

13 March 2018
CG-M-27-2017 non-confidential

**Final non-confidential minutes of the 27th meeting of the
Coordination Group (CG)**

16-17 January 2018

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the twenty seventh CG meeting (CG-27). 33 members and experts from 24 Member State Competent Authorities (MSCAs) and NO, and four representatives from three ASOs 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-27-2018) and invited participants to add any items under AOB. One agenda point was added to the AOB of the closed session on how to clarify some uses in the already submitted draft SPCs for the renewal of PT14 products. 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-26

The Chair explained that the draft confidential CG-26 minutes had been uploaded for commenting via Newsgroups. Comments were received from one CG member. The CG members agreed with the comments and the confidential draft minutes from the CG-26 were agreed.

Actions:

SECR: to upload the CG-26 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 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 informed the meeting that three referrals had been closed via written procedure after the CG-26 meeting. An agreement by consensus was reached for all three products (i.e. they meet the conditions in Article 19(1) for granting an authorisation).

Fifteen formal referrals were tabled for discussion. An agreement was reached by consensus for ten referrals and the authorisation of the products can be granted. The discussion of the other five referrals will be continued by teleconference.

- 1) A referral concerning a PT18 product containing deltamethrin as active substance was discussed. Several points of disagreement were raised concerning the combined exposure assessment of the product, instructions of use, and efficacy claims against several target organisms. An agreement was reached by consensus for all points except for the one related to efficacy against flies at rest flying insects. This point will be further discussed by teleconference.
- 2) A referral was discussed concerning a PT18 product containing imidacloprid as active substance. The points of disagreement were related to the validity of the efficacy data of the product. The referral will be further discussed by teleconference.
- 3) , 4) Two referrals with similar points of disagreement were discussed concerning two PT 14 products from the same applicant containing difenacoum as active substance. The main point of disagreement was related to the dermal absorption values used in the assessment and the necessity of including use of gloves as risk mitigation measure (RMM). This point was raised in several referrals. CG members agreed by consensus that in this case the use of gloves could be applied as a RMM. The products meet the condition for granting an authorisation in Article 19(1)(b)(iii) of the BPR. These formal referrals were therefore closed.
- 5) A referral was discussed concerning a PT14 product containing chlorophacinone as active substance. One point of disagreement was related to the shelf life of the product which was resolved based on previous agreements reached by the CG (CG-20). This point was also raised in referrals (6) and (7) and the same approach was followed. The second point of disagreement concerned the value used for the assessment of dermal absorption. The same approach was followed as that for referral (3). CG members agreed by consensus on the outcome. The product meets the condition for granting an authorisation in Article 19(1)(b)(iii) and 19(1)(d) of the BPR. This formal referral was therefore closed.
- 6) A referral was discussed concerning a PT14 product containing bromadiolone as active substance. The point of disagreement was related to the shelf life of the product. The same approach as for referral (5) was followed and CG members agreed by consensus on the outcome of the referral. The product meets the condition for granting an authorisation in Article 19(1)(d) of the BPR. This formal referral was therefore closed.
- 7) A referral was discussed concerning a PT14 product containing chlorophacinone as active substance. In addition to the shelf life of the product, the second point of disagreement was related to the function of a co-formulant in the product. The referral will be further discussed by teleconference.
- 8) A referral was discussed concerning a PT14 product containing coumatetralyl as active substance. The point of disagreement was related to the need of additional physico-chemical data. CG members agreed by consensus that no additional data was needed. The product meets the condition for granting an authorisation in Article 19(1)(d) of the BPR. This formal referral was therefore closed.
- 9) , 10) Two referrals were discussed concerning two similar PT14 product containing brodifacoum as active substance. The main points of disagreement were related to (a) the minimum pack size for professional users and (b) whether field trials were needed to support the efficacy of the products. CG members agreed that for point (a) the minimum pack size specified in the anticoagulant rodenticides SPC template was only a recommendation and for point (b) the efficacy assessment should not be re-opened. The products meet the conditions in Article 19(1)(b)(i), Article 19(1)(c) and Article 19(1)(d) of the BPR. These formal referrals were therefore closed.

