EUROPEAN COMMISSION

Health and Food Safety Directorate General

82nd Standing Committee on Biocidal Products

6 December 2023

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP82-Doc.A.01)*

The agenda was adopted.

A.02 Adoption of the minutes of the 81st SCBP meeting *(SCBP82-Doc.A.02)*

The minutes of the 81st SCBP meeting were adopted.

A.03 Information on ethylene oxide

The Commission informed the Member States on the latest developments on the state of play of the ethylene oxide (EtO) application for approval under the BPR and reminded the conclusion of the Commission that the use of EtO for the disinfection of medical devices should fall under the Medical Devices Regulation (MDR), and thus a non-approval under the BPR would follow. The Commission highlighted that the timing of the non-approval of EtO under the BPR is under internal discussion and underlined concerns expressed by economic operators to avoid a potential market disruption of EtO within the MDR. The Commission invited Member States to liaise with their national authorities responsible for MDR on the matter.

One Member State informed the SCBP about the concerns of their national authorities working on MDR about the regulatory status of the use of EtO under the MDR, and not under the BPR, for devices treated with EtO that are still under production phase. The Commission asked that Member State to transmit their concerns in writing by the end of 2023.

The Commission services responsible for the implementation of MDR highlighted a number of concerns pointed by the MDR authorities regarding the regulatory use of EtO under the MDR.

One Member State asked the Commission to inform in writing the SCBP providing details on the issue. The Commission agreed to provide the state of play of EtO in writing after the SCBP.

A.04 Information on the application for a Union authorisation for the biocidal product family 'CHLOROCRESOL BASED PRODUCTS-CID Lines NV'

This agenda item was discussed in the context of agenda item B.03, as both products are based on the active substance chlorocresol and both procedures concern the question of the consequence of the exceedance of an MRL established during the assessment for a use of the product. For this Union authorisation, for the use as a concentrated skin disinfectant, an exceedance of the default MRL of 0.01 mg/kg for chlorocresol of Regulation (EC) No 396/2005 was identified, but no consumer health risk was identified. The Commission explained that it proposes to follow the same approach as for the Article 36 (3) decision for Phenogen, and to authorise the use. Since the use is currently not included in the SPC, it would have to be included before the Commission can submit a proposal of decision for vote to the SCBP, and this could be done by sending a mandate to ECHA to enable a discussion and agreement of the BPC on that use.

On request of one Member State, the Commission confirmed that the proposal to authorise the use despite the identified MRL exceedance deviates from the proposal the Commission made in a first draft submitted to the SCBP in an earlier meeting, as it was subject to further internal discussion. One Member State expressed its concern about the authorisation of the use in this case despite the identified MRL exceedance and made reference to the approach followed for plant protection products according to which a product can only be authorised if there are no exceedances of MRLs. If such exceedances are expected first an MRL application for a higher MRL must be made.

Member States were asked to submit their comments on the proposed way forward by 31 January 2024.

Section B Draft(s) presented for an opinion

B.01 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of indoxacarb 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 *(SCBP82-Doc.B.01)*

The Commission introduced the draft Decision. One Member State mentioned its support to the 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 23 January and 5 February 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 cholecalciferol 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 *(SCBP82-Doc.B.02)*

The Commission introduced the draft Decision. One Member State mentioned that the examination should be finished by the end of 2024. The same Member State also highlighted that the timelines mentioned in the BPR when a limited evaluation is made are difficult to be met and should be re-considered once the BPR is under the future REFIT process. Another Member State agreed with the previous Member State and 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 23 January and 5 February 2024: favourable opinion

B.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 Phenogen in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP82-Doc.B.03)*

The Commission presented the Draft Decision to resolve the objections raised by Germany for the authorisation of the biocidal products Phenogen. The objections were on the assessment of the product made by France, and concerned the compliance with Article 19(1), point (b)(iii) and point (e) of Regulation (EU) No 528/2012 (the BPR).

