

# **EUROPEAN COMMISSION**

Health and Food Safety Directorate General

# **Standing Committee on Biocidal Products**

24 June 2022 10:00 – 17:00 Webex meeting

CIRCABC Link: https://circabc.europa.eu/w/browse/2c6ec631-2c9e-41fa-b1b1-e8d316924b64

### MINUTES

### Section A <u>Information and/or discussion</u>

A.01 Adoption of the Agenda

One Member State expressed concerns about the late availability of some documents intended for agreement and informed they will not be able to express a position on those documents. The Commission apologised for the late distribution of these documents, due to the high workload and resource limitations, and clarified that the vote on the drafts in section B will be launched via written procedure after the meeting. Therefore, there will be sufficient time for Member States for internal consultations before expressing their position. The agenda of the meeting was then adopted.

A.02 Adoption of the minutes of the 75<sup>th</sup> SCBP meeting

One Member State noticed that one of their comments provided in writing had not been included in the minutes. The draft minutes of the 75<sup>th</sup> SCBP meeting were then adopted, with the inclusion of the comment in question.

A.03 Exchange of views on the examination of the approval of cyanamide for use in biocidal products of product-type 3 and 18

Following the earlier consultation of the Standing Committee on whether the conditions for approval for cyanamide are met, the Commission proposed to proceed with a draft decision for non-approval. In the light of the outcome of the evaluation, the applicant had not demonstrated that a product containing cyanamide would have no unacceptable effects itself, or because of its residues, on human or animal health, or on the environment, based on the data available. In particular, it had not been established that there would be no unacceptable risks arising from the endocrine disrupting properties of this active substance for human health and the environment (non-target organisms). An essential requirement to allow an approval is therefore not met. Five Member States had already indicated that they could support that conclusion.

The Commission requested the views of the Member States who had not yet expressed their opinions before moving forward with the decision.

Five additional Member States informed to agree with the Commission. One of them considered in addition that there is no indication that the substance is needed for pig stables disinfection within its territory.

One Member State asked whether for backlog dossiers on substances identified as endocrine disruptors, the conclusions would be always that the substance could not be approved if no unacceptable risks could be demonstrated. The Commission replied that this is a case-by-case analysis, recalling that for cholecalciferol and DBNPA which were not backlog dossiers, the risks had been found acceptable. In general, it is expected that the BPC would conclude based on the availability of data and methodologies to assess the risks for endocrine disruptors. The Commission informed the Standing Committee that in a response to a letter from the applicant for approval, the Commission had indicated that a non-approval will be proposed.

**A.04** Exchange of views on the examination of the approval of DBNPA for use in biocidal products of product-type 4

Taking into account the former consultations of the Standing Committee on the subject, the Commission concluded that the majority of Member States considered that the criteria for derogation to exclusion under Article 5(2) seem not be met as alternatives are available, which is a key consideration to assess the derogation criteria. Six Member States already indicated that they would support a non-approval although for different reasons. The Commission asked the other Member States to inform whether they could support the non-approval of DBNPA for PT4.

Eleven Member States indicated that they supported non-approval.

The Commission asked the Member States to follow up in writing to explain if they considered the risk of using DBNPA reflected in the BPC opinion as negligible, in order to gather more views on how Member States assess this criteria from the BPR. ECHA concurred with the request of the Commission and requested more clarity on the concept of negligibility of the risks identified. It would be also useful to clarify whether the availability of alternatives would take precedence on the assessment of the risks. Three Member State spontaneously indicated that the availability of alternatives with a better profile is a key consideration and is sufficient to motivate a non-approval. Another one mentioned that both the risks for human health and for the environment cannot be considered negligible, and that alternatives exist.

The Commission invited Member States to send their views within three weeks to help the Commission to prepare the rationale for the non-approval.

**A.05** Exchange of views on the cancellation of the approval of tolylfluanid as an active substance for use in biocidal products of product-type 7

The Commission introduced the background of this item and highlighted that this is the first time that the Commission proposes to cancel the approval of an active substance. One Member State mentioned that it supports the proposal of the Commission. No other comments were made. The Commission informed that the vote on the draft Regulation for cancelling the approval of this substance will be launched in written procedure in early September.

