27 September 2023

BPC-M-47-2022

Final non-confidential minutes of the 47th meeting of the Biocidal Products Committee (BPC)

05-07 June 2023

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 47th BPC meeting which took place as a hybrid meeting – both in ECHA premises in Helsinki and via Webex.

The Chair then informed the BPC members of the participation of 27 members, including three alternate members.

25 Advisers and 5 representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Six representatives from the European Commission and one EFSA observer attended the meeting.

Applicants were invited and present for their specific substances under agenda item 7, biocidal products under agenda item 8, Article 38 item under agenda point 9 and Article 75(1)(g) under agenda point 10 where details are provided in the summary record of the discussion for the substances and in Part III of the minutes.

2. Agreement of the agenda

The Chair introduced the final draft agenda (BPC-A-47-2022_rev2) and invited any additional items. No additional items were presented and the agenda was adopted. The final version of the agenda will be uploaded to the BPC Interact/Website as part of the meeting minutes.

The Chair informed the meeting participants that the meeting is recorded for the purpose of the minutes and that the recording would be deleted after the agreement of the minutes.

The list of meeting documents and the final version of the agenda are included in Part IV of the minutes.

3. Declarations of potential conflicts of interest to the agenda

The Chair invited BPC members, alternates and advisers to declare any potential conflict of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-46

The revised confidential and non-confidential draft minutes from BPC-46 (BPC-M-46-2023), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-46 meeting were carried out.

Actions:

- **SECR:** to upload the agreed minutes from BPC-46 to the BPC Interact and the non-confidential minutes to the ECHA website after the meeting.

5. Administrative issues

5.1 Administrative issues

The **Chair** informed the meeting that the next meeting will be virtual and the meeting in November face-to-face. The **Chair** informed the meeting on the status of the recruitment of the new **Chair**.

The **Chair** informed the members on the upcoming consultation for the update of the Guidance on IR&CSA Chapter R.11 and specific sections of Chapters R.7b and R.7c. Members to receive next week an email from ECHA PBT Expert Group functional mailbox asking their inputs in the form of an Interact collaboration by 7 July. The Chair mentioned that only BPC members will be included and not the Environment WG members. Therefore, BPC members were asked to contact their Environment WG members, where relevant.

6. Work Programme for BPC

6.1 BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC

The Chair informed members that the Work Programme for active substance approval was revised after the last BPC meeting. Members were invited to contact the SECR on possible changes on the revised programme after which an updated version will be published on the ECHA website.

The Chair stated that for 2023 the planned opinions are listed in the “Outlook” document.

The total number of expected adopted opinions for 2023 will be maximum 32 (for process flow (PF) 48 for applications for Union authorisation (UA) 4 opinions are expected to be adopted). For UA as well as active substance approval (AS) there is a decrease in the number of adopted opinions compared to 2022: from 21 to 12 and 19 to 13 (Review Programme 12 to 9), respectively.

Three Article 75(1)(g) draft requests have arrived: i) returning three opinions adopted on UA; ii) one returning 10 opinions adopted for 4 active substances for different PTs; iii) returning one opinion adopted for an active substance for one PT. ECHA is consulting with the Commission (COM) on the draft mandates where one has been added to the agenda under item 9.2.

For the ED overview the Chair informed that the evaluation of the ED properties of salycilic acid (PT 2, 3 and 4) will be submitted by the eCA NL for process flow 50.

The Commission expressed concerns on the general progress which is still insufficient to conclude the Review Programme by 2024. It reminded that Member States must implement the actions agreed at the CA meeting and in the ECHA Active Substance Action Plan. Progress must especially be made on backlog dossiers for which decisions must still be based under the BPD as this is becoming more and more problematic. The Commission urged Greece, Malta, the Netherlands, Poland and Sweden to make progress on their backlog dossiers.

The Chair asked the evaluating Competent Authorities being rapporteur for active substances or Union authorisations scheduled for discussion at the next BPC meeting of 2023 (BPC-48) to confirm their planning to the SECR as soon as possible.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **22 June 2023.**

6.2 Update on active substance approval and Union authorisation

An update on Union authorisation (UA) and Active substance approval (AS) was given by the SECR:

i) Workload on AS and UA

SECR presented the current workload of AS and UA dossiers in the opinion forming process and the overview of new submissions for the opinion forming phase by the eCAs coming in.

ii) Update from AS processes

The SECR informed the members on the publication on the ECHA website of the MSCA planned submissions, and reminded the members to keep the planning document updated in the Interact Collaboration tool.

The SECR reported on the info session on data requests held on 20 April 2023 and thanked them for their participation. The SECR informed that there will be another info session in October 2023.

The SECR updated the members regarding the CLP Regulation revision; the revised Annex I already in force and on the combined CLH-CAR template. The members appreciated the improvement on the coordination between classification and biocides units in ECHA and the update of the combined template. COM invited the MSs biocides (and pesticides) experts to liaise with their CLP experts; and informed on the current discussions on possible transitional measures.

iii) Update from UA processes

The SECR asked the members to keep the planning document updated in the Interact Collaboration tool.

During the meeting, the SECR noted:

- in relation to the PAR and SPC and their preparation. Particularly noting that PAR provided for the opinion forming process should include clear conclusions ofthe eCA;
- ECHA in consultation with the Commission created the SPC checklist for the applicants and the MSs. This is under check in pilot-cases. It is considered to be used together with the Recommendations on preparing SPC for single biocidal products and biocidal product families to check the SPC before eCAs submit the conclusions of the assessment for the opinion forming process;
- Guiding principles on providing data during Union authorisation process is published on the ECHA website and is applicable immediately;

- in order to establish closer relationship between ECHA and the dossier managers in the Member States and streamline the cooperation, the SECR will invite in the future the eCA dossier managers for a short meeting before the dossier is submitted for the accordance check.

