EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL

Directorate E – Food and feed safety, innovation
E4 - Pesticides and Biocides

STANDING COMMITTEE ON BIOCIDAL PRODUCTS

MINUTES

69TH MEETING ON 23 SEPTEMBER 2020, FROM 9:30 TO 14:00

Remote meeting by Webex

Representatives of all Member States, except Italy, attended the meeting.

1. **Adoption of the Agenda (*SCBP69 - Doc.1*)**

The agenda was adopted without further request for changes.

2. **Adoption of the Minutes of the 68th SCBP meeting (*SCBP69 - Doc.2*)**

The minutes were adopted without any change.

Items presented for discussion and/or information

Section 1 – Active substances

3. **Commission Implementing Decision not approving chlorophene as an existing active substance for use in biocidal products of product-type 2 (*SCBP69-Doc.3.1*)**

The Commission introduced the draft Decision. No Member State commented.

The Commission announced that the opinion of the Committee on this draft Decision would be sought via written procedure.

4. **Commission Implementing Regulation approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4 (*SCBP69-Doc.4.1*)**

The Commission introduced the draft Implementing Regulation and clarified that the active substance does not meet the exclusion or substitution criteria of the BPR. It added that a non-EU country commented on the draft following notification under the Technical Barriers to Trade (TBT) agreement of the World Trade Organisation (WTO). The Commission had prepared a draft reply to be sent to the WTO addressing the points raised by this non-EU country. This procedure does not prevent the Commission to move forwards with the proposal. No Member State commented on the draft Regulation.

The Commission announced that the opinion of the Committee on this draft Regulation would be sought via written procedure.

5. **Commission Implementing Regulation approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3 (*SCBP69-Doc.5.1*)**

The Commission recalled that, as the evaluating Member State had submitted the assessment report prior to 1 September 2013, a decision shall be taken in accordance with the principles of the Biocidal Products Directive (BPD) as set out in Article 90(2) of the BPR. It indicated that, at the last meeting, one Member State had expressed its position that decisions in such cases should no longer be taken in accordance with the principles of the BPD. Following internal consultation on this view, the Commission confirmed that decisions in such cases need to be taken in accordance with the BPD principles. The Commission stressed that with the restrictive conditions introduced in the legal act, the substance would be approved for only 3 years, and Member States will have full latitude to authorise or not authorise the making available on their markets of products containing formaldehyde as Article 5(2) of the BPR applies for the authorisation of products.

One Member State informed that it continued to disagree with the Commission's interpretation of the transitional provisions of Article 90(2) of the BPR, and that it would vote against the draft Regulation.

Another Member State informed that it might abstain because of the hazard profile of the substance. It had analysed alternatives on its market and concluded that for some uses alternatives do exist but this might not be the case for other uses. According to this Member State, the BPC should have searched for alternatives and should not have limited its opinion to solely reporting information on alternatives submitted in the public consultation. The Commission reiterated that the decision needs to be taken in accordance with the principles in the BPD in this case and that the BPD did not contain exclusion criteria. The intention of the Commission is to propose a very short approval period so that an analysis of the derogations possibilities from the exclusion criteria will be conducted at EU level at the renewal of the active substance at EU level. In the meantime Member States would have to do so for their territories prior to granting an authorisation.

The Commission announced that the opinion of the Committee on this draft Regulation would be sought via written procedure.

6. **Commission Implementing Regulation approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10 (*SCBP69-Doc.6.1*)**

The Commission introduced the draft Regulation and the opinion adopted by the BPC. The environmental risk assessment showed unacceptable risks for water and sediments due to leachates during service life from treated paints (PT7) and plasters (PT10) from city house facades that are flushed with rainwater and reach sewer systems for the city scenario. However, the risks were acceptable for the country side scenario. The BPC recommended particular attention to be given during product authorisation to the adverse effects on water and sediments from treated paints/plasters but it had not recommended any restriction at the approval stage for outdoor use of treated paints and plasters.

The Commission repeated its willingness to introduce some restrictions in the approval conditions concerning the use of biocidal products in treated articles, namely to restrict the placing on the market of treated articles for outdoor uses and to impose labelling measures. It reminded that, as previously agreed by this Committee, the key criterion to introduce restrictions at the approval stage for treated article is whether a major concern exists.