A.06 Exchange of views on the approval of (13Z)-Hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19

The Commission explained that this active substance is a pheromone used as an attractant for the control of pine processionary moths by mating disruption. The BPC recommendations specified that only professionals should be allowed to apply biocidal products containing the substance by using a specific mode of application. This restriction was motivated by the adaptation of the data requirements accepted by the eCA and the BPC. If used in other types of product formulations and conditions of use, some of the waivers may no longer be acceptable and additional data on the active substance may have to be submitted.

This restriction might however be a deterrent to innovation for the development of other PT19 attractant products containing the substance but used under other conditions. If approved with these restrictions, an applicant would have first to submit an application to request the modification of approval, before being able to apply for product authorisation. In addition, the current practice so far has been to introduce restrictions at the approval stage only in case unacceptable risks are identified, which has not been the case in this dossier. The Commission asked for the views of the Committee on whether the substance should be approved with restrictions or if a more open approach could be envisaged.

The evaluating Member State clarified that a restrictive approach is needed because of the structure of the dossier submitted by the applicant. The data package was based on a specific use for which low exposure for human health and the environment could be demonstrated. The applicant did not propose any other use. The Commission answered that a restriction may not be the right tool to capture the situation. A recital could for example explain the circumstances of the assessment as explained above and clarify that for other uses, a more comprehensive data package should be submitted as part of the product application.

Four Member States supported the views of the Commission as active substances of this nature (pheromones) should be in general more widely available for other uses. If the evaluating Competent Authority identified a safe use for the product supported by the data package, it should be also possible to submit additional data for another type of formulation and uses at the product authorisation stage.

Two Member States supported the more restrictive approach. One of them argued that requesting Member States to pay particular attention for other uses not covered by the approval at the product authorisation stage would not be less burdensome as additional information on the active substance would have to be submitted in the authorisation dossier. The Commission replied that this case could well be handled during product authorisation which is less burdensome than requiring an amendment to the approval decision.

The Commission concluded the discussion by opening a newsgroup until mid-August.

A.07 Exchange of views on the approval of Alkyl (C12-16) dimethylbenzyl ammonium chloride (C12-16-ADBAC/BKC) as an active substance for use in biocidal products of product-type 2

The Commission introduced the background of this item, highlighting the BPC opinion proposing the approval of the substance, as well as the minority opinions expressed on the environmental risk for the soil compartment and due to lack of sufficient time during the peer review process to assess the proposals for a revision in the environmental risk assessment. The Commission also reminded the Committee of the applicant's letter circulated prior to the meeting with an argumentation against the concerns raised in the minority opinions.

ECHA mentioned that a recent soil degradation test on ADBAC/BKC was submitted and available for the evaluation of the applications for approval in PT 1 and 2, which had not yet been available for previous PTs. It provides new additional evidence on degradation despite

strong sorption. This study had thus not been taken into consideration in the CAR to support degradation in the Sewage Treatment Plant (STP) or refining the fractions released from the STP to soil. It had also not been discussed by the Environment Working Group for the following reasons:

- a) There was no exceedance of the PEC/PNEC ratio of 1 (no risk) before the Environment Working Group meeting. Only when the risk assessment was adjusted taking into account the Environment Working Group conclusions, a risk was identified for soil and this became clear only after the Environment Working Group meeting.
- b) Since there was no risk, there were no issues raised or comments made in regard to looking at the soil degradation test as additional argument, neither by the applicant nor by any commenting Member States in the RCOM table (which is the basis for identifying items for discussion at the Working Group meetings).

However, ECHA was of the opinion that the use of the soil degradation study to support the use of the study on degradation in the STP could have had an impact on the outcome of the risk assessment, i.e. revealing that the risk in the soil assessment is acceptable. In addition, ECHA also stressed that the BPC had concluded already in this direction. Thus, ECHA pointed out that this discussion would not need to go back to the Environment Working Group.

