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Food and feed safety, innovation
Pesticides and Biocides

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DRAFT MINUTES

69th 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

28 February 2017

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TUESDAY 28 FEBRUARY 2017

Afternoon Session	**Closed session**	**13:00 – 15:30**

1. Adoption of the agenda	For adoption *CA-Feb17-Doc.1-rev.1*	

The draft agenda of the 69th 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-Febr17-Doc.2-rev.2 (minutes 21 December 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-Febr17-Doc.3.1.a* *a revised draft delegated regulation* *CA-Febr17-Doc.3.1.b revised annex to the draft delegated act*	

The Chair welcomed the experts and informed that three experts of the EP (including two political advisers) were present while no expert of the Council was present. A revised version of the draft delegated act was uploaded on CIRCABC on 7 February 2017.

The Commission informed that in the morning an indicative vote had been taken on the draft act for criteria for plant protection products in the Standing Committee for Plants, Animals, Food and Feed (SC PAFF), which indicated that no qualified majority would have been achieved. Many Member States which indicated they would abstain or voting against would have supported the criteria if the draft measure would have included also the text on the amendment to the derogation on negligible exposure. No formal vote was taken.

The Commission explained the procedure for delegated acts. While the criteria to be set on the basis of the PPPR under the "PRAC procedure" provide for a vote in the Standing Committee for Plants, Animals, Food and Feed (SC PAFF), under the BPR there is no vote in the Standing Committee on Biocidal Products on the draft delegated act. Under the BPR, the Commission adopts the delegated act, which then can be objected by the Council or the European Parliament. Before the adoption of the delegated act, the Commission has to inform

the experts about the conclusions to be drawn from the discussions, the reactions and how the Commission intends to proceed. In case there is no objection from either the Council or the Parliament within 2(+2) months against the delegated act, the delegated act will be published and enters into force. In case either the Council or the Parliament object explaining the reasons for such objections, the delegated act cannot be published and does not enter into force. In this case, the Commission may prepare a new proposal. The voting rules as regards the objection are the same for delegated acts and regulatory procedure with scrutiny (RPS/PRAC): the Parliament objects with majority of component members, the Council with qualified majority.

Considering the outcome in the SC PAFF during the morning session (no vote yet taken on the scientific criteria due to lack of qualified majority) the Commission indicated that it will reflect on the next steps in the process. The Commission highlighted that further postponing the criteria is not benefitting the environment or human health. Furthermore, the Commission reminded the Member States that the EU General Court declared that, by not adopting the criteria under the BPR, the Commission failed to act. Although the Commission has had several rounds of discussion with experts on the draft delegated act, it is still failing to act until adopting the scientific criteria. This is different from the situation under the PPPR, where the Commission's legal obligation consists in submitting to the SC PAFF a proposal for scientific criteria. The Commission informed the Member States that it needs to comply with this judgment.

The Commission highlighted the main differences compared to the December 2016 version of the draft delegated Regulation, which were the changes agreed during the SC PAFF meeting in December which were transferred to the biocidal text: a transition clause of 6 months, a revision clause, and the redrafted provision for growth regulators.

The Commission also outlined the few changes introduced to the draft as a consequence of the discussion with MS during the SC PAFF in the morning of the 28 of February. These were clarifications to the text and not on content. As the intention is to adopt the same criteria for both PPPR and BPR, the changes introduced in the morning session should be reflected also in the draft delegated act. Compared to the version sent out on 7 February 2017, the provision on growth regulators has been moved up from point (2)(e) of the Annex to be a stand-alone point (3) of Section B. This makes clear that this provision is not part of the principles of the criteria which detail how the weight of evidence should be assessed and it is rather a stand-alone point. Should the criteria be transposed in future to other chemical legislation, it will be clear that this point is only relevant for biocidal products and plant protection products, where active substances may have <u>intended</u> endocrine modes of action to control harmful organisms. Further, during the PAFF SC, the provision has been amended in order to clarify that vertebrates would not be in the scope of this provision.

Another amendment since the December meeting is a review clause which will require the Commission to submit an assessment of the working experience of the scientific criteria after seven years since their application. After discussion during the SC PAFF, the wording is slightly changed since the revision sent on 7 February 2017 to further clarify that after seven years the assessment shall be presented within the deadline indicated in the provision. Article 3 now reads: "*Within seven years from [date of application], the Commission shall assess the experience gained from the application of the scientific criteria for the determination of endocrine disrupting properties introduced by the present Regulation, in light of the objectives of Regulation (EU) No 528/2012*."

