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

CA- June16-Doc.1

MINUTES

65th 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

22 June 2016,

9h30 – 12h30

Centre Borschette, room 2.D, rue Froissart, 36 at Brussels

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22 JUNE 2016

1. Adoption of the agenda	For adoption *CA-June16-Doc.1*	

The draft agenda of the 65th 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.

2. Adoption of the draft minutes of the previous CA meeting	Postponed to the next meeting	

3. Draft delegated acts		
3.1. **Commission delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012**	For discussion *CA-June16-Doc.3.1 (draft regulation)* For information *CA-June16-Doc.3.2 (EC Communication)* *CA-June16-Doc.3.3 (impact assessment)*	Closed session

The Commission introduced document CA-June16-Doc.3.2 which is an EC Communication adopted July 15, 2016, and which is based on the impact assessment report (document CA-June16-Doc.3.3). The impact assessment report is based on a screening study and additional evidence, which was analysed via a Multi Criteria Analysis. Commission informed that the impact assessment report does not conclude in any preferred option and the decision regarding the drafting of the criteria has been taken based on scientific considerations.

It was explained that because the draft criteria are being proposed in a delegated act, the discussions take place in an expert group and in accordance with the Inter-Institutional Agreement Council and Parliament may send experts to the meeting on the delegated act. One expert from the Council (an administrator) and three from the European Parliament (one representing the Green party group, one representing the EPP, an administrator of the ENVI committee) were present. A letter from five MEP was provided by the expert representing the Green party group asking to circulate it. The Commission intends to make future comments and letters on the draft delegated act on endocrine disruptors (EDs) available on the part of CIRCABC concerning this expert group.

It is explained that in the Standing Committee for Plants Animals Food and Feed (SCPAFF), which takes place the same day during the afternoon, the draft implementing act on EDs under Regulation 1107/2009 will be discussed. The CA meeting will focus exclusively on the draft delegated act, however, the criteria are identical to the PPP criteria. The discussion processes of both acts will be conducted in parallel with the aim to have the same criteria under both regulations. Therefore, there has to be a vote in the SCPAFF on the implementing

act before the Commission can adopt the delegated act. The Commission encouraged delegations to coordinate their position on both draft acts at national level.

The intention is to adopt the criteria as soon as possible. The Commission informed that WTO (through the TBT committee) had been notified of the criteria on biocidal products (SPS has been notified for the draft implementing act on plant protection products (PPP)). Through the feedback mechanism the public is consulted on the delegated and implementing acts, starting 30 June 2016. A meeting with stakeholders is taking place on 30 June 2016.

The Commission is aware that this meeting was called on with a very short notice, but it was important to inform the experts as soon as possible on the criteria. Since delegations had not much time to reflect on the proposed criteria, views expressed in the meeting are therefore considered preliminary.

Questions were raised regarding procedural issues, and the following was clarified:

- The Commission has the legal mandate to prepare criteria under the PPP and BP Regulations (i.e. two legal acts, one implementing and one delegated). Once they are adopted it is anticipated that they may have an impact on other pieces of legislation. The screening exercise for the impact assessment to determine active substances with potential endocrine disrupting properties has taken this into account and, in addition to BP and PPP other substances from REACH and the Water Framework Directive were covered.

- The draft acts set criteria for EDs and there will be discussions in both BP expert meeting and in SCPAFF in parallel. The Commission intends to align the PPP and BP processes. Currently there is no timetable for the next meetings.

Regarding document CA-June16-Doc.3.3 a few Member States and also the expert representing the Green party group asked some questions that the Commission answered.

One Member State wondered for how many active substances out of the 600 that were screened sufficient data on EDs was available to be assessed. The expert representing the Green party group was critical of the impact assessment referring to the opinion of the Regulatory Scrutiny Board but acknowledged the relevance of the screening study that was conducted by the contractor. The Commission explained that details on data availability can be found in the study report of the contractor, which is about to be published on SANTE website at the end of June 2016. Data availability for the screening varied both between substances used in BP, PPP, h REACH and cosmetics. Expert judgement was needed to assess substances and the method description explains how the assessment was done. The main advantage of the screening study is that three years ago it was not known how many substances could be affected by ED criteria, but now an estimation is available for several possible ED-criteria options. Due to lack of data and short time frame the Commission stressed the screening is an estimate and its results should not have regulatory consequences.

