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

68TH MEETING ON 15 MAY 2020, FROM 10:00 TO 13:30

Representatives of all Member States were present.

1. **Adoption of the Agenda (*SCBP68 - Doc.1*)**

The agenda of the meeting was adopted with the inclusion of three AOB points for discussion: improvement of the renewal procedure for active substances already meeting the exclusion criteria; proposal for a draft decision on the extension of an action taken by the United Kingdom in accordance with Article 55(1); and the time required to assess an application for inclusion of nitrogen generated *in-situ* into Annex I to the BPR.

2. **Adoption of the Minutes of the 67th SCBP meeting (*SCBP68 - Doc.2*)**

The minutes of the 67th SCBP meeting were adopted.

Items presented for discussion and/or information

Section 1 – Active substances

3. **Commission Implementing Decision postponing the expiry date of approval of acrolein for use in biocidal products of product-type 12 *(SCBP68-Doc.3.1)***

The Commission presented the draft Decision. The evaluating Member State (Czech Republic) explained that it was conducting a full evaluation and had to assess the substance in accordance with the ED criteria.

One Member State requested clarifications regarding the need to have an alignment between Member States on product authorisations that have to be extended, and expressed its wish to have a discussion on this item in the Coordination Group, as had been done for creosote. The Commission confirmed that a coordinated approach in relation to the extension of product authorisations had taken place for wood preservatives in the past and agreed that the correct forum to start such a discussion would be the Coordination Group.

The Commission informed that the opinion of the Committee on the draft Decision will be sought via written procedure in June.

4. **Commission Implementing Decision postponing the expiry date of approval of creosote for use in biocidal products of product-type 8** ***(SCBP68-Doc.4.1)***

The Commission presented the draft decision, explaining that the renewal process is on-going since 2016. Following BREXIT, the role of evaluating Member State has been taken over by Poland. A first extension of approval until October 2020 was granted in 2017 because the UK considered it necessary to perform a full evaluation. The draft renewal report had been submitted to ECHA in September 2019. A second extension of the expiry date of approval of the substance is needed, as the review of the substance will not be completed before October 2020, in particular, the BPC opinion will not be available before October 2020. Moreover, discussions have to take place in this Committee on whether the conditions for derogation to exclusion are met, and the relation with the current restriction in REACH - and its forthcoming amendment - for wood treated with creosote needs to be clarified. The Commission proposed an extension of one year following the discussions that took place in this Committee on extensions of substances meeting the exclusion criteria.

One Member State considered that the extension should be limited to uses that are essential (railway sleepers in its view), and would like the Commission to initiate an early review and take a decision under Article 15 in parallel, based on the information currently available to the Biocidal Products Committee. In their view, the review of the restriction under REACH is not a pre-condition for taking a decision on the renewal of approval as active substance. This Member State indicated that it expected the restriction dossier under REACH to be submitted mid-2021. The Commission explained that initiating an early review in parallel to the renewal would be a duplication of the already on-going examination .

ECHA informed that although data had been missing to assess the ED properties of the substance by the original eCA, it was nevertheless decided to make progress and go to the BPC meeting. Following the submission of the draft renewal report by the evaluating competent authority ECHA performed its public consultation under Article 10(3) of the BPR on the availability of alternatives last year and a high number of comments had been received. The preliminary view on the analysis of the derogation to exclusion in the renewal report of the UK was that conditions may be met for railway sleepers, transmission (electricity/telephone) poles, and poles used in orchards. The results of the public consultation need now to be analysed by Poland as the new evaluating competent authority (eCA). Poland informed that it received the dossier from the UK at the end of January. The evaluation of the original eCA had been discussed in working groups of the BPC and, based on this, additional data had been requested from the applicant. This information should be available in June 2020.

One Member State informed that it cannot agree with recital 6 as proposed in the draft decision. The Commission asked for a text proposal for this recital by 20 May from that Member State together with the indication of whether it can support the proposal.

One Member State supported the proposal in order to allow a thorough examination of the possibilities for substitution of the active substance and to allow Member States sufficient time to reflect on how the use of treated wood can be most effectively limited. A few Member States regretted this extension although recognising the need for it, and appreciated the efforts made by Poland who had to take over the role of eCA for this substance. The Commission reminded that Member States are allowed to provide a statement together with their vote also during a vote in written procedure. Another Member State informed that it had a national strategy for the substitution of creosote. A

further Member State indicated that it did not support the extension, as it considered that the substance does not meet the conditions for derogation in Article 5(2)(c).

