EUROPEAN COMMISSION

Health and Food Safety Directorate General

**Standing Committee on Biocidal Products**

**8 December 2022**
**10:00 – 17:00**
**Hybrid meeting**

# MINUTES

## Section A Information and/or discussion

**A.01** Adoption of the Agenda

The agenda of the meeting was adopted.

**A.02** Adoption of the minutes of the 77th SCBP meeting

Two Member States provided comments which were incorporated in the version distributed for the meeting. The minutes were then adopted.

**A.03** Exchange of views on the examination of the renewal of approval of propiconazole for use in biocidal products of product-type 8

The Commission introduced the background of this item and invited Member States to indicate whether they agree with Commission's preliminary conclusions that the condition for derogation to exclusion (c) of Article 5(2) would be met for use classes 3.2 and 4 (industrial treatment of structural wood), use classes 2 and 3.1 (professional treatment of joinery), and brush or spraying (professional use). The Commission also asked the position of the Member States if this condition would also be met for the anti-sapstain use or not.

7 Member States supported the Commission's proposal.

When it comes to the anti-sapstain use, one Member State mentioned that there are 20 biocidal products for PT8 in their national market for such use, and that 9 of them contain propiconazole. That Member State was inconclusive whether any restriction for such use should be included in the renewal of propiconazole, but indicated it can be flexible on this. Another Member State pointed that there are several products containing propiconazole for anti-sapstain use in their country, and thus would support the renewal of the approval also for that use. An additional Member State was uncertain to take a position for the anti-sapstain use, mentioning that the alternative substance – IPBC – is under evaluation, might have ED properties and it is not ideal for all circumstances for the related use.

When it comes to treated articles and possible risk mitigation measures (RMMs), a Member State supported to include RMMs in the renewal decision, especially for treated articles that come to direct contact with food and feed. Another Member State asked for harmonization of RMMs on treated articles. An additional Member State asked to pay attention for RMMs for treated articles that come to direct contact with the general public.

A Member State underlined its reservations to take a decision on the renewal or not of propiconazole, mentioning that an holistic approach should be instead taken place, considering and comparing all active substances in PT8. The Commission replied that it would welcome such an effort but pointed that this would take a lot of time and a decision on the renewal of propiconazole should be taken soon, since its approval has been already extended 3 times so far. The Commission also reminded that a possible renewal would last for only 7 years.

Finally, a Member State inquired about the industrial use of class 4 'vacuum pressure', for which no risk assessment was presented in the BPC Opinion. The Commission clarified that such risk could still be examined at the biocidal product authorization level.

Based on the discussions, the Commission concluded that it will start working on a draft renewal of propiconazole for all uses referred above, and that references to RMMs will be included in the draft proposal, to be presented in the next meeting.

**A.04** Information on the administrative change to the Union authorisation of the biocidal product family "Quat-Chem's iodine based products"

The Commission informed that, based on the feedback from the Commission Legal Service, the SCBP will no longer be consulted on applications for changes to Union authorisations as such consultation is not required according to Article 50(2) of the BPR. Member States did not comment and took note.

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

**B.01** Exchange of views of the Committee on a draft Commission Implementing Decision not approving cyanamide as an active substance for use in biocidal products of product types 3 and 18

The Commission introduced the item and asked the Standing Committee members to provide their view on the draft proposal. The Commission also mentioned the frequent communications with the applicant and that the applicant's comments have been taken into consideration when forming the final proposal for non-approval.

Two Member States stated their support to the Commission's proposal. Another Member State pointed that they would abstain due to having a different opinion at ECHA BPC level. Two Member States were not sure yet to provide an opinion, one of them mentioning that they need first to analyse the letters they received from the applicant. Two other Member indicated that they need to check their national market first and to check the legal basis of the decision respectively.

The Commission clarified that the dossier was evaluated based on BPD provisions, and that the non-approval proposal is based on the fact that it has ultimately not been demonstrated that the representative biocidal product containing cyanamide for product-types 3 and 18 may be expected to not have unacceptable effects itself, or as a result of its residues, on human health and on the environment.

