17 January 2018

CG-M-26-2017 non-confidential

Final non-confidential minutes of the 26th meeting of the Coordination Group (CG)

21 – 22 November 2017

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the twenty sixth CG meeting (CG-26). 29 members and experts from 23 Member State Competent Authorities (MSCAs), NO and CH, and three representatives from three ASOs participated in the meeting. One representative from DG SANTÉ and four 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-26-2017) and invited participants to add any items under AOB. One agenda point was added to the AOB of the closed session regarding alternative dossiers. The agenda was agreed with this modification.

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

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. There were no potential conflicts declared.

4. The draft minutes from CG-25

The Chair explained that the draft confidential CG-25 minutes had been uploaded for commenting via Newsgroups. Comments were received from two CG members and the minutes were amended accordingly. No further comments were received during the meeting. CG members agreed on the confidential draft minutes from the CG-25.

Actions:

SECR: to upload the CG-25 minutes into the relevant folders in the CG CIRCABC.

5. Formal and informal 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 as well uploaded 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

The Chair updated the meeting on four referrals that were closed after the CG-25 meeting. An agreement by consensus was reached for two referrals (i.e. both products meet the conditions in Article 19(1) for granting an authorisation). One referral was closed following the withdrawal of the mutual recognition application in the initiating concerned Member State (icMS). The fourth referral was closed after the conclusion of the CA

meeting in September that the product was not eligible for provisional authorisation under Article 55(2) of the BPR.

Seven formal referrals were tabled for discussion. An agreement was reached by consensus for four referrals and the authorisation of the products can be granted.

1) 2) Two related referrals from the same applicant concerning two PT14 products with brodifacoum as active substance were discussed. The point of disagreement was related to the acceptable exposure level (AEL) and dermal absorption values to be used in the exposure assessment. It was agreed to use the same AEL value used in the Competent Authority Report (CAR) of the active substance. The referrals will be closed by written procedure once the Product Assessment Reports (PARs) are updated.
3) A referral was discussed concerning a PT20 product containing aluminium phosphide. The only remaining open point in this referral was related to the package size of the product. CG members agreed to list all package sizes in the Summary of Product Characteristics (SPC). MSs may then apply derogation from MR in accordance with Article 37 of the BPR and authorise only those sizes relevant to their market. The product meets the condition for granting an authorisation in Article 19(1)(b) of the BPR and this formal referral was therefore closed.
4) A referral was discussed concerning a PT 19 product containing DEET as active substance. The points of disagreement were related to the completeness of the efficacy data package. It was agreed to close the referral by written procedure.
5) A referral was discussed concerning a PT 8 product containing cypermethrin, IPBC and propiconazole as active substances. The point of disagreement was related to the personal protective equipment (PPE) and risk mitigation measures (RMMs) to be applied to the different uses of the product. CG members agreed on the PPE and RMMs to be applied. The product meets the condition for granting an authorisation in Article 19(1)(b)(iii) of the BPR. This formal referral was therefore closed.
6) A referral was discussed concerning a PT18 product containing etofenprox as active substance. The disagreement concerned the uses to be authorized and numerous corrections needed in the PAR and SPC. Considering the data available, CG members agreed to restrict the use of the product to one use. Considering the updated PAR and SPC, the product meets the condition for granting an authorisation in Article 19(1)(b) of the BPR. This formal referral was therefore closed.
7) A referral concerning a PT18 product with etofenprox as active substance was discussed. Numerous points of disagreement were raised related to corrections needed in the PAR and SPC in addition to the uses to be authorized. CG members agreed to authorize only one of the proposed uses of the product. Considering the updated PAR and SPC, the product meets the condition for granting an authorisation in Article 19(1)(b) of the BPR. This formal referral was therefore closed.

Actions:

1), 2) SECR: Confirm the AEL values used in the CAR of the active substance.

1), 2) SECR: To organise a follow up teleconference on the 5th December.

3), 5), 6), and 7) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

4) Applicant: to provide the agreed information.

4) refMS: Assess information as soon as possible.

4) All: to review new information and take a decision by 5th December.

4) SECR: to organise a teleconference for 5 December.

