27 June 2023

BPC-M-46-2023

Final non-confidential minutes of the 46th meeting of the Biocidal Products Committee (BPC)

1-2 March 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 46th BPC meeting which took place as a Webex meeting.

The Chair then informed the BPC members of the participation of 28 members, including two alternate members.

19 member's advisers and four representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Six representatives from the European Commission 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 where details are provided in the summary record of the discussion for the substances and in Part III of the minutes. Applicants were not invited for agenda point 9.2 and neither for agenda point 10. Article 75(1)(g) opinion requests as these were for information in nature.

2. Agreement of the agenda

The Chair introduced the final draft agenda (BPC-A-46-2023_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-45

The revised non-confidential and confidential draft minutes from BPC-45 (BPC-M-45-2022), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-45 meeting were carried out:

- All procedural documents agreed at this meeting were finalised and published on the ECHA website on the BPC web-page;
- The guidance entitled "Analysis of alternatives to biocidal active substances" was published on the ECHA web-site (guidance document: https://echa.europa.eu/documents/10162/1276600/guidance_analysis_alternativ

es_biocides_en.pdf/10646cd2-8ec9-36a8-2f00-201fcc49c43e?t=1675846602684 and the accompanying template: https://echa.europa.eu/documents/10162/992028/template_analysis_alternatives_biocides_en.docx/5d12c177-f042-6df2-050d-311886da9acf?t=1675847083579&download=true). The Chair informed that the dates of implementation for the guidance decided by the Commission are 1 March 2023 for active substances meeting the exclusion criteria and 1 January 2025 for active substances considered to be a candidate for substitution.

Actions:

- **SECR:** to upload the agreed minutes from BPC-45 to the BPC Interact and to the ECHA website after the meeting.

5. Administrative issues

5.1 Administrative issues

The **Chair** informed the meeting that the next meeting in June will be face-to-face.

The SECR gave a presentation on the azole resistance mandate: "Request for a Scientific Report on the impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus spp*." The mandate is published on the ECHA website.

The SECR explained the main questions to be tackled in this report and the progress of the work done by five agencies (EMA, EFSA, EEA, ECDC and ECHA). The BPC will receive this report in 2024. The BPC and the MSCAs were asked to reply to a survey by 6 April 2023, which was launched in order to establish trends in quantities and geographical variation in use of azole fungicides in the EU/EEA.

Actions:

- **SECR**: to upload the presentation to Interact.
- **Members:** to fill in the survey by **6 April 2023**.

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 Chair indicated that the total number of opinions foreseen to be adopted will in 2023 be lower compared to 2022: for active substance the number is foreseen to be similar but of Union authorisation applications the number is foreseen to decrease.

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 Action Plan, in particular to deliver the draft assessment reports and to not postpone discussions on their substances. Progress must especially be made on backlog reports submitted before 1 September 2013 for which decisions must still be based under BPD principles, which is becoming more and more problematic. The Commission urged Greece, Malta, the Netherlands, Poland and Sweden to make progress on their dossiers. The Commission noted that there are still 2 years ahead before the deadline of end of 2024 so progress can be made in the meantime. The Commission informed that discussions will start at the next CA meeting on a possible extension of the 2024 target.

The Chair asked the evaluating Competent Authorities being rapporteur for active substances or Union authorisations scheduled for discussion at the second BPC meeting of 2023 (BPC-47) 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 **16 March 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 work coming in 2023.

ii) Update from AS and UA processes

The SECR asked the members to keep the planning document updated in the Interact Collaboration tool if there are changes in their planning of submissions. In addition, the SECR reminded about the revised working procedures for Active substance approval and Union authorisation which are applicable starting from those process flows where the submission window is closing in March 2023 (AS-PF 49, UA-PF 48). The SECR noted that the 30 days commenting table must be provided together with the conclusions of the assessment. In the absence of such document the applications will not be processed further by the SECR, i.e. the accordance check will not be initiated.

The SECR updated the committee regarding the CLP review where its impact in the active substance approval process is under analysis and on the "One substance One assessment approach" (1S1A). The BPC members acknowledged the importance of these topics and requested further discussions regarding the expectations and responsibilities for eCAs within 1S1A.

In relation to the UA linguistic review process CAs were invited to ensure that there are no comments in the SPC xml file, i.e., the file needs to be opened in the SPC editor. All comments have to be included in the LRUA-F1 form.

