EUROPEAN COMMISSION

Health and Food Safety Directorate General

84th Standing Committee on Biocidal Products

21 June 2024
10:00 – 17:00

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP84-Doc.A.01)*

A.02 Adoption of the minutes of the 83rd SCBP meeting *(SCBP84-Doc.A.02)*

A.03 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 *(SCBP84-Doc.A.03)*

The Commission recalled the preliminary conclusions of the past SCBP meeting discussion (SCBP-83) on the derogation conditions of Article 5(2) and provided a short summary of the input received in the latest newsgroup about the Article 5(2) conditions. It inquired whether several active substances listed in the SCBP-84 document could be considered as potential alternatives to RP 1:1 and RP 3:2.

Two Member States pointed that more technical discussion is needed to conclude on the suitability of the specific alternatives listed in the SCBP-84 document. One of them expressed their tentative support that Article 5(2)(c) is met and asked to proceed with a draft approval to avoid further delays in the evaluation of the two substances. They inquired whether the approval should be only for 3 years period. Similarly, a third Member State asked to proceed with a draft approval. That Member State remarked that the PT6 use should be approved only for fuel preservation.

The Commission concluded that Article 5(2)(c) is met for RP 1:1 and RP 3:2 for all examined PT/uses, as was proposed in the preliminary analysis of the SCBP-83 document. It will prepare a draft act proposing a 5-years approval for the related uses identified meeting the derogation conditions, and only for fuel preservation for PT6. It will present a related document in the next SCBP meetings.

A.04 Exchange of views on the applicability of the derogation conditions to exclusion, set in Article 5(2), for DBNPA for PT6 *(SCBP84-Doc.A.04)*

The Commission recalled the preliminary conclusions of the past SCBP meeting discussion (SCBP-83) on the derogation conditions of Article 5(2) and provided a short summary of the input received from Member States in the latest newsgroup about the Article 5(2) conditions. It highlighted additional uses brought forward in the newsgroup by two Member States, concerning the preservation of detergents, washing additives, varnishes, premix plasters and wall fillers.

One Member State supported the conclusions of the Commission. They remarked that the use of DBNPA for the preservation of detergents and washing additives does not fulfil Article 5(2)(c).

Another Member State inquired whether there are alternatives to DBNPA for the preservation of paints. The Commission clarified that DBNPA is used for short-term preservation of paints, for which there seem to be no alternatives based on the information analysed so far.

The Commission concluded that Article 5(2)(c) is met for DBNPA for the examined uses, including varnishes, premix plasters and wall fillers, but not for the preservation of detergents and washing agents. It will prepare a draft act approval to be presented in the next SCBP meetings.

A.05 Information on Union authorisations and the use for disinfection of water in pools *(SCBP84 – Doc.A.05)*

The Commission informed the SCBP that the requests for derogation in accordance with Article 44 (5) submitted by one Member State concerning the use concentrations for the disinfection of water in public swimming pools for three Union authorisations have been withdrawn. Therefore, the Commission intends to proceed with the drafting of the acts in accordance with the recommendations of the BPC.

A.06 Information on ethylene oxide

The Commission informed the SCBP members on a specific workshop held about ethylene oxide, organised by DG Sante services in charge of medical devices (DG Sante D3) on 8 April 2024, which gathered Member States authorities on medical devices as well as competent authorities on biocidal products. In that workshop, it was clarified to attendees that products used for the disinfection of medical devices are not regulated under the BPR, being regulated under the MDR.

The Commission informed that it will proceed with a draft non-approval act of ethylene oxide under the BPR by the end of 2024, to be presented for discussion in the SCBP.

A.07 Information on the revision of Fees Regulation (EU) No 564/2013

The Commission informed that it is working a revision of the Fee Regulation (Regulation (EU) No 564/2013). The main purpose of the amendment is the adjustment of the fees for inflation in 2021 and 2022 (12.3%, as measured by Eurostat). In addition, some changes are introduced concerning the SME reductions and the annual fees for Union authorisation. On the former point, applicants who wish to claim SME reductions would be requested to await the outcome of the company size by ECHA and would have to provide the ECHA decision granting the SME status. Also, the validity of the ECHA decision granting SME status would be changed from two to three years, to align it with the approach adopted under the REACH Fee Regulation. With regard to annual fees for Union authorisation, it would be proposed that for cases in which the Union authorisation in cancelled before the timing due for the payment of

the annual fee (the first and subsequent anniversaries of the date of authorisation), a proportionate fee be levied for the respective part of the year. The rationale of this provision is that all applicants having benefitted from Union authorisations must contribute to the financing of ECHA.

