EUROPEAN COMMISSION

Health and Food Safety Directorate General

81st Standing Committee on Biocidal Products

27 September 2023
10:00 – 17:30

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP81-Doc.A.01)*

The agenda was adopted with the addition by the Commission of a point concerning the inclusion of a new trade name in a Union authorisation.

A.02 Adoption of the minutes of the 80th SCBP meeting *(SCBP81-Doc.A.02)*

The minutes of the 80th SCBP meeting were adopted.

A.03 Exchange of views on the application for Union authorisation for the biocidal product family 'Kersia's lactic acid based products' (*SCBP81-Doc.A.03)*

The Commission introduced the document concerning an application for Union authorisation of a lactic acid based BPF of teat disinfectants containing a co-formulant that was subject to a REACH substance evaluation procedure which concluded that the harmonised classification of that substance should be updated with regards to the categories carcinogenic 2 and reprotox 1B. However, the CLH dossier to initiate the process has not been submitted. In addition the co-formulant has a potential transformation product that is classified as carcinogenic 1 B.

The Commission asked the members of the Standing Committee if they agree with the approach that the classification of the BPF is based on the existing classification of the co-formulant, that the co-formulant is however considered as a substance of concern for other reasons and the pre-milking uses will not be authorised due to a dietary risk identified and that the uncertainties concerning the long-term risk from the transformation product of the co-formulant mentioned in the BPC opinion only relate to the pre-milking uses which will not be authorised. During the discussion for this UA at the BPC meeting the applicant explained that they are working on the replacement of the co-formulant and intend to submit an application for a change.

All members supported the approach. One Member State suggested to include a restriction to either request the applicant to submit the request for a change or to restrict the duration of the authorisation. The Commission agreed to consider this proposal but indicated that since the

BPC concluded that the post-milking uses would be safe and the pre-milking uses would not be authorised it would be difficult to justify a restriction of the authorisation.

It was agreed that the Commission will continue to draft and present a draft act to the Standing Committee in accordance with the presented approach.

A.04 Exchange of views on the questions regarding the second comparative assessment of anticoagulant rodenticide biocidal products (*SCBP81-Doc.A.04*)

The Commission explained the outcomes of the consultation of the Committee over the summer on the BPC opinion on questions related to the second EU comparative assessment on anticoagulant rodenticides. Most of the responding Member States expressed concerns about the use of mechanical traps as alternative to anticoagulant rodenticides for mice control indoor. Several stakeholders expressed the same in letters addressed to the Commission in spring. Their main concern is that the BPC conclusion is based on a single field study that according to those Member States and stakeholders is not representative of all types of situations and level of mice infestation.

On the opposite two Member States indicated that the use of mechanical traps indoor is a suitable alternative for the control of mice. A list of traps meeting the criteria of the NoCheRo guidance is however urgently needed. One of them also argued that mechanical traps should be also available to the general public and not only to professionals. One additional Member State and an EFTA country agreed with that statement. The Commission mentioned that further reflections is needed on the possibility for non-professionals to use mechanical traps instead of anticoagulant rodenticides for mice control inside buildings.

Another Member State backed up the conclusions of the BPC and recalled that the assessment of the efficacy of the mechanical trap followed the principles of the NoCheRo guidance which are the same as the ones used for the evaluation of anticoagulant rodenticides. In order to approach ambitious outcomes as regards the consideration of non-chemical alternatives, it considered that a clear decision is needed ahead to discussions on a next renewal on how many efficacy studies will be accepted as sufficient. That Member State also urged the Commission to give clearer advice to the Member States on the uses of anticoagulant rodenticides that could be replaced by safer alternatives.

The Commission recalled that not all Member States and stakeholders supported the BPC opinion and that the Commission has the obligation to listen and consider diverging opinions. The Commission proposed to follow the BPC opinion and to include some wording on the diverging opinions expressed by some Member States and interested stakeholders.

The Commission concluded by mentioning that a draft implementing decision will be prepared and discussed at the next Standing Committee meeting. The draft will be put to vote soon after the December meeting for a publication in January 2024. At the renewal of the active substances, the Commission expects more information on the efficacy of other mechanical traps for mice control indoor from the BPC opinions. This information will be useful to decide whether further restrictions on the use of anticoagulant rodenticides are needed.

A.05 Exchange of views on the application for the Union authorisation for the biocidal product family ‘Sodium hypochlorite liquid disinfectant’ *(SCBP81-Doc.A.05)*

The Commission explained the content of the note and recalled that in other similar cases, the BPC decided that as regard the formation of chlorates after surface disinfection for PT4 products, no dietary risk assessment would be needed and that it would be sufficient to require professional users to apply a rinsing step and ensure compliance with the MRLs values on chlorate in food set in Regulation (EU) No 2020/749.

