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

DRAFT MINUTES

71st 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

7 April 2017

Starting at 10h00 – Ending at 14h00

Charlemagne building, room Lord Jenkins

Closed session

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FRIDAY 7 APRIL 2017		

Morning Session	Closed session	**10:00 – 1400**

1. Adoption of the agenda	For adoption *CA-April17-Doc.1*	

The Chair informed the participants that the Commission would like to add under AOB input from the Commission's Legal Service (LS) in reaction to a specific legal question raised by one Member State in writing. An expert of the EP asked whether this AOB point could be discussed at the beginning of the meeting to allow a discussion about the application of the exclusion criteria to substances identified as endocrine disruptors (EDs) under the scientific criteria in the presence of the LS. The Chair clarified that this was already foreseen.

The draft agenda was adopted as proposed.

2. Adoption of the draft minutes of the February CA meeting on EDs	For adoption *CA-April17-Doc.2 (minutes 28 February 2017)*

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-April17-Doc.3.1.a* *a revised draft delegated regulation* *CA-April17-Doc.3.1.b revised annex to the draft delegated act* *Doc-April17-Doc.3.1.c - comments*	

The Chair welcomed the experts and informed that three experts of the EP (including two political advisers) were present, and noted that experts from the Council and 8 Member States were absent.

A representative of the Legal Service (LS) of the Commission clarified that the exclusion criteria will not be triggered for active substances determined as ED only based on adverse effects on non-target organisms (i.e ED for the environment). According to one MS the part in the Article 5(1)(d) of the Biocidal Products Regulation (BPR) stating *'may cause adverse effects in humans*' only applies for the interim criteria and not for the scientific criteria. The LS indicated that different linguistic versions of this article clearly follow the English version

in which this part of the article 5(1)(d) applies to both scientific and interim criteria. Therefore, there is no discrepancy between the different linguistic versions, and the exclusion criteria apply only to active substances identified with the scientific criteria as ED for adverse effects in humans. The exclusion criteria do not apply to active substances identified with the scientific criteria as ED for the environment.
One MS, subsequently supported by another MS and echoed by a question from an expert of the EP, pointed out that Article 5(1)(d) covers also ED for the environment as references are made to articles 57(f) and 59(1) of REACH regulation. The LS stated that, under Article 57 of REACH, an equivalent level of concern has to be demonstrated and one reason for adding a substance to the Candidate List of REACH could be ED properties due to adverse effects to the environment. The reference to Articles 57(f) and 59(1) of REACH in Article 5(1)(d) of the BPR implies that an additional route applies and, if a substance is identified as an ED under REACH due to effects on humans or the environment, the exclusion criteria in the BPR are met for that substance, and the regulatory consequences included in the BPR will apply. The LS therefore clarified that the restriction for human health in Article 5(1)(d) of the BPR applies only for substances identified as ED under the scientific ED criteria set under the BPR, but does not apply for substances identified by the route of REACH. In other words, active substances identified as ED for the environment under REACH will be subject to the exclusion criteria under the BPR.

One MS, and an expert from the EP also asked if the provisions of Article 19(4) of the BPR are only applicable to EDs identified on the basis of adverse effects in humans, or also to EDs for adverse effects on the environment. The LS pointed out that no restriction is included in Article 19(4) in relation to effects on human health or the environment: this means that the provisions of Article 19(4) apply to all substances with ED properties.

An expert of the EP pointed out that a delegated act can amend only non-essential elements of a basic act. He asked whether it was in the mandate of the Commission to include in the draft delegated act the provision on intended endocrine mode of action. The provision would lead to a de-identification of certain substances presenting ED properties. That expert of the EP further indicated that the judgement of the General court on the case Sweden versus Commission (T-521/14) included that the Commission cannot call into question the balance in the regulation between an improvement in the functioning of internal market on the one hand, and the preservation of a high level of protection of human and animal health, on the other. According to that representative, the de-identification of certain substances calls into question this balance as the exclusion criteria under Article 5(1)(d) would no longer be applicable to these active substances and moreover, that the the regulatory consequences laid down by the legislator in Article 19(4)(d) on use by the general public, which do not foresee any derogation, would no longer apply, He referred also to the summary record of the discussion on setting ED criteria for plant protection products which states that this provision would allow no to apply the cut-off criteria.
The Commission responded that the provision on growth regulators has been requested by several Member States in the discussions of the implementing act for setting ED criteria for plant protection products. This provision in the draft act does not affect the exclusion criteria under the BPR as the exclusion criteria are not triggered by active substances identified as ED under the scientific criteria in the delegated act based on environmental adverse effects. The LS pointed out that the Commission was given a broad empowerment by the legislation to set these criteria on what an ED is and recalled that the Court of Justice has established that the Commission has a wide appreciation on technical and scientific matters in exercising its delegated powers.

