20 January 2016

CG-M-14-2015 Final PUBLIC

Final minutes of the 14th meeting of the Coordination Group (CG)

10 November 2015

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the fourteenth CG meeting. 37 members from 27 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and three representatives from ECHA were present for the full meeting. The list of attendees is given in Part III of the minutes.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-14-2015) and invited participants to add any items under AOB. The agenda was agreed with the inclusion of an additional point under AOB regarding the nomination for Vice-Chair position for the CG.

The Chair remarked that a document (CG-14-2015-07_rev1) for AP 6.6 had been uploaded to CIRCABC at a later stage.

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. Agreement of the draft minutes from CG-13

The SECR explained that the draft confidential CG-13 minutes had been uploaded for commenting via Newsgroups. No comments had been received on the confidential minutes. No comments were received during the meeting and the CG members agreed on the draft minutes from CG-13 meeting.

Actions

SECR: to upload the CG-13 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. The SECR informed that this overview is as well uploaded to the Disagreements folder in CIRCABC and will be permanently available to the Contact Points. The table will be updated and revised before each Coordination Group meeting.

Actions

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

5.2 Informal referrals on mutual recognition disagreements before Article 35 of the BPR

No informal referrals are ongoing at the CG. The Chair mentioned that the absence of informal referrals can be interpreted as a proof that good communication exists within MSs to solve points for disagreement before raising them to the Coordination Group.

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

There was a discussion on two formal referrals.

1) On the first formal referral, the involved Members States were given the opportunity to provide clarifications about the status of the disagreement. The applicant attended the meeting and thanked the CG members for their will to reach an agreement. An agreement was reached by consensus at the CG meeting and this referral is therefore closed.
2) On the second formal referral, the initiating cMS and rMS provided some background for the discussion regarding the environmental risk assessment. Several Member States expressed their support to the position of the rMS on the assessment conducted. Since the commenting period established in the Coordination Group Working Procedures was ongoing, further discussions will follow via written procedure.

On a more general note, MSs requested that the draft outcome of formal referrals is circulated to all MSs before CG meetings, in order to facilitate the possibility of reaching agreements during the meetings. Until now, the practice had been to distribute the document in advance to the Chair of the CG, the rMS, concerned MSs and the Commission.

Actions

SECR:

1) Upload the outcome of the referral onto CG CIRCA BC and to produce an executive summary to be made publicly available.
2) To follow-up the discussion as stated in the Working Procedures.

All:

2) To provide comments by 16 November.

6. Any Other Business (closed session)

6.1 Late procedures

The Commission briefly introduced the reports prepared by ECHA and invited MSs and ECHA to double check the information regarding SBP cases. As mentioned in previous CG meetings, the Commission has looked at the information available in R4BP on the pending applications submitted under the BPD.

Several members raised some issues that might lead to delays in the product authorisations processes.

Actions

All MS: To check the information in the reports, and where relevant notify the SECR of any discrepancies.

6.2 Harmonized RMM for DEET containing products

The CG SECR informed the meeting about status of the discussions taking place on the harmonization of RMMs for DEET containing products. Before CG-13 meeting it had been agreed to forward the technical discussions with regard to the RMMs to the Ad hoc Working Group on Human Exposure.

The *Ad hoc* Working Group has been consulted on the reduction of the percentage of uncovered skin and the reduction of the use frequency. For that purpose a conference call of the *Ad hoc* Working Group took place from which a draft document has been prepared and was circulated to the Working Group members for further elaboration. Once the discussions in the Human Exposure Group are finalized, the final document will be forwarded to the CG members in order to be taken into account for further discussions.

Actions

SECR: to follow-up and report back to the CG once the feedback from HEAdhoc is received.

6.3 Revised PNEC value for imidacloprid and impact on existing product authorisations

The CG SECR informed that a revised PNECwater value for imidacloprid had been agreed during BPC-11, as proposed the DE CA and after agreement by the Environmental WG. The revised value has been included in an updated Assessment Report, published on the ECHA website and on CIRCABC.

