EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Food and feed safety, innovation
Pesticides and Biocides

CA-Nov16-Doc.XXX

DRAFT MINUTES

66th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

21-23 September 2016

Concerning point 3.1 of the Agenda

"Draft Commission delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012"

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WEDNESDAY 21 SEPTEMBER 2016		
Afternoon Session		**14:30 – 17:30**
1. Adoption of the agenda	For adoption *CA-Sept16-Doc.1*	

The draft agenda of the 66th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available and use of biocidal products (CA meeting) was adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Sept16-Doc.2a (minutes 25-26 May 2016)*	For adoption on the morning of 22/09
	For adoption *CA-Sept16-Doc.2b (minutes 22 June 2016)*	**Closed session**

It was decided to schedule the adoption of the draft minutes of the previous CA meeting of 22 June 2016 to the next CA meeting in order to include the comments of Austria and to provide the opportunity to representatives of EP and Council to submit comments.

The minutes concerning the meeting of 25-26 May 2016 will be submitted for comments to the participants and scheduled for adoption at next CA meeting.

3. Draft delegated acts		
3.1. Draft Commission delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012	For discussion CA-Sept16-Doc.3.1 documents	**Closed session**

The Commission clarified that the main objective of the meetings was to report back to Member States (MS) about the outcome of the various consultation processes held over the

summer, to give those MS which on 22 June were not in a position to express their views the opportunity to do so, and to invite those MS which had so far neither taken a position in writing nor orally to share their views.

The Commission informed MS 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 document from the Commission via the feedback mechanism was made available on CIRCABC. For the feedback mechanism the individual responses are available via the Better Regulation Portal[1]. Following the introduction no participant asked the floor on the feedback mechanism.
The EU has the obligation to consult members of the World Trade Organization (WTO) on the draft delegated act. A document summarising the responses to the TBT notification (Technical Barriers to Trade) was made available to MS prior to the meeting on CIRCABC. The Commission agreed, following a question, to make available also the summary document concerning the SPS notification (Sanitary and Phytosanitary Measures) concerning the draft implementing act (plant protection products). The Commission also informed there will be an information session on the notified draft regulations on EDs in the margins of the Committee for SPS measures in October 2016 in Geneva.
An expert of the European Parliament asked the Commission about the nature of this notification procedure. The Commission indicated that in accordance with the relevant procedure members of the WTO were notified about the draft delegated act and provided the opportunity to submit comments. The EU has to discuss the comments received on the notification and take account of the comments .

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

1) Scope of the WHO definition
The Commission indicated that all MS 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 its opinion that the scope of the WHO definition is not reduced in the draft act because in the second part of the draft act a clear

[1] Responses received for the Draft Commission Delegated Regulation on BPs are available at the following link: https://ec.europa.eu/info/law/better-regulation/initiatives/ares20163071671_en.

reference is given to the relevance of animal studies and in vitro studies for the identification of EDs and the term "biological plausibility" is included. The Commission clarified that the draft act allows evidence to be considered derived from animal studies. The Commission indicated it will reflect on how to address these comments as they seem to be a concern for many parties.

One MS expressed concern about the use of the words 'known to cause' in the draft act. According to this MS the Commission exceeds its mandate by using 'known to cause' and not 'may cause' as it is included in the BPR. Moreover, this MS does not consider this drafting in line with the precautionary principle. Another MS also pointed out that the Commission is going beyond its delegated powers by this draft act as it is changing the cut-off criteria by not utilising 'may cause' in the proposal for setting criteria. One MS stated that the legal text should be clear and clarifications should be included in the draft act and not in the minutes of this meeting. This view was supported by another MS. One MS asked clarification why the same drafting included in the CLP-Regulation[2] of 'known to' and 'presumed' was not used. Another MS indicated that it is inconsistent to use 'known to' in the draft act but not to include 'presumed'. Another MS underlined that the CLP-Regulation has a different function than the draft act and therefore it is not appropriate to look at parallels. One MS asked whether the Commission purposefully did not follow the CLP-legislation. Another MS pointed out that the option 2 of the roadmap contained "known to" and "presumed". One MS agreed not to follow CLP. An expert of the EP indicated that EDs are very similar to CMR-substances. Under the CLP-legislation a system of classification of chemicals is established that can be considered the yardstick for classification.
One MS asked why 'plausibility' was not included in the first paragraph of the sections.

Two MSs pointed out that the criteria have to look at the mode of action as adverse effects can be the outcome of non-ED actions. They encouraged a clear distinction between CMR (focus on outcomes) and EDs (focus on mode of action). Therefore parallels with the CLP classification of CMR are not appropriate.