In addition, the SECR provided a short update form the Coordination Group meeting.

The SECR informed the BPC that UA working procedure step 6 will be revised in order to reflect the long-established practice that SECR can submit comments (if it considers it necessary) during the commenting period to ensure consistency between BPC opinions. The revised procedure will be published on ECHA website.

Actions:

- **SECR**: to upload the presentation to Interact.

6.3 Procedure for the submission, evaluation and dissemination of data generated after active substance approval

The SECR introduced the topic on Procedure for the submission, evaluation and dissemination of data generated after active substance approval.

The document has been updated with the comments received from the BPC members and stakeholders after its discussion at BPC-46. A cover note was provided explaining the SECR considerations. The following changes were suggested: no revision of the risk assessment of the reference product; the possibility of the eCA of the approval to update the LoEP on a voluntary basis; more clarity on the possible consultation of the WG; a template for Art 75(1)(g) requests; to provide possible timelines, and the information and involvement of the applicant. The document was adopted with those agreed changes.

Actions:

- **SECR**: to update the document with the changes agreed at the meeting and upload the documents to Interact.

7. Applications for approval of active substances

7.1 Draft BPC opinion on Garlic extract for PT 19

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. It was agreed to redefine garlic extract to thermally treated garlic juice. The reason for the redefinition will be explained in the BPC opinion. It was also agreed to clarify in the opinion that emissions of polysulfides reaching soil are attributed to agricultural emission.

The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2023.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish it on the ECHA website.

7.2 Draft BPC opinion on Willaertia subsp. magna, C2c.Maky for PT 11

The Chair informed the members that the applicant will not join the discussion. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table.

An initial application was submitted in 2013, resulting in a non-approval BPC opinion in April 2018. In August 2019 a new application was submitted by the same applicant containing some additional data. After the BPC Working Group discussion in December 2022 the applicant decided to withdraw its application. However, it was decided to continue with the opinion forming process. The conclusions in the assessment report and draft BPC opinion presented at the BPC-47 indicated that the main initial concerns remain unresolved, i.e. (1) an unclear mode of action of the active substance which could lead to Trojan horse effects with a potential risks for human health and the environment, and (2) the lack of evidence of efficacy. Overall, the eCA's evaluation concluded that no safe use of the active substance can be identified and therefore a non-approval is recommended.

During the discussions at the BPC the eCA clarified that the overall conclusion presented in the draft opinion only addressed the environmental assessment but in response to comment #10 of the open issue table this will be amended to cover the overall assessment and all the main issues identified.

Following a question from a member, the SECR clarified the reasons why the evaluation and opinion-making processes were not terminated after the applicant's withdrawal: since the applicant's withdrawal happened after the initiation of the opinion-making process and that no provision exists in the BPR in such cases, it was decided for transparency reasons to finalise the process and publish the opinion. COM confirmed this and indicated that they would pursue with a decision on the non-approval on this case.

The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2023.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.**SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish it on the ECHA website.

7.3 Draft BPC opinion on Pentapotassium bis(peroxymonosulphate) bis(sulphate) for PT 2, 3, 4 and 5

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table.

The substance has been renamed to a more accurate name. It was decided to add also the acronym KMPS to the title of the opinion, as this is the name which is most commonly used to refer to this active substance.

For PT2 the use disinfection of equipment via dipping by professionals – assessed in human health and environmental scenarios - was discussed. The Commission stated that the Medical Devices Regulation (EU) 2017/745 covers products specifically intended for the cleaning, disinfection or sterilisation of medical devices. This means that depending on the type of equipment disinfected, this use may be considered outside the scope of the BPR. A general clarification on this topic is on the agenda of the next CA/SC meeting following the adoption of the opinion on ethylene oxide for PT 2 by the BPC. It was discussed what type of equipment is disinfected for KMPS and whether the use needs to be removed. Another option would be to include a note in the opinion referring to the clarification provided by the Commission that if equipment refers to medical devices the use is outside the scope of the BPR. It was decided that the eCA and the SECR will further look into this use and the type of equipment disinfected. If considered needed by the eCA and the SECR the opinion will subsequently be amended. As other safe uses have been identified, it was concluded that this does not prevent the adoption of the opinion.

For PT 2 the unacceptable risk identified for the use in disinfection of swimming pools in the Southern European countries scenario was discussed. In particular the consequences for product authorisation – as indicated in section 2.4 of the opinion – was discussed. The underlying reason for the different conclusions for the Northern and Southern European countries scenarios was mentioned, i.e. the different number of swimming pools connected to a Sewage Treatment Plant. It was clarified that a refinement of the assessment may be feasible at product authorisation and it will be up to the applicant to demonstrate that there are no unacceptable risks for the environment. It was concluded that there is no need to further specify or define the Southern and Northern European country scenario.

The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2023.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish it on the ECHA website.

7.4 Second renewal of active substance used in anticoagulant rodenticides

The SECR introduced the topic on Second renewal of active substance used in anticoagulant rodenticides. The ASOs were not allowed to be present during the discussion but were afterwards informed of the results which are presented below.

The impact of the evaluation of the ED data on the timeline for submission of the assessments to ECHA should be investigated as well as requesting the APCP data on physical hazards.

A follow-up coordination meeting with the involved eCAs will be organised by the SECR to discuss the way forward.

Actions:

- **SECR**: to upload the documents to Interact.

8. Union authorisation

8.1 Draft BPC opinion on a Union authorisation application for a biocidal product family containing L (+) lactic acid for PT 3

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

A member expressed a general concern regarding the acceptance of *in vivo* data generated by the applicant in deviation of the BPR and CLP animal welfare provisions and established step-wise approaches. It was noted that although the animal data are more reliable then the CLP calculation method, *in vivo* testing should be applied as a 'last resort' and preceded by an applicant's inquiry sent formally to ECHA in this regard. Referring to Article 62 of the BPR, the Commission reminded that vertebrate animal testing should be avoided to the extend possible and the established procedures in that regard should be respected; otherwise, the Member States may consider imposing penalties for applicants in line with BPR provisions. There was a common understanding between the members that existing *in vivo* studies should be considered in the evaluation but the duty of the applicant to make a request to the agency according to the Article 62 of the BPR should be respected. It was concluded that a more detailed explanation may be needed in the Product Assessment Report (PAR) but that the concern raised has no impact on the conclusions of the evaluation.

