10 November 2015

CG-M-13-2015 FINAL PUBLIC

Final minutes of the 13th meeting of the Coordination Group (CG)

15-16 September 2015

Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the thirteen CG meeting. 32 members from 24 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and a representative from ECHA were present for the full meeting, and another representative from ECHA attended the discussion on AP 14 & 16.4. 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-13-2015) and invited any items under AOB. The agenda was agreed with the inclusion of an additional point under AOB.

The Chair remarked that two documents (CG-13-2015-15; CG-13-2015-14) for AP 7.2 and AP 7.3 were 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-12

The SECR explained that the draft confidential CG-12 minutes had been uploaded for commenting via Newsgroups. Comments had only been received from one member. No comments were received during the meeting and the CG members agreed on the revised draft minutes from CG-12.

Actions

SECR: to upload the CG-12 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. After the suggestion of a member, this overview table now includes the name of the active substance in the biocidal product. Also the wording has been changed in the column "outcome" to differentiate when a way forward has been found between the initiating cMSs and the rMS from a CG agreement.

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

Currently, there are no informal referrals going on.

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

There was only one ongoing formal referral. An agreement was reached by consensus at the CG meeting and this referral is therefore closed.

Actions

SECR: upload the outcome of the referral onto CG CIRCA BC and to produce an executive summary to be made publicly available.

6 Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/ EC (closed session)

The Commission updated the meeting for the last time on the current status of the formal actions that a rMS decided to take concerning some first authorisations subject to Article 4(4) notifications submitted under the BPD.

7 Any Other Business (closed session)

7.1 Late procedures

The Commission introduced the reports prepared by ECHA, which aim to monitor the performance of the authorisation system at EU and at MS level.

Some CG members confirmed having experienced some issues with the use of R4BP, which would affect the statistics.

Actions

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

7.2 Harmonized RMM for DEET containing products

The CG SECR informed the meeting about the outcome of the conference call with the MSs, which was made available to all CG members before the meeting. The SECR explained which technical issues were identified to be forwarded to the *ad hoc* Human Exposure Working Group. The regulatory implications of the technical discussions will be discussed at the CG and where relevant, other policy implications should be discussed at the CA meeting level.

Actions

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

7.3 Combination of a reference product and a diluted product in the Product Assessment Report

The member presented the updated document and the 2 possible options to handle the situation, the view of the applicant and their preferred option.

Members agreed that both options presented by the member are possible and the decision will be up to the applicant.

This point is now closed.

7.4 Classification of a change for a wood preservative

The member explained the background for the question.

Several members commented and explained their approach.

The Commission contested the approach that, in the absence of an ECHA opinion, any change that is not listed as an administrative or minor change in the Annex of the changes Regulation is considered as a major change. This might be disproportionate as:

- there is no legal basis to make the request for an ECHA opinion mandatory (may clause).

- this might create unnecessary work duplication both for ECHA and applicants for very similar cases.

- according Article 2(1) of the changes Regulation, only certain categories of changes are listed in the tables of the Annex (i.e. it is not an exhaustive list for minor changes).

As a general approach, the Commission suggested the following way forward to decide on the classification of changes:

- In case of doubt, applicants should request a pre-submission meeting with the CA to present his proposed classification and the grounds for it.

- Where the CA cannot agree with that classification, the applicant should ask for an ECHA opinion in accordance with Article 2 of the changes Regulation before submitting the application.

The member considered the point closed.

7.5 Feedback from e-consultations

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

7.6 Validity dates of products containing certain active substances

The Commission invited MSs to check the authorisations of products containing certain active substances being candidates for substitution that were authorised under the BPR.

Actions

All: To check their PA containing those a.s. and report back to the Commission by 9 October.

8 – Agreement of the action points and conclusions

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-13-2015) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed with the inclusion of two items under AoB:

- The members raised some points with regard to the SPC editor, which will be discussed under point 16.4.
- Developing guidance on carriers in biocidal products.

The Chair remarked that the documents for AP 14.3 (CG-13-2015-17 & 18) and 16.3 (CG-13-2015-16) 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.

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. Agreement of draft minutes (non-confidential part) from CG-12

The SECR explained that the draft non-confidential CG-12 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-12.