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 Union Authorization (UA) applications (CG-26-2017-02). The intention of publishing this list is to allow eCAs of national authorisations of products based on the same active substance to be informed about the issues identified in UA applications.

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 Iodate used as stabilizer

The SECR presented an overview (CG-26-2017-17) of the products that would be affected by the conclusions reached during the APCP WG-2017-IV meeting on the basis of chemical considerations (i.e. iodate/iodide generating iodine should be considered an active substance irrespective of the source of iodide) would be confirmed.

The majority of CG members considered that allowing an arbitrary 10% tolerance in the concentration of iodine in the products was not relevant for this case if iodate/iodide generating iodine is considered as a new active substance. Allowing this tolerance would create a precedent difficult to justify from a legal point of view.

As a way forward, several CG members proposed to provide applicants with some kind of "transitional period" to adapt products containing iodate.

This topic will be further discussed in the 75th CA meeting.

Actions:

COM: To communicate the outcome of the discussion to the CA meeting.

6.3 PT 14 products renewal timelines

Some CG members acting as refMSs updated the meeting on the status of the applications for renewal of PT14 products (i.e. SPC agreement phase).

In the context of the SPC agreement phase for the renewal of anticoagulant rodenticides, some refMSs indicated that they are already using the new deadlines of the amended SoPs. To avoid confusion and to ensure an efficient procedure, CG members discussed which timelines should be applied for the SPC agreement (60+30 vs. new SoP).

It was agreed that for procedures for which the SPC agreement phase started after the SoP was agreed (CG-25), cMSs are invited to follow the SoP unless this creates organisational issues, which should be communicated to the refMS. In the latter case, the 60+30 day approach will apply. To help facilitate more rapid outcomes, it was also agreed that where the 60+30 approach was applied in this case, that cMS would inform the RMS of their evaluation decision as soon as this was available within the 60 day period, including where this was agreement with the draft SPC.

Where the SPC agreement phase started before the new SoP was agreed and for which the 60+30 day period was applied, that approach should not be modified.

Actions:

cMSs: In cases where a deadline for commenting of 40 days is already sent, to inform refMS whether the comments will be sent within 60 days.

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.

7.2. Feedback on e-consultations

Five e-consultations were tabled for discussion:

1) Permethrin products environmental risk assessment

A CG member presented the document (CG-26-2017-18) with the conclusions of the e-consultation related to the harmonisation of the environmental risk assessment of permethrin containing products (PT18) for non-professional uses.

The CG member briefly summarized the outcome of the consultation. Three MSs provided comments and supported as way forward the preferred option proposed by the CG member (option (iii): 1) use a wet cleaned area surface of 5.9 m^2 in the case of pet related flea treatments, 2) application of refinements as agreed at the ENV-WG-IV-2017 and 3) not to consider zero wet cleaning as a realistic RMM.

CG members agreed by consensus on the proposal (option (iii))

On a more general note a CG member informed that new data were submitted by the applicant for the permethrin aquatic PNEC refinement. These data is currently being evaluated.

The Commission explained that as agreed in document CA-March16-Doc.4.15-Final, unless the endpoints for an active substance are modified, the existing agreed end points have to be used for the evaluation of product authorisation applications. Applications should not be put on hold.

2) Innovative insecticide product

A CG member presented the document (CG-25-2017-22) with the conclusion of the e-consultation on a case on how to consider biphasic products and products including different mixtures. Different independent mixtures as described in the case presented by the CG member should have their own authorization number and trade name.

A biphasic product is to be considered as one mixture (one product). Applicants should consider the requirements of Article 69(1) of the BPR.

CG members agreed by consensus on the document that will be updated to include the clarification on bait stations.

3) Simplified authorisation of PT19 products

A CG member presented the document (CG-26-2017-16) with the conclusions of the e-consultation related to the eligibility for simplified authorisation of a PT 19 product when taking into consideration the co-formulants included in the product. CG members agreed by consensus that the product was eligible for the simplified authorisation procedure.

4) Use of same name in products of different PTs

A CG member introduced an e-consultation on whether different products can have the same trade name (CG-26-2017-15). Different views were expressed. The discussion will continue during the CG-27 meeting.

