EUROPEAN COMMISSION

Health and Food Safety Directorate General

80th Standing Committee on Biocidal Products

28 June 2023
10:30 – 17:30

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP80-Doc.A.01)*

The Commission welcomed the participants and introduced the agenda of the meeting. The agenda was then adopted.

A.02 Adoption of the minutes of the 79th SCBP meeting *(SCBP80-Doc.A.02)*

The Commission informed that comments on the draft minutes of the previous meeting had been provided by two Member States and were included in the version distributed for this meeting. One Member State remarked that for two acts discussed at the meeting and voted upon in the written consultation, the minutes indicated that there was a positive opinion, while this Member State had abstained. The Commission clarified that it was correct to indicate that the written consultation resulted in a positive opinion of the Committee, as the indication did not mention whether the positive opinion was by unanimity or qualified majority. The Commission also invited this Member Stateto reconsider their approach, as in the Standing Committee, different from the Coordination Group, all Member State are expected to express their position, regardless of whether they are involved in the related mutual recognition procedure or not. Otherwise, no decision could ever be adopted on disagreements during mutual recognition if all Member States were following that approach. The Member State who had abstained, explained that they are a concerned Member State in the mutual recognition procedures triggering the two Commission Decisions. The actual reason for abstaining from voting was, however, that harmonisation will not be reached until renewal.

A.03 Exchange of views on the applications for approval of silver zeolite and silver zinc zeolite as existing active substances for use in biocidal products of product-type 4 (*SCBP80-Doc.A03*)

The Commission provided an overview of the substances' evaluation, focusing on the unacceptable risk identified for infants for the use of the substances in water filters. The

Commission referred to a letter sent on 3 May 2023 by one of the applicants, which had been made available to the Committee. The applicant considered that the BPC conclusions on the risk related to water filters represent an unduly disproportionate approach to risk management, and that the applicant's proposed Risk Mitigation Measures (RMMs) should not have been dismissed by the BPC.

The Commission had asked Member States via email prior to the meeting of the Committee to confirm whether they still support their past position that the RMMs proposed by the applicant are not appropriate to ensure the safety of infants, or whether, considering the arguments put forward in the letter of the applicant, they would change their position. Two Member States replied that they retained their initial position that the RMMs are not appropriate to mitigate the unacceptable risk and that they continued to support a non-approval.

During the meeting, 7 Member States reacted and they all expressed their position that the RMMs proposed by the applicant are not appropriate to mitigate the unacceptable risk for infants, and that the arguments brought forward in the applicant's letter of 3 May 2023 did not provide substantial evidence to change their position on the matter. Consequently, all Member States who expressed an opinion supported a non-approval of the two silver substances.

Based on this outcome, the Commission indicated that it will present a draft non-approval decision at the next meeting of the Committee in September 2023.

A.04 Information on ethylene oxide

The Commission informed that following the Commission's conclusion that the use of ethylene oxide (EtO) for disinfecting medical devices is within the scope of the Medical Devices Regulation (MDR), the applicant of EtO expressed interest in supporting: a) sterilisation of medicinal products; b) sterilisation of packaging, intended for either medical devices or medicinal products, but without the product itself being present during sterilisation; and c) sterilisation of 'combi-products' which contain elements defined in both medical device and medicinal products regulations (e.g. a drug-coated catheter or stent). After analysing the cases, the Commission concluded that none of these uses is within the scope of the BPR, as again, they are within the scope of the Union legislation on medicinal products or medical devices, respectively. As a result, none of the intended uses of EtO is in within the scope of the BPR and the Commission intends to proceed with proposing a decision on the non-approval of EtO under the BPR, to be presented to the Committee by the end of 2023.

A.05 Exchange of views on the application for Union authorisation for the biocidal product family 'Sodium hypochlorite liquid disinfectant biocidal product family' (*SCBP80-Doc.A.05)*

The Commission explained that several minority opinions had been expressed after the BPC meeting of March 2022 or during the adoption of its opinion by written procedure on 19 August 2022. The family contains active chlorine released from sodium hypochlorite which is recognised to be an unstable active substance that may lead to the formation of chlorates during storage. A dietary risk assessment (DRA) was therefore conducted by the eCA for PT4 products as the general public may be exposed to chlorate residues via the consumption of food in contact with disinfected surfaces. The DRA identified a risk that could only be mitigated by the introduction of a rinsing step after application of the product.

