is one of the input parameters to the MCAs (Annex 6 and 7).

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

The current regulatory consequences for substances considered to be endocrine disruptors (EDs) differ between Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012 (see for details Annex II, Section 3.6.5 and Article 4.7 of the PPP Regulation and Article 5 of the BP Regulation). Considering no change to the current decision making (Option A), the following regulatory consequences are foreseen for substances identified as ED:

- non-approval of active substances (BP for general public, most cases for PPP);
- approvals limited to situations where negligible exposure is demonstrated on a case by case basis (some PPP cases);
- approvals limited to situations where negligible risk is demonstrated on a case by case basis (BP professional uses);
- approvals limited to situations where certain socio/economic considerations are considered (PPP to fight a serious danger to plant health; BP professional uses, when the substances is needed to prevent or control serious dangers to human health, animal health or the environment or measures would lead to disproportionate negative effects on society).

In detail, substances having ED properties shall not be approved, unless any of the following derogations is applicable:

- For a Plant Protection Product:
  - *the exposure is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005. […], or*
  - *the substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical method (this provision can only be applied for a maximum period of 5 years);*
- For a Biocidal Product (professional use):
  - *the risk to humans, animals or the environment from exposure to the active substance […] is negligible […], or*
  - *[…]the substance is essential to prevent or control serious dangers to human health, animal health or the environment, or*
  - *not approving the substance would have disproportionate negative impacts on society when compared with the risk […].*

Article 19(4) of the BP Regulation stipulates that a biocidal product having ED properties (i.e. not specifying 'which may cause adverse effects') shall not be authorised for use by the general public.

This regulatory context needs to be considered in each of the sections below.

2. LEGAL CERTAINTY AND PROPORTIONALITY

Legal certainty would – in principle - be ensured by any of the options 1 to 4, since criteria to identify EDs would be in all cases defined in the context of Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012. This also applies to any of the options A to C, once they are defined in the respective legislation. However, it can be expected that some options may be inconsistent with the World Trade Organization (WTO) agreement, which was ratified by the EU, thus triggering consequence at international level or in front of the EU courts (see sections below).

Both the PPP and the BP Regulations entered into force recently and provide for transition periods in order to facilitate the transition from the previous legal rules. As a consequence, experience applying the derogations mentioned above is still scarce thus leaving uncertainty on the practical implementation of the regulatory consequences for EDs active substances.

For instance, technical guidance on how to interpret the wording "negligible exposure" in section 3.6.5 to the PPP Regulation is currently under discussion within the Standing Committee for Plants, Animals, Feed and Food (PAFF) after having consulted Member States (MS) and EFSA experts as well as stakeholders. Further, the European Food Safety Authority (EFSA) has been mandated for particular active substances to assess negligible exposure and to consider whether is it possible to grant derogations on the basis of Article 4.7 of the PPP Regulation regarding the need to control a serious danger to plant health. However, the experience gained during the progress on these mandates has shown that further discussion between EFSA and MS is needed in order to assess the concrete impact of these provisions. In fact, as demonstrated by the recent discussions at the Standing Committee PAFF concerning PPP, the implementation of these derogations is complex and still needs considerable discussions among MS and the European Food Safety Authority (EFSA) in order to draw a way forward. All this creates a situation of uncertainty to applicants, stakeholders, and MS when it comes to concrete cases of decision making (approval/non approval) regarding a particular active substance. Regarding the implementation of the derogations for BP active substances, it is so far not clear how MS would decide in case they would be applicable.

Based on the rationale explained in the previous paragraph, some options are linked to legal uncertainties (in particular Option A). Consequently the more derogations may be applied for, the higher the potential uncertainties. As a consequence, it can be concluded that the more substances identified as EDs, the more uncertainty to applicants and stakeholders could be expected due to the application of the case-by-case derogations. This implies that the options would be ranked like 4 > 2/3 > 1 based on the results of the screening, and C > B > A based on the fact that Option C (consideration of socio/economic elements) would lead to less non-approvals than Option B (consideration of risk elements) and Option A (decision making mainly based on hazard).

