21 November 2017

CG-M-25-2017 non-confidential

Final non-confidential minutes of the 25th meeting of the Coordination Group (CG)

26 – 27 September 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 fifth CG meeting (CG-25). 29 members and experts (including 8 remote participants for AP 5.2) from 22 Member State Competent Authorities (MSCAs), NO and CH, and four representatives from three ASOs participated in the meeting. One representative 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-25-2017) and invited participants to add any items under AOB. One agenda point was added to the AOB of the closed session regarding the reports on the authorisation of creosote containing 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-24

The Chair explained that the draft confidential CG-24 minutes had been uploaded for commenting via Newsgroups and that no comments were received. The CG members agreed on the confidential draft minutes from the CG-24.

Actions:

SECR: to upload the CG-24 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 informed the meeting that two referrals had been closed via written procedure after the CG-24 meeting. An agreement by consensus was reached for both products (i.e. they meet the conditions in Article 19(1) for granting an authorisation).

Thirteen formal referrals were tabled for discussion. An agreement was reached by consensus for seven referrals and the authorisation of the products can be granted. The CG members did not reach an agreement on one referral. This referral will be referred to the Commission under Article 36(1) of the BPR.

1) A formal referral was discussed concerning a PT 18 product family. The disagreement was related to the composition of the family, risk mitigation measurements (RMMs), efficacy and shelf-life. The CG members agreed on all points except for one which was related to efficacy of the product family. This point will be referred to the Commission under Article 36(1) of the BPR.

2) A formal referral was discussed concerning a PT 18 product. The disagreement was related to a potential risk of exposure of the product to bees, efficacy of the product, and shelf-life. An agreement was reached by consensus on all the points of disagreement. The product meets the condition for granting an authorisation in Article 19(1) and the referral has been closed.

3) A formal referral was discussed concerning a PT 18 product. The disagreement was related to a potential risk of exposure of the product to bees The CG members agreed by consensus on an additional RMM to be included in the SPC. The product meets the condition for granting an authorisation in Article 19(1) and the referral has been closed.

4) A formal referral was discussed concerning a PT 18 product. The disagreement was related to the validity of the efficacy data submitted by the applicant. The CG members agreed by consensus that the efficacy data submitted was sufficient to support the claimed use of the product. The product meets the condition for granting an authorisation in Article 19(1)(b)(i) of the BPR and the referral has been closed.

5) A formal referral was discussed concerning a PT 14 product. The disagreement was related to the validity of the efficacy data submitted by the applicant and the applicability of Article 55(2) to this case. The CG members agreed by consensus that the efficacy data submitted was sufficient to support the claimed use of the product. The regulatory issues on the applicability of Article 55(2) will be discussed in the CA meeting in September and the outcome of that discussion will be considered in order to conclude this referral procedure.

6) A formal referral was discussed concerning a PT 8 product. The disagreement concerned a) the environmental risk assessment of the scenario for the outdoor use of pallets, and b) several aspects of the human health risk assessment of the product. The CG members agreed by consensus on the refinement of the human health assessment and the environmental risk assessment of the product. The product meets the condition for granting an authorisation in Article 19(1) and the referral has been closed. On a more general note, the CG members agreed that a harmonised approach to address the pallet scenario is needed.

7) 8) and 9) Three referrals (PT 14) were covered in one discussion as they originated from the same applicant and had the same point of disagreement. The disagreement concerned the classification and labelling of a co-formulant and the application rates used for the efficacy studies. The CG members reached an agreement by consensus on all point of disagreement. The product meets the condition for granting an authorisation in Article 19(1) and the referral has been closed.

10) A formal referral was discussed concerning a PT18 product. The disagreement concerned the environmental risk assessment and shelf-life of the product. The referral discussion will be continued by teleconference.

11) A formal referral was discussed concerning a PT 18 product. The disagreement concerned the efficacy of the product. The discussion of the referral will be continued by teleconference.

12) 13) Two formal referrals were briefly discussed concerning two PT 18 products. Due to the large number of open points, a teleconference will be organised for the refMS and icMSs to discuss bilaterally.

