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

56TH MEETING ON 19 JANUARY 2018, FROM 14:30 TO 16:30

Bulgaria was represented by Belgium, Croatia was represented by Slovenia, Lithuania was represented by Luxembourg and Slovakia was represented by the Czech Republic.

1. Adoption of the Agenda (*SCBP56 - Doc.1*)

The agenda was adopted with the inclusion of two items under "Any Other Business".

2. Adoption of the Minutes of the 55th SCBP meeting (*SCBP56 - Doc.2*)

The minutes of the 55th SCBP meeting were endorsed.

Section A – Draft(s) presented for an opinion

Section A.1 - Article 55(1) decisions

3. Draft Commission Implementing Decision concerning the extension of the action taken by Belgium on the making available on the market and use of the biocidal products VectoMax G and Aqua-K-Othrine in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

The Commission presented the draft Implementing Decision, briefly explaining the reasons allowing Belgium to extend the derogation. After a final examination of the proposal, the Committee gave a favourable opinion.

Section B – Items presented for discussion and/or information

Section B.1 – Active substance approvals

4. Applicability of the conditions of derogation to exclusion set in Article 5(2) for **reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio**

1:1) (originally notified as HPT) for use in biocidal products of **product-types 2, 6, 11 and 13**

5. Applicability of the conditions of derogation to exclusion set in Article 5(2) for **reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio 3:2) (originally notified as MBO)** for use in biocidal products of **product-types 2, 6, 11, 12 and 13**

On item 4 and 5, the Commission services asked whether Member States have collected further information at national level, and have already a view as regards to whether these substances could meet one of the conditions for derogation to exclusion for each of these product-types. As agreed at the last meeting, the Commission services informed that further information will be requested to the applicant, and that an opinion will be requested to ECHA on the technical information submitted during the last public consultation.

One Member State indicated that it will be vigilant concerning the draft decision for these substances. The Commission services invited Member States to analyse at national level whether the conditions for derogation could be met for these substance-product type combinations and share this information so that an informed discussion can take place in the Committee.

Another Member State informed that it has produced a report concerning possible alternatives to formaldehyde and formaldehyde releasers that could be also considered in the decision-making process. The Commission invited this Member State to submit this report.

Once the additional information from the applicant and the opinion of ECHA are received the discussion will continue in the Standing Committee

Section B.2 Article 36 decisions

6. 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 (*SCBP56-Doc.6.1*)

The Commission briefly introduced document SCBP56-Doc.6.1, which takes into account the previous discussions in the Committee and the contributions provided by some Member States during the last commenting period. The main elements raised by MSs during the discussion were the following:

- So far MSs have followed the agreed CA document as a guidance, which seems to still be valid. The Commission services clarified that once the current decision will be adopted, the CA document will be amended accordingly.
- It should be clarified how oher authorised products will be impacted for which the active substance concentration has been expressed in accordance with the CA document. The Commission services clarified that the SPCs should be adapted in the context of changes to the product authorisations affecting the SPC or at the renewal stage at the very latest.
- In relation to recital 5, a Member State indicated that product formulators use to buy the active substance in a solvent or in different working dilutions. Therefore, if the

concept of "technical material" is referred to the form in which the active substance is supplied to a product formulator, then this might change from one supplier to another and lead to a situation that will be difficult to manage in practice. The Commission clarified that where the active substance is supplied and diluted in a solvent, etc.., it should no longer considered a substance but a mixture including the active substance. In this case, what that Member State would consider as the "pure" active substance is in fact the "technical" active as it was approved (i.e. including its impurities).

The Chair invited Member States to submit any written comments to the proposal by 5 February 2018. The Commission services will consider the received comments and start the internal procedures within the Commission in order to be able to seek the opinion of the Committee in an upcoming meeting.

7. 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 (*SCBP56-Doc.7.1*, *SCBP56-Doc.7.2*)

The Commission services introduced this agenda item with the support of a presentation (document SCBP56-Doc.7.2). The applicant was invited to provide its views on the matter and Member States had the opportunity to ask questions to the applicant. The applicant indicated the need for a level playing field for all applicants in the same product-type as well the need to consider some principles included in the BPR (i.e. not to apply any overdose that is not needed).

