



## STANDING COMMITTEE ON BIOCIDAL PRODUCTS

### MINUTES

#### 60<sup>TH</sup> MEETING ON 28 SEPTEMBER 2018, FROM 09:30 TO 11:30

Malta was represented by Greece. All other Member States were present.

1. Adoption of the Agenda (*SCBP60 - Doc.1*)

The agenda was adopted without modification.

2. Adoption of the Minutes of the 59<sup>th</sup> SCBP meeting (*SCBP60 - Doc.2*)

The minutes of the 59<sup>th</sup> SCBP meeting were adopted with the modifications proposed by one Member State.

#### **Section A** – Draft(s) presented for an opinion

##### **Section A.1 – Active substances**

3. Commission Implementing Decision on the **non-approval of certain biocidal active substances** pursuant to Regulation (EU) No 528/2012

- (a) Examination of the draft Commission Implementing Decision (*SCBP60-Doc.3.1*)
- (b) Opinion of the Committee on the draft Commission Implementing Decision

The Commission presented the proposal. One Member State requested whether recital 4 covers both the case of redefinition of in-situ generated active substances and the withdrawal of support for active substance/product-type combinations included in the review programme. The Commission confirmed that recital 4 covers both cases. At the request of another Member State, the Commission clarified that the usual provisions of Article 89 of the BPR apply regarding the deadlines for no longer making available on the market and the use of existing stocks of biocidal products concerned by the non-approval decision.

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

## Section A.2 – Article 3(3) decisions

4. 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
  - (a) Examination of the draft Commission Implementing Decision (*SCBP60-Doc.4.1*)
  - (b) Opinion of the Committee on the draft Commission Implementing Decision

The Commission introduced the proposal and reported that during both the so-called "feedback mechanism" on its Better Regulation Portal and the WTO TBT consultation, no comments had been submitted on the proposal. The Commission also referred to written comments from one Member State, which aimed at further clarifying the two possible modes of action of the bacteria on mosquito populations (controlling the size of populations and reducing the ability to transfer pathogens). These comments and a revised version of the proposal had been made available on Circabc before the meeting.

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

5. 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
  - (a) Examination of the draft Commission Implementing Regulation (*SCBP60 - Doc.5.1*)
  - (b) Opinion of the Committee on the draft Commission Implementing Decision

The Commission introduced the proposal and reported that that during both the so-called "feedback mechanism" on its Better Regulation Portal and the WTO TBT consultation no comments had been submitted on the proposal.

Nine Member States indicated that they could not support the proposal and three would abstain since the use of this kind of products, either against animals or humans, is regulated under national weapons legislation. On account of the views expressed by Member States and in accordance with the margin of discretion provided by Article 3(3) of the BPR, the Chair informed the meeting that the draft act would not be put forward for a formal opinion of the Committee.

6. Union authorisation of "Teat Disinfectants Biocidal Product Family of CVAS"
  - (a) Examination of the draft Commission Implementing Regulation (*SCBP60 - Doc.6.1*)
  - (b) Opinion of the Committee on the draft Commission Implementing Decision

The Commission informed that a vote could not take place since the internal procedures had not been finalised in time to present a proposal to the Committee for opinion at this meeting. The Commission pointed to two changes in the draft Implemented Regulation

resulting from those internal procedures compared to the already adopted Regulations granting earlier Union authorisations:

- In recital (2) the wording used in previous Regulations granting Union authorisations was adapted since the criteria to determine endocrine-disrupting properties of substances are now applicable;
- In recital (6) the sentence referring to Article 71(6) of the Biocidal Products Regulation was deleted, since the obligation for the Commission to record the relevant elements in Register for Biocidal Products already flows from the BPR itself (i.e. no need to repeat it in each individual authorisation).

The Commission invited Member States to provide written comments on the draft Implementing Regulation by 5 October, in order to proceed with the request of translations and thereafter obtain the Committee's opinion by written procedure. No Member State objected to using the written procedure for obtaining the Committee's opinion.

On a more general note, the Commission emphasised the need to ensure a good quality of the translations of the summary of the products characteristics (SPC). In order to achieve that goal, the quality of the translations provided by the applicant as well as the check performed by Member States before ECHA sends the translations to the Commission are of major relevance. Moreover, the Commission underlined that one critical aspect is that the English version of the SPC sent to the applicant for translations is identical to the one agreed by the Biocidal Products Committee of ECHA. Otherwise, any possible inconsistency or mistake in the SPC sent to the applicant would need to be addressed in all linguistic versions. The Commission informed of on-going discussions with ECHA on how this could be avoided.

## **Section B – Items presented for discussion and/or information**

### **Section B.1 – Active substances**

7. Approval of cholecalciferol as an active substance for use in biocidal products of product-type 14 (*SCBP - Doc.7.1*)

The Commission presented the proposal for approval of cholecalciferol. The proposal was based on the discussion in the 58<sup>th</sup> meeting of the Standing Committee on Biocidal Products in May 2018. The recitals followed the example of those in the Regulations on the renewal of the anticoagulant rodenticides and explain the process followed and the reasons for a derogation to exclusion. The Commission also highlighted that in the Annex containing the specific conditions, provisions have been included specifying that products having endocrine disrupting properties cannot be authorised for use by the general public, in accordance with Article 19(4) of the BPR.

One Member State emphasised its reservations to approve this substance having endocrine-disrupting properties. The Commission pointed out that other rodenticides made available on the market in the Union have certainly no better hazard profile and recalled the well-known need that better control methods for rodenticides should become available.

One Member State indicated that it is consulting a second time its national sector in order to define whether it can support the approval proposal. Several Member States questioned whether it was needed to indicate that products having ED properties should not be authorised for use by the general public as this is already stated in the BPR, and also considered that, in the light of these provisions set already in Article 19(4) of the BPR, the conditions in the Annex referring to use by the general public should be deleted. One Member State noted that it was favourable to a use by the general public but recognised that this is not possible in line with the provisions set in Article 19(4) of the BPR. The Commission recognised that the provisions of the BPR do not allow use of biocidal products having endocrine-disrupting properties and agreed to remove the part in the Annex that repeat provisions included in the BPR.

Member States were invited to send comments by 19 October 2018 on the draft proposal. The opinion of the Committee will be sought at a subsequent meeting.