Actions:

1) RefMS: to refer to COM (SECR in cc) the open point from these referrals following the provisions in Article 36 of the BPR.

1) SECR: to upload the detailed statement from the refMS in S-CIRCABC for information of the other MSs.

2) to 4) SECR: to follow-up the outcome of the referrals as stated in the Working **Procedures.**

5) COM: to table for discussion in the CA meeting in closed session the regulatory issues related to Article 55(2) affecting this referral.

6) to 9) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

10) RefMS: to provide the updated PAR by 10 October.

11) SECR: to organise a teleconference to continue the discussion on 18 October.

11) RefMS: to consult with the applicant the possibility to reduce the term of the shelf life of the product to 2 yr.

11) All: to provide comments in the newsgroups available for this referral by 6 October on the shelf life of the product.

11) SECR: to organise a teleconference to continue the discussion on 18 October.

12) RefMS: by 29 September: to provide answers to the comments received by the icMSs and to inform the applicant of the foreseen restrictions in uses for the authorisation of the product.

12) SECR: to organise a teleconference to continue the discussion bilaterally between the refMS and icMSs on 4 October.

13) All: To comment on the referral by 4 October 2017

13) SECR: to organise a teleconference to continue the discussion bilaterally between the refMS and icMSs after the commenting period.

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-25-2017-14). 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 update on the conclusions of the APCP WG-IV 2017 (CG-25-2017-23 and CG-25-2017-16) on whether iodate/iodide should be considered as a stabiliser in iodine or iodine PVP containing products.

Different views were expressed on whether an increase in 10% of the iodine concentration in products is acceptable.

Actions:

SECR: To open a newsgroup for comments on the proposal and provide feedback on products affected with and without the 10% rule.

refMSs: To comment by 19 October 2017.

6.3 Practical considerations for the renewal of PT8 products

A CG member presented the document CG-25-2017-12 considering the comments received after the CG-24 meeting on whether the renewal of PT8 products authorised under the BPD containing different combinations of the active substances IPBC, propiconazole and tebuconazole should be postponed after the renewal of the active substances (2020). The CG member pointed out that many issues would be avoided if the renewal of these products would be postponed, and indicated that, during the renewal of the active substance the list of endpoints could be changed substantially. The CG member proposed to prolong the existing product authorisations using Article 31(7) of the BPR.

During the discussion the CG members commented that the following should be clarified:

- The procedure to be applied by the cMSs in order to prolong the authorisations for existing products;
- How the expiry dates of the product authorisation in the refMS and in the cMSs should be aligned. During the discussion it was proposed by some CG members to have the same expiry dates for the authorisation in the refMS and in the cMS.

The Commission explained that the only legal basis that could be used for extending the expiry date of the product authorisations would be Article 31(7) of the BPR, which requires to have a submission of an application for renewal. Article 31(7) addresses the following two points (a) the step of the process in which the validity of an authorisation can be extended, (b) the period of time that is allowed for an extension. It was also indicated that the provisions of Article 31(7) only apply when the evaluation has already been started and the necessity for the additional information has been identified.

For this case, the same approach followed as for the PT14 products should be considered, i.e., submission of an application for renewal, validation, and start of evaluation. Considering that more information would be necessary for the renewal of the products, the evaluations could be put on hold, and the expire date of the authorisation could be prolonged for the period necessary to complete the evaluation.

The CG members supported the presented proposal and agreed that the discussion should be continued in the CA meeting.

Actions:

MS: To prepare a proposal with deadlines and procedural steps to be presented in the CA meeting.

COM: To table this point for discussion for the November CA meeting.

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 for comments from refMSs to provide feedback on late applications, and provide a forecast on the completion date of the assessment.

RefMSs: To comment by 19 October 2017.

7.2. Feedback on e-consultations

Three e-consultations were tabled for discussion:

1. **Permethrin products environmental risk assessment**

A CG member presented the document (CG-25-2017-21) 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. Several aspects were discussed related to the refinement of the environmental assessment of this products.

The CG members were invited to provide further comments on the topic.

2. **Innovative insecticide product**

Due to time constraints, the discussion of this e-consultation was postponed to the CG-26 meeting.

