26 September 2018

CG-M-30-2018 non-confidential

Final non-confidential minutes of the 30th meeting of the Coordination Group (CG)

3-4 July 2018

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the thirtieth CG meeting (CG-30). 33 members and experts from 21 Member State Competent Authorities (MSCAs), CH and NO participated in the meeting. Two representatives from DG SANTÉ and three representatives from ECHA were present in the meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-30-2018) and invited participants to add any items under AOB. One item was added to the agenda related to the renewal of SBP authorisations. The agenda was agreed with this addition.

Actions:

SECR: to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.

3. Declaration of interest in relation to the agenda

The Chair invited the representatives of the MSCAs (referred to hereafter as 'members') to declare any potential conflict of interests. No declarations of conflicts of interest were made.

4. Draft minutes from CG-29

The Chair explained that the draft confidential CG-29 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. The draft confidential CG-29 minutes were agreed.

Actions:

SECR: to upload the CG-29 minutes into the relevant folders in the CG CIRCABC.

5. Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

The Chair presented the overview table of the referrals discussed so far at CG level. This overview is uploaded as well to the Disagreements folder in S-CIRCABC.

Actions:

SECR: to produce a revised overview table for next CG meeting.

5.2 Formal referrals on mutual recognition disagreements under Article 35 of the BPR

Two formal referrals were discussed during the meeting.

1) The first referral was related to a PT18 product containing synthetic amorphous silicon dioxide as active substance. The point of disagreement was related to the validity of the characterisation data submitted for the active substance in the product. The discussion will be continued during the CG-31 meeting.
2) The second referral was related to a PT8 product containing 3-iodo-2-propynylbutylcarbamate as active substance. Several points of disagreement were raised, the most critical ones being related to the human health risk assessment of

the product. Agreement was reached on several points and the discussion of the remaining open points will continue after the meeting. The referral will be closed by written procedure.

Actions:

1) refMS and icMSs: To propose a way forward by 25 July.

1) All: To comment on the way forward by 1 Sept.

2) refMS: To provide the updated PAR at the latest by 25 July.

2) All: To agree on the updated PAR within one week.

2) SECR: If agreement is reached on the updated PAR, to organise agreement of the outcome by written procedure.

6. Harmonisation of technical and regulatory issues in relation to product authorisation

6.1 Issues identified in the context of UA

The SECR presented an updated list of issues identified in the context of UA applications (CG-30-2018-25). The intention of publishing this list is to allow refMSs of national authorisations of products based on the same active substance to be informed about the issues identified in UA applications.

The SECR confirmed that all MSs will be informed and invited to participate in the discussions of issues arising as part of the coordination process among e-CAs evaluating UA applications with the same active substance(s)/PT(s) combination.

Actions:

MSs: To take note of the information provided in the table.

SECR: To provide an updated list for the next CG meeting.

6.2 Post-authorisation conditions in product authorisation

The SECR presented an updated proposal (CG-30-2018-19) on how to address post-authorisation conditions for product authorisations. The discussion will continue during the CG-31 meeting.

Actions:

SECR: to open a newsgroups for comments.

All: to comment on the proposal by 25 July.

7. Any Other Business (closed session)

7.1 Late procedures

The Commission presented the overview of late procedures.

Actions:

MSs: to review the document and communicate to ECHA any inaccuracies in the data.

SECR: to open a newsgroups for comments.

refMSs with more than 10 late procedures: To provide feedback on the state of play of the applications by 25 July.

7.2. Feedback on e-consultations

Two e-consultations were discussed and one e-consultation was briefly introduced:

1) **Efficacy requirements concerning a BPF for disinfection in dishwashing systems.**

A member presented an e-consultation on the efficacy requirements concerning a biocidal product family (BPF) authorisation application for disinfection of dishes in dishwashing systems (CG-30-2018-08). It was agreed that, in the absence of a harmonised standard, alternative methods could be used to prove the efficacy of a product. Technical issues of the alternative standards could be discussed at the efficacy WG if necessary.

