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

65TH MEETING ON 19 SEPTEMBER 2019, FROM 09:30 TO 11:30

Bulgaria was represented by Belgium, Estonia was represented by Latvia, Croatia was represented by Slovenia, Italy was represented by Malta and the UK was represented by Finland. All other Member States were present.

1. **Adoption of the Agenda (*SCBP65 - Doc.1*)**

The agenda of the meeting was adopted with the inclusion of two AOB points: renewal of authorisations for products for which UK was the reference Member State in the mutual recognition process and the status of the decision process on formaldehyde for PTs 2 and 3.

2. **Adoption of the Minutes of the 64th SCBP meeting (*SCBP65 - Doc.2*)**

The minutes of the 64th SCBP meeting were adopted without modification.

Section A – Draft(s) presented for an opinion

Section A.1 – Active substances

3. **Non-approval of silver zeolite as an active substance for use in biocidal products of product-types 2 and 7**
   (a) Examination of the draft Commission Implementing Decision (*SCBP65 - Doc.3.1*)
   (b) Opinion of the Committee on the draft Commission Implementing Decision

4. **Non-approval of silver copper zeolite as an active substance for use in biocidal products of product-types 2 and 7**
   (a) Examination of the draft Commission Implementing Decision (*SCBP65 - Doc.4.1*)
   (b) Opinion of the Committee on the draft Commission Implementing Decision

5. **Non-approval of silver sodium hydrogen zirconium phosphate as an active substance for use in biocidal products of product-types 2 and 7**

    (a) Examination of the draft Commission Implementing Decision (*SCBP65 - Doc.5.1*)

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

The Commission presented the draft Decisions for items 3 to 5 on the agenda jointly. In particular, the Commission explained that it had received extensive comments during the 60-day commenting period under the WTO TBT procedures from the US, who forwarded the concerns from some US stakeholders on the draft measures. Comments had also been received from two other stakeholders from the US and Japan during the same period outside the WTO process. Finally, comments had also recently been received from the applicant. All these comments, together with the EU draft reply to the US under the WTO procedures, had been shared with Member States in advance of the meeting. The Commission also informed that it had met the applicant in February at the applicant's request to present its concerns on the conclusions reached by ECHA's BPC. The Commission explained that it had reviewed all these comments and concluded that it was appropriate to follow the unanimous recommendations of the BPC to not approve these active substances for these uses as sufficient efficacy was not demonstrated. No Member State raised objections or comments.

After a final examination, the Committee gave favourable opinions on each of these three proposals.

6. **Non-approval of carbendazim as an active substance for use in biocidal products of product-type 9**

    (a) Examination of the draft Commission Implementing Decision (*SCBP65 - Doc.6.1*)

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

The Commission presented the draft Decision. After a final examination of the proposal, the Committee gave a favourable opinion.

7. **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 (*SCBP65-Doc.7.1)*

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

The Commission presented the draft Decision. Following the discussions at the last Standing Committee meeting, the Commission had decided to still propose an extension for 2.5 years for propiconazole in the light of the time needed to complete the current procedures for the examination of the application for renewal of approval, similar to previous cases.

One Member State, supported by a few other Member States, could at present not support an extension and considered that the criteria for derogation to exclusion should be assessed before any extension is granted. The Commission expressed sympathy with the objective to not maintain on the market unnecessarily substances meeting the exclusion criteria, but reminded that the current approval expires on 31 March 2020, leaving not enough time for the examination of the possibilities for derogation from exclusion. Therefore, an extension for some time is unavoidable. In particular, the type and the levels of risks together with the possible risk mitigation measures linked to the use of the substance need to be established to evaluate the condition of Article 5(2)(c) of the BPR for derogation from exclusion: this is normally the purpose of the ECHA opinion following the draft evaluation submitted by the evaluating CA (Finland). The Commission noted the absence of the draft report from the evaluating CA who currently plans to submit it in March 2020. The Commission further reminded that the evaluating CA is responsible to decide whether a limited or full assessment is needed, and that extending the approval when the examination cannot be finalised before the expiry date of approval is an obligation coming from Article 14 of the BPR. Furthermore, Member States can only extend their national authorisations when the extension of approval on the active substance has been adopted: the more time is taken by the Committee to come to decision, the less time Member States will have to perform this duty. Providing an extension for less than 2.5 years may lead to the need to adopt in the future another extension decision. As regards to the possibility that the conditions for derogation from exclusion, preliminary information provided by the eCA indicates that 61% of authorised products in PT 8 in R4BP contain propiconazole and that it is thus not straightforward to conclude that a derogation from exclusion would not be justified. Consequently, the analysis and discussions on the possibility for derogation from exclusion with Member States are likely to take time.

