EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL

Directorate E – Food and feed safety, innovation
E4 - Pesticides and Biocides

STANDING COMMITTEE ON BIOCIDAL PRODUCTS

MINUTES

66TH MEETING ON 22 NOVEMBER 2019, FROM 09:30 TO 11:00

Cyprus was represented by Greece, Slovenia was represented by Slovakia, Bulgaria and the United Kingdom were not represented. All other Member States were present.

1. **Adoption of the Agenda (*SCBP66 - Doc.1*)**

The agenda of the meeting was adopted.

2. **Adoption of the Minutes of the 65th SCBP meeting (*SCBP66 - Doc.2*)**

The minutes of the 65th SCBP meeting were adopted.

Section A – Draft(s) presented for an opinion

Section A.1 – Active substances

3. **Postponement of the expiry date of approval of propiconazole for use in biocidal products of product-type 8**

   (a) Examination of the draft Commission Implementing Decision (*SCBP66-Doc.3.1)*

   (b) Opinion of the Committee on the draft Commission Implementing Decision

Before discussing the draft decision postponing the expiry date of approval, the Commission provided a presentation specifying the timelines of the renewal procedure and possible ways to optimise the renewal process for active substances meeting one or more of the exclusion criteria, and invited the Member States to reflect on the matter. In particular, the Commission pointed out that the evaluation of the risks of using the substance – which for one of the derogation possibilities have to be compared to the impacts on society when not renewing the approval - only become available the moment the evaluating competent authority delivers its draft assessment report. To answer the question of one Member State whether an evaluating Competent Authority (eCA) have to conduct an evaluation of all data when it performs a full evaluation, the Commission clarified that although the term 'full evaluation' is used in the legal text of the Biocidal

Products Regulation, this does not mean that all the data in the first approval dossier need to be re-assessed if there is no specific reason to do so. The Commission further pointed out that for a 'full evaluation' the eCA can ask for additional data. This is not foreseen in the BPR for the case of a "limited evaluation".

On the draft proposal postponing the expiry date of approval of propiconazole, the Commission explained that in the light of the preferences expressed by some Member States at the least meeting of the Committee, it had revised its original proposal to propose an extension for one year only. Despite this reduction of the extension period, two Member States indicated not to be in a position to support the proposal as a matter of principle because the substance is meeting one of the exclusion criteria. The Commission noted that it changed its proposal to obtain the widest support of Member States although it could have obtained a simple majority for its original proposal. The Commission further noted that such position of principle was not helpful as these two Member States were not giving technical justifications why the approval should not be extended and had so far not analysed themselves whether this substance would meet the derogation possibilities for their own territory. In addition, pursuant to the BPR, the Commission has the legal obligation to extend the approval of active substance when the examination of the renewal cannot be concluded before the expiry of the approval. The Commission invited Member States to look at the presentation and asked to receive proposals on how to accelerate the renewal process for substances meeting one or more of the exclusion criteria and announced that possibilities to improve the renewal process will be revisited at the next meeting of the Committee.

The Member State hosting the evaluating Competent Authority of this substance explained the reasons for the need of an extension. The Member State pointed out that new data are available and therefore there is a need to update the risk assessment. The situation on this substance evolved since the original approval, in particular as it is now classified toxic for reproduction category 1B. This will change the structure of the market as products classified as toxic for reproduction category 1B are not allowed for use by the general public. Also an assessment of endocrine-disrupting properties has to take place. The Member State pointed out to have preferred an extension of 1,5 years as it considers that it will be challenging to complete the renewal before 30 March 2021, and as a preliminary view would consider that the condition of derogation to exclusion would be met in its territory. It is however ready to support an extension for one year. The Commission confirmed that it would have to extend the approval a second time in case it is likely that the renewal process is not finalised by 30 March 2021.

After a final examination of the proposal, the Committee gave a favourable opinion.

<u>Section B</u> – Items presented for discussion and/or information

Section B.1 – Union authorisations

4. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "HYPRED's octanoic acid based products" (*SCBP66-Doc.4.1)***

The Commission introduced the draft Regulation granting a Union authorisation for a biocidal product family containing the active substance octanoic acid. The Commission informed that the opinion of the Committee on this draft Regulation will be sought via written procedure.

5. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "SOPURCLEAN BPF" (*SCBP66-Doc.5.1)***

The Commission introduced the draft Regulation granting Union authorisation for a biocidal product family containing the active substances octanoic and decanoic acid. One Member State indicated that the products contain a substance of concern and recalled that in the Biocidal Products Committee (BPC) it was agreed to include substances of concern in the section related to human health of the BPC opinion and requested to modify the opinion accordingly. ECHA pointed out that substances of concern, and the justification for their identification, are always included in the general part of the opinion. ECHA also explained that in general an opinion is not amended after the adoption and publication. The Member State then indicated that it can accept to have it mentioned in the general section of the BPC opinion. The Commission thanked the Member State for its flexibility and informed that the opinion of the Committee on this draft Regulation will be sought via written procedure.

6. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "INSECTICIDES FOR HOME USE" (*SCBP66-Doc.6.1)***

The Commission introduced the draft Regulation, emphasising that it was consistent with the BPC opinion and indicating that it has two annexes. Annex 1 sets out an authorisation condition and Annex 2 is the summary of biocidal product characteristics. The Commission informed that during the meeting of the BPC, a member of the Committee expressed a minority position related to a concern about the inadequacy of the risk mitigation measure to keep cats away from treated surfaces without having a specified time limit.

One Member State expressed concerns about the risks of this product for cats as this species is specifically sensitive to the active substance in the products. It argued that the proposed risk mitigation measure "*Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity*" is not sufficient to protect cats, since the product is effective for six months. This Member State proposed that the product should not be used in households were cats are around, and expressed the intention to use the provisions of Article 44(5) to request the Commission to adjust the conditions of the Union authorisation for its territory. Another Member State underlined that it is not favouring to apply Article 44(5) for restrictions that have a horizontal dimension valid in all Member States. A third Member State expressed its concerns about the effectivity of the risk mitigation measure referring to the practicability of keeping cats away of areas treated with the product for six months and asked the Commission to clarify the process to be followed for a co-formulant contained in a biocidal product that has been identified having potential endocrine disruptive properties. The Commission clarified that the procedure is already established in agreed CA-guidance and recalled that during the discussion on the amendment of the data requirements of the Annexes to the Biocidal Products Regulation, the vast majority of the Member States had preferred to identify endocrine disrupting properties of a co-formulant under REACH. The Commission invited the Member State to therefore propose the identification of the co-formulant as having endocrine disrupting properties in accordance with the relevant REACH procedures. The Commission also emphasised that if it is confirmed that this co-formulant is an endocrine disruptor, the Commission will review the Union authorisation for the products and take appropriate measures.

The Commission asked the views of the Member States on the stricter risk mitigation measure proposed by one Member State. Several Member States indicated to support a stricter risk mitigation measure to reduce the risks for cats. One Member State expressed a scrutiny reservation, another Member States asked the possibility to further reflect on it. The Commission concluded that the written procedure for voting on the draft Regulation will not be launched until the issues around the risk mitigation measure are addressed and asked Member States to provide their views on the risk mitigation measure within one week.

7. **Any Other Business**

No items were discussed.