Actions:

CG member: To provide a final version of the document including the comments agreed in the meeting.

SECR: To publish the document in the confidential section of S-CIRCABC.

2) **Data requirements for storage stability for simplified authorisation (SA)**

A CG member introduced the conclusions of an e-consultation related to data requirements for setting the shelf life of a product following a simplified product authorisation procedure (CG -29-2018-03). The consultation was on whether for a simplified authorisation it was possible to submit efficacy data to set the shelf life of a product instead of submitting long term and accelerated storage stability data.

CG members agreed that, in the case of a simplified authorisation, the shelf life of a product could be set based on either efficacy data or long term chemical storage stability data. Accelerated storage stability data would not be needed in the case of the shelf life being supported by efficacy data. In all cases the analytical methods for analysing the concentration of active substance would need to be validated.

Action points:

CG member: To provide a final public version of the document including the comments agreed in the meeting.

SECR: To publish the document in the confidential section of S-CIRCABC.

3) **RMM for PT18 products for industrial textile treatment**

A CG member introduced an e-consultation on risk mitigation measures (RMMs) to be applied to control the risk for the environment for PT18 products used for treating fabrics (CG-30-2018-03). The commenting period is still ongoing for this e-consultation and the discussion will be continued during CG-31 meeting.

Action points:

All: To comment by the end of the commenting period (5 July).

7.3 Risk assessment of biocidal products on animal health

The SECR presented an updated proposal (CG-30-2018-09) considering the comments received during the discussion of the CG-29 meeting on how to evaluate biocidal products and treated articles having a primary biocidal function for use on animals.

Where the risk assessment for animals is not covered by the risk assessment for human health, the SECR proposed to use existing BPR guidance on performing the exposure assessment as well as guidance available from other regulatory frameworks (e.g. veterinary medicinal products). CG members agreed on the proposal and confirmed that developing additional guidance is currently not a priority.

Actions:

SECR: To provide a public version on the document and publish in S-CIRCABC.

7.4 Update on questions forwarded from the CG to ECHA

The SECR presented an updated overview of the status of the questions referred from the CG to be addressed by ECHA (CG-30-2018-10).

In order to estimate the impact of each topic and help setting priorities for the discussions in the WGs, feedback from MSs was requested on the number of cases affected by each issue, the date when an answer would be needed, and a justification of the proposed date.

On a more general note, the Commission informed CG members that EFSA was working on the development of guidance for the environmental risk assessment to honeybees. The Commission invited ECHA to cooperate with EFSA in order to ensure consistency in the development of the guidance applicable to pesticides and biocides.

Actions:

All: To provide comments on the newsgroups opened for this purpose by 25 July.

7.5 Cases where an applicant is unable to find a refMS

A discussion took place on this topic. The applications that triggered this discussion have been finally accepted by the relevant MS.

7.6 CG and WP meeting organisation

A discussion took place on the best way to schedule the CG and the WP-BPF meetings.

Actions:

SECR: To evaluate how to best schedule the meetings.

7.7 Comparative assessment

The Commission reminded CG members of the requirement in Article 23(2) of the BPR to provide the comparative assessment reports to ECHA for all products containing substances that are candidates for substitution. This requirement does also apply to the cMSs in case of mutual recognition procedures.

7.8 Renewal of SBP of AVK PT14

An e-consultation will be initiated on this topic.

Actions:

CG member: To send request for an e-consultation to the SECR.

8. Agreement of the action points and conclusions

The list of action points and conclusions for the closed session was agreed by the CG meeting.

Open session

9. Welcome to the open session

The Chair welcomed ASOs to the open session. Three observers from two ECHA accredited stakeholder organisations (ASOs) were present for the open session of the meeting.

10. Agreement of the agenda for the open session

The agenda for the open session was agreed.

Actions:

SECR: to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.

11. Declaration of interest in relation to the agenda, open session

No declarations of conflicts of interest were made.