One Member State stated it was unhappy that the criteria only cover hazard identification and not also hazard characterization. Under BPR, the situation is manageable since there are several derogations, but for other sectors (e.g. the PPPR) this would be problematic because decisions may be taken without similar risk-based derogations being available.

Two MS raised concerns regarding the inclusion of co-formulants in the draft delegated act. The issue is whether the criteria will apply also to co-formulants, and if so, what consequences this may lead to in terms of implementation and resources needed for the assessment of biocidal products. Considering there can be between twelve and fifteen, even up to twenty co-formulants in a product, applying the criteria to them, in addition to the active substance, would have major implications on workload if these are going to be assessed under the BPR. One MS wondered which Article in the Regulation would apply for co-formulants as Article 5 is drafted for active substances while Article 19 is for products. Furthermore, there would also be the issue of who would have the responsibility to supply the data, and if the data to be submitted should be new or whether decisions would rely on existing data (e.g. safety data sheet). Further clarifications are needed in order to know how best implement the criteria in practice.

Three MS and one EEA country welcomed the transitional period.

One MS raised concerns that there may be problems with double work for active substances already undergoing assessment by ECHA, and wondered whether there are other ways to set the cut-off-date for application of the criteria, rather than applying the criteria to all substances where a decision has not yet been taken by the Standing Committee. Specifically, that MS suggested that the criteria should not apply to dossiers where the draft Competent Authority Report has already been submitted to ECHA to start the review process. If the criteria apply to all substances in the pipeline, that MS also asked whether the applicants could voluntarily apply the new criteria from the date of entry into force of the criteria, rather than having to apply the interim criteria until the transitional period had elapsed. Under the Regulation on classification and labelling for instance, voluntary application of a new classification is accepted from the date of entry into force of the moment an Adaptation to Technical and Scientific Progress (ATP) is available. The same might be proposed here for the new criteria. The MS also raised the issue of what new data requirement applicants would be asked to submit.

Another MS stressed the importance of having the Guidance Document (GD) ready when the criteria enter into force. It will be in the GD that the actual burden of proof is decided and detailed. The MS highlighted that in the framework of BPR and PPPR, risk managers and risk assessors can ask for data until the substances are proved to be safe.

Two MS and one EEA country welcomed the review of the criteria which should be completed after seven years. One MS proposed an amendment to the review clause pointing out that such clause should explicitly indicate that, if necessary, the criteria should be revised based on the working experience and, if required, the Commission should be able to propose an amendment.

Nine MS and one EEA country did not agree with the inclusion of the provision clarifying the scope of growth regulators under point (2)(e) of Section B [from now on point (3) of Section B] of the Annex. One MS, subsequently supported by others, claimed that the BPR already includes Article 5(2) that can be used to make derogations where an active substance is considered to meet the exclusion criteria in Article 5(1). The MS were concerned that active

substances with intended endocrine disrupting effects are exempted and therefore excluded from Article 5(1). In addition, this may lead to the fact that such substances will not qualify a biocidal product as having ED properties and that the restrictions on use by the general public cannot be applied. Three of the MS which raised this point further explained that the inclusion of a provision on growth regulators is part of the risk management process and irrelevant for the scientific criteria that are to be set.

Two MS supported the inclusion of the provision on growth regulators. One of these Member States stressed that only with this provision, horizontal criteria between BPR and PPPR can be achieved.

One MS, subsequently supported by others, would like active substances with an intended endocrine disruptive effect to be labelled as endocrine disruptors. The same MS would also, for point (3) of Section B in the Annex, like to see a change from *phylum* to *order*.

One MS repeated its concern regarding the requirement for evidence, which the MS believes is too high. The MS also re-iterated their concerns regarding coherence with other legislations.

One MS welcomed the new text although it would have liked that the plausibility of the link between the effect and the cause in the text were highlighted also in the first part of the criteria (the three commandments).

One MS asked to include "*known or presumed"* to cause adverse effects. Two MS 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".

