EUROPEAN COMMISSION

Health and Food Safety Directorate General

Standing Committee on Biocidal Products

30 September 2021
10:00 – 16:00
Webex meeting

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP73-Doc.A.01)*

Three AOB points were added to the draft agenda, related to: (i) an Article 3(3) request, (ii) corrective act to shorten the duration of a granted Union authorisation and (iii) update on the application for inclusion into Annex I of in-situ generated nitrogen.

A.02 Adoption of the Minutes of the 72nd SCBP meeting *(SCBP73-Doc.A.02)*

The minutes of the 72nd SCBP meeting were adopted.

A.03 Exchange of views on the examination of the approval of diamine for use in biocidal products of product-type 8 *(SCBP73-Doc.A.03)*

The Commission recalled the past discussions on whether setting a maximum number of two cycles of treatment per operator per day in the authorisation of biocidal products containing diamine could be a suitable risk mitigation measure given that, via the product label, employers would have clear information on what is needed to ensure the safety of workers.

Several Member States did not consider this risk mitigation measure suitable arguing that it cannot be enforced and controlled. Some Member States also argued that a number of three cycles of treatment per day per operator constitutes the realistic worst case used in the scenario for the evaluation, and that even more than three cycles of treatment per day per operator are performed in certain treatment plants. After the last meeting of this Committee, the Commission considered that based on the positions expressed by Member States, it appeared that that no qualified majority would be reached if the Commission proposed an approval but also that no qualified majority would be obtained for a proposal for non-approval. However, several Member States had still not expressed any position yet.

The Commission invited all Member States to express their position in the meeting on a proposal for non-approval. The Commission concluded that in the light of the positions expressed, a qualified majority of Member States would support a non-approval. The Commission indicated that it will, therefore, prepare a draft decision not approving the active substance which will be presented for vote at a future meeting of the 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 *(SCBP73-Doc.A.04)*

The Commission introduced the topic and explained that the views of Member States would be sought on three important aspects of a potential proposal for renewal of approval, i.e. the actual uses that would remain approved, the conditions of approval and the duration of the approval.

First, regarding the uses, the Commission explained that based on the information provided by Member States and the earlier discussions in this Committee, the conditions for derogation under Article 5(2) seemed to be met in a number of Member States for railway sleepers and transmission poles, but that the situation is less clear for three other uses supported solely by three individual Member States. The Commission asked whether those Member States would still consider the derogation condition(s) met for them, as from the information provided it was not clear why the situation is so unique in those Member States that would require a continuous use of creosote for those uses. The Commission also clarified that already installed wood treated with creosote would not be affected by the decision under the BPR.

On the use of creosote to treat foundation poles for bridges and glulams for bridges, the Member State requesting a derogation for that use explained that an alternative biocidal product to creosote had been only recently authorised and that more time is needed to adapt the current treatment processes and build up experience with this alternative. Moreover, several bridges are being built in small private roads in remote agricultural and woodland areas, which means that the use of treated wood is important to economic sectors of agriculture and forestry.

The Commission asked whether these bridges are of cultural value as in this case it might be possible for the Member State to request a derogation under Article 55(3). The Member State concerned replied that this is not the case.

The other Member State supporting the use of creosote to treat wood for fencing in agriculture, farming and for equestrian centres informed that livestock production is an important economic sector for the country and that most of the wooden fences are still treated with creosote. The specific climatic conditions of the country require the use of creosote to ensure the durability of traditional wooden fencing and hence the safety of livestock. The current alternatives do not meet (yet) the durability properties of creosote and time is needed to adapt and gain experience with new products entering the market. Lastly, it was noted that this use would be only authorised for the local market and that no export to other EU Member States would be allowed.

Lastly, the Member State supporting the use of creosote to treat agricultural support poles argued that current alternatives do not meet the necessary requirements in terms of durability and prices which could cause economic problems for the hop industry. Creosote has also the advantage not to corrode steel compared to other impregnating agents. Regarding the risks of using the substance, tests conducted on hop plants show that the transfer of PAHs compounds from creosote to the plant is very limited. The Member State requested more time to consolidate its opinion by consulting other national ministries.