12. Draft minutes (non-confidential part) from CG-29

The Chair explained that the draft non-confidential CG-29 minutes had been uploaded for commenting via Newsgroups. Comments were received from one CG member during the commenting period and the minutes were updated considering the comments. CG members agreed with the non-confidential draft minutes from the CG-29.

Actions:

SECR: to upload the CG-29 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

No administrative issues were tabled for discussion.

14 Harmonisation of technical and procedural issues in relation to product authorisation

14.1 Assessment of PT21 products – New assessment tool

A CG member presented an updated proposal considering the feedback received from MSs for the application of the new tool/model for assessing PT21 products in saltwater scenarios (CG-30-2018-18). Two refMSs expected to have the draft output of their assessments in autumn 2018, while the output from two other refMSs would only be available in mid or late 2019.

A newsgroup will be opened in S-CIRCABC for MSs to provide the draft outputs from the two seawater marina models. By end of September 2018, a CG member will compare all the data submitted at that point in time. The outcome of this comparison will be presented and discussed in the CG.

It was suggested that the results could then be used by the CA meeting for future discussions to inform on the potential impact of PT21 assessments on environmental protection as well as on the supply chain and control of invasive species at regional and/or Community level.

CG members agreed with the proposal.

Actions:

CG member: To provide a public version of the agreed document.

SECR: To publish the document.

14.2 Date of applicability of Technical Agreements of Biocides (TAB) entries

The SECR presented an updated proposal for discussion to clarify the date of applicability of TAB entries related to product authorisation (CG-30-2018-20). The list of the types of TAB entries was modified considering the comments received during the commenting period prior to the CG-30 meeting.

A discussion was initiated on how to address the case where new guidance was developed on how to make an assessment but this new guidance would not require the generation of new data. CG members agreed that this scenario should be divided in two cases: (i) no prior guidance was available on the subject, and (ii) previous guidance was available on the subject.

CG members agreed on the date of applicability of the different types of TAB entries:

a) Editorial changes of the existing guidance would be applicable as of the reference date.
b) Clarification/interpretation of the existing guidance would be applicable as of the reference date.
c) New guidance as new technical scientific advice was given which would trigger new data requirements would be applicable according to the approach agreed in the CA-July12-Doc.6.2d-Final document.
d) New guidance as new technical scientific advice was given on how an assessment should be done (without new data requirements).
    (i) Where no prior guidance was available on the subject, the new guidance may be applied if available at least six months before finalisation of the evaluation of an application. The period referred as "stop of the clock" would not be counted.
    (ii) Where prior guidance was available on the subject, the new guidance will be applied according to the provisions in the document CA-July12-Doc.6.2d-Final.

CG members commented that ECHA should ensure that every new published TAB entry should clearly indicate the date of publication and applicability.

The Chair proposed that the SECR would update the proposal and upload it in S-CIRCABC for written comments. The discussion will continue during the CG-31 meeting.

Actions:

SECR: To prepare an updated version of the proposal including the agreed timelines.

SECR: To open a newsgroups for comments on the updated proposal (3 weeks).

All: To comment on the updated document.

SECR: To table the document for agreement for the CG-31 meeting.

14.3 Preparation for the second renewal of AVK PT14 products

The SECR presented an updated list of issues to be addressed prior to the second renewal of AVK PT14 products (CG-30-2018-23).

The following items were discussed:

- A CG member proposed to include in the list the need to develop guidance on how to address resistance to anticoagulants. The Commission commented that, since information on resistance has to be provided at active substance level, it could be a duplication of work to provide this information also at product level. On this point, a CG member commented that resistance could be addressed at active substance level; however, information on resistance should also be provided at national level. Considering this, it would be probably necessary to have some kind of assessment of resistance also performed at product authorisation level. This view was supported by

another CG member who commented that resistance would need to be addressed at both, active substance and product level. The SECR commented that this point would be added to the list, however, considering the relatively short timeframe and the procedural aspects to develop new guidance, it was unlikely that this guidance could be applicable for the second renewal of the AVK products.