5) Efficacy requirements for PT18 Horse ware blanket

A member presented the conclusions of an e-consultation on the efficacy requirements for the use of PT18 products in horse ware blanket. The discussion will be referred to ECHA for consideration in the Efficacy Working Group.

Actions:

1) CG member: to provide a non-confidential version of the document.

1) SECR: To publish the conclusions document in the relevant space in S-CIRCABC.

2) CG member: to provide a non-confidential version of the updated document.

2) SECR: To publish the conclusions document in the relevant space in S-CIRCABC.

3) CG member: to provide a non-confidential version of the document.

3) SECR: To publish the conclusions document in the relevant space in S-CIRCABC.

4) SECR: To open a newsgroup for comments on the document provided for discussion.

4) All: To comment by 5 December 2017.

5) SECR: To refer the issue to ECHA to be considered for discussion by the appropriate forum.

5) SECR: To inform the CG on the outcome of the discussion.

7.3 Standard operating procedure for the Mutual Recognition phase

The SECR presented a proposal for the steps of the SoP (CG-26-2017-04) for the mutual recognition process in sequence.

The following points were discussed:

- The main difference of the MR processes in parallel (MR-P) and in sequence (MR-S) is that the MR-S process originates from an already authorized product. The Commission clarified that, if during a MR-S process the refMS and the icMS agree that the SPC needs to be amended, this should be considered as a disagreement in the conditions of authorization of the product and, therefore, the disagreement should be referred to the CG. This is necessary since the change of the conditions of authorization would also affect all cMSs where the product is already authorized. The disagreement should be referred to the CG in accordance with the timelines agreed in the SoPs. Regarding amendments to the PAR, the Commission indicated that the PAR is not part of the product authorisation and can be amended if during the MR phase it is recognised as necessary.

- A CG member commented that for MR-S procedures only critical comments affecting the SPC should be submitted during the MR commenting period, as the authorization is already granted and all amendments of the SPC need to be agreed by all cMSs. In the same line of thought, the Commission encouraged MSs to refer a disagreement to the CG only where the conditions of Article 19 (1)(b) of the BPR are not met, i.e., there is a serious concern on the safety of the product, efficacy or impact to environment.

- A CG member (DE) disagreed with the sentence included in Step 1 "The refMS will only consider for discussion those comments received during the commenting period." This sentence would be against the German national administrative law. The DE CA indicated that, in case of a major concern, it should be possible to initiate a referral within the legal deadline of 90 days, independently of when a comment was raised.

The CG members, with the reservation of DE on Step 1, agreed on the proposal for the SoP for the MR-S process. The procedure will be implemented in MR procedures starting as from 1 January 2018.

CG members also agreed that the SoPs for MR-P and MR-S will be applied to the relevant steps of the renewal and major changes applications.

Actions:

SECR: To upload the SoP document in the relevant S-CIRCABC folder.

SECR: To communicate the ECHA IT the outcome of the discussion in order to adapt R4BP 3 to support the new procedure for the mutual recognition phase in sequence.

7.4 Template for providing comments in the Mutual Recognition phase

An updated proposal for the template of the commenting table to provide comments during the MR phase (RCOM) was presented by the SECR (CG-26-2017-05).

The template was agreed by the CG members.

Actions:

SECR: To upload the document in the relevant S-CIRCABC folder.

7.5 Process flow for Mutual Recognition phase

The SECR presented a template (CG-26-2017-06) that could be used to make a process flow to help MSs with planning the resources needed for the different steps of the new SoP of the MR phase.

The template was agreed by the CG members.

Actions:

SECR: To upload the document in the relevant S-CIRCABC folder.

7.6 Mutual Recognition phase document consolidation and dissemination

The SECR presented a proposal for the dissemination and consolidation of the agreed documents related to the SoP for the mutual recognition phase.

CG members agreed to maintain the SoPs as independent documents and not combine them with the working procedure for resolving disagreements. The document with the SoPs, the RCOM and the process flow templates will be uploaded in the relevant S-CIRCABC space.

Actions:

SECR: To upload the documents in the relevant S-CIRCABC folder.

