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

**CA-Dec16-Doc.2**

# DRAFT MINUTES

# 67th 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

## 18 November 2016

## Points 2 and 3 (ED session)

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| **WEDNESDAY 16 NOVEMBER 2016** | | |
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| **1. Adoption of the agenda** | For adoption<br>*CA-Nov16-Doc.1* | |

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| **2. Adoption of the draft minutes of the previous CA meeting** | For adoption<br>*CA-Nov16-Doc.2a (minutes 25-26 May 2016)* | |
| | For adoption<br>*CA-Nov16-Doc.2b (minutes 22-23 September 2016)* | |
| | For adoption, ED session<br>*CA-Nov16-Doc.2c (minutes 22 June 2016)* | **Closed session, for adoption on <u>18/11 morning</u> (9h30-12h30)** |
| | For adoption, ED session<br>*CA-Nov16-Doc.2d (minutes 21 September 2016)* | **Closed session, for adoption on <u>18/11 morning</u> (9h30-12h30)** |

The minutes of the ED session of the meeting held on 22 June 2016 were adopted.

The Commission received comments of MSs on the draft minutes of the ED session of the meeting held on 21 September. Those comments were included in the revised version uploaded on CIRCABC. A representative of the EP indicated he sent comments to the minutes of the meeting held on 21 September 2016 which had not been included. He suggested setting precise deadlines for comments on the draft minutes of the present and of future meetings. The editorial comments of the EP representative were read out by the Commission. The draft minutes of the ED session of the meeting held on 21 September 2016, including the comments of the EP Representative, were adopted.

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| **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 | **Closed session, <u>discussion on 18/11 morning</u> (9h30-12h30)** |

The Commission welcomed participants and informed that the objective of the meeting was to present a revised text for the draft delegated act on the criteria, and that a meeting focusing on the draft act under the plant protection products Regulation will take place during the afternoon. 22 Member States (MS) were present. The Commission informed that three representatives of the EP are present, while the representative for the Council apologised.

Written comments on the revised criteria were received from 4 MS prior to the meeting. The Commission informed that they will consider the comments received applicable to both biocides and plant protection products acts, as the criteria should be the same, unless otherwise indicated. Two MS confirmed that their comments were relevant for both BP and PPP.

The Commission reminded that a proposal for the criteria has been available since June 2016, i.e. for 5 months, and therefore, the preliminary views of all MS will be requested at the end of the meeting.

A revised draft act on the criteria was made available about two weeks before the present meeting. The overall approach has not been changed, i.e. no introduction of categories or potency.
The Commission has clarified the scope of the WHO definition by following strictly the wording of the WHO definitions. The wording "may cause adverse effect" has been introduced in order to maintain the original wording of the legislation. On the section referring to the kind of scientific evidence to be used, the word "primarily" has been removed in order to clarify that no hierarchy exists for the type evidence to be assessed; however, the two sub-points (a) and (b) are kept separate to acknowledge the fact that studies according to agreed study protocols will always be available because they are mandatory due to the data requirements.

The Commission presented the changes in the text paragraph by paragraph. For instance, it was explained that changes to recital 3 are linked to a better clarification of the scientific evidence that may be used and of the data requirements set in the BPR. Changes in recital 4 clarify better the entry into force and the implementation of the criteria. There are no changes to the articles.
In the Annex, the changes are clarifications aiming to a better alignment to the WHO definition of an endocrine disruptor and to the BPR. A better link is made between the first part of the text (three elements of the WHO definition of an ED, the "three commandments") and the second part (principles on how to implement the criteria). Also the three elements of the draft act related to the WHO definition of an ED have been redrafted accordingly.
In section B, similar changes to section A have been introduced where appropriate. The word "population" has been changed into "(sub)population" where appropriate in the text. Reference to field and monitoring data was redrafted because it would be inconsistent to neglect this type of evidence if the approach is to consider all available evidence.

