

11 April 2017 BPC-M-19-2017

Minutes of the 19th meeting of the Biocidal Products Committee (BPC)

1-3 March 2017

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 19th BPC meeting and informed the meeting that no changes occurred recently in the BPC membership.

The Chairman informed the BPC members of the participation of 24 members, including seven alternates.

Five advisers, one invited expert and one representative from accredited stakeholder organisations (ASOs) were present at the meeting. Two representatives from the European Commission also attended the meeting. Apologies were received from three members.

Applicants were present for their specific substances and the 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 Chairman introduced the final draft agenda (BPC-A-19-2016_rev3) and invited then any additional items. No additional items were added to the agenda.

The agenda was then adopted. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chairman informed the meeting participants that the meeting would be recorded for the purpose of the minutes and that the recording would be destroyed 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 Chairman 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-18

The revised draft minutes from BPC-18 (BPC-M-18-2016), incorporating the comments received from members, were agreed. With regard to the actions following BPC-18, the Chairman noted that most of them have been carried out. The Chairman then informed the meeting on the follow-up for acetamiprid for PT 18 that had been discussed at the previous meeting: the conclusion following the consultation on the reference values for human health was to use the lower value, which is in line with the EFSA opinion. The Chairman noted then that the BPC and the ENV Working Group were asked to comment on a revision of the REACH guidance on PBT/vPvB identification prepared by ECHA. The

BPC has also been consulted on the combined CAR-CLH report template and the final version of the template is expected to be available at the end of March. The participants were also informed that the document indicating the dates of the meetings in 2018 and the next process flows will be made available in the following days on the ECHA website and on CIRCABC.

Actions:

• **SECR:** to upload the agreed minutes from BPC-18 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

The SECR highlighted the key aspects of the housekeeping rules including the safety and security rules.

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-19-2017-01 covering the administrative updates and the report form the other ECHA Committees, provided to members for information purposes. The Chairman noted that this report also contains updates from the PBT and ED Expert Groups together with background information on the activities of the two expert groups.

6. Work Programme for BPC

6.1. BPC Work Programme

The Chairman presented the revised Work Programme, mentioning that this version is a revised version of the previously disseminated one, following consultations with the MSCAs.

The Chairman expresses the concerns of SECR about meeting the objectives for active substance approval due to the delays in the submissions. He continued stating that the progress will be discussed at the next CA meeting, where SECR will present their observations and together with the COM will reflect on some proposals to prevent possible further delays. With respect to the BPC planning the Chairman mentioned that after the draft agenda is sent out with the invitations for the meeting it is impossible for the SECR to reschedule the meeting days, therefore he urged the BPC members to stick to the planning once the draft agenda is distributed.

The Commission also expressed concerns regarding the progression of the review programme, the delays in the submission of the draft assessment reports by eCAs and frequent postponement of BPC discussions. These can jeopardise the organisation of the work, and most importantly, the achievement of the objectives commonly agreed for the achievement of human, animal and environmental health safety and the harmonisation of the EU market. The Commission invited the members to reflect on the present

situation in order to find solutions and have fruitful discussions during the CA meeting in March.

The Chairman also informed the meeting that the first Union authorisation application (for iodine) is likely to enter the peer review before summer, leading to a BPC discussion in the last 2017 meeting.

With regard to applications under Article 93 and 94 of the BPR, the Chairman mentioned that around 45 applications for active substance PT combinations have been received and validated by ECHA and are now in the eCA validation stage. He also stated that ECHA has started to coordinate between the involved eCAs for those applications where there are multiple applicants for the same active substance.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR **by 10 March 2017**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA web site and in the BPC CIRCABC IG.

7. Applications for approval of active substances

7.1 Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

The Chairman informed the meeting that no changes were made after the last BPC meeting.

7.2 Draft BPC opinion on cypermethrin for PT 18

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The rapporteur introduced the substance. The general issues related to the assessment report (AR) and opinion were then discussed in detail (modifications are described in the open issues table). Several changes to the AR had been introduced to the environmental section of the CAR, the main being that for indoor use with an application of twice per year followed by dry cleaning of the treated area a safe use has been identified (same approach as agreed for permethrin).