The Commission invited the Member States that were not sure yet on their position, to provide their final position to the Commission by the end of the year.

**B.02** Exchange of views of the Committee on a draft Commission Implementing Decision not approving DBNPA as an active substance for use in biocidal products of product type 4

The Commission introduced the item and asked the Standing Committee members to provide their view on the draft proposal

One Member State pointed that they would abstain due to having different opinion at BPC level. No other comments were raised.

The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion*

**B.03** Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT) for use in biocidal products of product-type 8

The Commission introduced the item. No comments were received. The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion*

**B.04** Exchange of views of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of imidacloprid for use in biocidal products of product-type 18

The Commission introduced the item. One Member State mentioned that it would abstain because this active substance is a neonicotinoid. No other comments were received. The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion*

**B.05** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Active chlorine based products BPF - CID LINES NV"

The Commission recalled the past discussions between two competent authorities on the acceptability of the risks for professional users of applying corrosive particles by coarse spraying. The Commission also noticed inconsistencies in the opinions adopted by the ECHA BPC on two products with very similar composition and uses, where in one case the BPC recommended to authorise the product with appropriate risk mitigation measures, whereas in another very similar case it recommended a non-authorisation. At this stage, it seems difficult to adopt decisions on those applications without asking ECHA for an opinion on whether the risk mitigation measures proposed in this application would be sufficient to mitigate the

identified risks. The Commission stressed that the same conclusions shall be applied consistently to ongoing and future cases when they are no objective reasons to treat them differently. The Standing Committee agreed to request an opinion from ECHA on the matter.

The evaluating Member State reiterated its frustration about the way the Commission is handling this case, which was already extensively discussed by the Committee in June, after which the Commission firstly concluded that the voting procedure of the Committee could start after that meeting.

ECHA confirmed that, according to the data collected, the products and the uses are similar and that the RMMs should be aligned. ECHA agreed to receive a Commission mandate to review the relevant opinions.

One Member State expressed its support to the evaluation made by the evaluating Member State.

Another Member State requested additional time to comment the Commission note distributed on CIRCABC.

The Commission concluded, that in the current situation, it is not yet possible for the Standing Committee to vote on a draft proposal, and a mandate will be sent to ECHA to provide the necessary clarifications.

**B.06** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L (+) Lactic Acid'

The Commission introduced the dossier and explained that there was no minority opinion, no request for derogation under Article 44(5) and no post authorisation conditions required for this application. The Commission also explained that, in order to be consistent with an Article 36 decision published last year, a reference to the relevant standards on personal protective equipment will be introduced from now on in the relevant sections of the SPC. As the SPC Editor does not allow the applicant to introduce the full titles of those standards in a footnote, the Section 6 of the SPC will be used for that purpose. The Commission also explained that an additional H statement was needed for meta-SPC 7.

One Member State noticed that the mention 'organic' is used in several trade names of products belonging to the family and asked whether this is compatible with the provisions of Article 69 of the BPR.

Another Member State expressed similar concern with the mention 'bio' in another Union authorisation on the agenda of the meeting. This is of particular concern for the labelling of consumer products as it might give the wrong impression that the products do not present any kind of risk. According to case law of the European Court (judgment of May 13, 2020 – T-86/19 ) the labelling of biocidal products with the term "bio" is sufficient to establish a serious risk of consumer perception. For that Member State, the term 'organic' is of less concern as it has no significance in their national language.

Three other Member States supported the view that the term 'organic' should be not be used and considered that the applicant should propose another trade name. A guidance on what could be labelled would be appreciated.

The Commission wondered that products for professionals could perhaps bear such terms in their trade names as it would be expected that professionals would be more knowledgeable of

the risks than the general public and may not be confused. A guidance on what cannot be labelled might be easier to handle.

Another Member State argued that the authorisation holder might have good reasons to use the term 'organic' as for example the active substance might derive from produce of organic agriculture.

Another Member State indicated that Article 69 does not differentiate between professionals and non-professionals. In national authorisations, the authorisation holders are forced to put a sentence explaining that the term 'organic' does not mean that the product is produced from organic production.

