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

Nota bene: ***These draft minutes are not final, as the experts attending the meeting still need to be consulted which might result in amendments and/or clarifications.***

DRAFT MINUTES - EXTRACT

73rd 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

12 July 2017

(b) Draft Commission Delegated Regulation of setting out scientific criteria for the determination of endocrine-disrupting properties	For discussion CA-July17.Doc.7.4.d.1 CA-July17.Doc.7.4.d.2	**Closed session** Scheduled for discussion at 11h30

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The Commission presented the new version of the draft Regulation, and explained that the changes introduced since the last meeting of the expert group aimed at alignment with the text of the draft Commission Regulation setting out criteria for the identification of endocrine disrupting substances used in pesticides, which had received a favourable opinion by qualified majority in the meeting of the Standing Committee for Plants, Animals, Food and Feed (PAFF) on 4 July 2017, so that the same ED-criteria are applicable under the biocidal and plant protection products legislations. The Commission detailed the changes introduced since the last meeting of this expert group (April 2017): introduction of Recital 4 specifying the identification of known and presumed ED substances and redrafting of Recital 5 in order to clarify the scientific and technical rationale for the provision related to substances with an intended ED effect on target organisms (e.g. insect growth regulators). In addition, Article 3 was amended to specify that an assessment of the experience gained from the implementation of these criteria will be presented to the expert group and, in the Annex more prominence was given on the biological plausibility by moving this aspect into a separate paragraph.

One Member State (MS) stated that it had significant concerns, already previously expressed, and indicated it could not support the proposal. Together with another MS, it re-iterated its views that the level of evidence required is too high, and that the provision related to substances with an intended ED effect on target organisms is not needed as the Biocidal Products Regulation already contains provisions to allow for exemptions for such substances if deemed necessary. Three other MSs and two EEA countries supported this Member State's view on the provision related to substances with an intended ED effect on target organisms.

One Member State supported the approach proposed by the Commission for such substances, but raised concerns about the inclusion of co-formulants in the scope of the ED-criteria, in particular because these are not included in the ED-criteria for plant protection products (PPP) and the impacts and procedures for implementation have not been examined. This MS would also prefer transitional measures which would establish that the criteria would not apply to active substances for which the assessment report is already submitted to ECHA. This MS could not provide a definitive position on the draft Regulation because it had been scheduled for discussion in the expert group on a very short notice.

An expert of the EP pointed out that the provision related to substances with an intended ED effect on target organisms implies that the provisions of Article 19(4) would not be applied for substances falling under this provision, and that products containing such substances would not be banned a priori for use by the general public. He indicated that the coordinators in the Environment Committee of the European Parliament (EP) had agreed to request an opinion of the Legal Service of the EP on whether that provision is compatible with the mandate of the Commission. The Commission referred to the last meeting in which it had clarified that the legislation gives a broad empowerment to the Commission to set the criteria.

In addition, the expert of the EP considered that the provision will give less possibility to Member States to request additional data on the properties of such substances and on the risks from using it. An expert of an EEA country expressed also some concerns that the possible impact of such substances on bees would not be assessed. The Commission clarified that the mode of action of the substance has to be identified ("intended mode of action"), and that a risk assessment has to be performed in all cases, which includes the assessment of possible impact on bees. Evaluating Member States would thus have full discretion to require all the data that they deem necessary.

The expert from the EP considered it illogic that this provision, which intended to exempt substances with known ED properties, was part of the proposal for setting criteria for identifying substances with ED properties. The Commission clarified that the provision as point 3 is clearly separated from the "3 commandments" in point (1) and the principles set in point 2 (a) to (d) to implement them. The Commission noted that in order to further clarify this separation, it will reflect on whether the provision could be moved to another position in the text.

One Member State referred to the press release following the vote on the Commission Regulation setting criteria under the plant protection product (PPP) legislation and asked for more details on the ED-strategy, in particular the timing and the involvement of Member States and stakeholders in the development of the strategy as that Member State would like to contribute and share their experience. The Member State also asked about details on the ED-related research projects on which the announced 50 million Euros would be spent. The Chair explained that so far no details on the process for the development of the strategy had been decided and took note of the interest from the Member States to be involved in the process. As to the research projects, he clarified that the normal process would apply, i.e. the Commission publishing calls for projects with certain themes and then interested consortia would have to submit their proposals which would then be evaluated according to merit by specialised juries. The call for projects will probably happen in 2018.

An expert of the EP repeated the wish to see read-across explicitly included in the text so that it would be easier to apply the criteria horizontally to other legislation (e.g. REACH, cosmetics, toys). The Commission reiterated that point 1.5 of Annex IV of the Biocidal Products Regulation (BPR) already refers to the possibility to use read-across - so it is clear that read-across can be applied for the assessment of substances used in biocides. The Commission pointed out that the criteria proposed in the Delegated Regulation are intended solely for the specific legal context of that Regulation – the forthcoming strategy will be the occasion to clarify how the criteria would be incorporated in other legal frameworks, including for the possibilities to use read-across in the processes set out in such other legislation.

