EUROPEAN COMMISSION

Health and Food Safety Directorate General

Standing Committee on Biocidal Products

3 June 2021
10:00 – 16:00
(organised remotely via Webex)

CIRCABC Link: *https://circabc.europa.eu/w/browse/f0b5db58-d19b-4a5f-b84e-4a0facfafba1*

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP72-Doc.A.01)*

The Commission informed that no document for point B.10 had been uploaded as further discussions between the reference Member State and the initiating concerned Member States are on-going. The point should be tabled for the next meeting of this Committee.

Under AOB, the Commission announced information related to the restricted approval for carbendazim and one Member State requested a clarification on the state of play for the Biobor JF product and in-situ generated nitrogen applications.

A.02 Adoption of the Minutes of the 71st SCBP meeting *(SCBP72-Doc.A.02)*

The minutes of the 71st SCBP meeting were adopted without additional changes.

A.03 Exchange of views on the examination of the approval of diamine for use in biocidal products of product-type 8 *(SCBP72-Doc.A.03)*

The Commission explained that this second discussion in the Committee aimed to obtain the views of all Member States before preparing an implementing act and moving to a decision. After the first discussion in the last meeting of this Committee, a newsgroup had been opened and eight Member States plus one EEA country considered that setting a maximum of two cycles of treatment per operator per day for diamine (the "risk mitigation measure") to achieve safe use would not be adequate and enforceable. Five Member States expressed the view that the measure would be acceptable.

The Commission explained that its Directorate-General for employment (DG EMPL) responsible for the legislation on the protection of workers indicated that such an organisational measure is in line with the principles of the workers' protection legal framework. The Commission pointed out that the Committee should indeed consider whether the measure is realistic and enforceable, taking into account other risk mitigation measures that had been

agreed and found acceptable by Member States for other substances to ensure that no unacceptable effects occur, for example the use of personal protection equipment. Based on recent information from a Member State, the Commission added that a further specific measure might have to be set for treated wood used in playgrounds for children in case this active substance were to be approved.

Lastly, the Commission recalled that the Regulation governing the Standing Committee requires that the Commission should look for a proposal for a decision that will obtain the widest possible support.

During the meeting 14 Member States indicated that they can support an approval with the setting of the proposed risk mitigation measure. One Member State indicated that additional actions, such as informing the responsible surveillance authorities, could be implemented if an approval is finally adopted. The Commission highlighted that product authorisation will be required before any product containing this active substance can be used and that Member States could facilitate enforcement by requesting companies to inform surveillance authorities if they would use this active substance.

Nine Member States and one EEA country did not support approval with setting the risk mitigation measure because they considered it not enforceable. Two Member States indicated that they would send comments in writing and one Member State informed that it will abstain if an approval is proposed. One Member State clarified that it might not be able to vote in favor of a proposal approving the substance, as it disagreed with applying the principles of the earlier Biocidal Products Directive for so-called 'backlog' dossiers for which the evaluation report was submitted before the Biocidal Products Regulation (BPR) became applicable (1 September 2013).

Based on the positions expressed by the Member States during the meeting, the Commission informed that no qualified majority would be reached either for a non-approval or an approval with restrictive conditions. A newsgroup will be opened to give again the opportunity for Member States to clarify their positions.

The Commission will inform the Committee of its intentions on how to proceed with decision-making at the next meeting of this Committee.

A.04 Exchange of views on the examination of the renewal of approval of creosote for use in biocidal products of product-type 8 *(SCBP72-Doc.A.04)*

The Commission recalled the first discussion at the meeting of this Committee on whether disproportionate negative impacts on society of not approving creosote compared with the risk to human health or the environment of continued use for some applications could be a basis for derogation to exclusion for the renewal of its approval. The objective in this meeting was to continue this discussion and to investigate possible risk-mitigation measures to address the placing on the market of treated wood in case the approval would eventually be renewed for some specific uses.