Actions

SECR: to upload the CG-12 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

13.1 Working procedures

The **SECR** informed the meeting about the revision of the Working procedures regarding:

- how to record CG agreements on referrals during the meeting;
- the submission of the relevant sections of the confidential CG minutes to the applicants;

- the publications of the executive summaries of CG agreements on the public CIRCABC space;
- the making available to all MSs of the document referred by the rMS to COM according to Article 36; i.e. rMS to keep the SECR in copy of that communication and SECR to upload the document in CIRCABC.
- and the changes to the November 2015 meeting schedule. The CG meeting will take place on the 10-11 November, back–to-back, to the BPR IT User Group meeting (9 Nov) and to the CA meeting (11-13 Nov).

A member commented that further details would be needed on the case when an application is withdrawn in the iCMS and 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.

Actions

SECR:

- to upload the updated and agreed version of the Working procedures onto CIRCABC;
- and to prepare a revised version for the next CG meeting.

13.2 Migration to Secure CIRCABC

The SECR informed about the migration to S-CIRCABC and how it will affect the access to the site, i.e. 2-day period with only read-only access. The SECR explained the user support that will be available once S-CIRCABC is operational. The SECR also mentioned that there is a delay in the migration.

Actions

SECR: to give an update on the migration status at the next CG meeting.

13.3 Public CIRCABC

The SECR informed about the set up of a Public CIRCABC CG IG which can be consulted without the login credentials. The executive summaries of the disagreements and the final minutes will be uploaded there.

Some members, ASOs and the Commission supported the approach of making the non-confidential documents to be discussed at CG meetings available on the public CIRCA BC site.

Some members commented that especially for documents that are not further endorsed at a CA meeting it would be very important to publish them on a public site. It was also remarked that publishing documents for discussion on a public site would be very useful but in this case, it will be necessary to upload the documents well in advance of the meetings. ASOs commented that a clear disclaimer would be needed that these documents are only drafts. It was also requested that minutes would still be published as now, i.e. not only on the public site.

As only few members commented at the meeting it was decided to open a Newsgroup discussion on this topic to see the opinion of as many members as possible.

Actions

SECR: to open a Newsgroup discussion on this topic with the proposed way forward.

All: to comment / agree by the 9 October.

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

14.1 Handling of changes to the C&L of authorised products

The Commission introduced document CG-13-2015-01, which takes into account the discussion held at the last CG meeting as well as the comments received afterwards from a CG member.

Upon request of a member, the Commission clarified that Article 4(2) of the changes Regulation allows grouping notifications (indent b) or applications (indent c), but not a mix of notifications and applications. This might also have consequences in terms of fees, as one group will be considered as one notification/application leading to a single fee.

Another member underlined the responsibility of the AH under paragraph 9 and that the position of the CAs is really dependent on what information is submitted by the applicant (e.g. as supporting documents). This member suggested following the approach in the paper and then see how it works.

A member expressed again some hesitations on whether the removal of a user category referred to in Annex I to the changes Regulation as an administrative change should only be applicable to cases where the user category is removed by the AH (e.g. for marketing purposes). The Commission views are that whatever the reason is for the removal of the user category, the main element here is that the change is implemented even if the SPC has not been updated by the CA yet.

The following changes were proposed by two CG members:

i) Adding one sentence on Article 30 of the CLP Regulation in footnote 6; and

ii) Deleting the example provided in brackets from paragraph 22.

With these changes, the document was agreed by CG members and will be referred to the 62nd CA meeting for formal endorsement.

Actions

COM:

- to update the document with the following changes:

i) adding one sentence on Article 30 of the CLP Regulation in footnote 6; and

ii) deleting the example provided in brackets from paragraph (22).

- to refer the document to the 62nd CA meeting for formal endorsement

14.2 Submission of example labels, instructions for use, safety data sheets and models or drafts of the labelling within an application for product authorisation

The Commission introduced document CG-13-2015-01, to which no comment was received during the commenting period. The Commission explained some changes

in the document resulting from the discussion held at the last CG meeting. These changes aim at avoiding some work duplication as pointed out by Industry.

In the context of BPF applications, two members referred to some possible constraints when checking the compliance of the example labels against the content of the meta-SPC until this is properly addressed in the SPC editor. The Commission referred to the work around disseminated by ECHA, where a filled-in draft SPC for the BPF in accordance with the latest agreed template has to be provided as supporting document.