The BPC discussed the need to address the environmental quality standards as cypermethrin is included as a priority substance in the Water Framework Directive. It was agreed that both the AR and BPC Opinion should address these standards referring to agreed guidance available.

The rapporteur informed that a revised secondary exposure assessment had been carried out, which could have an impact on the outcome of the risk assessment and the need for RMMs (e.g. label restrictions for infants and toddlers). The Chairman proposed to circulate the revised secondary exposure assessment for a check within the BPC. The

updated opinion will be circulated at the same time including the changes in the exposure assessment, with the aim of adopting the BPC opinion via written procedure.

Other issues, such as the alignment between the AR and opinion regarding the neurotoxic potential of the active substance, the inclusion of a justification for not assessing indirect exposure via food due to the intended use of the product and the fact that according to the current criteria on endocrine disruption cypermethrin is not considered to have endocrine disrupting properties were discussed. There was a short general discussion about how to handle active substances which are not considered to have endocrine disrupting properties according to the interim criteria but might fulfil the criteria on endocrine disrupting properties in the future. COM clarified that they will prepare a CA-document on this issue.

A member commented that some clarifications should be provided in the opinion in order to improve the readability of the document (e.g. uses intended, assessed or not by the eCA, conclusions of the risk assessment for each use, terminology). The eCA accepted to further clarify the opinion in that way.

Actions:

- **Rapporteur:** to prepare a note including the assessment of secondary exposure and address the relationship with EQS set in the WFD.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and in accordance with the amended assessment in consultation with the rapporteur.
- **SECR:** to launch the written procedure of the draft opinion and the amended assessment in order to adopt the opinion **by 21 March 2017**.

7.3 Draft BPC opinion on MIT for PT 12

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The draft opinion was discussed at BPC-18, where it could not be adopted because of the potential risks for microorganisms in the Sewage Treatment Plant (STP). The weight of evidence approach used by the rapporteur was forwarded to and discussed by the Environment WG at their first meeting of 2017. For BPC-19 the rapporteur has prepared a revised Assessment Report, a revised draft BPC opinion and a "Note to the BPC members" explaining what has been done with respect to the issue of the potential risks for the STP. The rapporteur introduced the revised documents that included various proposals for risk mitigation measures (RMM) related to the STP.

It was agreed that the supporting calculations presented by the rapporteur showing that the RMMs lead to safe use will be included in the CAR and the outcome in the assessment report. It was clarified that the naming of the scenario "realistic worst case conditions" refers to the naming used in the ESD for PT 12 and the term in Annex VI of the BPR refers instead to environmental parameters, like water flow used in the exposure calculations. Therefore, to differentiate between the terms the scenario will refer to its description i.e. "paper mill with or without connection to a pulp mill."

The BPC decided to include a non-exhaustive list of potential RMMs, a list of choices that may be considered at product authorisation. It was acknowledged that RMM are required due to the minor exceedance of the risk ratio. However, as the functioning of the on-site STP is crucial for the operation of the paper mill, this risk can be adequately mitigated. A member strongly discouraged too prescriptive description of the RMMs. These will also depend on the site of application, on the use of other substances, functioning of the STP, retention times and other measures applied. Measuring the concentration of MIT and prescribing a fixed concentration threshold may not always be a suitable measure; the choice which measure is the most appropriate should be left open. Another member suggested to investigate at product authorisation together with the applicant which RMM may be applicable for the given product as some measures are more restrictive than others. This point was reflected in the section 2.4 of the Opinion.

The general presentation of personal protective equipment (PPE) in the "summary table: human health scenarios" of the opinions was agreed. Details of any PPE requirement will be included under the description of the scenario, whereas in the column under conclusion only the acceptability will be mentioned indicating "with PPE", in case required for any task within the scenario.

The assessment report was agreed by the BPC. The BPC adopted by consensus the opinion for the approval of this active substance/PT combination.

Actions:

- **Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 18 April 2017**.
- **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 2017** and publish it on the ECHA website.