In the first minority opinion in the BPC, a member appointed by one Member State considered that the worst-case chlorate concentration mentioned in the DRA does not match with the data provided in the storage stability test. According to the eCA, the chlorate concentration in the DRA is correct. In the storage stability test, the concentration was expressed based on sodium

chlorate which needs to be converted into chlorate in the DRA to be compared with the toxicological reference values used in the risk characterisation.

Moreover, the same Member State claimed that the use of a default factor of reduction of exposure to 1% after rinsing was not supported by any solid data and that even if this reduction can be proven by experimental data, such a risk mitigation measure is usually not accepted to ensure a safe use of PT4 biocidal products by non-professionals as it is not guaranteed that the general public applies such a risk mitigation measure. The Commission explained that a rinsing step has been introduced in similar cases for which several Member States granted national authorisations. The Commission considered that it can be expected that the general public follows the use instructions on the labels of biocidal products and stressed that coherent decisions need to be taken as they are based on the same BPR guidance documents.

Three Member States expressed concerns about the efficacy of the rinsing step, one of them having specifically consulted their national enforcement authorities. In their view, the BPR guidance on estimating the dietary risks from transfer of biocidal active substance into food states that this step cannot be expected to be performed by non-professionals. One Member State repeated its request to clarify this matter again at the human health working group and the BPC (as it concerns risk mitigation measures) to avoid discrepancies between national and Union authorisations. That Member State also recalled that the original dietary risk assessment did not identify a risk for consumers because the chlorate concentration was much below the concentration used in the revised dietary risk assessment presented for the written consultation. The dietary risk assessment and the efficacy of the rinsing i.e., to reduce the presence of chlorate to 1% were never discussed at the working group nor in the BPC. Another Member State informed that according to a national survey on consumers' use of biocidal products, 50% of non-professional users do not respect the rinsing step instructions.

On the opposite, one Member State recalled that a decision was already taken by the BPC despite these minority opinions and proposed to move forward without a new request to ECHA according to Article 75(1)(g) of the BPR. ECHA informed that the issue had indeed been intensely discussed at the BPC and argued that, without any additional information, it is likely that the conclusions would be the same. The decision to propose a rising step was based only on analytical Methods and Physico-chemical Properties and Physical hazards (APCP) data i.e. chlorates are highly soluble in water without efficacy data. The Commission expressed doubt that this very technical question could be solved by this Committee.

The eCA argued that the 99% efficacy of the rinsing step was proposed in the approval of the active substance for the representative products for PT3, and therefore they applied the same approach for this product as the efficacy of this step was discussed and assessed at the approval stage. The acceptability of rinsing as a risk mitigation measure for the general public could be discussed at Committee level but its efficacy has been discussed and agreed by the BPC.

Another Member States explained its general concern about the overdosing of the active substance in the product to increase shelf life. In their view this is in contradiction with the provisions of Article 18(a) of the BPR and the current Analytical Methods and Physico-Chemical Properties Technical Agreement for Biocides. More similar minority opinions in the future are to be expected if this issue is not solved. This position was supported by another Member State.

The eCA explained that the guidance on setting shelf life had been followed and that the efficacy of the product had been demonstrated at the end of the shelf-life (even if this led to overdosing the active substance at initial production). According to the eCA, the issue is again not so much technical but rather a risk management issue i.e. is it necessary to set a shorter shelf life for products containing active chlorine. ECHA added out that this issue is well known for the unstable active substance active chlorine and recognised that this should be investigated further. It confirmed that these technical issues were discussed by the BPC members appointed by the Member States and that a majority of them decided to support the revision of the dietary risk assessment conducted by the eCA without further discussions in the WG and BPC. Finally, ECHA noticed that to reach a shelf life of two years, the concentration of the active substance must be higher in the formulation after production. One Member State reacted by indicating that the concentration was set very high in this case and that in other situations, applicants have been more reasonable, and a shorter shelf life was granted which also reduces the chlorate formation.