During the BPC, it was requested that the consequences during product authorisation for imidacloprid-containing biocidal products should be clarified, especially on when the new PNEC value shall be applied and how this affects the existing product authorisations and on-going applications.

Commission clarified that regarding open cases, paragraph 8(a) of Annex VI to BPR obliges the evaluating Competent Authority to take into consideration the new endpoint or other relevant technical or scientific information available with regard to the properties of the biocidal product and its components (i.e. the active substance).

Regarding already authorised products, Article 47(1)(a) and (2) of the BPR shall apply. Therefore, the authorisation holders should notify CAs which should examine whether or not the product authorisation needs to be amended or cancelled in accordance with Article 48(1)(a) of the BPR. Here the Commission underlined the key role of the refMS in order to avoid unnecessary work duplication.

MSs agreed on this specific document but a MS raised general issues on when existing product authorisations should be amended. This MS considered that existing product authorisations should be amended if the new information is the outcome of a procedure in accordance with Article 15 of the BPR. It was agreed that further written comments on the general issues could be submitted by CG members.

Actions

SECR: to set up a Newsgroups to accommodate general comments related to this paper.

All: to comment by 1st December.

6.4 How to deal at product authorisation with reference sources with a higher purity than the minimum purity in the implementing regulation

The SECR presented document (CG-15-2014-06) and asked for MSs views on whether TE should be requested within the application for product authorisation for one of the two notifiers of an active substance.

A notifier had requested whether the establishment of TE is needed at product authorisation, as there is a change in the manufacturing process (i.e. change in the raw starting material). With this change in the manufacturing process, the purity specification would be lower than the value in their reference specification, but it would be in line with the minimum purity specification used for the inclusion regulation of both notifiers.

ECHA informed that according to the guidance on application for technical equivalence, the establishment of technical equilvance might not be necessary provided that several conditions are kept.

Some MSs considered that this issue should be better placed for discussion under a technical forum, while others considered that this was a policy discussion. Some members expressed that in this particular case TE would not need to be requested to the applicant.

Since different views were presented, the Chair proposed to have further discussions via written procedure.

Actions

SECR: to set up a Newsgroups in CIRCABC

All: to comment by 1st December.

6.5 Feedback from e-consultations

No closed e-consultations had taken place from the last meeting.

6.6 Procedural issues and delays identified in product authorisation

The Commission briefly informed the meeting of a document tabled for discussion at the 62nd CA meeting, underlining that its main purpose was to compile a number of identified issues (some of them already discussed in previous CG or CA meetings) and to encourage MSs to take the appropriate actions. It was also stressed that action has to be taken now, as the number of applications are expected to significantly increase in the near future when the number of AS approvals per year will increase from 10-15 to 50.

6.7 In-can preservatives in rodenticides and other PTs

The Commission briefly reminded MSs about the task referred to in paragraph 22 and footnote 4 in document CA-Sept14-Doc.5.5 – Final.

Actions

rMSs: to submit the relevant information to the CG SECR.

6.8 Data requirements of residue analysis in air for an active substance for product authorisation

A member presented the document and the way forward. A similar way forward had already been agreed by the Coordination Group in a related case for other active substances and was also supported by the CG members for this case.

CG agreed on the way forward presented in the document.

6.9 Nomination of Vice-Chair for the CG

The Chair informed that since the term of the Vice-Chair expires by the end of the year, according to the rotating EU presidency, nomination letters can be accepted for the Vice-Chair position.

Members were invited to nominate themselves for the position of Vice-Chair of the Coordination Group.

Actions

SECR: to set up a Newsgroups in CIRCABC.

All: to submit nomination letters by 1st December.

7. Agreement of the action points and conclusions

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

Open session

8. 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.

9. Agreement of the agenda for the open session

The Chair introduced the draft agenda (CG-A-14-2015) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed without any further addition.

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.

10. 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.

11. Agreement of draft minutes (non-confidential part) from CG-13

The SECR explained that the draft non-confidential CG-13 minutes were uploaded for commenting via Newsgroups. No comment had been received on the non-confidential minutes. No further comments were received during the meeting and the CG members agreed on the draft minutes from CG-13.