- A CG member commented that a harmonised approach should be agreed on how to report product packaging in the SPC. This item will be included in the list.
- Industry proposed to have a Working Party to address the issues related to AVK products. The SECR commented that, considering the broad nature of the different issues, it would be difficult to set up a Working Party with a group of experts to address all the items. In principle, the items identified could be addressed by either the WGs or the CG.

The Chair proposed to update the list of issues and upload it in S-CIRCABC for written comments.

Actions:

SECR: To provide an update list of issues and open a newsgroups for agreement on the list and inform ASOs.

All: In case of disagreeing with the document, to comment on the newsgroups (1 week).

14.4 Revised Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content)

The Commission presented a proposal (CG-30-2018-17) for the modification of the Q&A pair (number 10) in the document CA-May15-Doc.4.4-Final.rev3. The Q&A pair is currently being modified taking into consideration the outcome of the discussion of the Standing Committee (May 2018) on an unresolved disagreement during mutual recognition of a product that was referred to the Commission. Related to this referral, the Standing Committee agreed that the active substance concentration would need to be reported in the SPC in line with the definition of substance according to the REACH regulation (i.e. including any additives or impurities), and not as pure active substance.

A CG member commented that it would be difficult in some cases to calculate the concentration of active substance according to the REACH definition of substance. In particular, for cases where the active substance would be supplied as a pre-mix, additional information should be included in the second table in the document on how to recalculate the active substance concentration. In case that this additional information would include any confidential information, this table could be included in the confidential section of the PAR. A CG member indicated that the best section to include this information would be the "qualitative and quantitative information" section.

A footnote will be added in the document indicating that, where relevant, additional confidential information could be included in the confidential annex of the PAR. The format of the table will be changed (rows instead of columns) to facilitate the inclusion of information.

A CG member commented that further clarification was needed on how to report the active substance concentration. The CG member will provide a proposal.

ASOs will provide further comments in writing.

Actions:

A CG member: To provide comments on a section of the document by 25 July.

ASOSs: To provide comments by 25 July.

COM: To update the document according the comments received.

SECR: To table the document for agreement for the CG-31 meeting.

14.5 Harmonised approach for filling in the PAR template

Due to time constraints this agenda point was postponed for discussion during the CG-31 meeting.

Actions:

SECR: To table this item for discussion for the CG-31 meeting.

15 – Feedback from working parties

15.1 Update on the WP on the BPF concept

The SECR updated the meeting on the progress of the WP. The WP-BPF-5 meeting would prioritise the discussion on the similarity of uses, in particular of uses corresponding to PT2 to PT4, and the application of exceptions. The proposal on similar level of risk and efficacy would also be discussed.

15.2 Documents already agreed by the WP

The SECR presented three documents to be agreed by the CG that were previously agreed by the BPF WP during the WP-BPF-4 meeting:

1) "Grouping of co-formulants" (CG-30-2018-07). CG members agreed with the document.
2) "Best practices for BPF pre-submission meetings" (CG-30-2018-06). CG members agreed with the document.
3) "Splitting of families" (CG-30-2018-05). A clarification will be included in the document related to the application of Article 89(3), where the text will be modified as: "The three-year deadline in Article 89(3) of the BPR would count as from the active substance approval date; *or the submission of the original application where the 3 year period is over for the relevant AS or PT*."

Actions:

SECR: To publish the documents in the Public section of S-CIRCABC.

15.3 Applicability of the documents agreed by the WP

A discussion was initiated on the date of applicability of the documents agreed by the CG under Agenda Point 15.2.

CG members agreed that the document on "Best practices for pre-submission meetings" would be applicable as of 3 July 2018. The commission commented that the document concerned "best practices" and was not a legally binding document. However, it is intended to be followed as much as possible for the purpose of good functioning of the system.

CG members agreed that the document on "Grouping of co-formulants" would be applicable by applicants as of 3 July 2018 on a voluntary basis.

