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

64TH MEETING ON 4 JULY 2019, FROM 09:30 TO 10:30

Bulgaria was represented by Belgium, Croatia was represented by Slovenia, Italy was represented by Ireland, Romania was represented by Slovakia. All other Member States were present.

1. **Adoption of the Agenda (*SCBP64 - Doc.1*)**

The agenda was adopted with the addition of one item under AOB regarding the decision-making process on silver zeolites active substances.

2. **Adoption of the Minutes of the 63rd SCBP meeting (*SCBP64 - Doc.2*)**

The minutes of the 63rd SCBP meeting were adopted.

Section A – Draft(s) presented for an opinion

Section A.1 – Union authorisations

3. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Boumatic Iodine product family"**

   (a) Examination of the draft Commission Implementing Regulation (*SCBP64-Doc.3.1)*

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

The Commission informed that the vote could not take place since the internal procedures in the Commission had not been finalised to present a draft Regulation to the Committee for opinion at this meeting. The Commission informed that during the interservice consultation period it received some comments, mostly editorial, from the Commission's Legal Service. The Commission also informed that an earlier comment made by one Member State, concerning the removal of a specific word from a risk mitigation measure, had been taken into account. Another Member State made a comment regarding the need for a common strategy on the accumulative exposure to products containing iodine. The Commission noted that it would reflect on this matter when the authorisations for iodine products are completed. The Commission announced that once the internal procedures will be finalised the opinion of the Committee will be

sought via written procedure. Taking into account the holiday period a longer period will be provided to Member States in order to respond.

4. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "BPF_Iodine_VET"**

    (a) Examination of the draft Commission Implementing Regulation (*SCBP64-Doc.4.1)*

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

The Commission informed that the vote on this item could not take place since the internal procedures in the Commission had not been finalised to present a draft Regulation to the Committee for opinion at this meeting. The Commission informed that it had received the same kind of comments as for the previous iodine biocidal product family proposal. One Member State asked whether the previous comment concerning the removal of the word from the risk mitigation measure for the biocidal product family "Boumatic Iodine product family" was also valid for this proposal. The Commission confirmed that the comment was valid for this proposal as well. The Commission announced that once the internal procedures are finalised the opinion of the Committee will be sought via written procedure.

5. **Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product 'Bird Free', containing the active substances peppermint oil and citronellal, in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

    (a) Examination of the draft Commission Implementing Decision (*SCBP64-Doc.5.1)*

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

The Commission introduced the draft Decision mentioning that no substantial changes had been made compared to the version presented at the last meeting, but only some editorial ones. The Commission reminded the Member States that the Decision followed the opinion delivered by ECHA on the matter. One Member State pointed to a couple of typing errors in the document and another Member State, who had already expressed its position in the previous meeting, reiterated that it will not be able to support the Decision, since in their view the efficacy of the product was not proven.

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

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

Section B.1 – Active substances

As a general introduction to these four agenda items on the postponement of the expiry date of approval, the Commission informed that it intended to no longer prepare such documents in the future and will directly present a draft Regulation to the Committee for opinion. In fact, such extensions of the expiry date of approval started to become frequent as most of the evaluating Competent Authorities (eCA) informed the Commission that they considered it necessary to carry out a full evaluation due to the need to assess the endocrine-disrupting (ED) properties of the active substances concerned. The Commission reminded that the eCAs have in any case to inform the Commission of their decision to perform a limited or full evaluation within 90 days from the acceptance of the application for renewal by ECHA: in case the eCA considers a full evaluation necessary, the procedure to extend the expiry date of approval is automatically triggered.

6. **Postponement of the expiry date of approval of propiconazole for use in biocidal products of product-type 8** ***(SCBP64-Doc.6.1)***

The Commission presented the need to extend the duration of approval for propiconazole for product-type 8 following the decision by the eCA to conduct a full evaluation.

A few Member States noted their concerns about extending the duration of approval for substances that meet the exclusion criteria, like propiconazole, and asked the Commission to look into possibilities to shorten the proposed period of extension of the approval. The Commission reminded that this was not the first case, and that this situation of the need to extend the expiry date with a full evaluation of the substance at renewal is systemic in the construction of the Biocidal Products Regulation (BPR). Like in previous cases, it encouraged the eCA to perform the work as quickly as possible, so that a decision can be taken as soon as possible on the renewal and, where relevant, the extension curtailed accordingly.

One Member State proposed that the evaluation of the possibility for a derogation to exclusion, which would be a necessary condition for renewal of the approval of the active substance under restricted conditions, is done prior to the evaluation in the renewal process. A Member State, supported by another one, would like to avoid assessing the ED properties of substances that are likely not to be approved because of already meeting other exclusion criteria. The Commission reminded the Committee about previous debates on this issue when the guidance for the assessment of ED properties of active substances has been established. At that time, it had been agreed that the opinion does not need to include an assessment whether the active substance could be considered to have ED properties according to the ED criteria if the opinion proposes a non-approval of the active substance. However, the opinion proposing a non-approval should include an ED assessment if the Standing Committee has the intention to decide that one of the conditions in Article 5(2) is met and the active substance may be approved subject to mitigation measures. The Commission noted the concerns of these Member States and indicated that it will reflect on the matter.

