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

67TH MEETING ON 7 FEBRUARY 2020, FROM 09:30 TO 11:30

Italy was represented by Spain and Bulgaria was not represented. Representatives of all the other Member States were present.

1. **Adoption of the Agenda (*SCBP67 - Doc.1*)**

The agenda of the meeting was adopted.

2. **Adoption of the Minutes of the 66th SCBP meeting (*SCBP67 - Doc.2*)**

The minutes of the 66th SCBP meeting were adopted.

Section A – Draft(s) presented for an opinion

Section A.1 – Union authorisations

3. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "HYPRED's octanoic acid based products"**

   (a) Examination of the draft Commission Implementing Regulation (*SCBP67-Doc.3.1)*

   (b) Opinion of the Committee on the draft Commission Implementing Regulation

The Commission introduced the draft Regulation, which had been discussed in the previous Standing Committee meeting, and informed about one minor editorial change in the draft compared to the version uploaded onto Circabc. This change concerned the splitting of recital 4 into two shorter recitals, numbered 4 and 5, for readability purposes. The Commission pointed out that all the changes in the Annex (summary of the product characteristics) following the comments received during the consultation of the Commission services were visible in the document uploaded for the meeting.

After a final examination of the draft Regulation, the Committee gave a favourable opinion by qualified majority.

4. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "SOPURCLEAN BPF"**

    (a) Examination of the draft Commission Implementing Regulation (*SCBP67-Doc.4.1)*

    (b) Opinion of the Committee on the draft Commission Implementing Regulation

The Commission introduced the draft Regulation, which had been discussed in the previous Standing Committee meeting, and informed that all the changes following the comments received during the consultation of the Commission services were visible in the document uploaded for the meeting.

After a final examination of the draft Regulation, the Committee gave a favourable opinion by qualified majority.

5. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "INSECTICIDES FOR HOME USE"**

    (a) Examination of the draft Commission Implementing Regulation (*SCBP67-Doc.5.1)*

    (b) Opinion of the Committee on the draft Commission Implementing Regulation

The Commission introduced the draft Regulation highlighting the amendments introduced following the discussion in the meeting of the Committee in November 2019, in particular those aimed at reducing the potential exposure of cats to the product. Member States agreed to these amendments.

One Member State proposed to include a recital on post-authorisation investigations related to a non-active substance contained in the product due to its potential endocrine disrupting properties. The Commission indicated that there is a precedent for such a recital in the Regulations authorising products containing the active substance iodine, which refers to potential action in accordance with Article 15 of the BPR. However, this would be the first time that a non-active substance is concerned. The Commission asked ECHA if during the Biocidal Products Committee (BPC) meeting deliberation had taken place on the strength of the evidence that this non-active substance could be an endocrine disruptor and what data would be necessary to come to a final conclusion. ECHA informed that at the BPC meeting there was no discussion on the robustness of the indications that the substance may have endocrine-disrupting properties and that the BPC did not analyse which data are needed for an assessment of whether the substance can be considered as having endocrine-disrupting properties .

Another Member State expressed doubts about including such a recital and pointed out that including it will set a precedent for upcoming authorisations at Union and national level, and could also require to revisit already granted authorisations. In reply to a question from the Commission, the Member State having proposed the inclusion of the recital indicated that currently in their national authorisations such a recital is not included. That Member State also informed that it had established a preliminary list of around 80 non-active substances used in biocidal products that could have endocrine disrupting properties. It intended to soon share that list with the other Member States, ECHA and the Commission.

The Commission considered this information important, pointing to the need to agree on a work programme and priorities for clarifying the concerns for such a number of non-active substances. This could result in an outcome that the specific substance contained in the product subject to the draft Regulation would not receive high priority so that the post authorisation investigation referred to in the proposed recital might not necessarily materialise. The Commission therefore asked Members States to reflect on the proposal of including such a recital on post-authorisation investigations of the non-active substance and an alternative solution to not include such a recital and instead record the need for further investigations and follow up steps in the record of the Committee meeting taking into account that there are many other non-active substances contained in biocidal products where this might be relevant.

Section A.2 – Article 55(1) decisions

6. **Commission Implementing Decision concerning the extension of the action taken by Sweden on the making available on the market and use of the biocidal product Care Plus Mosquito Net in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

    (a) Examination of the draft Commission Implementing Decision (*SCBP67-Doc.6.1)*

    (b) **Opinion of the Committee on the draft Commission Implementing Decision**

The Commission introduced the draft Decision, which concerns a biocidal product (mosquito net impregnated with permethrin) intended to protect humans against stinging and biting insects, for which an application for Union authorisation is under evaluation. A temporary permit had been granted by Sweden in September 2019 allowing the making available on the market and use of this product on grounds of protection of public health, since the transmissions of pathogens from insect vectors to humans might pose a risk to health. As a means of ensuring a limited and controlled use of the product, specific conditions were included in the Swedish permit, among which the distribution of the product exclusively in vaccination clinics.