The applicant in response to a member's question also clarified that the provided qualitative animal health risk assessment does not need to be further revised, as it is based on external limit values and, thus, the agreed 100% dermal absorption for animal health is not impacting the conclusions reached. This was confirmed by the eCA.

SECR recalled that the German CA performed a substance evaluation under REACH for the co-formulant diethanolamine (DEA) and they concluded that there are indications for a potential classification and labelling of the substance as Repro Cat 1B and Carc Cat 2. The (non-peer reviewed) substance evaluation report from the German CA is available on the ECHA website and a CLH proposal to amend the existing CLP Annex 1 entry may be submitted by the end of the year. The underlying data for the German CA conclusion have been disseminated on ECHAs website in the form of robust study summaries. In

order to not pre-empt the outcome of an anticipated CLH-process, the applicant and the eCA did not assess these data for possible additional (self-)classification of the co-formulant with impact on the products. Notwithstanding, the applicant expressed at the meeting that they are working towards phasing out the co-formulant and reformulating the products in this family, which is feasible by year end. Hence, a change application can be submitted following product authorisation. SECR would appreciate a discussion at CA-level on the development of criteria for diverging from the general approach regarding the use of all available data to determine product classification and labeling. In addition, it expressed concern that neither reformulation nor a revised classification an labeling will take place within a reasonable timeframe.

The eCA in response to the SECR intervention stated that the concerns regarding the co-formulant were addressed in the evaluation provided during the opinion forming process. They also stated that SECR should add such concerns in the open issues table in the future to allow the eCA to be better prepared. The applicant reassured that the co-formulant will be replaced and a dossier will be submitted as soon as possible as a change application. The Commission agreed in principle with SECR that there needs to be a conclusion on the classification and labelling in the authorisation. However, in this case it seems that the Working Group was not able to conclude based on the information available. However, the same data led to the identification of the co-formulant as Substance of Concern based on the provision in the BPR on “other grounds for concern”. It was concluded that the eCA and SECR will consider if this shoulc be clarified in more detail in the opinion.

Based on a request for clarification the SECR and the eCA explained the uncertainties identified (e.g. unknown transformation product amount NDELA converted post-application to carcinogenic nitrosamines and associated carcinogenicity risks through the human diet following regular, long-term product use) by the Working Group Human Health in the performed quantitative risk assessment for the co-formulant DEA. It was further discussed whether the BPC could recommend shortening of the authorisation period (this to encourage the faster replacement of this co-formulant in the product formulations)as it was stated in the draft opinion that it was considered not possible to assess the long-term carcinogenicity risk of NDELA formation because of insufficient information whereas the risk was considered low if exposure is short-term. It was concluded that this is not possible as it would be difficult to quantify the reference to short-term. It was also discussed if it is possible to qualify the long-term risk more clearly. Here it was agreed that this is not feasible following the discussions and conclusions reached in the Working Group Human Health. COM clarified that a clear conclusion on the safety of the product is needed in the opinion. In theory it is possible to grant an authorisation for a shorter period but this has to be well justified. It was noted by the Chair that in the draft opinion it is stated that the conditions for authorisation are met in the section on human health.

All other items in the open issues table were addressed and conclusions reached were recorded in the open issues table.

The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023.**

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **30 June 2023** and publish them on the ECHA website.

8.2 Draft BPC opinion on an Union authorisation application for a biocidal product containing Hydrogen peroxide and L (+) lactic acid for PT 2, 3, 4

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

The Applicant noted that, as a result of the evaluation, one of the uses had become redundant and asked whether it could be removed. The eCA agreed that the dossier indeed contains two very similar uses and clarified that they cannot be removed from the PAR, since the assessment of the intended claimed uses has to be presented there. COM and the SECR suggested that the use can be removed from the SPC which contains the recommendations for authorisation of the BPC but left in the PAR, to which the Applicant and the BPC members agreed.

One BPC member questioned whether risk management measures (RMMs) should be added to address inhalation exposure during manual mixing and loading for professional users when the packaging size of the product is more than 5 litres. It was clarified by the eCA that according to the model they used, for volumes above 5 litres the user would not be exposed, and for larger volumes the product cannot be expected to be handled manually, but via semi-automatic mixing and loading.

Another BPC member made a comment that for harmonisation with other cases, it should be noted for several PT 3 uses that the efficacy has been demonstrated for “enveloped viruses only” instead of “enveloped viruses”. The Chair noted that this topic can be addressed in the SCBP.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **30 June 2023** and publish them on the ECHA website.

8.3.1 Evaluation of post-authorisation data submitted for a biocidal product containing L (+) lactic acid for PT 2

The applicant did not attend the meeting for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

There were no items in the open issues table. During the meeting it was requested to refer in the opinion to the post authorisation requirements in the Implementing Regulation containing the decision to authorise the product. This was agreed.

The opinion was adopted by consensus.

Actions:

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish it on the ECHA website.

8.3.2 Evaluation of post-authorisation data submitted for a biocidal product family L (+) lactic acid for PT 1, 2, 3 and 4

Applicant had not registered for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. During the meeting it was requested to refer in the opinion to the post authorisation requirements in the Implementing Regulation containing the decision to authorise the biocidal product family. This was agreed.

The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **30 June 2023** and publish them on the ECHA website.