The expert representing the Green party group also wondered if DG SANTE will ask JRC to conduct a new screening based on the newly proposed criteria. DG SANTE indicated that it will not ask JRC to do another screening study. Once the criteria are adopted they will be applied under the relevant BP Regulation. It is expected that the criteria proposed would, once applied, end up with a result in line with the screening exercise.

One Member State wondered who was involved in the Impact Assessment for the economic assessment and the Commission clarified that it was done in-house.

One Member State wanted clarification regarding the finalisation of the impact assessment. The Commission explained that the Regulatory Scrutiny Board provided a positive opinion and the impact assessment was finalised on 15 June 2016. The report on the screening study by the contractor will be published the end of June. The results of the PPP and BP substances were available in February and are included in the impact assessment. The screening of substances used in REACH and Cosmetics was finalised by the contractor the beginning of June.

One Member State wondered about the number of substances falling under Option 3. It was explained that 26 BP substances in Cat II and 8 in Cat III were determined, as detailed in Annex 5 of the impact assessment report.

The expert representing the Green party group asked why the option chosen to define the criteria was not one of the options as included in the roadmap. The Commission explained that Option 2 in the roadmap is reflected in the proposed act, although the wording had to be adapted in the legal act.

Several Member States supported the alignment of ED criteria in PPP and BP regulation. Two Member States stressed it is important to have horizontal criteria applicable to all chemicals.

The Commission introduced document CA-June16-Doc.3.1 which is the draft regulation and the core of the criteria was explained. The criteria are based on the WHO definition and thus consist of three core elements; presence of an adverse effect, presence of the mode of action and the causal link between the two. Letters have been sent to the ECHA and the EFSA asking the agencies to prepare themselves of the work ahead.

The Commission clarified that the current derogations stated in the PPP and BP Regulations to approve ED substances under certain conditions are different. The proposed adjustment of the derogation included in the draft implementing act (PPP) will be discussed in the afternoon as it is not relevant for this expert group.

The Commission further clarified splitting the criteria into human health and environment was needed in order to reflect the current structure in the BP and PPP Regulations. One Member State supported the split of the criteria in human health and environment.

Several Member States thanked the Commission for producing the criteria. Two Member States thanked the Commission for not taking potency on board while one Member State expressed disappointment that the Commission had not included potency in the criteria.

Numerous Member States voiced concerns over getting too little time to scrutinise the criteria. Several Member States indicated that the draft act is subject to scrutiny by the Parliament and the Council. Commission is aware that the delegations have not had much time to reflect on the proposed criteria. For the next meeting Member States are invited to examine the criteria carefully before taking position and giving comments.

Several Member Stated raised concern over the wording in the criteria "known" and "presumed". Member States asked the Commission to clarify on what scientific grounds the draft act proposes to identify only known and not also potential/presumed EDs as this is not considered in line with Option 2 in the Roadmap. The Commission explained that the criteria are based on the WHO definition (the 3 principles adverse effect, mode of action, link) but the

wording of the implementation is inspired by the CLP legislation. The WHO definition reads “alters function” and not “may alter function”, and in light of this the Commission does not believe the draft act reduces the scope. It is not the intention to reduce the scope of the regulation and the wording "known to cause" is mentioned only to the first part of the criteria (i.e. the three principles of the WHO definition). In the second part of the criteria, i.e. the implementation part of the criteria, a wider scope is evident as it is explained how to implement the criteria; e.g., under consideration of weight of evidence, biological plausibility, etc.

One Member State indicated that the precautionary principle is not taken into account in the current proposal.

Two Member States wondered why the Commission did not include categories in the criteria. The Commission explained that it considers not having a mandate to come up with a classification as applied in the Classification, Labelling and Packaging Regulation (CLP), which has a different objective. The mandate of the Commission is to set criteria to identify ED in the context of approvals of active substances (AS) for PPP and BP, where a "yes or no" answer is needed. The Commission believes not to have the mandate to propose a prioritisation of active substances in particular under the regulatory system of PPPs and BPs, where there would be no direct regulatory consequences for additional categories.

One Member State stated that categorisation is relevant for PPPs, referring to Annex 2 section 4 that deals with Candidates for Substitution. This Member State explained that a categorisation is needed in order to assess which substances are candidates for substitution. Another Member State referred to the substitution and exclusion criteria in the BP Regulation that provide possibility of categorisation. The Commission notes that its reading of Candidate of Substitution (CfS) may differ because ED-substances would either be non-approved or approved under one of the derogations. In the latter case, substances would be classified as a CfS and thus approved under restricted conditions, shorter period of time, etc.