Another Member State emphasised the need for innovation and indicated that it was not convinced that the extension was necessary for concluding on the renewal.

A further Member State informed to have had discussions with their economic operators on the need of the substance for electricity poles and to have requested a socio-economic analysis from its national operators.

Finally, another Member State stressed that a strong message should be sent to industry on the need to substitute the substance, as it had been regulated and subject to restrictions since a long time.

The Commission indicated that it will wait for the proposal of the Member State for recital 6 and inform the Committee whether it can accommodate it, and if so, circulate a revised version by email. The Commission announced that the opinion of the Committee on the draft Decision would be sought via written procedure in June.

5. **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 *(SCBP68-Doc.5.1)***

The Commission introduced the draft Decision, which had been presented for discussion at the previous meeting of the Committee. The Commission had taken into account the comments received from one Member State and from ECHA, leading to the removal of two active substance/product-type combinations from the Annex to the draft Decision and the inclusion of two other combinations in the same Annex.

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

6. **Commission Implementing Regulation approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3 (*SCBP68-Doc.12.1*)**

The Commission presented the draft Regulation. It explained the particular context for this substance, for which the evaluation reports had been submitted before 1 September 2013. Similarly to previous substances in the same situation, the Commission proposed that the substance be approved subject to the condition that Member States shall not authorise products unless one of the conditions for derogation to exclusion set out in Article 5(2) of the BPR is met in their territories. The Commission noted that, compared to previous cases, it proposed a shorter approval period, i.e. 3 years instead of 5 years, considering that this active substance had benefitted from the transitional provisions set in the biocides legislation for a significant amount of time and had been under peer review at ECHA level since August 2013. Furthermore, this would ensure a swift examination of whether the conditions for derogation to exclusion would be met at the renewal stage, if a renewal is applied for.

One Member State contested the legal interpretation of Article 90 of the BPR, and considered that the BPR provisions on exclusion should fully apply also for active substances for which the assessment report had been submitted before 1 September 2013. This Member State pointed out that, if this decision would go forward, this substance can be considered to fulfil the criterion of major concern and therefore a debate on the use of

treated articles should take place. In any case, this Member State informed that it did not support the draft Regulation.

Another Member State asked whether the Commission could analyse whether the substance meets the derogation criteria before the approval of the substance and considered that the possible use of the substance should already be restricted at the approval and the draft Regulation should list the possible uses that Member State can authorise and treated articles that can be placed on the market. The same Member State indicated that it was surprised by the part of the BPC opinion regarding the analysis of alternatives, as it appears to be solely based on the information received during to the public consultation, which leads to a partial analysis. The Member States emphasised that it would have expected a proactive analysis by the BPC of the existing alternatives. It also proposed to include the risk of skin sensitisation in the provisions on labelling requirements for treated articles. It also enquired on the coordination of the renewal of procedure of the active substance and the work of Member States for product authorisations. Finally this Member State pointed out that even in the case where it would not authorise biocidal products containing this active substance on its market, treated articles could be made available. Therefore the Member State considered it important that the active substance approval contains conditions for treated articles.

The Commission reminded the Committee that the approval had to be decided in accordance with the provisions of the earlier Biocidal Products Directive and referred to the discussions on the implementation of the transitional provisions set out in Article 90 of the BPR that took place in 2013. This implies that the derogation conditions cannot be assessed at this stage. Formaldehyde is not the first case in such a situation. In preparing the approval decision, the Commission had taken a restrictive approach to the maximum extent possible, and reminded Member States that they have full latitude to not authorise products containing this active substance on their markets, based on their analysis of whether the conditions for derogation to exclusion are met in their territories. As regards the provision on treated articles, a standard text had been agreed with Member States in 2015, that has been included systematically in all approval Regulations of substances meeting the exclusion criteria and still falling under the provisions of the Biocidal Products Directive. The Commission informed that it will verify whether restrictions under REACH apply for this substance or any restriction procedure is ongoing as such a restriction applies also for treated articles. Finally, on the coordination between the product authorisation process and the renewal process, the Commission noted that Member States may refer to the EU level questions linked to the comparative assessment that they must make in the context of product authorisations, pursuant to Article 23(5) of the BPR, if such applications would eventually be submitted. The Commission indicated that it is extremely unlikely that there would be treated articles with formaldehyde for uses in PT 2 and 3.