The Commission explained that in the assessment report prepared by the evaluating Member State it is stated that the conditions for derogation in Article 5 of the BPR could be met for railway sleepers, transmission poles, and agricultural poles and fencing. The Biocidal Products Committee (BPC) of ECHA had concluded that there are suitable chemical or non-chemical alternatives on the market for these various uses, however, without specifying which Member States would have more difficulties to substitute these uses and the time needed for substitution.

The Commission also referred to the outcome of the stakeholder consultation performed earlier this year to collect information on whether or not the conditions for derogation would be met, and for which uses. The results of the consultation were summarised in a document tabled for this meeting of the Committee. Overall, the outcome of the public consultation showed that a majority of treatment plants and end-users who provided contributions are still supporting some uses of creosote for practical and economic reasons while a minority of stakeholders opposed the renewal of approval of creosote at least for some uses when alternatives are available. For several contributors it was not clear whether their comments concerned the whole Union or only the territories of the Member States where they were located. The Commission also pointed out that recently the product Tanasote S40 had been authorised in several Member States and according to the available information it may be a viable alternative for creosote in all applications. The availability of this alternative product on the market was not yet known during the public consultation.

From the replies collected during the Member States consultation of March 2021, it emerged that eight Member States considered the derogation met for railway sleepers. During the discussion, in this meeting of the Committee, ten additional Member States supported the derogation for railway sleepers, whereas six others opposed arguing that alternatives exist on the market for railway sleepers. One Member State informed that it would provide its position by 30 June 2021.

Five Member States had informed that the use of creosote for transmission poles would be needed. During the discussion in this meeting of the Committee, 12 Member States informed that this use was not necessary for their territories, whereas four additional Member States considered it necessary to continue to use creosote-treated transmission poles. Six Member States and one EEA country had no position and were invited to provide their views by 30 June 2021.

As to foundation timber, only one Member State indicated that this use would be needed for bridges and gluelams. One Member State indicated that it would inform about its position by 30 June 2021. The Member State supporting the use proposed to come back with additional information demonstrating that this use is essential for the thousands of wood bridges already built across the country. The Commission does not contest the usefulness of wood as a construction material, but the question is whether an alternative wood treatment is available.

For environmental barriers, none of the Member States had indicated a need for derogation for this use.

Only three Member States had indicated a need for the use of creosote treated wood for agricultural and equestrian centre fences. Two Member States indicated that further investigations would be conducted to confirm whether this use would require a derogation. The Commission invited the Member States supporting the use to provide further justification before 30 June 2021.

Two Member States had indicated that the use of creosote for agricultural support poles would meet the conditions for derogation to exclusion. The Commission highlighted that the risk assessment in the BPC opinion does not provide data concerning potential residues in food from such uses. The Commission also noted that the existing restriction in Annex XVII to the REACH Regulation already prohibits the use of treated wood to make "materials which may contaminate intermediate or finished products destined for human and/or animal consumption". One of the two Member State supporting the use explained that no suitable alternatives exist but indicated its willingness to analyse further the issue. At the request of another Member State, the Commission clarified that existing support poles treated with

creosote will not have to be replaced by alternatives if the approval of the substance is not renewed for that use. The renewal decision will only concern the placing on the market of newly treated poles.

Regarding the impregnation methods, the majority of Member States clarified that the only authorised method should be the vacuum pressure impregnation. One Member State indicated that the brushing of transmission poles would be needed for small repairs and maintenance. The Commission pointed to the high risk of exposure for operators and the environment from brushing.

