EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

EXTRACT FROM THE SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 17-18 MAY 2017

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

The Complete Summary Report is available at the CIRCABC Link:
https://circabc.europa.eu/w/browse/3b2f1718-61bc-4d2d-b713-a3dedb8bed9c

Pt B 08.00 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 after the last discussion of this Standing Committee on Plants, Animals, Food and Feed (SC PAFF) on criteria to identify endocrine disruptors (EDs) on 28 February 2017, a meeting on the ED-criteria took place on 7 April 2017 with the Member States Competent Authorities for biocidal products. This meeting focused on the growth regulators provision, which had been already agreed in the SC PAFF.

After a discussion on the way forward concerning EDs in the College on 16 May, the Commission has now decided to progress first on the legal act for plant protection products.

The Commission recalled that a revised text for the criteria on plant protection products had been uploaded on CIRCABC two weeks before the meeting. The Commission presented the changes introduced in the last revised version of the criteria. The main changes with respect to the draft discussed on 28 February are:
1) in recital 4, it is clarified that the criteria identify known and presumed EDs with respect to human health;
2) in recital 7, the provision on growth regulators (GR) is better explained;
3) in the annex, the provision on biological plausibility is redrafted and given more prominence in the text;
4) in the annex, the provision on growth regulators is unchanged, except for one sentence which has been moved to the corresponding recital.

The Commission presented few additional minor clarifications introduced to the text uploaded in CIRCA in the last days. A paper copy was distributed to the Member States delegates and the corresponding file uploaded on CIRCABC. The changes are:

1) in recital 4, it is explained in clearer terms that this recital is only relevant for human health;
2) in recital 7, it is specified why growth regulators are not expected to pose a risk to vertebrates and that even organisms of the same phylum of the target organisms will be subject to a risk assessment.

Three MS asked the Commission to clarify when the text on the amendment to point 3.6.5 of Annex II of Regulation 1107/2009 will be tabled.

One MS asked to clarify which guidelines are referred to in the revised provision on biological plausibility. The same MS asked whether the provision on growth regulators could specify that ED properties for invertebrates will be sufficiently assessed in the risk assessment. In their view, this would be necessary because current data requirements do not specify this enough. In order to do so, this MS suggested inserting in the text that "particular attention should be paid to the ED properties of GR in non-target invertebrates". A revised text was agreed upon addressing this comment.

One MS asked whether the words "unacceptable effect" in recital 7 should rather read "unacceptable risk". The Commission clarified that the wording comes from Regulation (EC) No 1107/2009.

One MS indicated that they appreciate the modification in recital 4 to clarify that this recital only applies to human health. They would suggest a different wording, but they can accept the wording proposed by the Commission, since it is equivalent in meaning. This MS also indicated that they would like to see, in the approval regulation of each GR approved, a recital which transparently acknowledges that the substance can be approved as growth regulator and under consideration of the provision on GR of the ED criteria.

The Commission reassured that it is standard procedure to clarify in the recitals in the approval regulations for single substances the specific conditions allowing their approval; in the case of substances with intended mode of action as GR, it would be appropriate to mention – if applicable - that the substance falls under the provision of the ED criteria specific for GR.

One MS thanked the Commission for having made all efforts to accommodate as much as possible the comments coming from different MS and encouraged all MS to consider this fact. This MS indicated that they wish all MS will implement the criteria in a harmonized way. In order to do so, they urge the Commission to make sure that the agencies finalize the guidance document (GD) in time for when the criteria are adopted. This MS also stressed it is in favour of the amendment to point 3.6.5 and would like to resume discussions on it.

One MS thanked the Commission for all the efforts done to accommodate comments on the criteria. Regarding recital 4, they agree with the clarification that the recital applies only to human health, but they believe that *in vitro* and *in silico* data should be mentioned as well, next to animal and human data. Moreover, for consistency with the wording used in the criteria, "scientific evidence" should be replaced by "scientific data". Finally, this MS believes that the provision on GR is too wide and that it is not in line with the principles of Regulation (EC) No 1107/2009. On the provision regarding biological plausibility, this MS would like to delete the text referring to "internationally agreed guidelines", because they fear this can be interpreted as the OECD guidance on the Adverse Outcome Pathways (AOP)

conceptual framework. In their opinion this would not be appropriate because it would further increase the burden of evidence required to identify EDs.

One MS indicated that it could support the criteria, provided the amendment to point 3.6.5 is put back on the table and a precise timetable concerning the discussions of this amendment is provided by the Commission. For the moment, it abstains, but could support the criteria if this is done.