- 11) , 12), 13) Three referrals were discussed concerning three similar PT14 products containing bromadiolone as active substance. The points of disagreement were related to the dermal absorption value used in the exposure assessment and the pack size of the product. CG members agreed to remove the use against mice only and to include gloves as a RMM for these cases. The products meet the condition for granting an authorisation in Article 19(1)(b)(i), and Article 19(1)(b)(iii) of the BPR. These formal referrals were therefore closed.
- 14) A referral was discussed concerning a PT8 product containing several active substances. Several points of disagreement were raised on the efficacy of the product, shelf life, exposure assessment and classification. CG members agreed on a few points and the discussion will continue by teleconference.
- 15) A referral was discussed concerning a PT8 product containing IPBC as active substance. The point of disagreement concerned the environmental risk assessment of the product. The discussion will be continued by teleconference.

Actions:

- 1), 7) SECR:** To organise a follow up teleconference on the 23rd January.
- 2), 14), 15) SECR:** To organise a follow up teleconference on the 2nd February.
- 2) Applicant:** To provide additional data by 23rd January
- 2) refMS:** To evaluate data by 27th January
- 2) All:** To consider the additional data to be discussed in the teleconference on 2nd February.
- 3) to 6), 8) to 13) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures.
- 7) refMS:** To clarify the function of a co-formulant.
- 14) refMS, applicant and icMSs:** discuss on how to resolve the remaining point of disagreement.
- 14) refMS:** To provide an interpretation of the guidance on SoCs as soon as possible.
- 14) SECR:** To open a newsgroup to comment on the interpretation of the guidance on SoC.
- 14) All:** To provide comments by 26th January
- 15) icMS and refMS:** To discuss bilaterally on the point of disagreement to be discussed and agreed during the teleconference.

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-27-2017-03). 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 Update on BPC opinions for UA applications

The SECR informed the CG meeting that two opinions were adopted during the BPC-23 meeting supporting two applications for Union authorisation for two biocidal product families containing iodine/PVP-iodine for use in veterinary hygiene.

6.3 Iodate used as stabilizer

The SECR presented an update on the conclusions of the BPC-23 meeting related to the use of iodate in iodine or iodine/PVP containing products. Relating to an application for Union Authorisation discussed at BPC-23, the BPC considered that, in this case, iodate could be regarded as a co-formulant. The "Technical Agreements for Biocides" (TAB) will be revised to take into account the conclusions of the BPC.

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 newsgroup to allow refMSs to provide feedback on late procedures including forecast of the start of the MR phase.

All: To provide comments by 6th February.

7.2. Feedback on e-consultations

One e-consultation was tabled for discussion:

A CG member introduced an e-consultation on whether different products can have the same trade name (CG-27-2018-14). Different views were expressed. The discussion will continue during the CG-28 meeting (open session).

Actions:

1) SECR: to table this item for discussion for the CG-28 meeting (open session).

7.3 Alternative dossiers.

The SECR informed the CG members that an updated list of alternative dossiers was available for review in S-CIRCABC. CG members were reminded to inform the SECR when an alternative dossier is received by a CA, and to follow the procedure as outlined in the document CG-17-2016-13.

Actions:

All: To review the alternative dossier list and communicate to ECHA any inaccuracies or missing information.

7.4 Clarification of some uses in already submitted draft SPCs for the renewal of PT14 products.

A CG member proposed to discuss how to clarify some uses for trained professionals (permanent, pulse and burrows baiting) in the already submitted draft SPCs for the renewal of some PT 14 products.

Applicants had identified that the non-standard uses mentioned above were not included in the draft SPCs and PARs provided by a refMS for commenting at the product renewal stage.

The CG member will provide a written proposal for comments.

Actions:

CG member: To provide a written proposal by 22 January.

SECR: To open a newsgroup for comments

All: To provide comments by 26th January.

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. Four 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-27-2018) 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-26

The Chair explained that the draft non-confidential CG-26 minutes had been uploaded for commenting via Newsgroups. Comments were received from one CG member. The CG members agreed with the comments and the non-confidential draft minutes from the CG-26 were agreed.

Actions:

SECR: to upload the CG-26 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

The Commission services thanked CG members and ASOs for the contributions provided during the commenting period after the last CG meeting. The Commission agreed with the views expressed by a CG member that Article 31 of the BPR does not provide for a legal basis to force applicants to submit a fully consolidated PAR as part of the application for renewal. A number of CG members supported though the benefits of having a fully consolidated PAR ready for dissemination after the renewal and to facilitate further MR-S procedures. The Commission also shared these views. A CG member mentioned that re-adapting the PAR provided by the applicant would be more time consuming than creating it by the refMS.