8.4 Minor change application of a Union authorisation

The SECR introduced the topic on minor change applications of a Union authorisation (UA-MIC) and informed of the change in procedure. The SECR presented the first Working Procedure for UA-MIC applications along with the related response to comments table (RCOM), a template for the BPC opinion and a supporting document for submission of UA-MIC applications. The ASOs were allowed to be present during the discussion.

Some BPC members raised concerns regarding the optional request for data in point 3 of the Working Procedure. It was clarified that this step is to be considered an exception. Data at this phase of the process can only be requested when specific criteria are met. One BPC member suggested that in case such a request happens, the new data should

be made available as soon as possible not only to the member state that raised the issue, but also to all (commenting) member states.

The SECR will finalise the documents by considering the discussion and publish them on the ECHA website and CIRCABC.

Actions:

- **SECR**: to upload the documents to Interact.

8.5 Working procedure for major changes application of a Union authorisation

The SECR presented the revised Working procedure for major changes application of a Union authorisation (UA-MAC) as well as a RCOM, a template for BPC opinion, timelines for submissions and a supporting document for submission of the UA-MAC applications. The ASOs were allowed to be present during the discussion.

The SECR noted that the Working procedure is simplified in order to allow sufficient time for commenting and discussion. Some members raised concerns that the Working Groups are not considered in the procedure. The SECR explained that this is not possible due to the short legal deadline to provide the opinion, i.e., 90 days. The members were encouraged to invite their experts to support them during the BPC discussion, if necessary.

It was also noted that procedure would be revised if necessary when experience will be gained.

The SECR will finalise the documents by considering discussion and publish them on the ECHA website and CIRCABC.

Actions:

- **SECR**: to upload the documents to Interact.

8.6 Revising the BPC document “Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation”

The SECR introduced the revised document agreed at an earlier BPC on “Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation”. The ASOs were allowed to be present during the discussion.

The SECR explained that procedure is revised by considering discussions at the Coordination Group (CG) on the national authorisation procedure. The SECR reminded the main principle, i.e., that in general post-authorisation conditions should remain exceptional. In addition it was pointed out that criteria included in the document should be followed.

The SECR noted that post-authorisation conditions can only be set when an authorisation is granted for biocidal product and biocidal product family application procedures and cannot be set in the course of other procedures, i.e. in the context of changes or renewal applications.

One member asked to include a scenario where the same biocidal product (SBP) authorisation holder provides the post-authorisation data themselves. The SECR noted that although such scenario is possible, it is very unlikely that the SBP authorisation holder will provide data. However, the SECR agreed to include a footnote to note the possibility of such a scenario.

The document will be finalised based on the BPC discussion and published on the ECHA website.

Actions:

- **SECR**: to upload the documents to Interact.

9. Article 38 opinion requests

9.1 Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 5 biocidal product family intended for disinfection of drinking water for animals

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

The limited number of items in the open issues table were addressed and conclusions reached were recorded in the open issues table.

The opinion was adopted by consensus.

Actions:

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check.
- **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish it on the ECHA website.

9.2 Mandate "Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying"*

The Chair introduced the mandate "Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying". The ASOs were not allowed to be present during the discussion.

Actions:

- **SECR**: to upload the mandate to Interact.

* Note SECR: it should be noted that the actual request is an Article 75(1)(g) request so in fact the agenda item should have been moved to section 10 of the agenda.

10. Article 75 (1)g opinion requests

10.1 Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides

There was no applicant for this agenda item as the request is not related to a specific application. The ASOs were allowed to be present during the discussion.

The SECR introduced the agenda item stating this relates to the remaining question of the mandate received by ECHA on the comparative assessment of anticoagulant (AVK) rodenticides: whether a distinction can be made in the hazard or risk profiles of the individual AVK rodenticide active substances (question f of the mandate). The SECR informed the BPC of the conclusions that for human health no distinction could be made while for environment this is possible between first and second generation AVK rodenticides but not between the individual active substances. The SECR referred for more details to the draft opinion including the annexes.

There were no comments raised in the commenting phase on the draft opinion. Subsequently, as no comments were raised during the meeting this part of the opinion was adopted by consensus. The Chair informed that this means that the overall opinion – including the part adopted at BPC-45 (questions a – e) - is adopted by majority.

Two members informed that they intended to submit some questions to the SECR on the conclusion of the opinion adopted at BPC-45 related to the use of non-chemical alternative for indoor control of mice.

The Commission stated that it received reactions from several stakeholders on the previous opinion adopted in BPC-45 from stakeholders, and that a meeting has taken and/or will be organised with CEFIC (Biocides for Europe) and CEPA. The Commission informed that a first discussion on the decision to be taken based on the opinion adopted in BPC-45 will take place at the Standing Committee meeting in June 2023. However, no draft decision will be prepared for this meeting. It also stressed that the decision that will be adopted is a decision to help member States carrying out their comparative assessment in the context of product authorisation.

CEFIC (Biocides for Europe) informed that the results of a study commissioned by them will soon be finalised and made available to the Commission and Member States. The study concerns a field trial for mice control indoor carried out according to the NoCheRo guidance which shows that the mechanical traps used in the study are not meeting the efficacy criteria as laid down in this guidance.

Actions:

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check.
- **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish it on the ECHA website.

10.2 Draft BPC opinion on re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT 2

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

ADBAC/BKC or alkyl (C_{12-16}) dimethylbenzyl ammonium chloride was separately notified as an existing active substance by two applicants in several products types (PTs). The active substance was approved for PT 8 in 2015 and more recently for PT 1, 3 and 4. For PT 2, the BPC delivered its opinion on ADBAC/BKC on 2 December 2021. With respect to the environmental risk assessment, the PEC/PNEC ratios for the soil compartment were less than one using the consumption based approach and using the tonnage based approach using the individual tonnages of either applicant. The exposure assessment considering the summed-up tonnages of the two applicants led to a PEC in soil slightly exceeding the relevant PNEC. A qualitative evaluation was carried out by the eCA to support the proposal for approval even considering the slight exceedance of the threshold for the soil PEC/PNEC ratio. Subsequently, the BPC opinion recommended an approval and was adopted by simple majority. Three BPC members provided minority opinions where they regarded the qualitative approach as not sufficient to demonstrate that the risk for soil organisms was acceptable.