Upon request of a member, the Commission also clarified the following:

- Paragraph 15 should not be read as a summary of the document, but just as the last paragraph of section 3.2 of the document.

- Paragraph 14 gives MSs the option to choose when the models or drafts are submitted (pre or post authorisation); however, where it is requested pre-authorisation, this request shall not delay the granting of the product authorisation.

The chairman noted that the document was agreed by CG members and will be referred to the 62nd CA meeting for formal endorsement.

Actions

COM: to refer the document to the 62nd CA meeting for formal endorsement.

14.3 Evaluation of alternative dossiers during product authorisation

ECHA explained at the CG meeting how the comments were addressed in the commenting table. The document from CG-11 has not been updated so it was not tabled for discussion at the meeting.

One member noticed that as their comments were included in the original document of CG-11, they are now not part of the commenting table that was worked on by ECHA. At the meeting it was clarified that the assessment of the Article 95 applications is not similar to the validation of the AS dossiers by the eCA (as it is currently written in the document under point 3.b). The validation by the eCA is completeness check and under Article 95 ECHA performs compliance check. This includes an additional step compared to the completeness check.

MSs indicated that they have further comments on this topic, therefore a commenting period will be allowed for MSs. Additional comments on the document will have to be submitted in writing.

The Commission asked how the document from CG-11 on alternative dossiers and the BPC document on new information becoming available after the approval of an AS are articulated and whether they cover together all possible cases including the possibility to modify the LoEP of an active substance based on data from an alternative dossier. ECHA replied that the coverage of all cases will be checked. The Commission also mentioned that it has to be considered in the whole discussion what to do with the existing product authorisations when this new information becomes available.

Actions

SECR: to open a Newsgroup discussion.

All: to comment by the 9 October.

ECHA: to prepare a revised version of the document for the next CG meeting.

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

The Commission briefly introduced document CG-13-2015-03, and thanked those members having contributed during the commenting period. CG members were also encouraged to agree this document at CG-13 so that the WP can be set up and start working as soon as possible.

A member and Industry requested removing footnote from page 1, while other members would be in favour of keeping it in the document. The Commission clarified that the footnote clearly mentions "where applicable", so only those agreed sentences for anticoagulant rodenticides which are also relevant for non-anticoagulant rodenticides should be used (e.g. use description, etc.). However, in order to avoid any kind of misunderstanding and taking into account that the core of the WP is to work on anticoagulants, it was agreed deleting footnote 1 and instead, record the above discussion in the minutes.

Upon request of CG members and Industry it was also agreed to include:

i) Under section 2.1, another indent referring to the recommendations in the RMM report, and

ii) Under section 2.2, a clarification that the implementation of the IT tool is out of the scope of the WP.

Finally, upon request of two members, the Commission invited those MSs having a set of harmonised sentences at national level to send (if they wish so) those sentences directly to the CEFIC contact point so that they can be considered by Industry when drafting the preliminary draft to be discussed by the WP.

With the above-mentioned changes, the chairman noted that the document was agreed by CG members. Once updated by the Commission, SECR will make the updated mandate available on CIRCABC and send an invitation by email to nominate members to the WP before the next CG meeting.

Actions

COM: to update the mandate with the agreed changes.

SECR:

- Make the updated mandate available on CIRCABC; and
- send an invitation by email to nominate members to the WP before the next CG meeting.

All:

- to nominate experts by the given deadline; and
- send the national sentences (if they wish so) directly to the CEFIC contact point

14.5 SBP authorisations and applications for MR in sequence

The Commission briefly introduced this topic as a follow-up of the discussion held at CG-12. The Commission explained that only three CG members contributed during the commenting period and that additional input from MSs would be needed before considering any further action.

Several CG members, while recognising that the MR-S of a SBP is legally possible, expressed their concern that this MR-S might lead to practical problems (e.g. lack of AR, role of the new rMS, Article 35 referrals, etc.). Most CG members considered that the provision of a LoA to each CMS does not create problems being specific for this procedure. Other members also expressed some concerns as to whether the IT tools will be able to ensure a good tracking of all the authorisations. IT wise, IND also acknowledged these concerns and expressed that the IT should be a tool and should not create barriers or constraints in the regulatory field.