Two Member States requested for additional time to address the above issues with their related experts.

The Commission proposed to further discuss this issue in a dedicated meeting between the interested Member States and ECHA, also involving the evaluating Competent Authority (eCA). This group should report back to the Commission by late August. ECHA and the Member States agreed to this approach.

A.08 Update on the application for approval of ethylene oxide as an active substance for use in biocidal products of product-type 2

The Commission explained that following detailed legal analysis the representative product presented in the approval dossier i.e. the disinfection of single use medical device before packaging falls within the scope of the Medical Devices Regulation (MDR) and not the Biocidal Products Regulation (BPR). The Commission intends to discuss with the eCA and the applicant to see if another representative product could be included in the dossier submitted under the BPR.

A.09 Exchange of views on the Union authorisation of the product ARCHE chlorine

The Commission recalled the discussion at the last meeting of the Standing Committee on this topic. Two questions were still open. One Member State authority had expressed concerns about the risk mitigations measures proposed by the BPC to mitigate the risks for surface water when the product is used to treat wastewater in a wastewater treatment plant, which is subsequently discharged. The concerned Member State supported the approach explained in a note provided by the Commission for this meeting, i.e. that national standards for active chlorine can be established for surface water at local level. That Member States therefore withdrew its request for derogation under Article 44(5) of the BPR.

The second issue concerned the use for swimming pool disinfection not recommended for authorisation because of a lack of demonstrated efficacy against viruses. The applicant eventually agreed with the conclusions and submitted an application for national authorisation in one Member State that contains such information. A law firm asked whether the publication of the Union authorisation could be postponed until the national authorisation is granted to avoid disruption in the supply of the product to swimming pools.

The Commission proposed not to extend the time to take decision on this dossier too much longer because the transition period laid down under Article 89(3) of the BPR has long been exceeded. Member States agreed with the position of the Commission.

## Section B Draft(s) presented for an opinion

**B.01** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of creosote as an active substance for use in biocidal products of product-type 8

The Commission presented the draft Regulation, which had been prepared in the light of the outcome of the earlier discussions on the renewal of the approval of creosote at previous meetings of the Committee.

The Commission explained that the draft contains the reasoning for the uses which are considered to fulfil the criteria of Article 5 (2) and explanations on the functioning of the list for the placing on the market of treated wood in accordance with the outcome of the discussions and information provided by the Member States. The additional three uses requested by individual Member States were not included. To provide sufficient time for alternatives to penetrate the market, , an approval for 7 years is proposed. In the Annex, the minimum purity of creosote is specified in line with the REACH restriction. The list of Member States agreeing to the placing on the market of treated wood for the two possible uses will be established by ECHA by 31 January 2023. Member States need to make a request to ECHA to be included for the respective use(s) they allow for treated wood. The UK had requested that Northern Ireland be included in the list for both uses (railway sleepers and utility poles).

One Member State provided information on the status of the REACH restriction dossier for creosote submitted in February 2022, which is currently discussed at the stage of admissibility before it can be assessed by RAC and SEAC of ECHA.

On request by a Member State, the Commission clarified that the approval can only cover the first placing on the market of treated articles, while the subsequent making available and use are expected to be covered by the REACH restriction, and that the treatment of wood for export outside the EU is not covered by the BPR.

The Commission also informed that references to specific alternative products will be removed from the draft Regulation. The proposed periods of grace for products and treated articles were clarified.

One Member State indicated that they will not support the proposal for renewal of approval as they already managed to phase out creosote from their market.

The Commission informed that drafting suggestions could still be sent until 15 July 2022 and that the consultation of the Standing Committee by written procedure will be launched in September.

**B.02** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving (L+) lactic acid as an active substance for use in biocidal products of product-type 6

The Commission presented the draft Regulation that includes in its Annex conditions for the placing on the market of a substance or mixture treated with or incorporating L-(+)-lactic acid at concentrations leading to classification of the substance or mixture for local effects concerning skin corrosion / irritation or eye damage / eye irritation and acute toxicity regarding corrosivity to the respiratory tract, labelling provisions in accordance with Article 58(3), second subparagraph, of the BPR and the possibility for Member States or the Commission to specify in the summary of the biocidal product characteristics of a biocidal product containing L-(+)-lactic acid the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012.