For the document "Splitting of families" it was discussed that this document clarified several aspects but did not include any new requirements for applications. Considering this, the document could be in principle directly applicable. A CG member commented that the current approach in document CA-Nov14-Doc.5.8–Final.rev3 does not clearly describe the possibility of splitting a family during the application process based on similarity, with the CG member's current interpretation being to not authorise any uses where the data/information submitted does not support. Therefore, the document would introduce a significant difference compared to the current practice. The Commission services indicated the need to double check whether the approach in the above-mentioned document is referring to the risk/efficacy assessment or to the similarity issue. Considering the need to double check this issue, it was decided to postpone the agreement on the date of applicability of this document to the CG-31 meeting.

The documents will be published including a disclaimer stating that the document CA-Nov14-Doc.5.8-Final.rev3 will be updated accordingly once the WP is concluded.

Actions:

COM: To look at the current CA document on the BPF regarding the possible consequences for cases where products in a family do not meet the similarity concept.

SECR: To open a newsgroup for comments on the topic once communicated by COM.

All: To comment on the newsgroup (3 weeks).

16 – Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the reports in document CG-30-2018-13 and CG-30-2018-14, which were made available for information.

16.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-30-2018-12, which was made available for information.

16.3 List of active substances meeting the exclusion or substitution criteria

The Chair invited the meeting to take note of the updated version of the list of active substances meeting the exclusion or substitution criteria (CG-30-2018-24).

Actions:

Rapporteur MS: To check the new information and report to CG-SECR by 10 July.

SECR: To transmit the updated version to COM to make it publicly available on CIRCABC.

If relevant, to produce an updated version for next CG meeting.

16.4 IT issues

The SECR updated the meeting on the dissemination project of R4BP 3 data (CG-30-2018-26). CG members were advised to check the following:

- Ensure that the final assessment reports, authorisations and decisions do not contain confidential information. The correct access level should be set for these documents.
- Ensure that the SPC does not contain any confidential information or inconsistencies. It was emphasised that the final SPC is always considered as not confidential and will be disseminated automatically.
- Check assets related to PT14 products which could be wrongly assigned to PT1.

The SECR presented a proposal to harmonise the names of documents (authorisations or decisions and assessments) to be used for dissemination. CG members were asked not to use product names in the name of files, as only trade names will be disseminated.

The following points were clarified during the discussion:

- The concentration of substances of concern should be included in the SPC in line with the provisions of Article 22(2)(e) of the BPR.
- Assessment reports with access level set as "public" uploaded before 1/1/16 will be disseminated.
- The refMS should check the final SPC before uploading in R4BP 3.

The SECR invited ASOs to inform companies about the dissemination project so that companies could check the confidentiality of documents in the relevant assets, the access level, and the consistency of information. In case of concern, the relevant CA would need to be contacted.

Actions:

All: To review the data to be disseminated related to confidentiality.

16.5 Feedback on e-consultations

The outcome of one e-consultation was presented for discussion and agreement:

1) **Understandable dose application rate for RTU spray products**

A CG member presented the outcome of an e-consultation on how to indicate in the SPC the application rate for ready to use (RTU) PT18 and PT19 spray products in an understandable manner for the users (CG-30-2018-21).

CG members agreed to indicate in the SPC for non-professional users of PT18 and PT19 products, and for non-trained professional users of PT18 products, the number of sprays and/or the duration of spraying per treated surface/volume. The information on the number of sprays should be included in the section "instructions of use" of the SPC.

For PT18 products intended to be used by trained professionals, including this information in the SPC would not be necessary. The application rate expressed as mg of product/m² would be sufficient. For repellent PT19 products to be used on humans, the user category "trained professional users" was considered as not relevant.

It was agreed that this approach would be implemented for new authorisations, for existing products during the renewal procedure, or as part of an application for changes that would also affect the content of the SPC and labels.

The Commission proposed to include a clarification that in the case of new authorisations following the procedure for mutual recognition in sequence (MR-S) this approach would not be applicable. A footnote will be included in the document to clarify this aspect.