CG members agreed that the refMSs will request applicants to provide a consolidated PAR or to support their tasks to produce the consolidated PAR. However, applications for renewal will not be rejected where the consolidated PAR is not submitted.

The Chair noted that following this agreed way forward, this discussion was closed.

14.2 Label requirements for clothing for PT 19 products

The SECR updated the meeting on the comments received on whether a label requirement for clothing for “wearing normal outdoor clothing” is acceptable for PT19 products (CG-27-2018-05).

During the meeting CG members agreed by consensus that wearing minimal clothing cannot be considered as a realistic worst case scenario for the risk assessment. As a consequence, a label requirement for normal outdoor clothing would not be necessary.

Actions:

SECR: To communicate to ECHA the outcome of the discussion.

14.3 Assessment of PT21 products – New assessment tool

A CG member presented an updated proposal on how to address the environmental assessment of PT21 products using the new assessment tool developed for the saltwater scenarios (CG-27-2018-01). According to the proposal, the refMSs would carry out the assessment of saltwater scenarios using both, the current method and the method based on the new tool. The comparison of the results of both methods would then form the basis of a so-called “impact assessment”. This impact assessment would consider the market impact and the impact on the local environments.

The final decision on the use and restrictions of the products would not be made before the conclusions of the impact assessment were evaluated and shared among MSs. Since the outcome of the assessment will depend on the protection goals included in the methodology, the protection goals would need to be agreed by all MSs within a particular region.

The following points were raised:

- Managing of timelines considering the additional workload introduced by conducting the two assessments.
- Clarification on the planning of the impact assessment specifying who would act as project leader, clear timelines and process steps. It should be clearly explained the exact data that needs to be reported, how to report the data, and how to share the impact assessment results.
- Related to the last paragraph in the document on fouling, a CG member suggested to delete the efficacy criterion of greater 75% protection and replace it with a reference to the relevant guidance document.
- Related to the environmental risk assessment, clarification is needed on whether the risk assessment should be conducted for the whole EU, per region or per MS.
- It should be clarified whether the protection goals should be set during or after the impact assessment.
- It should be clarified the concept of “region” and what countries should be involved in the context of the impact assessment.
- Clarification is needed on what cases need to be referred to the Environmental WG where a higher tier approach is necessary for the risk assessment.
- Related to management of over effective products, a CG member commented that this aspect would in any case be integrated in the environmental risk assessment of the product.

The Commission suggested for consideration the following points:

- Considering that the previous policy approach for PT21 was agreed in a CA document, the CA meeting should be the appropriate forum to agree on the final decision of the impact assessment.
- Related to the mutual recognition process, a reference to Article 37 of the BPR is necessary.
- In the section dealing with the need to reduce the use of PT21 as much as possible, two references to the BPR are possible: Article 17(5) about proper use of biocidal products, and paragraph 77 of Annex VI where it is mentioned that the active substance content should be the minimum possible to ensure efficacy.

The CG member will provide an updated document based on the comments provided by the CG members.

Actions:

CG member: To provide an updated version of the document by 7 February

SECR: To open a newsgroup for comments.

All: To comment (3 weeks).

14.4 Guidance on assessment of SBP applications

The SECR informed the meeting that a preliminary proposal concerning the target content of the guidance is expected to be presented at the CG-28 meeting.

Actions:

SECR: To table this item for discussion for the CG-28 meeting.

15 – Feedback from working parties

15.1 WP on the biocidal product family concept

The SECR updated the meeting on the discussion that took place during the second meeting of the WP on the biocidal product family concept that took place on 15 January. The following points were discussed and agreed during the WP meeting:

- A matrix based on Annex V to the BPR will be developed to define similar uses.
- Similarity of composition will be addressed as part of similarity of levels of risk and similarity of level of efficacy.
- A document will be prepared with best practices for pre-submission meetings.
- A template will be prepared to explain the rationale of a family as a supporting document to the application. This supporting document could also be used during the pre-submission meetings with the eCA and during the pre-submission phase in case of UA procedures.
- A template was presented in order to define the composition of complex families and is available in case of need.

The WP experts expressed their interest in initiating the topic on grouping of co-formulants. CG members agreed that the discussion of this topic may be initiated after the CG-27 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-27-2018-07 & CG-27-2018-12, 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-27-2018-09, 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-27-2018-10).

