EUROPEAN COMMISSION

Health and Food Safety Directorate General

83rd Standing Committee on Biocidal Products
13 March 2024

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP83-Doc.A.01)*

A.02 Adoption of the minutes of the 82nd SCBP meeting *(SCBP83-Doc.A.02)*

The minutes of the previous SCBP meeting were adopted.

A.03 Updates on ethylene oxide

The Commission briefly mentioned past discussions on ethylene oxide and informed the SCBP members on the feedback received by several Member States following the latest discussion in the 82nd SCBP meeting of December 2023. Some Member States raised concerns that the use of ethylene oxide for disinfection of medical devices when these are still under manufacture process should be regulated under the BPR and not under the Medical Devices Regulation (MDR). The Commission announced that, after internal analysis, it considers that such case is also covered under the MDR. One Member State mentioned that ethylene oxide use in medical devices should be regulated under the BPR.

The Commission informed the SCBP members about an online meeting organised by DG SANTE on ethylene oxide and its use in medical devices, open to both regulators and stakeholders, scheduled for 8 April. An agenda of the meeting will follow soon.

A.04 Exchange of views on the applicability of the derogation conditions 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, and for reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (originally notified as MBO) for product-types 2, 6, 11, 12 and 13 *(SCBP83-Doc.A.04)*

The Commission presented briefly its preliminary conclusions whether the derogation conditions of Article 5(2) are met for RP 3:2 and RP 1:1 and asked the SCBP members whether they agree with the conclusions of the BPC Opinion that there are no suitable alternatives for the two substances for the related product-types and uses.

One Member State mentioned that based on stakeholders' feedback at national level there is an additional use of the substances in paints, which is not covered by the current analysis. The Commission invited it to send more information in writing.

The same Member State expressed concerns whether some substances (e.g. BIT) should be considered as suitable alternatives to RP 3:2 and RP 1:1 based on their better hazard profile, despite the BPC conclusions on the contrary. The Commission agreed that such cases should be reflected in more detail.

The Commission invited for the views of the Member States by 30 April on the preliminary conclusions of the document, and in particular on the conclusions on the BPC opinion on the availability of alternatives.

A.05 Exchange of views on the applicability of the derogation conditions to exclusion, set in Article 5(2), for DBNPA for PT6 *(SCBP83-Doc.A.05)*

The Commission presented briefly its preliminary conclusions whether the derogation conditions of Article 5(2) are met for DBNPA. As several uses analysed in the current document were not included in the application for approval dossier, the related risks were thus not assessed for these uses.

One Member State tentatively agreed with the analysis presented in the document, concluding that the substance could meet the derogation condition of Article 5(2)(c) for the uses investigated. Another Member State asked for clarification if the use of DBNPA referring to raw materials is linked with the paper production. The Commission confirmed that this use refers to paper production. An additional Member State mentioned that, though it does not have a position yet on the document, two additional uses have been mentioned by the applicant (wall filler putties and premix plasters) during the Article 5(2) consultation. The Commission will check on these two uses.

The Commission invited for the views of the Member States by 30 April on the preliminary conclusions of the document whether the derogation conditions of Article 5(2) are met for DBNPA for the examined uses.

A.06 Information on the application for a Union authorisation for the biocidal product family 'CHLOROCRESOL BASED PRODUCTS-CID Lines NV'

As in the last SCBP meeting, this agenda item A.06 was discussed in the connection with item B.20. The Commission reminded that for the use of the products as a concentrated animal skin disinfectant, the assessment identified an exceedance of the default MRL of 0.01 mg/kg provided for by Regulation (EU) No. 396/2005 but no dietary risk. Therefore, it is intended to follow the same approach as for the draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Phenogen as presented under agenda item B.20.

One Member State agreed that the Commission should mandate ECHA in accordance with Article 75 (1) (g) to enable a discussion in the BPC on the inclusion of the use in the SPC which is currently missing. No further comments were received and the Commission informed that it will proceed to draft such a mandate.

A.07 Information on decisions on amendments to Union authorisations under preparation or published *(SCBP83-Doc.A.07)*

The Commission recalled that the Committee is not consulted for its opinion on Articles 48 and 50(2) decisions on amendments to Union authorisations as, according to these articles, the Committee does not need to formally express an opinion. However, as mentioned during the 81st meeting, the Commission will continue to inform the Committee about the draft amending acts in preparation and published.

