EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)7413111

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 18 NOVEMBER 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/0925c754-ae28-4ecd-9a8a-c914eb078408*

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/…of XXX setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009.

The Commission welcomed participants and informed that the objective of the meeting was to present a revised text for the draft implementing act on the criteria, and that a meeting focusing on the draft act under the biocidal products Regulation took place during the morning. 27 Member States (MSs) were present.

Written comments on the revised criteria were received from four MSs prior to the meeting. The Commission informed that they will consider the comments received applicable to both biocides and plant protection products acts, as the criteria should be the same, unless otherwise indicated. Two MSs confirmed that their comments were relevant for both BP and PPP.

The Commission reminded that a proposal for the criteria is available since June 2016, i.e. 5 months, and that therefore the preliminary positions of all MSs will be requested at the end of the meeting.

1. General presentation of the revised draft criteria by the Commission

A revised text for the criteria was made available two weeks before the meeting. The overall principle has not been changed, i.e. the criteria neither consider categories nor potency. The amendment to point 3.6.5 of Annex II to the PPPR is maintained. The Commission has clarified the scope of the WHO definition by following strictly the wording of the WHO definitions. The wording "may cause adverse effect" has been reintroduced in order to maintain the original wording of the legislation. On the section referring to the kind of scientific evidence to be used, the word "primarily" has been removed to clarify that no hierarchy is given for the evidence to be assessed; however, the two sub-points related to the kind of scientific evidence to be used are

kept separate to acknowledge the fact that studies according to agreed study protocols will always be available because they are mandatory due to the data requirements.

The Commission presented the changes in the text paragraph by paragraph. For instance it was explained that the new recital 5 was added to provide a justification for the changes in point 3.8.2. There are no changes to the articles.

Concerning the annex (draft criteria), it was explained that a better link is made between the first part of the text (three elements of the WHO definition of an ED, the "three commandments") and the second part (principles on how to implement the criteria). Further to the changes already mentioned, to follow more closely the WHO definition the three elements of the WHO definition of an ED have been redrafted accordingly.

Concerning the environmental section of the criteria, there is a new point added (3.8.2.1 which is the current text as it is in the annex, in order to have the same structure of the criteria for the sections on human health and environment). Further, the word “population” has been changed into “(sub)population” where appropriate in the text. Reference to field and monitoring data was redrafted because it would be inconsistent to neglect this evidence if on the other side it is asked to consider all available evidence.

2. Discussion on the draft criteria

One MS insists that the words "known and presumed" and "plausibility" are added in the 3 "commandments".

Another MS thanked the Commission for the major redrafting and acknowledges that most comments have been taken on board. This MS indicated that its comments relate to the PPPR but would like to apply them also to the BPR in order to follow the approach "one substance = one assessment". That MS asked for more in depth information on the legal arguments concerning the PPPR amendment, going beyond what had been summarized in the minutes of the last meeting. That MS reminded that during the last meeting in the Council, some MSs were very positive hearing that the Commission will make the utmost to make sure that a guidance document is developed in parallel to the process for adoption of the criteria.

Another MS thanked the Commission for the revised text, which is an improved version of the previous one but which does not address all concerns. That MS would like to maintain the concept of "negligible exposure". That MS would also like the words "known or presumed" and "plausible endocrine mode of action" to be included in the three elements of the WHO definition.

One MS indicated that many of its concerns had been addressed with the revised drafts. That MS stressed the need for a guidance document as an essential step to move forward for MSs to be able to assess EDs. It indicated that his ENV and AGRI Ministers had asked in the Council for a working group that would include MS experts because they are those who will have to implement the criteria. That MS also

mentioned that they would like regular updates on the guidance documents and the timelines.

Another MS indicated its preference for the words "known and presumed" to be included, for "negligible exposure" rather than "negligible risk" and stressed the need of a guidance document in which experts from MS would be involved. This MS also indicated being in favour of categories.

Another MS recognised the improvements made to the text by the Commission. This MS indicated being in favour of categories. It also would like the words "known and presumed" and "plausibility" to be added.

According to another MS, the "may" implies possibility and it might be interpreted by some parties as covering categories 1, 2 and 3 outlined in the roadmap (i.e. including also potential endocrine disruptors or endocrine active substances). That MS wanted to know whether this was the intention of the Commission and warned this would have huge impact in terms of number of substances affected.

One MS indicated that the changes made in the text in relation to the precautionary principle were satisfactory but it still considered that the Commission had gone beyond its mandate.