Actions:

- **SECR**: to upload the presentation in Interact & SCIRCA-BC

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

The SECR presented a proposal for updating the existing procedure for the submission, evaluation and dissemination of data generated after active substance approval. The proposal stems from the agreement reached at CA meeting level and also implies the revision of the equivalent document developed by Coordination Group.

The BPC document focuses on the handling and peer-review of the new data by the BPC and its Working Groups and on the revision of the List of Endpoints (LoEP) for an approved active substance. The four original scenarios where the revision of the LoEP can take place have been kept in the proposal with further elaboration of the procedure in particular when the data are submitted in the context of product authorisation. The objective in this case is that the data are evaluated only once by a MS and thereafter peer-reviewed by other MSs. The conditions for a peer-review are that the data are considered as reliable and that they have the potential for revising the LoEP, either by including a new endpoint or by revising the value of an endpoint already agreed by the LoEP.

The BPC members indicated their preference to have a combined document for the CG and BPC on the handling of this type of data to facilitate the procedure. The SECR noted that the existing procedure is described in two documents and the focus of the documents is different.

Additional comments were made to the proposal to include further details in the proposal for the peer-review steps and deadlines. It was noted by the COM that the revision of the data submitted during product authorisation should be conducted within the evaluation phase of the product as required by the BPR, stressing that it concerns only limited data compared to the whole data set presented on the active substance, while some members considered it not feasible to achieve this within the product evaluation phase.

Further comments were made, i.e. whether the right to use of data should be part of the document, who should be responsible for amending the AR and the use of IUCLID. The ECHA SECR invited the BPC members to submit comments via written procedure by 31 March 2023 and ECHA will revise the proposal for the next BPC.

Actions:

- **SECR**: to open written commenting procedure and revise the document for the next BPC. Dead line for members to comment is **31 March 2023**.

7. Applications for approval of active substances

7.1 Draft BPC opinion on Nitrogen generated from ambient air (inclusion in Annex I)

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

Nitrogen generated from ambient air is intended to be used by professionals for control of arthropod pests that affect commodities, such as museum artefacts food storage areas or machinery. The nitrogen is used to create a controlled atmosphere with a very low oxygen concentration (anoxia) in permanently or temporarily sealed treatment tents or chambers.

It was confirmed that the substance should be considered as a new active substance and clarified that this decision would have limited consequences in terms of data protection periods since most of the data comes from public literature.

The main discussion point was related to the need to recommend a restriction in the Annex I entry to ensure that the issue of anoxia is adequately considered at product authorisation level. The members agreed that introducing measures might be necessary at product level to ensure that oxygen levels remain at or return to safe levels, especially in areas accessible for the general public. It was discussed whether the simplified product authorisation procedure (per Article 25 of the BPR) would require a restriction in the Annex I entry for introducing such risk mitigation measures at product level (if necessary) of or if a recommendation in section 2.4 of the BPC opinion on the active substance would be sufficient. It was also mentioned that some Member States have national regulatory measures related to working with gases and anoxia which remain valid irrespective of the BPR. However, it was noted that some Member States might not have such specific regulations and that clear indications in relation with the safe use of nitrogen as biocidal active substance could therefore be necessary. One member noted that it might be problematic for a Member State to restrict a biocidal product according to Article 27(2) of the BPR if no restriction is included in the Annex I entry.

It was concluded that the introduction of a restriction in the Annex I entry would provide reassurance that the issue of anoxia is actually considered in the simplified product authorisation procedure and would provide a more solid legal basis for the potential introduction of risk mitigation measures at product level.

It was agreed that the opinion would be amended with a proposal presented at the meeting by the rapporteur for a restriction of an Annex I entry which is sufficiently generic not to hamper innovation but sufficient to highlight the potential concern at product level.

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 assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 April 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 **24 March 2023** and publish it on the ECHA website.

7.2 Combined List of Endpoint for ozone generated from oxygen

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The SECR briefly introduced the case: two applications submitted to two different eCAs (DE and NL) where the opinions were already adopted by the BPC at BPC-42 and BPC-44, respectively. At BPC-44 it was decided that a combined list of endpoints (LoEP) will be prepared to facilitate the product authorisation process.

The combined LoEP was presented by the SECR. The SECR informed that in the meantime the RAC provided its opinion on classification and labelling regarding all endpoints except for carcinogenicity. This has resulted in a need to align some discrepancies in the combined

LoEP after BPC-44 with regard to the STOT SE and STOT RE classification relating to the target organs. This was agreed. It was agreed – contrary to the previous agreement - to publish therefore the combined LoEP as a standalone document, separate from the individual Assessment Reports.