The Commission concluded that the Member State who raised the concern related to overdosing should prepare an issue paper to be submitted to the CA meeting to better raise awareness among Member States. On the issue of the efficacy of the rinsing step and its pertinence as risk mitigation measure for the general public, the Commission expressed doubt that this very technical question could be solved by this Committee. Therefore, on the basis of the discussion in the Committee, the Commission will prepare an Article 75(1)(g) request to ECHA.

A.06 Exchange of views on the questions regarding the second comparative assessment of anticoagulant rodenticide biocidal products (*SCBP80-Doc.A.06*)

The Commission explained the content of the note summarising the answers to the questions related to the second comparative assessment of anticoagulant rodenticides addressed to the BPC. The main conclusions from the BPC are that carbon dioxide would be a suitable alternative to anticoagulant rodenticides for permanent baiting for use by professionals and that mechanical traps would be a suitable alternative for mice control indoor for use by professionals or trained professionals.

The Commission also informed that the chemical and the food industries expressed strong concerns about the conclusion that mechanical traps could be considered as a suitable alternative in all situations of indoor mice infestations. According to these stakeholders, this is not in line with the current good practice of integrated pest management where both anticoagulants and traps are indispensable elements of an overall strategy to combat rodents.

One Member State explained its intention to reduce as far as possible the use of anticoagulant rodenticides but that this step needs to be assessed very carefully. Another Member State stated that if alternatives exist, anticoagulant rodenticides should no longer be approved. Two others mentioned that anticoagulant rodenticides are still needed as traps might not be efficacious in all situations. The Commission recalled that the uses at stake are against mice indoors and that there is no doubt that anticoagulant rodenticides are still necessary for other target organisms and other uses.

Another Member State asked what the consequences of the BPC conclusions for national authorisation would be. The Commission replied that the objective of a forthcoming decision

based on the BPC opinion is to help Member States in the preparation of their comparative assessments, but that the responsibility of granting or not the authorisation of anticoagulant rodenticide for the control of mice will remain under the control of national authorities. A decision on a possible ban of anticoagulant active substance for some uses will be only considered at EU level during the renewal of the approval which is normally expected by 2025. ECHA will open a stakeholder consultation under Article 10(3) of the BPR to collect information on potential alternatives in due time.

One Member State explained that the BPC opinion reflects the discussion at the BPC where industry representatives had been present and expressed their concerns. No new information has been provided since then and the BPC opinion should be accepted as transmitted by ECHA. The Commission explained that the opinion is apparently not clear to everyone, in particular on how the BPC derived its conclusions as the study underlying the conclusion in relation to mechanical traps was not publicly available. According to a survey conducted recently by an association of pest controllers mechanical traps are not considered as efficient as anticoagulant rodenticides, in particular in case of large mice infestation. One Member State asked when this study will be made available. The Commission indicated that stakeholders will be invited to proactively participate in the Article 10(3) consultation on alternatives during the renewal of anticoagulant substances. The study submitted recently by industry could then be examined at that time.

The Commission invited Member States to reflect whether a reasonable shift to mechanical traps can be made to control mice indoor under certain level of infestations. One Member State argued that traps are much more adaptable (e.g. by using different lures) than in the past and can address different situations but that there might be some scenarios where chemical rodenticides would still be more suitable. The situations where mice traps can be used effectively should be determined.

ECHA informed that industry had requested access to the study assessed by the BPC. A check of the confidentiality claims will be performed but it is likely that the results of the study will be made public. ECHA explained that the BPC discussed the matter in depth (conclusion on the basis of one study, different levels of quality of traps, on the market, efficacy of traps in case of high infestation) but that at the end the opinion was adopted although with several abstentions.

A newsgroup to collect the views of the Member States was opened until 31 August. The Commission will summarise the outcome at the meeting of this Committee in September and intends to propose a draft decision for the meeting in December.

A.07 Reminder on Union authorisation processes

The Commission reminded that Member States are required to perform the linguistic review of the SPCs for Union authorisations. In general, only half of the Member States regularly conduct the review, which is essential for the Commission in order not to delay the adoption and publication of the Union authorisations. When a linguistic review is not performed, the Commission needs to fix the issues identified very late in the process by seeking support from Member States representatives, which creates further delays in the process.

The Commission invited the Committee to duly take note of the lists of issues identified recently in SPCs for Union authorisation, and to implement the solutions proposed in the note to the Committee.