The Commission commented that the reasons for the presence of these terms should be requested from the applicant in order to assess how far they are attached to them. If they do not want to change the trade name, a sentence could be included in the SPC to explain that the term 'organic' does not mean that the product is of organic origin.

Another Member State indicated that they could not find a justification in the BPR to not grant an authorisation if the applicant refuses to modify the trade name. Some guidance on the topic would be welcome.

The Commission concluded that the authorisation holder will be contacted to get clarifications on the reasons to use trade names that include the denomination 'organic'. The Commission will further reflect internally on this topic.

**B.07** Draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'C(MIT)/MIT formulations'

The Commission recalled that the Standing Committee already expressed a positive opinion on this Union authorisation in 2021 together with its reference product. However, due to some issues identified in the SPC of the reference product at the very late stage of the regulatory process, the SPC of the same biocidal product needed to be revised to ensure coherence with the reference product. The Committee was invited to comment the revised version of the SPC. No comment was received.

The Commission also informed the Committee about the objections raised by the ENVI Committee of the European Parliament on the UA "CMIT MIT solvent based" because of the generation of dioxins when the product is used to protect fuels. The Commission will have to respond to the objections of the EU Parliament which are however not binding.

The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion*

**B.08** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family Evonik's Hydrogen Peroxide Family'

The Commission introduced the draft act proposing to grant a Union authorisation of this product family containing hydrogen peroxide as active substance and intended for use by sole professionals. The BPC opinion recommended the authorisation of this biocidal product family. The Commission mentioned that the draft SPC will be amended to include references to EN standards for personal protection equipment in the 'risk mitigation measures' sections.

The Commission also mentioned that eight of the trade names of the family contain 'bio' in their trade names. Similarly to the case discussed at point B.06, the Commission informed that it will contact the applicant to indicate that these names might not be in line with the requirement of Article 69(2) of the BPR and to recommend that they remove those trade names from their portfolio.

It was agreed to suspend the procedure for this draft act until the issue of the trade names is solved.

**B.09** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not granting a Union authorisation for the biocidal product family 'UL Hydrogen Peroxide Family 1'

The Commission introduced the draft act proposing not to grant an authorisation for this biocidal product family, in line with the BPC opinion, due to unacceptable risks identified for human health and the environment and also due to data gaps that did not allow to conclude on the physical and chemical properties of the products. The Commission mentioned that the applicant has been informed about the intention of non-authorisation and no reaction was received prior to the meeting. No comments were raised by Member States in the meeting.

The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion.*

**B.10** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not granting a Union authorisation for the single biocidal product "Insecticide Textile Contact"

The Commission presented the draft decision following the recommendation of the BPC not to authorise the product due to unacceptable risks identified for human health and the environment. The applicant has been informed about the intention of non-authorisation and no reaction was received at the time of the meeting. Member States did not comment.

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

**B.11** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Airedale PAA product family'

The Commission presented the draft decision proposing to authorise the product as recommended by the BPC. The applicant informally informed the Commission that the name of the manufacturer of the active substance will change as from January 2023 and requested to implement this change in the draft. It was agreed to wait for the official request from the applicant before making any modification[1].

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

[1] The applicant finally informed the Commission after the meeting that it does not request to change the name of the manufacturer.

*Outcome of the vote by written procedure that took place between 23 January and 3 February 2023: favourable opinion.*

**B.12** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product 'TWP 094'

The Commission presented the draft decision to authorise the product as recommended by the BPC. It was agreed to implement changes to Annex I of the draft act as proposed by one Member State .

The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion*

**B.13** 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 A-Quasan in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

The draft decision that intends to resolve the disagreement on the mutual recognition of the product A-Quasan was discussed in the 77th SCBP meeting of September 2022 and Member States were invited to provide comments on the draft decision by 31 October. One Member State made a proposal to modify the wording of the CA document CA-May15-Doc8.3[2] ('the CA document') that was the origin of the disagreement in the Coordination group, to clarify that is possible to assign, to product-type 2, biocidal products for general surface disinfection in veterinary health care area when the products are used in human and veterinary clinics. The Commission informed Member States that the CA document CA-May15-Doc8.3 will be proposed to be amended as suggested by that Member State, to avoid misinterpretations on the allocation of the product-types. The ECHA Efficacy Guidance has been already amended to only refer to the CA document CA-May15-Doc8.3. The Commission also informed that internal discussions on the wording for some of the recitals are still ongoing and that an amended version will be circulated after the meeting.