Actions:

- **SECR:** to update the document (in line with RAC 63) on Interact and disseminate it via the ECHA website as a standalone document and inform MSCAs and the two applicants.

8. Union authorisation

8.1 Draft BPC opinion on an Union authorisation application for a biocidal product family containing mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13

The Chair welcomed the applicant for the following discussion. The ASOs were not allowed to be present during the discussion. The rapporteur briefly introduced the case.

No conclusion could be reached on the evaluation and the adoption of the opinion was postponed consequently.

8.2 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 2

The Chair welcomed the applicant for this item. The ASOs were not 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. Members were reminded by the SECR to take note of a presentation of the Commission at the CA meeting containing guidance on the quality of the SPC and to make sure that future SPCs comply with this. 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 **20 March 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 **24 March 2023** and publish them on the ECHA website.

8.3 Harmonisation of the calculation of the PAA concentration from the product dilution

The Chair invited the member from Germany to introduce the item. The ASOs were not allowed to be present during the discussion. The proposal was agreed by the BPC and a TAB entry will be prepared by the SECR to be discussed in the relevant Working Group.

Actions:

- **SECR:** to upload the document on Interact and prepare a TAB entry for the relevant areas based on the agreed proposal in the document.

9. Article 38 opinion requests

9.1. Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 3 biocidal product intended for disinfection of livestock animal housing and equipment and animal transportation vehicles

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 – which were all of minor importance - 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 **24 March 2023** and publish it on the ECHA website.

9.2 Request for a 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 introduced the mandate and opinion request of this Article 38 request. The ASOs were not allowed to be present. The SECR will act as rapporteur for this request.

Actions:

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

10. Article 75 (1)g opinion requests

10.1 Request for a 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 introduced the mandate and opinion request of this Article 75(1)(g) request. The ASOs were allowed to be present. The mandate will be published on the ECHA website. It was agreed that the member from Italy will act as the rapporteur for this request.

Actions:

- **SECR:** to upload the mandate on Interact and BPC CIRCABC IG.

10.2 Request for a BPC opinion on the Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)

The Chair introduced the mandate and opinion request of this Article 75(1)(g) request. The ASOs were allowed to be present. The mandate will be published on the ECHA website. It was agreed that the member from Austria will act as the rapporteur for this request.

Actions:

- **SECR:** to upload the mandate on Interact and BPC CIRCABC IG.

11. Any other business

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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 46th meeting of BPC

1-2 March 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-45	
The revised version of the minutes of BPC-45 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 that the June meeting will be organised as a face-to-face meeting.	
5.1. Presentation on the azole resistance mandate	
The BPC took note of the presentation provided by the SECR.	**SECR**: to upload the presentation on Interact/BPC CIRCABC IG.
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 **16 March 2023.**
6.2 Update on active substance approval and Union authorisation	
The BPC took note of the presentation provided by the SECR and agreed on some of the questions raised in it.	**SECR:** to upload the presentation on Interact/BPC CIRCABC IG.
6.3 Procedure for the submission, evaluation and dissemination of data generated after active substance approval	

The BPC discussed the document provided by the SECR.	**SECR:** to open written commenting procedure and revise the document for the next BPC. **Members:** to provide written comments by **31 March 2023**.
Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion on Nitrogen generated from ambient air (inclusion in Annex I)	
The BPC adopted by consensus the opinion on the approval of the active substance for inclusion in Annex 1.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **28 April 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 **24 March 2023** and publish them on the ECHA website.
7.2 Combined List of Endpoint for ozone generated from oxygen	
The BPC took note and agreed on the document provided by the SECR.	**SECR:** to update the document (in line with RAC 63) on Interact and disseminate it via the ECHA website as a standalone document and inform MSCAs and the two applicants.
Item 8 – Union authorisation	
8.1 Draft BPC opinion on an Union authorisation application for a biocidal product family containing mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13	
The BPC discussed the opinion on the authorisation of this application for Union authorisation. The application will be sent back to the evaluation phase and subsequent opinion forming phase.	
8.2 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 2	
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 **20 March 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 **24 March 2023** and publish the opinion on the ECHA website.