The Commission replied that internal consultation could continue but argued that all the elements put forward so far would also apply to other Member States that are already phasing out creosote for the uses indicated above. It is not demonstrated so far that the situation in those Member States for the uses in question is unique compared to the overall majority of other Member States. The Commission asked the other Member States on whether an inclusion of the three uses requested by the three Member States in the list of approved uses et EU level would be acceptable so that the Member States could then continue to authorise products for those uses in their territories. Three Member States indicated that they would oppose such flexibility considering that an ambitious restriction is needed to phase out this dangerous substance. Three other Member States did not oppose such flexibility, and two others indicated that they could also support the approach depending on how the legal requirements to prevent the presence on their market of wood treated with creosote for such uses would be laid down. One Member State indicated that it had no opinion and another one that it would abstain if such a proposal was proposed for a vote. One Member State recalled that it opposed the renewal of approval of creosote under any conditions.

The Commission introduced some preliminary drafting of possible approval conditions inspired by the previous approval, the opinion of the BPC on creosote and labelling provisions from restrictions under the REACH Regulation on other substances. The latter could be used to indicate where the treated wood can be placed on the market.

The Commission presented in particular the drafting proposed to ensure that Member States could only authorise uses that they consider necessary for their territories. Concretely, the three uses discussed above supported by only three Member States could only be authorised for biocidal products in the three Member States, which means that treatment plants would have

to be in place in their territory to supply their local markets. One of those three Member States reacted by mentioning that, even if these 'minor uses' are left in the approval decision, this is not requiring other Member States to authorise those uses, as Member States can decide whether to authorise them or not. The Commission recalled that this is not allowed by the provisions of Article 5(2) of the BPR (products can only be authorised for use where they are needed), and that some Member States indicated that national operators had managed to phase out creosote and that they should be rewarded for their efforts.

Regarding the minimum packaging size of creosote made available to industrial settings, a Member State proposed to increase the volume to 200 litres to take into account the volume of creosote needed for wood treatment. The Commission noted the proposal and indicated that it would discuss it with the services responsible for the REACH Regulation. ECHA reported that a packaging size over 200 litres is mentioned in the assessment report of the BPC.

Another Member State asked whether exports to non-EU countries would fall under the scope of the BPR. The Commission clarified that exports to non-EU countries are indeed not covered by the BPR and should be dealt with by the Member States who have to verify that non-authorised products or articles treated with such products are actually exported outside of the EU.

The Commission further explained that the provisions related to the safety of consumers and maximum residue limits would be maintained or not depending on whether the use of creosote in agriculture would still be allowed. The Commission invited the relevant Member State to look at the transfer of residues of creosote into livestock and whether livestock could also be exposed via dermal absorption. ECHA confirmed that data for residues had been provided by the applicant for the use of creosote in agricultural poles in fruits but no equivalent data had been provided by the applicant for fencing in agriculture or cattle farming. Lastly, a Member State proposed to replace the term professional with industrial users. The Commission agreed as the term professional may cover a larger category of users than was actually intended.

Regarding the conditions for treated articles, the Commission introduced a key provision derived from a proposal of one Member State. A list of Member States could be made publicly available on the European Chemicals Agency's (ECHA) website, indicating where and which treated wood may be placed on the market. Member States may ask ECHA to remove one or all uses from the list at any time. When ECHA removes one or all uses for a Member State from the list, the date of removal would be indicated, and treated wood for the concerned use may no longer be placed on the market of that Member State 180 days after the date of removal.

The Commission also repeated that restrictions in the BPR can only cover the first supply to the market of treated wood and that further supplies, reuse and second hand market have to be dealt with in the context of the restriction in Annex XVII of the REACH Regulation for which one Member State is preparing a dossier to propose an amendment. In addition, the Commission could consider introducing a provision for the phasing out of the placing on the market of treated wood for the uses no longer allowed in any of the Member States following the renewal of approval of the active substance, as the BPR does not contain specific provisions on the matter in its Articles 14(6), 48 or 52.

One Member State confirmed that it is preparing a dossier to propose an amendment of the existing restriction under REACH and intends to submit it early next year. It indicated support for the approval provisions with a reservation concerning the phasing out of the uses no longer authorised by the Member States.