The Commission invited the Committee to discuss the possible drafting of the conditions in the legal text if the approval were to be renewed for some uses. As to the placing on the market of treated wood, the Commission recalled that Member States can only authorise biocidal products within their territory for uses for which a derogation condition is met. After the previous meeting of this Committee, a Member State put forward a proposal to prevent the placing on the market of wood treated with creosote for a certain use in the Member States where the derogation to exclusion for this use would not be met. The proposal of that Member State suggests the creation of a list of Member States indicating the uses for which the conditions for derogations to exclusion are met on their territories. Such a list could be maintained by ECHA – based on information provided by the Member States - and made available on its website. The Member State at the origin of the proposal explained that such a list would be the most transparent and predictable way for companies to know in which Member States they could place treated wood on the market. The Commission added that this could be coupled with labelling obligations to make clear throughout the supply chain where the treated wood could be placed on the market. In addition, following remarks from several Member States, the Commission proposed to clarify in the legal text renewing the approval that the restrictions should similarly apply to wood treated outside and imported into the Union. Five Member States supported the proposal. One Member State suggested to include this list in the legal text renewing the approval to facilitate control actions. The Commission noted that this option would be more cumbersome in case Member States provide new information about their needs for derogation for certain uses but would further analyse the proposal.

The Commission asked whether Member States who consider that the conditions for derogation would not be met for some (or all) uses in their territories, could still support a renewal provided it contained conditions clearly forbidding the placing on the market of treated wood in their territories for the uses for which they do not consider that the conditions for derogation to exclusion are met. One Member State indicated that it would not support a renewal containing uses that would not meet the conditions for derogation for their territory. Another one could support such an approach with the condition that certain uses are prohibited at Union level because they do not fulfill the conditions for derogation of Article 5(2) in any Member State. The Commission replied that, based on the information available so far, a majority of Member States seemed to support a renewal of approval of creosote only for two uses: railway sleepers and transmission poles. One Member State wanted more time to reflect on the proposal.

The Commission explained that the approval of creosote can be renewed up to 7 years, however, a shorter period could be set taking into account the time needed for substitution. Also a differentiation could be considered for the different uses. A renewal for 5 or 7 years means that an application for renewal will have to be submitted within 3.5 or 5.5 years, respectively. Four Member States and an EEA country supported a period of renewal of no longer than 5 years. Two Member States supported seven years.

The Commission recalled that the BPR can only address the placing on the market of treated articles (i.e. the first making available) and that subsequent sales of treated wood (in particular

also for old second-hand wood) have to be addressed under the REACH Regulation. The Commission invited one Member State who had triggered the safeguard clause under the REACH Regulation to provide an update about its intentions to submit a dossier for proposing updated restrictions in accordance with Articles 69 to 73 of REACH. That Member State explained that the proposal for updating the existing restrictions under REACH would be relevant for the second hand market. It explained that its proposal was delayed due to the need to assess how the future restrictions under the BPR would need to be complemented. As this aspect is being clarified, that Member State will provide additional details to the REACH Committee by the end of June 2021. The Commission invited the other Member States to discuss the matter with their national colleagues responsible for the implementation of the REACH Regulation.

In conclusion, the Commission explained that although good progress had been made at this meeting of the Committee, an extension of the current expiry date of the approval of creosote (31 October 2021) might be necessary in order to have sufficient time to finalise the discussion in the Committee, draft the Implementing Regulation, and conclude the adoption procedure.

The Commission announced that a newsgroup will be opened for Member States to provide further contributions by 30 June 2021.

A.05 Exchange of views on the examination of the approval of silver zeolite, silver zinc zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate for use in biocidal products of product-type 4 ***(SCBP72-Doc.A.05)***

The Commission recalled that these substances are proposed to be only used in food contact materials and in water filters. The dietary risk assessment was therefore quite central during the discussion at the BPC. In its opinion, the BPC identified unacceptable risks for infants from the consumption of water filtered with silver treated active carbon, while it found risks acceptable for other age groups. The Commission pointed out that the applicant proposed in a document tabled for the BPC discussions to restrict the use of the water filters to commercial, hospitality and institutional establishments. The BPC had considered that the risk mitigation measures proposed by the applicant to reduce the risks identified for infants to an acceptable level were not satisfactory, and the BPC did not identify other suitable risk mitigation measures. More details were available in the document tabled for the meeting of this Committee.

During the BPC discussion, it was estimated that if less than 60% of the daily intake of water of an infant is water passing through silver-treated filters, risks would be acceptable. The Commission therefore invited the Member States to express their views on the possibility to achieve overall safe use by restricting the use of such filters to (commercial) hospitality settings and share any information they might have whether infants may consume 60% of their daily water intake from sources in commercial, hospitality and institutional establishments, like restaurants.