One Member State disagreed with that approach and reiterated that a rinsing step with a rinsing factor of 1% needs to be backed up with data. The Commission asked that Member State to reconsider its position in light of the other cases reported in the Commission note where the BPC and the expert appointed by this Member States agreed to not request such data if the conditions mentioned in the first paragraph above are fulfilled. Another Member State supported the approach of the BPC. A third Member State commented that the need for data on the rinsing step was not discussed at the BPC meeting but was raised later when the Committee voted on the opinion a few weeks later. Still, the Commission suggested to remain consistent with the overall approach taken in other cases and proposed to open a newsgroup until 31 October 2023 to collect the views of the other Members on the two options presented in the note and discussed at the meeting.

On a general note, one Member State asked if the Commission will continue to address such technical details at the Committee meeting. The Commission answered that whenever a minority opinion is filed by a BPC expert appointed by a Member State, it is expected that the same question will be raised at the Standing Committee meeting where the Commission proposal will be tabled. The Commission has therefore addressed these minority opinions to the Committee to verify whether the majority reached at the BPC still stands in Standing Committee.

A.06 Information on decisions on amendments to Union authorisations under preparation *(SCBP81-Doc.A.06)*

The Commission recalled that the Committee will no longer be consulted for its opinion on Articles 48 and 50(2) decisions on amendments to Union authorisations as these articles does not envisage the consultation of the Standing Committee. The Commission will keep Member States informed of the decision-making process on such amendments. Therefore, twice a year, the Commission therefore intends to put forward a table summarising the status of the ongoing files and the date of publication.

The Committee did not comment the proposal, and the Commission will proceed accordingly.

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of propiconazole as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP81-Doc.B.01*)

The Commission introduced the draft Regulation, highlighting the past discussions on the topic in previous meetings of the Standing Committee. The Commission mentioned that several Member States provided comments and suggestions on the draft proposal after the last meeting, either through the latest newsgroup opened or via emails to the Commission. In addition, one stakeholder provided comments on the draft act based on the version uploaded in the TBT

notification in August 2023. Based on the comments received, the Commission clarified the latest revisions in the draft proposal, which were also communicated in advance to the members of the Standing Committee.

The Commission underlined that an agreement should be sought in the current meeting and proceed with voting by written procedure; otherwise, another extension of the approval of the substance will be necessary (expiration on 31/12/2023).

Two Member States marked their support with the draft proposal. Another Member State inciated that it agreed in principle with the draft proposal, although they mentioned that they need more time to provide a final position and that it was still reflecting internally whether the uses for decking and fences should be excluded, since the approval should be limited to the extent necessary.

One Member State asked the Commission about the period of grace on treated articles which should not be placed anymore in the EU market after the renewal of approval of propiconazole. The same Member State referred to the related provision followed in the renewal of approval of creosote. Another Member State agreed with these remarks. The Commission replied that the BPR does not include relevant provisions on this matter and invited that Member State to come up with a concrete proposal or that this issue is addressed under the Forum of enforcement authorities.

Another Member State inquired why the related provisions about setting restrictions on treated articles related with food and feed were removed from the latest version of the draft act. The Commission clarified that, after discussing the issue internally, it was decided that this provision was redundant since the allowed uses described in the draft act are de-facto not related with food and feed.

The Commission indicated that the draft Regulation would be submitted to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023: favourable opinion

B.02 Exchange of views on a draft Commission Implementing Decision not approving silver zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP81-Doc.B.02*)

B.03 Exchange of views on a draft Commission Implementing Decision not approving silver zinc zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP81-Doc.B.03*)

The Commission introduced the two draft Decisions under agenda items B.02 and B.03 jointly, reminding that the two substances have been substantially discussed in previous meetings of the Standing Committee. No Member State had any comments.

The Commission indicated that the draft Decisions would be submitted to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023 on the two acts: favourable opinion

B.04 Exchange of views of the Committee on a draft Commission Implementing Regulation approving formic acid as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.04)*

The Commission introduced the draft Regulation. No Member State had any comments.

The Commission indicated that the draft Regulation would be submitted to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023: favourable opinion

B.05 Exchange of views of the Committee on a draft Commission Implementing Regulation approving sulfur dioxide generated from sulfur by combustion as an active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.05)*

The Commission introduced the draft Regulation, highlighting that the exact same draft proposal was discussed in the last meeting. No Member State had any comments.

The Commission indicated that the draft Regulation would be submitted to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023: favourable opinion

B.06 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of hydrochloric acid for use in biocidal products of product-type 2 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.06)*

The Commission introduced the draft Decision. No Member State had any comments.

The Commission indicated that the draft Decision would be submitted to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023: favourable opinion

B.07 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'GHC Chlor' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.07)*

B.08 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'PPC Chlorine liquid' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.08)*

Points B.07 and B.08 were discussed together. The Commission explained that the draft proposals aim at granting an authorisation for two same biocidal products of the reference biocidal product 'Arche Chlorine'. The Committee had no comment.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023 on the two acts: favourable opinion

B.09 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'CHLOROCRESOL BASED PRODUCTS-CID Lines NV' *(SCBP81-Doc.B.09)*

This point was removed from the agenda due to ongoing internal discussions.

