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

57TH MEETING ON 15 MARCH 2018, FROM 11:00 TO 13:00

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

1. Adoption of the Agenda (*SCBP57 - Doc.1*)

The Chair informed that for items 7, 8 and 10 in the agenda the Committee will not be asked to deliver an opinion in this meeting as the draft Decisions were not yet available. Agenda item 13 was withdrawn from the agenda. A new agenda item for information on Union authorisation was added under AOB. With these changes, the agenda was adopted.

2. Adoption of the Minutes of the 56th SCBP meeting (*SCBP57 - Doc.2*)

The minutes of the 56th SCBP meeting were endorsed, with the changes proposed by one Member State in writing ahead of the meeting.

Section A – Draft(s) presented for an opinion

Section A.1 - Active substance approvals

3. Non-approval of **Chlorophene** as an active substance for use in biocidal products of **product-type 3**

The Commission services presented the proposal. One Member State supported the non-approval proposal noting that no safe use had been demonstrated, as no suitable risk mitigation measure could be identified for professional users. This Member State enquired whether the approach was consistent with the decision taken on glutaraldehyde, where the use of personal protection equipment of a double coverall has been considered as a suitable risk mitigation measure, The Commission services clarified that for glutaraldehyde another safe use had been identified (which did not require the use of double coverall).

Another Member State noted that consistency must be ensured, and that it should be clarified in guidance documents in which cases the double coverall can be considered as an appropriate risk mitigation measure. The Commission services acknowledged this need for updating guidance, and this was noted by ECHA.

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

4. Approval of **PHMB (1415; 4.7)** as an active substance for use in biocidal products of **product-types 2 and 4**

The Commission services presented the proposal. After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

5. Non-approval of **PHMB (1415; 4.7)** as an active substance for use in biocidal products of **product-types 1, 5 and 6**

The Commission services presented the proposal. After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

6. Approval of **Azoxystrobin** as an active substance for use in biocidal products of **product-types 7, 9 and 10**

The Commission services presented the proposal. A Member State asked why the relevant impurities were not mentioned in the draft approval Regulation. The Commission services pointed out that the relevant impurities are never indicated in a draft approval regulation but are mentioned in the ECHA BPC opinion.

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

Section A.2 - Article 36 decisions

7. Request for a Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product containing deltamethrin referred by Sweden in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

The Commission services thanked those Member States that had submitted comments after the meeting in January 2018. In the light of the discussion at that meeting and the comments received, it seemed that now there is a common understanding on the matter. The Chair informed that the opinion of the Committee will be sought at a subsequent meeting.

8. Request for a Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product containing ethyl butylacetylaminopropionate (IR3535) referred by Belgium in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

The Commission services thanked those Member States that had submitted comments after the meeting in January 2018. On a more general note, the Commission services emphasised the need to ensure coherence between the approach to be followed for products containing different active substances and encouraged ECHA to develop the required guidance on how to generate efficacy data at the recommended application rates

as soon as possible. The Chair informed that the opinion of the Committee will be sought at a subsequent meeting.

Section A.3 - Article 55(1) decisions

9. Draft Commission Implementing Decision concerning the extension of the action taken by France on the making available on the market and use of the biocidal product Phéro-Ball Pin in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

The Commission services presented the proposal. One Member State requested a slight amendment of the wording in Recital 4, to also reflect the lack of chemical means of control in the Member State that requested the extension. In reply to a question from another Member State related to the scope (use as biocide vs. use as plant protection product), it was clarified that the product is intended to protect humans and animals against the harmful effects on health that the processionary caterpillars may have and not to protect the plants on which they feed. The same Member State enquired whether the Article 55 notification template agreed at a previous meeting of competent authorities for the implementation of Regulation (EU) No 528/2012 was or will be used on this occasion. The Commission services indicated that the template agreed is to be used for the notifications by the Member States of the temporary permits granted and not in the context of the requests for extension.

The Chair informed that the opinion of the Committee on this draft act would be sought via written procedure, given that the draft Decision had been made available to the Committee only a few days before the meeting.

Section A.4 - Article 37 decisions

10. Request for a Commission Implementing Decision on a derogation from mutual recognition of the authorisation of a biocidal product family containing creosote by France in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

The Commission services informed that since the Commission had not adopted a Decision in accordance with Article 37(3) of the Regulation (EU) No 528/2012 within 90 days from the submission of the request, France may already grant the product authorisations and implement the proposed derogation. The Chair informed that the opinion of the Committee will be sought at a subsequent meeting.

Section B – Items presented for discussion and/or information

Section B.1 - Active substance approvals

11. Postponement of the expiry date of approval of **sulfuryl fluoride** for use in biocidal products of **product-type 8** *(SCBP57 - Doc.11)*

The Commission services explained that the evaluating competent authority had identified the need to carry out a full evaluation. Therefore an extension of the expiry

date of approval of sulfuryl fluoride for PT08 will be needed, as the examination of the application for renewal will not be finalised before 31 December 2018 (current expiry date of approval). A suitable new expiry date could be 30/06/2021 as this date aligns the renewal procedures for PT18 and PT8 for this specific substance. The situation of the renewal of this active substance is explained in the tabled document.

One Member State indicated concerns that were raised by industry about the availability of PT08 wood preservatives active substances.

Member States agreed that an extension of the approval is needed, and supported the coordinated approach concerning the renewal of product authorisations as discussed during the 77th meeting of competent authorities for the implementation of Regulation (EU) No 528/2012.

The Commission services will prepare a draft decision postponing the expiry date of approval of sulfuryl fluoride for PT08. The Chair informed that the opinion of the Committee will be sought at a subsequent meeting.

Section B.2 - Article 3(3) decisions

12. Request for a Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on pepper containing sprays to be used in case of attacks by aggressive dogs (*SCBP57-Doc.12.1*)

A short discussion took place on the possible consequences of the adoption of a decision concluding that these products fall under the scope of Regulation (EU) No 528/2012, particularly regarding similar products used to repeal attacks by humans. The Commission services informed the meeting that they will prepare a draft decision for discussion at the next meeting of the Committee. However, the opinion of the Committee will not be sought immediately since the TBT notification procedure will not be concluded by then.

13. Request for a Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a permethrin containing topical insecticide used for the purpose of controlling insects on livestock (*SCBP57-Doc.13.1*)

This item was withdrawn from the agenda.

Request for a Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on Wolbachia trans-infected mosquitos used for vector control purposes (*SCBP57-Doc.14.1*)

The Commission services informed the meeting that they will prepare a draft for discussion at the next meeting of the Committee. However, the opinion of the Committee will not be sought immediately since the TBT notification procedure will not be concluded by then. Upon request of a Member State, the Commission services indicated that sterilisation of mosquitoes by using chemical substances for the purpose of

controlling mosquitoes populations would also fall under the scope of Regulation (EU) No 528/2012.

Any other business

14. Union authorisation

The Commission services informed that the Implementing Regulations granting the Union authorisation to the first four applications will be tabled for an opinion in the May 2018 meeting of the Committee. It was also mentioned that in the future the opinion of the Committee may be sought through written procedure, in order not to delay the adoption of authorisation decisions. This approach is also followed by the Commission services for the centralised authorisation of medicinal products.