In this context a member suggested that, if supported by MSs, the above-mentioned problems could be prevented by introducing a restriction in the context of the review of the SBP Regulation. The Commission briefly mentioned that the legal basis for a MR-S of a national authorisation is in the BPR and that such restriction could probably only be set by amending the BPR and not the SBP Regulation.

The CG agreed to raise this issue within the CA meeting in the context of the review of the SBP Regulation and the chairman noted that this point was closed.

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

The Commission introduced document CG-13-2015-04 underlying the main changes in the paper:

- Annexes II and III make now reference to the SPC template for BPFs already agreed.

- Annex IV includes two new Q&A pairs regarding the meta-SPC concept (14 & 15) and one Q&A on the Post-authorisation notification of new products (28).

Regarding Q&A 14, some CG members supported the proposed answer, while Industry and two members would support a case by case approach in those cases where the risk assessment is done at the family level and any possible products within a given meta-SPC are not relevant for such assessment. Industry mentioned that "empty" meta-SPCs could be suitable for products which are still under development at the product authorisation stage. In some cases, this might just involve the final adjustment of the PPDs concentration in the final product.

The Commission referred to the definition of a BPF in the BPR (i.e. a group of biocidal products), so the BPF authorisation should list all the individual products in the BPF at the authorisation stage. Therefore, the BPF authorisation shall only contain those products which are clearly identified in the application at the third information level (i.e. including the exact composition). On the other hand, the note for guidance describes the meta-SPC as the description of a group of products within the BPF having some similar properties. As a consequence, if there is no product to be grouped under a given meta-SPC of the family, there is no reason to have an "empty" meta-SPC in the BPF.

ECHA also mentioned that from a practical point of view, it could be easier for companies including within the application just one product falling within the concentration ranges of the proposed meta-SPC. This would avoid a later application for a change to create a new meta-SPC in order to accommodate the new product.

Regarding Q&A 15, some MSs commented on the wording and will send further contributions in writing.

Concerning Q&A 28 and upon request of a CG member, the Commission clarified that there should be two separate procedures under two different legal basis: first,

the change to the composition of the BPF should be agreed (in accordance with the changes Regulation) and then, the new product should be notified (in accordance with Article 17(6) of the BPR).

Due to time constraints, the chairman invited CG members and AOSs to send further contributions in writing. With a view to have the document agreed at the next CG meeting (and eventually referred to the 62nd CA meeting for endorsement), the Commission will update the document following the commenting period and SECR will launch a pre-meeting consultation on the updated version.

Actions

SECR: to open a Newsgroup discussion on Q14, 15 & 28.

All: to comment by the 9 October.

SECR: to organise a pre-meeting consultation on the updated version before the next CG meeting (in the light of agreeing on the document at the next CG meeting).

15. Feedback from working parties

No updates on the Working Parties.

16. Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the reports, which were made available for information.

Actions

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

16.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the reports, which were made available for information.

Actions

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

16.3 List of substances meeting the exclusion or substitution criteria

The Chair 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.

16.4 Questions regarding R4BP 3 / IUCLID

ECHA gave an update on R4BP 3 to the CG meeting. ECHA explained that thanks to the higher fee income than foreseen, more financial resources will be spent on IT development if the Management Board so agrees. Upcoming development is foreseen to include:

- Upgrade from IUCLID 5 to IUCLID 6;
- Introducing the metaSPC concept in the BP Family;
- Amendments of the same BP Regulation;
- Implementing processes relevant to the Review Programme Regulation;
- Changes and amendments related to Union Authorisation to be implemented in R4BP.

The priorities for next year are the adaptation to IUCLID 6 (to be released in Q2 2016), metaSPC in the BP Family, amendments of the same BP Regulation, and if possible, part of the RP Regulation and the most urgently needed missing case types for the secondary legislation.

ECHA also informed the meeting that within 1 year the xml SPC will be the basis for the dissemination of SPCs. This is planned to happen Sept-Oct next year.

IT User Group will take place on 9 November in Brussels and ECHA would like to welcome a larger number of MS and industry participants.

Several members commented on the difficulties with regard to the xml SPC requirements in relation to mutual recognition. CG members voiced their concern with regard to the dissemination of the SPCs. It is unclear to members how to complete the SPCs as this task may involve many actors and requires a significant amount of time to complete. They pointed out that for products already authorised there might not even be agreed SPCs. Some CG members expressed the view that the IT system imposes additional requirements to the legal ones, as for the older authorisations granted under the BPD there was no SPC required.