As regards the wording of the BPC opinion, ECHA highlighted that the analysis of the alternatives depends on the information provided by Member States during the public consultation, which has been limited so far. Up to now contributions to public consultations are mostly coming from industry stakeholders. Member States were therefore reminded to contribute to improve the analysis of alternatives in BPC opinions. The Commission agreed that Member States should indeed contribute to the public consultations and recalled its view that ECHA should also look proactively for available information, for example from REACH registration dossiers.

One Member State informed that it was analysing the situation on its market. If this analysis showed that this substance is needed, it might support the draft Regulation.

Another Member State requested to have a second discussion before the vote. The Commission reminded Member States that any postponement of the vote would mean that products containing formaldehyde will remain further on their markets without being subject to the BPR authorisation system and its restrictive conditions.

The Commission requested Member States to send comments by 30 June 2020, in particular those Member States who had legal arguments on the interpretation of the transitional provisions set out in Article 90 of the BPR. Depending on the received written feedback the Commission will decide whether a second discussion on this substance will be organised at the meeting of the Committee in September or whether a vote in written procedure will be initiated.

7. **Commission Implementing Regulation approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10 (*SCBP68-Doc.13.1*)**

The Commission presented the draft Regulation for carbendazim, for which the situation is similar to formaldehyde (i.e. meeting the exclusion criteria but evaluation report submitted before 1 September 2013).

Two Member States expressed the same position as for formaldehyde, and considered the exclusion provisions should fully apply already for this approval process.

Furthermore, one Member State underlined the difference with formaldehyde, as it is likely that there will be treated articles (i.e. paints) containing this active substance on the market. It asked why the Commission did not apply the CA document on approvals and treated articles. Both these Member States considered that treated paints should be banned for outdoor use.

ECHA explained that the BPC had followed the same approach as for similar substances in a similar situation where an unacceptable risk had been identified for the environment during the service life of treated articles for outdoor use, like folpet. The Commission explained the approach agreed in 2013-2014 on treated articles at the approval stage as included in document "*CA-Nov14-Doc.6.2 - Final - Conditions on TA in approvals*"[1], which is similar as for the setting of conditions for biocidal products authorisations in approvals: at the approval stage usually no restriction is included if no major concern is identified and it is expected that refinement of the evaluation – or the setting of risk mitigation measures - will lead to a safe use when assessing applications for product authorisation. Only when a safe use cannot be achieved by risk mitigation measures or refinement of the evaluation, the use will be banned at the approval stage. In the same CA document it was also agreed that approval conditions for a substance can be reviewed at the renewal stage, or via early review of the active substance in accordance with Article 15 of the BPR, based on experience and/or significant indications of risks found during product authorisations. This approach had been followed consistently for provisions on treated articles in all approvals.

One of the Member States further highlighted that the substance is classified as mutagenic and toxic for reproduction, and the treated articles may be used by professionals and non-professionals, and wondered again why the conditions as included in the CA-document are not applied. Another Member State indicated that it will analyse

[1] CA-Nov14-Doc.6.2 - Final - Conditions on TA in approvals.doc

the alternatives for outdoor use and this will define its position. A Member State indicated that there are indications that carbendazim is an endocrine-disruptor, as it has a metabolite identified as ED under the plant protection products legislation.

The Commission agreed to further check the risks identified for the service-life of treated paints for outdoor use and the consistency of the proposed approval conditions with previous active substances. The Commission asked Member States to send comments and possible proposals for amendments of the draft Regulation, in particular on restrictions on treated articles, by 30 June 2020. A second discussion on this substance will be organised in the meeting of the Committee in September before a vote will take place.