Three Member States supported the idea of introducing restrictions related to treated paints and plasters. In their view, the substance presents a major concern as it fulfils the exclusion criteria. A refinement at the product authorisation stage would not prevent imported treated articles (paints, plasters) to be made available on the European market.

Another Member State proposed a coordinated evaluation of PT7 and PT10 active substances, as most of the active substances used in biocidal products in those product types are problematic for human health and/or for the environment. A ban of one substance should not result in an increase of the use of a more problematic substance. That Member State proposed to start a comparative assessment for substances used in PT 7 and PT10 biocidal products. At this stage, this Member State expressed not to have a definitive position on whether or not to support further restrictions in the draft Regulation. The Commission reminded that priority lists in the review programme were set precisely to ensure that coordinated decisions could be taken, but this had not proven possible as the Member States had not respected the deadlines set for delivering the assessment reports for the substances on the priority lists, and it urged for a quick decision on carbendazim.

Another Member State indicated that it did not share the view that Article 90(2) of the BPR required to take the decision on the basis of the principles of the BPD and that it cannot support the draft Regulation.

The Commission announced that a new version of the draft Regulation will be circulated after the meeting that would include restrictions on the uses of biocidal products and treated articles. A final discussion on the revised proposal will take place at the next meeting of this Committee.

7. **Commission Implementing Regulation (EU) approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product-type 1 (*SCBP69-Doc.7.1*)**

8. **Commission Implementing Regulation (EU) approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product types 2, 3, 4 and 5 (*SCBP69-Doc.8.1*)**

The draft Regulations were discussed jointly.

The Commission introduced the draft Regulations. It recalled that the actual purity of active chlorine will depend on the performance of the device and the quality of the precursor sodium chloride. While the quality of the precursor is described in the approval, the performance of the devices will have to be examined during the evaluation of the application for product authorisation. It added that this substance had not been supported in the review programme for use in PT1 and therefore it could not benefit from the transitional provisions of Article 89(2) of the BPR, as opposed to the use of the active substance in biocidal products of product types 2 to 5. Two separate legal acts were

therefore necessary to address the different legal situation of the active substance for the relevant product-types.

At the request of a Member State, ECHA clarified that active chlorine does not meet the criteria of the BPR for being listed in its Annex I. The Commission also clarified that two sets of acts are proposed to cover either the situation where active chlorine is produced in situ or the situation where active chlorine is placed on the market in containers (not generated in situ).

Another Member State noted that the BPC opinions include that there are indications that one of the impurities (chlorates) may have endocrine disrupting (ED) properties and proposed to have an early review of approval of the substance. It announced that it would abstain in the vote on the current proposal. ECHA replied that available data were insufficient to conclude on the ED properties of chlorates and that there are only indications that chlorates may have ED properties. It added that the assessment report had been submitted prior to 1 September 2013, and that, therefore, it was not necessary to conclude on the ED properties of the active substance. ECHA also noted that it was not clear yet which specific tests would be needed to further assess the ED properties for these substances. The Commission added that a discussion will take place in the CA meeting on the regulatory consequences for active substance if impurities or disinfection-by-products generated during use are considered as having ED properties. The Commission also recalled that for this case a decision must be based on the available information on ED properties.

One Member State indicated that it did not share the view that Article 90(2) of the BPR required to take the decision on the basis of the principles of the BPD and that it might abstain in the vote.

The Commission announced that the opinion of the Committee on these draft Regulations would be sought via written procedure once the 60-day period following notification under the WTO TBT agreement will be over.

9. **Commission Implementing Regulation (EU) approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product type 1 (*SCBP69-Doc.9.1*)**

10. **Commission Implementing Regulation (EU) approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product types 2, 3, 4 and 5 (*SCBP69-Doc.10.1*)**

The draft Regulations were discussed jointly.

The Commission introduced the draft Regulations and mentioned an error that slipped in the text of footnote 3. The texts will be corrected prior to the vote. No Member State commented on the draft Regulations.

The Commission announced that the opinion of the Committee on these draft Regulations would be sought via written procedure once the 60-day period following notification under the WTO TBT agreement will be over.