Actions

SECR: to upload the CG-13 minutes into the relevant folders in the CG CIRCABC.

12. Administrative issues

12.1 Working procedures

The SECR informed the meeting about the revision of the Working procedures regarding how to proceed when an application for MR is withdrawn in the iCMS, how rMS and other cMS will need to be informed, and how to proceed with the disagreement as it will be still relevant for the other cMSs.

Some members supported the possibility for other cMSs to take over the disagreement keeping the deadlines from the first submission. Otherwise, the disagreement should be considered as withdrawn.

The possibility of withdrawing the referral by the initiating cMS as an alternative to a Coordination Group agreement was deleted from the Working Procedures.

The CG members supported the proposed changes and the revision of the Working Procedures was agreed.

Actions

SECR: to upload the updated and agreed version of the Working procedures onto CIRCABC.

12.2 Migration to Secure CIRCABC

The SECR informed about the dates for the migration to S-CIRCABC and how this would affect the access to the site, i.e. 2-day period with only read-only access. The upload of documents or posting of comments in the Newsgroups will not be available during the migration.

12.3 Public CIRCABC

The SECR informed about the set up and the content of the Public CIRCABC CG IG which can be consulted without the login credentials.

Non-confidential meeting documents would be published in the public CIRCABC after the decision is made by the CG. Therefore, from CG-15 onwards the documents will be uploaded in the public CIRCABC including a clear disclaimer that they are only drafts and that they have not been agreed. This had been the preferred option for those MSs having expressed their views in Newsgroups.

The minutes from the non-confidential section will be published retroactively in the public CIRCABC and will be therefore duplicated in both public and restricted CIRCABC. As minutes contain personal data such as the names of the participants to the meetings, this list of participants will be taken out from the minutes before its publication. The public summary of the discussion and conclusion of the formal referrals (including those formal referrals already discussed at the CG) will be published after confidentiality check with the applicant and consultations with the rMS, iCMs and COM.

It was also agreed that product names, to be used to identify the executive summary of formal referrals as the outcome of the CG discussions, should not be seen as confidential information. The confidentiality claims will be checked with the applicant, involved MSs and Commission before the document is published.

Actions

SECR: to populate the public CIRCABC with previous CG meeting minutes and executive summaries of formal referrals.

13. Harmonisation of technical and procedural issues in relation to product authorisation

13.1 Evaluation of alternative dossiers during product authorisation

ECHA introduced document CG-14-2015-12, which includes further clarifications requested during the discussions held at previous CG meetings as well as the comments received from MSs via Newsgroups.

Members States asked for further clarification regarding the consequences triggered by the different processes (i.e. completeness and compliance check) conducted by the reference MS for an alternative dossier. ECHA clarified that the validation of an alternative dossier does not lead automatically to the inclusion in the Article 95 list, until a compliance check has been performed by the rMS during the evaluation of the quality of the dossier.

ECHA also clarified that the peer-reviewed and agreed LoEP should always be used in the assessment of applications for product authorisation unless the LoEP is replaced by another peer-reviewed and agreed LoEP. The Commission supported ECHA's views and added that the review of the agreed LoEP should be limited to very exceptional cases, as it might trigger the review of existing authorisations (e.g. imidacloprid case). ECHA and Commission provided further clarifications to questions raised by CG members regarding Annex III requirements (i.e. the core data set shall be provided in order to validate an

dossier submitted for product authorisation) and the conditions for the review of an active substance approval in accordance with Article 15 of the BPR (i.e. it should only be launched where there are significant indications that the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met). .

Actions

SECR: to set up a Newsgroups in CIRCABC.

All: to comment by 1st December.

13.2 Note for guidance on BPF: update

(number of family members in a meta SPC)

The Commission introduced document CG-14-2015-13, underlying the main changes in the Q&A pairs resulting from the comments submitted by four CG members after CG-13 and those submitted during the latest pre-meeting consultation by another CG member.