Taking into account the arguments raised by France, Germany, Austria, Denmark, and the ECHA opinion, the Commission considers that the product meets the condition laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, as there is no dietary risk for the consumer arising from the use of the product even if the existing default MRL established for chlorocresol under Regulation (EC) No 396/2005 was to be exceeded in edible tissues, as the consumer exposure would not exceed the acceptable daily intake of chlorocresol. Therefore, the Commission also considers that it is not necessary that the instruction to rinse surfaces in which the product has been applied before letting the animals enter the facilities, is included in the summary of product characteristics.

The Commission also considers that, as chlorocresol is classified as a substance for which no MRL is required pursuant to Regulation (EU) No 37/2010 and, even if the existing default MRL established for chlorocresol under Regulation (EC) No 396/2005 for other reasons was to be exceeded in food, there is no dietary risk for the consumer arising from the use of the product, and it seems therefore not appropriate to require, on the basis of Regulation (EU) No 528/2012, the establishment of MRLs for food and feed in accordance with Regulation (EC) No 470/2009 or in accordance with Regulation (EC) No 396/2005 with respect to chlorocresol contained in a biocidal product. Consequently, the condition set in Article 19(1), point (e), of Regulation (EU) No 528/2012 can be considered to be met.

The Commission explained that the same conclusion that will be adopted on this case will be applied for the Union authorisation of biocidal product family 'CHLOROCRESOL BASED PRODUCTS-CID Lines NV' (agenda point A.04). The Commission also clarified that the same conclusion would normally apply to all biocidal active substances that are used in animal husbandry and classified as pharmacologically active substances pursuant to Commission Regulation (EU) No 37/2010, and for which a conclusion that no MRL is required was reached pursuant to Regulation (EU) No 37/2010, and for which there would be no risk for the consumers from the use of the biocidal product containing that active substance.

The Commission clarified that the applicability of the requirement established in Article 19 (e) of the BPR is to be analysed on a case-by-case basis for each of the active substance and biocidal products and taking into account the outcome of the dietary risk assessment of the products. The Commission is working on a list of approved biocidal active substances and their situation as regards the MRLs established in accordance with Regulation (EC) No 396/2005 and with Regulation (EC) No 470/2009.

A Member States enquired what will happened to the animal commodities for which an MRL under Regulation (EC) No 396/2005 will be exceeded. The Commission confirmed that those animal commodities will not be compliant with Regulation (EC) No 396/2005 and that to solve this issue a revision of the MRL value under that regulation would need to be performed. The Commissions is working internally to align the approach for setting MRLs under all the relevant legal frameworks (pesticides and veterinary medicines).

A Member State pointed out that this approach would significantly impact their internal practice, as so far, their line has been to align the authorisation with the MRLs established under Regulation (EC) No 396/2005, disregarding that under the veterinary medicines there is no MRL required. The Commission pointed out that this approach leads to a paradoxical situation in which the same substance used in a veterinary medicinal product would be allowed with no MRL required. Also, in the case of chlorocresol, the substance is approved for hand disinfection of toddlers, and at the same time, the use in animal stables would be proposed to be restricted due to the exceedance of the MRL for pesticides.

The Commission pointed out that this type of situations needs to be addressed at the approval stage on the active substance if possible, with a holistic approach and considering all the routes of exposure for consumers. The Commission is working on a list of approved biocidal active substances for which issues with compliance with MRLs established by other sectorial legislation (pesticides MRLs and VMPs) is to be expected and will share it with Member States. As the situation is quite complex, the Commission requested Member States to liaise with their colleagues dealing with MRLs for pesticides and veterinary medicines, and to provide their views by 31 of January 2024.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision addressing questions regarding the second comparative assessment of anticoagulant rodenticide biocidal products in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP82-Doc.B.04)*

The Commission explained that the text of the draft Commission Decision was extensively modified following its interservice consultation to focus only on the replies to the questions asked by the Competent Authority meeting of March 2021. The text of the decision should indeed not give the impression that the Commission is doing the comparative assessment as this is a responsibility of national competent authorities.

Two Member States took the floor to inform that they could support the draft decision provided that some additional elements would be included into the current text.
One Member State specifically mentioned:

- the larger negative impact on animal welfare of anticoagulant rodenticides in comparison to well-designed killing traps.
- that non-chemical alternatives are an important part of integrated pest management ('IPM') approach for rodent control, even if most of them were not found eligible to be considered for the purpose of this comparative assessment. Anticoagulant rodenticides should always be used as a last resort.