11. **Commission Implementing Decision (EU) not approving esbiothrin as an active substance for use in biocidal products of product-type 18 (*SCBP69-Doc.11.1*)**

The Commission presented the draft Decision and explained that a non-approval is proposed as the assessment had identified unacceptable risks for human health due to the toxicity of degradation products. No Member State commented on the draft Decision.

The Commission announced that the opinion of the Committee on this draft Decision would be sought via written procedure once the 60-day period following notification under WTO TBT agreement will be over.

12. **Commission Implementing Decision (EU) not approving carbon dioxide as an active substance for use in biocidal products of product-type 19 (*SCBP69-Doc.12.1*)**

The Commission presented the draft Decision and informed that a non-approval decision on "non in situ" carbon dioxide for use in PT 19 is necessary because this use was no longer supported by the participant in the review programme. The Commission added that, as carbon dioxide is already included in Annex I to the BPR, manufacturers of PT19 products available on the market have to apply for product authorisation in time in accordance with the provisions of the Regulation if they want to maintain their products on the market. No Member State commented on the draft Decision.

The Commission announced that the opinion of the Committee on this draft Decision would be sought via written procedure once the 60-day period following notification under WTO TBT agreement will be over.

13. **Information on the decision-making process for glyoxal for use in biocidal products of product-types 2, 3 and 4**

The Commission informed that a proposal for a decision on this substance is still pending. The Commission noted that this case required particular attention, as data are lacking to reach a conclusion on carcinogenicity. It recalled that the BPC had proposed approval, considering that the use of the product in the authorisation procedure will be strictly restricted, as the substance is genotoxic without threshold. The Commission informed the Committee that it was still analysing whether an approval is possible or not.

Section 2 – Article 55(3) decisions

14. **Commission Implementing Decision allowing the Netherlands to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage *(SCBP69-Doc.14.1)***

The Commission introduced the draft Decision allowing the Netherlands to authorise products consisting of in-situ generated nitrogen, which is considered essential for the protection of cultural heritage. The Commission highlighted that this draft Decision is similar to the six similar decisions already adopted and addressed to other Member States, since the applications of Member States on which they were based contained very similar elements. No Member State commented on the draft Decision.

The Commission informed that the opinion of the Committee on this proposal would be sought via written procedure.

Section 3 – Article 55(1) decisions

15. **Draft Commission Implementing Decision concerning the extension of the action taken by the French Ministry for the Ecological and Inclusive Transition permitting the making available on the market and use of the biocidal product BIOBOR JF in accordance with Regulation (EU) No 528/2012** ***(SCBP69-Doc.15.1)***

16. **Commission Implementing Decision concerning the extension of the action taken by the UK Health and Safety Executive permitting the making available on the market and use of the biocidal product BIOBOR JF in accordance with Regulation (EU) No 528/2012** ***(SCBP69-Doc.16.1)***

These two draft Decisions were discussed jointly.

The Commission introduced the draft Decisions allowing France and the United Kingdom, respectively, to extend the temporary permit granted under Article 55(1) of the BPR for BIOBOR JF, a biocidal product used for the prevention and the treatment of microbiological contamination of aircraft fuel tanks and fuel systems. The Commission reminded that the need for using this aircraft fuel preservative had been discussed at the CA meeting in May 2020. Due to the flight restrictions resulting from the Covid-19 pandemic, a large part of the aircraft fleet in Europe had to be temporarily grounded. The prolonged immobility of aircraft is an aggravating factor for the microbiological contamination that may occur in aircraft fuel tanks and fuel systems, which, if not controlled, could compromise the airworthiness of the aircraft and lead to serious air transport safety issues. Supply of the only biocidal product authorised in the Union for this purpose had been discontinued in March 2020 following engine failure incidents reported after the use of that product. BIOBOR JF is a biocidal product which is not authorised for use in the EU and the active substances it contains have not been evaluated so far. The product has been used for decades in non-EU countries. It is the only alternative product allowed for this use by aircraft and engine manufacturers. As to alternative methods for the removal of microbiological contamination, manual in-tank cleaning is not always possible and would expose operators to toxic gases and should therefore be avoided.

In light of the considerations above the two Implementing Decisions propose to allow France and the UK, respectively, to extend the temporary permit granted for BIOBOR JF.