Nevertheless, the Commission was open to study proposals from Member States for alternatives to the draft Decision, and asked whether each Member State has already a position whether propiconazole would meet the criteria for derogation from exclusion. A few Member States expressed a position of principle to not support a 2.5 year extension for substances subject to exclusion, but had not made any analysis whether there are alternatives on their market and whether the criteria for derogation from exclusion would be met. Two of these Member States informed that they cannot support any extension of any length at present, but were willing to reconsider whether a shorter period could be supported. The evaluating CA expressed the preliminary view that the substance would be needed on its market and that the criteria for derogation could be met.

One Member State considered that, in case data are missing to assess ED properties, new tests on vertebrate to assess this property should be required only in case the criteria for derogation from exclusion would be met. Several Member States asked the Commission to consider changing the earlier agreed guidance that the assessment of ED properties is always required for substances meeting the exclusion criteria. The Commission stated that it will consider the request, i.e. to modify the guidance so as to request the assessment of ED properties only if is confirmed that the substance can benefit from the derogation possibilities from the exclusion criteria.

One Member State expressed its general concern about triazole substances referring to possible induction of resistance of fungi to medicinal products, and would like to reduce the use of these substances. The Commission invited to submit all relevant information on the possible creation of resistance to the eCA so that it can be taken into account

during the peer review, and during the examination of whether the criteria for derogation from exclusion are met. In response to a question from the Commission, the Member State indicated that it had not considered withdrawing their national authorisations, and had not yet a position on the need for continued use of the substance or whether the criteria for derogation from exclusion would be met.

The Commission noted that evaluating CAs must carefully consider all aspects and the level of assessment needed to decide whether a full evaluation is necessary on a substance already meeting one of the exclusion criteria, as a full evaluation inevitably leads to the necessity to extend the expiry date of approval. Another Member State noted that decisions of evaluating CAs on the need to perform a full evaluation have to be respected.

ECHA suggested that the public consultation on the identification of alternatives according to Article 10(3) of the BPR could be done after the submission of the application by the applicant and before ECHA receives the draft assessment report from the evaluating CA for peer review and suggested that the public consultation on the derogation to exclusion could be done at the same time. It can even be considered to merge both public consultations.

In conclusion, the Commission indicated that it will reflect on the comments made during the discussion. The Commission stated that it was prepared to review its proposal as regards the duration of extension. It invited Member States who could not support a 2.5 year extension to consider whether they could support a shorter extension period. The Commission also informed that it will further reflect on the need to conduct an assessment of ED properties for substances meeting already one of the exclusion criteria and that it may bring a discussion to the CA meeting concerning the renewal process for active substances subject to exclusion. The opinion of the Committee on the draft Decision will be sought at a subsequent meeting.

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

    (a) Examination of the draft Commission Implementing Decision (*SCBP65-Doc.8.1)*

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

The Commission presented the draft Decision. One Member State indicated to not be able to support the extension of approval as the substance is meeting the criteria to be considered a candidate for substitution. Another Member State could not support the draft Decision either and informed that it will abstain in the vote. The Commission reminded that extending the approval when the examination cannot be finalised before the expiry date of approval is an obligation coming from Article 14 of the BPR. It also reminded that the BPR does not foresee the ban of substances meeting the criteria to be considered candidates for substitution, but rather that Member States can choose to not authorise products after performing comparative assessments.