One MS asked clarifications on the procedures to follow to identify EDs under REACH. The LS indicated that what matters is that there is an equivalent concern to CMR or PBT/vPvB substances in order to list a substance on a candidate list. A Court of Justice ruling made clear it is a case-by-case hazard assessment to establish if there is an equivalent level of concern. Article 15 of REACH only excludes biocidal active substances from the registration requirements of REACH, but other provisions of REACH are applicable. Therefore, a MS may decide to trigger the Article 59 procedure to include a substance (biocidal active substance or co-formulant) on the candidate list under REACH by preparing the corresponding dossier and submit it to ECHA. One MS pointed out that, to build such dossier, data are needed on the substance. This MS fears that it will be difficult to obtain data of the applicant on ED properties, if the substance is not identified as an ED under the scientific criteria.

One MS pointed out that an expert group on questions related to REACH and CLP (the CARACAL) is deliberating on how to deal with EDs in REACH. This MS asked whether it would be possible to have a note of the LS on the discussed legal issues. The LS explained that its role is supporting the Commission and not MS, and that any note from LS is internal. He referred to the minutes of this meeting for having the LS views on legal issues.

One MS pointed out that the CARACAL is going to determine the implementation of Article 57 in relation to EDs. This may trigger differences between the REACH approach for EDs, and the scientific criteria for biocides and plant protection products. An expert of the EP pointed out that the situation may occur that a substance with an intended endocrine mode of action would be considered not to have ED properties under the established scientific criteria under the BPR or PPPR, but could be identified as an ED under REACH. The LS pointed out that there are different procedures under BPR and REACH for determining whether substances may have ED properties. These routes can be considered as complementary routes of classification that may capture different substances. Under REACH the situation is clear as dossiers submitted under Article 59 have to demonstrate an equivalent level of concern.
DG GROW stated that the recent discussions at CARACAL concerned the report on the REACH ED Review, which was published end of December 2016. This review was required according to Art. 138(7) of REACH, and the Commission was specifically requested by this article to determine, taken latest developments in scientific knowledge into account, whether substances identified under REACH using Art. 57(f) and Art. 59 as having ED properties could only be authorised following the so-called socio-economic route, similar to CMRs with no threshold and to PBT/vPvB-substances. The discussions at CARACAL were not about how to identify EDs under REACH. DG GROW clarified that the report is finalised (and published). The report states that the decision on which route under the REACH authorisation procedure has to be followed is a case-by-case decision and depends whether applicants for authorisation can demonstrate whether a threshold for the ED-related effect exists.

The Commission clarified the provision in the draft act concerning active substances with an intended endocrine mode of action (presentation).

One MS, subsequently supported by five other MSs, indicated that, in its opinion, this provision mixes the setting of criteria with risk management and considered there is no scientific justification to exclude active substances with intended endocrine mode of action from the ED criteria. This MS considered that, if the exclusion criteria under the BPR only apply to substances identified as ED for humans via the scientific criteria, this provision should be deleted and that active substances with an intended endocrine mode of action shall still be identified as ED. This MS also said that arthropods are 80% of animals, and these

may be exempted from the criteria. Further, the provision would make it difficult to obtain appropriate data of an applicant on unacceptable effects on non-target organisms. The Commission responded that the provision in the draft delegated act on intended endocrine mode of action only applies for the determination of ED properties with respect to the specific modality (axis) of this intended endocrine mode of action. A risk assessment must in any case be performed to conclude whether unacceptable effects on non-target organisms may occur. The appropriate data can be required from the applicant in order to perform such risk assessment. The Commission clarified that there is a scientific justification for the provision on the intended ED mode of action, since the mode of action of such active substances are different from those known to be relevant for vertebrates.