The Committee discussed the lack of guidance in relation to the assessment of the efficacy and of the health risks of exposure to the substance. The Committee also discussed several options as a basis for the draft decision. Two Member States indicated that they would be in favour of a non-authorisation decision. Another Member State indicated that considering the dose resulting from the efficacy studies and the provisions in Article 19(5) of the BPR could be a way forward. Another Member State stressed that the efficacy of a product should be shown, however, the efficacy may have been demonstrated by another approach. In this context, several Member States supported the option of granting an authorisation based on the available information including a post-authorisation condition requiring the authorisation holder to submit additional information within a reasonable timeframe following the adoption of new guidance to be agreed at the EU level.

The Chair invited Member States to submit any written comments by 5 February 2018. The Commission services will consider the received comments and draft a proposal intended to be tabled for discussion and/or decision in an upcoming meeting of the Committee.

8. Request for a Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product 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 (*SCBP56-Doc.8.1*)

The Commission services briefly informed the Committee that the reference Member State has very recently submitted its detailed statement to the Commission in accordance with Article 36 (1) of the BPR. In this respect, the Commission encouraged reference Member States to do so as soon as possible after the discussions in the coordination group, as required under Article 36(1).

As the outstanding issue for this case concern technical matters, the Commission will request an opinion of ECHA's Biocidal Product Committee in accordance with Articles 36(2) and 38 of the BPR.

Section B.3 Article 3(3) decisions

9. 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

The Commission services informed the Committee about the preliminary legal analysis of the specific case. The Committee discussed two options in relation to this request. Several Member States stressed the need to establish a decision in order to provide clarity to enforcement. Several other Member States expressed their reluctance to consider such type of products in the scope of the BPR.

The Chair invited Member States to submit any written comments by 5 February 2018. The Commission services will consider the received comments and conclude whether or not to draft a proposal to be tabled for discussion in an upcoming meeting of the Committee.

10. 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 product used for temporary preservation of human corpses

As this request concerns technical matters, the Commission will request an opinion of ECHA's Biocidal Product Committee in accordance with Article 75(1)(g) of the BPR.

11. 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 (*SCBP56-Doc.11.1*)

The Commission services briefly introduced this agenda item by clarifying that the documents submitted by the applicant were not intended to be discussed in the meeting, but just to make them available to all Member States via Circabc.

With the support of a short presentation, the Commission services also introduced the discussions on some procedural aspects identified with this request, as they could be relevant for other requests in the future. The Committee agreed that an Article 3(3) decision should be based on the relevant information submitted by the Member State on the product, article or good in question as included in the original request.

In connection with one of the documents provided by the applicant, a Member State stressed that there is a need to have a Commission decision as soon as possible. The

Commission services indicated that it is the intention to seek the opinion of the Committee on a proposal at the March or at the May meeting at the very latest.

On a more general note, the Commission briefly referred to a statement in the comments submitted by a Member State (also present in the Article 3(3) request sent by the Member State), pointing out that the product seems to have a repellent effect for flies. The Commission services reminded that permethrin in not approved for PT 19 and therefore, deterring flies would be an illegal use/claim for any permethrin containing product.

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 Wolbachia trans-infected mosquitos used for vector control purposes

The Commission services informed the Committee on this request. The Member State submitting the request provided further details on the background of the request. The Commission services indicated that it is the intention to discuss this request in the next meeting of the Committee.

13. Any Other Business

The Commission informed the Committee to have received a request in accordance with Article 37 and another request in accordance with the third paragraph of Article 55(1):

- 13.1 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 (*SCBP56-Doc.13.1*)

  The Commission briefly introduced this agenda item by giving the floor to the concerned Member State, which provided further details on the background of the derogation from mutual recognition. The concerned Member state will not authorise the use to treat communication poles, which was previously authorised by the reference Member State, and will only authorise the use to treat railway sleepers. The concerned Member State also suggested that the renewal of creosote as an active substance should be limited to the treatment of railway sleepers only.

  The Commission services will draft a proposal to be tabled for discussion or decision in the next meeting of the Committee.

- 13.2 Request for a 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 (*SCBP56-Doc.14.1)*

  The Commission services will draft a proposal to be tabled for discussion or decision in the next meeting of the Committee.