The standard sentences to be used in the SPC included in the document CG-30-2018-21 were also agreed by the CG. The Commission commented that the wording of the standard sentences was given as an example. However, it would be in the benefit of the applicant to use the proposed wording in order to facilitate the authorisation and MR processes.

CG members agreed on the proposal which will be updated considering the agreements reached during the discussion regarding applicability of the approach and the proposed foot note for MR-S procedures.

Actions:

CG member: To provide an updated public version of the agreed document.

SECR: To publish the document.

17. Agreement of the action points and conclusions

The list of action points and conclusions was agreed by the CG meeting.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

30th meeting of the CG

3-4 July 2018

Agenda point	**Action requested after the meeting**
Conclusions / decisions / minority positions	**by whom/by when**
CLOSED SESSION	
1.- Welcome	
2 – Agreement of the agenda.	
The agenda for the closed session was agreed with the addition on one point on renewal of SBP authorisations.	**SECR:** to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.
3 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
4 – Draft minutes from CG-29	
The draft confidential minutes of the CG-29 meeting were agreed without modifications.	**SECR:** to upload the CG-29 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed about the update of the overview table of the referrals discussed so far at CG level.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
Two formal referrals were discussed. 1) The discussion will be continued during the CG-31 meeting. 2) An agreement was reached by consensus on several points of disagreement. The discussion of the open points will be finalised by 5 August.	**1) refMS and icMSs:** To propose a way forward by 25 July. **1) All:** To comment on the way forward by 1 Sept. **2) refMS**: To provide the updated PAR at the latest by 25 July. **2) All**: To agree on the updated PAR within one week. **2) SECR**: If agreement is reached on the updated PAR, to organise agreement of the outcome by written procedure.
6 – Harmonisation of technical and regulatory issues in relation to product authorisation	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
6.1 - Issues identified in the context of UA – The SECR presented the list of issues identified in Union Authorisations.	**MSs:** To take note of the information provided in the table. **SECR:** To provide an updated list for the next CG meeting.
6.2 - Post authorisation conditions in product authorisation	
The SECR presented an updated proposal in order to decide on what grounds a post authorisation condition could be justified. The discussion will continue during the CG-31 meeting.	**SECR:** to open a newsgroups for comments **All:** to comment on the proposal by 25 July
7 – Any Other Business	
7.1 - Late procedures	
COM presented the overview of late procedures.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data. **SECR**: to open a newsgroups for comments. **refMSs with more than 10 late procedures**: To provide feedback on the state of play of the applications by 25 July.
7.2 - Feedback on e-consultations	
Three e-consultations were discussed: 1) Efficacy requirements concerning a BPF for disinfection in dishwashing systems. CG members agreed on the proposal including several amendments. 2) Storage stability for simplified authorisation. CG members agreed on the data requirements for the application for authorisation presented in the e-consultation. 3) RMM for PT18 products for industrial textile treatment. A CG member introduced the e-consultation. The discussion will take place during the CG-31 meeting	**1) CG member:** To provide a final version of the document including the comments agreed in the meeting. **1) SECR:** To publish the document in the confidential section of S-CIRCABC. **2) CG member:** To provide a final public version of the document including the comments agreed in the meeting. **2) SECR:** To publish the document in the confidential section of S-CIRCABC. **3) All:** To comment by the end of the commenting period (5 July).
7.3 – Risk assessment of biocidal products on animal health.	
The SECR gave an update on the comments received on this topic. CG members agreed that developing additional guidance is not a priority.	**SECR:** To provide a public version on the document and publish in S-CIRCABC.
7.4 - Update on questions forwarded from the CG to ECHA	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
The SECR presented an overview of the status of the questions referred from the CG to be addressed by ECHA. CG members were asked to give feedback on the impact of the issues in order to prioritise the discussion of different questions.	**All:** To provide comments on the newsgroups opened for this purpose by 25 July.
7.5 - Cases where an applicant is unable to find a refMS	
A discussion took place on this topic. The applications that triggered this discussion have been accepted by the relevant MS.	
7.6 - CG and WP meeting organisation	
A discussion took place on the best way to schedule the CG and the WP-BPF meetings	**SECR**: To evaluate how to best schedule the meetings.
7.7 - Comparative assessment	