Section B **Draft(s) presented for an opinion**

B.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate as an active substance for use in biocidal products of product-types 2 and 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.B.01)*

(PLAN/2023/640)

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

Procedure: Examination procedure

B.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) approving reaction mass of N,N-didecyl-N-(2-hydroxyethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-hydroxyethoxy)ethyl)-N-methylammonium propionate and N,N-didecyl-N-(2-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.B.02)*

(PLAN/2023/639)

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

Procedure: Examination procedure

The Commission introduced the draft Regulations under agenda items B.01 and B.02 jointly. One Member State asked if there was also a need to amend the name of the substance in product authorisations already granted for product-type 8. The Commission replied that, in a pragmatic approach, this seemed not necessary.. Another Member State noticed a change in the wording of a standard sentence used in the Table of the draft Annex. The Commission replied that this was done for clarity reasons.

The Commission indicated that the draft Regulations 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 02 August and 31 August 2023 on the 2 acts: 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 copper hydroxide for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.B.03)*

(PLAN/2023/900)

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

Procedure: Advisory procedure

B.04 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of basic copper carbonate for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.B.04)*

(PLAN/2023/899)

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

Procedure: Advisory procedure

B.05 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of copper (II) oxide for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.B.05)*

(PLAN/2023/898)

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

Procedure: Advisory procedure

The Commission introduced the 3 draft Decisions under agenda items B.03, B.04 and B.05 jointly. No Member State had any comments.

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

Outcome of the vote by written procedure that took place between 02 August and 31 August 2023 on these 3 acts: 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 sulfuryl fluoride 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 *(SCBP80-Doc.B.06)*

(PLAN/2023/1105)

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

Procedure: Advisory procedure

The Commission introduced the draft Decision. A Member State asked why there were long delays in the renewal evaluation which resulted in the need for 3 extensions of the approval for this active substance. The evaluating Member State explained that the delays were due in particular to the requests for additional data to determine whether the substance is an endocrine disruptor and the subsequent analyses.

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

Outcome of the vote by written procedure that took place between 02 August and 31 August 2023: 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 alphachloralose for use in biocidal products of product-type 14 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.B.07)*

(PLAN/2023/1255)

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

Procedure: Advisory procedure

The Commission introduced the draft Decision and pointed to a few recent changes in recital 7, which had been suggested by the evaluating Member State. The latter clarified the reason behind these changes, aiming to reflect more appropriately the need for the extension of approval.

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

Outcome of the vote by written procedure that took place between 02 August and 31 August 2023: favourable opinion

B.08 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'EuLa Hydra Lime' *(SCBP80-Doc.B.08)*

(PLAN/2022/2053)

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

Procedure: Examination procedure

B.09 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'EuLa Oxi Lime' *(SCBP80-Doc.B.09)*

(PLAN/2022/2057)

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

Procedure: Examination procedure

The Commission introduced the draft Regulation for agenda items B.08 and B.09 jointly, due to their similarity. Both had been discussed at the 79th SCBP meeting due to a minority opinion of one Member State. The Commission explained that the proposed drafts reflect the outcome of the discussion. No requests for derogations were received for these Union authorisations. The Commission indicated that some changes were introduced in the SPCs for clarification. Those clarifications especially concerned the presentation of the risk mitigation measures (RMM) and the requirements for personal protective equipment (PPE). The Commission invited Member States to have a look at these changes and used the occasion to emphasise the importance of clear and comprehensive provisions on RMMs in the SPC as only with their implementation the identified risks are reduced to an acceptable level.

No Member State raised any comments. The Commission indicated that the draft Regulations would be submitted to the vote of the Committee by written procedure.

Outcome of the vote by written procedure that took place between 02 August and 31 August 2023 on these 2 acts: favourable opinion

B.10 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product 'DEC-SPORE 200 Plus' *(SCBP80-Doc.B.10)*

(PLAN/2023/1103)

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

Procedure: Examination procedure

The Commission presented the draft act Regulation. Some changes had been introduced in the SPC for clarification of the RMMs. No minority opinions or requests for derogations were received. A Member State had requested to add a reference to national OELs in section 5.2 of the SPC prior to the meeting. This addition was presented to the Committee which agreed that it should be included.