One Member State asked whether an official letter should be sent to ECHA to establish the list. The Commission replied that the first version of the list could be drawn up based on the information already collected at the meetings of this Committee. Every change should be notified in writing to ECHA with copy to the Commission.

A further Member State raised a question about the shipment of transmission poles between Member States when the treated wood would be in transit in a Member States where their placing on the market and use is not authorised. The Commission recalled that the BPR can only regulate the first placing on the market of treated articles and that subsequent placing on the market should be dealt with by the upcoming revision of the REACH restriction for creosote.

The Commission introduced a range of labelling provisions intended to help enforcement authorities to avoid misuses or placing on the market of creosote-treated wood where it is not allowed. A Member State requested the inclusion of the name of the Member State where the use would be allowed. Another Member State agreed with the provision, as there is a need to reinforce controls and enforcement of creosoted wood, but proposed to inverse the order of the provisions to make sure that the controllers first verify the list of ECHA and then check the labelling. Another Member State proposed to extend the scope as follows:

The person responsible for the placing on the market of treated wood with creosote shall ensure that the following restrictive statement is communicated to end-users of treated wood by appropriate means, including but not limited to labelling of treated wood: "The placing on the market is restricted only to certain Member States in the European Union: verify where the placing on the market is allowed".

The Commission noted the proposal.

The Commission explained that certain labelling provisions had been recommended by the BPC but modified to take into account that the BPR can only address the first placing on the market of treated wood. The BPC had proposed to make a distinction between temporary and permanent storage sites. The Committee discussed the relevance of this distinction and agreed on a proposal to merge the two provisions to ensure a general protection of human health and the environment during storage. ECHA explained that this provision in the BPC opinion aimed to address the risks of temporary storage by companies responsible for the maintenance of the electricity grid (e.g. in case of a need for repair in a remote location). The two provisions could indeed be grouped provided that it includes a restriction for the access to the general public and measures to restrict the risks of leakage into the environment.

Finally, as to the duration of the renewal, the Commission proposed to go for the full period possible (i.e. 7 years) considering that most – if not all - of the uses still considered essential today would no longer be considered so by then, and taking into account that resources are very scarce while starting a new assessment of an application for renewal of approval in 3,5 years (which would be the case if the approval were to be limited to 5 years) would bring only limited added value. It also reminded that, even if the approval of creosote would be renewed, the approval conditions discussed earlier would allow Member States to not authorise biocidal products and the pacing on the market of treated wood as soon as they consider them not needed anymore. Four Member States proposed 5 years for the renewed approval noting that extensions had been already granted and previous approvals were granted for 5 years for similar substances. Three Member States supported a 7 year renewal and one had no position.

The Commission thanked the Committee for its input and indicated that political guidance will be sought on the points discussed at the meeting and that a formal proposal will be tabled at a forthcoming meeting of the Committee.

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 *(SCBP73-Doc.A.05)*

The Commission recalled the discussion at the last meeting of the Committee on whether the restriction to use in commercial establishments proposed by the applicant could be suitable to mitigate the risks for infants as regards the use of silver compounds in water filters. Member States had also been requested to look at available data on water consumption of infants in commercial establishments and reflect on the likelihood for infants to consume more than 60% of their daily water intake from such sources.

The Commission also informed that EFSA had published in August 2021 an opinion finding that the use of silver nanoparticles in food contact materials would be safe. It noted however that silver as nanomaterial was not approved as an active substance for use in biocidal products of product-type 4, following the withdrawal of the application for approval as the applicant had failed to pay the required fees to the evaluating Competent Authority. Despite this positive opinion of EFSA, it is therefore no longer possible to place on the market silver as nanomaterial for use in food contact materials unless a new application for approval for use in PT 4 is submitted and the outcome of the evaluation would allow approval under the BPR.

None of the Member States responding after the last meeting had data on the sources of water consumed by infants, and only one indicated that it might support the approval of the silver substances for use in water filters only if risk mitigation measures are possible.

One Member State opined that it is not for the authorities to provide evidence of non-exposure, and that no relevant data had been available in the application.

