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

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DRAFT MINUTES

68th 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

Brussels, 21 December 2016

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WEDNESDAY 21 DECEMBER 2016		
Morning Session	**Closed session**	**9:30 – 11:30**

1. Adoption of the agenda	For adoption *CA-Dec16-Doc.1-rev1*	

The draft agenda of the 68th 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 (CA meeting) was adopted as proposed.

2. Adoption of the draft minutes of the previous CA meeting	For adoption, ED session *CA-Dec16-Doc.2 (minutes 18 November 2016, ED session)*

The draft minutes were adopted.

3. Draft delegated regulation		
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-Dec16-Doc.3.1.a revised draft delegated regulation* *CA-Dec16-Doc.3.1.b revised annex to the draft delegated act*	

The Chair welcomed the experts and informed that two representatives of the EP were present while no representative of the Council was present. A revised version of the draft delegated act was uploaded on CIRCABC on 7 December 2016.

The Commission highlighted the main differences compared to the November version. In the annex the term "active substance" has been changed to "substance". This implies that coformulants contained in biocidal products are now in the scope of the draft criteria. In order to be consistent the Commission proposed to change the drafting of Article 1 into the following: "*The scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 are set out in the Annex to this Regulation*".

Another amendment is the addition of paragraph (e) to point 2 of the section B of the Annex. This paragraph was introduced following requests from MS during the discussion on the draft implementing act for setting ED criteria for plant protection products in the Standing Committee of 18 November 2016 to refer to "non-target vertebrates" rather than "non target organisms". In the meeting the Commission proposed to amend this paragraph slightly to: "*If*

the intended mode of action of the active substance being assessed, as defined under point 6.5 of Title 1 of the Annex II to Commission Regulation (EU) No 528/2012, consists of controlling target organisms via their endocrine system, it shall not be considered for the identification of the substance as endocrine disruptor with respect to non-target organisms". The Commission also suggested adding the following recital in order to explain the rationale: "*For active substances whose intended plant protection mode of action, as defined under Regulation (EU) No 528/2012 Commission Regulation (EU) No 283/2013, is to control target organisms via their endocrine system, this mode of action should not be considered for the identification of the endocrine disrupting properties*. ". The Commission clarified that this recital will be updated for biocides.

Following comments from a Member State the Commission also suggested moving the following text in brackets of point (2) (a)(i) of Section A and Section B "(*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*)" to (2)(a) of both Section A and B. So, point 2(a) of sections A and B would read the following: "all relevant scientific data (*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*):[…]".

One Member State (MS) pointed out that the draft text provides that the criteria shall not apply where the Standing Committee has voted on a draft regulation. This MS proposed to include that the criteria shall not apply where a scientific committee and/or working group discusses a substance.

One MS indicated that point 2(e) of section A is a repetition of the sentence "*unless there is information demonstrating that the adverse effects identified are clearly not relevant to human*s" in point 1 of section A. This MS considered paragraph (e) to point 2 of the section B too broad and proposed to restrict the scope to similar non-target organisms.

Another MS stated that paragraph (e) to point 2 of the section B is very broad, considered it a risk management issue and cannot accept it. This MS welcomed that the revised act covers coformulants. However, this MS stressed that it is difficult to establish the impact of the draft criteria without the availability of guidance. This MS also stated its concerns on the high level of evidence required to identify EDs and the lack of coherence with other relevant legislation. It was proposed to include the words "known and presumed" and "biological plausibility in the three points in the first part of sections A and B. This MS also proposed to include read-across in the draft act and to add amphibians to point 2(c)(i) of section B.

Another MS supported to include amphibians in the act.

One MS would like to have an additional article containing a revision clause of the act: "*the regulation shall be reviewed no later than 5 years after entering into force*". The same MS proposed to have a transitional period until the relevant guidance would be available.

Another MS asked to include "known or presumed" to cause adverse effects. Also was requested that point 1(c) of section A and B is changed to "it is biologically plausible that the adverse effect is a consequence of the alternation of the hormone system". For this MS the exception in point 5 of section B should be deleted as an intended endocrine mode of action is

not a reason to exclude this mode of action from the identification process as it may have an effect on non-target organisms.