An expert of the EP pointed out that the proposed draft act is different from the WHO definition as the WHO definition does not speak about 'relevant for human health' and 'known to'. The expert referred to Article 5(1) of the BPR that specifies 'may cause' and indicates that the proposal suggests identifying substances that are 'known to have effects on humans'. According to the expert this drafting limits the scope of the cut-off values in Article 5 of the BPR. The expert indicated that considering the wording 'may cause' present in the BPR, in analogy of CLP-Regulation, the Commission should have come up with the category of 'presumed' EDs.

The Commission indicated that it was the intention to apply the WHO definition in the EU legal system and not to follow the CLP-legislation approach. It was also indicated that a roadmap issued in the context of an impact assessment is not legally binding. The Commission clarified that the proposal does not limit data to data derived from humans but explicitly allows the use of data derived from animal and in-vitro studies. Therefore, translating it to CLP-classes, it could be considered that the draft act already covers both 'known to' and 'presumed'.
The Commission indicated it will reflect on how to address the comments. Concerning the comments that Commission would have exceeded its legal mandate, the Commission pointed

[2] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

out that the draft act was legally scrutinized by the Legal Service before being presented to the Committee.

2) Categories/potency

The Commission indicated that some MS asked in the written responses for the inclusion of categories and some for the inclusion of potency. Option 2 was chosen by the Commission as it was less scientifically controversial than the options 3 and 4. The Commission clarified that option 3 was not proposed because, according to the legal mandate in the BP Regulation, the Commission has to set criteria to determine ED properties and not to set various categories. Option 3 would lead to legal uncertainty as the BP Regulation does not provide for regulatory consequences for the different categories.

An expert of the EP indicated to understand that the option chosen by the Commission is different of the option 2 in the roadmap. The Commission clarified that the basis for this draft act is option 2.

Three MSs expressed their preference for criteria including categories. One of these MS pointed out to include 'known to' and 'presumed', even if the regulatory consequences would be the same for both categories. One MS stressed not to see the argument that categories would lead to legal uncertainty. One MS indicated that potential EDs could be addressed in guidance by asking additional data. Two MSs stated to support the inclusion of potency. One of these MS indicated that potency could be useful for ranking of chemicals. Another MS expressed to disfavour to include potency. An expert of EP indicated that an emerging scientific consensus makes clear that potency is not part of hazard identification. The Commission pointed out that there is a need of clear opinions of the scientific committee in ECHA whether a substance has endocrine disrupting properties. The Chair concluded that diverging views between MSs still appear to exist on categories and potency.

3) Scientific evidence

The Commission clarified what type of scientific evidence could be considered for identifying EDs. It was highlighted that all available scientific evidence should be considered. The Commission pointed out that some data generated in accordance with international agreed protocols belong to the core data set of data requirements in the Regulation. The use of the word 'primarily' should not be interpreted as given priority to this type of data but reflects that it is obligatory for any active substance to submit certain data generated in studies performed according to internationally agreed study protocols. It is a misunderstanding that one type of data would be more important than the other. The Commission would reflect on how to accommodate the comments.

With regards to the wording of population vs. (sub)population raised by some MS, the Commission will consider to increase consistency with the WHO definition which refers to (sub)population.

One MS pointed out that in the evaluation of biocides not much data is being used from field studies. This MS stressed that evidence from field studies is being used for risk assessment and not for hazard identification. Those comments were supported by two other MS. One of those MS pointed out that the intention of the Commission appears to be that data of field studies could be considered but without having preference. However, the draft act implies that data of field studies overrules other data. The Commission indicated that results of field studies may be used in hazard identification for PBT assessment and could not be discarded a priori. The Commission indicated it will need to rethink the wording about field studies.

One MS pointed out that in Article 5(1)(d) only includes 'may cause adverse effects in humans ' and this article does not refer to adverse effects to the environment. One MS and an expert of the EP asked to specify in the act the use of 'read across' .

4) Structure of the current text

Some MS welcomed in the written responses the fact that criteria for human health and environment are separated while others would prefer to have one set of criteria covering both. The Commission explained that it could not agree to one text for human health and the environment because the Regulation on plant protection products is built on human health and environment and for the draft act for biocides the same logic was followed to have the criteria as much as possible harmonized between the two sectors. Moreover, some modalities for the environment are not relevant for the human health part.