In addition, **Option 3** introduces the concept of **additional categories**, i.e. Category II and III. These additional categories would have no regulatory consequences but would identify substances so called "suspected EDs" (Category II) and "potential EDs or endocrine active substances" (Category III). In particular, substances would fall under Cat II when there is some evidence that they may be EDs, but the evidence is not convincing for instance because

of poor data quality. Substances would fall under Category III when there is some evidence of an endocrine mode of action but no evidence of an adverse effect.

However, using categories similarly to those used for classification under Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation) may lead to confusion. It may be misinterpreted that substances categorised under the criteria to identify ED as Category II or Category III are classified as such under the CLP, while this is not the case. The criteria to identify EDs were mandated by the legislators only for PPP and BP. It is assumed that if the legislators would have intended to classify and label all chemicals, they would have initiated such process under the CLP Regulation, which was not the case so far. Thus, using categories could be considered as expanding the scope of the mandates given under the PPP and BP Regulations. Further, it may be confusing with respect to other overarching pieces of EU legislation (CLP), and thus negatively affect legal certainty and operability.

Furthermore, the categories foreseen under Option 3 (Cat I, II and III) do not follow the same rationale as those used in the Regulation CLP. For instance, under the CLP Regulation, carcinogen substances are classified as Cat IA (confirmed carcinogen, evidence based on human data), Cat IB (carcinogen, evidence based on animal data) and Cat II (suspected carcinogen). Under Option 3, no distinction between categories Cat IA and Cat IB would be realised because human data on EDs are missing. Instead, Cat III is created additionally (potential EDs or endocrine active substances). From the different kind of categories used, it appears that EDs are not yet ready to be classified under the CLP Regulation, as it was done for mutagens, carcinogens and substances toxic for reproduction, and may be thus not proportionate at this point in time.

It may be considered that "flagging" through the criteria for identification of EDs all substances that are “suspected EDs” or “potential EDs” would be a benefit. For instance, it has been claimed that “potential concerns” would be identified through the legislation and that assessors would not be forced to choose between ED and non-ED, but they would be provided with intermediate categories for classification, in analogy with the system under classification and labelling of Regulation 1272/2008. However, in the context of the PPP and BP Regulation, no system for categories is in place. If the legislator's intention was to align EDs classification with the system under Regulation 1272/2008, this would have been specified. Thus, defining additional measures which are not regulatory and, so far, not provided in the legislation would imply a considerable degree of legal complexity, with no regulatory added value. In addition, such approach might go beyond what is necessary to reach the objective of protection of human and animal health that the EU co-legislator put into effect in the PPP and BP Regulations. As a consequence, a measure that would "flag" not only “EDs” but also “suspected EDs” or “potential EDs” might breach the proportionality principle. Such regulatory actions do not seem necessary and would likely determine fear in consumers′ minds towards substances that are safe, but labelled as “suspected or potential EDs” thus altering consumers behaviour and market share, while not introducing any added value for health and environmental protection. In fact, such additional categories could be used easily by media to generate mistrust of consumers towards certain products.

In addition, the creation of additional categories may lead to different interpretation among the MS during the assessment of active substances, or the authorisation of PPP and BP, decreasing as a consequence harmonisation in the EU with respect to the decision making regarding PPP and BP. In fact, it is reasonable to wonder which would be the regulatory consequences of these “suspected EDs” or “potential EDs” in the procedure for granting products authorisations at national level. In the absence of any reference in the legislation, it is likely to foresee that MS would take different approach in the evaluation of products containing such substances. This would hinder principles of the legislation in place, such as the mutual recognition of products under the PPP Regulation, and therefore will be in contradiction with the objectives of "strengthening the functioning of the internal market", without introducing any benefit for the objective "ensuring a high level of protection to human health and the environment" as no regulatory consequences are set in the legislation for Cat II and Cat III.

