EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2017)1691319

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 28 FEBRUARY 2017

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/5f729d18-d852-4a32-a00e-4bebaa0bbb2c*

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

The Commission reminded that this is the fifth time this proposal is discussed in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). Again, a back to back meeting with the Member States' Competent Authorities meeting was foreseen in the afternoon, where the draft delegated act on biocides was also discussed for the fifth time.

No Member State required modification to the agenda, no points under AOB were required.

The Commission recalled that it had initially proposed both the criteria and the technical amendment in a single draft act. Following the discussions with Member States, it separated the initial proposal into two texts, which were both presented in December 2016. The reason for the split was to offer the Member States, and later on the European Parliament and the Council, the possibility to express opinions separately on each of the two drafts. The discussions in the meeting of December 2016 confirmed the difficulties to take a decision on the criteria even with the text being split. Furthermore, the legal basis of the Commission to propose the technical amendment has been challenged, not only by some Member States in the PAFF Committee, but very vocally by the European Parliament. The Commission has made it clear since the beginning that it is convinced about the legality of the proposal.

The Commission believes that it is important to terminate the current situation of uncertainty, where interim criteria are applicable which are not fit for purpose (as confirmed by the Commission's impact assessment) and not supported by Member States, stakeholders and scientists. This is why it has been decided to first progress with the draft establishing the criteria and, at a later stage, with the technical amendment. With this approach, it should be ensured that discussions in the Council

and the European Parliament during the scrutiny period can focus on the scientific criteria alone.

Bilateral discussions with several Member States over the last few weeks have revealed some misunderstandings about the scrutiny process and in particular about the consequences in case the Parliament and/or Council object to the draft measures. The Commission provided an overview of the procedures for the adoption of the criteria under the plant protection product regulation (PPPR) and the biocidal product regulation (BPR), respectively.

1. Regulatory Procedure with Scrutiny (RPS), also known with the French acronym PRAC (Procédure de Réglementation Avec Contrôle)

This is applicable to the pesticide draft for establishing the criteria (and also for the technical amendment). The text(s) would be proposed for a vote in the PAFF Committee.

In case a qualified majority (QM) is achieved, the Commission submits the draft to the Parliament and Council for a 3 month scrutiny period. If, during this period, one or both of the institutions oppose, the Commission shall not adopt the measure (i.e. the outcome is binding for the Commission - unlike in the resolutions adopted by the Parliament on e.g., glyphosate and bentazone). Subsequently, the Commission may submit an amended draft to this PAFF Committee or present a legislative proposal.

In order to oppose, the Parliament has to act by majority of its component members and the Council by QM. When opposing, the institutions have to indicate that the draft measure either: a) exceeds the implementing powers provided for in the basic instrument; or b) is not compatible with the aim of the basic act; or c) does not respect principles of subsidiarity or proportionality.

In case of no opposition, the Commission adopts the measure, which will be published and subsequently enter into force.

2. Scrutiny procedure for delegated act

Establishing scientific criteria under the BPR follows a different procedure. because it is a delegated act. Unlike for the PRAC draft measure foreseen in this PAFF Committee, there are no votes on draft delegated acts. The Commission has to inform the experts of the conclusions that it draws from the discussions, of the Commission's reactions and of how it intends to proceed. At the end of the consultation with experts, the Commission adopts the delegated act before it is submitted to the Parliament and the Council for scrutiny.

In case the Council and/or the Parliament do not object against the delegated act, the measure will be published and enter into force. The standard scrutiny period is 2 months, but the Council and/or the Parliament can request an additional 2 months extension.
In case the Council and/or the Parliament object, the delegated act cannot be published and does not enter into force. In this case, the Commission may prepare a

new proposal. The reasons for an objection are not defined but the institution must explain, but it is not bound to, the three reasons indicated for the PRAC procedure.

Analogously to the RPS/PRAC, the Parliament objects with majority of component members, the Council with QM.

3. Final remark on procedures

The Commission reiterated that it aims to have the same criteria for pesticides and biocides and reminded that these are the only sectors where the Commission has a legal mandate to establish criteria. Therefore, all discussions have been conducted back to back and in full transparency.