7.4 Draft BPC opinion on fludioxonil for PTs 7, 9 and 10

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The rapporteur introduced the substance and its uses in PT 7, 9 and 10. The issues related to the assessment report (AR) and to the opinion were then discussed in detail. The issues related to the assessment report (AR) were discussed first followed by the issues (general and specific to each PT) related to the three opinions. The specific points discussed are summarised below.

The rapporteur clarified that even if the active substance shows innate efficacy, it is intended to be used in combination with other fungicides in order to prevent the development of resistance.

The BPC agreed that the reference specifications will remain unchanged, noting it may be different from the one under evaluation for the renewal of the active substance under the PPPR. After the finalisation of the ongoing mutagenicity test with a higher content of one of the impurities, a technical equivalence application under the BPR can be made by the applicant in order to being able to use the material from the alternative source for future product authorisation applications.

The assessment report was agreed by the BPC. The BPC adopted by consensus the opinions for the approval of PTs 7, 9 and 10.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 18 April 2017.**
- **SECR:** to revise the draft opinions in accordance with the discussion 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 2017** and publish them on the ECHA website.

7.5 Draft BPC opinion on Margosa extract for PT 19

The Chairman mentioned that the applicant was not present at this meeting.

The rapporteur introduced the substance and the general issues related to the assessment report (AR) and to the opinion were then discussed in detail (modifications are described in the open issues table).

The BPC agreed that, as additional information is required to clarify the P and T status, the substance cannot be included on Annex I. It was concluded that this information is required at renewal stage but if it is available earlier the conclusion on Annex I inclusion could be reconsidered.

The list of studies foreseen at WG ENV level according to a tiered approach to conclude whether the limonoids meet the P and/or T criteria will be presented in the AR.

A need to review the suitability of the available CA documents¹ for natural plant extracts was identified.

With regard to the environmental risk identified for the consumption based approach, the BPC identified a need to review the PT 19 ESD with respect to the simultaneity factor where, as worst case, the one of PT 18 is used. This issue will be addressed by the Environment WG.

The assessment report was agreed by the BPC. The BPC adopted by consensus the opinion for the approval of this active substance/PT combination.

Actions:

 Rapporteur: to revise the assessment report in accordance with the discussion in the BPC and submit them to the SECR by 18 April 2017.

¹ "How to deal with extracts and oils of plant or animal origin?", endorsed at the 23rd CA-Meeting and "Guidance to Member States and industry on the data requirements for naturally occurring substances used as attractants/repellents", endorsed at the 18th CA-Meeting

- **SECR:** to revise the draft opinion in accordance with the discussion 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 2017** and publish it on the ECHA website.

7.6 Revised Assessment Report following the submission of data after active substance approval for permethrin PT 18

The rapporteur introduced the relevant documents and the BPC members were invited to agree on the revised LoEP and on the Assessment Report. Several comments were made on the revised LoEP by the members which will be incorporated by the member from IE. With respect to the derivation of the PNECsoil considering the additional data a revised proposal was prepared by the member from IE. It was concluded that first a consultation of the Environment Working Group was required. Considering the on-going product authorisation applications it was concluded to initiate this consultation as soon as possible after the BPC meeting.

One member pointed out, that DCVA is a common metabolite of the pyrethroid active substances. In the meantime, several half-life values have been derived within the approval processes of the different active substances. For product authorisation, there is a need to coordinate and clarify which value should be used. The issue will be taken up by ECHA.

Actions:

- Rapporteur: to prepare a note to start the e-consultation on the PNECsoil.
- **SECR:** to initiate e-consultation with the ENV WG as soon as possible.

7.7 Public consultation on potential candidates for substitution

The Chairman introduced this agenda item, which was related to a consultation for which information on the active substance was submitted. The involved eCA was of the opinion that this information should not be taken into account as it is not the purpose of the consultation to obtain information on the active substance itself. Although the latter was confirmed by the BPC, it was recommended to incorporate the information received. It was then also discussed how to improve the quality of the information submitted during the public consultation where it was reiterated that the purpose is to obtain information on possible alternatives. The Chairman then indicated that the SECR will amend the current information on the ECHA web-site to describe this more clearly.