During the 77th meeting of the Standing Committee of Biocidal Products (SCBP) in October 2022 it was decided that further discussion was needed on this aspect at technical level. Subsequently, a mandate was given to ECHA according to Article 75(1)(g) to address the concerns raised in the minority opinions. The eCA for ADBAC/BKC acted as the rapporteur.

The original evaluation was revised based on a read across to a structurally-related quaternary ammonium compound called DMPAP. Using this new information it was demonstrated that the risk for soil was acceptable, which was discussed and agreed at the Environment Working Group I 2023. The conclusions of the risk assessment as well as the revision of all the necessary parts of the evaluation were presented at the BPC. The BPC confirmed the agreement reached at the Environment Working Group.

Discussion was held on whether to include the results of the study with DMPAP which was used for read-across in the List of Endpoints (LoEP). In principle, the relevant parameters or endpoint values will need to be used for the environmental risk assessment carried out at product authorisation. This in spite of the fact that it is unlikely that the tonnage approach carried out at product authorisation (which is sometimes performed, for example if the applicant is a consortium) will lead to similar levels of risk compared to the assessment at the approval stage as tonnages will be significantly lower. Following a question from one of the members it was clarified that the results of the study with DMPAP cannot be claimed confidential. It was concluded that the relevant results of the study with DMPAP will be added to the LoEP and that the study will be included in the reference list, naming the data owner.

The question was raised whether the results of the study with DMPAP included in the LoEP for PT 2 will also need to be used for product authorisation applications for other PTs and whether a letter of access to this study will subsequently be needed. The SECR stated that these results will need to be used as the most recent LoEP for an active substance for any PT needs to be used. However, the SECR will look further into this question and inform the BPC at the next meeting.

All other items in the open issues table were addressed and conclusions reached were recorded in the open issues table.

The opinion was adopted by consensus.

Actions:

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check.
- **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish it on the ECHA website.

11. Any other business

-

12. Agreement of the action points and conclusions

Part II contains the main conclusions and action points which were agreed at the meeting.

Part II - Main conclusions and action points Main conclusions and action points

Agreed at the 47th meeting of BPC
5-7 June 2023

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom / by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed without changes.	**SECR:** to upload the agreed final agenda to the BPC Website/Interact as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-46	
The revised version of the minutes of BPC-46 was agreed.	**SECR:** to upload the agreed confidential minutes to the BPC Interact and non-confidential minutes to the ECHA website.
Item 5 – Administrative issues	
The Chair informed the meeting that the next meeting will be virtual and the meeting in November face-to-face. The Chair informed the meeting on the status of the recruitment of the new Chair. The Chair informed the members on the upcoming consultation for the update of the Guidance on IR&CSA Chapter R.11 and specific sections of Chapters R.7b and R.7c.	
Item 6 - Work programme for BPC	
6.1 BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC	
-	**Members:** to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **22 June 2023.**
6.2 Update on active substance approval and Union authorisation	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact.
6.3 Procedure for the submission, evaluation and dissemination of data generated after active substance approval	
The BPC discussed and agreed on the document provided by the SECR.	**SECR:** to upload the documents on Interact and publish it on the ECHA website.

Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion on Garlic extract for PT 19	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 19.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2023**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM by **30 June 2023** and publish them on the ECHA website.
7.2 Draft BPC opinion on Willaertia subsp. magna, C2c.Maky for PT 11	
The BPC adopted by consensus the opinion on the non-approval of the active substance for PT 11.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2023**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM by **30 June 2023** and publish them on the ECHA website.
7.3 Draft BPC opinion on Pentapotassium bis(peroxymonosulphate) bis(sulphate) for PT 2, 3, 4 and 5	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 2, 3, 4 and 5.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2023**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM by **30 June 2023** and publish them on the ECHA website.
7.4 Second renewal of active substance used in anticoagulant rodenticides	
The BPC discussed the document provided by the SECR and agreed to request the data concerning APCP data requested at the first renewal in the BPC opinion. The results of the discussion on the assessment of data on ED properties will be taken into account by the involved eCAs and ECHA coordinating the process.	**SECR:** to upload the document on Interact.
Item 8 – Union authorisation	
8.1 Draft BPC opinion on a Union authorisation application for a biocidal product family containing L-(+)-lactic acid for PT 3	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023.**

	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **30 June 2023** and publish the opinion on the ECHA website.
8.2 Draft BPC opinion on a Union authorisation application for a biocidal product containing Hydrogen peroxide and L-(+)-lactic acid for PT 2, 3, 4	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **30 June 2023** and publish the opinion on the ECHA website.
8.3.1 Evaluation of post-authorisation data submitted for a biocidal product containing L(+) Lactic acid for PT 2	
The BPC adopted by consensus the opinion on the post authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion and final PAR to COM by **30 June 2023** and publish the opinion on the ECHA website.
8.3.2 Evaluation of post-authorisation data submitted for a biocidal product family L-(+)-lactic acid for PT 1, 2, 3 and 4	
The BPC adopted by consensus the opinion on the post authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **30 June 2023** and publish the opinion on the ECHA website.
8.4 Minor change application of a Union authorisation	
The BPC took note of the presentation and discussed and agreed on the documents provided by the SECR.	**SECR:** to upload the presentation and the documents on Interact and publish the working procedure on the ECHA website.