The Commission clarified that it is important to define the basic principles in the act, for example how to interpret the WHO definition. In addition there is a need for more detailed guidance. One MS raised concerns that without detailed guidance it is very difficult to determine the level of protection of health and environment. It makes it for MS very hard to agree to a draft act if the level of protection is unclear. This MS wished that guidance is developed in parallel with the discussion on the criteria. Another MS indicated to prefer a concise and clear text. This MS did not see how to detailed scientific criteria could be established for the identification of EDs with the current level of knowledge. The same MS asked to change 'non-target organism' to 'environment', and expressed concern that in the current draft the burden of proof is moved from applicants to authorities. The same MS stressed the importance of data requirements as the required level of data will end up easily in arguments between companies and authorities. One MS supported the views expressed by this MS.

5) Entry into force of the criteria and implementation

The Commission indicated its views on how the ED-criteria should be implemented. The proposal provides that the criteria would apply immediately. The current principles and practice for the evaluation of active substances should continue until the delegated act establishing the scientific ED criteria enters into force. Pending the entry into force of the ED criteria, the evaluating Competent Authority shall therefore point out in the assessment report whether the substance is an ED according to the interim criteria and similarly the Biocidal Product Committee (BPC) of ECHA in its opinion.

As a result, in accordance with Article 5(2) and paragraph 10 of Annex VI to the BPR, a biocidal product containing a substance that meets the interim ED criteria shall only be authorised by a Member State where at least one of the conditions set in Article 5(2) is met on its territory. Once the scientific ED criteria enter into force, these criteria would apply to all on-going procedures for the approval and the renewal of active substances. The related consequences will also apply to the authorisation and the renewal of biocidal products which contain substances meeting the scientific ED criteria.

For the on-going procedures on the approval or renewal of approval of active substances taking place after the criteria enter into force, the Competent Authority will have to point out in the assessment report, and similarly the BPC in its opinion, whether the active substance has endocrine disrupting properties in accordance with the scientific ED criteria. In that context, the evaluating Competent Authority, or the BPC, the applicant shall be given the opportunity to provide additional information that could be relevant for the purpose of concluding about the criteria. The Commission indicated that this is consistent with the general principle that, if you change the rules, applicants should have the opportunity to react.

One Member State pointed out the practical situation that many dossiers in procedure will be caught by the criteria. Also it is unclear for this MS what would happen with approved active substances. Another MS asked for a clear mapping of the different scenarios pointing out the stage in which the approval or renewal procedures might be by the date of application of the criteria and how the criteria will be implemented. According to this MS many questions have to be answered and MSs have also to meet legal deadlines in the review programme Regulation. Another MS asked for a CA document addressing how the criteria will be implemented. The Commission agreed to map how the criteria should be implemented for the different procedures and stages in those procedures.
The Commission acknowledged that the impact in practice will relate to the transitional period included in the final act. The Commission clarified that the development of guidance is launched but indicated guidance can not be established before the criteria are adopted and enter into force. A meeting in Brussels is scheduled for the 4th of October with Agencies and the Commission. However, a time line for the finalisation of guidance document cannot be given. An expert of EP stressed the transitional phase and asked when the Commission expect a response of ECHA to look at existing substances in the review programme, knowing that the clock stop is only applicable by the evaluating competent authority.

6) The meaning of criteria for other legislation
One MS expressed its support for horizontally applicable criteria and indicated the criteria will have an impact on other legislation. The MS points in this context to the legislation on cosmetics that refers to the criteria that will be adopted by the Commission. The Commission indicated that in the Communication from the Commission on EDs[3] a section discusses what the criteria set for biocides and PPPs mean for other regulatory areas. An expert of EP points out that the roadmap enables horizontal application of the criteria and considers that criteria would impact discussions in REACH. He is in favour of coherence between different pieces of legislation.

At the end of the meeting the Chair concluded that there are a number of issues on which diverging views exist. MSs, and in particular those MS that have not expressed their views and positions are invited to provide 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.
One MS pointed out to send additional comments on the fact that the draft act only concerns active substances. In its view all substances should be included, like co-formulants. One MS supported this view.
One MS indicated it will probably agree an official position the beginning of October.
Another MS indicated it put EDs on the agenda of the of ENV and AGRI/FISH councils. The Chair indicated to be aware that this MS is in contact with Presidency supported by another MS.
The Chair pointed out that the deadline for comments is the end of September. One MS indicated it would like to have written answers. The Chair pointed out that minutes are made of each meeting and the Commission will respond to the comments by a revised text.

[3] http://ec.europa.eu/health/endocrine_disruptors/docs/com_2016_350_en.pdf