Section B Draft(s) presented for an opinion

B.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 *(SCBP84-Doc.B.01)*

(PLAN/2024/305)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(4)(b)

Procedure: Examination procedure

B.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 *(SCBP84-Doc.B.02)*

(PLAN/2024/896)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(5)

Procedure: Advisory procedure

The Commission introduced the two agenda items B.01 and B.02 together. It mentioned that several stakeholders contacted the Commission and specific Member States competent authorities within the last months arguing that there are no alternatives of sulfuryl fluoride and that derogations for the preservation of cultural heritage should be provided in case of non-renewal of approval.

The Commission made also reference to the position paper shared by the applicant a few days before the current SCBP meeting, asking to not proceed with the process of non-renewal.

The Commission recalled the reasons driving the proposal for non-renewal of approval. It highlighted that the investigation of alternatives for sulfuryl fluoride 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.

The Commission concluded that there are no reasons to hold the process. No Member State objected on this conclusion.

No comments were raised on these two agenda items by any SCBP member.

The Commission announced that voting via written procedure on the draft acts will normally take place in mid-July.

Outcome of the vote on B.01 and B.02 by written procedure that took place between 18 July and 16 August 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 metofluthrin for use in biocidal products of product-type 18 *(SCBP84-Doc.B.03)*

(PLAN/2024/PLAN/2024/1061)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(5)

Procedure: Advisory procedure

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 18 July and 16 August 2024: favourable opinion.

B.04 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of Didecyldimethylammonium chloride (DDAC) for use in biocidal products of product-type 8 *(SCBP84-Doc.B.04)*

(PLAN/2024/PLAN/2024/1058)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(5)

Procedure: Advisory procedure

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 18 July and 16 August 2024: favourable opinion.

B.05 Exchange of views of the Committee on a Draft Commission Implementing Decision (EU) postponing the expiry date of the approval of Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)) for use in biocidal products of product-type 8 *(SCBP84-Doc.B.05)*

(PLAN/2024/PLAN/2024/1060)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(5)

Procedure: Advisory procedure

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 18 July and 16 August 2024: 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 pyriproxyfen for use in biocidal products of product-type 18 *(SCBP84-Doc.B.06)*

(PLAN/2024/PLAN/2024/1059)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(5)

Procedure: Advisory procedure

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 18 July and 16 August 2024: favourable opinion.

B.07 Exchange of views of the Committee on a Draft Commission Implementing Decision (EU) postponing the expiry date of the approval of formaldehyde for use in biocidal products of product-types 2 and 3 *(SCBP84-Doc.B.07)*

(PLAN/2024/PLAN/2024/1107)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(5)

Procedure: Advisory procedure

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.

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 18 July and 16 August 2024: favourable opinion.

B.08 Exchange of views of the Committee on a Draft Commission Implementing Decision (EU) postponing the expiry date of the approval of dinotefuran for use in biocidal products of product-type 18 *(SCBP84-Doc.B.08)*

(PLAN/2024/PLAN/2024/1063)

Legal Basis: Regulation (EU) No 528/2012 – Article 14(5)

Procedure: Advisory procedure

The Commission introduced the draft Decision. One Member State mentioned that it would abstain on this Decision because the substance meets the substitution criteria of the BPR and because it is a neonicotinoid.

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 18 July and 16 August 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 family 'Sodium hypochlorite liquid disinfectant biocidal product family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP84-Doc.B.09*)

(PLAN/2024/283)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The Commission introduced the draft Implementing Regulation for the Union authorisation of the biocidal product family based on sodium hypochlorite for PT 2 and 4. One Member State had provided comments on the SPC concerning the presentation of the value of the active substance content, a sentence in the instructions for use in meta-SPC 1, 2, 3, 4 and 9 and a risk mitigation measure to ensure that the concentration of chlorate present in food does not exceed the MRL in meta-SPC 7, just prior to the meeting. During the meeting, changes to the SPC

were presented to the SCBP to address the comments. No Member State disagreed with the proposed changes.

The Commission concluded that the draft Implementing Regulation will be submitted to the vote of the SCBP by written procedure. One MS indicated that it will vote against the proposal related to a minority opinion submitted to the BPC opinion concerning the chlorate content in the aged products.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.10 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Hydrogen Peroxide product family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.10)*

(PLAN/2024/895)

Legal Basis: Regulation (EU) No 528/2012 – Article 44(5)

Procedure: Examination procedure

The Commission introduced the draft Implementing Regulation for the Union authorisation of the biocidal product family based on hydrogen peroxide for PT 2 and 4. Prior to the meeting the Commission had received comments on the draft SPC concerning a risk mitigation measure for re-entry after use and the use of a calibrated sensor that was only included for meta SPC 5 but had been agreed by the BPC to be included in all meta SPCs and the assigned protection factor (APF) of the respiratory protective equipment (RPE) to be used for the different dilutions agreed at the BPC as a risk mitigation measure in meta SPC 5. At the meeting the Commission proposed changes to the SPC to address these comments.