Another MS would like the words "known and presumed" and "plausibility" to be added. This MS indicated being in favour of categories.

One MS welcomed the new text and the use of the WHO definition of an ED. This MS supported the reintroduction of the words "may cause" but would like the words "known and presumed" and "plausibility" to be also added.

One MS indicated its general support for the current proposal of the Commission and the amendment made since last meeting but stressed the need of a guidance document as soon as possible.

Two other MSs confirmed the text was better now and expressed its support for it. These MSs also stressed the need of a guidance document as soon as possible.

One MS had drafting suggestions: some words are redundant and could be deleted.

Two MSs asked to which guidance the systematic review was referring to and the Commission clarified it was the guidance on systematic review that is also mentioned in the communications from the Commission.

One MS stated that the words "may cause" can imply a lower burden of proof but this MS could accept this. According to this MS, the categories' approach is difficult to reconcile with the PPPR. A guidance document is required but they understand the argument of the Commission that a guidance document cannot be finalized and noted before the criteria are adopted. This MS is generally supportive of the draft. This MS indicated that the "plausibility" issue was already covered in the rest of the text.

One MS thanked the Commission for its efforts: the texts had been updated on the basis of its comments. That MS had no final position yet as national internal discussions were still ongoing.

One EEA country asked how the Commission would deal with substances where there is some evidence for an endocrine mode of action or an adverse effect, but this evidence is insufficient for their identification as ED. For this MS, it is unclear what the words "shows an adverse effect" mean.

One MS thanked the Commission for the revised drafts. It agrees with the words "shows an adverse effect" and agrees not to mix the language used in the criteria on EDs with the language of the CLP. In the taxonomic groups listed as examples, this MS suggested to include also amphibians but mentioned this is a minor comment. This MS expressed its support for the criteria.

For one MS, the majority of the text seemed satisfactory. In the environmental section of the criteria, that MS wants to refer to "non-target vertebrates" rather than "non target organisms". If the text is unchanged, useful and safe PPPs like insect growth regulators and plant hormone inhibitors (e.g. gibberellins) may be removed from the market because identified as EDs. This MS mentioned it could not believe this was the intention of the Commission proposal. This comment was supported by another MS, in particular because these active substances are of great importance for Integrated Pest Management (IPM). The same MSs can agree with two other MSs that the words "may cause" might widen the scope of the criteria. This would be counterproductive because the criteria would identify too many substances, having as a consequence that natural toxins may rise and harm human health. This MS stressed the need of a guidance document.

One MS indicated that the revised draft does not reach the adequate level of protection. "Negligible exposure" rather than "negligible risk" is supported.

Concerning the mandate, the Commission indicated that the reply letter of Commissioner ANDRIUKAITIS to MEP LA VIA has been published on the Commission's website and clarifies the position of the Commission.

Concerning the guidance document, the Commission indicated that an outline is expected from the agencies by the end of this year. The Commission will report to this group. The mandate has been published on the Commission's website. ECHA and EFSA started already working on the mandate.

Concerning the three elements of the WHO definition of an ED mentioned in the draft criteria, the Commission explained it reflected very closely the WHO definition. The word "plausibility" is not mentioned in the WHO definition, and the intention is to stick to the WHO definition and not to modify the WHO definition. The same is valid for the words "known and presumed", which are not mentioned in the WHO definition but come from the CLP Regulation. It was clarified that if the words "known and presumed" were used, this could create confusion with the CLP. Commission reminded that the role of the criteria put forward with the draft legal acts is to identify EDs (in the context of the PPPR and BPR) and not to set categories for their classification labelling and packaging. It was also clarified that it was not the

intention to cover categories 1; 2 and 3 with the words "may cause an adverse effect", but that the "may…." is already in the legislation and merely copied.

Concerning substances where there is some evidence for an endocrine mode of action or an adverse effect, but this evidence is insufficient for their identification as EDs, the Commission indicated they would still undergo a normal risk assessment and if there is a concern, they will not be approved. There is therefore no legislative gap.

The Commission explained again the reason why it did not choose categories: the PPPR and BPR only require the Commission to give a yes/no answer on whether a substance is an ED or not. In fact, clear regulatory consequences are set in these two regulations for substances identified as ED. On the contrary, no regulatory consequences are foreseen for substances that would be classified as suspected EDs (category 2) or endocrine active substances (category 3). The Commission has no mandate to set these consequences with the proposed legal act. The Commission also clarified the "known and presumed" terms in CLP: "known" refers to evidence from human studies and "presumed" refers to evidence from animal studies (categories 1A and 1B in the CLP, respectively). The Commission has chosen the words "shows an adverse effect" which will cover both "known and presumed" in the sense of the CLP, being at the same time a more neutral term which avoids confusion with the CLP.