Another Member State commented that the substance silver zeolite could be approved if a suitable risk mitigation measure is implemented to reduce the risks for children. The Commission asked if such measure exists and if it is described in the application. It recalled that so far the opinion of the BPC, as well as the Standing Committee, was that there is no evidence that the 60% water consumption of infants is not exceeded from the use of such filters in commercial establishments. The Member State responded that there might be a possibility to reduce the risks if the use is authorised only in commercial environments where children are not present, but it needed further reflexion.

The Commission requested that Member State to come back with its definitive opinion in the matter within two weeks after the meeting so that the Commission can take it into account in its reflections on the way forward.

A.06 Exchange of views on the Union Authorisation of the BPF CMIT-MIT Solvent based *(SCBP73-Doc.A.06)*

During the 34th meeting of the BPC in March 2020, ECHA had adopted its final opinion on the application for a Union authorisation of the biocidal product family (BPF) "CMIT-MIT SOLVENT BASED" for use as preservative, crude oil and middle distillate fuel (Product-type 6). The BPF contains 'reaction mass of 5-chloro-2-methyl-1,2-thiazol-3(2H)-one and 2-methyl-1,2-thiazol-3(2H)-one [C(M)IT/MIT]' as the active substance.

In the discussion in this Committee, several Member States had noted that the presence of halogenated organic compounds, such as C(M)IT/MIT, in fuel may result in the formation of dioxins during fuel combustion. Human exposure to dioxins and dioxin-like substances has been associated with a range of toxic effects, including chloracne; reproductive, developmental and neurodevelopmental effects; immunotoxicity; carcinogenicity, effects on thyroid hormones, liver and tooth development.

On 24 July 2020, the Commission had requested from ECHA an opinion under Article 75(1)(g) of the BPR to estimate the amount of formation of dioxins from the use of "CMIT-MIT SOLVENT BASED" in fuels used for road and water transport and to estimate the contribution to the overall emissions of dioxins from all sources. ECHA was also requested to clarify the level of the risks to the environment and the level of the risks for human health due to the exposure to dioxins via the environment from the use of the BPF.

The BPC adopted its opinion at its 39th meeting. One of the conclusions of the opinion is that "*although the potential consequence of the use of C(M)IT/MIT as preservative in oil and fuel cannot be neglected, it is not possible to draw any conclusions either on the magnitude of the potential contribution of the use of C(M)IT/MIT in fuels with respect to dioxin exposure, nor on the potential consequence of chlorine additive such as C(M)IT/MIT in fuels on human health and on environment*".

In order to facilitate the decision-making on the Union authorisation of this BPF the Commission consulted Member States on four issues and 7 Member States and Switzerland responded. In summary:

- 3 Member States and Switzerland have rules in place banning addition of halogenated organic compounds to fuels or rules regulating the end product (crude oil and middle distillate fuel)
- 1 Member State considers the use of preservatives for fuels not necessary, 1 Member State considers the use of preservatives containing C(M)IT/MIT not necessary, 2 Member States consider the use of preservatives for fuels occasionally necessary and Switzerland considers the use of preservatives for fuels necessary for storage of diesel fuels for road transport. The situation in one Member State as regards the need of these products is not clear.
- 3 Member States and Switzerland have preservatives for fuels authorised under national rules of which:
    i. C(M)IT/MIT and dimorpholinomethane are approved for PT 6.
    ii. Reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio 3:2) (MBO), 1,2-Benzisothiazol-3(2H)-one (BIT), (ethylenedioxy)dimethanol are in the review programme.
- 2 Member States and Switzerland provided information on other active substances without halogenated compounds that can be used as preservatives for fuels of which:
    i. glutaraldehyde and dimorpholinomethane are approved for PT 6
    ii. reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio 3:2) (MBO), 1,2-Benzisothiazol-3(2H)- one (BIT), ethylenedioxy)dimethanol, 2-octyl-2H-isothiazol-3-one (OIT), 2-methyl-2H-isothiazol-3-one (MIT), pyrithione zinc, 2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol, pyridine-2-thiol 1-oxide sodium salt are in the review programme.