In November 2019 Sweden requested the Commission to allow an extension of the permit, in accordance with the third paragraph of Article 55(1), on the same grounds of protection of public health. Considering the reasoning and justification in the request - the continued danger to public health posed by the possible transmission of pathogens from insect vectors to humans and the fact that the alternatives for insect vector control do not allow a sufficient control of insect vectors - the Commission would consider it appropriate to allow Sweden to extend its action of permitting the making available on the market and use of this biocidal product until 25 September 2021.

After a final examination of the draft Decision, the Committee gave a favourable opinion by qualified majority.

<u>Section B</u> – Items presented for discussion and/or information

Section B.1 – Active substances

7. **Discussion on the derogation to exclusion for DBNPA as an active substance for use in biocidal products of product-type 4 (*SCBP67-Doc.7.1)***

The Commission presented its preliminary analysis on whether the conditions for derogation to exclusion set out in Article 5(2) of the BPR could be considered met. In particular, based on the current available information, the conditions in subparagraphs "b" and "c" of Article 5(2) would not be considered met, but the condition in subparagraph "a" on the negligible risk would need further analysis, based on the information provided by the applicant during the consultation. The Commission also pointed out that the BPC opinion was not fully conclusive on the level of the risks, as the opinion states first that the risk assessment showed no unacceptable risks for DBNPA for humans and for the environment, but then also states that a risk related to the ED properties for the general public and the environment cannot be excluded.

The Commission enquired about the analysis and views of Member States on the matter, and in particular about information on active substances used in their territories for similar uses as DBNPA. Three Member States informed that there were no biocidal products containing DBNPA on their market, which indicates that there are alternatives available. They however could not give more precise information on the alternatives used for the disinfection of food processing vessels and indicated they could probably agree to the preliminary analysis presented by the Commission. One Member State indicated its stakeholders appeared not particularly disturbed by the possible ban of DBNPA, but intended to further investigate the availability of alternative products which may be used in its territory.

Another Member State noted that the burden of the proof is on the applicant, and that it should not be up to the authorities to demonstrate that there are sufficient alternatives. The Commission agreed in principle, but noted that it could be useful to have information on the alternatives used in Member States to the extent possible.

ECHA pointed out that the review of DBNPA took place in a specific context, with the new ED criteria coming into application when the assessment of the active substance was almost concluded, which led the BPC to apply the approach to update its draft opinion specifically on the ED assessment. Before this new ED assessment, the risks had indeed been considered acceptable. However, once it was concluded that the substance was an ED the existence or absence of a threshold was not further assessed.

The Commission invited Member States to provide comments as well as information on alternatives on their markets by 1 March 2020, and indicated that further analysis may be requested from ECHA at technical level concerning the level of the risks and the arguments provided by the applicant on the safety values set at WHO level and the environmental background levels of bromine.

8. **Commission Implementing Decision on the non-approval of certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP67-Doc.8.1*)**

The Commission introduced the draft Decision, indicating that was only tabled for information and discussion since the notification procedure under the WTO Technical Barriers to Trade (TBT) agreement was still ongoing. The draft non-approval Decision is a routine measure brought forward by the Commission in order to remove from the

Review Programme those active substance/product-type combinations no longer supported (i.e. combinations for which no compliant notification was submitted following the invitation to take over the role of participant and combinations for which, following a compliant notification, no application for approval was submitted within the legal deadlines). The Commission also informed that a revision of the Review Programme Regulation will be carried out later on, in order to reflect the non-approval of those active substance/product-type combinations.

One Member State enquired on the consequences of the non-approval of an active substance on treated articles already on the market. The Commission clarified that the BPR only regulates the placing on the market of treated articles, which, in case of a non-approval of the active substance, has to cease 180 days after the date of non-approval. The non-approval decision has no consequence on treated articles containing the substances concerned that are already present on the market.

The Commission communicated that comments regarding the inclusion of two active substance/product-type combinations in the Annex of the draft Decision had been received before the meeting. The Commission will analyse the situation of these two active substance/product-type combinations and the opinion of the Committee on the draft Decision will be sought at the next meeting.