8.3 Harmonisation of the calculation of the PAA concentration from the product dilution	
The BPC discussed and agreed on the document provided by Germany.	**SECR:** to upload the document on Interact and prepare a TAB entry for the relevant areas based on the agreed proposal in the document.
Item 9 – Article 38 opinion requests	
9.1 Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 3 biocidal product intended for disinfection of livestock animal housing and equipment, and animal transportation vehicles	
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 **24 March 2023** and publish the opinion on the ECHA website.
9.2 Request for a 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 took note and discussed the mandate and opinion request provided by the SECR.	**SECR:** to upload the mandate on Interact.
Item 10 – Article 75(1)(g) opinion requests	
10.1 Request for a 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 took note and discussed the mandate and opinion request provided by the SECR.	**SECR:** to upload the mandate on Interact/BPC CIRCABC IG and publish it on the ECHA website.
10.1 Request for a BPC opinion on the Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)	
The BPC took note and discussed the mandate and opinion request provided by the SECR.	**SECR:** to upload the mandate on Interact/BPC CIRCABC IG and publish it 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
CY	HADJIGEORGIOU	Andreas
CZ	MIKOLAS	Jan
DE	TENTSCHER	Peter
DK	GREGERSEN	Nina Falk
EE	SULG	Helen
EL	VAGIAS	Vasileios
ES	GONZALEZ MARQUEZ	Luisa
FI	KOIVISTO	Sanna
HR	VRHOVAC FILIPOVIC	Ivana
HU	SZENTGYORGYI	Timea
IE	PIERCE	Louise
IT	BALDASSARRI	Lucilla
LT	HAKAITE	Palmira
LU	ZIGRAND	Jeff
LV	BROVKINA	Julija
MT	MALLIA	Lothar Paul
NL	LEENDERS	Rebekka
NO	ESPEVIK RANDALL	Marit
PL	RZODECZKO	Helena
PT	BORGES	Teresa
RO	DRAGOIU	Simona
SE	HAHLBECK	Edda
SI	ČEBAŠEK	Petra
SK	MIKOLASKOVA	Denisa

Alternate members		
CH	GYALPO	Tenzing
FR	COLLET	Romy

Stakeholder Observers		
	GYSSELS	Roman
	SIMOES	Ines
	VAN BERLO	Boris
	WEIß	Aharon

Advisors		
BE	LEROY	Celine
DE	BLOCH	Carsten
DE	LUERICK	Anna
DE	PÖHLER	Robert
DE	WEINHEIMER	Viola
ES	DE RIVAS	Ana
ES	RUIZ LOPEZ	Elena Fuensanta
FI	HÄMÄLAINEN	Anna-Maija
FI	NIEMINEN	Timo
FR	CHEZEAU	Aurelie
IT	UBALDI	Alessandro
MT	MAGRI DEMAJO	Suzanne
NL	BOS	Carina
NL	KALKERS	Lucas
NL	LANS	Martine
NL	VAN DEN BERG	Suzanne
SE	ASK BJÖRNBERG	Karolin
SK	HORSKÁ	Alexandra
SK	LISKOVA	Simona

Commission observers		
DG SANTE	CAINZOS GARCIA	Marta
DG SANTE	CHATELIN	Ludovic
DG SANTE	DELVAUX	Vincent
DG SANTE	GRUHN	Lena
DG SANTE	MASELLIS	Cecilia
DG SANTE	TSIAMIS	Konstantinos

Applicants
EuOTA
EurO3zon
Stiftung Preussischer Kulturbesitz
SYNTHESE ELEVAGE
Troy Chemical Company B.V.
Veltek Associates

ECHA staff	
BIELSKA	Lucie
CARLON	Claudio
D'AGOSTINI	Valeria
ESTEVAN MARTINEZ	Carmen
HONKA	Anni
JARDIN	Helene
LATSONE	Aiga
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 GALEN	Joost
VETELAINEN	Kaisa
ZBIHLEJ	Tomas

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-46

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-46 meeting

Agenda Point	Number	Title
2.	BPC-A-46-2023_rev2	Draft agenda
4.	BPC-M-45-2022	Draft minutes from BPC-45
5.1	presentation	Administrative issues and report from the other Committees Presentation on the azole resistance mandate
6.1	BPC-46-2023-01	BPC Work Programme for active substance approval
	BPC-46-2023-02	BPC Work Programme Union authorisation
	BPC-46-2023-03	outlook for BPC
	BPC-46-2023-04	outlook for BPC and ED assessment
6.2	Presentation	Update on active substance approval and Union authorisation
6.3	BPC-46-2023-05	Procedure for the submission, evaluation and dissemination of data generated after active substance approval
7.2	BPC-46-2023-07	Combined List of Endpoint for ozone generated from oxygen
8.3	BPC-46-2023-10	Harmonisation of the calculation of the PAA concentration from the product dilution
9.2	BPC-46-2023-12A BPC-46-2023-12B	Art. 38: Request for a 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
10.1	BPC-46-2023-13	Art. 75(1)(g): Request for a BPC opinion on re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT 2
10.2	BPC-46-2023-14	Art. 75(1)(g): Request for a BPC opinion on evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)