The Commission indicated that in the light of the information provided it intended to proceed with the granting of the Union authorisation and requested those Member States for which an adaptation of the Union authorisation in accordance with Article 44(5) of the BPR will be needed to notify this within one month.

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 postponing the expiry date of the approval of creosote for use in biocidal products of product-type 8 *(SCBP73-Doc.B.01)*

The Commission introduced the draft Decision explained that an extension of the date of approval of creosote is needed in order to complete the examination of the renewal of approval and the discussions on the derogation to exclusion under agenda item A.04 of the meeting. One Member State indicated that it would vote against the proposal as it cannot support the postponement of the expiry date of approval of active substances meeting exclusion criteria. Another Member State informed that it can also not support the proposal as it considers that creosote is a highly hazardous substance that should be withdrawn from the market. A third Member State abstained because it believed that a strong signal should be sent to industry to phase out rapidly this active substance.

The Commission submitted the draft Decision to a vote in the meeting. The Committee gave a 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 N,N'-diethyl-meta-toluamide (DEET) for use in biocidal products of product-type 19 *(SCBP73-Doc.B.02)*

The Commission introduced the draft Decision and explained 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. No Member State had any comments.

The Commission informed that the vote in written procedure will be launched without delay after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion

B.03 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(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP73-Doc.B.03)*

The Commission introduced the draft Decision which aims at solving a disagreement raised in a mutual recognition procedure concerning a biocidal product family of surface disinfectants containing hydrogen peroxide as active substance in concentrations between 12% and 49% w/w. The disagreement concerned the determination of the physical hazards of the products in the family with regard to the oxidising liquids property, more specifically the non-classification of the products as oxidising liquid proposed by the reference Member State. The reference

Member State considered that specific concentration limits as set out in Annex VI of the CLP Regulation were applicable and, since none of the products of the family met the lower limit of 50%, the products were not to be classified in relation to the oxidising liquids property. The Member State having raised the disagreement was of the opinion that the experience in handling and use of mixture containing the substance which shows them to be oxidising should be considered, and in application of the UN Model Regulations on the Transport of Dangerous Goods (UN RTDG Model Regulations) they should be classified as Oxidising liquid, Packing group III. Since the reference Member State recommended authorisation only for those products of the family which contain hydrogen peroxide in a concentration of 12%, the Decision refers only to those products.

The Commission presented the main elements of the reasoning in the draft Decision, namely the relevant provisions in the CLP Regulation concerning classification as oxidising liquids, the harmonised classification of solutions containing hydrogen peroxide set out in Annex VI to the CLP Regulation, the classification of such solutions in accordance with the UN RTDG Model Regulations and the interplay between those Regulations and the EU legislation on the carriage of dangerous goods.

The Commission Decision concludes that the products of the biocidal product family which contain hydrogen peroxide in concentration of 12% should be classified as Oxidising liquid, Packing Group III, in accordance with the UN RTDG Model Regulations, corresponding to Oxidising liquid, Category III, in accordance with the CLP Regulation. No Member State objected to the proposed Decision.

The Commission informed that the vote in written procedure will be launched without delay after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the on unresolved objections regarding the terms and conditions of the provisional authorisation of a biocidal product containing 5-Chloro-2-methyl-2H-isothiazol-3-one (C(M)IT) referred by France in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP73-Doc.B.04)*

The Commission introduced the draft Decision which aims to resolve a disagreement raised in a mutual recognition procedure of a provisional authorisation. The disagreement was on the possibility to set risk mitigation measures for treated articles at the product authorisation stage.

One Member State noted that some of the dates mentioned in recital 2 of the draft Decision were not correct. The Commission agreed to amend them as required. Another Member State communicated its intention to abstain as the underlying matter is being discussed in the expert group of the Competent Authorities for Biocidal Products and they expressed concerns that this decision may set a precedent. The Commission indicated that it will clarify in the minutes of the meeting that the decision does not pre-empt the ongoing discussions in the expert group, and that, depending on the outcome of the discussions in the expert group, this decision may be revised, and invited the Member State to reconsider its position.