8. Article 75(1)(g) requests

8.1 Article 75(1)(g) request on the comparative assessment for anticoagulant rodenticides

The rapporteur (ECHA) introduced the draft opinion document and the cover note on the questions forwarded by the Commission for the comparative assessment of

anticoagulant rodenticides (ARs). The rapporteur explained that written comments from MSs were received prior to the meeting and proposed to review the comments with the objective of reaching an agreement.

The rapporteur indicated that the draft opinion had been written following the tiered approach described in the Technical Guidance Note (TGN) "CA-May15-Doc.4.3.a – Final". The available information on non-chemical alternatives was not sufficient to prove the efficacy of the presented non-chemical alternatives, which were considered as not eligible for the purpose of this comparative assessment. The BPC members agreed that, given the available information, the general conclusion of the opinion was valid. However, several MSs expressed the need to set the criteria on how to assess non-chemical alternatives and to provide clear guidance on what would be regarded as robust scientific evidence in the context of a comparative assessment for non-chemical alternatives.

The BPC members agreed that integrated pest management (IPM) should be promoted, and the conclusion of the opinion should not discourage users from using non-chemical alternatives as part of an IPM approach. It was agreed that the text of the opinion and the cover note will be modified accordingly in order to reflect this aspect better.

The Commission noted that the use of IPM is already contemplated in article 17.5 of the BPR and emphasised the need of improving the public consultation procedure by MSs in order to receive valid information and data that can be used for assessing non-chemical alternatives. This might involve further clarifying which information is expected from contributors (e.g. in the templates used for the consultation) and that MS further spread the consultation and ensure that it reaches the key involved sectors (e.g. manufacturers or users of non-chemical alternatives). Further, the Commission explained that non-chemical alternatives are not in the scope of the BPR, and therefore setting criteria for assessing these alternatives would be better achieved by trade or manufactures' associations.

One member proposed to include in the cover note to the COM the need to establish a European certification scheme for non-chemical control methods in order to promote the development of these methods. However, the BPC agreed not to include this proposal in the cover note as this is again not in the scope of the BPR.

On a more general note, a few MSs were of the opinion that the application of the Technical Guidance Note (TGN) "CA-May15-Doc.4.3.a – Final" leads to unintended results in conflict with the intention of recital 15 and article 23 of the BPR and, therefore, according to these MSs, this document should be revised.

The BPC members agreed by consensus with the text of the opinion and the cover note amended with the modifications indicated in the open issues table.

Actions:

- SECR: to revise the draft opinion in accordance with the discussions in the BPC.
- **SECR:** to prepare a cover note for COM to accompany the opinion, indicating the issues raised during the BPC-19 meeting.

8.2 Other Article 75(1)(g) requests

The Chairman informed that meeting that ECHA has received in January 2017 two request from COM for an Article 75(1)(g) opinion. The first one refers to the status of copper sulphate in two biocidal products for PT 3 and the second one concerns the eligibility of certain food and feed active substance for inclusion into Annex I to the BPR. For both requests the BPC opinion has to be delivered by October 2017.

With regard to the rapporteurs to be appointed, the Chairman stated that for the first request the member from France is willing to acts as rapporteur and a draft opinion will be discussed at the Efficacy WG. For the second request, SECR proposed that ECHA will act as rapporteur and a written consultation will be launched for the adoption of a draft opinion. The BPC agreed to the proposals for rapporteurship for the two requests.

9. Union authorisation

9.1 Update on Union authorisation

An update on Union authorisation was given by the SECR to present: an overview of the current status of the applications submitted so far; an outline of the ongoing activities; and a proposal about the planning for the discussion at the Working Group and BPC meetings of the first applications expected to enter the peer-review phase in 2017.

In relation to the ongoing activities, SECR explained that the document "Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings" had been uploaded to S-CIRCABC in both the clean and track changes versions. The document aims at highlighting potential issues that might be raised during the discussions at the Working Group and BPC meetings and is considered as a living document which can be updated, while experience in the peer-review of Union authorisation applications is built up. In the long run, when expertise is consolidated, the document can be archived.

Actions:

• BPC members to provide any further input on the document to SECR by contacting the functional mailbox bpc@echa.europa.eu. No deadline is set for this action, as input can be sent anytime, as soon as they are identified.