An expert of the EP stated that he will refrain from repeating the questions about the lack of consistency with the WHO definition and the principles of Better Regulation that he had raised at the previous meeting. On the topic of biological plausibility, he asked if point (1)(c) of the Annex requires complete evidence or a plausible link to demonstrate that the adverse effect is a consequence of the endocrine mode of action (MoA). He furthermore asked for clarification whether “read across” would apply in the proposed weight of evidence approach, as Recital 3 refers to the CLP Regulation, which in turn explicitly includes the possibility to apply "read across", while there is no reference to read across in the operative part under Point 2. He pointed out that this may be relevant if the criteria were to be applied in other fields, such as for example medical devices. In the politically agreed complete revision of the Medical Devices Regulation , there is a specific cross-reference to the delegated act for ED criteria for the identification of EDs. However, there are no general provisions on read across in Medical Devices Regulation. Further legislations may want to apply the criteria, and it would therefore be important to know if read across can be used in those contexts to identify EDs. In the absence of read across, individual testing might be necessary for every substance, which could lead to delays in the identification and to unnecessary animal testing. With regards the provision on growth regulators, he asked for the scientific basis to de-identify substances and whether the Commission’s proposal would not rather deal with issues that are of a regulatory nature beyond their mandate to come up with scientific criteria. He asked how it would legally be possible to first to 'de-identify' endocrine disruptors, and then still require a full environmental risk assessment of those substances for precisely those properties.

The Commission responded to the EP expert that the plausible link is considered in point (2)(c)(iii) of Section A and point (2)(c)(iv) of Section B: "*the biological plausibility of the link*

between the adverse effects and the endocrine mode of action." It is not present in point (1) because the Commission aimed to stay as close as possible to the WHO definition. Regarding read across, this is implicit as an essential principle in the BPR. It is furthermore covered implicitly in the bracket for in vivo, in vitro and in silico studies under point (2)(a) in the annex, as in silico studies include read across.

The Commission explained the main regulatory consequences where a biocidal product has ED properties due to a co-formulant. The relevant articles are: Article 19(4) of the BPR where it states that, as soon as a biocidal product has ED properties, it cannot be authorised for use by the general public. Moreover, pursuant to Article 22(2)(e) of the BPR, the summary of product characteristics (SPC) shall also indicate the qualitative and quantitative composition of the co-formulant in the product, as the co-formulant will be considered as a substance of concern (i.e. an endocrine disruptor).

The Commission explained the rationale behind the provision on growth regulators. From a scientific basis, if an active substance mimics the hormones of insects, it means that it works through an endocrine MoA and that this is intended. This kind of substances are already foreseen in both the biocidal and plant protection products legislations, i.e. in the PPP legislation there is a major group of substances and an entire chemical class with this type of MoA that is particularly useful in integrated pest management (IPM). Further, substances with this mode of action have specific data requirements, which mean that they are already considered as a class of active substances with a specific and intended MoA.

The Commission re-iterated that these ED-criteria are cut-off criteria only based on hazard assessment. A full risk assessment for human health and for the environment is always foreseen, even if a substance is not identified as endocrine disruptor. In other words, in any case an active substance can only be approved if there are no adverse effects demonstrated for humans and no unacceptable effects for non-target organisms.

The Commission notes that there are some MS who would like to delete the provision on growth regulators. The Commission stressed the importance of this provision for the SC PAFF and clarified that the provision only applies to active substances and not to co-formulants. The Commission informed that two MS in the morning session explicitly supported the provision and many other MS indicated they could support the criteria as proposed by the Commission, i.e. with the inclusion of the provision on growth regulators. If this provision in the BP criteria is removed, there will be a situation where active substances are identified as ED under the BPR but not under the PPPR. This illustrates why it is not possible to lower the taxon order: certain active substances are used in biocides to control mosquitos and flies (order Diptera) while they are used to control e.g. larvae of the order Lepidoptera when used in PPPs. For a scientific point of view, phylum is the taxon that has to be mentioned in this provision.

The Commission further clarified that a substance acting as an endocrine disruptor for vertebrates would always be identified as such. In fact, the provision on growth regulators only applies to substances with an endocrine MoA for insects and plants, and on the environment section of the criteria. The provision is not applicable to the human health section of the criteria nor to vertebrates.