The Commission recalled that these provisions had been discussed with Member States and stakeholders in the meeting of the expert group of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

One Member State indicated to support the proposal and asked how to implement it for imported treated articles. The Commission replied that there is no specific provision on imported treated articles as Member States had found earlier proposals from the Commission not enforceable in practice.

The Commission informed that drafting suggestions could still be sent until 15 July 22. The consultation of the Standing Committee by written procedure will be launched in September.

**B.03** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision not approving methylene dithiocyanate as an existing active substance for use in biocidal products of product-type 12

The Commission introduced the background for the draft Decision. No Member States had any comments. The Commission informed that the vote for the non-approval of this substance will be launched in written procedure in September.

- **B.04** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide as an active substance for use in biocidal products of product-type 19
- **B.05** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving *Chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents as an active substance for use in biocidal products of product-type 19

The Commission introduced the background of the items B.04 and B.05) together and mentioned two letters, which had recently been sent to the Commission on behalf of the applicants, requesting to suspend the decision for approval of these two active substances, due to issues associated with the endpoints and reference specifications of the substances. The Commission explained that it had consulted ECHA on these two letters, and that a delay for the approval of the substances is not justifiable. Therefore, the Commission proposed to proceed with the approval of *Chrysanthemum cinerariaefolium* extracts for PT19.

One Member State pointed out that they will not support the approval of the *Chrysanthemum cinerariaefolium* extracts because the evaluations were carried out based on the provisions of Directive 98/8/EC on biocidal products (the BPD) and not following the BPR provisions. No other comments were made.

The Commission informed that the votes on the draft Regulations for the approval of these two active substances will be launched in written procedure in September.

**B.06** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving didecyldimethylammonium chloride as an active substance for use in biocidal products of product-types 1 and 2

The Commission introduced the background of this item. One Member State pointed out that they will not support the approval of didecyldimethylammonium chloride because the evaluation was carried out based on the BPD provisions and not following the BPR provisions. Another Member State mentioned that it will support the proposal for approval. No other comments were made.

The Commission informed that the vote on the draft Regulation for the approval of this active substance will be launched in written procedure in September.

**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 tebuconazole for use in biocidal products of product-type 8

The Commission introduced the agenda item, and highlighted and corrected an error regarding the dates mentioned in recital 7: *...expects to submit the renewal assessment report to the Agency in the first half of 2024*' - instead of May 2025. The new expiry date was also corrected to 30 June 2026 instead of 30 September 2026 (recital 8 and Article 1).

The Commission explained that tebuconazole might possibly meet the exclusion criteria of the BPR (Repr. 1B, ED) according to the on-going evaluation, and that additional time will be needed to decide on its approval or non-approval. If it meets the exclusion criteria, a public consultation on possible alternatives will be needed to verify whether the criteria for derogation from exclusion in Article 5(2) of the BPR are met. Taking into account that the evaluating competent authority expects to submit the renewal assessment report to ECHA in the first half of 2024, the Commission proposed to postpone the expiry date of the approval of tebuconazole to 30 June 2026.

One Member State mentioned that they do not support the extension of tebuconazole until 30 June 2026, but proposed an extension of 1,5 year, aiming to deliver the overall message that there is a need to speed-up the process of renewals. The Commission replied that although it fully agreed that there is a need to speed-up the process for renewals, there is a need for realism, since it is already a certainty that the prolongation of 1,5 year will not be enough for the case of tebuconazole. The Commission invited this Member State to reconsider its position.

