

1 April 2016
BPC-M-14-2016

**Minutes of the 14th meeting of
the Biocidal Products Committee (BPC)**

16 February 2016

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the fourteenth BPC meeting.

The Chairman informed the meeting that no changes occurred in the BPC membership since the last meeting. He also mentioned that this was the first meeting in which the Maltese member, Wayne Giordmaina, participated.

The Chairman informed the BPC members of the participation of 25 members, including three alternates.

Four advisers, one representative of the European Commission and two representatives from accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from four members and two ASO representatives.

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-14-2016_rev2) and indicated that items 7 b)-d) will be discussed after the agenda item on cyfluthrin.

The Chairman invited then any additional items. Three additional items were included in the agenda, upon suggestion from BPC members: i) further information on the anticoagulant rodenticides renewal process; ii) applications for renewal under the 'normal' renewal process, particularly the expectations from applicants and iii) DBDCB discussions in the Human Health Working Group.

The agenda was adopted with the proposed changes. 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 conflicts of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-13

The revised draft minutes from BPC-13 (BPC-M-13-2015), incorporating the comments received from members, were agreed.

Under the follow-up of the actions arising from BPC-13, it was communicated to BPC members that the revised working procedure reflecting the future use of R4BP 3 as the main tool for formal communication was published on the ECHA website. With respect to the improvement of the communication tool function of R4BP 3, the Chairman mentioned that MSCAs can now send documents via ad-hoc communication if these are zipped. Further discussions on possible improvement will take place in the context of the IT R4BP User Platform organised by ECHA. The Chairman added that all active substance approval applications have been migrated to R4BP (including Review Programme and applications under Article 11 of the BPD), which will allow better reporting.

On the documents agreed in the previous BPC meeting in the context of the follow up of the March 2015 workshop on active substance approval, the Chairman reported that the document on the role of the SECR was distributed to members via CIRCABC, while the documents concerning the applicability of new guidance and the introduction of new information during the peer review process were published on the ECHA website. In addition, actions are undertaken to raise awareness: the BPC Working Groups were informed in January, a Chemical Watch publication was organised and ASOs will be informed via the March stakeholder newsletter from ECHA.

In addition, the Chairman informed the BPC that ECHA will create an overview concerning the timing of the upcoming active substance renewals. Furthermore, the BPC was informed that for union authorisations a separate interest group will be established on SCIRCABC.

To follow, the Chairman provided a brief update on the project related to the harmonisation of the dossier format between biocides and harmonised classification and labelling: a task force was created following the invitations sent by ECHA in December 2015. In addition to the harmonisation of the dossier format it will also discuss other issues related to harmonisation between the two regulations.

Actions:

- **SECR:** to upload the agreed minutes from BPC-13 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-14-2016-01 covering the report from the other ECHA Committees and provided to members for information purposes.

The Chairman informed the meeting that two organisations already accepted as ECHA accredited stakeholders, ASD - Aerospace and Defence Industries Association of Europe - and HSI - Humane Society International, have updated their interest and included the work of the BPC. Following the agreement of the Committee members to accept these organisations as accredited stakeholders, the list of accredited stakeholders published on the ECHA website will be updated.

To follow, the Chairman mentioned the membership renewal exercise launched in January with a view to collect the renewal of appointments or new nominations by the beginning of March.

The Chairman also reminded the members of the timelines for providing to SECR the final assessment reports and other documents for dissemination (42 days after the meeting for the final assessment reports and 120 days after the meeting for the non-confidential version of Doc IIIA). In this context the Chairman also reminded that the eCAs are responsible for ensuring that the documents provided for dissemination do not contain any confidential information and that ECHA cannot bear responsibility for the involuntary disclosure of confidential information from documents inadequately prepared for publication.

Actions:

- **SECR:** to update the accredited stakeholders list on the ECHA website;

6. Work Programme for BPC

6.1 Revised Work Programme 2016-2017

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.