The Commission informed that the vote in written procedure will be launched without delay after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Konservan P40 in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP73-Doc.B.05)*

The Commission introduced the draft Decision which aims to resolve a disagreement raised in a mutual recognition procedure. The disagreement concerns the dermal absorption value and migration rate of permethrin to be used for the human risk assessment for the product.

The Commission explained that it had sought the opinion[1] of the BPC on the matter and that the draft Decision follows the conclusion of the opinion. Therefore it is considered that the product meets the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the authorisations granted by Member States stipulate the condition that the biocidal product shall not be used for manufacturing of clothing intended for use by the general public.

One Member State suggested restricting the product to use in clothing for forest workers and soldiers only. However, the Commission noted that the conclusion in the BPC opinion is that the product complies with Article 19(1), point (b)(iii) provided it is not used for manufacturing of clothing for the general public.

Another Member States indicated its intention to abstain, as they were not concerned Member State in the mutual recognition procedure for this product.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on unresolved objections regarding the terms and conditions of the authorisation of the biocidal product Teknol Aqua 1411-01 in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP73-Doc.B.06)*

The Commission introduced the draft Decision which aims at solving a disagreement raised in a mutual recognition procedure concerning a wood preservative intended to be used for preservation of wood in use class 2 (indoor use) and use class 3 (outdoor use, not in contact with the ground). The disagreement concerned the presence in the product, in very low concentration (significantly below 0,1%), of three non-active substances (D4, D5 and D6) which have been identified as PBT and vPvB in accordance with Annex XIII to the REACH Regulation. According to the Member State having raised the disagreement, those non-active substances should be considered substances of concern and the application of Point 48 of Annex VI to the BPR should lead the evaluating body to conclude that the biocidal product does not meet the condition laid down in Article 19(1) point (b)(iv), and, therefore, the use class 3, in which a partial leaching of the product in the environment is expected, should not be authorised. The reference Member State considered that, given the very low concentrations

[1] https://echa.europa.eu/documents/10162/3443002/konservan_p40_bpc_opinion_en.pdf/bc6eca40-f4c5-90de-72f8-15e42df14995?t=1635932979584

of these non-active substances their presence in the product does not result in unacceptable effects on the environment.

The Commission referred to the discussion at the expert group of Competent Authorities for Biocidal Products during its meeting in June 2021[2], where the note for guidance on categorisation of a biocidal product containing a non-active substance identified as PBT and/or vPvB had been agreed, and which had been instrumental in preparing the draft Decision. For reasons of coherence, the same concentration limit (0.1%) as agreed in the expert group should be applied to determine whether a non-active substance identified as having PBT and/or vPvB properties and contained in a biocidal product is a substance of concern.

The Commission further indicated that one important element in the definition of a substance of concern, laid down in Article 39(1)(f) of the BPR, is that the substance is present or produced in a biocidal product in sufficient concentration to present risks. Following the reasoning detailed above implies that, since the total concentration of D4, D5 and D6 in the biocidal product is lower than 0,1%, these non-active substances are not to be considered substances of concern. Therefore, point 48 of Annex VI to the BPR is not applicable and it can be concluded that the product does not have unacceptable effects on the environment due to the presence of these non-active substances.

The Commission informed that the vote in written procedure will be launched without delay after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the Ministry of Health of the Czech Republic 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 *(SCBP73-Doc.B.07)*

The Commission introduced the draft Decision which aims at allowing the Czech Republic to extend to 550 days the temporary permit granted for the biocidal product Biobor JF. The Commission indicated that the content of the draft Decision corresponds to the Decisions addressed to other Member States already adopted for the same biocidal product.

The Commission informed that the vote in written procedure will be launched without delay after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing 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 of the biocidal product Micronclean Hand Sanitiser in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP73-Doc.B.08)*

[2] The minutes of the meeting are available at https://circabc.europa.eu/w/browse/2b1ea6b5-4b37-49d4-853e-370458c5a3f8

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by United Kingdom Health and Safety Executive permitting the making available on the market and use of five biocidal products for hand disinfection in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP73-Doc.B.09)*

Points B.08 and B.09 were discussed jointly, as they regarded draft Decisions which aim at allowing the United Kingdom to extend to 550 days in respect of Northern Ireland the temporary permits granted for hand disinfection products. The first decision relates to the permit for a product containing propan-2-ol as active substance and the second relates to the permits for five products, of which four contain propan-2-ol and one contains active chlorine released from sodium hypochlorite as active substance.