The Commission also informed that, according to the notifications it had received, 15 Member States had granted derogations for this product in accordance with Article 55(1) of the BPR. In addition to France and the UK, one other Member State had already submitted a request for extension and one had announced that it will do so shortly. One Member State enquired whether, in light of the fact that several Member States issued temporary permits, the Commission could consider proceeding with one common decision of extension of these permits. The Commission invited all Member States which intend to seek an extension of the temporary permits for the product to signal this to the Commission in the two successive weeks and indicated it will consider the option of a common act, also based on the feedback from Member States.

The Commission informed that the opinion of the Committee on the two draft Decisions presented at the meeting would be sought via written procedure.

Section 4 – Union authorisations

17. **Commission Implementing Decision (EU) not granting a Union authorisation for the biocidal product family "Contec Hydrogen Peroxide"** ***(SCBP69-Doc.17.1)***

The Commission presented the draft Implementing Decision for a biocidal product family containing the active substance hydrogen peroxide and noted that it was the first Decision not granting a Union authorisation. The Commission indicating some purely formalistic changes compared to the earlier version. Those changes came in consequence of the change of the prospective authorisation holder and of the evaluating Competent Authority, due to the withdrawal of the United Kingdom from the European Union.

One Member State asked for confirmation of whether the efficacy outcome was agreed in the efficacy working group of the Biocidal Products Committee (BPC) or overruled by the opinion of the BPC. ECHA clarified that based on the available information it was not possible for the efficacy working group to conclude and therefore the decision process took place at the BPC meeting based on some additional information provided by the applicant.

The Commission announced that the opinion of the Committee on the draft Regulation would be sought via written procedure.

18. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2018/1258 as regards the administrative change of the information submitted to the Union authorisation for the biocidal product family "Ecolab Iodine PT3 Family"** ***(SCBP69-Doc.18.1)***

19. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2018/1261 as regards the administrative change of the information submitted to the Union authorisation for the biocidal product family "Hypred's iodine based products" (*SCBP69-Doc.19.1*)**

20. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2018/1853 as regards the administrative change of the information submitted to the Union authorisation for the biocidal product family "Teat disinfectants biocidal product family of CVAS" (*SCBP69-Doc.20.1*)**

These three draft Implementing Regulations (agenda points 18-20) were discussed jointly.

The Commission introduced the draft Regulations and noted that they were the first proposals amending existing Union authorisations as regards administrative changes sought by applicants. The Commission indicated some changes compared to the earlier version in the draft Regulation under agenda point 19, which came in consequence of comments received during the consultation of all relevant services of the Commission.

The Commission announced that the opinion of the Committee on the three draft Regulations would be sought via written procedure.

21. **Commission implementing Regulation (EU) granting a Union authorisation for the biocidal product family "DEC-AHOL® Product Family" (*SCBP69-Doc.21.1*)**

The Commission presented the draft Regulation granting a Union authorisation for a biocidal product family containing the active substance propan-2-ol. One Member pointed to an error in recital 3 of the draft Regulation regarding the date of the submission of the assessment report by the evaluating competent authority to the Agency, which needs to be corrected.

The Commission also informed that the draft Regulations under agenda items 21-24 are currently under consultation among the relevant Commission services and announced that the opinion of the Committee would be sought via written procedure following the closure of these consultations. If amendments are deemed necessary in the light of the comments received during this consultation, Member States will be informed and a revised version will be circulated, before the launch of the written procedure.

22. **Commission implementing Regulation (EU) granting a Union authorisation for the single biocidal product "Aero-Sense Aircraft Insecticide ASD" (*SCBP69-Doc.22.1*)**

The Commission presented the draft Regulation granting a Union authorisation for a biocidal product family containing the active substance 1*R*-trans phenothrin. No Member State commented on the draft Regulation.

23. **Commission implementing Regulation (EU) granting a Union authorisation for the biocidal product family "Hydrogen Peroxide Family 1" (*SCBP69-Doc.23.1*)**

The Commission presented the draft Regulation and informed that the biocidal product family contains two non-active substances for which it was not possible to conclude before the expiration of the legal deadline for product authorisation whether they have endocrine disrupting (ED) properties, and, therefore a similar recital is included in the draft Regulation as applied in a former Union authorisation in the same situation.