The Commission has fulfilled, although late, its legal obligation under Regulation (EC) No 1107/2009, which required that a draft is submitted to this PAFF Committee. However, the Commission continues not to meet its legal obligations under the BPR, where it is asked to adopt a delegated act. The Commission has been brought to the EU General Court which declared the failure to act. The Commission has had several rounds of discussions with experts on the draft delegated act. Nevertheless, it continues to be in breach of legislation. The Commission will certainly not be in a position to uphold this situation for long. The draft presented at this PAFF Committee is more or less identical to the delegated act which will be discussed with the biocidal experts. The Commission believes that this text is mature, stable and proportionate and reflects the widest support possible.

The Commission presented the changes introduced in the last revised version of the criteria. These changes had been agreed with the Member States at the last meeting of this PAFF Committee on 21 December 2016. These changes are:

- Recital 5 clarifies the reasoning for the provision on growth regulators (i.e. the clarification of scope).
- Recital 6 explains the rationale for the review clause and Article 3 is adding the review clause.
- A small change in Recital 7 was added to motivate the insertion of the transitional period of 6 months and Article 4 has been modified to take the transitional period into account
- In the annex: the 1st paragraph of the part on human health, the term "information" has been substituted with "evidence". In the second paragraph, the bracket detailing the kind of scientific data to be evaluated has been moved up (no change in content). Point 1.4 has been deleted at the request of some Member State because the same sentence is already stated under point 1.
- In the part on environment, the very same changes were introduced and in addition the term "amphibians" was added to the examples listed in brackets under point 2(2)(a). Finally point 4 was agreed with Member States at the meeting on 21 December 2016. The taxonomic level was added at the request of some Member States.

Written comments on the current proposal were received from five Member States and one EEA country. Since these comments raised some concerns, the Commission repeated why the terms "known and presumed" are not included in the draft text, by

comparing and explaining the terms used in the Regulation on classification, labelling and packaging (CLP) and in the criteria (Point (1)(1) to point (1)(3) in Section 1 and 2 in the Annex, also called "the commandments"). The Commission clarified again that the criteria are not introducing a classification in the sense of the CLP Regulation and this is why the terms are not used. However, the criteria and level of evidence and kind of studies required for the identification of endocrine disruptors are the same as the one requested for the classification of substances (e.g. carcinogenic and toxic for reproduction) in the CLP Regulation. Therefore, the criteria allows identification of endocrine disruptors of equivalent concern or level of evidence as those "known and presumed" in the sense of the CLP Regulation.

Furthermore, the rationale behind the provision on active substances with intended endocrine mode of action (below called growth regulators (GR)) was explained. It was reminded that if a substance is not identified as an endocrine disruptor, it will always undergo a full risk assessment as regards human health and the environment. The provision on GR allows that the cut-off criteria will not be applied to substances with an intended endocrine mode of action (MoA). Many of these substances have generally a low toxicity profile: they are regularly used for integrated pest management (IPM) and some are approved for use in organic farming. There are furthermore specific data requirements foreseen for these substances in Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

The Commission reminded that the main concerns regarding endocrine disruptors are the oestrogen, androgen, thyroid and steroidogenesis (EATS) axes. These axes are those where there is information and tests available. It should be noted that an initial proposal for the scope of the criteria was to limit them to vertebrates due to the reasons just explained. However, it has been decided to keep all groups of organisms in the scope, but with the provision on GR. If the GR provision is not maintained, a full class of generally rather safe chemicals would be lost by default, with practically no possibility of derogation at least in the pesticide sector.

The Commission explained that the provision on GR is limited in scope for several reasons: first it is only applicable to the part of the criteria related to the environment and not to human health. Moreover, it only covers certain organisms in the environment depending on the target organism (e.g. plants and a subset of invertebrates). This means that if a GR is an endocrine disruptor for human health or for organisms other than the phylum of the target organisms, the provision would not be applicable. The Commission also stressed that if a substance does not fall under the cut-off criteria, it will always undergo a full risk assessment.

The Commission noted that in the meeting with the experts for biocides in December 2016, some Member States argued that the provision on GR is not needed for biocides because other derogations already present in the BPR would allow approval of active substances with these properties. However, if the GR provision is not kept in the criteria for biocides, the criteria would no longer be harmonized for PPPs and BPs because a substance could be identified as an endocrine disruptor under the BPR and not under the PPPR.