7.7 Confidential information from third parties in same biocidal product applications

A CG member introduced the topic related to confidentiality issues where the authorization holder (AH) or applicant of a reference product and that of a same biocidal product (SBP) linked to this product are not the same. In the opinion of the CG member, according to Article 2 of the SBP regulation, evidence that the products are identical should be provided by the applicant of the SBP or by the AH of the reference product. The CG member mentioned that this would mean that the eCA should have access to the full composition of both products, which could be provided either by the applicant or the AH of the reference product, or by the applicant of the SBP. When the CG member consulted this matter with the ECHA helpdesk, the response was that, due to confidentiality issues, the applicant of the SBP is not required to submit the composition of the product. The CG member did not agree with this view.

Different opinions were expressed. A CG member commented that the applicant of the SBP should always know the composition of the product. The Commission referred to the CA document "CA-May14-Doc.5.1-Final", where it is mentioned that an applicant/AH does not need to know the composition of a product. However, it should be noted that, in all cases, the AH is still fully responsible for the biocidal product.

CG members agreed that guidance is needed in this area and the matter will be referred to ECHA to develop the necessary guidance.

Actions:

SECR: To inform ECHA of the need of further guidance on this area.

7.8 Clarification on the information needed in different sections of the SPC

Due to time constraints this agenda point has been postponed and will be discussed during the CG-27 meeting.

Actions:

SECR: To table this item for discussion for the CG-27 meeting.

7.9 Alternative dossiers

The SECR reminded the CG members to follow the agreed document on alternative dossiers.

8. Agreement of the action points and conclusions

The list of action points and conclusions 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 three ECHA accredited stakeholder organisations (ASOs) were present for the open session of the meeting.

10. Agreement of the agenda for the open session

The Chair introduced the draft agenda (CG-A-26-2017) and invited CG members and ASOs to propose any other items under AOB. No additional items were proposed and the agenda was agreed.

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

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

The Chair invited the members to declare any potential conflict of interests. There were no potential conflicts declared.

12. Draft minutes (non-confidential part) from CG-25

The Chair explained that the draft non-confidential CG-25 minutes were uploaded for commenting via Newsgroups. No comments were received during the commenting period. Two editorial type of comments were raised during the meeting and the minutes will be amended accordingly. The CG members agreed on the draft minutes from the CG-25 meeting.

Actions:

SECR: to upload the CG-25 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 Consolidated version of the AR at the renewal of PTs other than PT14

As a follow-up of the discussions held in the CG-25 meeting, the Commission briefly introduced this topic by pointing out to what would be the legal basis for requesting a fully consolidated PAR from the applicant in the context of the applications for renewal (see Article 31(3) of the BPR).

Some CG members indicated that despite the lack of an explicit legal basis in the BPR, the support of applicants to produce a fully consolidated PAR will be part of the discussions with applicants before accepting to act as refMS for the renewal procedure. A CG member suggested that this approach should be followed by all MSs.

A CG member expressed the need to double check back home whether this proposed way forward can be supported and to send written comments after the meeting.

Actions:

SECR: To open a newsgroup for comments.

All: To comment by 5 December 2017

ASOSs: to provide comments on the topic.

14.2 Label requirements for clothing for PT 19 products

The SECR presented a proposal from the HEAdhoc WG related to label requirements for clothing in PT19 products (CG-26-2017-19). The worst case scenario for exposure assessment for PT19 products agreed as part of the Recommendation 11 of the HEADhoc WG was based on individuals wearing normal outdoor clothes. This would result in a body surface area to be treated of 55%. Since minimal clothing was not considered as a worst case, the WG proposed for discussion in the CG that a label requirement could be added to PT19 products indicating the need to wear normal outdoor clothes.

Several CG members and the Commission considered that a RMM to wear normal outdoor clothes could be considered as acceptable from the perspective of being observed by the general public. The Commission expressed some concerns as to whether the wearing of minimal (bathing) clothing could be considered as a realistic scenario.

CG members will provide further comments in writing and the discussion will be continued during the CG-27 meeting.

Actions:

SECR: To open a newsgroup for comments.