The Commission informed that the vote on the draft Decision for the extension of approval of tebuconazole will be launched in written procedure without delay after this meeting of the Committee.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: 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 spinosad for use in biocidal products of product-type 18

- **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 etofenprox for use in biocidal products of product-type 8
- **B.10** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of medetomidine for use in biocidal products of product-type 21
- **B.11** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of K-HDO for use in biocidal products of product-type 8
- **B.12** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of approval of IPBC for use in biocidal products of product-type 8
- **B.13** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of approval of DDACarbonate for use in biocidal products of product-type 8
- **B.14** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision postponing the expiry date of the approval of acrolein for use in biocidal products of product-type 12

Items B.08 to B.14 were discussed jointly. The Commission briefly introduced the draft decisions, which intended to extend the expiry date of the approvals of the listed active substances due to delays in the completion of the respective evaluation processes.

One Member State informed the Commission that it will abstain in the vote on the draft Decision for the extension of the expiry date of medetomidine because it is a candidate for substitution under the BPR. Another Member State proposed that the extension of the expiry dates for all active substances should be no more than 1,5 year. The Commission pointed out that it is already known with certainty that a prolongation of 1,5 year will not be enough for all the substances concerned (B.08 to B.14) and invited this Member State to reconsider its position.

The Commission informed that the votes on the draft Decisions 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 8 July 2022 and 5 August 2022: favourable opinion for all seven acts.* 

**B.15** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 on a product containing '*Capsicum* oleoresin expeller pressed'

The Commission introduced the draft Decision and explained that, following the comments received during the public consultation on the draft, some changes had been made compared to the version distributed for the previous meeting of this Committee. To address the concern that the scope of the decision would cover also self-defence capsicum sprays, references to the intended use were included in recital (2) and in Article 1 of the draft Decision. Also, since the product manufacturer claimed that their capsicum oleoresin is different from the one for which information is available on the ECHA website, the reference to this information was removed from the draft Decision.

The Commission also informed that a meeting with the product manufacturer had taken place at the end of May 2022. During the meeting the Commission had explained in detail the main elements of the Decision to the manufacturer and had informed it that, once the legal act is adopted, the manufacturer will have twelve months to make a declaration of interest to notify its intent to seek the approval of the substance, pursuant to Article 15 of the Review Programme Regulation, which makes reference to wrong guidance received by applicants. The Commission had also invited the manufacturer to liaise with ECHA in order to clarify the substance identity, since this is a crucial element in the declaration of interest to notify. The company committed to make efforts to ensure compliance of the product with the national requirements in those Member States where the product is made available (Belgium, Luxembourg, Netherlands and France). The Commission invited these Member States to work constructively with the manufacturer in their efforts to have the product legally made available on the market.

One Member State informed to have been contacted by the manufacturer on the issue. In reply to a question from this Member State on the possible future status of the active substance (Review Programme or Annex I substance), the Commission clarified that assessing whether the criteria for inclusion into Annex I are fulfilled is in ECHA's remit. The same Member State mentioned that they are not in a position to act as evaluating Member State for a potential future application for substance approval/inclusion into Annex I and informed the other Member States that they might be contacted by the manufacturer with regard to their willingness to act as evaluating Member State. ECHA also informed to have been in touch with the manufacturer; however, no technical details had been discussed at this stage.

The Commission informed that the vote on the draft Decision in written procedure will be launched in the course of July.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.16** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Preventol A12 TK50 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

The Commission presented the draft Decision to resolve the disagreement in the coordination group for the authorisation of this product that contains propiconazole as active substance. The disagreement related to the risk mitigation measures for placing on the market of treated articles treated with or incorporating the product, which according to the Member State that initiated the disagreement can only be included in an authorisation of a biocidal product if they are referred to in the conditions of approval of the active substance.

The Commission explained that the necessary conditions or restrictions for ensuring a safe use of the biocidal product taking into account the way in which treated articles treated with or containing the biocidal product may be used were indeed not set in Implementing Regulation (EU) 2015/1609 by which propiconazole was approved for product-type 7 and in accordance with Article 58(3) cannot be laid down in the authorisation of the biocidal product, the use of the biocidal product in the treated articles would have unacceptable effects on human health and the environment.