With regard to the first priority list the Chairman informed the meeting that ECHA will prepare a letter to the Commission containing those active substance PT combinations for which it is foreseen that the Agency cannot meet its legal obligations by initiating to work on the preparation of the opinion by March 31. Currently these are: empenethrin, d-tetramethrin, tetramethrin, d-allethrin, esbiothrin, prallethrin, carbon dioxide, sodium cacodylate, lavandin oil, zinc pyriothione, polymeric betaine and geraniol.

For the second priority list (PT 3, 4 and 5) for which the deadline for the submission of the evaluation is 31 December 2016, the Chairman stated that in total 99 active substance PT combinations remain: 22 are scheduled for the WG and BPC while 79 are not yet scheduled.

Members were requested to stick to the work programme and to give priority to the second priority list. With respect to the forecast of resources for MSCAs as well as the SECR and for the predictability for applicants for product authorisation this is highly important. The Chairman also mentioned the ongoing disinfectants project, asking for more support and cooperation from MSCAs to identify relevant issues for this project.

Actions:

- **Members:** to send information on any further changes to the Work Programme (WP) to the SECR by 23 February 2016.
- **SECR:** on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.

6.2 Outlook

See above under item 6.1.

7. Applications for approval of active substances

7.1 Templates and formats for active substance

a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage

The Chairman introduced the document (BPC-15-2015-04) mentioning that the document was revised based on the new wording convention of the conditions and the experience gained in their application. A member asked to distinguish between new and existing substances in the standard phrase for the submission of additional data.

Actions:

- **Members:** to apply the standard phrases in future draft opinions.
- **SECR:** to revise and upload the catalogue to the BPC CIRCABC IG after the meeting.

b) Template for BPC opinion

One member asked to clarify in the text below the summary table for the environment of section 2.1.c) that the focus must not only be on unacceptable risks and the need for mitigation but also a description of acceptable risks.

Actions:

- **Members:** to send comments via CIRCA BC to the SECR by **11 March 2016**.

c) Template for the Assessment Report

One member asked to introduce a similar table as is included in the opinion template in the section on classification and labelling 2.1.3. A member asked to move section 2.2.2.4 on fate and distribution in the environment to after section 2.2.2.1 on hazard identification and effects assessment.

Actions:

- **Members:** to send comments via CIRCA BC to the SECR by **11 March 2016**.

d) Manual/instructions on preparing the draft BPC opinion on an application for approval of an active substance

Several members and the COM asked to state only the name of the eCA under "Rapporteur" in the section on "Adoption of the BPC opinion". The rationale for this is that the evaluation is prepared by the eCA which a BPC member represents, and receives instructions from. The BPC member is not acting independently, which is different compared to other committees, for example the RAC where the members are independent nominated experts. It was agreed this will also be taken over in the template for the BPC opinion.

Actions:

- **Members:** to send comments via CIRCA BC to the SECR by **11 March 2016**.

7.2 Draft BPC opinion on *bacillus thuringiensis* subsp *Kurstaki* for PT 18

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had objected to the presence of ASOs during the discussion. The session was therefore closed to stakeholder observers.

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 31 March 2016
- **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 11 March 2016 and publish it on the ECHA website.

7.3 Draft BPC opinion on citric acid for PT 2

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 general issues related to the assessment report (AR) were discussed. The reasoning for the classification and labelling proposal for citric acid for skin and eye irritation was explained. The proposal is based on actual data and an explanation will be added to the relevant part of the assessment report. It was clarified also that the impregnated tissue does not need to be classified for these endpoints based on tests with the impregnated tissue. Following a question from a member it was clarified that additional data will be needed at product authorisation on efficacy for the impregnated solution and the tissue tested with a shorter contact time compared to the available tests. It was decided that this information will be added to the assessment report. After some discussion it was concluded by the chairman, in line with earlier opinions, that no statement is required on this in the opinion. However, it was concluded that further discussion may be needed at the Working Group on Efficacy depending on the claims made by the applicant at the product authorisation stage.