One MS and one EEA country regretted that the Commission had not taken into account their comments, in particular concerning their opinion that the burden of evidence required by the criteria is too high and that the criteria lack precaution and consistency with other legislation. As regards the revised provision on biological plausibility, they reiterated that they would like the criteria to be able to identify EDs for which not enough evidence is available and that the criteria should mirror the fact that science is not yet ready to establish a causal link between the endocrine mode of action and the adverse effect. They also regretted that the wording "read across" is not explicitly mentioned in the criteria, considering cases where not enough evidence would be available on either the adverse effect or the endocrine mode of action. This EEA country expressed concerns that adverse effects may not be identified if the mode of action is not known. On the provision on GR, this MS stated that despite the clarifications made with the revised recital, they believe the current text still mixes hazard identification and risk management issues. This MS agrees that GR should be given the possibility to be approved, but that the considerations of risk management should be separated by those of hazard identification. Finally, this MS believes that "phylum" should be replaced by "order" because the taxonomic phylum is too wide and will not allow adequate protection of the environment.

The Commission explained that they are aware of the concerns of two MS and one EEA country, as their points were already raised in all previous meetings. The Commission had already widely explained why it disagrees with their views. Regarding the proposal to reduce the scope of the GR provision to the taxonomic "order", the Commission reiterated that this would make the provision useless. The Commission reminded that the scope of the GR provision has been already reduced as much as possible compared to the initial proposals from MS, which was to define non-target-organisms as non-target-vertebrate-organisms. The Commission clarified that the international guidelines mentioned in the provision on biological plausibility refer to the GD which is currently being developed by the European agencies ECHA and EFSA, with the support of the Joint Research Centre (JRC). A more specific reference to a GD was not added in the criteria to be able to consider any further revision or development of that GD. On the question of read across, the Commission reminded that this approach is never mentioned in Regulation (EC) No 1107/2009 or Regulation (EU) No 283/2013 and thus it would be inappropriate to introduce this concept in the criteria. As regards the concern that adverse effects may not be detected if tests on the mode of action are not available, the Commission reminded that in the impact assessment report it is clearly documented that most pesticide active substances known to have endocrine disrupting properties today, have been already removed from the market during the past years because of their adverse effects, even without knowing their specific mode of action.

One MS appreciated the efforts of the Commission to accommodate all comments from MS, which were even coming from opposite positions. This MS appreciates the clarification made to recital 4 and 7, although on recital 7 they would suggest the Commission considering

splitting this long recital in two parts, one addressing the hazard identification part and the second one addressing the risk assessment issues.

One MS thanked the efforts made by the Commission in finding a qualified majority. They indicated they will support the Commission proposal on the criteria, provided the amendment to point 3.6.5 is not re-introduced.

The Commission reassured that the GD development is progressing well, despite a slight delay with respect to the original time planning. Therefore, it can be expected that a GD (or at least a very advanced draft GD ready for use) would be available when the criteria become applicable. The Commission invited EFSA to give an update on the GD development. EFSA indicated that they received over 1000 individual comments during the first round of consultation of the Consulting Group. The agencies are now analysing these comments and will have a consolidated version ready for the second commenting round which is expected to be from mid-July until end August 2017. In September, the agencies will analyse and address the comments received. A consolidated revision of the GD is expected to be ready by early October 2017 for public consultation.

The Commission addressed the question coming from four MS on when the text on the amendment to point 3.6.5 would be tabled. The Commission recalled that the amendment was initially included in the same legal text as the criteria. In December 2016, the criteria were split from the amendment in order to give MS the possibility to express their views separately on these two aspects. The decision to keep the two texts separate is still valid. The Commission reassured MS that it will resume work on the amendment to point 3.6.5 once the criteria are adopted. The postponement was decided to focus the discussion first on the criteria. The exact timing depends on when a qualified majority for the criteria is reached.

The Commission asked the MS to express their indicative vote in a tour de table on 17 May. It then invited the delegations not supporting the criteria due to the absence of the amendment to point 3.6.5 to get back to their capitals and see whether with the new information provided (the Commission reassures that it will resume work on the amendment to point 3.6.5 once the criteria are adopted) a change in position could be expected on 18 May.

On 18 May, the Commission presented and circulated a further revised text where some suggestions on recital 4 and recital 7 were taken over. The Commission asked the MS to express their indicative vote in a tour de table and the positions of MS were the following:

- 15 MS supporting;
- 8 MS abstaining, 7 MS because the amendment to point 3.6.5 is not tabled and 1 MS because of the GR provision;
- 3 MS against, 2 MS due to too high burden of evidence required and 1 MS because the amendment to point 3.6.5 is not tabled;
- 1 MS no position.

Two MS abstained, but could support provided the Commission makes an additional commitment (besides the commitment to resume the discussion on the amendment to point 3.6.5 when criteria are adopted) that the EFSA/ECHA GD concerning the implementation of the criteria will be subject to the advisory procedure for endorsement.

The Commission informed that a formal vote will not be taken during this meeting and that a new meeting is planned (30 May 2017, subject to confirmation). On that day, the intention would be to take vote and not reopen detailed discussion.