



EUROPEAN COMMISSION

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 SEPTEMBER 2016
(Section Phytopharmaceuticals - Plant Protection Products - Legislation)**

CIRCABC Link: <https://circabc.europa.eu/w/browse/ed678a76-5b81-4c4e-a45e-47a8d7b537bb>

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

The Commission clarified that the main objective of the meetings was to report back to Member States about the outcome of the various consultation processes held over the summer, to give those Member States which on 22 June were not in a position to express their views the opportunity to do so, and to invite those Member States which had so far neither taken a position in writing nor orally to share their views.

The Commission informed Member States of the feedbacks received from (1) stakeholders via the "feedback mechanism" and (2) third countries following notifications in the context of WTO, SPS and TBT. The summary documents were made available to Member States prior to the meeting on CIRCABC. For the feedback mechanism the individual responses are available via the Better Regulation Portal. Following the introduction no participant asked the floor on the feedback mechanism. The Commission also informed there will be an information session on the notified draft regulations on Endocrine Disruptors (EDs) in the margins of the Committee for Sanitary and Phytosanitary measures in October 2016 in Geneva.

The meeting focused on the comments received from Member States on the draft criteria to identify EDs. The Commission thanked Member States for the comments received so far. Some Member States have so far not given any indication regarding this draft, other Member States who had submitted comments indicated that they are still consulting internally for a final position. Although all comments, including drafting comments, will be considered, the discussion during the meeting focused on main areas of concern as follows:

1) Scope of the WHO definition

The Commission indicated that all Member States expressing their views on the WHO definition supported the use of the WHO definition for setting scientific criteria.

Some comments indicated however that there was a perception that the scope of the WHO definition was reduced. The Commission clarified that the original idea when drafting the criteria was to stick to the WHO definition (first part of the criteria, i.e. the "3 commandments"). The second part of the criteria intends to indicate how the WHO definition should be implemented. It was clarified that the words "known or presumed" are not part of the WHO definition. The Commission indicated that in its opinion the scope of the WHO definition is not reduced because in the second part of the draft criteria a clear reference to and relevance of animal studies, in vitro studies and "biological plausibility", is given. The Commission indicated it will reflect on how to address these comments as they seem to be a concern for many parties.

One Member State stressed the importance of being clear. Clarifications were requested on the meaning of the word "known" in Annex (1).2.1 and "may" in Annex (1).3.6.5.1. The Commission indicated that the intention was not to mirror the Classification, Labelling and Packaging (CLP), but that the WHO definition needed to be adapted in order to distinguish EDs for human health from EDs for the environment, in line with the structure given by the Plant Protection Products Regulation (PPPR) (Annex II point 3.6.5 and Annex II point 3.8.2).

One Member State expressed its general favourable position to the approach taken and indicated that details are still being looked at internally.

One Member State indicated that the criteria put forward contradict the precautionary principle and reminded that the implementing regulation must respect the choice of the legislator. The criteria should include "known and presumed" substances. This Member State asked for written answers to the comments provided by the Member States from the Commission. The Commission indicated that the right place to exchange was in this Committee and that the questions would be addressed in this Committee.

One Member State indicated that it had not yet submitted comments. The text is still under consideration at national level. This Member State indicated it was worried that the proposal would have negative impacts on the agricultural sector and the availability of plant protection products and requested clarifications on "negligible risk" and on the process of identifying EDs.

One Member State indicated its preference for option 3 of the roadmap (criteria including categories) and that experts from its scientific body support categories. Written answers to its comments were also requested.

One Member State indicated that discussions were still ongoing at national level. In general, this Member State indicated it could support the proposal and the use of the WHO definition but believed the precautionary principle should be reflected and the words "or presumed" should be added.

One Member State indicated that discussions were still ongoing at national level and expressed its support for horizontal criteria and appreciated that the Commission would go back and reflect on how to redraft. It expressed satisfaction that the criteria did not include potency.

Two Member States took scrutiny reservation because discussions are still ongoing internally.

Another Member State supported the use of the WHO definition but before expressing its position, wanted clarification on negligible risk and "high level of consumer protection". This Member State called for development of harmonized guidance.

One Member State indicated that the comments sent so far were not final as discussions are still ongoing internally but in general, it favoured cross cutting criteria that would apply to both regulations. This Member State highlighted that huge impacts are expected following the adoption of the acts for PPPs.

Another Member State asked for clarifications on the concept of negligible risk and asked whether the restrictions that would apply to EDs would also apply to carcinogenic, mutagenic or toxic for reproduction (CMRs).

Another Member State expressed its support for horizontal criteria and wanted to know whether/how the criteria would be applicable to cosmetics. It favoured one section for human health and environment and was worried about "known to cause".

One Member State indicated it had a parliament scrutiny reservation, asked clarification on "negligible risk" and requested as soon as possible guidance on the implementation of the criteria.

One Member State indicated that they had not yet submitted written comments. This Member State agrees with the proposed criteria and would welcome more elements of risk assessment in the assessment of EDs. It is in favour of potency and it reminded that potency is used in CLP Regulation to identify several acute and chronic endpoints. It believes that adding categories with words such as "presumed, suspected" will only add more confusion and will not help risk managers.