One Member State thanked the Commission for the initiative. Another one asked whether the list will be limited to the draft amending acts for which ECHA received a recent application or if other requests for amendments will be also addressed by the Commission in a near future. The Commission explained that the priority is to grant authorisations to reference and same biocidal products. Major and minor changes in combination with administrative changes (if relevant), and amending acts for the transfer of authorisation holder, are then addressed. Corrigenda to fix linguistic issues are also processed as quickly as possible.

The Commission recalled that the applicant can implement administrative changes referred to in Section 1 of Title 1 of the Annex to the Change Regulation No 354/2013 45 days following receipt of the notification submitted to ECHA in accordance with Article 11 of the Change Regulation.

A.08 Information on Union authorisations and the use for disinfection of water in pools *(SCBP83 – Doc.A08)*

The Commission informed about the on-going internal discussions on three applications for Union authorisations of active chlorine-containing products, which include the use for the disinfection of water in public swimming pools.

For all three applications the Commission received a request from one Member State for a derogation from the authorisations in accordance with article 44 (5) of the BPR to insert for their territory additional lower use concentrations to allow for the products to be used in accordance with a national norm to which public pools are generally operated to ensure compliance with the national law. The Commission is still assessing whether the request is justified based on one of the grounds of Article 37 (1) of the BPR.

The BPC opinions for these applications conclude that the conditions for authorisation are fulfilled and recommend the authorisation, while also stating that is not possible to conclude on the potential risks from disinfection by-products (DBPs) for human health or the environment due to missing or inconclusive guidance and data. The Commission pointed out that this issue is not restricted to these three Union authorisations but also concerns national authorisations and mutual recognition of similar products. ECHA and Member States were requested to provide an update on the status of the work concerning the guidance development and envisaged timeline to enable conclusive assessments of risks from DBPs. One Member State working on the development of the human health part of the guidance explained that, despite it being a priority, they struggle to finalise the work due to the complexity of the subject. Another Member State working on the environmental part of the guidance explained that the assessment is taking longer than expected due to the same reason.

The Commission will follow-up on these two issues.

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

B.01 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of hexaflumuron for use in biocidal products of product-type 18 *(SCBP83-Doc.B.01)*

The Commission introduced the draft Decision. One Member State mentioned that it would vote against this Decision because the substance meets the exclusion criteria of the BPR. Another Member State mentioned its concerns on the delays caused by ED data in the evaluations of renewals, but they stated that they will not abstain on this particular draft Decision.

The Commission concluded 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 4 April and 22 April 2024: favourable opinion

B.02 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of cis-tricos-9-ene for use in biocidal products of product-type 19 *(SCBP83-Doc.B.02)*

The Commission introduced the draft Decision. No comments were made by Member States.

The Commission concluded 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 4 April and 22 April 2024: 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 hydrogen cyanide for use in biocidal products of product-types 8, 14, 18 *(SCBP83-Doc.B.03)*

The Commission introduced the draft Decision. No comments were made by Member States.

The Commission concluded 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 4 April and 22 April 2024: favourable opinion

B.04 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Soft Care Med H5' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.04)*

The Commission introduced the draft act with the SPC annex for the authorisation of the single biocidal product containing propan-1-ol and propan-2-ol for PT 1 uses.

The Commission informed that a comment was received from one Member State prior to the meeting related to the agreement from the BPC to remove "general public" from the user category and to only refer to "non-professional" users had not been implemented in the draft SPC. The Commission confirmed that the SPC will be updated accordingly.

No further comments were received, and the draft will 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 4 April and 22 April 2024: favourable opinion

B.05 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'ClearKlens wipes based on IPA' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.05)*

The Commission introduced the draft act with the SPC annex for the authorisation of the single biocidal product based on propan-2-ol for PT2 uses.

No comments were made and the Commission concluded to submit the draft to the vote of the Committee by written procedure as early as possible.

Outcome of the vote by written procedure that took place between 4 April and 22 April 2024: favourable opinion

B.06 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Contec calcium hypochlorite Product Family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.06)*

The Commission briefly introduced the draft act and its annex. Compared to the version proposed by the BPC, the draft annex SPC was slightly improved with the support of the evaluating Member State. No comments were made by Member States.

The Commission concluded 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 4 April and 22 April 2024: favourable opinion

B.07 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'SICO Biocidal Product Family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.07)*

See Point B.08.

B.08 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Sure Lactic Family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.08)*

Agenda points B.07 and B.08 were introduced together, as these biocidal products applications refer to the same reference biocidal product family. In both cases, the Committee supported the deletion of some misleading terms in trade names and their replacement by a trade name more in line with the CA document "CA-June 23-Doc.4.9-Final rev1" and Article 69.2 of the BPR. The Committee also accepted the inclusion of other trade names at the request of the applicants.