There was no final agreement on the required APF for the RPE and it was agreed to open a newsgroup to provide comments on the proposed changes to the draft SPC until 12 July 2024.

B.11 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Oxivir Excel BPF' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.11)*

(PLAN/2024/981)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The Commission introduced the draft Implementing Regulation for the Union authorisation of the biocidal product family based on hydrogen peroxide for PT 2 and 4. Prior to the meeting the Commission had received comments concerning the names of the manufacturer and the manufacturing locations presented in the draft SPC. During the meeting the Commission presented amendments to the SPC to address those comments. No further comments were received.

It was concluded that the draft Implementing Regulation will be submitted to the vote of the SCBP by written procedure.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.12 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Teat disinfectants L(+)_Lactic_acid based biocidal product family of Novodan' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.12)*

(PLAN/2024/983)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The Commission introduced the draft Implementing Regulation for the Union authorisation of the biocidal product family based on lactic acid for PT 3, highlighting the moving of the information on the formulation of the products and the required pH value. No comments were made, and it was concluded that the draft Implementing Regulation will be submitted to the vote of the SCBP by written procedure.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.13 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Neporex 2SG' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.13)*

(PLAN/2024/984)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The Commission introduced the draft Implementing Regulation for the Union authorisation of the biocidal product based on cyromazine for PT 18. No comments were made, and it was concluded that the draft Implementing Regulation will be submitted to the vote of the SCBP by written procedure.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.14 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Diversey Hydrogen Peroxide Product Family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.14)*

(PLAN/2024/986)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The Commission presented the draft Implementing Regulation granting a Union authorisation for a same biocidal product family related to the reference authorisation of 'Evonik's Hydrogen Peroxide Product Family'. No comments were received, and the draft will be submitted to the vote of the SCBP by written procedure.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.15 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Hydroflex IPA 70 Biocide' in

accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.15)*

(PLAN/2024/985)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The Commission presented the draft Implementing Regulation granting a Union authorisation for a same biocidal product related to the reference authorisation of 'Brenntag GmbH Propan-2-ol Product Family'. No comments were received, and the draft will be submitted to the vote of the SCBP by written procedure.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.16 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'EuLA Ca(OH)2 template' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.16)*

(PLAN/2024/677)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

B.17 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Ca(OH)2 PT03' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 84-Doc.B.17)*

(PLAN/2024/678)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

B.18 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Ca(OH)2 PT02' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 84-Doc.B.18)*

(PLAN/2024/679)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

B.19 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'BIOCALCO S' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 84-Doc.B.19)*

(PLAN/2024/680)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

B.20 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Nordkalk SL 90' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.20)*

(PLAN/2024/674)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

B.21 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Nordkalk SL' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.21)*

(PLAN/2024/675)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

B.22 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'Nordkalk Filtra G' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.22)*

(PLAN/2024/676)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The drafts regulations under agenda items B.16 until B.22 were presented together as they all concern the authorisation of same biocidal products related to the reference product 'EuLA hydra-lime 23'. No comments were received, and the drafts regulations will be submitted to the vote of the SCBP by written procedure.

Outcome of the vote on B.16 to B.22 by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.23 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Divosan PAA products' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.B.23)*

(PLAN/2024/1104)

Legal Basis: Regulation (EU) No 528/2012 - Article 44(5)

Procedure: Examination procedure

The Commission presented the draft Implementing Regulation for a Union authorisation for a same biocidal product family related to the reference authorisation of 'Airedale PAA product family'.

The Commission informed that for the reference authorisation 'Airedale PAA product family' a corrigendum of one of the language versions was necessary due to a mistake in the translation.

The Commission reminded the Member States to carefully check the language versions of the SPC during the linguistic review to ensure high quality translations.

No comments were received, and the draft will be submitted to the vote of the SCBP by written procedure.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.24 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 *(SCBP84-Doc.B.24)*

(PLAN/2022/2091)

Legal Basis: Regulation (EU) No 528/2012 – Article 36(3)

Procedure: Examination procedure

The Commission presented the amended draft decision. After analysis, the Commission services concluded that chlorocresol was never assessed or approved as an active substance under Council Directive 91/414/EEC or Regulation (EC) No 1107/2009 of the European Parliament and of the Council. As there is no evidence that chlorocresol is currently or was formerly used in plant protection products in the EU and third countries, the Commission concluded that chlorocresol does not fall within the scope of Regulation (EC) No 396/2005 and consequently that the default value of 0.01 mg/kg set out in Article 18(1), point (b), of Regulation (EC) No 396/2005 does not apply to the biocidal active substance chlorocresol. Therefore, the Commission considers that the biocidal product Phenogen complies with the conditions of Article 19(1), point (b)(iii), and Article 19 (1)(e) of Regulation (EU) No 528/2012.