With regard to the exposure of non-professional users of the biocidal products (consumers using and disposing the tissue) it was decided that a section will be added to the AR.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting.

Several issues relevant for the assessment report were taken over for the opinion in a similar way. The BPC adopted by consensus the opinion for the approval of this active substance/PT combination, subject to the changes agreed during the meeting.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 March 2016
- **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 11 March 2016 and publish it on the ECHA website.

7.4 Draft BPC opinion on cyfluthrin 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 and informed BPC members that during the public consultation further information had been received to conclude that the substance is no longer a candidate for substitution as it meets only one of the PBT criteria.

General issues related to the assessment report (AR) were discussed. Other items such as the adversity of the sensory irritation effects were not discussed as the eCA had already taken account of the conclusions of the Working Group on Human Health. The eCA informed that the CLH proposal will be submitted to ECHA in Q1-Q2 2016.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting.

The draft opinion was then discussed. The efficacy of the isomers and its implication for the fulfilment of the substitution criteria was discussed. The Commission proposed to include in the Opinion that with the current information the substance does not meet the substitution criteria. The BPC considered that data on the efficacy of all the isomers should be provided at the latest at the renewal of the active substance approval.

It was also discussed whether or not the classification of one of the metabolites as vP would lead to the inclusion of the standard phrase on treated articles. It was agreed that until further reflection is made by the Commission, this standard phrase should not be included.

With regard to measures proposed to avoid resistance development and applicable for non-professional users the BPC decided to take over the sentence agreed for PT 14 at the last WG meeting. The reason behind the decision is the same as for PT 14: a non-professional user has not enough knowledge to decide on alternative active substances/biocidal products when resistance occurs.

The BPC adopted by consensus the opinion for the approval of this active substance/PT combination, subject to the changes agreed during the meeting.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 March 2016
- **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 11 March 2016 and publish it on the ECHA website.

7.5 Dissemination of data generated after active substance approval

The discussion on this document was postponed to the next BPC meeting. The Chairman informed that a revised version will be prepared taking into account the discussions in the Coordination Group on the evaluation of information of alternative dossiers.

7.6 Follow up on the Workshop “Reviewing the active substance assessment process”: a proposal to revise the working procedure

The Chairman introduced the document containing three possible options to amend the working procedure including an impact assessment. All members agreed that the process needs to be improved, so option 1 (not amending the working procedure) was not supported. Several members supported option 2 (amending the procedure so that there is more time between the WG and the BPC meetings) as the current timelines after the submission of the draft opinion to the SECR are very or too short. In addition, it was stated that this is especially relevant in cases where a MSCA supports one active substance for multiple product types. Several members expressed their concerns over this option as it would reduce the time for commenting on the draft competent authority report (CAR) submitted to the SECR for the commenting phase after the accordance check. For this reason several members supported option 3 (moving the commenting phase to before the start of the peer review). The SECR agreed with this concern, but stated ECHA is taking actions to improve the accordance check, for example the development of detailed checklists, with the idea to improve the quality of incoming draft CARs. Several members stated that the latter is of the utmost importance, as option 2 does not concern this aspect. The SECR stated it is taking other actions like more interaction between SECR and the eCA in the evaluation phase and the scheduling of early WG discussions. One member recommended to not shorten the timelines for the trilateral discussions. Other members stated that maybe a mixture of option 2 and 3 could be developed. COM stated that they consider option 3 is not a viable option as it is not compliant with the BPR and the Review Regulation, referring to the timelines for the evaluation by the eCA and the peer review. However, the SECR explained that this concern also applies for early WG discussions which have already been established. COM also indicated that pro-active actions can be taken to ensure a smoother review, in particular with an active coordination by SECR during the evaluation phase of active substances.

The Chairman concluded that a decision could not be taken at this meeting and that the SECR will consider first all comments made, and prepare a revised proposal for the next BPC meeting.