The expert of the EP noted that despite the Commission's declared intention for alignment of the criteria for biocides and PPP there were differences, e.g. in point (2)(a). The Commission explained that these differences reflect the different legal frameworks and are needed to ensure consistency within each framework.

The expert of the EP also enquired about the progress made in the development of the guidance by EFSA/ECHA, in particular because political oversight by Member States and EP is needed. The Commission referred to the timeline stated in the outline paper published in December 2016. The draft EFSA/ECHA guidance is expected to be ready for public consultation in autumn, which will be launched once at least one of the Regulations setting ED-criteria is published. ECHA and EFSA had / will consulted Member States on earlier drafts, and ECHA and EFSA intend to organise a workshop to discuss the draft guidance. Furthermore, in the meeting of the PAFF Committee on 4 July, the Commission had made the commitment to apply the procedure described in Article 77 of the PPP Regulation to this guidance document, which would thus ensure political oversight.

The expert of the EP also enquired about the timing of the scrutiny process for the Delegated (BP) and Commission (PPP) Regulations and asked to delay the submission of the PPP Commission Regulation until after the Parliament's summer recess so that both, the PPP and BP Regulations can be scrutinised together giving time to the EP for the preparation of a possible objection. The Chair explained that for the time being the Commission intended to submit the Commission Regulation before the summer recess for the scrutiny period of 3 months and the Delegate Regulation after the summer period as there a 2-month period for possible objection applies. In this way, there will be a large overlap for the scrutiny period and the period of possible objection – so Council and Parliament can evaluate both acts in parallel and the scrutiny periods for both draft Regulations would end more or less at the same time. The expert of the EP reiterated the preference for submission of both draft Regulations after the summer recess and announced that the Parliament might send a letter signed by the chair of the Environment Committee with such a request.

The Commission concluded the discussion by recalling the process followed for preparing the Delegated Regulation and mentioning the most important issues that had been discussed in the previous six meetings of the expert group:

- consistency of the criteria with the WHO definition,
- the level of evidence or burden of proof required to determine that a substance has endocrine disrupting properties,

- the type of evidence that may be used and how to compare/integrate it, the link between the draft criteria and the precautionary principle,
- the strength of the link between the occurrence of an adverse effect and the mode of action of a substance (biologically plausible),
- the introduction of categories depending on the strength of the evidence for a substance having ED properties (known/presumed/suspected),
- the inclusion of potency in the identification of ED properties,
- the specification that an intended mode of action shall not be considered in the scope of the criteria for target organisms and non-target organisms of the same phylum (also referred to as the 'growth regulator provision'),
- the applicability or coherence of the criteria with other legal frameworks (i.e. whether the criteria would apply/have repercussions on other chemicals related legislation / horizontal application),
- the link between the exclusion criteria and the identification of a substance as having endocrine-disrupting properties with respect to humans or to non-target organisms,
- the link between the exclusion criteria and the identification of a substance as SVHC due to ED properties in accordance with Article 57(f) of the REACH Regulation
- the scope of the substances covered, i.e. whether the criteria would apply also to co-formulants contained in biocidal products,
- the availability of scientific guidance to identify endocrine disrupting properties, the transitional arrangements for the applicability of the criteria, i.e. whether they would apply directly or with a transitional period so that affected parties can prepare themselves,
- the introduction of a review clause in the draft Regulation, and the availability of guidance on how the criteria would be implemented in relation to on-going procedures and approved active substances and authorised biocidal products.

The Commission pointed out that all views expressed by the experts (either in the meetings or in writing) had been carefully considered by the Commission, and when accepted had led to substantial changes in the draft Regulation compared to the original version. The different versions of the draft Regulation had been made available to experts via CIRCABC and were also published on DG SANTE's website, in order to ensure maximum transparency. The minutes of the various meetings provide a detailed summary of the discussions that took place and the conclusions of such discussions. The minutes are also publicly available on the section of DG SANTE's website dedicated to EDs and in the public part of CIRCABC concerning this expert group for biocidal products.

Given that all arguments have been discussed extensively during the preceding meetings, the Commission now considers that the discussions are finalised. The version of the draft Delegated Regulation as distributed for this meeting will be the basis for the next steps in the procedure. The Commission has the firm intention to keep the criteria for PPPs and BPs aligned and the outcome of the vote in the PAFF showed that these criteria are broadly supported. However, in the light of the discussion at this meeting, the Commission will still reflect on the best place for the provision on substances with an intended ED effect on target organisms (such as growth regulators).

As to the next steps, the Commission, having taken into account the discussions and views of the experts, views of stakeholders, and comments received during these consultations, will adopt the Delegated Regulation soon and will submit it to the Council and the Parliament for possible objection after the summer recess period, i.e. after 21 August 2017. The period for a possible objection is 2 months, which can be extended by another 2 months.

In the absence of an objection by the EP or Council, the Delegated Regulation will be published in the Official Journal and enter into force 20 days thereafter. The criteria will then apply as from 6 months after the entry into force. In case the Council and / or Parliament object, the Delegated Regulation can neither be published nor enter into force. In this case, the Commission may prepare a new Delegated Regulation.

The Commission thanked all experts involved in the discussions, in particular also in view of the fact that preparing their position had been challenging at some times.