One MS considered that the exception in paragraph (e) to point 2 of the section B of the Annex is not needed in the biocides sector. However, it agrees that it could be included for plant protection products. The MS noted that the reference to guidance is deleted in the former version of the Annex of the draft act ("Guidance on the implementation of Regulation (EU) No 528/2012, issued by the European Chemicals Agency") and indicates it would like to keep it. This MS supported to include a revision clause in the text.

One MS supported the inclusion of the exemption in point (e) of Section B. However, a recital should be included to clarify the objective of this exemption.

One MS agreed to the overall approach of the draft act but has a reservation of the change from 'active substance' to 'substance'. This change could lead to a significant extension of the scope so the text should only extend to coformulants. It was emphasised that a biocidal product may include up to 12-15 coformulants. This MS also stressed the need for guidance to have a harmonised approach.

One MS pointed out that the ED criteria should be limited to active substances. Establishment of ED criteria for substances, including coformulants, should occur by amending the CLP legislation.

Another MS welcomed the inclusion of coformulants in the draft act, and was confident that a proportionate approach can be later agreed in the competent authorities meetings when these criteria would have to be implemented in the context of product authorisation. This MS also referred to the need to introduce 'known and presumed' and "plausible consequence" and proposed to delete the following text in points 2(e) of section A and 2(c)(iii) of section B: "representative field or monitoring data and/or results from population models". This MS would like to delete point (e) of section B and supported the views of previous Member States on this point. This MS stressed that it should be clarified how the ED criteria should be implemented and it favoured an early discussion on transitional arrangements.

Another MS made similar comments with regards to "known and presumed" and "plausibility".

One MS considered that point (e) of section B is not needed for biocides. However, it indicated that it could support the Commission proposal on the criteria.

Another MS referred to the need to introduce 'known and presumed' and "plausible consequence" and support that coformulants would be covered by the criteria. However, it should be ensured that this would not lead to any additional burden for applicants.

One MS supported the inclusion of coformulants and the overall approach of the criteria. At the moment it is unclear whether this MS can support the new provision in point (e) of section B.

Although it would have preferred horizontal criteria across chemicals-related legislation, an EEA country welcomed the proposal and the inclusion of coformulants but expressed reservation about the new provision in point (e) of section B.

An EP representative, referring to the principles of Better Regulation, notably to consistency, asked the Commission how it would justify the inconsistencies of the proposal with the roadmap, the Seventh Environment Action Programme, the CLP Regulation, the WHO definition and Commission communication accompanying the proposal . It was pointed out that due to these inconsistencies, guidance is being requested, which in turn means that the discussions on EDs will probably continue after the adoption of the criteria in the context of the development of the relevant guidance (with no right of scrutiny for the EP and Council) . The EP representative also noted that in section A point 1 (chapeau) and in point 2 (new point e) a similar sentence is included ("unless there is information demonstrating that the adverse effects identified are clearly not relevant to humans"), and asked why it was put twice. He also noted that "clearly" was mentioned in both parts in the text on biocides, but was lacking in the chapeau in pesticides, and asked which version was the correct one. . The EP Representative also asked why the revised text does not include "it alters function(s) of the endocrine system" (as stated in the WHO definition) and "biological plausibility" (as stated in the Commission Communication) in point 1 of sections A and B. The EP representative asked why the proposal did not specify in the act the possibility to apply "read across" even though the act makes a cross-reference to the weight of evidence approach of CLP (which includes "read across") in Recital 3. The representative considered this as important as the criteria will be applied horizontally and not all legislations include provisions on read-across like the BPR. He asked the Commission how it would reconcile the absence of provision on read-across with its policy to minimize animal testing. In relation to point 2(e) of section B the EP representative referred to Article 19(4) of the BPR which includes that a biocidal product should have no unacceptable effects on non-target organisms and stated that it seems that the new point 2(e) would now exempt substances having ED effects on non-target organisms from the regulatory consequences by de-identifying such substances as ED substance. The expert asked the Commission to explain why it would be in its mandate to modify the regulatory consequences of the BPR in the context of the development of scientific criteria for ED substances.