The Commission concluded 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 on item B.07 and B.08 that took place between 4 April and 22 April 2024: favourable opinion

B.09 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Saniswiss H2O2' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.09)*

See Point B.10

B.10 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product ‘‘Sanoserv H2O2’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.10)*

Agenda points B.09 and B.10 were introduced together, as these biocidal products applications refer to the same reference biocidal product family. The first application still contains a term identified as misleading in the annex to the CA document “CA-June 23-Doc.4.9-Final rev1”. The Commission will therefore come back to the applicant and request a modification of this term before proceeding to the vote.

The Commission concluded 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 4 April and 22 April 2024: favourable opinion

B.11 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product ‘CaO PT03’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 83-Doc.B.11)*

See Point B.18

B.12 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product ‘CaO PT02’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 83-Doc.B.12)*

See Point B.18

B.13 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product ‘CaO PT02-PT03’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 83-Doc.B.13)*

See Point B.18

B.14 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product ‘BIOCALCO Q’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.14)*

See Point B.18

B.15 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product ‘Nordkalk QL 90’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.15)*

See Point B.18

B.16 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product ‘Nordkalk CL 90-Q’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.16)*

See Point B.18

B.17 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Nordkalk QL 0-2' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.17)*

See Point B.18

B.18 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Nordkalk QL 0-0,1' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 83-Doc.B.18)*

Agenda points B.11 to B.18 were introduced together, as these biocidal products applications refer to the same reference biocidal product family. The discussion focused on item B.14 for which the Commission recently identified a misleading term in some of the trade names proposed by the applicant. The Commission will therefore come back to the applicant and request a modification of this term before proceeding to the vote.

The Commission concluded 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 on items B.12 to B.18 that took place between 4 April and 22 April 2024: favourable opinion

B.19 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Thonhauser PAA' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 83-Doc.B.19)*

The Commission introduced the draft for the authorisation of the same biocidal product family making reference to the biocidal product family 'Airedale PAA product family'.

No comments were made and it was concluded to submit the draft to the Committee for voting in written procedure as early as possible.

Outcome of the vote by written procedure that took place between 4 April and 22 April 2024: favourable opinion

B.20 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 *(SCBP83-Doc.B.20)*

The Commission presented the changes introduced to the draft after further internal discussions. An incorrect reference to the veterinary medicines legislation has been deleted in recital 13 of the act. The statement in recital 15 saying that there was no need to revise the maximum residue limit (MRL) for chlorocresol established under Regulation (EC) No 396/2005 has also been deleted, as the Commission services are reflecting on how to increase this MRL to prevent compliance issues of commodities from animals exposed to the product with the legislation on residues of pesticides. With that aim, the Commission enquired with the European Food Safety Authority (EFSA) whether it had monitoring data on residues of chlorocresol in animal commodities, but as Member States are not monitoring the residues of chlorocresol, there are no available monitoring data. The Commission is exploring other means to revise the MRL.

The Commission has also tried to retrieve information from the assessment reports of biocidal products authorised by Member States containing chlorocresol, and has encountered inconsistencies in the way the exposure assessment is performed. The Commission reminded Member States that they need to ensure consistency of the assessments. The Commission informed Member States that, to ensure that there will be no exceedance of the MRL for chlorocresol leading to compliance issues on the market, it considers conditioning the authorisation of the product to the revision of the MRL.

The Commission explained that it intends to propose a harmonised way forward on MRLs in the CA meeting, once the legal situation has been clarified. The Commission is also working on a list of biocidal active substances for which issues with MRLs may be encountered and will share the list with Member States in upcoming meetings of the Competent Authorities.

The Commission will keep Member States informed on the development on this file.

B.21 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 *(SCBP83-Doc.B.21)*

The Commission explained that the same considerations as for agenda point B.20 apply. The Commission is working on a revision of the MRLs established for lambda-cyhalothrin in poultry commodities under Regulation No 396/2005, using monitoring data provided by EFSA.

The Commission will keep Member States informed on the development on this file.

B.22 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 Elector in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.22)*

The Commission introduced the draft decision on the unresolved objections for the renewal of the product Elector.

The first disagreement concerned the use of refined Predicted No Effect Concentration (PNEC) values for soil for spinosad and its metabolites, as the refined values have not been agreed for use in the risk assessment of biocidal products and are less conservative than the values used in the assessment report for the active substance approval. To resolve this point, the Commission requested an opinion from ECHA in accordance with Article 36(2) of Regulation (EU) No 528/2012. According to ECHA, the refined PNEC values can be used for the environmental risk assessment leading to the conclusion that the product meets the conditions of Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012 as regards the risks for the soil compartment. The Commission concurs with the conclusions of ECHA.