Consequently, the Commission considered that given that the safe use of the biocidal product in treated articles cannot be ensured only by imposing conditions on the use of the biocidal products in the treated articles without simultaneously imposing obligations on the persons placing on the market of treated articles, the product does not meet the conditions laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012. One Member State asked whether, in case the product is needed in a Member State, it can be authorised in accordance with Article 19 (5). The Commission replied that in principle it seems possible to do so.

One Member State indicated that it supported the draft Decision, while it would have preferred a more flexible approach to the setting of risk mitigation measure for treated articles in the authorisation of biocidal products and noted that it is impossible to cover all possible uses and related mitigation measures at the approval stage of the active substance. That Member State also indicated that they supported that an early review of the approval of propiconazole for PT-7 and PT-9 has been initiated as it will help to resolve this issue.

The Commission informed that it had consulted the applicant on the draft Decision, and to be able to take potential comments on board, the vote on the draft Decision in written procedure will be launched in September.

- B.17 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Mouskito Spray in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council
- B.18 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal products Mouskito Junior Lotion in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

Points B.17 and B.18 were discussed jointly, as they related to the same point of disagreement raised during the mutual recognition of the authorisations for two products having a similar composition. The products under discussion are ready-to-use products intended to protect human skin from bites of various insects, among which bees and wasps.

The Commission explained that the outstanding point of disagreement, which the draft Decisions intended to settle, concerns the claimed efficacy of the products against wasps and bees, which, according to the initiating concerned Member State, had not been demonstrated in the simulated-use test provided by the applicant. In order to decide on this matter, the Commission had requested an opinion from ECHA according to Articles 36(1) and 38 of the BPR.

According to the ECHA opinion, the data submitted by the applicant from the simulated-use test could demonstrate the efficacy of products intended as spatial or surface repellents, but the test is not relevant for the intended use, that is topical repellents against wasps and bees to be applied on human skin. The treated surface of the traps in the test performed does not sufficiently mimic the practical use situation, therefore the test design cannot be considered suitable to demonstrate efficacy of the products for the claimed use.

In light of the ECHA opinion, the draft Decisions conclude that the condition in Article 19(1) point (b)(i) of the BPR cannot be considered to be met for the use of the products as repellents against wasps and bees.

The Commission informed that the vote on the draft Decisions in written procedure will be launched in the course of July 2022.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.19** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "CMITMIT SOLVENT BASED"

The Commission presented the draft Regulation for authorisation of the biocidal product family which reflected the requests made by Germany and Denmark to adjust the conditions and not to apply the Union authorisation, respectively, of the biocidal product family "CMIT/MIT SOLVENT BASED" in the respective territories of those Member States in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012 justified on the grounds of the protection of the environment and the protection of health and life of humans pursuant to Article 37(1), points (a) and (c), of that Regulation as the presence of halogenated organic compounds, such as C(M)IT/MIT, in fuel may result in the formation of dioxins during fuel combustion.

Two further Member States indicated their intention to submit requests for adaptation of the Union authorisation in their territories, based on the same grounds as Germany and Denmark, one of them also raising concerns as regards compliance with Regulation (EU) 2019/1021on persistent organic pollutants with regard to dioxins.

Another Member State welcomed the adaptation of the authorisation for their territory and expressed the opinion that this product should not be authorised because of the Stockholm Convention's obligations with regard to dioxins.

The Commission reminded the Member States that this issue had been extensively discussed in earlier meetings of this Committee, including its compatibility with the Stockholm Convention and the EU Regulation on persistent organic pollutants. Member States had had ample opportunities to submit requests for derogation at earlier stages of the process. Nonetheless, the Commission informed that Member States can still send their request for adaptation of this Union authorisation until 15 July 2022.

**B.20** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for single biocidal product "Ecolab UA Lactic acid single product dossier"

The Commission presented the content of the draft Regulation. No Member State had any comment. The Commission informed that the vote on the draft Regulation in written procedure will be launched in the course of July.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.21** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Active chlorine based products BPF - CID LINES NV"

The Commission presented the content of the draft Regulation. One Member State indicated not to be in favour to authorise the product to be consistent with the minority opinion of the member of the BPC appointed by that Member State. For this Member State, the safety of workers applying this corrosive product by coarse spraying cannot be ensured. This Member State explained that their view is consistent with similar decisions taken at national level including in mutual recognition. The Commission however clarified that the topic had been extensively discussed at the BPC and that the experts decided to not take into account the arguments put forward by the member appointed by that Member State.