One Member State supported the prohibition of such filters for domestic uses and considered the proposed restriction possible but asked to reinforce it by excluding also nurseries, services in hospitals and any other place where infants are likely to be in contact with water passing through such filters.

Two other Member States expressed reservations as the risk mitigation measure would not exclude completely exposure of infants to the substances. In case of doubts, an approval should not be granted. The Commission clarified that, if an approval were to be proposed, the intention would be to allow the use of such water filters only in restaurants and other commercial places.

The key question is therefore to know whether it is likely that infants will get 60% or more of water consumption from such places.

One Member State clarified that the use of the substances in food contact materials presents also a risk and stated that an approval should specify the allowed uses and so do not leave open the possibility that the substance could be used for other uses. The Commission agreed and indicated that the conditions for approval would have to be carefully drafted in case the substances would be eventually approved.

One Member State inquired about the objective of impregnating water filters with the silver compounds. The Commission and ECHA replied that the intention is to prevent the clogging of filters with organic matter. ECHA further informed that the usefulness of such filters had not been discussed in the BPC.

No Member State had reliable information on the likelihood that infants consume more than 60% of their daily water intake from commercial places, while some pointed to the possibility that children of owners or managers of such establishments could possibly have higher intakes of such water. No Member State proposed other risk mitigation measures for further investigation.

The Commission requested the Member States to provide by the end of June their views on:

- the risk mitigation measure proposed by the applicant,
- other risks mitigation measures they might have identified, and
- on the likelihood that infants would consume more than 60% of their daily water intake from sources in commercial, hospitality and institutional establishments, like restaurants, and provide any relevant information/evidence in this regard (e.g. food consumption studies).

A.06 Exchange of views on a request under Article 3(3) of Regulation (EU) No 528/2012 on a product containing the biocidal active substance "Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))" and claiming to be a cleaning product *(SCBP72-Doc.A.06)*

The Commission presented a note for the discussion of a request submitted by a Member State pursuant to Article 3(3) of the BPR with regard to a product containing the active substance "ADBAC/BKC (C12-16)", which is included in the Review programme of existing active substances for use in product-type 2 (algaecide). The product at hand is made available on the market as a cleaning product. According to the Member State submitting the Article 3(3) request, the product is also intended to control and prevent the growth of algae.

The Commission summarised the information on the marketing material and concentration of the product provided by the Member State and described in the document tabled for the meeting. Based on the information received:

- The manufacturer describes the product as "long-acting" and, for the concentrated version of the product, that it can be used diluted as a "preventive" method against deposits/coating.
- The manufacturer states that heavily soiled surfaces should first be cleaned.
- A distributor and an online point of sale refer, to, e.g., "protection from regrowth" and "preventive effects".
- In an online point of sale, the product is included in a category of products which are described as having a direct effect on algae on surfaces.

The Commission considered that the application of a detergent would in general not have a prolonged/preventive effect and that the recommendation to clean heavily soiled surfaces before application of the product gives a further indication that the intent is different than acting only as a detergent. The Commission subsequently noted that, according to the requesting Member State, the concentration of the active substance in the product is similar to the concentration in algae-removing products containing the same active substance and authorised as biocidal products in another Member State . The Commission added that the Member State submitting the request reported that its national inspectors occasionally identified products containing ADBAC/BKC with similar concentration and claiming to be algae removing products. Such products were removed from the market as no algae-removing products containing this active substance are authorised in that Member State.

The Member State that submitted the request underlined that this is a long-standing issue in the country and that the problem is not limited to the product under discussion but concerns many other products. It welcomed the intent of the Commission to adopt a decision clarifying that the product is a biocidal product, which would facilitate national enforcement actions.

13 Member States informed that, based on the information provided, they were inclined to support the view that the product at hand is a biocidal product.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft 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 *(SCBP72-Doc.B.01)*

The Commission informed that compared to the previous version of the draft Decision, other substances had been added to the list in Annex I because they were no longer supported and therefore a non-approval decision was required.