The second point of disagreement concerned the presence in the product of a substance identified as PBT/vPvB in a very low concentration. The Commission considers that, for reasons of coherence with the approach for the assessment of technical equivalence of active substances with regard to PBT and/or vPvB properties and the approach for determining whether constituents, impurities and additives are relevant for the PBT/vPvB assessment under Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008, the same concentration limit of 0,1 % (w/w) should apply to determine

whether a substance identified as having PBT and/or vPvB properties and contained in a biocidal product, is a substance of concern. As the concentration of the substance in the product is below 0,1 % (w/w), the product should therefore not be considered as containing a substance of concern for the purpose of the assessment of the product in accordance with point 14 of Annex VI to Regulation (EU) No 528/2012. It follows that the presence of octamethylcyclotetrasiloxane in the product does not imply that the product has unacceptable effects on the environment within the meaning of Article 19(1), point (b)(iv), of Regulation (EU) No 528/2012.

Member States had no comments. The Commission concluded 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 4 April and 22 April 2024: favourable opinion

B.23 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 *(SCBP83-Doc.B.23)*

The Commission introduced the draft decision on the unresolved objections related to the authorisation of the biocidal product BOMBEX® PEBBYS® CS and introduced the two points of disagreement raised by concerned Member States during the mutual recognition procedure, related to the potential presence in the final product of toxicologically relevant compounds due to the manufacturing process and to the presence in the product, in very low concentrations, of three cyclosiloxanes (D4, D5, D6) identified as PBT/vPvB substances in accordance to Annex XIII of the CLP Regulation.

The Commission explained that, on the first point of disagreement, an ECHA opinion was requested. The opinion concluded that, while the presence of residual isocyanates in the final product could be excluded after a few days of storage, the presence of free aromatic amines could not be excluded. In a worst-case approach, a level of 0,3 % (w/w) free aromatic amines was estimated to be possibly present in the biocidal product. Considering that all aromatic amines suspected to be present in the product are classified or notified as genotoxic carcinogens in accordance with the CLP Regulation, these non-active substances are to be considered as toxicologically relevant. No data on the potential presence of these non-active substance was provided by the applicant in the initial application. The Commission considered it appropriate to allow the applicant to provide additional analytical data, however these data failed to address the presence of all aromatic amines suspected to be present in the product and proved to be inadequate. Taking into account the ECHA opinion, the fact that no data on the presence of aromatic amines were provided in the application and the inadequacy of the data provided subsequently by the applicant, the Commission considered that the condition in Article 19(1), point (c), of the BPR, requiring that the chemical identity and quantity of toxicologically or ecotoxicologically significant and relevant impurities and non-active substances can be determined, is not met for the product BOMBEX® PEBBYS® CS.

With regard to the second point of disagreement, the Commission explained that, in line with previous decisions on this matter and for reasons of coherence with the

approach followed for the technical equivalence assessment with regard to PBT and/or vPvB properties of impurities under the BPR and for determining whether constituents, impurities and additives are relevant for the PBT/vPvB assessment under the REACH Regulation, the same concentration limit of 0,1 % (w/w) should be applied to determine whether a substance identified as having PBT and/or vPvB properties and contained in a biocidal product, is a substance of concern. Since the total concentration of cyclosiloxanes in the product (0,0266 %) is lower than 0,1 %, they should not be considered as substances of concern and point 48 of Annex VI to the BPR should not apply when evaluating the biocidal product in relation to the presence of those substances. It follows that the presence of those substances in the biocidal product does not imply that the biocidal product has unacceptable effects on the environment within the meaning of Article 19(1), point (b)(iv), of the BPR.

- No questions were raised by Member States. The Member State that had acted as reference Member State in the mutual recognition procedure for the product BOMBEX® PEBBYS® CS informed that, when the BPC opinion was put forward for a vote of the committee, their position was to abstain as it considers that further assessment is warranted when one realizes that a certain step within the production process can lead to dangerous by-products; however, since the assessment normally not covers the method of production, the reference Member State does not necessarily have to verify this. They informed that they are still considering which position would be most appropriate in this matter.

The Commission indicated that 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 4 April and 22 April 2024: favourable opinion.