3. **Same biocidal product**

Due to time constraints, the discussion of this e-consultation was postponed to the CG-26 meeting.

Actions:

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

1) All: To comment by 19 October 2017.

2), 3) SECR: To table these items for discussion on the CG-26 meeting.

7.3 Standard operating procedure for the Mutual Recognition phase

The SECR presented a revised proposal for the steps of the SoP for the mutual recognition phase (CG-25-2017-18). The procedure was amended taking into account the comments received during the meeting. The CG members, with the reservation of one CG member on Step 1, agreed on the proposal. The procedure will be implemented in MR procedures starting as from 1 January 2018.

Actions:

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

SECR: To provide an adapted proposal for the SoP of the MR-S process.

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.

SECR: to inform the ECHA IT team of the need to provide a tool to accurately detect changes in SPCs in xml format.

SECR: to prepare a template for the process flow in step 0 to be agreed during the CG-26 meeting.

7.4 Template for providing comments in the Mutual Recognition phase

A draft for the harmonised template to provide comments during the MR phase was presented by the SECR (CG-25-2017-08).

The following points were agreed:

- Considering that the PAR includes the SPC, it would not be necessary seperatly to indicate whether comments are relevant for the PAR or SPC.
- Comments on substance identity and product composition will be included in the section- Analytical Methods and Physico-chemical properties.

The template will be tabled for agreement in the CG-26 meeting.

Actions:

SECR: To open a newsgroup for comments on the template.

All: To comment by 19 October 2017

7.5 Creosote containing products

The Commission reminded MSs to submit any pending reports on the authorisation of Creosote containing products as per the inclusion directive.

Actions:

MSs: To submit any pending reports to COM as soon as possible.

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-25-2017) 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-24

The Chair explained that the draft non-confidential CG-24 minutes were uploaded for commenting via Newsgroups. No comments were received during the commenting period. The CG members agreed on the draft minutes from the CG-24 meeting.

Actions:

SECR: to upload the CG-24 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

13.1 Template for submission of referrals

The SECR presented an updated version of the template for the submission of referrals (CG-25-2017-01) in order to align the template with the last revision of the working procedure for resolving disagreements. The CG members agreed on the document.

Actions:

SECR: to upload the form into the relevant folder in the CG CIRCA BC.

13.2 Supporting document for tracking changes

The SECR presented a template to be used as a supporting document to record changes in product authorisations (CG-25-2017-10). The document was agreed by the CG members. The SECR informed that taking as a basis the agreed document, all supporting documents for different types of changes will be updated accordingly. The document will be available in the ECHA website.

Actions:

SECR: to update the document with all different types of changes and upload the form in the ECHA website.

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 Chair invited CG members to discuss on whether the agreed approach for the AR for the renewal of PT14 products should be used for other PTs.

Different views were expressed. Most CG members preferred to have a fully consolidated version of the PAR provided by the applicant at the submission of the renewal application. On the other hand, the ASOs expressed their concern about requesting the applicant to make a fully consolidated PAR. This would result in a significant workload and it is not part of the information requirements for the renewal.

The Commission commented that Article 31(2)(b) of the BPR does not explicitly requires that submission of information. However, it should be considered that the PAR will be disseminated after the renewal and it is also the applicant's interest that the PAR is clear and understandable.

CG members and ASOs were invited to provide comments on this topic. The discussion will be continued in the next CG meetings.

Actions:

SECR: To open a newsgroup for comments.

All: To comment by 19 October 2017.

ASOSs: to provide comments on the topic.

14.2 The list of existing national registrations prepared for National and Union Authorisation

The SECR presented an updated version of the template for applicants to give an exhaustive list of products (including those currently on the EU market and new ones) for which a National authorisation or Union authorisation is being applied for. The template was agreed.

Actions:

SECR: To upload the document in the ECHA website.

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-25-2017-09). The SECR informed that during the validation step of Union authorisation applications for SBP, the SECR had encountered several cases where the administrative changes and the corresponding change numbers, according to Regulation (EU) No 354/2013, were not easy to identify.

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 clarification of the change number is included to help applicants to provide the right information.

CG members and ASOs were invited to provide comments on the document.