The Commission answered that suggestions could be sent in writing before 31.12.2023 but also recalled that the new information should not go beyond the scope of the questions listed in the Annex. The Commission will then analyse the feedback received and will amend the text of the proposal if needed.
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 23 January and 5 February 2024: favourable opinion

Section C Drafts presented for discussion

Procedure: Examination procedure

C.01 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone and flocoumafen 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 *(SCBP82-Doc.C.01)*

The Commission introduced the draft Decision. One Member State mentioned that it would vote against this Decision because these substances meet 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 23 January and 5 February 2024: favourable opinion

C.02 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP82-Doc.C.02)*

C.03 Exchange of views of the Committee on a draft Commission Implementing Decision (EU) postponing the expiry date of the approval of magnesium phosphide 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 *(SCBP82-Doc.C.03)*

Both agenda items C.02 and C.03 were introduced together by the Commission. No Member State had any comments.

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

Outcome of the vote on items C.02 and C.03 by written procedure that took place between 23 January and 5 February 2024: favourable opinion

C.04 Exchange of views of the Committee on a draft Commission Implementing Decision not approving certain active substances for use in biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP82-Doc.C.04)*

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

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

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Taski-Room Care - Suma Family based on Lactic Acid' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. *(SCBP82-Doc.C.05)*

The Commission informed that the term 'Sure' is present in 21 trade names of products belonging to this family. The Commission checked the position of the applicant on whether this term is in line with the provisions of Article 69(2) of the BPR and the CA document on trade names[1]. The applicant confirmed that the term 'Sure' has no safety connotation in English but rather means that the products can be used without any doubt that the right level of hygiene will be met. It was also mentioned that many products containing this term have already been authorised at national level.

Two Member States expressed concerns about the presence of this term in trade names either because it could confer an advantage compared to competitors or that it could be misleading with respect to human hygiene. The Commission explained that competitive advantage is not a legal ground to force the applicant to change its trade names and repeated that the term has no safety connotation in English.

The Commission also noted that some non-active substances are still present in the composition tables of meta SPC 3 and 4 although they are not identified as substances of concern as indicated in the Section 6 of those meta SPCs. The Commission suggested to remove these non-active substances from the SPC if they are not identified as substances of concern like in two already granted authorisations. The Commission acknowledged that the technical solution to achieve this i.e. put at 'zero' the concentration of those non-active substance for each meta SPC is not elegant but explained that a solution will be provided by ECHA with the new SPC tool in IUCLID.

One Member State explained that in meta SPC 1 and 2, those non-active substances are substances of concern and are therefore listed in the relevant composition tables. The current XML version does not allow to select which non-active substances are not to be considered substance of concern. The work around solution proposed by the Commission is not satisfactory as there is no legal ground to put 'artificially' the concentration of those substances at zero as they are present in the composition of the products of meta SPCs 3 and 4.

Another Member State fully supported the position of the Commission.

The Commission concluded that it would open a newsgroup until 31 December 2023 to collect the views of the other Member States, and 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 23 January and 5 February 2024: favourable opinion

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'Kersia's Lactic acid based products' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 82-Doc.C.06)*

[1] CA-June23-Finalrev1-Misleading terms in trade names

The Commission recalled that this Union authorisation concerns a BPF for lactic acid-based teat disinfectants in PT3 containing a co-formulant which was considered as a Substance of concern and a dietary risk was identified for the pre-milking uses. At the last meeting the way forward to proceed with the authorisation excluding the pre-milking uses was agreed. The draft could not be uploaded since the internal consultation was not finalised in time to submit the draft two weeks before the meeting but was finalised at the day of the meeting.

On request of one Member State, the Commission explained that it does not see a possibility to include a condition that the co-formulant needs to be replaced or to restrict the duration of the authorisation as a restriction would have to be well justified. It reminded that it was concluded that the conditions for authorisation are fulfilled if the pre-milking uses are excluded. It also recalled that the applicant announced to work on the replacement of the co-formulant and to submit a respective change once the authorisation is granted.