B.24 Exchange of views of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the Malta Competition and Consumer Affairs Authority on the making available on the market and use of the biocidal product 'Wofasteril® SC super' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.B.24)*

The Commission introduced the draft decision allowing Malta to extend the temporary permit granted for a biocidal product containing peracetic acid as active substance and used in a specific unit (Hight Degree Isolation Unit) of Mater Dei hospital in Msida. The product is used for the disinfection of the personal protective equipment of medical personnel, before its removal. The use of this product is needed, as it is the only product validated for the use in the specific decontamination system in place in the HDIU. The discontinued use of this biocidal product would not allow the proper decontamination of personal protective equipment of healthcare professionals and would constitute a threat to public health, given the highly infectious nature of the diseases treated in the HDIU, and that threat cannot be adequately contained by any other means. The Commission considers it therefore appropriate to allow Malta to extend the temporary permit for 'Wofasteril® SC super' for 550 days, in accordance with Article 55(2) of the BPR.

No questions or comments were raised by Member States.

The Commission indicated that 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 4 April and 22 April 2024: favourable opinion.

Section C Drafts presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) not renewing the approval of sulfuryl fluoride as an active substance for use in biocidal products of product types 8 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.C.01)*

See Point C.02

C.02 Exchange of views of the Committee on a draft Commission Implementing Decision repealing the postponement of the expiry date of the approval of sulfuryl fluoride as an active substance for use in biocidal products of product types 8 an 18 *(SCBP83-Doc.C.02)*

The Commission introduced the two agenda items together (C.01 and C.02).

One Member State mentioned that they received information from national stakeholders that the substance is needed in their market in the absence of alternatives and should meet the conditions for derogation under Article 5(2) of the BPR, especially when it comes to preservation of cultural heritage artifacts. The Commission clarified that the investigation of alternatives for sulfuryl fluoride under Article 5(2) of the BPR is not relevant in the present case since the applicant failed to submit data requested by the eCA, needed to determine if the substance meets Article 5(1) with regard to reprotoxicity and ED properties. They also mentioned that there are other active substances (e.g. CO2 or nitrogen) which may be used for preserving cultural heritage.

Another Member State inquired whether Article 55(1) of BPR would be still applicable for sulfuryl fluoride biocidal products after the non-renewal of the substance. The Commission replied positively with reservations.

The Commission announced that voting via written procedure on the draft act will take place at least after two months or later (i.e. end of May or June), pending the TBT notification procedure. In the meantime, Member States are invited to send their comments on the draft act to the Commission in writing by 30 April. Taking into consideration the comments to be received by the Member States, the Commission will reflect whether to include the draft act in the next SCBP meeting of June or proceed with a vote via written procedure before.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Sodium hypochlorite liquid disinfectant biocidal product family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.C.03)*

The Commission informed that this item will be on the agenda of the next meeting.

C.04 Exchange of views of the Committee on a draft Commission Implementing Decision on a derogation from mutual recognition of an authorisation for a biocidal product containing hydrogen cyanide by Hungary in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council

The decision concerns a product used for fumigation, for the use of which the presence of an antidote on the site of fumigation is required, and that the content of the decision

will be similar to a decision adopted in 2019 related to the same product. In that latter decision it was concluded that, since the presence of an antidote at the site of use could not be ensured, the Member State concerned could apply the derogation from mutual recognition.

The Commission indicated that the draft act will be presented at the next meeting of the Committee.

C.05 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

C.06 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

The Commission will propose a draft act for the next Standing Committee meeting.

C.07 Exchange of views of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the Luxembourg Environment Agency on the making available on the market and use of the biocidal product 'Raidox 35%' in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.C.07)*

The Commission introduced the draft decision allowing Luxembourg to extend the temporary permit for a product containing hydrogen peroxide as active substance and used for the disinfection of the isolator at Centre hospitalier de Luxembourg. The operation of the isolator (required for the aseptic preparation of injectables) require the use of biocidal products for the disinfection of its internal surfaces. Raidox 35% is the only biocidal product that has been validated by the manufacturer of the isolator, hence its continued availability is essential for the operation of the isolator. The discontinued use of this product would constitute a threat to public health, given that the delivery of essential care to patients would no longer be ensured. Based on these considerations, the Commission considered it appropriate to allow Luxembourg to extend the temporary permit for Raidox 35% for 550 days, in accordance with Article 55(2) of the BPR.

No questions or comments were raised by Member States.

The Commission indicated that draft Decision would be submitted to the vote of the Committee by written procedure as early as possible after the consultation of the other Commission services is concluded.

Outcome of the vote by written procedure that took place between 4 April and 22 April 2024: favourable opinion.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP83-Doc.C.08)*

The Commission indicated that a draft proposal will be presented in the next Standing Committee meeting.