Actions:

Rapporteur MS: to check the new information and report to CG SECR by 25 January 2018.

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 progress on data dissemination and provided instructions to MSCAs to properly prepare and address confidentiality issues (CG-27-2018-15).

The new dissemination website will be launched on November 2018. The information on NA, SA/SN, and UA will be disseminated. During the dissemination the following documents from each authorisation will be disseminated: SPC (finalised or updated after 1/1/16), PAR, authorisations/decisions, BPC opinions (UA).

The SECR invited MSs to take actions in order to support the dissemination process, i.e.: (a) check that assets and ongoing cases contain a non-confidential PAR (confidentiality claims made by the applicant need to be checked as well as authorisations, decisions and properly filled SPCs; (b) make sure that the documents have the correct type/access level combination (public, restricted, restricted-authority) in all the process steps; (c) be consistent in naming the PAR and authorisation documents.

The following points were clarified during the discussion:

- Only the final SPC which is part of the national authorisation (i.e. in the official language(s) of the MS) will be disseminated.
- The relation between the refMS and the cMS in MR will be available in the dissemination page. This information will not be provided for same biocidal products.
- All documents marked as public by a MS will be disseminated. There is no technical possibility to mark only some sections in a document as confidential (except in IUCLID). Special attention is needed for those MSs where the authorisation/decision contains confidential information and it is only provided to the authorisation holder.

On this point, the Commission clarified that Article 67(2) of the BPR refers also to the terms and conditions of the authorisations, that is, authorisation decisions should be made publicly available. If the authorisation/decision contains confidential information, one of the possibilities, is to make two documents: confidential and non-confidential.

- The different access levels (public, restricted, restricted-authority) available in R4BP 3 were explained: public – document which can be disseminated, restricted – for information exchange between MS and authorisation holder, restricted-authority – for information exchange among MSs (i.e. not available to the authorisation holder).
- There will be some search and comparison functionalities available, including search in free text fields.

Actions:

SECR: To make available the final version of the presentation

16.5 Feedback on e-consultations

Two e-consultations were tabled for discussion:

1) Same biocidal product with reference to a same biocidal product

A CG member presented an updated document with the conclusions of the e-consultation on a same biocidal product with reference to a same biocidal product (CG-27-2018-16). A discussion took place on whether company C could be prevented from knowing the identity of company A when having a letter of access (LoA) to the data from company A.

The Commission explained that according to the current R4BP 3 set up, it seems that the authorisation holder of an asset (e.g. a SBP) would have access to the documents uploaded in the case related to the asset. If so, since any LoA must indicate the data

owner, company C would always know that company A is the data owner. The SECR mentioned that, in the case that a CA would be the one uploading a document in the related case, this document could be marked as having restricted access only for CAs. In this case, if the LoA would be uploaded by a CA, this could prevent the authorisation holder of company C to have access to the LoA from company A, and consequently to the identity of company A. The same approach could be considered also in the context of preventing an authorisation holder to have access to the composition of a product.

CEFIC commented that an alternative option could be to include a licence on a LoA from company A to company B to allow sublicensing a LoA. This construction would allow company B to grant a LoA to company C without company C knowing the identity of company A.

The Chair proposed to upload the document in S-CIRCABC for written comments. This topic will be incorporated as part of the SBP guidance that will be prepared by ECHA. The discussion be continued during the discussion of the guidance.

Actions:

SECR: To open a newsgroup for comments.

All: To comment by 8 February.

SECR: to communicate to ECHA the need to incorporate this topic in the SBP guidance

2) Authorisation of room disinfectants

A CG member presented the document (CG-27-2018-06) with the conclusions of the e-consultation on the authorisation of room disinfectants and equipment which are used for this purpose.

According to the Efficacy Guidance Assessment and Evaluation (Volume II Efficacy, Parts B+C) *"The product authorisation will only be granted for use with the equipment described in the application."*

Although it is acknowledge that the technical properties of diffuser equipment contribute to efficacy in room disinfection, it was questioned whether the specific equipment used for the application should be part of the authorisation.

The CG member presenting the topic commented that an applicant should demonstrate that a biocidal product can act as an efficient room disinfectant in specified conditions that are in concordance with the claimed use(s). The applicant should specify the diffusion techniques (e.g. vaporization, fogging, spraying, and fumigation) that are applicable for the product and show disinfection efficacy of the techniques with a device specified in the study report. However, authorisation should not be limited to the tested equipment model(s).