The Commission also informed that it had noted some issues in the construction of the renewal process in the register for biocidal products (R4BP) which does not seem in line with the regulatory process set in the BPR. For instance, when an eCA asks the applicant to re-submit the application after the acceptance by ECHA, the process re-starts from the beginning in R4BP, which is not in line with the legal text. Similarly, no validation phase is foreseen in the legal text but exists in R4BP. ECHA indicated that it will check these points.

The opinion of the Committee on a draft Regulation extending the approval will be sought at a subsequent meeting.

7. **Postponement of the expiry date of approval of tebuconazole for use in biocidal products of product-type 8** ***(SCBP64-Doc.7.1)***

The Commission presented the need to extend the duration of approval for tebuconazole for product-type 8 following the decision by the eCA to conduct a full evaluation.

The opinion of the Committee on a draft Regulation extending the approval will be sought at a subsequent meeting.

8. **Postponement of the expiry date of approval of IPBC for use in biocidal products of product-type 8** ***(SCBP64-Doc.8.1)***

The Commission presented the need to extend the duration of approval for IPBC for product-type 8 following the decision by the eCA to conduct a full evaluation.

The opinion of the Committee on a draft Regulation extending the approval will be sought at a subsequent meeting.

9. **Postponement of the expiry date of approval of K-HDO for use in biocidal products of product-type 8** ***(SCBP64-Doc.9.1)***

The Commission presented the need to extend the duration of approval for K-HDO for product-type 8 following the decision by the eCA to conduct a full evaluation.

The eCA had informed that, in order to perform the ED assessment, it would need significantly more time. Requesting all the relevant data would lead to a need to extend the approval until the end of 2024 according to its experts, while applying the strategy of stepwise testing would lead to a need to extend the approval until the end of 2026.

One Member State pointed out that, as K-HDO is not known so far to be meeting the exclusion or substitution criteria, it would have no issue to accept a longer extension of the approval period. According to this Member State priority should be given in the renewal process to substances meeting the exclusion or substitution criteria.

The Commission recalled the general discussion on-going at the CA meeting on the renewal process of active substances and the need to conclude the renewal process as quickly as possible.

The opinion of the Committee on a draft Regulation extending the approval will be sought at a subsequent meeting.

Section B.2 – Article 37 decisions

10. **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 (*SCBP64-Doc.10.1*)**

The Commission presented the revised draft Decision, indicating the main changes compared to the version presented at the previous meeting. These changes regarded clarifications in relation to the requirement in the summary of the biocidal product

characteristics that the operators be equipped with the antidote when performing the fumigation operations and to the impossibility, under the Polish Pharmaceutical Law, for the operators to have these at their disposal, as they are considered medicinal products. The revised draft also clarified the difference between the product under discussion and other fumigation biocidal products authorised in Poland, in that for none of these latter ones the SPC requires operators to be equipped with the antidote.

The Commission indicated that the written comments received prior to the meeting will be addressed and then the consultation of the Commission services on the draft act will be initiated, with a view to presenting the draft Decision for a vote at the meeting of the Committee in September.

Section B.3 – Union authorisations

11. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Contec IPA Product Family" (*SCBP64-Doc.11.1*)**

The Commission introduced the draft Regulation for this biocidal product family, indicating that it differed slightly from former Union authorisations as it consists of the act and two annexes. Annex 1 sets out an authorisation condition and Annex 2 is the summary of biocidal product characteristics. The Commission informed that the opinion of the Committee on this draft Regulation will be sought at the subsequent meeting.

12. **Commission Implementing Regulation granting a Union authorisation for the single biocidal product "CVAS Disinfectant product based on Propan-2-ol" (*SCBP64-Doc.12.1*)**

The Commission introduced the draft Regulation for this single biocidal product indicating that a scope issue had been identified concerning the proposed use of this product for "disinfection of gardening equipment". The Commission informed that this use for "disinfection of gardening equipment" will be discussed in the upcoming meetings of representatives of Member States competent authorities for the implementation of the BPR and the Standing Committee on Plants, Animals, Food and Feed, section phytopharmaceuticals , in order to find an agreement on whether this use is considered to fall in the scope of the legislation of biocidal products or plant protection products, respectively. The Commission informed that the opinion of the Committee on this draft Regulation will be sought at the subsequent meeting.

13. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Pal IPA Product Family" (*SCBP64-Doc.13.1*)**

The Commission introduced the draft Regulation for a biocidal product family containing the same active substance as the biocidal product family "Contec IPA Product Family" presented under agenda item 11, indicating that it consists of the act and two annexes. Annex 1 sets out an authorisation condition and Annex 2 is the summary of biocidal product characteristics. The Commission informed that the opinion of the Committee on this draft Regulation will be sought at the subsequent meeting.

14. **Any Other Business**

The Commission informed the Committee on the decision-making process on silver zeolites active substances. The Commission services had been made aware that Member States recently received a position paper from the applicant for these substances, contesting the draft proposals for non-approval prepared by the Commission. The Commission indicated that the proposed decisions follow the BPC opinions and informed that the Commission had already met the applicant to discuss the draft decisions. The Commission also informed that the draft decisions had been notified under the WTO Agreement on Technical Barriers to Trade for a 60-day commenting period, and that comments had been sent by the USA. The Commission further informed that it intends to seek the opinion of the Committee at the subsequent meeting.