Under consideration of this additional factor, the options are ranked as 4 > 2 > 1 > 3 based on the results of the screening, and C > B > A based on the fact that Option C (consideration of socio/economic elements) would lead to less non-approvals than Option B (consideration of risk elements) and Option A (decision making mainly based on hazard).

3. OPERABILITY FOR REGULATORY DECISION MAKING

As mentioned above, the PPP and the BP Regulations entered recently into force and, as a consequence, experience in applying the derogations present in both regulations is scarce. Recent discussions at the Standing Committee for Plants, Animals, Feed and Food (PAFF) concerning PPP showed that the implementation of these derogations is far from reaching an operable stage because it still needs considerable discussions among MS and the European Food Safety Authority (EFSA).

It is also clear that the implementations of the derogations provided in Annex II, point 3.6.5 and Article 4.7 of Regulation (EC) No 1107/2009, are increasing the burden to national and EU administrations with respect to the standard risk assessment procedures, which were in place before the approval criteria ("cut-off" criteria) defined in the same Regulation were implemented. This is because the derogations mentioned above are applicable if a substance is falling under point 3.6.5 (the substance is identified as ED). However, even when a substance is identified as an ED and derogations are applicable, a full risk assessment will always be needed to verify whether a decision on approval can be taken. As a consequence, the cut-off criteria for EDs are not necessarily simplifying the decision making, but adding additional assessments. Thus, it can be expected that the more substances are identified as EDs, the more administrative burden is created to verify the applicability of the derogations. As foreseen in Article 82 of the same Regulation, the Commission is intending to present a report on the functioning of these and other provisions introduced by Regulation (EC) No 1107/2009.

In summary, it can be concluded that the more substances are identified as EDs, the higher operability difficulties and additional burden may be expected because of the application of the case-by-case derogations. This implies that the options would be ranked as 4 > 2/3 > 1, and C > B > A.

Option 3 introduces the concept of **additional categories**, i.e. Category II and III with no regulatory consequences, as detailed above in Section 1 in this annex. It is uncertain in the context of the PPP and BP legislation how these categories would be made operable. The legislation does not provide for a framework of categories with no regulatory consequences in addition to the substances identified as EDs but approved under the foreseen derogations (see above), which would be listed as "candidates of substitution"[1]. In addition, using categories similarly to those used for classification under Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation) may lead to confusion and thus negatively affect operability, as explained in the previous section. Further, the creation of additional categories may increase the burden to administrations and applicants, which would add to the implementation of derogations for the options which have regulatory consequences.

Under consideration of this additional factor, the options are ranked as 4>2>1>3 and C>B>A.

4. COHERENCE BETWEEN BP AND PPP LEGISLATION

As detailed above, the regulatory consequences for substances identified as EDs under the BP Regulation and the PPP Regulation are different. This seems in contradiction with the aim to present harmonised criteria for PPP Regulation and BP Regulation, as they would only be harmonised if they would be implemented following similar scientific principles.

The BP Regulation was adopted three years after the PPP Regulation. In the PPP Regulation, the derogation on negligible *exposure* is provided for in a long and complex sentence which is also giving examples. This sentence is raising controversial discussions among MS and stakeholders, so that a common interpretation has not yet been agreed because of differences in the technical interpretations. The corresponding derogation on negligible *risk* in the BP Regulation is provided for in a much shorter and clearer sentence, which seems easier to interpret from a technical point of view.

In addition, as regards EDs, European scientific committees have recently concluded that risk assessment makes best use of available information on EDs and that these substances *can therefore be subject to risk assessment and not only to hazard assessment* (EFSA Opinion 2013 on EDs, SCCS Memorandum on EDs, 2014).

As a consequence, coherence between provisions for EDs under the BP and the PPP Regulations would be given if the same criteria would be applied to scientifically similar derogations (e.g. aligning negligible exposure and negligible risk) or socio/economic derogations. This alignment would also have the benefit of a simpler and clearer text for the PPP Regulation, if aligned with the BP Regulation.