## 1. DISCUSSION ON SECTION A OF THE DRAFT CRITERIA

One MS thanked the Commission for the revised proposal, in particular they are pleased that the drafting "known to cause" has been removed. However, they believe that the use of the word "shows" requires the same level of evidence as "known to cause". In their opinion, the use of 'shows' and the requirement that "*the adverse effect is a consequence of the endocrine mode of action*" will make it very difficult or impossible to demonstrate that a substance is an ED. Moreover, the level of evidence is higher than for other classes of chemicals like CMRs. This MS supports to have categories in the criteria similarly to the CLP Regulation. They do not see the problem in using the same wording of the CLP Regulation for categories in the ED criteria. Finally, they note that the proposal only covers active substances and the legal requirements of BPR for EDs also cover biocidal products including co-formulants.

One MS indicated that some of the changes in the revised text go in the right direction. However, they have similar concerns to the previous MS speaking. They proposed to have included “known or presumed” or “potential” or “expected” in points A.1 and B.1. They have submitted written suggestions for a revision and simplification of the text. They recall the Commission reluctance in September to introduce categories. The MS acknowledges that Article 5 does not have categories. However, this article also does not state that no categories can be set. According to this MS for a second category of EDs, potential EDs, can become candidates for substitution. They indicated that the criteria required in Article 5.3 speak about ED properties and they do not limit the requirement to active substances.

One MS indicated that they would like to have more details how provided comments are taking into account. They propose to consider not only the WHO definition of an ED, but also the WHO definition of a “potential ED”. They also propose 3 categories: known, presumed and suspected. They believe the subcategorization is legally possible. They believe that the proposed changes in the draft act are not substantial and the required level of proof is still too high, e.g. *in silico* studies are not considered. By end of November the formal position of the scientific agency of this MS will be circulated. The MS placed a scrutiny reservation on the draft act.

On the methodology for assessing comments, the Commission indicated that the comments received were accommodated where possible in the revised proposal discussed at the current meeting. Some comments are not addressed as the Commission maintained its position on potency and categories.

One MS asked a clarification how the “the unless clause” introduced in section A corresponds with “may cause adverse effect”. Another MS believed that without a guidance document (GD) it will be difficult for MS to implement the criteria. Therefore they propose to have a GD finalized at the time of application.

One MS indicated that, despite some progress, improvements in the text are still needed.

One MS indicated that they support many of the written proposals put forward by another MS. Although “may cause” is now reintroduced in the text, it should be stated more clearly that “may” also covers “presumed”.

One MS indicated that they welcome the proposal as many of their comments were taken into account. They made some editorial suggestions by proposing to delete texts that are redundant. This MS also recalls that scientific data generated in accordance with internationally agreed study protocols are not all relevant for ED assessment.

One MS indicated that they can agree with the term “shows” although they initially supported the word “presumed”.

An EEA country indicated that they believe the text has improved, but they support the written comments from one MS.

An EP representative indicated that the revised criteria are not yet fully aligned with the WHO definition as it is referred to the "endocrine mode of action" instead of to "alteration of the function(s) of the endocrine system" and asked the Commission whether it would agree that these were different matters and why the draft criteria are not fully aligned to the WHO definition.. It was also asked why there was no reference to “biological plausibility” in the

three commandments for the link between the adverse effect and an alteration of function(s) of the endocrine system in line with the Commission's Communication on the criteria, rather than to require that the adverse effect is a consequence of an endocrine mode of action. With regard to the views of some MSs that the criteria should apply to BPs covering also substances of concern. The same EP representative wanted to know how the Commission want MSs to implement the provision of Article 19 on biocidal products, which also cover other substances of concern, if the revised criteria were limited to active substances only. . It was also asked why "read across" a (in contrast with CLP and with the roadmap) was not referred to in the methodology for assessing data with regard to the criteria..