Regarding Q&A 15, a CG member expressed that the current wording was not clear enough and that the same approach in terms of hazard and precautionary (H&P) statements should be possible for a single biocidal product or for an individual product in a BPF. The Commission mentioned that the proposed answer underlines that the H&P statements of the individual product should be "compatible" with those of the meta-SPC to which the product belongs, and that nothing prevents the eCA from setting these H&P statements in the same way as for a single biocidal product. The Commission invited CG members to consider whether this Q&A pair was too complex or too specific to be addressed in Annex IV to the note for guidance.

The CG member being at the origin of this question mentioned that the answer provided was clear enough and proposed to keep it in the document as it was.

The Chair noted that the document was agreed by the CG meeting. As this document is also tabled at the 62nd CA meeting for endorsement, the Commission will inform the CA meeting that the document was agreed by the CG with no changes.

Actions

COM: to inform the CA meeting that the document was agreed by the CG.

13.3 CEPE request to hold a workshop on authorisation of PT21 products

The CEPE representative presented a proposal for holding a workshop on authorisation of antifouling products back to back to CG meeting. Member States requested further clarification on the purpose of the workshop in order to identify the appropriate forum to discuss the issues proposed in the agenda, since there were different technical/policy issues to be discussed for which the CG is not the appropriate forum.

CG members expressed that further considerations shall be given to the different topics in order to find the appropriate forum to hold this discussion.

Actions

Chair/COM/ CG SECR: to make a proposal to the CG members on the way forward on where CEPE can best discuss the issues on this topic.

13.4 Paragraph 10 of Annex VI to BPR and applications for changes

The Commission introduced document CG-14-2015-15, which addresses a question raised by a MS at the 61st CA on whether paragraph 10 of Annex VI would also apply to the assessment of applications for a change to the authorisations of biocidal products granted under the BPD and containing an active substance (AS) meeting the exclusion criteria.

The Chair noted that CG members agreed on the approach proposed in the document that CAs should not consider whether or not the conditions for derogation in Article 5(2)

of the BPR are met at MS level in the context of applications for a change to authorisations of biocidal products.

CG agreed on the way forward presented in the document.

13.5 Data requirements for simplified authorisation

A CG member presented the question (CG-14-2015-16) on the data to be required for simplified authorisation.

Some CG members expressed the need for further guidance regarding some procedural aspects for this type of applications and the notifications in accordance with Article 27(1) of the BPR. CG members also supported the need to develop a PAR template starting from the agreed template for NA/UA.

Concerning some contributions by CG members, the Commission clarified that under the simplified procedure there is no validation phase, but just an acceptance of the application once the fees have been paid. The Commission also clarified that the SAP does not set any bilateral discussions with other MSs before the product authorisation is granted by the eCA. Therefore, the PAR should only be used to make available to MSs notified in accordance with Article 27(1) a summary of the evaluation. This PAR would be then a useful tool for the notified MSs to decide whether or not a case should be referred to the CG. Finally the Commission encouraged MSs to keep the SAP simplified, in line with the spirit in the BPR.

The Chair invited CG members to send any questions linked to the simplified authorisation procedure requiring further clarification.

Actions

SECR: to set up a Newsgroups in CIRCABC

All: to comment by 1st December.

14. Feedback from working parties

14.1 Development of standardised sentences for the SPC sections of anticoagulant rodenticides

ECHA presented the nominated experts for the Working Party (see document CG-14-2015-17). From an operational point of view, a Secure-CIRCABC platform has been set up in order to support the discussions of the Working Party.

The Commission also informed CG members of the contributions to be made by the Rodenticide working group (RWG) of Cefic to the WP. The RWG will submit its proposal to the Commission by the first week of December, with a view to be sent to WP members and ask them for a first round of comments. The Commission will then integrate those comments and prepare an updated version for further discussion. If needed, a physical meeting will be arranged back to back to the January 2016 CG meeting in Madrid.

The RWG will prepare two separate documents: one for products intended for the general public and other products intended for trained/professional users (wide meaning). The harmonised sentences will be included in the relevant sections of the SPC template for single biocidal products (CA-Sept14-Doc.5.4 - Final).

Actions

COM: to forward the input from IND to the Working Party.