One Member State asked for the possibility to reflect on the new amendment to the proposal.

The Commission invited Member States to comment by 11 June 2021 and announced that the vote in written procedure will be launched shortly thereafter.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of boric acid for use in biocidal products of product-type 8 *(SCBP72-Doc.B.02)*

The Commission noted that the substance meets the exclusion criteria, but given that the procedure for the evaluation of the application for renewal is significantly delayed, proposed an extension of the current approval by 2.5 years to allow sufficient time for the evaluating Member State and ECHA to complete the risk assessment and considering the outcome of the discussion on alternatives at the previous meetings of the Standing Committee. The Commission recalled that if the work is completed before the extension ends, the act postponing the expiry date would be repealed.

One Member State did not oppose the extension but expressed concerns about the justification included in the draft recitals, as it may give the impression that an extension would be automatically required each time the fulfilment of the conditions of Article 5(2) would have to

be checked for substances meeting the exclusion criteria. That Member State proposed an alternative wording that was accepted by the Committee. Another Member State indicated that it would oppose the extension as a matter of principle because the substance meets the exclusion criteria.

The Commission informed that a vote by written procedure will be launched once the amended recital will have been checked with the other Commission services concerned. and that the vote in written procedure will be launched shortly thereafter.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of disodium tetraborate for use in biocidal products of product-type 8 *(SCBP72-Doc.B.03)*

For the same reasons as for boric acid, the Commission proposed an extension of the current approval by 2.5 years. One Member State opposed the extension as a matter of principle because the substance meets the exclusion criteria. Similarly to the draft decision on boric acid (see preceding agenda item), an amendment to a recital was proposed by a Member State.

The Commission informed that a vote by written procedure will be launched once the amended recital will have been checked with the other Commission services concerned and that the vote in written procedure will be launched shortly thereafter.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of hexaflumuron for use in biocidal products of product-type 18 *(SCBP72-Doc.B.04)*

The Commission explained why the extension of the approval was necessary and that the drafting of the recitals would take into account the suggestion that one Member State made for the Decisions related to borates. The Commission informed that it had sent a mandate to ECHA to assess possible alternatives by June 2022.

One Member State proposed a shorter extension period taking into account that a pilot case on the early assessment of possible alternatives had been launched. The evaluating Member State responded that additional data on efficacy and data to assess endocrine disrupting criteria had been requested from the applicant and should be submitted in the second quarter of 2022. The proposed extension is necessary to finalise the assessment and the peer-review.

Another Member State indicated that it could not support the extension as a matter of principle because the substance meets the exclusion criteria. A further Member State opposed the extension as well because hexaflumuron meets the exclusion criteria. The Commission indicated that the extension of the approval should be long enough to allow for the completion of the assessment as explained by the evaluation Member State and explained that the substance is included in products used against termites and that such product might not be present on the market of all Member States.

The Commission informed that the vote in written procedure will be launched shortly after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of aluminium phosphide for use in biocidal products of product-types 14 and 18 *(SCBP72-Doc.B.05)*

The Commission informed that the evaluating Competent Authority had decided to conduct a full assessment for both product-types and proposed to align the extensions of approvals to 31 July 2024. The Commission noted that the substance does not meet the exclusion criteria.

One Member State indicated that the substance is very toxic and a serious incident occurred during the use of a product containing it. According to that Member State, the substance possibly could be considered as candidate for substitution meeting the criterion of Article 10(1)(e) of the Biocidal Products Regulation. However, this Member State did not oppose the extension of approval.

The Commission explained that the substance had been approved under the former Biocidal Products Directive and proposed to organise a debate on the topic in the context of a meeting of the expert group of competent authorities for the implementation of the Biocidal Products Regulation, thus in the presence of stakeholders. The Commission invited that Member State to provide its reasoning why it considered that the criterion of Article 10(1)(e) is fulfilled.