One Member State supported the Commission proposal and requested guidance on negligible risk and on whether/how plant protection products would be handled in the European Chemicals Agency Endocrine Disrupter Expert Group (ECHA EDEG).

One Member State indicated that in general terms, it could agree with the Commission proposal. There is a need to align the plant protection and biocidal products regulations in terms of criteria and definition but it expressed concerns on how risk assessment will be done and on the heavy workload in terms of proving biological plausibility. The need for further guidance was restated.

The Commission took note of all the comments. It indicated that it is not possible to establish guidance before the criteria (legal text) are agreed upon. However, the Commission indicated that steps towards the preparation of guidance between agencies have already been initiated and a meeting in Brussels is scheduled for the 4th of October with agencies and the Commission.

2) Categories/potency

The Commission indicated that some Member States asked for the inclusion of categories and some for the inclusion of potency. Option 2 has been chosen because it is the option receiving the widest support amongst scientists if criteria are exclusively intended for hazard identification of EDs. The Commission clarified that categories are not proposed because the PPP and Biocidal Products (BP) legislation does not foresee any regulatory consequences for categories. Therefore, criteria including categories would lead to legal uncertainty, because Member States and stakeholders may interpret differently the consequences of being identified as an ED category 2 or an ED category 3. On the other hand, setting regulatory consequences for EDs category 2 and category 3 would be beyond the Commission's mandate. Two Member States supported the current proposal because it gives legal certainty, avoids confusion and reflects the need of the legislation. Three Member States expressed their preference for criteria including categories because they consider that setting categories would be consistent with the CLP Regulation.

3) Implementation of the criteria

Concerns were raised that more importance is given to studies performed according to "primarily" internationally agreed study protocols compared to other scientific information. The Commission explained that the draft criteria ask for all scientific information, and that the two sub points (a) and (b) in Annex (1).3.1 have legally the same level of importance. However, it has to be kept in mind that there is a core set of data requirements carried out according to international study protocols for both plant protection and biocidal products. These data requirements are legally requested, and thus need to be reflected in the draft criteria. This is why the two sub-points are needed and why the word "primarily" is present in the draft legal act. The proposed draft criteria go beyond the "standard" data requirements and ask for additional scientific information with no difference of ranking of importance when analysing the data in a weight of evidence approach. Considering the concern expressed by various Member States with respect to the term "primarily", the Commission indicated it would reflect on how to accommodate the comments.

On the comment made by some Member States concerning "Effects at population/subpopulation level", the Commission indicated it would reflect on how to accommodate the comment.

One Member State requested not to consider field studies (environmental section) as part of the scientific evidence, because these studies should rather be part of the risk assessment where realistic conditions of exposure can be taken into account. The Commission considered field studies are part of the overall scientific evidence and should not be discarded a priori. If field studies were to be discarded for the environmental section, it could be argued also that epidemiological studies should not be considered in the human health section. The Member States clarified that field studies are higher tier studies used in the conventional risk assessment and cannot be directly compared to epidemiological studies in humans.

One Member State indicated the need to rework on the translation of the text in their national language and wanted to examine more carefully this point.

4) Structure of the current text.

Some Member States welcomed the fact that criteria for human health and environment are separated, while others would prefer to have one set of criteria covering both areas. The Commission explained that it could not agree to one single text for human health and the environment because the structure of the annex of the Plant Protection Products Regulation needs to be followed (Annex II 3.6.5 for the human health separated from Annex II 3.8.2 for the environment).

Some Member States asked to remove the second part of the criteria, as this is more suited for a guidance document. The Commission clarified that the second part of the criteria is needed in the legal text in order to define basic principles for the implementation of the criteria. Further details will certainly be given in a guidance document, but basic principles should be agreed in the legal text in order to facilitate the implementation.

5) Process and entry into force of the criteria

The Commission indicated that the criteria should apply with no transitional period.

One Member State expressed concerns regarding the immediate entry into force (how would national authorities manage it and do it in time). Moreover, further guidance is needed for the implementation.

Another Member State was concerned that there was no transition period foreseen. Companies may not have submitted data necessary for the assessment just because the “goal-posts” are moving. It seems inevitable that some active substances would be non-approved while the applicants were simply not given the opportunity to submit the necessary data. Standard procedure has been up to now, to only apply guidance document available at the time of data submission. This Member State suggested another approach, e.g. approvals subjected to confirmatory data.

Another Member State indicated that a transitional period would be welcomed and that guidance needs to be available soon.

The Commission acknowledged that there is a need to give the applicant the possibility to submit new data. The Commission also clarified that in the current data requirements, some tests on EDs are already listed. These data requirements are intended anyway to be updated on a regular basis to include new test protocols.

One Member State requested that guidance should be available before the criteria enter into force and requested a clear timeline. The Commission explained that a meeting with agencies is planned for beginning of October to initiate the first steps on the guidance document. At the moment no precise timeline could be given but certainly there is a political will to apply the criteria as soon as possible. It is acknowledged that guidance should be available when the criteria are implemented in

practice. Therefore, developing draft guidance in parallel while fine tuning the draft criteria has been initiated (see above).