The Commission summarised the points raised by the experts. It was proposed to focus on new points and not to re-discuss the issues concerning "known/presumed" and "is a consequence of" related to point 1 of sections A and B as the Commission provided its views on these points in former meetings. The position of the Commission on these points has not been changed. The views of the experts on including coformulants in the scope of the ED criteria are noted. The Commission stressed that point 2(e) of section B was introduced as a response to view of MSs at the previous meeting discussing the draft act for plant protection products (November 18, 2016). It was also pointed out that the endocrine system differs substantially between different groups of organisms (e.g. vertebrates, invertebrates). It was noted the view of a few MS that this point may only be relevant for plant protection products, however the Commission stressed that there are active substances used in biocidal products which effectiveness is based on affecting the endocrine system of target organisms.

One MS reiterated its view that the current drafting of this point 2(e) of section B is very broad and will exempt substances having effects on non-target organisms. Moreover, there is no need for this point 2(e) because of the possibilities for derogation to exclusion in Article 5 of the BPR.

The EP representative asked whether it was the Commission's intention that active substances that are known to be ED substances should be allowed to have adverse effects on non-target organisms.

The Commission underlines that the clarification on the scope of the criteria with respect to substances where the intended biocidal mode of action is via a endocrine system only applies to the section B of the Annex (non-target organisms). It implies that these would be excluded from being identified as ED based on this intended mode of action, but that in any case they would be subjected to a full environmental risk assessment as any other biocidal active substance. A biocidal active substance will only be approved and a biocidal product will only be authorised if no unacceptable effects occur on non-target organisms. The Commission also pointed out that it prefers to keep the text of the criteria aligned between plant protection products and biocidal products.

One MS indicated that several MSs consider the current drafting of exemption too broad for various reasons. Several MSs proposed to restrict the scope to address this. The Commission indicated that the drafting of point 2(e) of section B was also chosen to avoid excluding new scientific developments and that because of this the draft text was not referring only to IGR.

To answer the proposal made by one MS that the criteria shall not apply where the substance is under discussion in scientific committee and/or working group, the Commission clarified that the conclusions of these committees can be substantially delayed in practice, and that the only date which gives clear legal certainty is when a vote already took place on an active substance in the Standing Committee.

The Commission indicated that the outline paper concerning the development of a Guidance document for the implementation of the hazard-based criteria to identify endocrine disruptors is published on the websites of ECHA, EFSA and DG SANTE.

A representative of ECHA provided an introduction to the outline paper of the Guidance Document for the implementation of the criteria that provides a plan of the drafting process, including timelines and the foreseen consultations. The ECHA' representative pointed out that the objective is that the Guidance document should provide guidance to both applicants and regulatory authorities. Although it is acknowledged that the ED criteria will only apply to BP and PPPs, the guidance document should take into account the applicability to other legislations. Currently the scope of the guidance is limited to vertebrates. It is recognised that other endocrine modalities may exist in non-vertebrates, however, this could be addressed in future updates of the guidance. Starting from January on, 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 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.

The Commission indicated that the Commission will reflect positively on the suggestions of including a review clause and transitional period, which will be also discussed in the Standing Committee on setting ED criteria for plant protection products which takes place immediately after this meeting. The Commission also pointed out that the Commission is preparing a note to facilitate the implementation of the ED criteria, in particular for the current applications under assessment in Member States.

Following the discussions and the clarifications provided by the Commission the Chair asked MSs to indicate whether they could support the draft act. Seven MS indicated that they could support the proposed text.

The Commission concluded that several Member States raised concerns on point 2(e) of section B whether the intended mode of action of active substances via the endocrine system should be considered in identifying EDs for non-target organisms, and that several MSs asked to redraft this provision in order to restrict the scope. Some MS also was asked to include "read-across" in the text. The change in the revised text from "active substance" to "substance" raised concerns of some MS. Also some editorial issues were raised in relation to point (1) and (5) of both sections. Several MSs asked for guidance how to implement the ED criteria in practice.
The Commission noted the issues concerning "known/presumed" and "is a consequence of" related to point 1 of sections A and B. Also are noted the points raised by an EP representative. A representative of ECHA introduced the outline paper to develop the scientific guidance and the opportunities to contribute to the drafting. The Commission showed a clear willingness to introduce a recital where the Commission would commit to review the ED act and to introduce in the text a transitional period. The Commission will also provide guidance on the provisions in the legislation in order to facilitate the implementation.

4. AOB		