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

70TH MEETING ON 10 DECEMBER 2020, FROM 10:00 TO 13:00

Remote meeting by Webex

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

1. **Adoption of the Agenda (*SCBP70 - Doc.1*)**

The agenda was adopted without request for changes.

2. **Adoption of the Minutes of the 69th SCBP meeting (*SCBP70 - Doc.2*)**

The minutes were adopted without request for changes.

Items presented for discussion and/or information

Section 1 – Active substances

3. **Commission Implementing Regulation approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10 (SCBP70-Doc.3.1)**

The Commission presented the revised proposal, modified along the lines agreed at the previous Standing Committee meeting, i.e. to introduce restrictions related to the outdoor use of paints and plasters treated with carbendazim, and informed that the European Parliament had recently adopted a resolution calling on the Commission to not approve the substance. At the debated in the ENVI Committee of the European Parliament, the Commission had informed about its intention to introduce some restrictions in the approval conditions concerning the use of biocidal products containing carbendazim and of articles treated with it. The Commission had also recalled that it is not possible to adopt a non-approval decision on this substance, as a safe use was identified. Furthermore, the exclusion criteria of the BPR do not apply in this case and the decision must be based on the criteria of the earlier Directive 98/8/EC.

One Member State welcomed the new Commission proposal but requested the ban of all outdoor uses of all treated articles, not only paints and plasters. It also reminded that carbendazim is not approved for PT9. The Commission clarified that no safe use had been identified for PT9. As a safe use was demonstrated for PTs 7 and 10, the situation is not

comparable. The Commission further explained that a restriction is proposed for some outdoor uses based on the conclusions of the BPC but that there is no information in that opinion about other outdoor uses than paints and plasters. However, Member States would have the possibility to not allow the preservation of products for other uses at product authorisation stage and could inform the Commission if unacceptable risks are identified for other uses. The Commission could then review the approval conditions if necessary.

Three other Member States supported the views of the Member State calling for a more restrictive approach. They considered that more restrictive conditions in the approval are needed to prevent that treated articles containing carbendazim are imported to the EU. One of them noted that, in any case, it cannot support a proposal based on criteria of the earlier Directive 98/8/EC considering that it disagrees with the Commission's interpretation of Article 90(2) of the BPR.

The Commission reiterated that there is no evidence in the current evaluation that further restrictions on other articles treated with carbendazim are necessary. The Commission invited those Member States to signal any such concerns based on experience from the assessment of other uses. It recalled that the renewal cycle would anyhow start rapidly and that, if an application is submitted and conditions for derogation met, the restrictions could be revisited then. It also reminded that the more the Standing Committee postpones its decision, the more products are allowed to continue to be placed on the market under less restrictive national rules. The Commission stressed that the current proposal is based on the current evidence and BPC opinions, and ensures already a high level of protection of human health and the environment.

One Member State and the evaluating Member State informed that they did not have an official position yet and that internal discussion on the issue raised in this meeting is necessary. The Commission asked the two Member States to clarify by 18 December 2020 whether they can support the revised proposal.

The Commission highlighted that an NGO contacted the Commission after the hearing in the European Parliament to express satisfaction with the revised Commission proposal to ban the use of carbendazim in outdoor paints and plasters. The Commission will provide the message from the NGO to Member States and also the link to the EP resolution.

The Commission informed that subject to confirmation of the positions of the wo Member States, it will launch a vote by written procedure on the draft Regulation in early January 2021.

4. Commission Implementing Decision postponing the expiry date of approval of propiconazole for use in biocidal products of product type PT 8 (*SCBP70-Doc.4.1*)

The Commission presented the revised proposal. It explained that a second extension of the expiry date of approval of propiconazole had become necessary because the evaluation was not yet finalised by the evaluating Member State. The evaluating Member State commented that the assessment report is almost finalised and that the applicant will be provided time to comment before the report is sent to ECHA.

One Member State requested clarification on the time period proposed for the extension. The Commission explained that considering the timelines foreseen for the work to be conducted by ECHA, and the follow-up discussions on the possibility for derogation from exclusion, the proposed date of 31 December 2022 was a realistic extension date to allow

for completion of the evaluation and decision-making process. In addition, it reminded that if a decision on the renewal can be adopted earlier, the extension will be repealed.

Two Member States informed that they could not support the extension and one Member State informed that it needed more time for a final position. The latter explained that propiconazole belongs to a group of substances that can induce resistance of fungi to azole-based medicinal products. The Commission explained that this concern had also been raised in the context of the Plant Protection Products Regulation and that it will mandate EFSA to look into the matter, based on the evidence provided by two Member States. ECHA will be associated. The other two Member States explained that as the substance meets the exclusion criteria, they cannot support an extension. One of these Member States recalled its proposal to assess the derogation possibilities as soon as possible so that a full assessment is conducted only for substances for which these apply. The Commission asked those Member States if they had already assessed whether the possibilities for derogations are met in their territories and if for example alternatives to the substance are available. One of the Member States clarified that it considered the substance to be necessary. The Commission remarked that the position of that Member State therefore seemed inconsistent, as not granting the extension would lead to a ban of the substance despite the need for it.