The Commission informed that the vote on the draft Regulation in written procedure will be launched in the course of July. However, in the note announcing the vote on various draft Regulations and Decisions in written procedure dispatched in July, the Commission explained that the vote on this draft Regulation had to be postponed pending further clarification on how to address the identified risks and if the proposed authorisation is consistent with national authorisations.

**B.22** Examination procedure Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product "Christiansen LD Bednet"

The Commission presented the content of the draft Regulation. One Member State expressed concerns about the length of the authorisation period taking into account that the active substance fulfils the criteria for substitution. That Member State will vote against the draft Regulation. The Commission recalled that in its view, a substance can only be recognised as fulfilling the substitution criteria when this is indicated in the approval or renewal decision, which is not the case for the active substance contained in the product. Therefore, the Commission could not accommodate the request of the Member State. The Commission informed that the vote on the draft Regulation in written procedure will be launched in the course of July 2022.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.23** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product "Hokoex"

The Commission presented the content of the draft Regulation. One Member State expressed concerns about the fact that the active substance fulfils the criteria for substitution because it generates a substance that is suspected to meet two of the substitution criteria. The Commission replied that this had not yet been confirmed by the BPC, nor is it stated in the approval of the active substance. The Commission informed that the vote on the draft Regulation in written procedure will be launched in the course of July.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.24** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Ecolab UA BPF 1-Propanol"

The Commission presented the content of the draft Regulation. No Member State had any comment. The Commission informed that the vote on the draft Regulation in written procedure will be launched in the course of July

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.25** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "IPA Family 1"

The Commission presented the content of the draft Regulation. No Member State had any comment. The Commission informed that the vote on the draft Regulation in written procedure will be launched in the course of July.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.26** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Colgate-Palmolive\_Lactic acid\_PT 2"

The Commission introduced the draft Decision.

On a general note, one Member State asked whether the opinion of the BPC could be made available on CIRCABC together with the draft Regulation. That Member State also asked whether in case the duration of the authorisation is less than 10 years, this would be specifically mentioned in the draft Regulation. The Commission indicated that the final BPC opinion is available to all Member States and the Commission via R4BP3, even if not yet published. Nevertheless, the Commission agreed that the opinion could be uploaded on the CIRCABC website of the Committee as it is not always available in due time on ECHA's public webpage. ECHA will check if there is a possibility to accelerate the publication of the opinions when the draft agenda of the Standing Committee is published. The Commission added that the duration of the authorisation is always indicated in the draft Regulation and is 10 years by default unless a shorter authorisation period is justified. The Commission informed that the vote in written procedure on the draft Regulation will be launched in the course of July.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.* 

**B.27** Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision allowing Finland to authorise products consisting of in-situ generated nitrogen

The Commission introduced the draft Decision, mentioning that its text is almost identical to that of the other nine similar Decisions adopted so far, with the only difference that recital (15) indicates that an application for inclusion of in-situ generated nitrogen into Annex I to the BPR had been submitted to the competent authorities in Germany in March 2022. The Commission also informed Member States that during the consultation of the Commission services concerned, a request had been made to include in the actual authorisations of the products a sentence stating that the authorisation applies without prejudice to workers' protection legislation. Member States were invited to include this sentence whenever granting authorisations for products consisting of in-situ generated nitrogen.

The Commission enquired whether, following the previous decisions, Member States had actually granted any authorisation for products consisting of in-situ generated nitrogen. One Member State informed to have granted one authorisation, while another Member State stated to have received one application for authorisation.

The Commission informed that the vote on the draft Decision in written procedure will be launched in the course of July.

*Outcome of the vote by written procedure that took place between 8 July 2022 and 5 August 2022: favourable opinion.*