15. Any Other Business (open session)

15.1 Trends in product authorisation

The Commission briefly introduced the reports prepared by ECHA (documents CG-14-2015-18&19). The Commission asked CG members for their views on the flat trend observed at page 3 of the report on product authorisations, with an increase of 120

authorisations in 2015. Two CG members reported a low number of applications received in the last months and another CG member referred to the pending DEET containing products as possible causes for this. The Commission also asked ECHA to check whether some cleaning of expired assets in the data base might have outnumbered the new authorisations granted during this period.

15.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-14-2015-20, which was made available for information.

15.3 List of substances meeting the exclusion or substitution criteria

The SECR informed the meeting that the updated version of the list includes changes concerning some approved active substances.

Actions

Rapporteur MSs: to check the new information and confirm to the SECR that it is correct as soon as possible.

SECR: Once the confirmation from the rapporteur MSs is received, 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.

15.4 Questions regarding R4BP 3 / IUCLID

ECHA updated the meeting about the latest IT developments (CG-14-2015-24) and informed about the vision for further developments for the next three years. ECHA presented the project plan for 2016 and invited MSCAs to get involved in the testing and analysis activities of the new R4BP & SPC Editor releases foreseen for next year. ECHA updated the CG about the outcome of the BPR IT User Group meeting and the main action points and conclusions reached during that meeting.

ECHA also asked MSs and Commission for input on how best to implement from an IT perspective the notifications for new family members in accordance with Article 17(6) of the BPR.

Actions

SECR: To set up a Newsgroups in CIRCABC.

COM/ECHA: to develop a proposal on how to implement the notifications of new family members in accordance with Art.17(6)

All: to comment by 1st December.

15.5 Dissemination of information related to product authorisations (including SPC)

ECHA presented the new timelines and a step-wise approach for dissemination of SPCs (CG-14-2015-23). ECHA informed that this development has been rescheduled and it will be technically possible to start with the automated dissemination of SPCs in Q3 2017. This will allow MSCAs to prepare the information and the provision of resources for the next years.

The different options for choosing the criteria for the progressive dissemination were presented (i.e. dissemination based on the date of the last update of the authorisations, dissemination based on the (initial) date of the authorisation or the date of expiry or a dissemination scheme based on a combination of the criteria above).

MSs asked for clarification on the proposed timelines for dissemination. It was clarified that the proposal considers Q3 2017 as the starting point from when the automatic

dissemination will be possible. Upon request of a CG member, it was clarified that for a product authorised under the BPD and for which no application for a change is made, the idea under option a) is that the SPC in xml format would have to be provided by the applicant at the renewal stage and will only be disseminated afterwards, once the renewal is agreed by the relevant CA.

ECHA informed the meeting that further discussion on this topic will follow at the CA meeting.

Actions

All: To inform CA representatives.

15.6 Feedback on e-consultations

Five e-consultations were presented for MSs consideration.

1) A member informed that the issue of the analytical methods for active substances in biocidal products is now under discussion at the APCP WG.

2) A member presented the summary of the contributions provided by MS on a survey regarding the presence of mosquitos vectors of diseases and products available in the national markers to control these insects. MSs thanked the member for the work and offered to submit further comments.

3) A member presented a consultation on how to deal with Article 55 of the BPR derogations via R4BP and asked for MSs inputs. The Commission reminded MSs that what is important, according to Article 55(1) of the BPR, is to inform the other MSs and the Commission without delay, including the justification for such a measure (i.e. danger to public health, animal health or the environment which cannot be contained by other means).

4) A member informed that a survey had been launch on articles treated with biocides and asked for MSs inputs. The member informed they would like to know if Competent Authorities consider some examples of products a treated article or a biocidal product.

5) A member presented an e-consultation about how to handle applications for BPF authorisations containing tinting pastes and asked for MSs inputs and how to proceed on these cases.

Actions

All:

2) to submit further comments to the CA.

3) to comment by 13 November in the Newsgroups in CIRCABC.

4) to comment by 25 November in the Newsgroups in CIRCABC.

5) to comment by 27 November in the Newsgroups in CIRCABC.