All: To comment by 5 December 2017

ASOSs: to provide comments on the topic.

14.3 SBP amendments- Overview of administrative changes

The SECR presented a proposal for a harmonised approach on how to classify and describe changes in applications for same biocidal products (CG-25-2017-11).

The proposal is a harmonised approach to be followed by ECHA and MSs during the validation of SBP applications. A description of the administrative changes and a clarification on the number of the change is included to help applicants to provide the right information.

ASOs commented that a clarification needs to be included in the document (e.g., footnote) that the document does not consist an exhaustive list of all changes relevant for SBP applications.

On a more general note, the Commission suggested that as ECHA has to develop further guidance on SBP applications, other on-going discussions regarding the SBP applications should also be covered (e.g. e-consultation initiated by LU).

CG members agreed on the proposal. The Annex presented in the document will be published in the ECHA website.

Actions:

SECR: To upload the document in the ECHA website.

14.4 Assessment of PT21 products – New assessment tool

A CG member introduced the topic. A new assessment tool to model the salt water scenario for PT21 products has been developed. This model will be published in the ECHA website, however, considering the two year cut off for application of new guidance, the use of this model by applicants is still not mandatory. The CG member explained that one applicant that had tested the tool had reported that the calculations coming from the

model result in a significant number of products failing to prove a safe use for the environment.

The CG member would like to propose that, even if an applicant provides the assessment of the salt scenario according to the approach followed in the CAR, MSs could still make the assessment using both methods, the approach followed in the CAR and using the new tool. This information could be then used to compare both methods and evaluate the impact of the use of the new tool. After assessment of this information, it could then be explored early in the product evaluation process whether further work on the tool was required (e.g. on protection goals) prior to any final decisions being made on what uses could be allowed.

Several MSs commented that, for this case, the two year rule for application of new guidance should not be followed in order to have a harmonized approach for the assessment of these products. The Commission did not support this view, since this would not be in line with the CA agreement on the application of new guidance. Furthermore, as indicated above, it was still necessary to assess the validity of the new assessment tool before it is fully implemented.

The Chair concluded the discussion and invited CG members to provide further comments in writing.

Actions:

CG member: To provide discussion document to the SECR.

SECR: To open a newsgroup for comments.

All: To comment by 5 December 2017.

15 – Feedback from working parties

15.1 Follow up on the WP on frequently used sentences in the SPC

The CG SECR updated the meeting on the comments received on the proposal to extend the Working Party (WP) on "frequently used sentences in the SPC" to PTs 6, 7, 9, 10, 11, 12 and 13. All CG members that provided comments proposed to postpone the extension of the WP so that MSs could gain additional experience in applications related to these PTs.

The CG members agreed to postpone the extension of the WP.

15.2 WP on the biocidal product family concept

The SECR updated the meeting on the status of the WP on the biocidal product family (BPF) concept. Nominations for experts have been received for all topics with 30 to 41 experts assigned to each topic. After the CG-25 meeting, on 13 October 2017, it was agreed by the CG members to focus the discussion of the WP on the first topic (Topic a) related to the clarification of the concept of similarity in the area of composition, uses and levels of risk and efficacy. The UK would be acting as the topic leader.

The first WP meeting would take place back to back with the CG-26 meeting (22nd November).

The Commission commented that one important point to be addressed by the WP was to decide at what time in the authorisation process the "similarity concept" in the family would need to be addressed. According to a CG member, the moment when fees are paid would be a critical moment to consider (i.e. to decide whether one or two applications are needed). Therefore, the design of the product family and the consideration of the similarity should be ideally addressed during the pre-submission meetings between the applicant and the eCA. This view was supported by several CG members and Industry.

The Commission commented that, in case of UA, the pre-submission phase should not become an evaluation of the application. The purpose of the pre-submission discussions is to determine similar conditions of use as defined in Article 42(1) of the BPR and such consideration is done only based on a preliminary draft SPC.

The discussion will be continued during the WP meeting.

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-26-2017-10 and CG-26-2017-11, 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-26-2017-09, 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-26-2017-20).

Actions:

Rapporteur MS: to check the new information and report to CG SECR by 29 November.