The Commission recalled that a formal designation of the substance as candidate for substitution would be decided at renewal if the approval of the substance is eventually renewed.

The Commission informed that the vote in written procedure will be launched shortly after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of magnesium phosphide for use in biocidal products of product-type 18 *(SCBP72-Doc.B.06)*

The Commission informed that the evaluating Competent Authority had decided to conduct a full assessment for both product-types, and that the substance has similar properties as aluminium phosphide, and proposed an extension of the approval until 31 July 2024. No Member State commented.

The Commission informed that the vote in written procedure will be launched shortly after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of dinotefuran for use in biocidal products of product-type 18 *(SCBP72-Doc.B.07)*

The Commission introduced the draft Decision and mentioned that the evaluating Competent Authority had decided to conduct a full evaluation of the substance and hence the date of approval needed to be extended to allow for completion of the evaluation before the current approval expires.

One Member State informed that it will abstain in the vote on the draft Decision as the substance meets the substitution criteria.

The Commission informed that the vote in written procedure will be launched shortly after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of indoxacarb for use in biocidal products of product-type 18 *(SCBP72-Doc.B.08)*

The Commission informed that the approval date needed to be extended for a second time, as the evaluating Competent Authority had requested the applicant to submit data to evaluate whether the substance meets the criteria to be identified as endocrine disruptor. The draft Decision proposes therefore an extension of the current approval by two years.

One Member State indicated that, in addition to determining endocrine disrupting properties, the evaluating Competent Authority has to perform a risk assessment of a substance identified as having endocrine disrupting properties. This Member State requested clarification on the methodology to be used to assess the risk of a substance identified as having endocrine disrupting properties.

The Commission replied that the proposed extension is necessary to enable the applicant to submit data to determine whether the substance is an endocrine disruptor. If this is confirmed additional work will indeed be needed to assess the risks due to these properties. The Commission recalled in that context the mandates that it had sent last year to ECHA related to DBNPA and cyanamide , in which ECHA is asked to clarify whether a safe level (threshold) can be determined for the ED properties of these substances.

The Commission informed that the vote in written procedure will be launched shortly after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of dazomet for use in biocidal products of product-type 8 *(SCBP72-Doc.B.09)*

The Commission explained that the evaluating Competent Authority had informed that it intended to conduct a full evaluation and hence an extension of the date of approval needed to be granted to allow sufficient time to conclude the evaluation before the current approval expires.

No Member State commented.

The Commission informed that the vote in written procedure will be launched shortly after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product family containing hydrogen peroxide referred by Belgium in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP72-Doc.B.10)*

Postponed (see point A.01)

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP71-Doc.B.11)*

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the Croatian Ministry of Health permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP72-Doc.B.12)*

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the Italian Ministry of Health permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP72-Doc.B.13)*

Items B.11-B.13 were discussed jointly, as they all regarded draft Decisions intending to allow the extension to 550 days of the temporary permits granted for the biocidal product Biobor JF by three Member States. The Commission indicated that the content of the draft Decisions is similar (and similar to the Decisions already adopted for other Member States), as the reasoned requests from Member States on which they are based are similar and include a similar

argumentation. The Commission also informed that it received a further request for extension from another Member State.

Upon request from a Member State, the Commission provided an update on the state of play of the application for approval of the active substances contained in Biobor JF. The prospective applicant informed the Commission that they had identified a competent authority willing to act as evaluating Competent Authority and that a first pre-submission meeting had taken place. Regarding the active substance identity (one active substance vs. mixture of two active substances), data presented by the applicant to the evaluating Competent Authority support the identification as one multi-constituent active substance. The evaluating Competent Authority preliminarily agreed with these findings and will share a position paper with the Working Group on analytical methods and physico-chemical properties of the Biocidal Products Committee in order to have a consensus regarding the identity of the active substance before the submission of the application. Considering the time needed to carry out the tests required in order to fulfil the data requirements, the estimated timeline for the submission of the application is mid-2022.

