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HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 21 DECEMBER 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/e3a3f9c3-91c7-4fa7-bfb5-5b045a4c9db4*

A.01 Implementation of acts listed in section B.

The European Chemicals Agency (ECHA) indicated that the outline for the content of the guidance document (GD) and its work plan was developed by the European Food Safety Authority (EFSA) and ECHA with support of JRC. The outline includes information on the consultation periods. The GD will apply in the context of the Biocidal Products (BP) and Plant Protection Products (PPP) legislations and it is destined to the assessors and the applicants. The focus will be on the information needed to carry out an ED assessment on effects on vertebrates and intends to apply the best science. Starting from January onwards, staff from ECHA, EFSA and JRC will draft the GD. They will be supported by a consultation body: on ECHA side, the Endocrine Disruptor Expert Group, on EFSA side a call was launched to select Member States (MS) experts and other stakeholders. The first draft is expected to be available not earlier than the end of May 2017 and it will be subjected to public consultation. A workshop is being planned shortly after the public consultation. Comments from the relevant agencies panels and committees will also be gathered before finalization.

One MS asked whether there would be a link between ECHA's and EFSA's work. ECHA answered that it is the case as the GD is a joint document.

Another MS asked what is the procedure and timetable. ECHA stated that the agencies can only start the public consultation once the criteria are adopted. So, the start of the public consultation depends on the adoption of the criteria.

Another MS asked about the adoption/endorsement of this document. The Commission answered that agencies will agree with the Directorate General for Health and Food Safety (SANTE) on procedures to endorse the GD.

Concerning the implementation of the new criteria, the Commission clarified that the new criteria won't apply to substances for which there is already a vote taken in the respective committee. The Commission has started reflecting on the on-going

renewal processes and is considering amending Regulation (EU) No 844/2012 in order to allow EFSA and Rapporteur MS (RMS) to request additional information from applicants where applicable. This would imply that the approval period will need to be extended for some active substances currently under renewal. Also for new substances for which applications are submitted additional information may be requested.

One MS asked who will decide if there are ED properties or not to ask for more data. The Commission answered it is for the RMS to conclude on whether criteria are met or not, and if more data are needed for the RMS to conclude on the criteria.

Another MS asked whether it would be at the discretion of the RMS to decide whether the data was enough. The Commission answered that it would be the case.

One MS pointed out that different terms are used in Regulation (EC) No 1107/2009 (information, studies) and asked whether the Commission intended to exclude studies by referring only to further "information" that can be requested from applicants. The Commission answered that this was not the intention. If studies are necessary, MS should ask for them.

One MS asked whether the changes that are planned were only for ED studies. The Commission answered that indeed the stop the clock mechanism is only foreseen in the context of the application of the new ED criteria and would not apply to other points in the dossier.

One MS asked whether the stop the clock procedure foreseen for renewals was a new provision. The Commission confirmed that the additional timing is not foreseen under the Regulation (EU) No 844/2012. Therefore, a timing to evaluate the additional data will be provided for.

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

The Commission explained that it split the text on PPP discussed in previous meetings into two draft acts (one containing the criteria and another one containing the amendment to the derogation) to give MSs the possibility to express their opinion on each text separately.

The Commission presented the changes introduced in the last revised version of the criteria.

In the human health part, a point 5 for non-relevance for humans (the unless-clause) has been reintroduced at the request of some delegations (the point was in the draft criteria that were made available in June and taken out in a previous version).

The very last paragraph of the annex (point 5, environmental section) is new and clarifies, based on a request of some delegations at the last PAFF meeting, that active

substances whose intended plant protection mode of action is via an insect or plant growth regulator action, are out of the scope of the criteria. The Commission clarified that this applies only to the environmental section (no clarification on scope is made under the human health section) and that active substances with this characteristic will be subjected to a standard in-depth environmental risk assessment. A recital clarifying this provision will be added.

Based on comments from another MS, the brackets in point (a) *"(in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action)"* will be moved up to point (1) in both the human health and environmental sections.

One MS thanked the Commission. The current interim criteria in place are not good and new scientific criteria are needed. The discussions can continue for a very long time and the texts could always be improved but a speedy solution is needed. This MS indicated that it was ready to work on the Commission's proposal and agree to it.