One Member State pointed out an ambiguity between the texts in the proposal and the Communication. See page 5 “How to determine causality” which acknowledges it is difficult to demonstrate conclusive evidence of causality and therefore the Commission intends to follow a concept of a “reasonable evidence (“biological plausibility”)” to determine causality. The Commission clarified that biological plausibility is clearly mentioned e.g. in Section A 2.(2) of the draft act.

One Member State wondered why not just the adverse effect was enough for a substance to be an ED and that an endocrine mode of action (MoA) is not needed. The Commission clarified that CMR substances are defined based on the adverse effect, while EDs are defined based on the adverse effect and the MoA, which is the innovative part at the core of the ED issue. It should be noted that some CMR substances may be also EDs.

One Member State indicated that adverse effect should be relevant at population level. However, this does not imply that adverse effects should be demonstrated at population level. In CLP Regulation it is sufficient to show an effect at animal level. The Member State wanted to make sure that also effects shown with valid in vitro methods would still be relevant for ED assessment. The Commission explained that a tiered approach is a normal procedure for environmental risk assessment. Commission thinks it is important to make the link to the population level also for EDs, in line with the WHO definition. Further, the draft acts on the criteria have to be considered in the regulatory context of BPs and PPPs in which animal

studies are key. The draft acts clearly state that it is assumed that adverse effects in animal studies are relevant, unless otherwise demonstrated.

One Member State commented that an adverse effect does not have to be demonstrated in animals. The expert representing the Green party group would like the Commission to clarify if human evidence will be needed for the identification an ED. The expert representing the Green party group also asked whether preference is given to internationally agreed study protocol in point 2.(1)(a) and mentioned that there are fewer studies available based on internationally agreed study protocol than independent peer reviewed studies. The Commission clarified that it is not asking for evidence or final proof in vivo in humans, referring to point 2(1) which refers to all available relevant scientific evidence. The intended scope of the applicable evidence is wide and does not only consider human data but a wide range of studies, including in vitro studies. Point (3)(a)(v) states clearly that the route of exposure is assumed to be relevant to humans, unless convincing evidence exists to explain the differences between test animals and humans. Read-across and QSAR data are not excluded.

One Member State wondered about the implications of the implementation of the delegated act on EDs. It was especially asked if there will be an impact on the review program and if applicants would be required to submit additional data. This may lead to situation that some substances would not be further supported in the review programme. The same Member State pointed out that losing products is not necessarily good for society. The Commission's intention is to implement the criteria as soon as possible but acknowledges it will be a challenge. The implementation may have implications for the review programme and the Commission is in contact with ECHA and EFSA regarding how to implement the criteria smoothly.

One Member State raised concern about the current lack of test methods, and said there will not be relevant tests available until 2025. The Commission acknowledged the issue of the lack of some test methods to establish the MoA. However, it was noted that some tests are available and that there are currently test methods under development and these will be considered in the future.

One Member State asked whether the Commission could respond in writing to the raised questions in the meeting. The Commission indicated that all received written comments will be made available to the expert group for further discussion at the next meeting.

The expert representing the Green party group wanted the Commission to justify the proposed changes made under the PPP Regulation. The expert representing the Green party group also pointed out that the criteria should be applied to other legislation (e.g. REACH). The Commission answered that its mandate is to set criteria that would apply only to PPP and BP legislations s and that the PPP draft act will be discussed in the corresponding Standing Committee.

On a question from a Member State on data requirements and the weight of evidence approach the Commission explained that there is no a-priori ranking between studies intended in the weight of evidence approach.

The Chair thanked for the comments received and reminded that the interventions of today are considered preliminary comments. The members of the expert group are invited to provide written comments by 7 July 2016. More meetings will be organised in which there will be

opportunity to provide comments and to raise questions. The Chair stressed that it is the intention to move as quickly as possible with the adoption of the draft act.

4. AOB	No issues raised	

Next meetings (provisional):

2016

CG	CA	BEG	BPC
7-July			
20 September	21-22-*23* September		
			10 - 14 October
15 November	16-18 November	*Week 8 November*	
			12-16 December

*Meetings in italics still to be confirmed