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 presented the new features introduced in the new release of R4BP 3.10 and the SPC 2.1 Editor (CG-26-2017-07). An overview of the items to be implemented in 2018 was also presented.

A CG member commented that there could be an issue related to archiving of messages. This issue will be followed up by the ECHA IT team.

Actions:

SECR: To follow up on an issue raised by a CG member.

16.5 Feedback on e-consultations

One e-consultation was tabled for discussion.

A CG member presented the conclusions of the e-consultation on how to address a SBP having as related reference product another SBP (CG-26-2017-08). This e-consultation was previously discussed in the CG-24 meeting during the closed session.

CG members agreed that a SBP application may be based on a product authorized following the SBP procedure. However, in these cases, access to all data supporting the original related reference product would be necessary and, therefore, the link between the original product authorization and the second SBP cannot be hidden to the CAs.

ASOs commented that they would like to review the document and provide further comments in writing. The agreement on the document was postponed to the CG-27 meeting to allow Industry to comment on the document.

Actions:

ASOs: To send comments to the SECR on the e-consultation.

CG member: To provide an updated document to be discussed during the CG-27 meeting.

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

26th meeting of the CG

21-22 November 2017

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 of one agenda point on alternative dossiers.	**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-25	
The draft confidential minutes of the CG-25 meeting were updated with the comments received during the commenting period. No additional comments were received during the meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-25 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	
The Chair informed that two referrals had been closed via written procedure since the previous CG meeting (CG-25) for which an agreement by consensus was reached. One referral was closed since the product was not eligible for provisional authorisation under Article 55(2) of the BPR. One referral was closed after the applicant withdrew the application in the icMS. seven formal referrals were discussed **1)** An acceptable risk will be found independently of the AEL value used. However, depending on the outcome of the discussion on the AEL values the PAR might need to be amended. **2)** Depending on the outcome of the discussion on the AEL values further discussion will be needed. **3)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **4)** The discussion will be finalised by 5th December. **5)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.	**1), 2) SECR:** Confirm the AEL values used in the CAR of the active substance. **1), 2) SECR**: To organise a follow up teleconference on the 5th December. **3), 5), 6), and 7) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **4) Applicant**: to provide the agreed information. **4) refMS**: Assess information ASAP **4) All**: to review new information and take a decision by 5th December. **4) SECR**: to organise a teleconference for 5 December.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
6) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **7)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.	
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA – The SECR presented the list of issues identified in the context of UA.	**MSs:** To take note of the information provided in the table. **SECR:** To provide an updated list for the next CG meeting.
6.2 - Iodate used as stabiliser The majority of CG members considered that allowing a deviation in 10% in the concentration of iodine in the products was not relevant for this case since iodate-iodide generating iodine is considered as a new active substance. However, several CG members supported to provide applicants with some kind of "transitional period" to adapt products containing iodate.	**COM:** To communicate the outcome of the discussion to the CA meeting.
6.3 - PT 14 products renewal timelines The CG members updated the meeting on the status of the applications for renewal of PT14 products. The procedures started before the new SoP was agreed and for which the 60+30 day period was applied should not be modified. For procedures started after the SoP was agreed, cMSs are invited to follow the SoP unless this creates organisational issues, which should be communicated to the refMS. In the latter case, the 60+30 day will apply.	**cMSs**: In cases where a deadline for commenting of 40 days is already sent, to inform refMS whether the comments will be sent within 60 days.
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.
7.2 – Feedback on e-consultations	
Five closed e-consultations were presented: 1) A member presented the conclusions of an e-consultation on the environmental assessment of permethrin containing products. The CG members agreed with the outcome (Option 3). 2) A member presented the conclusions of an e-consultation on innovative products containing more than one mixture. The CG members agreed with the outcome with a minor modification. 3) A member presented the conclusions of an e-consultation on the simplified authorisation of PT19 products. CG members agreed that the	**1) CG member**: to provide a non-confidential version of the document. **1) SECR:** To publish the conclusions document in the relevant space in S-CIRCABC. **2) CG member**: to provide a non-confidential version of the updated document.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
product is eligible for the simplified procedure. 4) A member introduced an e-consultation on whether two different products can have the same trade name. The discussion will continue during the CG-27 meeting. 5) A member presented the conclusions of an e-consultation on the efficacy requirements for PT18 horse ware blanket. The discussion will be referred to ECHA for consideration in the Efficacy Working Group.	**2) SECR:** To publish the conclusions document in the relevant space in S-CIRCABC. **3) CG member**: to provide a non-confidential version of the document. **3) SECR:** To publish the conclusions document in the relevant space in S-CIRCABC. **4) SECR:** To open a newsgroup for comments on the document provided for discussion. **4) All:** To comment by 5 December 2017. **5) SECR**: To refer the issue to ECHA to be considered for discussion by the appropriate forum. **5) SECR:** To inform the CG on the outcome of the discussion.