Other issues were raised such as:

- Renewal of anticoagulant rodenticide products, where MS cannot see whether they are concerned or reference MS.
- Xml SPC can only be generated and linked to the product authorisation in one language.
- SPC is not readable after printing.

The Commission considers that for MR in sequence of products authorised under the BPD, as for applications for a SBP or for changes requiring a draft SPC, it is the applicants' responsibility to propose a draft SPC reflecting the terms and conditions of the BPD authorisation. In order to close ongoing MR in sequence cases, the Commission asked whether the prerequisite to have a xml SPC for the first authorisation in the refMS could be removed. In so doing, this would contribute to populate R4BP3 with xml SPCs in the CMSs before the dissemination date.

ECHA acknowledged the difficulties and concerns of MSs, and explained that the dissemination deadline is not a hard deadline for providing the properly filled in SPCs. ECHA also explained that the IT requirements are difficult to change as the system requires some minimum information. ECHA acknowledged that the consequences of the change of the data model had not been fully identified when the decision was made in 2014.

MSs asked for identifying the minimum SPC data required by R4BP 3, if the system can't be changed. They suggested that the SPC requirements would only apply from the product renewal stage.

It was proposed that MS would submit comments within one week and ECHA would also reply to them within one week.

Actions

SECR:

- to make the presentation available on CIRCABC.
- To create a Newsgroups discussion on the CIRCABC.

All: to comment by 23 September.

ECHA: to answer by 30 September.

16.5 Feedback on e-consultations

A member presented the conclusions of an e-consultation regarding the possibility for read-across on analytical methods for active substance in biocidal product. Further consultation will take place on this topic at the relevant ECHA WG. An update will be provided at the next CG meeting.

On the 2nd e-consultation a member presented the new Newsgroup discussion on products to control mosquitos which are vectors for diseases.

Actions

1st e-consultation:

The member: to present an update at the next CG meeting.

2nd e-consultation:

All: to comment by 9 October.

17 – Agreement of the action points and conclusions

The list of action points and conclusions were agreed via written procedure after the meeting.

Actions

SECR: to set up a Newsgroups discussion on the CIRCABC.

All: to comment by 18 September, at 12:00.

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MAIN CONCLUSIONS & ACTION POINTS

Agreed after the 13th meeting of the CG

18 September 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 with the inclusion of an additional point under AOB: - asking MS for feedback on products containing certain a.s.	**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-12	
No comments were received during the meeting on the CG-12 minutes. The minutes were agreed.	**SECR:** to upload the CG-12 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 Chair presented 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 - 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	
One formal referral was discussed. An agreement was reached by consensus and this referral is therefore closed.	**SECR**: upload the outcome of the referral onto CG CIRCA BC and to produce an executive summary to be made publicly available.
6 – Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/EC (closed session)	
An update was provided by Commission on outstanding actions by a rMS on previous notifications in accordance with Article 4(4) of the BPD. This point is now closed.	