8.5 Working procedure for major changes application of a Union authorisation	
The BPC discussed the documents provided by the SECR. The BPC agreed on the revised working procedure.	**SECR:** to upload the documents on Interact and publish the revised working procedure on the ECHA website.
8.6 Revising "Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation & Linguistic review procedure for same biocidal product applications for Union authorisation	
The BPC discussed and agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact and publish it on the ECHA website.
Item 9 – Article 38 opinion requests	
9.1 Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 5 biocidal product family intended for disinfection of drinking water for animals	
The BPC adopted by consensus the opinion.	**SECR:** to revise the draft opinion in accordance with the discussions in the BPC. **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish the opinion on the ECHA website.
9.2 Mandate "Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying"	
The BPC took note and discussed the mandate and opinion request provided by the SECR. The BPC agreed with the proposal to appoint ECHA as rapporteur and the member from BE as co-rapporteur for question 4 of the mandate.	**Members:** to inform the SECR by **21 June 2023** if they are willing to contribute to the first three questions of the mandate. **SECR:** to upload the mandate – once agreed with the Commission - on Interact.
Item 10 – Article 75(1)(g) opinion requests	
10.1 Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides	
The BPC adopted by simple majority the opinion.	**SECR:** to revise the draft opinion in accordance with the discussions in the BPC. **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish the opinion on the ECHA website.
10.2 Draft BPC opinion on re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT 2	
The BPC adopted by consensus the opinion.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 June 2023**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC. **SECR:** to forward the adopted opinion to COM by **30 June 2023** and publish the opinion on the ECHA website.
Item 11 – Any other business	

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Part III - List of Attendees

Members		
AT	JOHN	Nina
BE	JARRETY	Helene
CZ	MIKOLAS	Jan
DK	GREGERSEN	Nina Falk
EE	SULG	Helen
EL	VAGIAS	Vasileios
ES	GONZÁLEZ MÁRQUEZ	María Luisa
FI	KOIVISTO	Sanna
FR	CHEZEAU	Aurelie
HR	VRHOVAC FILIPOVIĆ	Ivana
HU	SZENTGYORGYI	Timea
IE	PIERCE	Louise
IT	BALDASSARRI	Lucilla
LT	HAKAITE	Palmira
LU	ZIGRAND	Jeff
MT	MALLIA	Lothar Paul
NL	LEENDERS	Rebekka
NO	ESPEVIK RANDALL	Marit
PL	RZODECZKO	Helena
PT	BORGES	Maria Teresa
RO	DRAGOIU	Simona
SE	HAHLBECK	Edda
SI	CEBASEK	Petra
SK	MIKOLASKOVA	Denisa

Alternate members		
CH	TENZING	Gyalpo
DE	WEINHEIMER	Viola
LV	BUKINA	Anna

Advisors		
AT	ALTMANN	Dominik
AT	HAUZENBERGER	Ingrid
BE	LEROY	Céline
DE	JÄGER	Stefanie
DE	LÜRICK	Anna
DE	PÖHLER	Robert
DE	TENTSCHER	Peter
DK	KIRKEGAARD	Maja
DK	NIELSEN	Jeanette
ES	RUIZ	Elena
FI	NIEMINEN	Timo
FR	BOITIER	Caroline
LV	BROVKINA	Julija
MT	MAGRI DEMAJO	Suzanne
MT	JEURISSEN	Nelleke
MT	VAN DEN BROEK	Anniek
MT	VANWORMHOUDT	An
NL	BOS	Carina
NL	KALKERS	Lucas
NL	LANS	Martine
NL	MUIJS	Barry
SE	ASK BJÖRNBERG	Karolin
SE	SCHMALHOLZ	Ellen
SK	HORSKA	Alexandra
SK	ROMAN	Olga

Commission observers		
DG SANTE	CAINZOS	Marta
DG SANTE	CHATELIN	Ludovic
DG SANTE	DELVAUX	Vincent
DG SANTE	GRUHN	Lena
DG SANTE	NEGULICI	Ligia
DG SANTE	TSIAMIS	Konstantinos
DG SANTE	CAINZOS	Marta

EFSA observer		
EFSA	LOPEZ-GALVEZ	Gloria
Accredited Stakeholder Observers		
A.I.S.E.	CAZELLE	Elodie
Aqua Europa	WEISS	Aharon
BfE Cefic	MIHAI	Camelia
BfE Cefic	VAN BERLO	Boris
EurO3zon	GYSSELS	Roman

Applicants

Ecospray Limited
Household & Commercial Products Association
HUVEPHARMA SA
HYPRED SAS
Labcorp Early Development Laboratories Limited
SCC GmbH (on behalf of KMPS Registration Group)
ToxMinds bvba

ECHA Staff	
AIRAKSINEN	Antero
BIELSKA	Lucie
CARLON	Claudio
DAMSTEN	Micaela
DE WOLF	Watze
HÄMÄLÄINEN	Eva
HONKA	Anni
LAITINEN	Jaana
LATSONE	Aiga
MARCON	Eva M
MOTTET	Denis
MUELLER	Gesine
PAPADAKI	Paschalina
RAULIO	Mari
ROCKE	Timo
SAEZ RIBAS	Monica
STASKO	Jolanta
SZANTO	Emese
SZYMANKIEWICZ	Katarzyna
UPHOFF	Andreas
VALKOVICOVA	Eva
VAN DE PLASSCHE	Erik
VAN DER LINDEN	Sander
VAN GALEN	Joost
VASILEVA	Katya

Part IV - List of Annexes

Annex I List of documents submitted to the members of the Biocidal Products Committee