The Commission indicated not to share the reading of some MS, which indicated that the derogations under Article 5(2) of the BPR can be applied to approve growth regulators. The Commission clarified that Article 5(1)(d) refers to endocrine disruptors with respect to

humans only, not to the environment. Thus, an active substance identified as an endocrine disruptor against the environmental criteria does not meet the exclusion criteria and could therefore not qualify to benefit from the derogations under Article 5(2). The active substance could be approved as a candidate for substitution according to Article 10(1)(e) of the BPR. However, any biocidal product containing such active substance would have ED properties and pursuant to Article 19(4) of the BPR, products could never be authorised for the general public as no derogation is possible under Article 19(5) of the BPR.

One MS proposed to remove the provision on growth regulators from the criteria and instead to discuss it at a later stage in the SC PAFF, together with the provision on negligible risk. The Commission responded that this would not improve legal clarity and instead increase workload for all parties.

One MS agreed that consistency with PPPR is important, but also stressed the need for consistency with other legislation related to BPR. The MS pointed out that under Article 5(1)(d) there is both a link to human health and to the environment (via the reference to REACH). This could mean that an active substance may be identified as an endocrine disruptor under REACH even if it is not under the BPR.

The Commission clarified that chemicals falling under REACH do not have intended biocidal or pesticidal MoA because substances used for the purpose of controlling target organisms are outside the scope of REACH. These active substances are only relevant under BPR and PPPR. The provision is a clarification on how to handle growth regulators, which are active substances falling under the BPR and PPPR. The provision on growth regulators has been now moved as a separate stand-alone point, so that the other parts of the criteria can be taken over by other legislations, without including the provision on growth regulators.

One MS expressed concerns and proposed to remove the provision on growth regulators from the criteria for the BPR. The criteria could then be applicable for REACH and the provision could still be kept for PPPR. Keeping the provision on growth regulators for BPR makes the criteria more difficult to apply horizontally. The MS highlighted that the BPR does not have extra data requirements for growth regulators as the PPPR does. The MS also raised the example of Iodine which, although it might be identified as an endocrine disruptor, is very important as a biocidal active substance and might be kept approved using the derogations. It concluded by stating that any policy provision should be in the main text of the legislation and not in the criteria.

The Commission indicated that it is already reflecting on how best to implement the criteria in practice with regards to product authorisations and co-formulants. There may be a potential problem with regards to product authorisation due to the legal deadlines to have all existing products authorised according to the BPR rules within 3 years from the date of approval of the active substance. It will be important to handle the implementation in a practical manner in order to avoid double work, since the assessment of the active substance is done at EU level while in most cases product authorisations are assessed and granted nationally. In this context, it should be considered how best to handle co-formulants and whether they could be addressed via REACH in an EU wide scheme. These issues will be discussed in a document under preparation which will be presented in an upcoming CA meeting.

The EP expert followed up on the Commissions response that it is not necessary to address biological plausibility and agreed that to include this in the first part of the criteria (three commandments) would complement the WHO definition. However, the criteria proposed by

the Commission are not mirroring the exact wording of the WHO definition, so the changes would be possible. He also pointed out that, regarding read across, the reference to in-silico studies only refers to the endocrine MoA and not for predicting adverse effect, and asked for the reasons of that limitation . He also re-iterated an earlier question and asked how it will be possible to assess the ED risks of a growth regulator for non-target organisms if the substance was de-identified as an endocrine disruptor precisely for those non-target organisms in hazard identification.

The Commission explained that for PPP, it is important to clarify the scope in the provision for growth regulators. A major group of chemicals and an entire chemical class of PPP would fall under the cut off criteria and banned if the conditions for the foreseen derogations are not met, while some of these growth regulators are low risk substances. The Commission also highlighted that the provision on growth regulators is used to clarify the scope for active substances which have an intended endocrine MoA via an axis very different from the EATS (endocrine/androgen/thyroid/steroidogenesis) axes (e.g., plant hormones such as gibberellin). The Commission reminded that the growth regulators will still undergo a full risk assessment, which includes consideration of effects on non-target organisms in the environment.

One MS informed that it had explained to its chamber of commerce - which had asked whether the criteria would be applied to REACH and cosmetics regulation - that the criteria may partly be applied to other legislations, but if those sectors would have specific problems, the criteria would be modified. Consequently, the criteria will not be identical to all sectors. The Commission confirmed that the criteria are drafted in such a way that they can be easily transposed to other legislation. However, they are not directly applicable to other legislations.