Actions:

- **Members:** to send comments by **11 March 2016** via CIRCABC;
- **SECR:** to revise the document in light of the discussions for BPC-15.

8. Any other business

Three additional items were included in the agenda:

i) further information on the anticoagulant rodenticides renewal process. The Chairman informed the BPC that the peer review phase for the draft opinions and assessment reports will be initiated by the SECR at the beginning of April with the intention to adopt the opinions at BPC-15. A commenting phase is foreseen.

ii) applications for renewal under the 'normal' renewal process, particularly the expectations from applicants: this item was postponed to BPC-15 where the SECR will inform the meeting on its activities.

iii) DBDCB discussions in the Human Health Working Group: the Chairman informed the meeting about the outcome of these discussions. The opinion and assessment report have now been forwarded to the COM.

Part II - Main conclusions and action points

Agreed at the 14th meeting of BPC

16 February 2016

Agenda point	
Conclusions / decisions / minority positions	Action requested after the meeting (by whom/by when)
Item 2 - Agreement of the agenda	
<p>The final draft agenda was <u>agreed</u> with the following additions:</p> <ul style="list-style-type: none"> - The process of anticoagulant rodenticides renewals for BPC-16; - Renewal of active substances; - DBDCB discussions in Working Group Human Health. 	<p>SECR: to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.</p>
Item 4 - Agreement of the minutes and review of actions from BPC-13	
<p>The revised version of the minutes of BPC-13 was <u>agreed</u> as proposed subject to several editorial modifications.</p> <p>The SECR informed the meeting of its intentions to prepare a document to clarify and harmonise the assessment of in-situ generated active substances.</p>	<p>SECR: to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting.</p> <p>Members: to provide feedback and topics to be covered in this document by 11 March 2016.</p>
Item 6 - Work programme for BPC	
6. a) Revised Work Programme 2016-2017	
<p>Priority shall be given to the second priority list substances of the Review Programme Regulation.</p>	<p>Members: to send information on any further changes to the Work Programme (WP) to the SECR by 23 February 2016.</p> <p>SECR: on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.</p>
Item 7 - Applications for approval of active substances	
7.1 Templates and formats for active substance approval	
<p>The catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval was agreed.</p>	<p>SECR: the document will be revised and distributed via CIRCA BC.</p> <p>Members: to send comments by 11 March 2016 via CIRCABC on the revised templates for the opinion and assessment report and the manual on preparing the draft opinion.</p>

7.2 Draft BPC opinion on <i>bacillus thuringiensis</i> subsp. <i>Kurstaki</i> PT 18	
The BPC <u>adopted by consensus</u> the opinion for the approval of this active substance/PT combination.	<p>Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 March 2016.</p> <p>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.</p> <p>SECR: to forward the adopted opinion to COM by 11 March 2016 and publish it on the ECHA website.</p>
7.3 Draft BPC opinion on citric acid for PT 2	
The BPC <u>adopted by consensus</u> the opinion for the approval of this active substance/PT combination.	<p>Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 March 2016.</p> <p>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.</p> <p>SECR: to forward the adopted opinion to COM by 11 March 2016 and publish it on the ECHA website.</p>
7.4 Draft BPC opinion on cyfluthrin for PT 18	
The BPC <u>adopted by consensus</u> the opinion for the approval of this active substance/PT combination.	<p>Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 March 2016.</p> <p>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.</p> <p>SECR: to forward the adopted opinion to COM by 11 March 2016 and publish it on the ECHA website.</p>
7.5 Dissemination of data generated after active substance approval	
The discussion on the document was postponed for the next BPC.	<p>Members: to send comments by 11 March 2016 via CIRCABC.</p> <p>SECR: to revise the document in light of the comments and present it at the next BPC.</p>
7.6 Follow-up on the Workshop "Reviewing the active substance assessment process"	
A proposal to revise the working procedure	
Several comments were made by the BPC on the proposals for amending the working procedure.	<p>Members: to send comments by 11 March 2016 via CIRCABC.</p> <p>SECR: to revise the document in light of the discussions for BPC-15.</p>
Item 8 – Any other business	