The Commission explained that it is important to reflect in the SPC the parameters of the application device under the Section of the SPC - Application methods, but not restrict the authorisation to the tested devices only. Any device could be used as long as it fulfils the requirements in terms of the parameters defined in the SPC. This would be in line with previous discussions in the context of the future approach for devices for generating in situ active substances. The BPR intention is not to authorise devices.

CG members agreed by consensus on the document with the conclusions of the e-consultations. The authorisation of room disinfectants should not be limited to the specific equipment used in the application.

The Efficacy guidance should be amended to reflect this conclusion.

Actions:

SECR: to communicate to ECHA the need to address this issue in the Efficacy guidance.

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

27th meeting of the CG

16-17 January 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 of one agenda point on how to clarify some uses in the already submitted draft SPCs for the renewal of PT14 products.	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-26	
The draft confidential minutes of the CG-26 meeting were agreed with the comments provided by a CG member.	SECR: to upload the CG-26 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	
<p>The Chair informed that three referrals had been closed via written procedure since the previous CG meeting (CG-26) for which an agreement by consensus was reached.</p> <p>Fifteen formal referrals were discussed</p> <p>1) An agreement was reached for most points of disagreement. The discussion will continue by teleconference.</p> <p>2) The discussion will be continued by teleconference.</p> <p>3) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>4) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>5) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>6) An agreement was reached by consensus and this</p>	<p>1), 7) SECR: To organise a follow up teleconference on the 23rd January.</p> <p>2), 14), 15) SECR: To organise a follow up teleconference on the 2nd February.</p> <p>2) Applicant: To provide additional data by 23rd January</p> <p>2) refMS: To evaluate data by 27th January</p> <p>2) All: To consider the additional data to be discussed in the teleconference on 2nd February.</p> <p>3) to 6), 8) to 13) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.</p> <p>7) refMS: To clarify the function of a co-formulant.</p>

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
<p>referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>7) The function of a co-formulant needs to be clarified by the refMS. The discussion will continue by teleconference.</p> <p>8) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>9) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>10) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>11) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>12) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>13) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>14) A few points were closed during the meeting. The discussion will be continued by teleconference for the remaining open points.</p> <p>15) The discussion will be continued by teleconference.</p>	<p>14) refMS, applicant and icMSs: discuss on how to resolve the remaining point of disagreement.</p> <p>14) refMS: To provide an interpretation of the guidance on SoCs as soon as possible.</p> <p>14) SECR: To open a newsgroup to comment on the interpretation of the guidance on SoC.</p> <p>14) All: To provide comments by 26th January</p> <p>15) icMS and refMS: To discuss bilaterally on the point of disagreement to be discussed and agreed during the teleconference.</p>
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
<p>6.1 - Issues identified in the context of UA – The SECR presented the list of issues identified in the context of UA.</p>	<p>MSs: To take note of the information provided in the table.</p> <p>SECR: To provide an updated list for the next CG meeting.</p>
<p>6.2 - Update on BPC opinions for UA applications The SECR informed the CG meeting that two Union Authorisations had been adopted for the authorisation of two Union Authorisation applications.</p>	
<p>6.3 - Iodate used as stabiliser The SECR updated the CG meeting on the conclusions reached by the CA meeting and the BPC-23 meeting related to the use of iodate as stabiliser in iodine and iodine/PVP containing products.</p>	
7 – Any Other Business	
7.1 – Late procedures	
<p>COM presented the overview of late procedures.</p>	<p>MSs: to review the document and communicate to ECHA any inaccuracies in the data.</p> <p>SECR: To open a newsgroup to allow refMSs to provide feedback on late procedures including forecast of the start of</p>