15.7 Dates for CG-15 & CG-16 meetings

The SECR informed that, for CG meeting in January, since the ES CA offered the venue, the meeting will take place in Madrid. The proposed dates are 20 January in the afternoon & 21 January morning. The invitations and provisional draft agenda will be sent the invitations by mid-December. If there is a need of an *ad-hoc* meeting of the Working Party on SPC sections for AVKs in January, it will be scheduled back to back to CG meeting.

For CG meeting in March, it was proposed to schedule the meeting on Monday, 14 March 2016, as an event organized by AISE on the professional use of disinfectants will take

place on 15 March.

16. Agreement of the action points and conclusions

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

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Part II - MAIN CONCLUSIONS & ACTION POINTS

Main conclusions and action points

(Agreed at 14th meeting of the CG)

(10 November 2015)

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
CLOSED SESSION	
2 – Agreement of the agenda for the closed session	
The agenda for the closed session was agreed after the inclusion of an agenda item under AoB on the nomination of Vice-Chair of the CG.	**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, closed session	
No declarations of conflicts of interest were made.	
4 – Draft minutes from CG-13	
No comments were received during the meeting on the CG-13 minutes. The minutes were agreed.	**SECR:** to upload the CG-13 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal and informal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The SECR informed that the overview table of the referrals discussed so far at CG level had been updated and will be available in the Disagreements folder in CIRCABC.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR	
There is no on-going informal referral.	
5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
Two formal referrals were discussed. 1) An agreement was reached by consensus and this referral is therefore closed. 2) Further discussions will follow via written procedure. On a general note, the CG agreed that the CG SECR will circulate the draft outcome of formal referrals to all MSs before the meetings.	**SECR**: 1) upload the outcome of the referral onto CG CIRCA BC and to produce an executive summary to be made publicly available. 2) To follow-up the discussion as stated in the Working Procedures **All**: 2) to provide comments by 16 November.
6 – Any Other Business	
6.1 – Late procedures	
COM presented the reports on timelines for	**All MS:** To check the information in

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
different procedures.	R4BP and where necessary, take the relevant actions.
6.2 – Harmonized RMM for DEET containing products	
The SECR informed the meeting about the status of the discussion of the technical issues by the Human Exposure Ad-hoc Working Group	**SECR:** to follow-up and report back to the CG once the feedback from HEAdhoc is received.
6.3 – Revised PNEC value for imidacloprid and impact on existing PA	
The SECR presented the background for the document. COM clarified the impact on the current and ongoing applications for PA. MSs raised some general issues but agreed on this specific document.	**SECR:** to set up a Newsgroups to accommodate general comments related to this paper. **All:** to comment by 1st December.
6.4 – How to deal at PA with reference sources with a higher purity than the minimum purity in the implementing regulation	
The SECR presented the document. Issues were raised on the suitability of the forum to discuss this issue.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 1st December.
6.5 – Feedback on e-consultations	
No closed e-consultation had taken place since the previous meeting.	
6.6 – Procedural issues and delays identified in product authorisation	
The Commission informed the meeting of the background for this document with a view to have a discussion at the CA meeting.	
6.7 – In-can preservatives in rodenticides and other PTs	
The Commission reminded MSs about their tasks.	**rMSs**: to submit the relevant information to the CG SECR.
6.8 – Data requirement of residue analysis in air for an active substance for PA	
A MS presented a document and a way forward. The CG agreed on the proposed way forward.	
6.9 – Nomination of Vice-Chair for the CG	
Since the term of the vice-Chair expires by the end of the year, members were invited to nominate themselves for the position of Vice-Chair.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to submit nomination letters by 1st December.
7 – Agreement of the action points and conclusions	
The list of action points and conclusions was agreed by the CG meeting.	
OPEN SESSION	
9 – Agreement of the agenda for the open session	
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.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
10 – Declaration of interest in relation to agenda, open session	
No declarations of conflicts of interest were made.	
11 – Draft minutes from CG-13 (non-confidential part)	
No comments were received during the meeting on the CG-13 minutes. The minutes were agreed.	**SECR:** to upload the CG-13 minutes into the relevant folders in the CG CIRCABC.
12 – Administrative issues	
12.1 Working procedures	
The SECR informed the meeting about the revision of the Working procedures regarding how to proceed when the application for PA has been withdrawn in the iCMS. Some MSs supported the possibility for other cMS to take over the disagreement. The possibility of withdrawing the referral by the iCMS as an alternative to a CG agreement was also deleted. The CG members supported the proposed changes.	**SECR:** to upload the updated and agreed version of the Working procedures onto CIRCABC.
12.2 Migration to secure CIRCABC	
ECHA informed about the foreseen date for migration to S-CIRCABC.	
12.3 – Public CIRCABC	
ECHA informed about the setup of a Public CIRCABC CG IG. CG members agreed with making the non-confidential documents available on a public CIRCABC site with a clear disclaimer that they are only drafts. Product names will be used to identify the executive summary of the formal referrals in the public CIRCABC, after confidentiality check with applicant.	**SECR**: to populate the public CIRCABC with previous CG meeting minutes and executive summary of formal referrals.
13 – Harmonisation of technical and procedural issues in relation to product authorisation	
13.1 – Evaluation of alternative dossiers during product authorisation	
ECHA presented a revision of the document. MSs and Commission asked for further clarification on specific sections. ECHA provided some clarification on the document.	**SECR:** to set up a Newsgroups in CIRCABC. **All:** to comment by 1st December.
13.2 – Note for guidance on BPF: update	
The Commission presented the revised document after the commenting period. The document was agreed by the CG meeting.	**COM:** to inform the CA meeting that the document was agreed by the CG.