One MS considered that the provision on the intended endocrine mode of action may lead to a lack of harmonisation with REACH as such substance (i.e growth regulator for invertebrates) could be identified as ED under REACH (art.57(f) and 59(1)) as mentioned in art 5(1) of the BPR.

One MS supported the objective of the provision in the draft act and suggested that another drafting may help to find agreement. One MS sympathised with the logic that identification of the hazard should not be mixed with risk management measures, but on balance thought that decisions on insect growth regulators should be made based on risk assessment. That Member State therefore supported the COM's position, though was open to alternative wording. This could make clear that substances with an intended endocrine mode of action are not being 'de-identified' as endocrine disruptors, but are not to be considered as endocrine disruptors for the purposes of certain provisions in BPR. A MS underlined the need to delete or rephrase the provision and indicated, subsequently supported by another MS, that the scope of the current exemption is too broad and proposed to have it at "order" and not at "phylum" level, as they do not consider acceptable to have such effects on non-target organisms of the same phylum. Another MS expressed its sympathy for the concerns expressed by the previous Member States on the provision. If kept, the provision should be rephrased.
The Chair noted that several of the MS present had so far not expressed their opinion and invited those experts to provide their opinion.

An expert of the EP asked the impact of this exemption of substances with an intended mode of action on the labelling provisions in Article 69(n) of the BPR, and as well as on data requirements to be submitted in applications for approvals or authorisations. He asked also whether the provision is needed as the 'unless clause'[1] in the draft delegated act could be applied. The Commission indicated that this provision on active substances with intended endocrine mode of action does not affect the other provisions in the BPR that allow the competent authority to ask for additional data needed to perform the risk assessment. The Commission indicated that the protection of the environment is ensured by the risk assessment that must be performed in any case and this assessment is looking at whether unacceptable effects may occur on arthropod organisms. The 'unless clause' will not be applicable for active substances with an intended endocrine mode of action, therefore, the provision is included in the draft act.
With regards to Article 69(n) the Commission indicated that this article specifies that, where applicable, the label must show information on any specific danger to the environment, thus a danger to the environment must be mentioned on the label.

[1] The draft delegated act contains the following sentence in section B1 of the draft annex: '[…] *unless there is evidence demonstrating that the adverse effects identified are not relevant at the (sub)population level for non-target organisms'.*

The Chair summarised that 8 MS were absent, 7 MS indicated their support for provision on intended endocrine mode of action, 10 MS asked to delete that provision or to reword it, and 3 MS did not express a position. The Chair concluded that the Commission would reflect on whether and how the concerns expressed by MS on the provision could be addressed.

An expert of the EP clarified by reference to the "Read across assessment framework" published by ECHA in March 2017 that it would actually not be correct to subsume read across under the term "in silico studies" (referred to solely in the context of endocrine mode of action, but not for adverse effects). According to ECHA, "*read-across is regarded as a technique for predicting endpoint information for one substance (target substance), by using data from the same endpoint from (an)other substance(s), (source substance(s))*".

Furthermore, according to the same ECHA document, in silico studies would be just one type of supporting evidence that could support a particular read-across hypothesis. In other words, read across would be a larger concept than in silico studies, in silico studies would merely be one tool to use in the context of read across. He thus asked whether the Commission was prepared to reconsider this point and to include explicitly in the draft act that read-across can be used for determining ED properties or mode of action. The Commission recalled that all the provisions of the BPR (including read-across as mentioned in Annex IV of the BPR) apply when implementing the criteria.

One MS asked about the future procedural plans of the Commission. The Commission indicated that based on this meeting, technical discussions may still be needed but that it is not yet possible to indicate if and when another meeting would take place.

4. AOB		

<u>Next meetings (provisional):</u>

2017

CG	CA	BEG	BPC	BPC's WG
19 January	-		-	I: 16-20/01
-	-		1 – 3 March	
14-15 March	15-17 March	31 March	-	II: 06-10/03
-	7 April		24 – 28 April	
10 May	11-12 May		-	III: 29/05-02/06
-	-		26 – 30 June	
11 July	12 July (only SCBP)		-	
26 September	27-29 September		-	IV: 04-08/09
-	-		02 – 06 October	
21* November	22-24 November		-	V: 20-24/11
-	-		11-15 December	

* 20 November, to be checked with ECHA: BPR IT user group meeting