EFSA questioned whether it might be appropriate to draft the provision on GR in a way that it would not be applicable for vertebrates, since some modes of action relevant for rodents might be applicable for humans. The Commission asked Member States whether they would support such a clarification.

Six Member States and one EEA country would prefer to delete this provision from the proposed criteria. Furthermore, the provision on GR can be dealt with by derogation under Article 4(7) of Regulation (EC) No 1107/2009 or otherwise should be introduced via co-decision. One of these MS stated that the provision on GR could slow down research on invertebrates. Another Member State recommended limiting the scope of the provision on GR by changing “taxonomic phylum” to “taxonomic order”.

Two Member States supported the provision on GR, while at the same time, one of the Member States urged the Commission to rethink the place where the provision is.

Two Member States indicated that in their view, the criteria are not meeting up to the level of the precautionary principle as it still lacks precaution as well as coherence with other regulations. They asked whether the draft criteria were implemented in practice for the identification of some substance under the Pesticide Regulation or under REACH.

Two Member States and one EEA country indicated they would like to have explicit reference in the text to the term “presumed effects” and “plausible link” (between the MoA (mode of action) and the adverse effect). They note that the guidance document is in progress and will include these concepts.

One Member State and one EEA country welcomed the withdrawal of the proposal for the technical amendment to the clause on negligible exposure. They believe it is a matter for co-legislators, and that the technical amendment does not meet the level of protection set by the legislator. They would also like the words *presumed* and *plausible* mentioned explicitly in "the three commandments" of the criteria. Moreover, the word progeny which is present in the WHO definition of an endocrine disruptor, should also be included in the text. Finally, they consider that monitoring data should not be considered as they are rather to be used in the risk assessment.

The Commission clarified that the technical amendment to the clause on negligible exposure is not withdrawn, but just postponed to a later stage in time. The Commission it is still convinced of the legality of this proposal.

The Commission clarified that the term "progeny" is not explicitly mentioned in the criteria for the environment because the WHO definition had to be adapted to consider non target organism. However, progeny is implicit in the term "(sub)population", which cover reproduction effects. The Commission believes that monitoring data should not be neglected when available, in particular considering consistency with the fact that all scientific evidence should be considered.

On the question about experience with the criteria, the Commission reminded that the experience with the screening performed for the impact assessment applied the criteria under discussion (Option 2 in the impact assessment) very close to those of

the draft legal act. All approved PPPs and BPs were screened plus a subset of substances from REACH. When drafting the criteria, the results of the screening were taken into account.

Regarding the statement that the provision on GR would not be needed because Article 4(7) of Regulation (EC) No 1107/2009 could be used, the Commission reminded that Article 4(7) is foreseen to control serious plant health, which would not be controllable with other means. The example of IGRs used to control e.g. Cydia pomonella shows that other tools (insecticides with less favourable toxicological profile) would be available. Following the rationale proposed by this Member State, we would exclude by default GR, where the alternatives would be of less favourable toxicological profile.

The Commission also clarified that the taxonomic group cannot be chosen at a lower level than phylum because in that case the provision on GR would simply not work. This is exemplified by the fact that some GR control one order of organisms under PPP and a different order of organisms under BP. This means that organisms under the same phylum (e.g. different orders) often share the same endocrine MoA.

On the observation that research would be slowed down if the provision on GR is kept, the Commission commented that the opposite would be expected. Indeed, if by default the entire class of GR is non-approved by default, then there would be no incentive for research on the endocrine system of insects.

Regarding the proposal of one Member State to move the provision on GR elsewhere within the legal text, the Commission suggested to move it to point 4. In doing so, the provision on GR would no longer be part of the criteria that is defining how the scientific evidence should be assessed. It would instead be included in a new paragraph, still under point 3.8.2, but separate from "the commandments" and separate from the principles where it is detailed how the weight of evidence should be assessed. Following the comment made by the EFSA, the words "other than vertebrates" could be added after the word "organism" and before the words "of the same taxonomic phylum". The Commission introduced the changes into the text and carried out an indicative vote on this revised draft.