The Commission clarified that "presumed EDs" are included in the criteria because it is clear that evidence from animal studies should be considered. The "unless clause" implies that adverse effects in animals are assumed to be relevant for humans, unless proven otherwise. The word "may" simply means that it is not affecting 100% of a population.
The Commission indicated it disagreed with the written proposal of a MS to significantly shorten the criteria by removing all the provisions on the 2nd part of the criteria, which detail how to gather and assess the evidence for the identification of EDs. This would also not be consistent with the request of many MSs to have guidance ready before criteria are adopted.
The Commission also clarified that it would be impossible to endorse a GD before adopting the criteria. However, it reminded that EFSA and ECHA have been mandated to develop a joint GD as soon as possible. The idea is that the GD would be ready for public consultation at the moment the criteria are adopted and enter into force.
The Commission reminded MS why it believes that categories would not be appropriate in the context of the PPPR and BPR: the consequences for different categories are not set in these two pieces of legislation. Defining the consequences for these categories is beyond the mandate of the Commission and having categories with no regulatory consequences would lead to legal uncertainty and unpredictability. It was clarified that if the words "known and presumed" were included in the criteria this could create confusion with the CLP. The Commission reminded MS that the role of the criteria put forward with the draft legal acts is to identify EDs (in the context of the PPPR and BPR) and not to set categories for their classification, labelling and packaging. The Commission has chosen the words "shows an adverse effect" with the objective to cover both "known and presumed", being at the same time a term which avoids confusion with the CLP.
Concerning substances on which some evidence exists for an endocrine mode of action or an adverse effect, but this evidence is considered to be insufficient for their identification as EDs, the Commission indicated these substances would still undergo a risk assessment and only approved if there are no unacceptable effects. Therefore no legislative gap exists.
As regards the consideration of read-across data, the Commission clarified that they are already set on a more general level in the BPR and therefore can be considered in the ED assessment.
As regards the comments on active substances and BP, the Commission indicated that they will reflect if this comment from several MSs can be accommodated.
On the word "shows", the Commission mentioned that they have made an effort to stick to the WHO definition and that they consider that "shown" is less stringent that "known". They reminded that the WHO definition actually speaks about "causes". It is true that the "mode of action" is not mentioned in the WHO definition. However, it is used in scientific opinions and publication. In fact, in the draft criteria "function(s) of the endocrine system" has been added to clarify what is meant with the "mode of action". "Biological plausibility" is already mentioned in section A.2. There is not justified to repeat it in section A.1 because it is not included in the WHO definition.

One MS indicated that several of their comments were taken on board. They believe a GD is essential and therefore asked for it at Council level. They understand that MSs and ED expert group will be more involved in the consultation phase as ECHA and EFSA have to progress, however, they recommend that the Commission would consult them frequently and asked to be informed about the work of the WG drafting the GD. They asked clarifications about the application of criteria also to co-formulants included in BPs.

The Commission confirmed that MS will be kept informed about the progress on the GD. Before the end of the year a scoping paper with an outline of the GD is expected. The Commission indicated that the Agencies are preparing the GD with the support of the JRC.

One MS pointed out that the BPR only speaks about active substances and not about co-formulants. The MS questioned whether the Commission could amend the BPR to be able to apply criteria also to co-formulants.

One MS indicated that they support option 2. They cannot support categories and potency.

One MS indicated that discussion is ongoing in their Parliament. Therefore they cannot express a formal position. They would agree to include co-formulants in the application of the criteria.

The Commission reminded that co-formulants are not in the scope of the implementing act on PPP.

One MS indicated that they support including co-formulants in the identification of EDs. This would help to better evaluate biocidal products.

One MS indicated that they believe categories should not be included.

One MS indicated that the today's clarifications of the Commission are not appearing in the draft act. One MS asked whether the Commission would align the burden of proof with the precautionary principle and noted that the Commission is not using the exact terminology of the WHO definition.

An EP representative pointed out that the CLP Regulation specifically defines which type of data can be used not to classify a substance and asked whether the Commission would be prepared to follow this approach. This representative asked why a systematic review is only foreseen for the scientific literature.
The Commission explained that a systematic review is thought to analyse studies in the literature. The data sent in accordance with established data requirements by the applicants need to consider anyhow due to the agreed rules, and therefore it makes no sense to subject them to a selection process in line with systematic review methodology.

## 2. DISCUSSION ON SECTION B OF THE DRAFT CRITERIA

One MS indicated that they would like to include in art 5.1.d there is a limitation to adverse effects in humans. Therefore a link between humans and non-target organisms should be made in the criteria.

One MS indicated that they would like to include in para 2.c.i, also amphibians as OECD test are available for these animals.

One MS indicated that under Point 2.c.3i, they would like to include “and other relevant effects" as, besides adverse effects on reproduction and growth/development, other adverse effecs (e.g. disruption of physiological effects affecting the migration of birds) could also have impact on (sub)populations.