Based on this rationale, the options are ranked based on the number of substances identified under each option (for Options 1 to 4), and based on the regulatory decision making (Options A to C), as follows: 4 > 2/3 > 1; and C > B > A.

[1] "Candidates of substitution" are approved for a shorter period of time and it is required to carry out a comparative assessment before authorising a PPP or BP, in order to verify if a better alternative PPP or BP is available. See Article 24 in Regulation (EC) 1107/2009.

5. INTERNATIONAL OBLIGATIONS (WTO AND CODEX ALIMENTARIUS)

Several respondents to the public consultation (mostly public authorities from third countries) highlighted the potentially significant trade implications of setting criteria to identify EDs and asked for a risk-based approach to be taken. They indicated that any decision on the criteria to identify EDs must respect the principles of international law, including certain Agreements of the WTO.

The EU must respect its international obligations while exercising its powers.[2] Therefore, any measures taken by the EU institutions shall be consistent with provisions of international law that are binding the EU, such as customary international law and treaties ratified by the EU[3].

The European Union (EU) and its 28 EU MS are members of the WTO and hence need to comply with its agreements: in this matter with the Agreement on Technical Barriers to Trade (TBT Agreement) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

The TBT Agreement aims at ensuring non-discrimination in the adoption and implementation of technical regulations and standards.

The SPS Agreement sets constraints on WTO Members' policies restricting the use of unjustified sanitary and phytosanitary measures for the purpose of trade protection. Article 2.1 of the SPS Agreement states that "*Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement*". Further, Article 2.2. states that "*Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5".*

The TBT and SPS Committees meet regularly, three times per year. In the TBT and SPS Committees the issue of EDs was raised by the US for the first time in October 2013 and in March 2014 respectively. Since then it has been discussed, in one form or another, at every TBT and SPS Committee meeting.[4]

Overall, the pressure on the EU is mounting as demonstrated by the growing number of WTO Members taking the floor to express concerns or to question the EU's work on defining the criteria to identify EDs.

At the SPS Committee meeting in October 2015 a Specific Trade Concern was raised against the EU jointly by the US and Argentina, supported by 21 other countries (Brazil, Burkina Faso, Canada, Chile, China, Colombia, the Dominican Republic, Egypt, India, Jamaica, Kenya, Madagascar, Malaysia, Mexico, Nigeria, Paraguay, Peru, Senegal, Sierra Leone, and Vietnam).

[2] See e.g., ECJ, case C-286/90, Poulsen, [1992] ECR I-06019, para. 9; and ECJ, case C-162/96, Racke, ECR [1998] I-3655, para 46.
[3] See e.g., Joined Cases C-21/72 & C-24/74, International Fruit Company, [1972] ECR I-1219.
[4] The summary reports of these meetings can be found on the WTO website:
TBT Committee: https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm;
SPS Committee: https://www.wto.org/english/tratop_e/sps_e/sps_e.htm

This situation is unprecedented in the SPS Committee and is expected to continue in the future, which makes the EU position very difficult.

In the SPS Committee the main concerns and requests of WTO Members to the EU are the following:

- questioning the scientific evidence underlying the options, and the consideration of any hazard-based "cut off" option instead of risk from actual exposure;
- claiming that none of the options outlined by the EU in its roadmap appeared to take risk into consideration, as required under WTO obligations. The proposal, as drafted, could thus impact billions of dollars of trade worldwide and potentially result in the withdrawal a large number of substances, as well as the products that contain them, from the EU;
- stating that the EU's hazard-based approach could disrupt trade and unnecessarily create a level of uncertainty among exporting countries, while increasing costs for agricultural and agri-food stakeholders in both the EU and exporting countries;
- requesting the EU to recognise risk-based endocrine programmes developed by other countries;
- asking that special attention should be given to minimising adverse impacts on international trade and especially on trade in agricultural products, but also to minimising socioeconomic losses in commodity-producing countries, in particular developing countries;
- encouraging the EU to publish the draft legislation, once developed, including any risk and impact assessments carried out;
- asking that future actions should be taken on a case-by-case basis and based on solid scientific evidence after appropriate risk assessment;
- calling for continued transparency and for evidence-based and risk-based decision-making;
- encouraging the EU to adhere to relevant international standards and to keep informing the Committees of any relevant developments;
- asking that the measure should be compatible with the TBT and SPS Agreements and non-discriminatory.