10. Any other business

10.1 Questions from WG Environment I 2017 to the BPC

The SECR informed the meeting on several questions which will be posed to the BPC by the Working Group Environment in the near future.

10.2 Inclusion on Annex I following the adoption of the BPC opinion

Following a question from one of the members, the Commission informed the meeting about the status of those active substances for which the BPC has concluded they are eligible for inclusion on Annex I.

11. 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

Agreed at the 19th meeting of BPC

1-3 March 2017

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 <u>agreed</u> without changes.	SECR: to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.		
Item 4 - Agreement of the minutes and review	y of actions from BPC-18		
The revised version of the minutes of BPC-18 was <u>agreed</u> as proposed subject to several editorial modifications.	SECR: to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting.		
Item 6 - Work programme for BPC			
6.1. Revised Work Programme 2017-2018 an	d Outlook for BPC		
	Members: to send information on any further changes to the Work Programme (WP) in particular on the second priority list, to the SECR by 10 March 2017.		
	SECR: on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG. Inform Commission about the status of the submissions for the second priority list.		
Item 7 - Applications for approval of active su	bstances		
7.2 Draft BPC opinion on cypermethrin for PT	18		
The BPC agreed to proceed with a written procedure to adopt the opinion: the updated opinion will address the relationship with the environmental quality standards (EQS) set in the Water Framework Directive (WFD) and amend the assessment of indirect exposure.	Rapporteur: to prepare a note including the assessment of secondary exposure and address the relationship with EQS set in the WFD.		
	SECR: to revise the draft opinion in accordance with the discussions in the BPC and in accordance with the amended assessment in consultation with the rapporteur.		
	SECR: To launch the written procedure of the draft opinion and the amended assessment in order to adopt the opinion by 21 March 2017.		
7.3 Draft BPC opinion MIT for PT 12			
The BPC <u>adopted by consensus</u> the opinion for the approval of the active substance/PT combination.	Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 18 April 2017.		
	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 2017** and publish it on the ECHA website.

7.4 Draft BPC opinion on fludioxonil for PTs 7, 9 and 10

The BPC <u>adopted by consensus</u> the opinions for the approval of the active substance/PT combinations.

Rapporteur: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by 18 April 2017.

SECR: to revise the draft opinions 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 2017** and publish them on the ECHA website.

7.5 Draft BPC opinion on Margosa extract for PT 19

The BPC <u>adopted by consensus</u> the opinion for the approval of the active substance/PT combination.

Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 18 April 2017.

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 2017** and publish it on the ECHA website.

7.6 Revised AR following the submission of data after active substance approval for permethrin PT 8 & 18

An e-consultation will be carried out on the Predicted No-Effect Concentration for the soil compartment (PNEC_{soil}).

Rapporteur: to prepare a note to start the econsultation on the $PNEC_{soil}$.

SECR: initiate e-consultation with the ENV WG as soon as possible.

7.7 Public consultation on potential candidates for substitution

The submission of information during public consultations was discussed.

Item 8 – Article 75(1)(g) requests

8.1 Article 75(1)(g) request on the comparative assessment for anticoagulant rodenticides

The BPC adopted <u>by consensus</u> the BPC opinion on the comparative assessment of anticoagulant rodenticides

SECR: to revise the draft opinion in accordance with the discussions in the BPC.

SECR: to prepare a cover note for COM to accompany the opinion, indicating the issues raised during the BPC-19 meeting.

8.2 Other Article 75(1)(g) requests

ВРС
SECR: to initiate an e-consultation with the BPC on the issues raised by the ENV-WG.
tion of the BPC opinion