Actions:

SECR: To open a newsgroup for comments.

All: To comment by 19 October 2017.

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14. Feedback from working parties

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

The CG SECR presented a proposal for a follow up of the working party (WP) on frequently used sentences in the SPC. The proposal included a) a procedure for the maintenance of the

current list of sentences and b) a draft mandate to extend the working party to identify sentences applicable to PTs 6, 7, 9, 10, 11, 12 and 13.

The CG members agreed to include a disclaimer in the list of sentences stating that the list is a supporting tool but it should not be regarded as mandatory.

Several MS noted that MSs had currently little experience with most of the PTs listed to extend the WP. It was suggested that the extension should be therefore postponed.

The CG members agreed on the procedure to maintain the list of frequently used sentences in the SPC and will provide written comments on the proposal of the extension of the WP.

Actions:

SECR: To open a newsgroup for comments on the mandate for the initiation of the WP.

All: To comment by 19 October 2017.

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 concept. The S-CIRCABC space including a confidential and a non-confidential space had been set up for allowing exchange of information in the WP. Experts from MSs and ASOs had been nominated for all topics.

Concerning topic leaders, the SECR informed that leaders were only nominated for two topics. The MSs were invited to nominate topic leaders for the remaining topics and comment on what topics should be prioritised.

The Commission encouraged ASOs to inform SMEs about the activities of the WP. The Commission also mentioned the need to identify as soon as possible the areas where the involvement of the WGs would be necessary.

CG members will provide written comments on possible priorities and nominate topic leaders.

Actions:

SECR: To open a newsgroup for comments on priorities and to provide volunteers for topic leaders.

All: To comment by 4 October 2017.

15. 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-25-2017-04 & CG-25-2017-05, 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-25-2017-03, 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-25-2017-02).

Actions:

Rapporteur MS: to check the new information and report to CG SECR by 4 October.

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

CG members and ASOSs asked several questions that were addressed by the CG SECR:

- The update of R4BP3 will be presented in the CA meeting.
- The date expected for the dissemination of the information from R4BP 3 is postpone to the end of 2018. The SECR reminded CG members that, since the SPCs (updated in R4BP3 after 1 January 2016) will be automaticly disseminated, MSs need to ensure that the SPCs are properly filled in.
- ASOs asked whether any measures have been taken in order to ensure that all necessary cases/assets are linked in R4BP 3 after the data export from R4BP2. The CG SECR informed that preventive steps were implemented with data correction and more flexibility is foreseen in R4BP3.

16.5 Feedback on e-consultations

No e-consultations were tabled for discussion for the open session

17. Agreement of the action points and conclusions

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

Actions:

SECR: To circulate the list of action points and conclusions for agreement.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

25th meeting of the CG

26-27 September 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 1 AOB point by the COM on creosote containing 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-24	
There were no comments on the draft confidential minutes of the CG-24 meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-24 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-24). Twelve formal referrals were discussed **1)** The CG members did not reach an agreement on one point. This unsolved point will be referred to the Commission under Article 36 of the BPR. **2)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **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)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members **5)** An agreement was reached by consensus on the efficacy of the product. The regulatory issues on the applicability of Article 55(2) will be discussed in the CA meeting in September and the outcome will be considered in order to conclude this referral procedure.	**1) RefMS**: to refer to COM (SECR in cc) the open point from these referrals following the provisions in Article 36 of the BPR. **1) SECR:** to upload the detailed statement from the refMS in S-CIRCABC for information of the other MSs. **2) to 4) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **5) COM:** to table for discussion in the CA meeting in closed session the regulatory issues related to Article 55(2) affecting this referral. **6) to 9) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures.