Renewal of anticoagulant rodenticides	
The SECR briefly updated the BPC on the process of the renewal of anticoagulant rodenticides.	
Process for renewal of active substance approval	
A discussion on this process will take place at BPC-15.	
DBDCB	
The SECR informed that the Working Group Human Health agreed to amend the List of Endpoints of DBDCB (as a follow-up of BPC-13), which is to be included in the Assessment Report.	

Part III - List of Attendees

Members	Advisers
BORGES Teresa (PT)	LEBLOND Annabelle
BROVKINA Julija (LV)	LEPAGE Anne
ČEBAŠEK Petra (SI)	PALOMÄKI Jaana
COSTIGAN Michael (UK)	RITZ Vera
DONS Christian (NO)	
DRAGOIU Mihaela-Simona (RO)	Accredited Stakeholder Organisations
GIORDMAINA Wayne (MT)	BRUYNDONCKX Raf (Cefic)
GONZALEZ MARQUEZ Luisa (ES)	MONTMOREAU Bertrand (CEPA)
HADJIGEORGIOU Andreas (CY)	
HAHLBECK Edda (SE)	ECHA Staff
HARRISON John (IE)	ESTEVAN MARTINEZ Carmen
JÄGER Stefanie (DE)	JANOSSY Judit
KOMEN Corine (NL)	KENIGSWALD Hugues
LARSEN Jørgen (DK)	MYOHANEN Kirsi
MIKOLASKOVA Denisa (SK)	NEGULICI Ligia
RUSCONI Manuel (CH)	VAN DE PLASSCHE Erik
SPATNY Nina (AT)	
SZÁNTÓ Emese (HU)	
TUUSA Tiina (FI)	
VAN BERLO Boris (BE)	
VRHOVAC FILIPOVIC Ivana (HR)	
Alternate members	
CRESTI Raffaella (IT)	
ENSCH Svenja (LU)	
MIKOLÁŠ Jan (CZ)	
European Commission	
CHATELIN Ludovic (DG SANTE)	

Applicants	Apologies
BLONDAZ Pascal (BAYER) for cyfluthrin PT 18	CAZELLE Elodie (AISE)
MUNDAY Denise (SCAE - Valent BioSciences Sàrl) for <i>Bacillus thuringiensis</i> subsp. <i>Kurstaki</i> PT 18	MERISTE Anu (EE)
STEWART Sonja (Kimberly Clark Europe) for citric acid PT 2	MAJUS Saulius (LT)
	JAWORSKA-LUCZAK Barbara (PL)
Experts accompanying applicants	REID Kirsty (Eurogroup for Animals)
HERRERO Maria, accompanying MUNDAY Denise for <i>Bacillus thuringiensis</i> subsp. <i>Kurstaki</i> PT 18	

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-14

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-14 meeting

Meeting documents			
Agenda Point	Number	Title	
2	BPC-A-14-2016_rev2	Draft agenda	
4	BPC-M-13-2015	Draft minutes from BPC-13	
4	BPC-14-2016-13	Clarifying and harmonising the approach for the assessment of <i>in situ</i> generated active substances	
5.2	BPC-14-2016-01	Administrative issues and report from the other Committees	
6.1	BPC-14-2016-02	BPC updated Work Programme 2015-2016	
6.2	BPC-14-2016-03	Outlook for second priority list	
7.1.a)	BPC-14-2016-04	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage	
7.1.b)	BPC-14-2016-05	Revised BPC opinion template	
7.1.c)	BPC-14-2016-06	Revised Assessment Report template	
7.1.d)	BPC-14-2016-09	Manual on preparing the draft BPC opinion on an application for approval of an active substance	
7.5	BPC-14-2016-07	Disseminating the revised Assessment Report following the submission of data after active substance approval	
7.6	BPC-14-2016-08	A proposal to revise the working procedure	
Substance documents			
Agenda Point	Number	Substance-PT	Title
7.2	BPC-14-2016-10A	<i>Bacillus thuringiensis</i> subsp. Kurstaki PT 18	Draft opinion
	BPC-14-2016-10B		Assessment report
	BPC-14-2016-10C_1		Open issues table
	BPC-14-2016-10C_2		Confidential open issues table
7.3	BPC-14-2016-11A	Citric acid PT 2	Draft opinion
	BPC-14-2016-11B		Assessment report