The Commission informed that the vote in written procedure will be launched without delay after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product "ARIEL chlorine Professional System 5 Chlorine Bleach for white wash" *(SCBP73-Doc.B.10)*

The Commission explained that in the light of the comments submitted by some Member States on the draft Regulation, additional time would be needed to clarify how to express the concentration of the ingredients of the product in Section 2.1 of the Specific Product Characteristics document (SPC) in case the active substance is released from a releaser. The Commission proposed to table this technical question for the next meeting of the BPC.

ECHA commented that neither the BPC itself nor its Working Groups had addressed the question in detail. ECHA therefore agreed to address the question at the next BPC meeting to ensure harmonisation for similar cases.

The evaluating Member State agreed with the Commission and ECHA that the issue needed further clarification.

The Commission concluded that a harmonised approach both for Union Authorisations and Mutual Recognition of national authorisations would be desirable and that the question should be discussed at technical level. If necessary, the IT tool supporting the drafting of the SPC should be adapted as quickly as possible to the decision to be taken. Depending on the progress made, the Commission will come back with a new draft Regulation for the meeting of the Committee in December 2021 or will consult the Committee in writing beforehand.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision allowing Belgium to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage *(SCBP73-Doc.B.11)*

The Commission introduced the draft Decision which intends to allowing Belgium to authorise products consisting of in-situ generated nitrogen which it considered essential for the protection

of cultural heritage and explained that it corresponded to the Decisions addressed to other Member States already adopted on the same matter.

The Commission informed that the vote in written procedure will be launched without delay after this meeting of the Committee.

Outcome of the vote by written procedure that took place between 18 October and 12 November 2021: favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views on a draft Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 on a product containing Alkyl (C12-16) dimethylbenzyl ammonium chloride and marketed as a cleaning product *(SCBP73-Doc.C.01)*

The Commission introduced the draft Decision, recalling that it had been prepared following 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)" and made available on the market as a cleaning product. The Commission also recalled that a document summarising and analysing the information made available by the Member State had been presented at the meeting of the Committee in June 2021. The draft Decision states that the product concerned is a biocidal product.

One Member State wondered about the nature of information in the marketing material that would be required to determine that a product is a biocidal product, stressing enforcement problems faced by its national inspectors for similar products if the Decision was too specific in this regard.

One Member State stressed that some recitals in the draft Decision would be useful for the purposes of enforcement also in other cases.

One Member State considered that the categorisation of a product as a biocidal product is based on a case-by-case assessment and pointed to relevant ongoing work in the BPR Subgroup of the Forum for Exchange of Information on Enforcement.

Another Member State was of the view that the Articles of the draft Decision should make reference to the marketing material.

One Member State stressed that some detergents on the market contain biocidal active substances in efficient concentration to act as biocidal products.

A further Member State suggested to delete the indication of the concentration of the active substance in the Article as otherwise companies could try to circumvent the Decision by lowering the concentration below that level.

The Commission invited the Member States to submit their comments and drafting suggestions within one month.

Section D AOB

D.01 Information on Article 3(3) request

The Commission informed that it had recently received an Article 3(3) request from a Member State concerning a product made available on the market and intended to repel cats and dogs

for which the active substance is ‘capsicum oleoresin expeller pressed’. Further details will be provided at the next meeting of the Committee.

D.02 Corrective act to shorten the length of a granted Union authorisation

The Commission informed that for a recently adopted Implementing Regulation granting a Union authorisation, a corrective act with retroactive effect will need to be prepared in order to shorten the duration of the authorisation to five years (instead of ten), since one of two active substances contained in the product meets the substitution criteria.

D.03 Update on the application for inclusion of in-situ generated nitrogen into Annex I to the BPR

The Commission informed that it had recently contacted the prospective evaluating competent authority, which is in contact with the prospective applicant and its consultants and according to the information received, the application is expected to be submitted in October 2021.