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) , 8), 9)** Three referrals were covered in one discussion as they originated from the same applicant and had the same point of disagreement. An agreement was reached by consensus and these referrals are therefore closed. The outcome of the referral was agreed by the CG members. **10)** The discussion of the referral was initiated. A follow up discussion will take place on 18 October by teleconference. **11)** The discussion of the referral was initiated. A follow up discussion will take place on 18 October by teleconference. **12)** The discussion of the open points was initiated. Due to the large number of open points, a teleconference will be organised for the refMS and icMSs to discuss, although other MSs may join the discussion if they wish to do so. **13)** The commenting period of this referral will end on 4 October. Due to the large number of open points, a teleconference will be organised after the commenting period for the refMS and icMSs to discuss, although other MSs may join the discussion if they wish to do so.	**10) Ref MS:** to provide the updated PAR by 10 October. **11) SECR:** to organise a teleconference to continue the discussion on 18 October. **11) RefMS:** to consult with the applicant the possibility to reduce the term of the shelf life of the product to 2 yr. **11) All:** to provide comments in the newsgroups available for this referral by 6 October on the shelf life of the product. **11) SECR**: to organise a teleconference to continue the discussion on 18 October. **12) RefMS:** by 29 September: to provide answers to the comments received by the icMSs and to inform the applicant of the foreseen restrictions in uses for the authorisation of the product. **12) SECR:** to organise a teleconference to continue the discussion bilaterally between the refMS and icMSs on 4 October. **13) All:** To comment on the referral by 4 October 2017 **13) SECR:** to organise a teleconference to continue the discussion bilaterally between the refMS and icMSs after the commenting period.
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 SECR informed the meeting about the discussions that took place during the APCP-IV-WG-2017 related to the use of iodate as stabiliser in iodine and iodine/PVP containing products. Different views were expressed on whether an increase in 10% of the iodine concentration in products is acceptable.	**SECR:** To open a newsgroup for comments on the proposal and provide feedback on products affected with and without the 10% rule. **refMSs:** To comment by 19 October 2017.
6.3 - Practical considerations for the renewal of PT8 products	**MS:** To prepare a proposal with deadlines and procedural steps to be presented in the CA meeting.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
A member proposed to postpone the date for the renewal of products after the one for the renewal of the active substance. The CG members supported the proposal.	**COM:** To table this point for discussion for the November CA meeting.
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 newsgroup for comments from refMSs to provide feedback on late applications, and provide a forecast on the completion date of the assessment. **RefMSs:** To comment by 19 October 2017.
7.2 – Feedback on e-consultations	
Three closed e-consultations were presented: 1) A member presented the comments of an e-consultation on the environmental assessment of permethrin containing products. 2) Due to time constraints the discussion is postponed to the CG-26 meeting. 3) Due to time constraints the discussion is postponed to the CG-26 meeting.	**1) SECR:** To open a newsgroup for comments on the document provided for discussion. **1) All:** To comment by 19 October 2017. **2), 3) SECR:** To table these items for discussion on the CG-26 meeting.
7.3 Standard operating procedure for the Mutual Recognition phase	
The SECR presented a revised proposal for the steps of the SoP for the mutual recognition phase. The procedure was amended to account for the comments received during the meeting. The CG members, with the reservation of one CG member on Step 1, agreed on the amended document. The procedure will be implemented on 1 January 2018.	**SECR:** To upload the updated SoP document in the relevant S-CIRCABC folder. **SECR**: To provide an adapted proposal for the SoP of the MR-S process. **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. **SECR**: to inform the ECHA IT team of the need to provide a tool to accurately detect changes in SPCs in xml format. **SECR**: to prepare a template for the process flow in step 0 to be agreed during the CG-26 meeting.
7.4 Template for providing comments in the Mutual Recognition phase	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
The SECR presented a proposal for a template for the RCOM table to be used in the MR phase. The CG members provided comments on how to improve the template.	**SECR:** To open a newsgroup for comments on the template. **All:** To comment by 19 October 2017
7.5 Creosote containing products	
COM reminded MSs to submit any pending reports on the authorisation of Creosote containing products as per the inclusion directive.	**MSs:** To submit any pending reports to COM as soon as possible.
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-24	
There were no comments on the draft non confidential minutes of the CG-24 meeting. The non-confidential minutes were agreed.	**SECR:** to upload the CG-24 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
13.1 Template for submission of referrals	
The SECR presented an updated version of the form to be used for the submission of referrals. The CG members agreed on the form.	**SECR:** to upload the form into the relevant folder in the CG CIRCA BC.
13.2 Supporting document for tracking changes	
The SECR presented a document to record changes in applications. The document was agreed by the CG members.	**SECR:** to update the document with all different types of changes and upload the form in the ECHA website.
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	
Different views were expressed on whether the consolidated version of the AR used for the renewal of PT14 products should also be used for other PTs.	**SECR:** To open a newsgroup for comments. **All:** To comment by 19 October 2017