The Commission addressed the point raised by two MS on the transition period and in particular on whether the criteria would be applicable to those substances where an opinion is already issued. The Commission explained that the intention was that the criteria would apply to all substances where a decision had not yet been taken on the approval.

One MS wondered whether the review programme would be exempted from the application of the new ED criteria.

The Commission responded that often new legislation is applied to new submitted dossiers. The criteria for endocrine disruptors are intended to be applied also to any on-going applications, e.g. to dossiers of active substances that are under revision by Member States, the agencies, or where there is an opinion or conclusion but a decision taken has not been taken yet. One consequence of this approach is that there would be a need to 'stop the clock' and ask the applicants for new data and to re-assess the substances. The current proposal is to apply the new criteria to all active substances where the vote in the committee has not been taken yet. This is in contrast with what one MS proposed, i.e., to apply the new criteria only to the cases where Member States are still assessing the dossiers (for cases were the Agency is already working or has concluded, the interim criteria would apply). The Commission acknowledged that its current proposal would generate additional work and lead to delays in the approval process, since applicants would need to be given time to submit the new data, and MS and agencies would need to assess these. The practical implementation on active substance approvals and product authorisation will be further discussed in upcoming CA meetings.

One MS asked the Commission if the intention is to adopt criteria for BPR first and then PPPR, or vice versa. The MS further wondered when it is expected that the criteria will be

submitted to the EP and Council for scrutiny. The Commission indicated that an answer to these questions cannot be given yet, since it depends on how the discussions will proceed in the CA meetings and in the SC PAFF.

One MS raised concern that the BPR mandated the Commission to explicitly set criteria only with respect to human health and not with respect to the environment. It wondered whether this could be a problem.

One MS came back to the issue that there is a link to REACH in Article 5 of the BPR which enables restrictions to be placed on active substances causing endocrine disruption in non-target organisms. This MS considered that the provision for growth regulators would be an overlap with the existing derogations in the BPR and, therefore, the need of this provision was not clear. The same MS also highlighted that if co-formulants would be included in scope of the criteria, more work would be created, while the requirement for assessing endocrine disrupting properties is already in the BPR via product authorisations.

The EP expert asked again why the reference to in-silico studies only refers to the MoA and not to adverse effects in the current proposal. The EP expert wondered whether read-across could be used also when assessing adverse effects, and recalled the importance to consider this in the context of any horizontal application of the criteria. The Commission responded that read across is already included in the BPR and thus there is no need to mention it explicitly. The Commission further re-iterated that the criteria are not intended to be directly applicable to other sectors. However, they are drafted in a way that they can be transposed to other sectors. Some adaptation before application to other sectors may be foreseen if needed.

The Commission concluded that several MS raised concerns on point (3) of section B of the Annex regarding the provision on growth regulators. The Commission indicated that it will reflect on the applicability of the existing derogations under the BPR to the growth reglators, and also with respect to the consequences regarding the horizontal application of the criteria, as the initial intention was to have the same criteria for PPPR and BPR. Removing the provision on growth regulators (GR) under the BPR would deviate from this approach. There were also points raised on the impact on product authorisation of applying the new ED criteria to co-formulants and on the practical application of the new criteria to any on-going approval procedure of active substances after the transitional period, details of which will be discussed further. The Commission also noted the points raised by the EP expert on read across (to which the Commission responded to) and on the horizontal applicability of the criteria to the current text for medical devices.

The Commission noted that the provision clarifying the scope on growth regulators was very welcome in the SC PAFF, in contrast with the response in the CA meeting. The Commission highlighted that the reason why there was no opinion on the criteria in the SC PAFF was rather related to the separation of the criteria from the provision on negligible risk than on the criteria, which have wide support.

The Commission reiterated that there are two different legal basis for the PPPR and BPR and two different procedures to adopt the criteria. For the BPR, the Commission cannot finally conclude on the current document given the discussions in particular on the provisions for growth regulators. The Commission can furthermore not confirm if the BPR criteria will be adopted while still waiting for the PPPR criteria.

The Commission finally expressed its disappointment about the fact that a significant number of the MS (7 delegations) were not represented by experts in the afternoon for the discussion on this sensitive file.

The Commission will keep MS informed regarding the date and venue of another meeting to discuss further the draft delegated act and conclude the discussions on it before moving to the adoption procedure.

4. AOB		