8. **Commission Implementing Regulation approving icaridin as an existing active substance for use in biocidal products of product-type 19 (*SCBP68-Doc.14.1*)**

The Commission presented the draft Regulation. Just before the meeting, the applicant had sent a letter requesting a postponement of the approval date for a year, from 1 February 2022 to 1 February 2023, justifying it by the fact of not having had pre-submission meetings with Member States due to the Covid-19 pandemic. The letter had been communicated to Member States. The Commission indicated that it would not favour such an extension to avoid creating a precedent that may also have an impact on the financing of ECHA and Member States activities, and considering that no convincing justifications had been provided by the applicant. Member States supported this view and the approval date was not changed. The Commission called upon Member States to answer positively to requests to have pre-submission meetings with prospective applicants for product authorisation, using all communication means available (phone conference, video-conference, etc.)

One Member State indicated that it would abstain, as the proposal is based on the criteria established by the earlier Biocidal Products Directive.

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

Section 2 – Union authorisations

9. **Commission Implementing Regulation granting a Union authorisation for the single biocidal product "ClearKlens product based on IPA" *(SCBP68-Doc.6.1)***

The Commission presented the draft Regulation granting a Union authorisation for a biocidal product family containing the active substance propan-2-ol, indicating some changes compared to the earlier version. Those changes came in consequence of comments and editorial suggestions received during the consultation period.

The Commission informed that it will make available the slightly amended version directly after the meeting and announced that the opinion of the Committee on the draft Regulation would be sought via written procedure in June.

10. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Iodine based products - CID LINES NV" *(SCBP68-Doc.7.1)***

The Commission presented the draft Regulation granting a Union authorisation for a biocidal product family containing the active substance iodine, indicating that the draft Regulation contains a recital stating that this family contains non-active substances that may have endocrine-disrupting properties and therefore further examination of these substances should take place. This recital had been discussed and agreed in this Committee for another Union authorisation. The Commission also indicated some changes compared to the earlier version which came in consequence of comments and editorial suggestions received during the consultation period.

One Member State indicated that it would abstain when voting in the written procedure due to the endocrine disrupting properties of the active substance iodine. The Commission pointed out that it initiated an early review procedure for iodine because of the indications that this active substance may have endocrine-disrupting properties.

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

11. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "PeridoxRTU Product Family" (*SCBP68-Doc.14.1*)**

The Commission presented the draft Regulation granting a Union authorisation for a biocidal product family containing the active substance peracetic acid, indicating some changes compared to the earlier version. Those changes came in consequence of comments from a Member State.

The Commission informed that the internal consultation of the Commission services was still ongoing and announced that the opinion of the Committee on the draft Regulation would be sought via written procedure in July.

12. **Commission Implementing Regulation granting a Union authorisation for the biocidal product family "perform-IPA" (*SCBP68-Doc.15.1*)**

The Commission presented the draft Regulation granting a Union authorisation for a biocidal product family containing the active substance propan-2-ol, indicating that the draft Regulation contains a recital stating that this family contains a non-active substance that may have endocrine-disrupting properties and therefore further examination of this substance should take place. The Commission also indicated some changes compared to the earlier version which came in consequence of comments during the consultation. Two Member States expressed support for the inclusion of a recital in the proposal stating that a non-active substance contained in the product may have endocrine-disrupting properties. Another Member State indicated it would abstain from voting in the written procedure, as it does not support the inclusion of the recital on the non-active substance having indications of ED properties considering that the BPC could not conclude whether this non-active substance meets the criteria for being identified as having ED properties and it objects to the disclosure of the name of the non-active substance under these circumstances. ECHA clarified that the name of the non-active substance is not included in the BPC opinion and indicated, following the decisions in the Standing Committee, that it has to be reconsidered whether in such situations the name should be identified in the opinion and in the non-confidential part of the product assessment report.

The Commission informed that the internal consultation of the Commission services was still ongoing and announced that the opinion of the Committee on the draft Regulation would be sought via written procedure in July.

Section 3 – Article 55(3) decisions

13. **Commission Implementing Decision allowing Austria to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage *(SCBP68-Doc.8.1)***

14. **Commission Implementing Decision allowing Spain to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage *(SCBP68-Doc.9.1)***

15. **Commission Implementing Decision allowing France to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage *(SCBP68-Doc.10.1)***

16. **Commission Implementing Decision allowing Portugal to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage *(SCBP68-Doc.11.1)***

These 4 agenda points (13-16) were discussed jointly. The Commission introduced the draft Decisions allowing the Member States concerned to authorise products consisting of in-situ generated nitrogen, which is considered essential for the protection of cultural heritage.