Annex II Final agenda of BPC-47

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-47 meeting

Agenda Point	Number	Title
2.	BPC-A-47-2023	Draft agenda
4.	BPC-M-46-2023 BPC-M-46-2023	Draft confidential minutes from BPC-46 Draft non-confidential minutes from BPC-46
5.1	presentation	
6.1	BPC-47-2023-01	BPC Work Programme for active substance approval
	BPC-47-2023-02	BPC Work Programme Union authorisation
	BPC-47-2023-03	outlook for BPC
	BPC-47-2023-04	outlook for BPC and ED assessment
6.2	Presentation	Update on active substance approval and Union authorisation
6.3	BPC-47-2023-05A	Procedure for the submission, evaluation and dissemination of data generated after active substance approval
	BPC-47-2023-05B	Cover note
7.4	BPC-47-2023-21	Second renewal of active substance used in anticoagulant rodenticides
8.4	BPC-47-2023-16A	Minor change application of a Union authorisation: UA-MIC_Working-procedure
	BPC-47-2023-16B	Opinion template for Union authorisation minor changes
	BPC-47-2023-16C	RCOM UA MIC
	BPC-47-2023-16D	Supporting document
8.5	BPC-47-2023-17A	Working procedure for major changes application of a Union authorisation: UA-MAC Working procedure_version2
	BPC-47-2023-17B	Timelines for the opinion-forming of UA-MAC applications
	BPC-47-2023-17C	UA-MAC opinion template
	BPC-47-2023-17D	UA-MAC RCOM
	BPC-47-2023-17E	Supporting document
8.6	BPC-47-2023-22	Revising “Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation.

9.2	BPC-47-2023-23	Mandate “Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying”		
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7.1	BPC-47-2023-06A	Draft BPC opinion on Garlic extract for PT 19	AT	Draft BPC opinion
	BPC-47-2023-06B			Assessment report
	BPC-47-2023-06C			Open issues
	BPC-47-2023-06D			Reference specification
7.2	BPC-47-2023-07A	Draft BPC opinion on Willaertia subsp. magna, C2c.Maky for PT 11	MT	Draft BPC opinion
	BPC-47-2023-07B			Assessment report
	BPC-47-2023-07C			Open issues
7.3	BPC-47-2023-08A	Draft BPC opinion on Pentapotassium bis(peroxymonosulphate) bis(sulphate) for PT 2, 3, 4 and 5 (KPMS)	SI	Draft BPC opinion
	BPC-47-2023-08-11B			Assessment report
	BPC-47-2023-08-11C			Open issues
	BPC-47-2023-09A	PT 3		Draft BPC opinion
	BPC-47-2023-10A	PT 4		Draft BPC opinion
	BPC-47-2023-11A	PT 5		Draft BPC opinion
8.1	BPC-47-2023-12A	Draft BPC opinion on a Union authorisation application for a biocidal product family containing L-(+)-lactic acid for PT 3	NL	Draft BPC opinion
	BPC-47-2023-12B			SPC
	BPC-47-2023-12C			PAR
	BPC-47-2023-12D			PAR Conf Annex
	BPC-47-2023-12E			Open issues
8.2	BPC-47-2023-13A	Draft BPC opinion on a Union authorisation application for a biocidal product containing Hydrogen peroxide and L-(+)-lactic acid for PT 2, 3, 4	FR	Draft BPC opinion
	BPC-47-2023-13B			SPC
	BPC-47-2023-13C			PAR
	BPC-47-2023-13D			PAR Conf Annex_MS_ONLY
	BPC-47-2023-13E			Open issues
8.3	BPC-47-2023-14A	Evaluation of post-authorisation data submitted for: A biocidal product containing L(+) Lactic acid for PT 2	LV	Draft BPC opinion
8.3.1	BPC-47-2023-14B			PAR
	BPC-47-2023-14C			Open issues
	BPC-47-2023-14D			Final report

8.3.2	BPC-47-2023-15A	A biocidal product family L-(+)-lactic acid for PT 1, 2, 3 and 4	BE	Draft BPC opinion
	BPC-47-2023-15B			SPC
	BPC-47-2023-15C			PAR
	BPC-47-2023-15D			Open issues
	BPC-47-2023-15E			Study reports_1
	BPC-47-2023-15F			Study reports_2
	BPC-47-2023-15G			Study reports_3
9.1	BPC-47-2023-18A	Art 38: Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 5 biocidal product family intended for disinfection of drinking water for animals	ECHA	Draft BPC opinion
	BPC-47-2023-18B			Open issues
	BPC-47-2023-18C			Mandate
10.1	BPC-47-2023-19A	Art 75: Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides	ECHA	Draft BPC opinion
	BPC-47-2023-19B			Open issues
	BPC-47-2023-19C			Annex V
	BPC-47-2023-19D			Annex V_annex_1
	BPC-47-2023-19E			Annex V_annex_2
	BPC-47-2023-19F			Annexes to Annex 2 of Annex V
10.2	BPC-47-2023-20A	Art 75: Draft BPC opinion on re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT 2	IT	Draft BPC opinion
	BPC-47-2023-20B			Open issues
	BPC-47-2023-20C			Mandate
	BPC-47-2023-20D			Assessment report
	BPC-47-2023-20E			BKC_EQC_Doc_IIB
	BPC-47-2023-20F			BKC_EQC_Doc_IIC
	BPC-47-2023-20G			BKC_US_ISC_Doc_IIB
	BPC-47-2023-20H			BKC_US_ISC_Doc_IIC
	BPC-47-2023-20I			Conf_ERA

29 May 2023
BPC-A-47-2023_rev2

Draft agenda

47th meeting of the Biocidal Products Committee (BPC)

5-8 June 2023

Meeting is held as hybrid

Meeting room Urho in ECHA / WebEx

Starts on 5 June at 13:00,
ends on 8 June at 14:00
The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-47-2023

For agreement

3. – Declarations of potential conflicts of interest to agenda items

4. – Agreement of the minutes and review of actions from BPC-46

BPC-M-46-2023

For agreement

5. – Administrative issues

5.1. Administrative issues

For information

6. – Work programme for BPC

6.1. BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC

BPC-47-2023-01; BPC-47-2023-02; BPC-47-2023-03; BPC-47-2023-04

For information

6.2. Update on active substance approval and Union authorisation

For information

6.3. Procedure for the submission, evaluation and dissemination of data generated after active substance approval

BPC-47-2023-05 A, B

For agreement

7. – Applications for approval of active substances[†]