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
	the MR phase. All: To provide comments by 6 th February.
7.2- Feedback on e-consultations	
One closed e-consultations was presented: A member presented the comments received on an e-consultation on whether two different products can have the same trade name. Different opinions were expressed. The discussion will be continued in the CG-28 (open session).	SECR: to table this item for discussion for the CG-28 meeting (open session).
7.3 - Alternative dossiers.	
The SECR requested CG members to provide feedback on product authorisation applications based on alternative dossiers. The SECR reminded CG members of the need to follow the procedure in the CG document <i>CG-17-2016-13</i> .	All: To review the alternative dossier list and communicate to ECHA any inaccuracies or missing information.
7.4 - Clarification of some uses in already submitted draft SPCs for the renewal of PT14 products.	
A CG member proposed to discuss how to clarify some uses for trained professionals (permanent, pulse and burrows baiting) in the already submitted draft SPCs for the renewal of PT14 products.	CG member: To provide a written proposal by 22 January. SECR: To open a newsgroup for comments All: To provide comments by 26 th January.
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-26	
The draft non confidential minutes of the CG-26 meeting were agreed with the comments provided by a CG member.	SECR: to upload the CG-26 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
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	
COM presented the conclusions of the comments received on this topic. CG members agreed that MSs will request applicants to provide a consolidated PAR, however, applications will not be rejected where the consolidated PAR is not submitted.	
14.2 - Label requirements for clothing for PT 19 products	
CG members agreed by consensus that wearing minimal clothing cannot be considered as a realistic worst case scenario.	SECR: To communicate to ECHA the outcome of the discussion.
14.3 - 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-28 meeting.	CG member: To provide an updated version of the document by 7 February SECR: To open a newsgroup for comments. All: To comment (3 weeks).
14.4 - Guidance on assessment of SBP applications	
The SECR informed the meeting that a proposal is expected to be presented on guidance for SBP applications on the CG-28 meeting.	SECR: To table this item for discussion for the CG-28 meeting.
Item 15 – Feedback from working parties	
15.1 - WP on the biocidal product family concept	
The SECR updated the meeting on the progress of the WP on the biocidal product family concept.	
16 - Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, 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 invited the meeting to take note of the document.	Rapporteur MS: to check the new information and report to CG SECR by 25 January 2018. 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.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
16.4 - IT issues	
The SECR presented the progress on data dissemination and provided instructions to MSCAs to properly prepare and address confidentiality issues.	SECR: To make available the final version of the presentation
16.5 – Feedback on e-consultations	
<p>Two e-consultations were tabled for discussion</p> <p>1) A CG member presented the conclusions on the e consultation on same biocidal products with reference to another same biocidal product. The latest updated document will undergo further commenting. Afterwards the topic will be referred to ECHA to be considered in the guidance on SBP.</p> <p>2) A CG member presented the conclusions on the e-consultation on the authorisation of room disinfectants. CG members agreed that an authorisation of a product should not be restricted to a specific equipment.</p>	<p>1) SECR: To open a newsgroup for comments.</p> <p>1) All: To comment by 8 February.</p> <p>1) SECR: to communicate to ECHA the need to incorporate this topic in the SBP guidance</p> <p>2) SECR: to communicate to ECHA the need to address this issue in the Efficacy guidance.</p>
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

16 January 2018

Final agenda 27th meeting of the Coordination Group (CG-27)

**16-17 January 2018 –
on 16 January 2018 from 9:30 to 17:00 and
on 17 January 2018 from 9.00 to 12.30**

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-27-2018

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 – Draft minutes from CG-26

CG-M-26-2017_Draft confidential

For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-27-2018-02

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-27-2018-03

For information

6.2 Update on BPC opinions for UA applications

For information

6.3 Iodate used as stabilizer

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-27-2018-08, CG-27-2018-11 & CG-27-2018-13

For information

7.2 Feedback on e-consultations

CG-27-2018-04, CG-27-2018-14

Links to e-consultations

For discussion and agreement

7.3 Alternative dossiers.

For information

7.4 Clarification of some uses in already submitted draft SPCs for the renewal of PT14 products.

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-27-2018

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-26

CG-M-26-2017_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
For discussion and agreement

14.2 Label requirements for clothing for PT 19 products
GC-27-2018-05
For discussion

14.3 Assessment of PT21 products – New assessment tool
CG-27-2018-01
For discussion and agreement

14.4 Guidance on assessment of SBP applications
For information

Item 15 – Feedback from working parties

15.1 WP on the BPF concept
For information

Item 16 – Any Other Business

16.1 Trends in product authorisation
CG-27-2018-07 & CG-27-2018-12
For information

16.2 Deadlines for application for product authorisation
CG-27-2018-09
For information

16.3 List of active substances meeting the exclusion or substitution criteria
CG-27-2018-10
For information

16.4 IT issues
CG-27-2018-15
For information

16.5 Feedback on e-consultations
CG-27-2018-06 & CG-27-2018-16
Links to e-consultations
For discussion and agreement

Item 17 – Agreement of the action points and conclusions

For agreement