7.3 Standard operating procedure for the Mutual Recognition phase	
The SECR presented a proposal for the steps of the SoP for the mutual recognition in sequence phase. CG members agreed with the proposal with a reservation on one CG member on one step. The SoP for MRS procedure will be implemented on 1 January 2018. CG members agreed that the agreed SoPs will be applied to the relevant steps of the renewal and major changes applications.	**SECR:** To upload the SoP document in the relevant S-CIRCABC folder. **SECR:** To communicate the ECHA IT the outcome of the discussion in order to adapt R4BP 3 to support the new procedure for the mutual recognition phase in sequence.
7.4 Template for providing comments in the Mutual Recognition phase	
The SECR presented an updated proposal for the template for the RCOM table to be used in the MR phase. CG members agreed on the proposal.	**SECR:** To upload the document in the relevant S-CIRCABC folder.
7.5 Process flow for Mutual Recognition phase	
The SECR presented a template to provide a process flow for the mutual recognition phase to support the new SoP. CG members agreed on the template.	**SECR:** To upload the document in the relevant S-CIRCABC folder.
7.6 Mutual Recognition phase document consolidation and dissemination	
The SECR presented a proposal for the dissemination and consolidation of the agreed documents related to the SoP for the mutual recognition phase. CG members agreed to provide the SoPs	**SECR:** To upload the documents in the relevant S-CIRCABC folder.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
independently of the working procedure for resolving disagreements. The document with the SoPs, RCOM and process flow templates will be uploaded in the relevant CIRCA space.	
7.7 Confidential information from third parties in same biocidal product applications	
A CG member presented the topic related to how the composition of SBP applications can be checked when the prospective authorisation holder of the SBP does not have access to the composition of the product. CG members agreed that more clear guidance is needed.	**SECR**: To inform ECHA of the need of further guidance on this area.
7.8 Clarification on the information needed in different sections of the SPC	
Due to time constraints this agenda point has been postponed.	**1) SECR:** To table this item for discussion for the CG-27 meeting.
7.9 Alternative dossiers	
The SECR reminded the CG members to follow the agreed document on alternative dossiers.	
Item 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-25	
The non-confidential minutes were agreed with two minor editorial changes.	**SECR:** to upload the CG-25 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 Consolidated version of the AR at the renewal of PTs other than PT14	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
COM introduced the topic on whether applicants have to provide a fully consolidated version of the AR for the renewal of products of PTs other than PT14. CG members agreed that a compromise should be found between the refMS and the applicant.	**SECR:** To open a newsgroup for comments. **All:** To comment by 5 December 2017 **ASOSs:** to provide comments on the topic.
14.2 Label requirements for clothing for PT 19 products	
The SECR presented the topic with a question from the HEADOC WG on whether a label requirement for clothing should be applicable for PT19 products to consider as worst case for the assessment outdoor clothing. The discussion will be continued during the CG-27 meeting.	**SECR:** To open a newsgroup for comments. **All:** To comment by 5 December 2017 **ASOSs:** to provide comments on the topic.
14.3 SBP amendments- Overview of administrative changes	
The SECR presented a proposal for a harmonised approach on how to classify and describe changes in applications for changes. CG members agreed on the proposal.	**SECR:** To upload the document in the ECHA website.
14.4 Assessment of PT21 products -New assessment tool	
A CG member presented the topic on the application of the new tool/model for assessing PT21 products in saltwater scenarios. The discussion will be continued during the CG-27 meeting.	**CG member:** To provide discussion document to the SECR. **SECR:** To open a newsgroup for comments. **All:** To comment by 5 December 2017.
Item 15 – Feedback from working parties	
15.1 Follow up on the WP on frequently used sentences in the SPC	
The SECR updated the meeting on the comments received for extending the WP to other PTs. CG members agreed to postpone the extension of the WP to gain experience on the additional PTs.	
15.2 WP on the biocidal product family concept	
The SECR updated the meeting on the progress of the WP on the biocidal product family concept. The topic on the concept of similarity will be discussed in the first WP meeting that will take place on 22 November 2017 in Brussels. A discussion was initiated on when similarity should be checked during the process. Several MSs proposed that applicants should check similarity before the submission with the refMS.	
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
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 invited the meeting to take note of the document.	**Rapporteur MS:** to check the new information and report to CG SECR by 29 November. **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 presented the new features of R4BP3 and the SPC editor.	**SECR:** To follow up on an issue raised by a CG member.
16.5– Feedback on e-consultations	
A CG member presented the conclusions on the e consultation on same biocidal products with reference to a same biocidal product. The discussion will continue during the CG-27 meeting.	**ASOs:** To send comments to the SECR on the e-consultation. **CG member:** To provide an updated document to be discussed during the CG-27 meeting.
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 II Final agenda