Another MS had technical comments. The paragraph on insect growth regulators (IGR) is required but is in the wrong place. It is not for identification of EDs. This MS considers that in its current form, the text is too broad and should be redrafted to "non-target organism from the same taxonomic group". On point 3c, any reference to field or monitoring data should be deleted because they are part of a risk assessment.

One MS supported the comments made by the previous MS concerning the place of point 5 on IGR.

One MS indicated its worry concerning recital 5: "substances that may cause adverse effects". In English this could include category 3 of the Commission's impact assessment, so this proposal may extend the scope to many more substances. This MS also indicated that the interim criteria are not fit for purpose and therefore need to be replaced as soon as possible but that a transitional period is needed because the current implementation is not feasible. It is not possible to provide further data and this MS believes recital 6 will not be sufficient, when e.g. data on the mode of action are not available.

One MS indicated it can support most of the text. On the IGR point, it proposed an alternative text submitted via the written comments. This MS would like to recognise IGR-substances as EDs but would like the possibility to approve them. This would also be important in the Biocides Products regulation (BPR) although there are derogations possibilities in the BPR.

One MS indicated not liking the split of the original legal act into two acts: criteria and amendment to point 3.6.5 of the Annex. For this reason it would abstain from voting. It is hard to communicate the content of the legislation to interested parties in the way the text is now. This MS had concerns on the date of entry into force because data requirements may not be sufficient, in particular because information on the Mode of Action (MoA) will not be available.

Another MS indicated not liking the split into two legal acts. It indicated that it could support one single document containing both the criteria and the amendment to point 3.6.5..

One MS stated that the word "shows" should be replaced by "known and presumed" and "plausibility" should be added in the three "commandments" of the criteria. The text referring to field studies needs to be deleted as this is part of a risk assessment. Concerning the text on IGR, this MS has strong reservations as it could be misinterpreted.

One MS thanked the Commission for its work and welcomed the fact that the criteria are now even closer to the WHO definition of an ED. This MS stressed the need for a guidance document and that this guidance document should be ready before the entry into force of the criteria, to ensure a harmonised implementation of the criteria by MS. This MS indicated it had a scrutiny of its Parliament currently ongoing, so if there would be a vote at the end of the meeting, this MS needs to abstain.

One MS stated it cannot support the text because it would like to have in the three "commandments" the words "known and presumed" and "plausibility". Concerning the IGR provision, it considers the text too broad and thinks it may be misinterpreted. Therefore, this MS disagreed with this addition unless it was better clarified, but did not have a specific proposal; therefore it proposed to delete this paragraph.

One MS maintained its support for the proposal but would like to support another MS regarding the proposed alternative sentence to the 5th paragraph for IGR.

One MS expressed its concern about the too high level of evidence required to identify EDs and the lack of coherence with other current legislation. This MS would like to add the word "clearly" in the unless-clause, as well as "known and presumed" and "plausibility". If the text is unchanged, this MS believes it would be very difficult to identify EDs. This MS wants to delete the repetition of the unless-clause. It would like to add amphibians in the list of examples mentioned in the environmental section. The field studies should be deleted as they are part of risk assessment. It suggested deleting the current paragraph on IGR.

Another MS considered the IGR provision as too broad. In the three "commandments" there is an inconsistency in the wording used compared to other chemical legislation. This MS suggests replacing the word "information" by "evidence" everywhere in the text.

One MS indicated not liking the split as it is a major change. It didn't like either the wording "may cause" and supported a review clause and transitional periods.

Another MS indicated not liking the split of the text into two draft acts. If the texts were put back together, it could support the proposal.

One MS indicated its support for the current text with the IGR provision.

One EEA country supported the comments made by one MS with regards to the too high burden of proof.

The Commission clarified that for IGR already today specific data requirements apply, in particular for bees where specific studies are asked.

The Commission also mentioned that the screening as included in the impact assessment only focussed on EATS pathways. IGRs and plant growth regulators were not considered in the screening study, which means that the number of active substances that would be potentially affected by the criteria would be significantly higher than the results of the screening study.

Based on the points raised during the meeting, the Commission shared a revised text with the Committee suggesting amendments which were further discussed and modified during the meeting.

During the discussion, one MS indicated to be pleased to have a recital on the review of the draft act but would like to have a review clause in the articles.

One MS asked that the text on the IGR provision clearly identifies the group of organisms affected by it. Another MS asked to specify the level of organism in the IGR provision and suggested the level of phylum.