A Member State proposed to get inspired by the recent pilot project on the early examination of the derogation possibilities for borates. A methodology for the identification of derogations possibilities and the assessment of alternatives should be developed. The Commission asked the Member States participating to the discussion to share their experience with the availability of alternatives to propiconazole but stressed that an extension is in any case required to complete the assessment.

The Commission informed that it will launch a vote by written procedure on the draft Implementing Decision in early January 2021.

5. Commission Implementing Decision postponing the expiry date of approval of alphachloralose for use in biocidal products of product type PT 14 (*SCBP70-Doc.5.1*)

The Commission introduced the draft Implementing Decision and clarified that the active substance does not meet the exclusion or substitution criteria of the BPR. Therefore, as for other similar substances, an extension of approval for 2,5 years was proposed. No Member State raised concerns.

The Commission informed that it will launch the vote by written procedure in early January 2021.

6. Commission Implementing Decision postponing the expiry date of approval of metofluthrin for use in biocidal products of product type PT 18 (*SCBP70-Doc.6.1*)

The Commission introduced the draft Implementing Decision and clarified that the active substance does not meet the exclusion or substitution criteria of the BPR. Therefore, as for other similar substances, an extension of 2,5 years of the approval of metofluthrin was proposed. No Member State raised concerns.

The Commission informed that it will launch the vote by written procedure in early January 2021.

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

The Commission recalled that this case required particular attention, as data are lacking to reach a conclusion on carcinogenicity. The BPC had proposed approval considering that the use of the products containing the substance will be strictly controlled, and in practice, products may probably only be authorised in closed systems, or subject to other risk mitigation measures limiting exposure. The Commission is still analysing the possible way forward on this case. As the data gap was identified during the peer review as an outcome of the BPC Working Group (WG) discussions and as the WG did not give the opportunity to the applicant to submit additional data within 10 days after the WG discussions to cover the data gap, the Commission is considering whether giving this opportunity to the applicant. The Commission is also analysing the provisions of Annex IV of the BPR which set general rules for the adaptation of the data requirements to see whether a provision of this Annex could be used in the present case. The Commission will keep the Standing Committee informed.

Section 2 – Union authorisations

8. Commission Implementing Regulation (EU) granting a Union authorisation for the single biocidal product "Pesguard® Gel" (*SCBP70-Doc. 8.1*)

The Commission presented the draft Regulation granting a Union authorisation for the single biocidal product containing the active substances clothianidin and pyriproxyfen. Following the agreement in the coordination group and competent authorities meeting, a warning statement for potential danger to bees is included in the SPC.

Two Member States, which had requested a derogation in accordance with Article 44(5) of the BPR, confirmed that the sentence is satisfactory, and that, therefore, the request is no longer necessary. Another Member State, although in principle not opposing the proposal, expressed reservation regarding the wording of the warning statement. A third Member State reiterated its disagreement with the wording, considering this statement contradictory with the BPC opinion which stated that the product is safe, as it might be interpreted that the product is dangerous to bees and not the active substance; however it did not oppose the Implementing Regulation. The Commission clarified that the word "dangerous" which is included in the statement relates to the active substance and not to the product.

The Commission also informed that it will consult the BPC about the strength of the indications that two non-active substances contained in the biocidal product may have endocrine disrupting properties as referred to in the BPC opinion. One Member State pointed out that it is not comfortable with the notion of significant indications, as it does not appear anywhere in flow charts assessing ED properties, and it does not know how those will be assessed. The Commission reminded that a recital referring to the presence of non-active substances for which there are indications that they may have endocrine disrupting properties without disclosing the names is not meaningful, as it does not help either consumers to make informed choices nor producers to consider replacing the substances. The Commission reminded that how to assess the strength of the indications will become clearer over time, based on experience and the actual evidence available.

9. Commission Implementing Regulation (EU) granting a Union authorisation for the biocidal product family "Hydrogen Peroxide Family 1" (*SCBP70-Doc.9.1*)

The Commission presented the draft Regulation, which had already been discussed in the previous meeting of this Committee and recalled that one Member State raised the need for further clarifications in the SPC concerning Substances of Concern (SoC), and another Member State asked for some explanations as regards the oxidising liquids properties of the product containing the active substance hydrogen peroxide.

In some meta-SPCs of the family there are non-active substances which, due to their low concentration level, should not appear as SoC. This is not technically feasible in the SPC-editor, and, therefore, the eCA indicated the concentrations of these non-active substances as zero, which is not in line with the confidential PAR, where the actual concentration is present. The Commission noted that this discrepancy between the Word and XML versions of the SPC is not desirable, and that ECHA must update the SPC-editor accordingly. It also announced that the relevant substances will be deleted from the Word version of the SPC as a way forward, until a solution is found.