7.1. Draft BPC opinion on Garlic extract for PT 19

Previous discussion: WG-I-2023

BPC-47-2023-06 A, B, C, D

For adoption

7.2. Draft BPC opinion on Willaertia subsp. magna, C2c.Maky for PT 11

Previous discussion: WG-14 December 2022

BPC-47-2023-07 A, B, C

For adoption

7.3. Draft BPC opinion on Pentapotassium bis(peroxymonosulphate) bis(sulphate) for PT 2, 3, 4 and 5

Previous discussion: WG-I-2023

BPC-47-2023-08 A, B, C

BPC-47-2023-09 A, B, C

BPC-47-2023-10 A, B, C

BPC-47-2023-11 A, B, C

For adoption

7.4 Second renewal of active substance used in anticoagulant rodenticides

BPC-47-2023-21

For agreement

8. – Union authorisation[**]

8.1. Draft BPC opinion on a Union authorisation application for a biocidal product family containing L-(+)-lactic acid for PT 3

Previous discussion: WG-I-2023

BPC-47-2023-12 A, B, C, D, E

For adoption

[†] For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft assessment report (AR) which may cover more than one PT (denoted by B) and a document containing open issues covering all the PTs to be discussed for that substance (denoted by C).

[**] For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft Summary of Product Characteristics (SPC) (denoted by B), a draft product assessment report (PAR) (denoted by C) and a document containing open issues to be discussed for the biocidal product or biocidal product familiy (denoted by E).

8.2. Draft BPC opinion on a Union authorisation application for a biocidal product containing Hydrogen peroxide and L-(+)-lactic acid for PT 2, 3, and 4

Previous discussion: WG-I-2023

BPC-47-2023-13 A, B, C, D, E

For adoption

8.3. Evaluation of post-authorisation data submitted for:

8.3.1 A biocidal product containing L(+) Lactic acid for PT 2

BPC-47-2023-14 A, B, C, D

For adoption

8.3.2 A biocidal product family containing L-(+)-lactic acid for PT 1, 2, 3 and 4

BPC-47-2023-15 A, B, C, D, E, F, G

For adoption

8.4. Minor change application of a Union authorisation

BPC-47-2023-16 A, B, C, D

For discussion

8.5. Working procedure for major changes application of a Union authorisation

BPC-47-2023-17 A, B, C, D, E

For agreement

8.6. Revising "Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation"

BPC-47-2023-22

For agreement

9. – Article 38 opinion requests

9.1. Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 5 biocidal product family intended for disinfection of drinking water for animals

Previous discussion: WG-I-2023

BPC-47-2023-18 A, B, C

For adoption

9.2 Mandate "Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying"

BPC-47-2023-23

For information

10.– Article 75(1)(g) opinion requests

10.1. Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides

Previous discussion: WG-I-2023

BPC-47-2023-19 A, B, C, D, E, F

For adoption

10.2. Draft BPC opinion on re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT 2

Previous discussion: WG-I-2023

BPC-47-2023-20 A, B, C, D, E, F, G, H, I

For adoption

11. - Any other business

12.– Action points and conclusions

13.– Ten years of BPC Symposium

Provisional time schedule for the

47th meeting of the Biocidal Products Committee (BPC)

Hybrid meeting (Meeting room Urho in ECHA / WebEx)

Starts on 5 June at 13:00 (EET), ends on 8 June at 14:00 (EET)

Please note that the time schedule indicated below is provisional and subject to possible change. The schedule is distributed to participants on a preliminary basis. If needed, follow-up discussions may take place on the following day for BPC opinions.

Monday 05 June: (starts at 13:00 EET / 12:00 CET, ends at 18:00 EET / 17:00 CET)

Items 1-5	Opening items and administrative issues
Item 6.1	BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC
Item 6.2	Update on active substance approval and Union authorisation
Item 6.3	Procedure for the submission, evaluation and dissemination of data generated after active substance approval
Item 7.1	Draft BPC opinion on Garlic extract for PT 19
Item 7.2	Draft BPC opinion on Willaertia subsp. magna, C2c.Maky for PT 11
Item 7.4	Second renewal of active substance used in anticoagulant rodenticides

Tuesday 06 June (starts at 09:30 EET / 08:30 CET, ends at 17:00 EET / 16:00 CET)

Item 7.3	Draft BPC opinion on Pentapotassium bis(peroxymonosulphate) bis(sulphate) for PT 2, 3, 4 and 5
Item 8.1	Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid for PT 3
Item 8.2	Draft BPC opinion on an Union authorisation application for a biocidal product containing Hydrogen peroxide and L-(+)-lactic acid for PT 2, 3 and 4

Wednesday 07 June: (starts at 09:30 EET / 08:30 CET, ends at 17:00 EET / 16:00 CET)

Item 8.3	Evaluation of post-authorisation data submitted for:
	8.3.1 A biocidal product containing L(+) Lactic acid for PT 2
	8.3.2 A biocidal product family containing L-(+)-lactic acid for PT 1, 2, 3 and 4
Item 8.4	Minor change application of a Union authorisation
Item 8.5	Working procedure for major changes application of a Union authorisation
Item 9.1	Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 5 biocidal product family intended for disinfection of drinking water for animals
Item 9.2	Mandate “Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying”
Item 10.1	Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides
Item 10.2	Draft BPC opinion on re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT 2

Item 8.6	Revising “Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation”
Item 12	Action points and conclusions

Thursday 08 June: (starts at 09:30 EET / 08:30 CET, ends at 14:00 EET / 13:00 CET)

Symposium: Ten years of the Biocidal Products Committee meetings: taking stock, looking ahead and… saying good-bye.

End of meeting

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