**B.14** 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 Vizaran in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

Points B.14 and B.15 were discussed together.

**B.15** 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 Rapid Pro in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP77-Doc.B.15)*

The two draft Decisions (B.14 and B.15) were presented together. The Commission informed that the internal consultations have not yet been concluded, substantial comments were

[2] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/0015a899-662d-4b86-ab1d-d73b42bf1888/details

received from the authorisation holders and that an application for the annulment of a similar decision (*Commission Implementing Decision (EU) 2022/1388 of 23 June 2022 on the unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Pat'Appât Souricide Canadien Foudroyant referred by France and Sweden in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council)*, has been made by the authorisation holder of the product before the General Court of the EU (case T-667/22). Due to all this, the discussion on these two draft Decisions will be postponed for the next meeting of the Standing Committee.

## Section C Drafts presented for discussion

**C.01** Exchange of views of the Committee on a draft Commission Implementing Decision approving (13Z)-Hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19

The Commission presented the draft proposal, mentioning the more open approval as mentioned in the draft proposal.

One Member State would prefer a less open approach but is flexible on the final decision. No other comments were made.

**C.02** Exchange of views of the Committee on a draft Commission Implementing Decision approving ozone generated from oxygen as an active substance for use in biocidal products of product type 2, 4, 5 and 11

The Commission presented the draft proposal, highlighting that the active substance does not belong to the review programme but pointed out that the transitional provisions of Article 93 of the BPR are applicable to the products. There were two separate applications from different applicants; evaluated by two different evaluating CAs, and this eventually resulted into two sets of opinions of the BPC. While there was consistency between the respective opinions on the different applications for product types (PT) 2, 4, 5, a deviation was observed in the recommendation made by in the two opinions for PT 11: a restriction on paying attention for the general public was proposed in one opinion, which was made in the opinion. No justification was included in the related BPC opinion. Based on the analysis of the Commission, there is no unacceptable risk to justify the proposed restriction. The eCA for that application confirmed this analysis.

The Commission also mentioned its current intention to refer to a norm standard on the minimum level of purity of the substance in the draft approval, but pointed it may change in the final version as it was not considered appropriate by its Legal Service in a previous case.

**C.03** Exchange of views of the Committee on a draft Commission Implementing Decision not approving d-Allethrin as an existing active substance for use in biocidal products of product type 18

The Commission presented the draft proposal. No comments were made. The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion*

**C.04** Exchange of views of the Committee on a draft Commission Implementing Regulation approving Alkyl (C12-16) dimethylbenzyl ammonium chloride (C12-16-ADBAC/BKC) as an active substance for use in biocidal products of product type 1

The Commission presented the draft proposal. One Member State pointed its support to the Commission's proposal, despite the fact that the active substance is a backlog dossier and has been evaluated under Directive 88/8/EC. No other comments were made.

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

**C.05** Exchange of views of the Committee on a draft Commission Implementing Decision not approving of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council

The Commission presented the draft proposal. No comments were made. The Commission indicated that the draft 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 23 January and 3 February 2023: favourable opinion*

**C.06** Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product 'EuLA hydra-lime 23'

Points C.06 and C.07 were discussed together.

**C.07** Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product 'EuLA oxi-lime 23'

The two draft Decisions C.06 and C.07 were presented together. The Commission explained that for both cases there was an on-going discussion due to a minority opinion submitted by one member of the BPC concerning the risk assessment from exposure by inhalation for certain uses. The Commission explained that there was a need for further clarification as for why qualitative approach was followed by the BPC despite it was possible to make a quantitative assessment. The Commission will ask ECHA for further support.