With regard to oxidising liquids properties, DG ENV, DG GROW and DG MOVE clarified that the classification may vary according to the purpose of classification. DG MOVE indicated that for the transportation of the biocidal products, the classification based on the provisions of the Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) in accordance with Directive 2008/68/EC on the inland transport of dangerous goods is mandatory, and therefore, the relevant classification criteria should be taken into consideration. DG MOVE advised to classify the products in accordance with the ADR classification. It also underlined that the issue will be discussed in the next expert group on 15 December, indicating that this topic might be brought to the attention of the UN subcommittee of dangerous goods, which oversees the classification criteria. The Commission had analysed the Safety Data Sheets for products containing hydrogen peroxide at different percentages, revealing that the majority of the active substance producers follows the ADR classification or apply even stricter concentration levels. Therefore, the Commission proposed to concur with the BPC opinion on the oxidising liquids properties classification for hydrogen peroxide. The Member State which had raised the matter indicated that after this explanation it will not oppose to maintain the classification as proposed by the BPC. It also pointed out that coherence as regards the classification of similar products containing hydrogen peroxide is needed, and that an Article 36 referral had already been triggered regarding a national authorisation for the same matter. The Commission clarified that it will propose to take the same approach, hoping that the discrepancy between CLP and the legislation concerning the Transport of Dangerous Goods could be resolved quickly. On the request of a Member State, the Commission agreed to make available the SDSs referred to earlier via Circabc for full transparency.

The Commission further explained that the consultation of the other Commission services is still ongoing. The Commission also informed that, as the products contain 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 properties, it will consult BPC about the strength of indications that these substances may have endocrine disrupting properties.

10. Commission Implementing Regulation (EU) granting a Union authorisation for the same biocidal product family "perform-IPA" (*SCBP70-Doc.10.1*)

The Commission presented the draft Regulation granting a Union authorisation for the same biocidal product family containing the active substance propan-2-ol. The Commission explained that due to an administrative error, the applicant used the name of the reference biocidal product family in R4BP3, while in the supporting document it indicated the correct name "Lyso IPA Surface Disinfection". The issue was identified during preparation of the draft Regulation, which explains the difference of the name in the Regulation compare to the name mentioned in the agenda item. ECHA will adjust the name in its opinion in order to align it with the Implementing Regulation.

One Member State wondered whether the Commission will also consult ECHA for the non-active substances with indications of endocrine disrupting properties. The Commission clarified that since the Implementing Regulation of the related reference biocidal product family is already adopted including a specific recital as supported by this Committee at that time, it will follow the identical approach for the same product family.

The Commission also informed that the draft Regulation is currently under consultation among the relevant Commission services and announced that the opinion of the Committee will 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.

11. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2019/2076 as regards administrative changes of the information related to the Union authorisation of the biocidal product family "Contec IPA Product Family" (*SCBP70 - Doc.11.1*)**

12. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2019/1844 as regards administrative changes of the information related to the Union authorisation of the biocidal product family "BPF_Iodine_VET" (*SCBP70-Doc.12.1*)**

13. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2018/1258 as regards administrative changes of the information related to the Union authorisation of the biocidal product family "Ecolab Iodine PT3 Family" (*SCBP70-Doc.13.1*)**

14. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2020/704 as regards administrative changes of the information related to the Union authorisation of the biocidal product family "INSECTICIDES FOR HOME USE" (*SCBP70-Doc.14.1*)**

15. **Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 2018/1853 as regards administrative changes of the information related to the Union authorisation of the biocidal product family "Teat disinfectants biocidal product family of CVAS" (*SCBP70-Doc.15.1*)**

These five draft Implementing Regulations (agenda points 11-15) were discussed jointly.

The Commission introduced the draft Regulations amending existing Union authorisations as regards administrative changes sought by applicants. The Commission announced that the draft Regulations are currently under consultation among the relevant Commission services and the opinion of the Committee will be sought via written procedure following

the closure of these consultations. If amendments are deemed necessary in the light of the comments received during these consultations, Member States will be informed and a revised version will be circulated, before the launch of the written procedure.

16. Any Other Business

16.1 Alpha-bromadiolone

One Member State informed that a dossier for the approval of the substance alpha-bromadiolone for PT 14 products is under assessment. The development of this new substance is based on the reduced hepatic persistence in rodents compared to other anticoagulant rodenticides, hence reducing the potential risks of primary and secondary poisoning of non-target organisms. This could be considered as an advantage compared to bromadiolone, which could be replaced by that substance.

However, the toxicological profile of alpha-bromadiolone is still of concern, as it fulfils the exclusion and substitution criteria. In addition, no conclusions on the ED properties of alpha-bromadiolone with regard to non-target organisms is available.

The evaluating Member State added that at the current stage of the evaluation (discussion in WGs) it considers that the conditions for derogations to exclusion are expected to be met for alpha-bromadiolone. It asked the other Member States and the Commission whether they agree and consider that the substance may be approved, before requesting additional studies to clarify the endocrine disrupting properties of the substance. It was therefore interested in an early assessment by the Committee of whether the substance may benefit from the derogation criteria of Article 5(2). The evaluating Member State also enquired what process could be followed to have such an early assessment by the Committee.

The Commission wondered whether the evaluating Member State for bromadiolone has already some views concerning the comparison between bromadiolone and alpha-bromadiolone.

The Commission proposed to consider whether the approach adopted to assess the availability of alternatives to borates, which is a pilot case, could be followed. The Commission concluded that it will further discuss with ECHA a possible way forward.