13.3 – CEPE request to hold a workshop on authorisation of PT 21 products	
CEPE presented their proposal for holding a workshop on authorisation of antifouling products. MSs requested further clarification in order to identify the appropriate forum to discuss the issues proposed in the agenda. CG members expressed that further considerations shall be given to the different topics in order to find the right forum for the discussion.	**Chair/COM/CG SECR:** to make a proposal to the CG members on the way forward on where CEPE can best discuss the issues on this topic.
13.4 Paragraph 10 of annex VI to BPR and applications for changes	
The Commission presented the topic and the proposed approach. CG members agreed on the approach proposed in the document.	
13.5 Data requirements for simplified authorisation	
A MS presented the question on the data requirements for simplified authorisation. Some CG members also expressed some concerns regarding procedural aspects and supported the need to develop a PAR template and guidance documents.	**SECR:** to set up a Newsgroups in CIRCABC. **All:** to comment by 1st December.
14 – Feedback from working parties	
The SECR presented the nominated experts for the Working Party. Commission informed that IND will submit their preliminary proposal early in December.	**COM:** to forward the input from IND to the Working Party
15 – Any Other Business	
15.1 - Trends in product authorisation	
The Commission presented the reports, available for information.	
15.2 - Deadlines for application for product authorisation	
The Commission presented the reports, available for information.	
15.3 – List of substances meeting the exclusion or substitution criteria	
The SECR informed the meeting that the updated version of the list includes changes concerning some approved active substances.	**Rapporteur MSs:** to check the new information and confirm to the SECR that it is correct within 1 week. **SECR**: Once the confirmation from the rapporteur MSs is received, 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.