A Member State reported some discrepancies in the summary of the product characteristics (SPC) about the content of substances of concern in some meta-SPCs, the proposed precautionary statements and an administrative error on the type of formulation specified for meta-SPC 10. The Commission agreed to look into the comments, and, where appropriate, amend the SPC.

The Commission informed about a note received from another Member State that products containing hydrogen peroxide should be classified as oxidising liquid. This Member State clarified in the meeting that the BPC took into account the values described in the Transport of Dangerous Goods Regulation for the classification of liquids regarding oxidising properties, rather than the values described in the assessment report of the biocidal active substance hydrogen peroxide which are based on the CLP Regulation. It also indicated that both the CLP and the Transport of Dangerous Goods Regulations are applicable, but that the classification criteria are not harmonised, and asked for the views of the Commission on the appropriate way for deciding on the classification in such a situation.

ECHA clarified that the BPC decided to propose the classification by applying the Transport of Dangerous Goods Regulation, since it was considered that the experience

gained from the transportation of several products containing hydrogen peroxide may overrule the conclusion of tests provided in the context of individual applications for biocidal products. The Commission underlined that, due to the late submission of the comment, the issue needs to be further investigated and invited another Member State which had been involved in the discussions at the BPC meeting, to provide written comments and to consider making a proposal on a harmonised CLP classification for hydrogen peroxide. The Commission also indicated that the services responsible for the implementation of the CLP Regulation will be consulted as well, and, therefore, this proposal will be revisited at the next meeting of this Committee in December.

24. **Commission Implementing Decision (EU) not granting a Union authorisation for the single biocidal product "Insecticide Textile Contact" (*SCBP69-Doc.24.1*)**

The Commission presented the draft Decision not granting a Union authorisation, for a single biocidal product containing the active substance permethrin. The Commission pointed out that according to the BPC opinion the use of the product leads to unacceptable risk for professional users and the environment. No Member State commented on the draft Decision.

The Commission informed that the draft Regulation is currently under consultation among the relevant Commission services and announced that the opinion of the Committee would be sought via written procedure following the closure of the consultation. If amendments are deemed necessary in the light of the comments received during this consultation, Member States will be informed and a revised version will be circulated, before the launch of the written procedure.

Section 5 - Article 3(3) decisions

25. **Request for a Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a product in the form of an insecticidal collar containing the active substance permethrin and intended to provide protection against fleas and ticks present in the animal's environment which occasionally appear on the animal and may cause it discomfort** (***SCBP69-Doc.25.1)***

The Commission presented a reflection document in which Member States were informed about the relevant parts of the BPR and Commission decisions pursuant to Article 3(3) in relation to insecticidal collars containing an active substance and intended to provide protection against fleas and ticks present in the animal's environment**.** The Member States were asked to inform the Commission on: (1) the number of similar products available on their market, whether these were authorised as veterinary medicinal product or biocidal product, the active substance(s) these product(s) contain, the targeted harmful organisms (fleas, ticks or other) and the targeted animals (dogs, cats or other); (2) if these products are authorised or available as biocidal product, information on the product-types (PT18, PT19 or both) applicable for these products, and (3) the reasoning applied in the Member State for the classification of animal collars as veterinary medicinal product or biocidal product.

The Commission indicated that it will ask ECHA to provide an opinion, based on Article 75(1)(g), on whether the active substance used in this collar may enter the body of animals and/or may treat or prevent diseases. This information could be useful for

considering whether the collars are biocidal products as set out in Article 3(1)(a) of the BPR and whether the BPR applied in the light of the provisions in Article 2(2)(c).

26. **Request for a Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a product containing the biocidal active substance "Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))" and the company claims to be used for cleaning (*SCBP69-Doc.26.1*)**

The Commission informed that a draft decision on this product will be presented in the meeting of this Committee in December.

27. **Any Other Business**

The Commission informed that, as the evaluating CA has still not concluded its evaluation in the context of the procedure for the renewal of approval of propiconazole and that therefore it will be obliged to prepare a second extension of the approval of the active substance for PT8, as the current approval expires on 31 March 2021.

The Commission also informed about the progress of the discussion on the evaluation of the active substance creosote in the BPC, and called the attention of Member States to this file so that they are ready for discussions in the coming months, noting the tight schedule to adopt a decision by 31 October 2021 (the expiry date of the approval).