Part III - List of Attendees

Members	European Commission
BROWN Finbar (IE)	CHATELIN Ludovic (DG SANTE)
CABALLO DIÉGUEZ Covadonga (ES)	LAS HERAS Alfonso (DG SANTE)
ČEBAŠEK Petra (SI)	
COSTIGAN Michael (UK)	Advisers
DRAGOIU Mihaela-Simona (RO)	CHRISTENSEN Anne Munch (DK)
GORDON Suzanne (NO)	CROIZÉ-POURCELET Gilles (FR)
HADJIGEORGIOU Andreas (CY)	HÄMÄLÄINEN Anna-Maija (FI)
HAHLBECK Edda (SE)	LEFÈBVRE Frédéric (BE)
JÄGER Stefanie (DE)	WEINHEIMER Viola (DE)
KOIVISTO Sanna (FI)	
KOMEN Corine (NL)	Accredited Stakeholder Organisations
LARSEN Jørgen (DK)	COGNAT Flore (CEFIC)
MIKOLASKOVA Denisa (SK)	
RUBBIANI Maristella (IT)	ECHA Staff
SZÁNTÓ Emese (HU)	ESTEVAN MARTINEZ Carmen
VAN BERLO Boris (BE)	JANOSSY Judit
VRHOVAC FILIPOVIC Ivana (HR)	LOPEZ SERRANO Paloma
ZOUNOS Athanasios (EL)	NEGULICI Ligia
Alternate members	PECORINI Chiara
COLLETT Romy (FR)	PRIHA Outi
ENSCH Svenja (LU)	SAEZ RIBAS Monica
GAVRIEL Alexandros (CY)	SCHIMMELPFENNIG Heike
ILMARINEN Kaja (EE)	VAN DE PLASSCHE Erik
MIKOLAS Jan (CZ)	
PUERGY Reinhild (AT)	
PYTHON François (CH)	
Invited expert	
HADAM Anna (PL)	

Applicants	Apologies
SAUER Frank (LANXESS Deutschland GmbH) for fludioxonil PT 7, 9, 10	BORGES Teresa (PT)
SCHOESTER Monika (Thor GmbH) for MIT PT 12	BROVKINA Julija (LV)
WHITELEY Alison (Arysta Life Science) for cypermethrin PT 18	GIORDMAINA Wayne (MT)
Experts accompanying applicants	
GOODYEAR Andrew, accompanying SAUER Frank, for fludioxonil PT 7, 9, 10	
UEBEL Caroline, accompanying SCHOESTER Monika, for MIT PT 12	

Part IV - List of Annexes

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

Products Committee

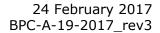
Annex II Final agenda of BPC-19

Annex I

Documents submitted to the members of the Biocidal Products Committee for the $\ensuremath{\mathsf{BPC-19}}$ meeting

Meeting documents					
Agenda Point	Number	Title			
2	BPC-A-19-2017	Draft agenda			
4	BPC-M-18-2016	Draft minutes from BPC-1	18		
5.2	BPC-19-2017-01	Administrative issues and	report from the other Committees		
6.1	BPC-19-2017-02	BPC updated Work Progra	amme 2017-2018		
6.2	BPC-19-2017-03	Outlook for the BPC			
7.6	BPC-19-2017-16, - 17, -18 and Annexes	Revised AR following the substance approval for pe	submission of data after active ermethrin PT 8		
7.7	BPC-19-2017-10 BPC-19-2017-20	Public consultation on pot	Public consultation on potential candidates for substitution		
8.1	BPC-19-2017-11, 12, 13, 14, 21	Article 75(1)(g) request on the comparative assessment for anticoagulant rodenticides			
8.2	BPC-19-2017-15 Annex I and II	Other Article 75(1)(g) requests			
9.1	BPC-19-2017-17	Update on Union authorisation			
Substance documents					
Agenda Point	Number	Substance-PT	Title		
	BPC-19-2017-04A		Draft BPC opinion		
7.2	BPC-19-2017-04B	Cypermethrin PT 18	Assessment report		
	BPC-19-2017-04C		Open issues		
	BPC-19-2017-05A		Draft BPC opinion		
	BPC-19-2017-05B		Assessment report		
7.3	BPC-19-2017-05C	MIT PT 12	Open issues		
/.5	BPC-19-2017-05D	111111111	Note to BPC members		
	BPC-19-2017-05E		Outcome of the written consultation of ENV WG		