15.4 – Questions regarding R4BP3 / IUCLID	
ECHA updated the meeting about the IT developments and reported on the BPR IT User Group meeting. ECHA asked for some input on how to implement from an IT perspective the notifications of new family members in accordance with Art. 17(6). Further discussions on this will follow via written procedure.	**SECR:** to set up a Newsgroups in CIRCABC. **COM/ECHA:** to develop a proposal on how to implement the notifications of new family members in accordance with Art.17(6) **All:** to comment by 1st December
15.5 – Dissemination of information related to product authorisation (including SPC)	
ECHA presented new timelines and a step-wise approach for dissemination of SPCs. MSs asked for clarification on the proposed start timelines for dissemination. Further discussion will follow at the CA meeting.	**All:** to inform CA representatives
15.6 – Feedback on e-consultations	
Five e-consultations were presented. 1) A member informed that the item is now being discussed at the APCP WG. 2) A member provided a summary of the contributions from MSs on products to control mosquitos which are vectors for diseases. 3) A member presented a Newsgroup discussion on the applications for an Art. 55 derogation in R4BP3. 4) A member presented a survey regarding articles treated with biocides. 5) A member presented an e-consultation on the BPF concept and tinting pastes.	**All**: 2) to submit further comments to the CA 3) to comment by 13 November in the Newsgroups in CIRCABC. 4) to comment by 25 November in the Newsgroups in CIRCABC. 5) to comment by 27 November in the Newsgroups in CIRCABC.
15.7 – Dates for CG-15 & 16 meetings	
The SECR informed the meeting about the proposed dates for CG-15 meeting (20-21 January 2016 in Madrid) and CG-16 meeting on (14 March 2016 in Brussels).	
16 – Agreement of the action points and conclusions	
CG meeting agreed on action points and conclusions.	

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ANNEX II

10 November 2015

Final agenda
14th meeting of the Coordination Group (CG)

10 November 2015 – from 9:00 to 17:30
Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-14-2015

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-13

CG-M-13-2015_draft-confidential

For agreement

Item 5 – Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-14-2015-01

For information

5.2 Informal referrals on mutual recognition disagreements before Article 35 of the BPR

For discussion

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

Links to disagreements

For discussion

Item 6 - Any Other Business

6.1 Late procedures

CG-14-2015-02&03

For information

6.2 Harmonized RMM for DEET containing products

CG-14-2015-04

For information

6.3. Revised PNEC value for imidacloprid and impact on existing product authorisations

CG-14-2015-05

For discussion

6.4 How to deal at Product Authorisation with reference sources with a higher purity than the minimum purity in the implementing regulation

CG-14-2015-06

For discussion

6.5 Feedback on e-consultations

For information

6.6 Procedural issues and delays identified in product authorisation

CG-14-2015-07_rev1

For information

6.7 In-can preservatives in rodenticides and other PTs

For information

6.8 Data requirement of residue analysis in air for an active substance for product authorisation

CG-14-2015-08

For discussion

6.9 Nomination of Vice-Chair for the CG

For information

Item 7 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 8 – Welcome

Item 9 – Agreement of the agenda

CG-A-14-2015

For agreement

Item 10 – Declaration of interest in relation to the agenda

Item 11 –Draft minutes from CG-13

CG-M-13-2015_draft-non-confidential

For agreement

Item 12 – Administrative issues

12.1 Working procedures

CG-14-2015-09

For agreement

12.2 Migration to secure CIRCABC

For information

12.3 Public CIRCABC

CG-14-2015-10

For agreement

Item 13 – Harmonisation of technical and procedural issues in relation to product authorisation

13.1 Evaluation of alternative dossiers during product authorisation

CG-14-2015-11&12

For discussion

13.2 Note for guidance on BPF: update
(number of family members in a meta SPC)

CG-14-2015-13

For discussion and agreement

13.3 CEPE request to hold a workshop on authorisation of PT 21 products

CG-14-2015-14

For discussion

13.4 Paragraph 10 of Annex VI to BPR and applications for changes

CG-14-2015-15

For discussion

13.5 Data requirements for simplified authorisation

CG-14-2015-16

For discussion

Item 14 – Feedback from working parties

14.1 Development of standardised sentences for the SPC sections of anticoagulant rodenticides

CG-14-2015-17_rev2

For information

Item 15 – Any Other Business

15.1 Trends in product authorisation

CG-14-2015-18&19

For information

15.2 Deadlines for application for product authorisation

CG-14-2015-20

For information

15.3 List of active substances meeting the exclusion or substitution criteria

CG-14-2015-21

For information

15.4 Questions regarding R4BP3 / IUCLID

CG-14-2015-22&24

For information

15.5 Dissemination of information related to product authorisations (including SPC)

CG-14-2015-23

For discussion

15.6 Feedback on e-consultations

For information

15.7 Dates for CG-15&16 meetings (January & March 2016)

For information

Item 16 – Agreement of the action points and conclusions

For agreement

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