Agenda Point	Number	Substance-PT	eCA	Title
7.1	BPC-46-2023-06A	Draft BPC opinion on Nitrogen generated from ambient air (inclusion in Annex I) PT 18	DE	Draft BPC opinion
	BPC-46-2023-06B			Assessment report
	BPC-46-2023-06C			Open issues

8.1	BPC-46-2023-08A	Draft BPC opinion on an Union authorisation application for a biocidal product family containing mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13	NL	Draft BPC opinion
	BPC-46-2023-08B			SPC
	BPC-46-2023-08C			PAR
	BPC-46-2023-08D			PAR Conf Annex
	BPC-46-2023-08E			Open issues
	BPC-46-2023-08F			Explanatory note
	BPC-46-2023-08G			Consultation results
8.2	BPC-46-2023-09A	Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 2	NL	Draft BPC opinion
	BPC-46-2023-09B			SPC
	BPC-46-2023-09C			PAR
	BPC-46-2023-09D			PAR Conf Annex
	BPC-46-2023-09E			Open issues
9.1	BPC-46-2023-11A	Art. 38: Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 3 biocidal product intended for disinfection of livestock animals housings and equipment, and animal transportation vehicles	FR	Draft BPC opinion
	BPC-46-2023-11B			Open issues
	BPC-46-2023-11C			Mandate
	BPC-46-2023-11D			ECHA note

21 February 2023
BPC-A-46-2023_rev2

Draft agenda

46th meeting of the Biocidal Products Committee (BPC)

1-2 March 2023

Meeting is held virtually in Webex

Starts on 1 March at 10:30,
ends on 2 March at 18:00
The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-46-2023

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-45

BPC-M-45-2022

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-46-2023-01; BPC-46-2023-02; BPC-46-2023-03; BPC-46-2023-04

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-46-2023-05

For discussion

7. – Applications for approval of active substances*

7.1. Draft BPC opinion on Nitrogen generated from ambient air (inclusion in Annex I)

Previous discussion: WG-IV-2022

BPC-46-2023-06A, B, C

For adoption

7.2. Combined List of Endpoint for ozone generated from oxygen

Previous discussion: BPC-41 & BPC-44

BPC-46-2023-07

For information

8. – Union authorisation**

8.1. Draft BPC opinion on an Union authorisation application for a biocidal product family containing mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13

Previous discussion: WG-IV-2022

BPC-46-2023-08A, B, C, D, E, F, G

For adoption

8.2. Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 2

Previous discussion: WG-IV-2022

BPC-46-2023-09A, B, C, D, E

For adoption

8.3. Harmonisation of the calculation of the PAA concentration from the product dilution

BPC-46-2023-10

For discussion

9. – Article 38 opinion requests

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* 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).

9.1. Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 3 biocidal product intended for disinfection of livestock animals housings and equipment, and animal transportation vehicles

BPC-46-2023-11A, B, C, D

For adoption

9.2. Request for a 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

BPC-46-2023-12A, B

For information

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

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

BPC-46-2023-13

For information

10.2. Request for a BPC opinion on evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)

BPC-46-2023-14

For information

11. - Any other business

12. – Action points and conclusions

Provisional time schedule for the

46th meeting of the Biocidal Products Committee (BPC)

Virtual meeting in WebEx

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.

Wednesday 1 March: (starts at 10:30 EET/09:30 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 7.1	Draft BPC opinion on Nitrogen generated from ambient air (inclusion in Annex I)
Item 7.2	Combined List of Endpoint for ozone generated from oxygen
Item 9.1	Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT 3 biocidal product intended for disinfection of livestock animals housings and equipment, and animal transportation vehicles
Item 9.2	Request for a 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 10.1	Request for a 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 10.2	Request for a BPC opinion on evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)

Thursday 2 March: (starts at 10:30 EET/09:30 CET, ends at 18:00 EET/17:00 CET)

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 8.1	Draft BPC opinion on an Union authorisation application for a biocidal product family containing mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13
Item 8.2	Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 2
Item 8.3	Harmonisation of the calculation of the PAA concentration from the product dilution
Item 11	Any other business
Item 12	Action points and conclusions

End of meeting

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