	BPC-19-2017-06A		Draft BPC opinion
	BPC-19-2017-06B	Fludioxonil PT 7	Assessment report
	BPC-19-2017-06C		Open issues
	BPC-19-2017-07A		Draft BPC opinion
7.4	BPC-19-2017-07B	Fludioxonil PT 9	Assessment report
	BPC-19-2017-06C		Open issues
	BPC-19-2017-08A		Draft BPC opinion
	BPC-19-2017-08B	Fludioxonil PT 10	Assessment report
	BPC-19-2017-06C		Open issues
	BPC-19-2017-09A		Draft BPC opinion
7.5	BPC-19-2017-09B	Margosa extract PT 19	Assessment report
	BPC-19-2017-09C		Open issues





Agenda

19th meeting of the Biocidal Products Committee (BPC)

1-3 March 2017

ECHA Conference Centre, Annankatu 18, Helsinki Starts on 1st March at 13:30, ends on 3rd March at 12:30

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2. - Agreement of the agenda

BPC-A-19-2017_rev3

For agreement

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

4. - Agreement of the minutes and review of actions from BPC-18

BPC-M-18-2016

For agreement

5. - Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-19-2017-01

For information

6. - Work programme for BPC

6.1. BPC Work Programme 2017-2018

BPC-19-2017-02

For information

6.2. Outlook for BPC

BPC-19-2017-03

For information

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

7.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

For information

7.2. Draft BPC opinion on cypermethrin for PT 18

Previous discussion(s): WG-IV-2016

BPC-19-2017-04A, B and C

For adoption

7.3. Draft BPC opinion on MIT for PT 12

Previous discussion(s): WG-IV-2016, BPC-18

BPC-19-2017-05A, B, C, D and E

For adoption

7.4. Draft BPC opinion on fludioxonil for PTs 7, 9 and 10

Previous discussion(s): WG-IV-2016

PT 7: BPC-19-2017-06A, B and C

PT 9: BPC-19-2017-07A, BPC-19-2017-06B and C **PT 10**: BPC-19-2017-08A, BPC-19-2017-06B and C

For adoption

7.5. Draft BPC opinion on Margosa extract for PT 19

Previous discussion(s): WG-III-2016

BPC-19-2017-09A, B and C

For adoption

7.6. Revised Assessment Report following the submission of data after active substance approval for permethrin PT 8

BPC-19-2017-16, 17, 18 and Annexes

For agreement

7.7. Public consultation on potential candidates for substitution

[†] 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 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 discussion

8. - Article 75(1)(g) requests

8.1. Article 75(1)(g) request on the comparative assessment for anticoagulant rodenticides

BPC-19-2017-11, 12, 13 and 14

For adoption

8.2. Other Article 75(1)(g) requests

BPC-19-2017-15, Annex 1 and 2

For information

- 9. Union authorisation
- 9.1 Update on Union authorisation

BPC-19-2017-19

For information

- 10. Any other business
- 10.1 Questions from WG Environment I 2017 to BPC

For information

10.2 Inclusion on Annex I following the adoption of the BPC opinion

For discussion

11. - Agreement of the action points and conclusions

For agreement



Provisional timeline for the

19th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki 1st March 2017: starts at 13:30; 3rd March 2017: ends at 12:30

Please note that the timings indicated below are provisional and subject to possible change. They are distributed to participants on a preliminary basis.

Wednesday 1 March: afternoon session

Items 1-5	Opening items and administrative issues
Item 6	Work programme for BPC 2017-2018
Item 7.1	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage
Item 7.2	Draft BPC opinion on cypermethrin for PT 18

Thursday 2 March: morning session

Item 7.3	Draft BPC opinion on MIT for PT 12
Item 7.4	Draft BPC opinion on fludioxonil for PTs 7, 9 and 10

Thursday 2 March: afternoon session

Item 8.1	Article 75(1)(g) anticoagulant roc	•	on	the	comparative	assessment	for
Item 8.2	Other Article 75(L)(g) reque	sts				

Friday 3 March: morning session

Item 7.5	Draft BPC opinion on Margosa extract for PT 19
Item 7.6	Revised Assessment Report following the submission of data after active substance approval for permethrin PT 8
Item 7.7	Public consultation on potential candidates for substitution
Item 9.1	Update on Union authorisation
Item 10	Any other business
Item 11	Agreement of the action points and conclusions

End of meeting

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