B.10 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Phenogen in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.10)*

This point was removed from the agenda due to ongoing internal discussions.

B.11 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Procalx in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.11)*

The Commission introduced the draft Decision, recalled that the draft had been presented for discussion at the previous meeting of the Committee and informed that no modifications of the text were made following the consultation of the other Commission services.

The Commission indicated that the draft Decision would be submitted to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023: favourable opinion

B.12 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product family INTEROX Biocidal Product Family 2 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.12)*

The Commission introduced the draft Decision, presented the two points of disagreement raised for this product family and summarised the arguments supporting the conclusions of the Decision. With regard to the point related to the efficacy of the product family, the Commission explained that, based on the ECHA opinion which indicated that, taking into account the data package included in the application and the additional study provided by the applicant in 2021, efficacy was not proven, the Decision concludes that the condition in Article 19(1), point (b)(i), of the BPR, is not fulfilled. Having regard to this conclusion, the Commission considered it was not necessary to decide on the second point of disagreement, namely the correct classification for environmental hazards, for the purpose of the fulfilment of the condition set out in Article 19(1), point (d), of that Regulation.

The Commission indicated that the draft Decision would be submitted to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023: favourable opinion

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.B.13)*

The Commission introduced the draft Decision allowing Poland to extend the temporary permit for the biocidal product Biobor JF and mentioned that the text is almost identical to that of the latest adopted similar acts.

The Commission indicated that the draft Decision would be submitted to the vote of the Committee by written procedure as early as possible after the meeting.

Outcome of the vote by written procedure that took place between 20 October and 6 November 2023: favourable opinion

Section C Drafts presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation approving Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12}-C_{16})) as an active substance for use in biocidal products of product-type 2 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.01)*

The Commission introduced the draft Regulation. No Member State had any comments.

The Commission indicated that the draft Regulation would be submitted to the vote of the Committee by written procedure as early as possible.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation approving trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) (KMPS) as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.02)*

The Commission introduced the draft Regulation. No Member State had any comments.

The Commission indicated that the draft Regulation would be submitted to the vote of the Committee by written procedure as early as possible.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation approving thermally treated garlic juice as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.03)*

The Commission introduced the draft Regulation, mentioning a change in recital (4) of the draft act concerning the redefinition of the substance based on Article 13 of the Review Programme Regulation. No Member State had any comments.

The Commission indicated that the draft Regulation would be submitted to the vote of the Committee by written procedure as early as possible.

C.04 Exchange of views of the Committee on a draft Commission Implementing Decision not approving Willaertia magna c2c maky as an active substance for use in biocidal products of product-type 11 *(SCBP81-Doc.C.04)*

The Commission introduced the draft Decision. No Member State had any comments.

The Commission indicated that the draft Decision would be submitted to the vote of the Committee by written procedure as early as possible.

C.05 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of boric acid for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.05)*

C.06 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of disodium tetraborate for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.06)*

The Commission introduced the 2 draft Decisions under agenda items C.05 and C.06 jointly.

The evaluating Member State provided detailed information concerning the reasons of the delays and why the extensions of approval are needed.

One Member State mentioned that it would vote against these Decisions because these substances meet the exclusion criteria of the BPR.

The Commission indicated that the draft Decisions would be submitted to the vote of the Committee by written procedure as early as possible.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Aeroclean' *(SCBP81-Doc.C.07)*

The Commission presented the draft act for the Union authorisation of this single biocidal product based on L-(+)-lactic acid and hydrogen peroxide for uses belonging to PT 2.

No comments were made.

The Commission indicated that the draft Regualtion would be submitted to the vote of the Committee by written procedure as early as possible.

C.08 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product BOMBEX® PEBBYS® CS in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.08)*

This point was removed from the agenda due to ongoing internal discussions.

C.09 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Icon 10 CS in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.09)*

This point was removed from the agenda due to ongoing internal discussions.

C.10 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product family Cypermethrin solids in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.10)*

This point was removed from the agenda due to ongoing internal discussions.

C.11 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product family Cypermethrin liquids in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP81-Doc.C.11)*

This point was removed from the agenda due to ongoing internal discussions.

Any other business - AOB

1) Discussion on a request for administrative changes to include new trade names in the UA 'CVAS Biocidal Product Family based on L(+) Lactic Acid'

The Commission requested a discussion on the inclusion of the new trade name 'Care4Cows' in the UA 'CVAS Biocidal Product Family based on L(+) Lactic Acid' in relation to the provisions of Article 69(2) of the BPR. Some Member considered that the proposed trade name is not misleading as regards the potential risks for animal health as the product's intention is to take care / protect animal health.
As only a few Member States reacted during the meeting, the Commission invited the Member States to react within maximum two weeks after the meeting if they would object the use of the trade name.