No Member State raised further comments. The Commission indicated that the draft Regulation would be submitted to the vote of the Committee by written procedure.

Outcome of the vote by written procedure that took place between 02 August and 31 August 2023: favourable opinion

B.11 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Lysoform IPA surface' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.B.11)*

(PLAN/2023/1088)

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

Procedure: Examination procedure

The Commission presented the draft Regulation for the Union authorisation of a same biocidal product family named 'Lysoform IPA Surface', for product-types 2 and 4. The related reference biocidal product family 'Lyso IPA Surface Disinfection' had been authorised by Commission Implementing Regulation (EU) 2021/978 of 10 June 2021 granting a Union authorisation for the biocidal product family "Lyso IPA Surface Disinfection".

One Member State noticed that same tradenames proposed are identical to those of the reference biocidal product and asked whether this is acceptable for two different authorisations. The Commission remarked that this is mostly a marketing issue and not relevant for the legal act.

One Member State mentioned that the Regulation granting the authorisation for the reference product contains reference to a non-active substance with potential endocrine disrupting

properties and asked whether this should be repeated in the legal act of the same biocidal product. The Commission recalled that since the publication of the Regulation for the authorisation of the reference product, it was decided to no longer refer to non-active substance with potential endocrine disrupting properties unless certain conditions are fulfilled, which is not the case for these same biocidal products.

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

Outcome of the vote by written procedure that took place between 02 August and 31 August 2023: favourable opinion

Section C Drafts presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the approval of propiconazole as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP80-Doc.C01*)

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

Procedure: Examination procedure

The Commission introduced the draft Regulation on the renewal of approval of propiconazole and its Annex, and suggested to focus the discussion on: a) the possible need to clarify that joinery can be treated by both industrial and professional treatment; b) the banning of biocidal products for use by the general public; c) that spray applications of biocidal products are only authorised for indoor use; and d) that treated articles treated with or incorporating propiconazole are not used to produce playground structures, garden furniture and balcony furniture.

A Member State asked why the anti-sapstain use proposed in the renewal of approval should be only temporary. The Commission replied that the proposal followed the wording of the BPC opinion on this use, and that all anti-sapstain uses are temporary (i.e. they have no permanent effect). The same Member State asked why the provision included in the Annex of the approval of lactic acid related to treated articles was not included in the draft Annex of this Regulation. The Commission replied that this provision was actually included in provision (l) related to biocidal products in the draft Annex.

A Member State mentioned that the terms ‘joinery’ and ‘structural wood’ are not clear and whether these could be defined in the draft Regulation. They also mentioned that provision n° 9 of the draft Annex could be simplified, i.e. to mention only the use classes without the type of the final wood product (joinery or structural wood). The Commission replied that the draft Annex followed the BPC wording on the uses and that it is difficult to establish definitions in the draft Regulation. The Commission would be willing to simplify the provision n°9 as suggested by that Member State, if the rest of the Member States also agree.

Another Member State asked the Commission why their proposal to ban propiconazole for use in ‘consumer products’ had not been taken into account. The Commission explained that the term ‘consumer products’ is too general and may encompass products that meet the derogation conditions of Article 5(2) (c) and are still allowed according to the provisions in the other parts of the Annex.

A Member State agreed with the proposal to ban the use of propiconazole for treating wood in playground structures. It was rather reluctant to the proposal of the previous Member State on 'consumer products'. It suggested that specifying the proposed ban of propiconazole to 'garden' and 'balcony' furniture is not needed, and thus a more general approach could be considered, i.e. to ban propiconazole for treating wood for all 'furniture'.

The Commission informed that a newsgroup will be opened until 31 August and invited the Member States to comment on the draft Regulation and its Annex.

C.02 Exchange of views of the Committee on a draft Commission Implementing Decision not approving silver copper zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP80-Doc.C02*)

(PLAN/2023/699)

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

Procedure: Examination procedure

C.03 Exchange of views of the Committee on a draft Commission Implementing Decision not approving silver sodium hydrogen zirconium phosphate as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP80-Doc.C03*)

(PLAN/2023/698)

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

Procedure: Examination procedure

The Commission introduced the draft Decisions under agenda items C.02 and C.03 jointly. No Member State raised any comments.