	BPC-14-2016-11C		Open issues table
7.4	BPC-14-2016-12A	Cyfluthrin PT 18	Draft opinion
	BPC-14-2016-12B		Assessment report
	BPC-14-2016-12C		Open issues table

02 February 2016
BPC-A-14-2016_rev2

Agenda

14th meeting of the Biocidal Products Committee (BPC)

16 February 2016

ECHA Conference Centre, Annankatu 18, Helsinki

Starts at 09:30, ends at 17:30

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-14-2016_rev2
For agreement

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

4. – Agreement of the minutes and review of actions from BPC-13

BPC-M-13-2015
For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-14-2016-01
For information

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2016-2017

BPC-14-2016-02
For information

6.2. Outlook for second priority list

BPC-14-2016-03
For information

7. – Applications for approval of active substances*

- 7.1. a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval** (introducing the new wording of the conditions for active substance approval)

BPC-14-2016-04
For discussion

- b) Template for BPC opinion**

BPC-14-2016-05
For information

- c) Template for the Assessment Report**

BPC-14-2016-06
For information

- d) Manual on preparing the draft BPC opinion on an application for approval of an active substance**

BPC-14-2016-09
For discussion

- 7.2. Draft BPC opinion on *Bacillus thuringiensis* subsp. *Kurstaki* for PT 18**
Previous discussion(s): WG-V-2015

BPC-14-2016-10A, B and C
For adoption

- 7.3. Draft BPC opinion on citric acid for PT 2**
Previous discussion(s): WG-IV-2014

BPC-14-2016-11A, B and C
For adoption

- 7.4. Draft BPC opinion on cyfluthrin for PT 18**
Previous discussion(s): TM-III-2011

BPC-14-2016-12A, B and C
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 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).

7.5. Dissemination of data generated after active substance approval

BPC-14-2016-07

For discussion

7.6. Follow-up on the Workshop "Reviewing the active substance assessment process":

A proposal to revise the working procedure

BPC-14-2016-08

For discussion

Item 8 – Any other business

8.1 The process of anticoagulant rodenticides renewals for BPC-16

8.2 Renewal of active substances

8.3 DBDCB discussions in Working Group Human Health

Item 9 – Agreement of the action points and conclusions

For agreement

**Provisional timeline for the
14th meeting of the Biocidal Products Committee (BPC)
ECHA Conference Centre, Annankatu 18, Helsinki
16 February 2016: starts at 09:30; ends at 17:30**

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

Tuesday 16 February: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme of the BPC 2015-16
Item 7.1	a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage b) Template for BPC opinion c) Template for the Assessment Report d) Manual on preparing the draft BPC opinion on an application for approval of an active substance
Item 7.2	Draft BPC opinion on <i>Bacillus thuringiensis</i> subsp. Kurstaki for PT 18
Item 7.3	Draft BPC opinion on citric acid for PT 2

Tuesday 16 February: afternoon session

Item 7.4	Draft BPC opinion on cyfluthrin for PT 18
Item 7.5	Dissemination of data generated after active substance approval
Item 7.6	Follow-up on the Workshop "Reviewing the active substance assessment process": A proposal to revise the working procedure
Item 8	AOB
Item 9	Agreement of the action points and conclusions

End of meeting

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