ANNEX II

22 November 2017

Final agenda

26th meeting of the Coordination Group (CG-26)

21-22 November 2017
On 21 November from 9:30 to 17:00
at the
Federal Public Service (FPS) Health, Food Chain Safety and Environment

and
on 22 November from 9:30 to 13:00
at the
Permanent Representation of the Czech Republic to the European Union
in Brussels

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-26-2017

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-25

CG-M-25-2017_Draft confidential

For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-26-2017-01

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-26-2017-02
For information

6.2 Iodate used as stabilizer

CG-26-2017-17
For discussion and agreement

6.3 PT 14 products renewal timelines

For discussion

Item 7 - Any Other Business

7.1 Late procedures

CG-26-2017-12, CG-26-2017-13 & CG-26-2017-14
For information

7.2 Feedback on e-consultations

CG-26-2017-03, CG-25-2017-22, CG-26-2017-08, CG-26-2017-15, CG_26-2017-16, CG-26-2017-18 Document to be distributed
Links to e-consultations
For discussion and agreement

7.3 Standard operating procedure for the Mutual Recognition in sequence phase

CG-26-2017-04
For discussion and agreement

7.4 Template for providing comments in the Mutual Recognition phase

CG-26-2017-05
For discussion and agreement

7.5 Process flow for Mutual Recognition phase

CG-26-2017-06
For discussion and agreement

7.6 Mutual Recognition phase document consolidation and dissemination

For discussion and agreement

7.7 Confidential information from third parties in same biocidal product applications.

For discussion

7.8 Clarification on the information needed in different sections of the SPC.

CG-26-2017-22
For discussion

7.9 Alternative dossiers.

For information

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-26-2017

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-25

CG-M-25-2017_Draft non confidential

For agreement

Item 13 – Administrative issues

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

14.1 Consolidated version of the AR at the renewal of PTs other than PT14

Link to newsgroups

For discussion and agreement

14.2 Label requirements for clothing for PT 19 products

CG-26-2017-19

For discussion

14.3 SBP amendments – Overview of administrative changes

CG-25-2017-11

For agreement

14.4 Assessment of PT21 products – New assessment tool

For discussion

Item 15 – Feedback from working parties

15.1 Follow up on the WP on frequently used sentences in the SPC

For discussion and agreement

15.2 WP on the BPF concept

CG-26-2017-21

For information

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-26-2017-10 & CG-26-2017-11

For information

16.2 Deadlines for application for product authorisation

CG-26-2017-09

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-26-2017-20

For information

16.4 IT issues

CG-26-2017-07

For information

16.5 Feedback on e-consultations

CG-26-2017-08

Links to e-consultations

For discussion and agreement

Item 17 – Agreement of the action points and conclusions

For agreement

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