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

Outcome of the vote by written procedure that took place between 02 August and 31 August 2023 on the 2 acts: favourable opinion

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation approving sulfur dioxide generated from sulfur by combustion as an active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP78-Doc.C.04)*

(PLAN/2023/1104)

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

Procedure: Examination procedure

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

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

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'CHLOROCRESOL BASED PRODUCTS-CID Lines NV' *(SCBP80-Doc.C.05)*

(PLAN/2023/1265)

Legal Basis: Regulation (EU) No 528/20–2 - Article 44(5))

Procedure: Examination procedure

The Commission explained that the consultation of the Commission services concerned on this draft Regulation was still ongoing and that it is the intention to provide a draft Regulation under section B of the agenda of the next meeting of this Committee.

The Commission highlighted that for one of the uses of the biocidal product family as a concentrated animal skin disinfectant, the BPC did not provide a conclusion – no risk was identified for this use but the assessment predicted the exceedance of the default MRL of 0,01 mg/kg of Article 18 of Regulation (EC) No 396/2005 in the meat if the livestock is treated. The draft presented reflects the current status of the internal discussion and would propose not to authorise this use because of the MRL exceedance as indicated in recital 6. The applicant could be advised to apply for setting a higher MRL for chlorocresol since for now it is a default MRL which is not based on an assessment. Depending on the outcome of this procedure the applicant may be able to apply for a change of the authorisation to include this use.

One Member State commented that they would have expected that the discussion on the consequences of MRL exceedance would take place during the CA meeting and not as part of the discussion of a specific Union authorisation. They highlighted that the wording of the BPR is not clear about the consequences of a MRL exceedance if no risk has been identified. The Commission explained that the consequence is that the meat of the treated livestock where the limit is found to be exceeded could not be sold. In the legislative framework for plant protection products (PPP), products are not authorised when an exceedance of the MRL is found, and the applicants need to apply for the review of the MRL.

Another Member State indicated that they follow the PPP approach on a national level and do not authorise the products if the MRL is exceeded.

The Commission highlighted that the first draft presented in this meeting may change depending on the outcome of the consultation of the Commission services concerned. Member States were invited to continue their reflections and to discuss with their colleagues responsible for PPP and provide further input.

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 Phenogen in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.C.06)*

(PLAN/2022/2091)

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

Procedure: Examination procedure

C.07 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 *(SCBP80-Doc.C.07)*

(PLAN/2023/592)

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

Procedure: Examination procedure

The Commission informed that draft Decisions for agenda items C.06 and C.07 could not be presented for this meeting, as the consultation of the other Commission services concerned was still ongoing.

C.08 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the product Procalx in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP80-Doc.C.08)*

(PLAN/2023/628)

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

Procedure: Examination procedure

The Commission introduced the draft Decision and summarised the main considerations that led to the conclusion that the product does not meet the conditions of authorisation under the BPR. The first one is that the allocation to an appropriate product-type is an intrinsic part in the approval of active substances and the authorisation of biocidal products. Product-type 3 includes products used to disinfect materials and surfaces associated with the housing or transportation of animals. However, disinfection is a process intended to destroy or inactivate micro-organisms (as also indicated in the ECHA efficacy guidance) and a product intended against crustaceans (as salmon lice are) is not compatible with the process of disinfection. Annex V to the BPR sets out a specific product-type (product-type 18, belonging to a different main group, namely pest control products), for the control of, among others, crustaceans. According to Article 19(1)(a) of the BPR, a biocidal product can be authorised only if the active substance it contains is included in Annex I or is approved for the relevant product-type. In order to be able to be authorised as a biocidal product under product-type 18, the active substance calcium oxide would first have to be assessed and approved for use in biocidal products of product-type 18. Therefore, although it could be possible to come to the conclusion that the product meets the definition of a biocidal product in connection with product-type 18, the product does not meet the description of a biocidal product of product-type 3 and it does not meet the conditions for authorisation under that product-type.

One Member State expressed their support for the draft Decision, noting that they had a different position in the discussions in the Coordination Group. Another Member State was of the view that the wording of Article 1 might suggest that the product is actually a biocidal product. The Commission clarified that the Decision does not state that the product is a biocidal product under the scope of the BPR, but if it were it could not be a product under product-type 3.