Four Member States expressed their appreciation and thanked the Commission for the fact that most comments from the Member States had been taken into account and that a revised text was ready for an indicative vote. One Member State stressed the fact that the interim criteria are not fit for purpose: therefore, there is a need to pass to new criteria as soon as possible. The Member State urged all other Member States to check the text very carefully and vote in favour of the proposal. Two of the four Member States mentioned that they would have preferred to have the technical amendment to the clause on negligible exposure for vote at the same meeting on the same day. However, as this not the case, they accept the proposal but *urge* the Commission that the technical amendment to the clause on negligible exposure should be presented to the PAFF Committee *as soon as possible*. Furthermore, the Member States agree on the fact that transitional measures of 6 months are now foreseen in Article 4 of the criteria. The two Member States would like to have the guidance document available at the moment the criteria are applicable, and was supported by another Member State

on this. Otherwise, it will be very difficult to have all Member States applying the criteria in a harmonized way.

Two Member States thanked the Commission for the proposals. They supported the fact that the interim criteria should be replaced as soon as possible. However, they would like a review clause by less than 7 years or at least specify in the text that a report of the review would have to be available by 7 years. This is for them a condition to be able to vote favourably on the proposal.

One Member State indicated it would abstain because they would have liked to vote at the same time on the technical amendment to the clause on negligible exposure. It asked reassurance that if the criteria are voted, the technical amendment separated by the criteria will not be blocked by the European Parliament.

The Commission confirmed that it plans to submit the technical amendment at a later stage. Whether the European Parliament and the Council would support or oppose to this proposal cannot be predicted.

One Member State stated it is generally supportive of the current text on the criteria. It believes that the current proposal for the criteria is slightly more precautionary than really needed. It sees the lack of risk elements as a concern and it worries on how the technical amendment to the clause on negligible exposure will be tabled in the future. Therefore, it will abstain.

One Member State indicated it does not yet have any position as there are still ongoing discussions among ministers of health, agriculture and environment. Therefore it will abstain.

One Member State stated it shares the concern of lack of risk assessment elements. It is very disappointed that the proposal is no longer composed of the two texts. Therefore it will abstain.

Answering the questions related to the timely availability of a guidance document, the Commission explained that a first draft of the guidance under development by EFSA, the ECHA and JRC is expected to be published for public consultation by mid 2017, provided that the criteria are adopted by that date.

The proposed text was slightly modified during the meeting to accommodate some comments received by Member States during the discussion. In particular, the timelines for the review clause were further clarified in the text; a sentence in the Article on the review clause was deleted, since it was a repetition of what was stated in the recital; the provision on GR was moved up and slightly amended to clarify that vertebrates would not be excluded from the assessment, even if they belong to the same phylum of the target organism.

One Member State asked why the clarification mentioned vertebrates rather than humans. EFSA answered that there are special protection goals applicable to vertebrates and not only to humans.

The Commission recalled that it will certainly not continue to accept the fact that it failed to act, as declared by the EU General Court, much longer. The intention to progress in parallel with both texts in order to arrive at identical criteria under the BPR and PPPR depends therefore on the position of this PAFF Committee. The Commission invited the Member States to take this into account when expressing their opinion. The Commission indicated its appreciation to hear that some Member States confirmed the urgent need to depart from the interim criteria.

An indicative vote was held:

- 11 Member States were in favour
- 8 Member States abstained: 7 because they would have liked the two texts on the criteria and on the technical amendment to the clause on negligible exposure tabled together; 1 because it disagreed with the provision on GR included in the text.
- 8 Member States were against: 5 because they would have liked the two texts on the criteria and on the technical amendment to the clause on negligible exposure tabled together; 3 because they considered that the level of evidence requested by the criteria is too high.
- 1 Member State was absent.

The Commission acknowledged the lack of QM and did not proceed to a formal vote.

The Commission concluded the meeting: a few Member States do not consider the criteria sufficiently protective; a bigger group of Member States state that the technical amendment to the clause on negligible exposure should be voted together.

The Commission will reflect on the next steps, taking into account that further postponing the vote would not bring benefits for human health and the environment because the interim criteria continue to apply. The Commission remains committed to fulfil its obligations and will continue to act in full transparency.

M.01 AOB

No points added.