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

62ND MEETING ON 15 MARCH 2019, FROM 10:00 TO 11:00

Bulgaria was represented by Belgium. All other Member States were present.

1. Adoption of the Agenda (*SCBP62 - Doc.1*)

The draft agenda was adopted without modification.

2. Adoption of the Minutes of the 61st SCBP meeting (*SCBP62 - Doc.2*)

No Member States had comments on the draft minutes of the 61st SCBP meeting, which were then adopted.

3. Rules of procedure of the SCBP meeting *(SCBP62-Doc.3)*

One Member State expressed its reservation on the proposed change of Article 8 of the Rules of procedure of the SCBP regarding the written procedure on account of the different level of discussions taking place in the Biocidal Products Committee and in the Standing Committee (on a technical-scientific level and on a political level, respectively). Not having a discussion in the Committee would therefore mean omitting one level of discussion. The Commission clarified that the amended rule is not meant to become an automatism for all the proposals and that a discussion will take place in the Committee whenever any Member State considers it necessary. Also during the written procedure, Member States will have the possibility to request that the draft measure will be brought in the Committee meeting if deemed necessary. Moreover, for decisions on Union authorisations Member States will be informed by email about the intention to have a vote in written procedure to which Member States may respond to signal their preference for a discussion in the Standing Committee.

In response to the request from another Member State to allow at least three weeks for the written consultation, the Commission explained that it will seek to foresee a minimum of three weeks for the consultations, except for urgent cases.

The amendment of Article 8 of the Rules of procedure was then agreed by the Committee.

Section A – Draft(s) presented for an opinion

Section A.1 – Active substances

4. Commission Implementing Regulation approving **cholecalciferol** as an active substance for use in biocidal products of **product-type 14**

    (a) Examination of the draft Commission Implementing Regulation (*SCBP62-Doc.4.1)*

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

The Commission presented the proposal. In particular, the Commission explained that a change was made compared to the previous version presented to the Committee as the Commission decided, after discussion with its Legal Service, to base the approval only on the condition for derogation set in Article 5(2)(c) of the BPR, and no longer also on condition (b) of the same Article. Condition (b) indeed requests that it shall be "*shown by evidence"* that the substance is "*essential*" to prevent or control a serious danger: in the present case, the substance is new and not yet on the market, which means that such evidence does not really exist.

One Member State emphasised its reservations to approve this substance having endocrine-disrupting properties and announced to abstain in the vote.

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

Section A.2 – Union authorisations

5. Commission Implementing Regulation granting a Union authorisation for the **biocidal product family Teat Dip Products BPF based on Iodine**

The Commission briefly introduced the proposal, expressed appreciation to two Member States for their constructive comments submitted before the meeting on the English version of the Implementing Regulation. The Commission informed that those comments had been taken into account and a revised version of both the act and Annex, containing the summary of the biocidal product characteristics (SPC), with the relevant amendments in track changes had been uploaded on CIRCABC since 13 March 2019. The Commission also announced that once the internal consultations will be concluded and the SPC in the respective linguistic versions will be received from ECHA, the opinion of the Committee will be sought via written procedure.

On a more general note, the Commission underlined that ECHA and competent authorities will need to jointly ensure the accuracy of the SPC in all the linguistic versions. The final SPC in English must be checked by the evaluating competent authority and ECHA in order to make sure it reflects all agreements reached at the BPC meeting when it is adopted. The Commission will also take care of the relevant manual adjustments in the Word version of the SPC in English and if possible in the other linguistic versions. Finally, competent authorities must check and adjust all the relevant amendments both in the XML and Word versions of the SPC in the respective languages.

Section A.3 – Article 36 decisions

6. Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product family containing **1R-trans phenothrin** referred by Ireland 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 (*SCBP62-Doc.6.1)*

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

The Commission presented the proposal, which had already been tabled for discussion in the previous meeting of the Committee.

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

Section A.4 – Article 55(1) decisions

7. Request for a Commission Implementing Decision concerning the extension of the action taken by Belgium on the making available on the market and use of the biocidal product Phostoxin in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

    (a) Examination of the draft Commission Implementing Decision (*SCBP62-Doc.7.1)*

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

The Commission introduced the proposal, which had already been tabled for information and discussion at the previous meeting of the Committee. Taking into account that the product is essential in order to adequately control the population of rabbits on the site of the airport, where no alternatives exist today to the use of this biocidal product, and that the absence of appropriate control of the rabbits on the site of the airport might lead to a danger to the transport of passengers and more generally to air transport safety, the draft Commission Decision would allow Belgium to extend the derogation.

One Member State indicated that they cannot support this proposal, and in general all proposals related to product-type 20 products for control of vertebrates, as this would go against their national laws on animal welfare. The Member State announced that it would abstain in the vote.

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

8. Postponement of the expiry date of approval of indoxacarb for use in biocidal products of product-type 18 *(SCBP62 - Doc.8.1)*

The Commission explained that an extension of the expiry date of approval of indoxacarb will be needed, as the evaluating competent authority had indicated that it will perform a full assessment, having requested various data to the applicant including those for the assessment of Endocrine Disrupting properties. Consequently, the examination of the application for renewal will not be finalised before 31 December 2019 (current expiry date of approval). The detailed situation was explained in the explanatory document tabled for the meeting of the Committee and proposing an extension of the approval for 2.5 years to carry out the necessary work and complete the process.

One Member State considered that the substance had been assessed recently for use in plant protection products and as a result the Commission had presented a proposal for non-approval. They consider that an extension of only one year should be sufficient. The Commission noted that the use in plant protection products is different and that no decision has yet been taken. The Commission further remarked that the evaluating authority having signalled the need for a full assessment (which necessitated the proposed extension) was from that same Member State now questioning the proposed extension. The Commission underlined that it is clear that the whole review process will not be finalised within only one year of extension of the current approval. It emphasised that the evaluating authority in that Member State can perform the evaluation as quickly as possible, and that the extension period will be repealed once a decision on the application for renewal is taken.

The Commission announced that it will prepare a draft Decision postponing the expiry date of approval of indoxacarb. The opinion of the Committee will be sought at a subsequent meeting.

9. Postponement of the expiry date of approval of etofenprox for use in biocidal products of product-type 8 *(SCBP62 - Doc.9.1)*

The Commission explained that an extension of the expiry date of approval of etofenprox for PT8 will be needed, as the evaluating competent authority had indicated that it will perform a full assessment. Consequently, the examination of the application for renewal will not be finalised before 31 January 2020 (current expiry date of approval). The detailed situation was explained in the explanatory document tabled for the meeting of the Committee and proposing an extension of approval for 2.5 years to carry out the necessary work and complete the process.

One Member State expressed its support for the proposed extension. Another Member State indicated to not have products on its market containing this active substance for product-type 8. However, this Member State has products on its market containing this active substance for product-type 18 and suggested to conduct an early review of the approval of the substance for product-type 18 based on the outcome of the renewal of approval for product-type 8 for this substance. More generally, this Member State expressed concerns about the systematic extensions of approval granted to perform the examination of the renewal of approval. The Commission noted this position, but recalled that the possibility for extending approvals was foreseen in the Regulation, that the requests for more data actually come from the evaluating Member States, and that the substantial delays in the review programme of existing substances are more problematic than these extensions of approval in relation to public health and the environment. Products containing substances in the review programme are mostly unregulated on the market compared to products containing approved active substances, which are placed on

the market after having received a positive assessment and authorisation from Member States.

The Commission announced that it will prepare a draft Decision postponing the expiry date of approval of etofenprox. The opinion of the Committee will be sought at a subsequent meeting.

10. Any Other Business

No discussion.