Concerning field studies the Commission believed this information should not be neglected. The paragraph had already been reformulated in November in order to accommodate MS comments. These data should not overrule other evidence, but it would still be considered in the evaluation process together with other information available.

One MS asked to make the application of the new criteria conditional to the availability of the GD. Another MS asked whether the proposed transitional period of 6 months after entry into force corresponds to the intended date of availability of the GD.

The Commission explained that from a legal point of view it is not possible to make the application of the new criteria conditional on the availability of the GD. It also explained that after the vote in Standing Committee on Plants, Animals, Food and Feed (PAFF), it can be estimated that there is one month for translation of the texts, three months for scrutiny of EP, one month for Commission's adoption, one month for publication. Therefore, it could be estimated that there is more or less 1 year from the date of the vote to the entering into force of the criteria which would correspond to the intended moment of having the GD.

The amendments discussed are summarised as:

- The inclusion of a new recital on IGR and an improved drafting of the IGR point in the environmental section
- A review provision of the draft act in the recital
- Amendment of recital n°7 arguing the need for a transitional period and introduction of an article to provide a transitional period.
- The unless-clause (non relevance for humans) in point 5 was deleted as it is covered by the unless-clause in the 1st part of the criteria.

- The word "information" had been changed into "evidence".
- Amphibians had been added to the list in the draft act as required by several MS (although it is still not an exhaustive list).

At the end of the meeting, a break of 10 minutes allowed delegations to consider again the revised act, and, where appropriate, to contact Member States' authorities. The Commission clarified that it cannot be guaranteed that current amendments would reappear in a revised version if the proposed text would not be supported. An indicative vote showed that:

- 10 MSs were in favour
- 7 MSs abstained because they were against the split of the two texts;
- 5 MSs abstained for internal reasons, such as scrutiny of national parliament or ongoing discussions between services
- 1 MS abstained because the burden of proof is too high
- 3 MSs were against the criteria (they would like the terminology "known and presumed", "biological plausibility");
- 1 MS was against because of the missing link between the entry into force of the criteria and the availability of the GD;
- 1 MS was absent

One Member State mentioned that its support is conditional on a clarification of the Commission that the criteria are in accordance with the WHO definition. Herewith the Commission confirms this, referring also to the summary reports of this Committee from the 22 of June, 21 of September, and the 18 of November 2016.

The Commission acknowledged the lack of qualified majority and did not proceed to a definitive vote. The Commission will reflect on the outcome of this vote and communicate in due time on how to further proceed.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge.

The Commission mentioned that clarifications on the rationale regarding this text were given at the last PAFF meeting on 6 December and that they will not be repeated during this meeting again. The Commission presented the changes introduced in the last revised version: Recital 5 was clarified in order to further explain the rationale for changing from negligible exposure to negligible risk from exposure; Recital 6 gives further information on this rationale with focus on MRLs.

One MS asked what the benefit of the MRL change was. Two MSs questioned whether the Commission exceeded its powers with this amendment.

The Commission clarified that, according to science, indeed it would be justified to change the general approach concerning EDs (i.e. to follow a risk based approach). However, the Commission emphasised that this is not done and that the approach of the legislation is fully kept. What is done is to amend technically the already foreseen

derogation, by changing negligible exposure to negligible risk from exposure. Concerning the MRL provision, the Commission explained that beside the fact that science is telling that this change is possible, the MRL legislation states that ED properties should be assessed in the MRL setting and that this would now be fully possible once the scientific criteria are available.

One MS stated that if no threshold can be determined for a substance, risk assessment should not be applied. The Commission confirmed that if a threshold cannot be defined, the MRL should be set at the analytical zero in any case as done already today. The Commission stressed that this would be a case by case assessment.

Another MS agreed with the split but didn't agree with the amendment regarding MRL.

At the end of the meeting, a break of 10 minutes allowed delegations to consider again the revised act. An indicative vote showed that:

- 12 MSs were in favour
- 3 MSs abstained because they believed the Commission exceeded its mandate;
- 3 MSs abstained because they insisted on one text;
- 4 MSs abstained because of ongoing internal discussions/scrutiny Parliament
- 1 MS abstained because of the missing link between the entry into force of the criteria and the availability of the GD;
- 4 MSs were against
- 1 MS was absent

The Commission acknowledged the lack of qualified majority and did not proceed to a definitive vote. The Commission will reflect on the outcome of this vote and communicate in due time on how to further proceed.