One MS indicated that the “unless clause” will provoke a lot of test submitted by applicants by non-standardised protocols which will make life for competent authorities very difficult. Another MS supported this statement.

An EP representative referred to the written comments from ECHA that that results from population models would introduce a risk assessment element in the ED identification, since such population models normally need an exposure value as input, while these criteria concern hazard identification, and not risk assessment  Field studies data and monitoring should be removed because these studies normally require an exposure assessment.
The Commission explained that exposure is also considered in laboratory studies. As regards the request of a MS to mention amphibians, it was pointed out that the draft act only lists examples but that it is not an exhaustive list.

ECHA clarified that all relevant data should be considered, including those from field studies. The concern of ECHA is that if the criteria will be horizontal, then the exposure scenarios could be different in PPP and in other sectors creating inconsistencies in the identification of EDs.
The Commission explained that field studies will be a piece of information amongst others with no overriding weight.

## 3. DISCUSSION ON THE RECITALS

One MS indicated that there should be no doubt that it is up to the applicant to demonstrate the active substance is not an ED. The recital should state more clearly that the burden of proof is on the applicant and this should be reflected in the data requirements.
The Commission explained that the burden of proof is on the applicant and that this is one of the underlying principles of the BPR.

One MS pointed out that the data requirements should be updated. The Commission indicated that these would be updated to technical and scientific progress.

One MS indicated that in Article 1 “determination of ED properties” is mentioned. However, the Annex only refers to active substance. This MS supports the inclusion of co-formulants.

One MS indicated that in Recital 2 they would like to include the EDEAG report, as already mentioned in their written comments of July. It also mentioned that mentioning EFSA as "the Authority" is not appropriate in the context of the BPR.

One MS asked clarification regarding recital 2. How the criteria will be implemented, i.e. will they be considered in all on-going evaluations of active substances? Would this mean in practice a stop of the discussion in committees? Another MS mentioned that the entering into force of the ED criteria implies that new data requirements would apply. In practice it implies that applicants would have to collect additional data and this would lead to a delay of evaluations. It could also jeopardise legal deadlines that apply for competent authorities to

finalise the evaluations in the review programme and the MS pointed out their concern regarding potential court cases.
The Commission clarified that the intention is to apply the criteria as soon as possible. On the other hand applicants have legal expectations. The Commission is reflecting on the best approach to ensure a smooth implementation of the criteria.
The Commission also reminded MS that currently substances are subjected to the interim criteria. However, it is clear that these interim criteria are not fit for purpose, as they detect many false positives and false negatives.
One MS asked clarification on the procedure for applicants that would be required to submit further data which would then not be allowed on the market. ECHA commented that this is relevant for new active substances, as many substances are already on the market and subject to the review programme.
The Commission reassured the MSs that this issue is being considered very carefully.

An EP representative reminded that in REACH the PBT requirements were changed over time. The EP representative asked whether the Commission could confirm that all applicants would have to amend their applications to show that the cut-off criteria for EDs are not met.
The Commission clarified that the procedures are not comparable for REACH. In BPR/PPPR, substances are approved for a certain time. The burden of proof is on the applicant. For on-going procedures the new criteria will be applied. This means that the applicants may need to submit further data.

The EP representative asked clarification about approved active substances. Will Article 14 of the BPR be used?
One MS suggested that first MSs have to agree on the criteria and then agree on the procedures on how to implement them.
One MS asked whether the Commission still intends to align adoption of the draft criteria for BP and PPP. The Commission confirmed this.

## 4. CONCLUSIONS

As anticipated at the beginning of the meeting, the Commission asked MS to indicate their views on the draft act in a tour de table:

- 1 MS indicated that they could support the proposed text
- 4 MS indicated that they were against the draft act
- 2 MS indicated they would abstain if they had to vote (even though this is not the procedure)
- 17 MS had no final position yet
- 4 MS were absent

The Commission invited the MSs to submit comments in writing by 30/11/2016. The Commission invited the MSs to respect the deadline and preferably also try to liaise with the PPP colleagues. The same deadline will be communicated in the afternoon to their respective colleagues of the PPPR. The date of the next meeting is not yet defined.

The Commission indicated that they will circulate as soon as possible the draft minutes of the meeting and they will give a short deadline for commenting. The revised draft minutes will be published on the Commission website.