The Commission indicated that the comment on the "non-target vertebrates" could not be addressed for the moment but would be reflected upon.

One MS was in favour of putting the second part of the criteria (the principles on how to implement them) in a guidance document because it believes that by leaving them in the legal text, it will be more difficult to update them later.

One MS indicated it would send further comments in writing.

One MS indicated they would leave the wording "target organisms" rather than changing it to "target vertebrates", but acknowledge this issue is important and suggested to solve it by adding a clear exception for substances whose target mode of action is via endocrine mode of invertebrates or plant hormonal systems. Another MS indicated this as an important issue where they would need to come back.

3. Discussion on the amendment to point 3.6.5 of annex II to Regulation 1107/2009

One MS disagreed with the amendment and indicated that it was not about the substance but that it believes the Commission is going beyond its mandate. For residues, the change is sensitive and because of this it disagrees.

Five other MSs believed the Commission was going beyond its mandate. One MS did not support the change for procedural reasons. One MS indicated this change is a political one and consistency should be kept with CMRs.

One MS stressed it was important to know what are the consequences of the amendment are and wanted to know whether the hazard based approach of the legislation concerning EDs was changed or not.

One EEA country did not support the amendment.

The Commission explained that there was no change to the hazard based approach. The change is in the technical implementation of the derogation, in light of current scientific and technical knowledge. The proposed amended text is not completely new but adapted inspired by the BP legislation which is more recent.

The Commission reminded that if an ED is approved under this derogation, it will be a candidate for substitution, which means a shorter period of approval, under restricted conditions of use, with the obligation of carrying out comparative risk assessments of the plant protection products by MS and with no mutual recognition.

The Commission reminded it is convinced that it has the legal mandate to propose this change, as it is explained in the reply to the letter sent from Commissioner Andriukaitis to MEP La Via, which is published on the Commission website.

One MS was satisfied with the clarification and said that it could agree now to this change.

One MS disagreed with the clarification provided and indicated that this was a political change. The opinions from the scientific committees quoted refer to risk assessment whereas the issue at stake is risk management.

One MS indicated its strong support for the Commission's proposal to amend point 3.6.5 with regards to negligible risk.

The Commission informed that there was recently an information session on EDs with third countries (WTO) and this was the only main element discussed. During the notification process to TBT/SPS, a total of 17 replies were received, most of them expressing concerns about "negligible exposure".

One MS reminded that article 78 of the PPPR talks about non-essential elements. For this MS the change is about essential elements.

4. Discussion on the recitals and main text

One MS stressed the importance of having transitional arrangements because there will be important consequences for active substances already in the approval / renewal process. There is also concern about the information which would be provided by the applicant. Recital 11 is not adequate for this MS.

One MS wanted to know why recital 8 no longer referred to experience from REACH.

The Commission explained that recital 8 referred to the proposed amendment to point 3.6.5. On the transitional period: it was clarified that it was a political decision. The Commission also reminded that until the new criteria are applicable, the current interim criteria continue to apply and they are clearly not fit for purpose nor supported by stakeholders or MS.

One MS required further details about the WTO meeting.

One MS asked what would be the next steps in terms of procedure.

The Commission outlined the WTO comments and the outcome of the information session organised by the Commission on request of 3rd countries in Geneva the 26 of October. There the Commission presented and explained the draft criteria under the PPP Regulation presented in June 2016. The main concerns raised by third countries during the notification and during the information meeting were the hazard based approach concerning the regulation of EDs at EU level (they consider that this is not in line with the SPS agreement), the impacts this would have on international trade but also agriculture.

5. Conclusions

In the final tour de table:

- 5 MSs indicated that they could support the proposed text
- 6 MSs indicated that they were against. 2 of them indicated they were against because of the expected impact on agriculture of the criteria
- 4 MSs indicated they would abstain if they had to vote. One of them indicated they could move to "support" of the text, given the clarification on the derogation provided
- 7 MSs had no final position yet. One MS indicated that they would abstain if they do not find agreement internally, between the various agencies involved
- 6 MSs were absent at the moment of the tour de table

Delegations were asked to submit comments on the revised drafts by 30 November 2016.

M.01 Date of next meeting.

The date of the next meeting is not yet defined.