COM reminded CG members of the requirement to provide comparative assessment reports to ECHA for all products containing substances that are candidates for substitution.	
7.8 – Renewal of SBP of AVK PT14	
An e-consultation will be initiated on this topic.	**CG member**: To send request for an e-consultation to the SECR.
8 – Agreement of the action points and conclusions	
The list of action points and conclusions for the closed session was agreed by the CG meeting.	
OPEN SESSION	
9 – Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.
11 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-29	
The draft non-confidential minutes of the CG-29 meeting were agreed.	**SECR:** to upload the CG-29 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
No administrative issues were tabled for discussion.	
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 - Assessment of PT21 products – New assessment tool	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
A CG member presented an updated document considering the feedback received from MSs for the application of the new tool/model for assessing PT21 products in saltwater scenarios. CG members agreed with the proposal. MSs will perform the salt water scenario assessment following the current method and the new tool. UK will summarise the data that will be then discussed in the CA meeting.	**CG member:** To provide a public version of the agreed document. **SECR**: To publish the document.
14.2 - Date of applicability of Technical Agreements of Biocides (TAB) entries	
The SECR presented an updated proposal for discussion to clarify the date of applicability of TAB entries related to product authorisation. CG members agreed on the approach regarding the date of applicability of TAB entries.	**SECR:** To prepare an updated version of the proposal including the agreed timelines. **SECR:** To open a newsgroups for comments on the updated proposal (3 weeks). **All:** To comment on the updated document. **SECR:** To table the document for agreement for the CG-31 meeting.
14.3 - Preparation for the second renewal of AVK PT14 products	
The SECR presented the list of issues to be addressed during the second renewal of AVK PT14 products. Several items were added to the list related to resistance monitoring and how to indicate pack sizes in the SPC.	**SECR**: To provide an update list of issues and open a newsgroups for agreement on the list and inform ASOs. **All**: In case of disagreeing with the document, to comment on the newsgroups (1 week).
14.4 - Revised Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content)	
The Commission presented an amended Q&A pair on how should the content of active substance be expressed in the SPC. The active substance concentration should be reported in line with the definition of substance according to the REACH regulation.	**A CG member**: To provide comments on a section of the document by 25 July. **ASOSs**: To provide comments by 25 July. **COM**: To update the document according the comments received. **SECR:** To table the document for agreement for the CG-31 meeting.
14.5 - Harmonised approach for filling in the PAR template	
Due to time constraints this agenda point was postponed to the CG-31 meeting.	**SECR**: To table this item for discussion for the CG-31 meeting.
15 – Feedback from working parties	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
15.1 - Update on the WP on the BPF concept	
The SECR updated the meeting of the progress of the WP.	
15.2 - Documents already agreed by the WP	
The SECR presented documents agreed by the WP. CG members agreed on the documents on "Best practices for pre-submission meetings" and "Grouping of co-formulants". The document on "Splitting of families" was agreed included a clarification on the provisions of Article 89(3).	**SECR:** To publish the documents in the Public section of S-CIRCABC.
15.3 - Applicability of the documents agreed by the WP	
CG members agreed that the document on "Best practices for pre-submission meetings" is applicable as of 3 July 2018. The document on "Grouping of co-formulants" is applicable by applicants as of 3 July 2018 on a voluntary basis. The agreement on the date of applicability of the document on "Splitting of families" will take place during the CG-31 meeting.	**COM**: To look at the current CA document on the BPF regarding the possible consequences for cases where products in a family do not meet the similarity concept. **SECR:** To open a newsgroup for comments on the topic once communicated by COM. **All**: To comment on the newsgroup (3 weeks).
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the report, available for information.	
16.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	
16.3 - List of active substances meeting the exclusion or substitution criteria	
The Chair presented the report, available for information.	**Rapporteur MS**: To check the new information and report to CG-SECR by 10 July. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an updated version for next CG meeting.
16.4 - IT issues	
SECR updated the meeting on the dissemination of R4BP 3 data. CG members were asked to check confidentiality of data to be disseminated and access level of the documents.	**All**: To review the data to be disseminated related to confidentiality.
16.5 - Feedback on e-consultations	