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

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

    (a) Examination of the draft Commission Implementing Decision (*SCBP65-Doc.9.1)*

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

The Commission presented the draft Decision. After a final examination of the proposal, the Committee gave a favourable opinion.

10. **Postponement of the expiry date of approval of K-HDO for use in biocidal products of product-type 8**

    (a) Examination of the draft Commission Implementing Decision (*SCBP65-Doc.10.1)*

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

The Commission presented the draft Decision. After a final examination of the proposal, the Committee gave a favourable opinion.

Section A.2 – Article 37 decisions

11. **Commission Implementing Decision on a derogation from mutual recognition of the authorisation of a biocidal product containing hydrogen cyanide by Poland in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

    (a) Examination of the draft Commission Implementing Decision (*SCBP65-Doc.11.1)*

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

The Commission presented the draft Decision, in particular the changes introduced following the discussions at the previous meeting and indicated that one typographical error, concerning the hazard statement code of the active substance, would need to be corrected.

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

Section A.2 – Union authorisations

12. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Contec IPA Product Family"**

    (a) Examination of the draft Commission Implementing Regulation (*SCBP64-Doc.12.1)*

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

The Commission presented the revised draft Regulation, indicating some minor changes in the summary of the biocidal product characteristics. Those changes came in consequence of comments and editorial suggestions received from a Member State and some Commission services during the consultation period.

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

13. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Pal IPA Product Family"**

    (a) Examination of the draft Commission Implementing Regulation (*SCBP64-Doc.13.1)*

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

The Commission presented the revised draft Regulation, indicating some minor changes in the summary of the biocidal product characteristics. Those changes came in consequence of comments and editorial suggestions received from a Member State and some Commission services during the consultation period.

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

14. **Commission Implementing Regulation granting a Union authorisation for the single biocidal product "CVAS Disinfectant product based on Propan-2-ol"**

    (a) Examination of the draft Commission Implementing Regulation (*SCBP64-Doc.14.1)*

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

The Commission presented the revised draft Regulation, indicating some minor changes in the summary of the biocidal product characteristics. Those changes came in consequence of comments and editorial suggestions received by a Member State and some Commission services during the consultation period.

Following the discussion during the last competent authorities meeting, the Commission had maintained the proposal to include the claim "Disinfection of gardening equipment for human hygiene purpose only" under the field of use of one of the proposed uses, as it was initially recommended in the BPC opinion. The Commission explained that it had well taken into account the comments of the Member States and the outcome of the discussions in the Standing Committee on Plants, Animals, Food and Feed – section phytopharmaceuticals legislation, which had been consulted on this borderline case.

One Member State expressed its concern regarding the credibility of this general hygiene claim, and informed that it will abstain in the vote. This Member State also proposed to discuss further the proper borderlines for claims related to general hygiene purposes. Another Member State indicated that it could not find justified reasons for excluding this claim. A third Member State expressed no sympathy with this claim and indicated to not be able to support the draft Regulation.

The Commission responded that it was willing to start a discussion on general hygiene claims in a forthcoming competent authorities meeting, and invited those Member States having expressed concerns on the draft Regulation to prepare a position paper. The Commission may then review the accepted claims in this specific case based on the outcome of those discussions.

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

Section B – Items presented for discussion and/or information

15. **Any Other Business**

(a) Renewal of authorisations for products for which UK was the reference Member State in the mutual recognition process

The Commission suggested that the renewal of product authorisations granted following a mutual recognition process in which the UK had been the reference Member State be managed similarly to the renewals for PT 8 and PT18 products, where the applications were shared among the concerned Member States. The necessary work sharing could best be discussed in the Coordination Group.

The Commissions also took the opportunity to remind Member States that active substances dossiers from the review programme were reallocated already since March, and that some Member States would appear to not have taken any action according to R4BP records. It strongly invited the relevant Member States to proceed with the examination of these dossiers to avoid further delays.

(b) Status of decision process on formaldehyde for PTs 2 and 3

The Commission informed that, according to the latest information provided by ECHA, the evaluation of ED properties of this substance should be discussed in ECHA's Biocidal Product Committee in December. Following completion, the BPC opinion will then come to the Commission for decision.