The Commission also informed that it was aware that other companies are trying to develop an alternative product to Biobor JF, having CMIT/MIT as active substance, similarly to the product removed from the market in 2020, but without the co-formulants that were identified as the cause of the safety incidents that occurred with the product withdrawn.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion for the three acts.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the same single biocidal product "SchwabEX-Guard" *(SCBP72-Doc.B.14)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a same biocidal product containing the active substances clothianidin and pyriproxyfen. The Commission noted that this single product is identical to the single biocidal product "Pesguard® Gel", for which the draft Regulation granting the authorisation will be put forward for adoption in a written procedure in the coming days. Furthermore, the same warning statement for potential danger to bees is included in the SPC of this product, since it includes the same active substances.

The Commission had contacted the applicant regarding the two non-active substances contained in the biocidal product, which may have endocrine disrupting properties, and the applicant agreed with the inclusion of the relevant recital in the Implementing Regulation. Furthermore, the applicant is currently looking for alternatives to replace these non-active substances.

The Commission also informed that the draft Regulation is currently under consultation of the Commission services concerned 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.

Outcome of the vote by written procedure that took place between 17 June and 3 July: favourable opinion.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "CMIT-MIT Aqueous 1.5-15" *(SCBP72-Doc.B.15)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing a mixture of CMIT/MIT and informed that some risk mitigation measures for treated articles have been reformulated in line with the recent agreement in the Coordination Group and the expert group of competent authorities. The Commission explained that a second point about instructions for treated articles in PT6 uses, which were included in the minority opinion of a Member State annexed to the opinion of the Biocidal Products Committee, need to be discussed further with that Member State, the evaluating Competent Authority and ECHA. The agreement on this point will be included in the final version of the draft Regulation, which will be circulated before the launch of the written procedure.

B.16 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the same biocidal product family "C(M)IT/MIT formulations" *(SCBP72-Doc.B.16)*

The Commission presented the draft Regulation intending to grant a Union authorisation for another biocidal product family containing a mixture of CMIT/MIT and informed that it is a same biocidal product family related to the previous family "CMIT-MIT Aqueous 1.5-15", and, therefore, the vote will be launched only after the procedure for the reference family will be finalised.

B.17 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "SOPUROXID" *(SCBP72-Doc.B.17)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing the active substances peracetic acid for product types 2, 3 and 4. One Member State had provided comments on the draft SPC. Those comments had been analysed together with the evaluating Competent Authority and had been taken into account.

The Commission also informed that the draft Regulation is currently under consultation of the Commission services concerned 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.

AOB

The Commission updated the Standing Committee on developments following the approval of carbendazim for PT7 and 10. Firstly, the applicant had submitted an access to documents

request for email exchanges between the Commission and ECHA, the Commission and the Member States, and between the Commission and the European Parliament in relation to the decision-making process for the substance. The documents that have been disclosed are publicly accessible on the Commission's website[1]. The Commission also informed that the applicant had brought a procedure for annulment of the approval decision to the European Court of Justice because it disagreed with the restrictions for outdoor uses.

One Member State requested an update on the dossier for the inclusion of *in-situ* nitrogen in Annex I to the Biocidal Products Regulation. The Commission explained that the prospective applicant had informed the Commission that it has regular meetings with a consultant, and it intends to submit the application during the summer. The evaluating Competent Authority confirmed this information.

The Commission informed that an early review of three substances considered as having endocrine disrupting properties had been launched and ECHA has been requested to form an opinion on the matter. In that context, ECHA has informed the Commission that it did not succeed to nominate a rapporteur for two active substances, as the evaluating Competent Authority for the approval had declined the request to become rapporteur. The Commission asked the Member State in question to reconsider this decision in the interest of efficiency and in line with the practice on the nomination of rapporteurs for opinions on active substances. The Commission also recalled that that Member State had repeatedly expressed its high interest in identifying and taking action on substances with endocrine disrupting properties and that this would be an occasion to put these intentions into action.

[1] https://webgate.ec.europa.eu/dyna2/extdoc/?showby=ar&keywords=2021%2F1796#searchpos