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 23 January and 5 February 2024: favourable opinion

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'LANXESS CMIT/MIT biocidal product family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP 82-Doc.C.07)*

The Commission explained that the draft for this act could not be submitted under section B of the agenda as its interservice consultation was not finalised in time. It was finalised at the time of the meeting and no major changes were introduced to the draft.

Based on a minority opinion submitted by a member of the BPC, the Commission proposed to clarify for the PT 12 use of the products (i.e. slimicide in water circuits in the paper industry) that the term "white water" used in the SPC refers to the water in short circulation of the paper machine. This can be done by either replacing it by the term "short circulation" or adding it in brackets for clarification.

Several Member States supported the proposal for clarification. One suggested to have a generic discussion in the BPC WG on the topic to have a harmonised approach for all upcoming authorisations containing that use.

It was agreed that the Commission will send a proposal to the SCBP after the meeting. In case of agreement, 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 23 January and 5 February 2024: favourable opinion

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family 'STERI-PEROX' *(SCBP82-Doc.C.08)*

The Commission introduced the draft Regulation, which proposed to grant an authorisation for this biocidal product family, containing hydrogen peroxide as active substance in product-type

2. The first meta-SPC covers ready-to-use wipes and the second meta-SPC covers products to be used by liquid spraying and liquid soaking. The Commission informed that the applicant expressed the intention to include two additional pack sizes in the SPC, one under meta-SPC 1 (individually packaged wipes in a case of one hundred) and one under meta-SPC 2 (946 ml HDPE bottle). The applicant also informed the Commission that the evaluating competent authority (eCA) confirmed that the two additional pack sizes are acceptable based on the risk assessment performed. The Commission has also reached out to the eCA to get confirmation that the two additional pack sizes were acceptable. No Member State opposed to the inclusion of the two new pack sizes in the SPC.

The Commission concluded that the SPC will be amended to include the two new pack sizes and 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 23 January and 5 February 2024: favourable opinion

C.09 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product BOMBEX® PEBBYS® CS in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP82-Doc.C.09)*

The Commission informed that the draft Decision could not be presented for this meeting, as the discussions with the other Commission services proved more complex than expected and have not been concluded yet.

The draft Decision will be presented at the next meeting of the committee.

C.10 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Icon 10 CS in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP82-Doc.C.10)*

The Commission presented the Draft Decision to resolve the objections for the authorisation of the biocidal products Icon 10 CS. The objections were raised by Germany on the assessment of the product made by Greece, and concerned the compliance with Article 19(1), point (b)(iii) and point ((e)) of Regulation (EU) No 528/2012 (the BPR).

The Commission considers that as even if the MRL established under Regulation (EC) No 396/2005 for lambda-cyhalothrin were to be exceeded in poultry commodities as there would be no dietary risk for the consumer from the use of the product, it is not appropriate to require, on the basis of Regulation (EU) No 528/2012, the revision of the MRLs for poultry commodities in accordance with Regulation (EC) No 396/2005 with respect to lambda-cyhalothrin contained in a biocidal product. Consequently, the condition set in Article 19(1), point (e), of Regulation (EU) No 528/2012 can be considered to be met. The Commission explained that in the case of lambda-cyhalothrin, no MRL was set under Regulation (EU) No 37/2010 for poultry, as the use in poultry as veterinary medicine has not been authorised.

The following points were raised by one Member State:

- Concerning the consequences of enforcement: if these products are enforced, they will need to be removed from the market due to exceeding the Maximum Residue Limit (MRL).
- An interservice consultation is still ongoing.
- If the approach presented by the Commission on the case ICON 10 CS is chosen, they will request that this be the result of an agreement between the competent authorities, and that all Member States adopt the same approach for all cases and active substances.
- In the absence of a clear and harmonised approach for managing these situations, they would vote against the draft decision if it were put to a vote.

The Commission requested the views of Member States on the draft decision by 31 January 2024.

C.11 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product family Cypermethrin solids in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP82-Doc.C.11)*

C.12 Exchange of views of the Committee on a Draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product family Cypermethrin liquids in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP21-Doc.C.12)*

The Commission explained that point C11 and C12 are still under internal discussion and asked Member States for their views regarding the application of the criteria set on Article 19 (1) (e) of the BPR to these products, with deadline 31 January 2024.