7 – Any Other Business	
7.1 – Late procedures	
COM presented the reports on timelines for different procedures. MSs reported some issues with the use of R4BP affecting the statistics.	**All MS:** To check the information in the reports, and where relevant notify the SECR of any discrepancies.
7.2 – Harmonized RMM for DEET containing products	
The SECR informed the meeting about the outcome of the phone conference held and the way forward to organize the discussion of the technical and regulatory / policy issues.	**SECR:** to follow-up and report back to the CG once the feedback from HEAdhoc is received.
7.3 – Combination of a reference product and a diluted product in the Product Assessment Report	
The member presented the updated document and the 2 possible options to handle the situation, and the view of the applicant and their preferred option. Members agreed that both options presented by the member are possible and the decision will be up to the applicant. This point is now closed.	
7.4 – Classification of a change for a wood preservative	
The member explained the background for the question. The Commission suggested a way forward on the classification of the change having a pre-submission meeting with the applicant or ask the applicant to ask for an ECHA opinion, if agreement on pre-submission meeting fails. Several members commented and explained their approach. The member considered the point closed.	
7.5 – Feedback on e-consultations	
No closed e-consultation had taken place since the previous meeting.	
7.6 – Validity dates of products containing certain active substances	
COM invited MS to check product authorisations containing certain active substances that were authorised under the BPR for longer than 5y.	**All MS:** To check their PA containing those a.s. and report back to the Commission by 9 October.
OPEN SESSION	
10 – Agreement of the agenda for the open session	
The agenda of the open session was agreed. - The members raised some points with regard to the SPC editor, which will be discussed under point 16.4. - Developing guidance on carriers in biocidal products.	**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, open session	
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-12 (non-confidential part)	
No comments were received during the meeting on the CG-12 minutes. The minutes were agreed.	**SECR:** to upload the CG-12 minutes into the relevant folders in the CG CIRCABC.
13 – Administrative issues	
13.1 Working procedures	
The SECR informed the meeting about the revision of the Working procedures regarding - how to record CG agreements on referrals during the meeting; - the submission of the CG minutes to the applicants; - the publication of the executive summaries of CG agreements on the public CIRCABC space; - SECR to upload in CIRCABC the document referred by the rMS to COM according to Art 36; - and the changes to the November 2015 meeting schedule; which were agreed by the CG members. Further amendments were suggested by a member that will be implemented in the next update.	**SECR:** - to upload the updated and agreed version of the Working procedures onto CIRCABC; - and to prepare a revised version for the next CG meeting.
13.2 Migration to secure CIRCABC	
ECHA informed about the delay of migration to S-CIRCABC and how it will effect the access to the site.	**SECR**: to give an update on the migration status at the next CG meeting.
13.3 – Public CIRCABC	
ECHA informed about the set up of a Public CIRCABC CG IG. Some members, ASOs and the Commission supported the approach of making the non-confidential documents available on a public CIRCA BC site with a clear disclaimer that they are only drafts.	**SECR**: to open a Newsgroup discussion on this topic with the proposed way forward. **All**: to comment / agree by the 9 October.
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 – Handling of changes to the C&L of authorised products	
The Commission presented a revised proposal on how administrative changes to C&L of authorised products should be handled. Further comments were made on the proposal and the document was agreed with some changes. This point is now closed.	**COM**: - to update the document with the following changes: i) adding one sentence on Article 30 of the CLP Regulation in footnote 6; and ii) deleting the example provided in brackets from paragraph (22). - to refer the document to the 62nd CA meeting for formal endorsement

14.2 – Submission of example labels, instructions for use, safety data sheets and models or drafts of the labelling within an application for product	
The Commission presented the document. Further comments were made by MSs, which were addressed by the Commission at the meeting. The document was agreed. This point is now closed.	**COM:** to refer the document to the 62nd CA meeting for formal endorsement.
14.3 – Evaluation of alternative dossiers during product authorisation	
ECHA informed the CG meeting that the comments were addressed in the commenting table. MSs indicated that they have further comments on the document; therefore, a commenting period will be allowed for MSs.	**SECR**: to open a Newsgroup discussion. **All**: to comment by the 9 October. **ECHA**: to prepare a revised version of the document for the next CG meeting.
14.4 Development of standardised sentences for the SPC sections of anticoagulant rodenticides	
The Commission presented the mandate for the Working Party (WP). Some suggestions were received from MSs. The CG meeting agreed on the document with the following amendments: - Delete footnote 1 and instead, record the discussion (some sentences can be used for non-anticoagulant rodenticides) in the minutes. - Include under 2.1 a further point on the recommendations from the RMM report. - Clarify under 2.2 that the implementation of the IT tool is out of the scope of this WP.	**COM:** to update the mandate with the agreed changes. **SECR:** - Make the updated mandate available on CIRCABC; and - send an invitation by email to nominate members to the WP before the next CG meeting. **All:** - to nominate experts by the given deadline; and - send the national sentences (if they wish so) directly to the CEFIC contact point
14.5 – SBP authorisations and applications for MR in sequence	
The Commission presented the issue and asked for the opinion of the meeting on the matter. Several MS expressed their concern about this possibility and would like to trigger a discussion on this issue in the context of the amendment of the SBP Regulation during the CA meeting. This point is now closed.	
14.6 Note for guidance on BPF: update	
COM presented the changes to the document: - Annex IV includes two new Q&As regarding the meta-SPC concept and one Q&A on the Post-authorisation notification of new products; - Annexes II and III make now reference to the SPC template for BPFs already agreed. Many members provided further comments on the new Q&A pairs and since an agreement was not reached, a commenting period will be allowed for MSs and ASOs.	**SECR**: to open a Newsgroup discussion on Q14, 15 & 28. **All**: to comment by the 9 October. **SECR**: to organise a pre-meeting consultation on the updated version before the next CG meeting (in the light of agreeing on the document at the next CG meeting).