Two of the proposals had already been presented for discussion or information in previous meetings of the Committee. The Commission highlighted that the draft Decisions are similar, since the applications of Member States on which they were based contained very similar elements.

The Commission informed that the International Council of Museums (ICOM) is in contact with a consultant in order to prepare a dossier for application for inclusion of the active substance into Annex I.

One Member State asked when a decision of the Commission could be expected for its Article 55(3) application submitted at the end of April. The Commission considered that the applications of this Member State and another Member State are very similar to the four proposals discussed today and therefore the opinion of the Committee could be sought via written procedure before the meeting of the Committee in September. Before initiating the written procedure the draft Decisions will be circulated for information and possible comments of the Committee.

The Commission announced that the opinion of the Committee on the 4 draft Decisions presented would be sought via written procedure in June.

17. **Any Other Business**

(a) Improvement of the renewal procedure for actives substances already known to meet the exclusion criteria

The Commission reminded the Committee about previous discussions in the CA-meetings and Standing Committee meetings on this topic with the objective to limit the

period of extensions of approvals to complete renewal evaluations and to prevent the need to grant repeated extensions. After the last CA and Committee meeting, two Member States had submitted comments. The Commission would like to make progress and would like to know if Member States would support the proposals presented on slide 4 of "*CA-Feb20-Doc.5.3 - Renewal process AS Exclusion.pptx*"[2]. In particular, the proposals aim at giving indications to the evaluating CA whether the conditions for derogations to exclusion are clearly not met, or whether the conditions for derogation may be met. In case there are indications that alternatives exist for the substance or the conditions for derogation are not met, the evaluating CA could decide to speed up the process.

Two Member States supported the proposals. One Member State indicated that ED properties should be assessed in case the conditions for derogation would be met, and wondered whether data on ED properties could be requested as a post-approval condition when these data are missing.

ECHA agreed to launch the public consultation after the acceptance of the application for renewal of approval of the active substance, but saw several difficulties and possible limits on the proposal to request a BPC opinion on the availability and suitability of alternatives, in particular the limited input provided so far in public consultations and by Member States' experts on alternatives, and a lack of expertise of the BPC on the suitability of possible alternatives.

The Commission noted the reservations of ECHA but considered that there is a need to progress on this item. The Commission insisted that all Member States need to prepare themselves so that early discussions in the Standing Committee on the derogation possibilities are meaningful. Member States should look at the information submitted and the justifications provided for derogation from exclusion, and make their analysis of the appropriateness of a derogation for their territory.

The proposals presented on slide 4 were agreed, and will be implemented for the new application for renewal submitted in March (boric acid and disodium tetraborate for PT 8).

(b) Draft Commission Implementation Decision concerning the extension of the action taken by the United Kingdom Health and Safety Executive permitting the making available on the market and use outdoors of the biocidal product Ficam D in accordance with Regulation (EU) No 528/2012

The Commission informed that the draft Decision concerns the extension of a temporary permit granted by the United Kingdom under Article 55(1) of the BPR allowing the use outdoors of Ficam D - a biocidal product containing bendiocarb - against Asian hornets, an invasive alien species of Union concern. Prior to the entry into application of the BPR the product had been authorised in the UK for outdoor and indoor use and was a central component in the UK response to controlling Asian hornets. The authorisation under the BPR restricted the use to indoor use, due to concerns for the environment from the use outdoors. The UK authorities were in the process of seeking alternatives to this product but they were still testing and analysing these alternatives. The draft Decision proposed to extend the temporary UK permit, thus allowing a limited and controlled use outdoors by suitably trained officials.

[2] CA-Feb20-Doc.5.3 - Renewal process AS Exclusion.pptx

The Commission indicated that, after the completion of the consultation process with the other Commission services, the draft act will be circulated for information and possible comments of the Committee and thereafter the opinion of the Committee will be sought by written procedure.

(c) Time required to assess an application for inclusion of nitrogen generated *in situ* into Annex I

Two Member States asked for clarification on the expected time required for the inclusion of nitrogen generated *in situ* in Annex I. The Commission underlined that the key step in the process is that an application of high quality for Annex I inclusion is submitted and that up to now the International Council of Museums (ICOM) did not provide a precise date for the application and the name of the evaluating competent authority. Following submission of an application, it would take probably two years to complete the process: one year for the evaluation and one year for the regulatory procedure.