Agenda point	**Action requested after the meeting**
Conclusions / decisions / minority positions	**by whom/by when**
One e-consultation was tabled for discussion related to understandable dose application rate for RTU spray products for PT18 and PT19. CG members agreed on the proposal which will be updated including several amendments.	**CG member**: To provide an updated public version of the agreed document. **SECR**: To publish the document.
17 – Agreement of the action points and conclusions	
The list of action points and conclusions for the open session was agreed by the CG meeting.	

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Part IV - List of Annexes

ANNEX I List of documents submitted to the members of the Coordination Group

ANNEX II Final agenda

ANNEX II

Final agenda
30th meeting of the Coordination Group (CG-30)

3 July-4 July 2018

on 3 July 2018 from 9:30 to 12:30 (OPEN SESSION)
and
on 4 July 2018 from 9:30 to 17:00 (CLOSED SESSION)

Venue:
Albert Borschette Conference Centre
Rue Froissart 36, 1040 Brussels, Belgium

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-30-2018
For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-29

CG-M-29-2018_Draft confidential
For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-30-2018-01
For information

5.2 Formal referrals on mutual recognition disagreements under Article 35 of the BPR

Links to disagreements
For discussion and agreement

Item 6 – Harmonisation of technical and regulatory issues in relation to product authorisation

6.1 Issues identified in the context of UA

CG-30-2018-25

For information

6.2 Post authorisation conditions in product authorisation

CG-30-2018-19

For discussion and agreement

Item 7 - Any Other Business

7.1 Late procedures

CG-30-2018-15, CG-30-2018-16 & CG-30-2018-22

For information

7.2 Feedback on e-consultations

CG-30-2018-03, CG-30-2018-04, CG-30-2018-08, CG-30-2018-11

Links to e-consultations

For discussion and agreement

7.3 Risk assessment of biocidal products on animal health

CG-30-2018-09

For discussion and agreement

7.4 Update on questions forwarded from CG to ECHA

CG-30-2018-10

For discussion

7.5 Cases where an applicant is unable to find a refMS

For discussion

7.6 CG and WP meeting organisation

For discussion

7.7 Comparative assessment

For discussion

7.8 Renewal of SBP of AVK PT14

For discussion

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-30-2018

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-29

CG-M-29-2018_Draft non-confidential

For agreement

Item 13 – Administrative issues

Item 14 – Harmonisation of technical and procedural issues in relation to product authorisation

14.1 Assessment of PT21 products – New assessment tool

CG-30-2018-18

For discussion and agreement

14.2 Date of applicability of Technical Agreements of Biocides (TAB) entries

CG-30-2018-20

For discussion and agreement

14.3 Preparation for the second renewal of AVK PT14 products

CG-30-2018-23

For discussion

14.4 Revised Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content)

CG-30-2018-17

For discussion

14.5 Harmonised approach for filling in the PAR template

CG-30-2018-02

For information

***For discussion* Item 15 – Feedback from working parties**

15.1 Update on the WP on the BPF concept

15.2. Documents already agreed by the WP

CG-30-2018-05, CG-30-2018-06 & CG-30-2018-07

For agreement

15.3. Applicability of the documents agreed by the WP

For discussion and agreement

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-30-2018-13 & CG-30-2018-14

For information

16.2 Deadlines for application for product authorisation

CG-30-2018-12

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-30-2018-24

For information

16.4 IT issues

CG-30-2018-26

For information

16.5 Feedback on e-consultations

CG-30-2018-21

Links to e-consultations

For discussion and agreement

Item 17 – Agreement of the action points and conclusions

For agreement

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