15 – Feedback from working parties	
No updates on the Working Parties.	
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair invited the meeting to take note of the reports, which were made available for information.	**All MS:** To check the information in the reports, and where relevant notify the SECR of any discrepancies.
16.2 - Deadlines for application for product authorisation	
The Chair invited the meeting to take note of the report, which was made available for information.	**All MS:** To check the information in the reports, and where relevant notify the SECR of any discrepancies.
16.3 – List of substances meeting the exclusion or substitution criteria	
The Chair informed the meeting that the updated version of the list includes changes concerning some approved active subtances.	**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.
16.4 – Questions regarding R4BP3 / IUCLID	
ECHA informed the meeting about the IT developments. Several MSs commented on the difficulties they are facing while using R4BP in conjunction with the SPC in xml format.	**SECR:** - to make the presentation available on CIRCABC. - To create a Newsgroups discussion on the CIRCABC. **All:** to comment by 23 September. **ECHA**: to answer by 30 September.
16.5 – Feedback on e-consultations	
A member presented the conclusions of an e-consultation regarding the possibility for read-across on analytical methods for a.s. in b.p. Further consultation will take place at the relevant WG. An update will be provided at the next CG meeting. A member presented the new Newsgroup discussion on products to control mosquitos which are vectors for diseases.	**The member:** to present an update at the next CG meeting. **All**: to comment by 9 October.
16.6 – Guidance on carriers in biocidal products	
The Chair invited members to volunteer to draft the guidance on how to deal with carriers in the authorisation of biocidal products.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to consider volunteering by 9 October.
17 – Agreement of the action points and conclusions	
It was agreed that list of action points and conclusions should be agreed via written procedure after the meeting.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to comment by 18 September, at 12:00.

16 September 2015

CG-A-13-2015_rev1

Final agenda

13th meeting of the Coordination Group (CG)

15 September 2015 – from 13:00 to 18:00 - Closed session
16 September 2015 – from 9:00 to 13:00 - Open session
Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-13-2015

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-12

CG-M-12-2015_draft-confidential_with comments

For agreement

Item 5 – Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-13-2015-06

For information

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

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

Links to disagreements

For discussion

Item 6 – Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/EC

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-13-2015-09 & 10

For information

7.2 Harmonized RMM for DEET containing products

CG-13-2015-15

For information

7.3 Combination of a reference product and a diluted product in the Product Assessment Report

CG-13-2015-14

For discussion

7.4 Classification of a change for a wood preservative

Link to Newsgroup Archive

For discussion

7.5 Feedback on e-consultations

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-13-2015

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-12

CG-M-12-2015_draft-non-confidential

For agreement

Item 13 – Administrative issues

13.1 Working procedures

CG-13-2015-05

For agreement

13.2 Migration to secure CIRCABC

CG-13-2015-07 & 08

For information

13.3 Public CIRCABC

For information

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

14.1 Handling of changes to the C&L of authorised products

CG-13-2015-01

For discussion and agreement

14.2 Submission of example labels, instructions for use, safety data sheets and models or drafts of the labelling within an application for product

CG-13-2015-02

For discussion and agreement

14.3 Evaluation of alternative dossiers during product authorisation

CG-13-2015-17 & 18

For discussion

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

CG-13-2015-03

For discussion

14.5 SBP authorisations and applications for MR in sequence

For discussion

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

CG-13-2015-04

For discussion and agreement

Item 15 – Feedback from working parties

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-13-2015-11 & 12

For information

16.2 Deadlines for application for product authorisation

CG-13-2015-13

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-13-2015-16

For information

16.4 Questions regarding R4BP3 / IUCLID

CG-13-2015-19

For information

16.5 Feedback on e-consultations

For information

Item 17 – Agreement of the action points and conclusions

For agreement

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