One Member State considered that it is important that chlorocresol is removed from the Annex to Regulation (EC) No 396/2005. Another member state asked for clarification if it is intended to remove chlorocresol from relevant database under plant protection regulation and if this process is coordinated with committees in charge. The Commission clarified that the PAFF committee on residues has been informed of the situation on chlorocresol, and that the matter should be addressed in September.

As the formal Commission's internal consultation procedure is still ongoing, Member States were invited to provide comments on the draft decision until 15 August.

Outcome of the vote by written procedure that took place between 2 and 17 September 2024: favourable opinion.

B.25 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 *(SCBP84-Doc.B.25)*

(PLAN/2023/592)

Legal Basis: Regulation (EU) No 528/2012 – Article 36(3)

Procedure: Examination procedure

The Commission informed that internal discussions are still ongoing, and the draft act was not presented.

B.26 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 *(SCBP84-Doc.B.26)*

(PLAN/2024/20)

Legal Basis: Regulation (EU) No 528/2012 – Article 37(2)

Procedure: Examination procedure

The Commission presented the draft decision, aiming to settle a disagreement between the Hungarian competent authority and the applicant, concerning the derogation from mutual recognition proposed by the authority, namely the intended refusal to grant an authorisation for this product. The grounds for the proposed non-authorisation are the protection of health and life and humans, considering the hazardous properties of the active substance contain in the product (hydrogen cyanide) and the difficulties in managing health risks related to the use of the product in Hungary. The health risks related to the use of the product cannot be properly addressed in Hungary, as the antidotes with which operators have to be equipped when performing the fumigations are not available in Hungary. The Commission mentioned that the decision is similar to a decision adopted in 2019 concerning a derogation from the mutual recognition of the same product proposed by the Polish competent authority.

No comments were made by Member States. The Commission concluded that the draft Implementing Decision would be submitted to the vote of the Committee by written procedure.

Outcome of the vote by written procedure that took place between 18 July and 16 August 2024: favourable opinion.

B.27 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 *(SCBP84-Doc.B.27)*

(PLAN/2024/586)

Legal Basis: Regulation (EU) No 528/2012 – Article 17(7)

Procedure: Examination procedure

The Commission introduced the draft Implementing Regulation.

Several Member States asked confirmation on the possibility of applying for a same biocidal product authorisation in case the reference product is an individual member or part of a biocidal product family. One Member State raised concerns about requiring that changes and cancellations should be applied simultaneously to both the reference products and the related same biocidal products. Another Member State enquired whether a period of grace would be applicable to same biocidal products in case of changes and cancellations. Another Member State argued that requiring same biocidal products and reference products to be identical, except for specific administrative changes, could lead to an additional administrative burden for Member States. Finally, another Member State asked clarifications on the transitional

regime that would be applicable to same biocidal products authorised under the current legal framework once the Implementing Regulation enters into force.

The Commission confirmed it plans to maintain the possibility of applying for a same biocidal product authorisation in case the reference product is an individual member or part of a biocidal product family and that this will be clarified in the draft text. In addition, it informed Member States that it will reflect internally and take into account the additional comments made and ask Member States to reflect on the transitional provisions to be applied once the new Regulation will enter into force.

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

Section C Drafts presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation approving silver zinc zeolite as an existing active substance for use in biocidal products of product-types 2, 7, 9 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.C.01)*

(PLAN/2024/1251)

Legal Basis: Regulation (EU) No 528/2012 – Article 89(1)

Procedure: Examination procedure

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

The Commission concluded that the draft Implementing 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 2 and 17 September 2024: favourable opinion.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation approving 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) as an existing active substance for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP84-Doc.C.02)*

(PLAN/2024/1105)

Legal Basis: Regulation (EU) No 528/2012 – Article 89(1)

Procedure: Examination procedure

The Commission introduced the draft Approval.

One Member State inquired why 10 years are proposed for the period of approval of the substance, despite being a candidate for substitution. The Commission clarified that the dossier is a backlog, and thus it follows the BPD principles.

The Commission concluded that the draft Implementing 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 2 and 17 September 2024: favourable opinion.

C.03 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 *(SCBP84-Doc.C.03)*

(PLAN/2023/1912)

Legal Basis: Regulation (EU) No 528/2012 – Article 36(3)

Procedure: Examination procedure

The Commission informed that internal discussions are still ongoing, and the draft act was not presented.

C.04 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 (SCBP84-Doc.C.04)

(PLAN/2023/1913)

Legal Basis: Regulation (EU) No 528/2012 – Article 36(3)

Procedure: Examination procedure

The Commission informed that internal discussions are still ongoing, and the draft act was not presented.