Some Member States wanted to know what would be the impact on farmers of the future criteria. The Commission referred them to the impact assessment where there is an estimation of the expected impacts.

II/ PPP amendment of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009

The discussion focused on the concerns raised by Member States:

1) Legal mandate of the Commission

One Member State indicated that Article 78(1)(a) of the Plant Protection Products Regulation only gives power to amend non-essential elements of the Regulation. It believed that the scope of the cut off rule was an essential element and that the Commission did not have a mandate to change it.

The Commission indicated that while the essentially hazard-based approach currently provided in point 3.6.5 constitutes an exception to the risk-based approach in the basic act, this does not necessarily mean that the detailed implementation of this exception is an essential element which cannot be changed in the light of scientific progress. This is, in particular, for the following reasons:

- There is no statement in the main text or the recitals suggesting that this exception would be an essential element. The exception should be understood as a particular criterion for approval which reflected the state of science on EDs at the time of adoption.
- Annex II to Regulation (EC) No 1107/2009 lays down procedures and criteria for approval. The content (scientific) elements of these criteria and not only the procedural elements can be subject to amendment in light of scientific knowledge. If on the contrary the Commission would be able to amend only the procedural elements in Annex II, this would seem to contradict the terms of Article 78(1)(a), namely that the annexes are to be amended in light of scientific progress.
- Article 1(4) of Regulation (EC) No 1107/2009 provides that the Regulation is "underpinned by the precautionary principle", which also requires that scientific assessments are based on as much available scientific information as possible. In this regard, new information on how to properly assess EDs recommends using a complete set of data including information on exposure and this cannot be ignored.
- The emphasis which the legislator put in Regulation (EC) No 1107/2009 on the need to safeguard the competitiveness of EU agriculture, which is also dependent on the availability of plant protection products, makes clear that the restrictions of the approval of active substances should not go beyond what is necessary to achieve a high standard of protection, in light of the latest science.

Several Member States requested the response of the Commission in a written form.

One Member State indicated that it did not disagree with the concept of "negligible risk" but is worried about the mandate.

2) Content

One Member State pointed out that the proposed amendment would make a difference with the provisions applicable to CMR substances. The Commission confirmed there would be different approaches for CMRs and EDs if this amendment is adopted and enters into force.

Another Member State asked what would happen if a substance is a "C1" and an "ED" which provisions would be considered. The Commission clarified that the stricter provision would be considered, as it is already now current practice for all approval criteria.

One Member State referred to the 2013 opinion of EFSA on endocrine disruptors and asked whether EFSA could briefly summarise the state of play. In the absence of EFSA at the meeting, the Commission recalled the opinion that states that EDs can be treated like any other substances and be subject to a risk assessment and not only to hazard assessment.

One Member State requested that EFSA explains how this will work in practice (how to assess ED based on risk). Another Member State asked how a risk assessment could be done without considering potency. The Commission asked to keep a clear distinction in the discussion between the amendment of the first paragraph of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 and the draft criteria. While the criteria are hazard based, the amendment concerns the decision making. Concerning the decision making the hazard approach stays: if a substance is identified as ED, it cannot be approved. The proposed changes only refer to the derogation, which is amended in order to take into account current scientific knowledge.

The Commission clarified that the proposal is not lowering the protection of human health referring to the clear statements of scientific bodies that consideration of risk is the best way for assessing EDs. Consideration of risk elements would make best use of scientific evidence and allow a case by case decision regarding active substances. Consideration of risk elements leads to a higher protection of human health than consideration of exposure alone, which may allow approving substances with very high hazard and negligible exposure and thus still pose a risk to human health. This applies to all exposure routes, including consumers. For instance, previous experience showed that MRL may be set at lower levels than default values, if there is a toxicological concern and relevant analytical methods are available (e.g. fipronil MRL 0,005 based on science). Maintaining a strict but fixed default value implies that case by case assessments would not be possible for EDs, which may still be a concern for public health in some cases.

The Commission explained that the amendment implies to set MRL in accordance with Regulation (EC) No 396/2005 and recalled that the MRL legislation is already highly protective: the MRL legislation considers the minimisation principle - ALARA principle (Recital 5); EDs (recital 27) and vulnerable groups including children and the unborn (Article 3, Article 14 diet for children standard in the process for setting

MRLs) and cumulative risk assessment (e.g. Article 14). In addition, the precautionary principle can be also applied following consideration of risk assessment and of the complete set of available scientific information, based on a case by case approach in case of uncertainties.

The Commission also pointed out that the proposed amendment (change from "negligible exposure" to "negligible risk from exposure") is expected to lead to a smoother implementation of the legislation because negligible exposure is difficult to define. A guidance document on negligible risk would need to be developed once the amendment is adopted and enters into force.

The Commission reminded that substances approved under this exception are candidates for substitution, which implies the need for comparative risk assessment by Member States when approving plant protection products and no need for mutual recognition.

When closing the meeting, the Commission asked that Member States send written comments by 30 September 2016. The date of the next meeting still needs to be determined but it was indicated that it would probably be in November. Revised draft criteria are expected for the next meeting.