Section B.2 – Article 3(3) decisions

9. **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 collars for dogs containing the active substance permethrin and intended to provide protection against fleas and ticks present in the animals' environment (*SCBP67-Doc.9.1)***

The Commission gave the floor to the Member State having submitted the request. The Member State explained that their request followed the receipt of an application for authorisation of a collar for dogs for which it is not claimed that it is intended to prevent transmission of diseases to dogs, but that it is only intended to control the organisms that may transmit diseases. The Member State hence was uncertain whether the product is to be authorised as a veterinary medicinal product (VMP) or as a biocidal product, or should be considered a treated article.

The Commission invited Member States to indicate by 1 March how animal collars containing active substances to control harmful organisms are placed on their market (as VMP/biocidal product/none of the two) and to provide their view as to whether the specific product should be considered a biocidal product or a veterinary medicinal product and their line of reasoning. Based on the input from Member States the Commission will decide on the next steps.

One Member State pointed out that Regulation (EU) 2019/6 contains a provision by which the Commission may decide whether a product is to be considered as a veterinary medicinal product and enquired whether it would be more appropriate to submit this type of borderline cases for discussion under this legislative framework. The Commission reminded that this new Regulation will enter into application on 28 January 2022, so only from that point on such cases could indeed be discussed in that legal framework.

Section B.3 – Article 37 decisions

10. **Request for a Commission Implementing Decision on a derogation from mutual recognition of the authorisation of a biocidal product containing permethrin for product-type 8 by Belgium in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP67-Doc.10.1*)**

The Commission informed that Belgium had submitted a request in accordance with Article 37 of the BPR related to a derogation from mutual recognition of a permethrin containing product and that the Commission intended to present a draft Decision at the next meeting of the Committee.

Section B.4 – Article 55(3) decisions

11. **Request for a Commission Implementing Decision allowing Austria to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage (*SCBP67-Doc.11.1)***

The Commission introduced the draft Decision and briefly explained its main sections, with a focus on the justification presented by Austria with regard to the essentiality of the active substance for the protection of cultural heritage and the absence of appropriate alternatives. The Commission recalled that extensive discussions on in-situ generated nitrogen had taken place in several meetings of the Competent Authorities for Biocidal Products in the course of 2019 and that, in connection with the Austrian request for a derogation, a public consultation had been organised, allowing all interested parties to provide their views.

The Commission presented a short summary of the input received during the public consultation. A considerable number of contributions had been submitted (approximately 1500), mostly from a great variety of cultural institutions (museums, libraries, archives, etc.), from art conservators and restorers and from academia. Of these contributions only three submitted by providers of alternative techniques for the treatment of cultural heritage were not in favour of granting a derogation.

The Commission informed that the non-confidential contributions received will be published soon on the ECHA website. The Commission noted that more than 75% of the contributions originated in one Member State and asked whether that Member State intended to submit a request for derogation (so far not done), since so many cultural institutions in its territory expressed strong support for allowing the in-situ nitrogen technique for the conservation of their artefacts. That Member State confirmed that they intend to submit a request for derogation, albeit reluctantly since in their view and as already expressed on other occasions, there would have been the grounds to consider that nitrogen is not in the scope of the BPR. The Commission reminded that nitrogen has been considered to be in the scope of the biocides legislation already since 1998 with the adoption of the Biocidal Products Directive.

The Commission communicated that, as next steps, the draft Decision will be circulated for consultation of the Commission services and will be tabled for vote at the next meeting of the Committee.

The Commission reminded that, if granted, the Article 55(3) derogation is only a first step towards the compliant use of products consisting of in-situ nitrogen, since the

authorisation of those products - based on an application for authorisation - in the Member State benefitting from the derogation should then follow.

The Commission mentioned that draft decisions were under preparation for two other applications for derogation, received from Spain and France.

One Member State asked whether the Commission had news on the status of the preparations of the application by ICOM/ICOMOS for inclusion of in-situ generated nitrogen into Annex I of the BPR. The Commission indicated that the two organisations were in contact with the Commission to enquire on various procedural aspects, but that it had no indication as to the possible timing of the preparation and submission of the application by these organisations.

In response to a question from a Member State, the Commission clarified that it was still possible for Member States to submit applications for derogation and invited those Member States which intend to submit an application to do so by May 2020.

12. **Request for a Commission Implementing Decision allowing the authorisation of biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage in Spain (*SCBP67-Doc.12.1)***

The Commission informed that the draft Decision was under preparation and that it will be presented for vote at the next meeting of the Committee.

13. **Any Other Business**

None.