Article 5.1 of the SPS Agreement states that "*Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.*"

Relevant EU legislative drafts need to be notified to the WTO[5] to allow Members to become familiar with the measures and to provide opportunity to present their observations. The comments from the EU's trading partners need to be taken into account, whenever justified, before the final legislation is eventually adopted. The WTO also provides for a procedure for resolving trade quarrels under the Dispute Settlement Understanding. A dispute arises when a member government believes another member government is violating an agreement or a

[5] See Article 7 and Annex B of the SPS Agreement, available on: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm, and Article 10 of the TBT Agreement, available on: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

commitment that it has made in the WTO. When a case is decided, the ultimate goal for the country is to comply with the ruling.

The unprecedented broad coalition of WTO Members challenging the EU policy when setting criteria to identify EDs strongly suggests that, depending on the final decision, formal WTO dispute could be expected.

Further, the Commission contributes to the development of international standards which underpin food law, for instance the harmonised international food standards in the context of the Codex Alimentarius. International standards are a key element in ensuring the safety and quality of food in international trade. Codex is the pre-eminent body setting standards to ensure consumer health protection and fair practices in food trade. The status of Codex as an international standard-setting body in the field of food safety is recognised in two key WTO agreements: the Agreements on the Application of Sanitary and Phytosanitary Measures and on Technical Barriers to Trade.

The **Codex Alimentarius** or "Food Code" was established by FAO and the World Health Organization in 1963 to develop harmonised international food standards, which protect consumer health and promote fair practices in food trade. It recommends, inter alia, Maximum Residue Limits (MRLs) of pesticides in food and feed. These MRLs are based on risk analysis principles, which are evaluated and reviewed as appropriate in the light of new generated scientific data. The risk analysis should follow the structured approach comprising risk assessment, risk management, and risk communication. Each of these steps should be fully and transparently communicated.

Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law in accordance with Article 5 of Regulation (EC) No 178/2002. Further, Article 13 of the same regulation says that without prejudice to their rights and obligations, the Community and the MS shall, inter alia:

- contribute to the development of agreements on recognition of the equivalence of specific food and feed-related measures;
- give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;
- promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.

As provided for in Regulation (EC) No 396/2005, the Community's trading partners should be consulted via the WTO about the MRLs proposed. MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being set, taking into account the corresponding good agricultural practices.

Against this background, it can be concluded that the more an option is hazard-based, the less it will be compliant with WTO and the worse performing it will be in the MCA analysis.

For assessing options 1 to 4, this argumentation considers only Option A of the roadmap (the current decision making applicable to the PPP and BP sectors remains unchanged). It is

mainly valid for the PPP sector as in the BP sector, the current decision making already considers risk/socio economic assessments, except for BP destined to consumers.

In this context, options 1, 2 and 3 are all based on the identification of hazard. However, Option 4, by including potency, which is one of the elements of hazard characterisation, goes one step further in the direction of risk assessment. Therefore, it can be considered that among the four options, Option 4 will perform comparatively better than the others in terms of compliance with WTO rules, i.e. option 4 > 2/3/1.

For assessing options A to C, the focus is on the PPP sector, because in the BP sector the decision making considers derogations with risk/socio economic elements, except for BP destined to consumers.

In Option A, the decision making is mainly based on hazard, while Option B considers the inclusion of further elements of risk assessment in the PPP sector (e.g. aligning PPP Regulation derogations on negligible exposure to BP Regulation derogation on negligible risk). Option C introduces elements of socio economy in the PPP sector, which would go beyond risk assessment. Therefore, the options regarding decision making would perform B/C > A.