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	ASOSs: to provide comments on the topic.
14.2 The list of existing national registrations prepared for National and Union Authorisation	
The SECR presented an updated template for applicants to give an exhaustive list of products currently on the EU market and new products for which a National authorisation or Union authorisation is being applied for. The CG members agreed on the document	**SECR**: To upload the document in the ECHA website.
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.	**SECR:** To open a newsgroup for comments. **All:** To comment by 19 October 2017.
Item 15 – Feedback from working parties	
15.1 Follow up on the WP on frequently used sentences in the SPC	
The SECR presented a proposal to extend the WP on frequently used sentences in the SPC in order to address PTs 6, 7, 9, 10, 11, 12 and 13. The CG members will provide comments on whether the setup of the WP will need to be postponed to gain experience in these PTs. A proposal for the maintenance of the current list was also presented. The CG members agreed with the proposal of the maintenance of the list.	**SECR:** To open a newsgroup for comments on the mandate for the initiation of the WP. **All:** To comment by 19 October 2017.
15.2 WP on the biocidal product family concept	
The SECR updated the meeting on the setup of the WP on the biocidal product family concept. The CG members were invited to volunteer as topic leaders and provide comments on priorities of the different topics (including possible merges).	**SECR:** To open a newsgroup for comments on priorities and to provide volunteers for topic leaders. **All:** To comment by 4 October 2017.
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 4 October. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	If relevant, to produce an updated version for next CG meeting.
16.4 IT issues	
CG members raised some IT questions that were addressed by the CG SECR.	
16.5– Feedback on e-consultations	
No e-consultations were tabled for discussion in the open session.	
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

26 September 2017

Final agenda
25th meeting of the Coordination Group (CG-25)

26-27 September 2017 –
On 26 September from 9:30 to 17:00 and
on 27 September from 9:00 to 13:00

Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-25-2017

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-24

CG-M-24-2017_Draft confidential

For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-25-2017-07

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-25-2017-14

For information

6.2 Iodate used as stabilizer

CG-25-2017-16 & CG-25-2017-23

For discussion and agreement

6.3 Practical considerations for the renewal of PT8 products

CG-25-2017-12

For discussion and agreement

Item 7 - Any Other Business

7.1 Late procedures

CG-25-2017-06, CG-25-2017-13 & CG-25-2017-15

For information

7.2 Feedback on e-consultations

CG-25-2017-17, CG-25-2017-21 & CG-25-2017-22

Links to e-consultations

For discussion and agreement

7.3 Standard operating procedure for the Mutual Recognition phase

CG-25-2017-18

Link to comments in newsgroups

For discussion and agreement

7.4 Template for providing comments in the Mutural Recognition phase

CG-25-2017-08

For discussion and agreement

7.5 Creosote containing products

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-25-2017

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-24

CG-M-24-2017_Draft non confidential

For agreement

Item 13 – Administrative issues

13.1 Template for submission of referrals

CG-25-2017-01

For discussion and agreement

13.2 Supporting document for tracking changes

CG-25-2017-10

For discussion and agreement

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 comments in newsgroups

For discussion and agreement

14.2 The list of existing national registrations prepared for National and Union Authorisation

CG-25-2017-09

For discussion and agreement

14.3 SBP amendments- Overview of administrative changes

CG-25-2017-11

For discussion

Item 15 – Feedback from working parties

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

CG-25-2017-19

For discussion and agreement

15.2 WP on the biocidal product family concept

CG-25-2017-20

For discussion and agreement

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-25-2017-04 & CG-25-2017-05

For information

16.2 Deadlines for application for product authorisation

CG-25-2017-03

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-25-2017-02

For information

16.4 IT issues

For information

16.5 Feedback on e-consultations

Item 17 – Agreement of the action points and conclusions

For agreement

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