15 September 2015

CG-M-12-2015 FINAL PUBLIC

Final minutes of the 12th meeting of the Coordination Group (CG)

07 July 2015

Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairperson welcomed participants to the twelfth CG meeting. 31 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. The list of attendees is given in Part III of the minutes.

The Chair welcomed the Serbian representative attending the Coordination Group meeting as an observer for the first time.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-12-2015) and invited any items under AOB. The agenda was agreed without changes.

The Chair remarked that version 2 of the revised agenda and the document (CG-12-2015-17) for AP 7.6 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 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-11

The SECR explained that the draft confidential CG-11 minutes had been uploaded for commenting via Newsgroups. No comment had been received on the non-confidential minutes. No comments were received during the meeting either and the CG members agreed on the revised draft minutes from CG-11.

Actions

SECR: to upload the CG-11 minutes into the relevant folders in the CG CIRCABC.

5. Formal and informal referrals to the CG

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. A comment was received to indicate in the outcome of the referral whether the agreement had been taken by consensus of the Coordination Group or as a result of an agreement between the initiating CMS and the rMS only (e.g. for informal referrals).

Actions

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

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

There are no informal referrals ongoing notified to the Coordination Group.

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

Three formal referrals were discussed and an update was provided by the relevant MSs on formal disagreements previously discussed at CG meetings.

For the first one, the composition of the biocidal product was discussed. CG members agreed that in this particular case the plastic carrier of the biocidal product should not be included as part of the biocidal product composition when considering the classification and labelling of the product. The applicant provided clarifications on questions and the CG reached an agreement by consensus on all the points of disagreement. A member offered to prepare in consultation with other MSs a first draft of a general guidance to further address the issue of carriers and product composition.

On the second formal referral, the applicant provided clarifications on questions and the CG also reached an agreement by consensus on all the points of disagreement. The identification of the substances of concern should be based on the biocidal product as placed on the market. It was also agreed that the applicant would need to submit a grouped application for the changes being a consequence of the new C&L of the product and that new leaching data would be required at the latest at the renewal of the product authorisation.

For the third formal referral, already discussed under an informal procedure, an initial discussion on the points of disagreement (exposure of children and non-target species and contamination of drinking water, food and feed) took place. The applicant attended the meeting and provided clarifications to questions by MSs. After the commenting period is expired further consultations will take place between the involved MSs to try to reach an agreement.

A member informed the meeting that on a referral discussed at CG-9, the stability tests required to the applicant had been finalized. Another rMS for a previous formal referral informed that their MSCA had uploaded to R4BP the updated PAR including the assessment of the additional data requested.

Actions

1) **First referral**
   SECR: to produce a summary of the referral and the CG agreement to be made publicly available.

   rMS: to register the CG agreement in R4BP3

2) **Second referral**
   SECR: to produce a summary of the referral and the CG agreement to be made publicly available.

   rMS: to register the CG agreement in R4BP3

3) **Third referral**
   All: to comment on the formal referral by 16 July

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 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.

The majority of CG members confirmed having experienced some issues with the use of R4BP, which would affect the statistics. The Commission mentioned that R4BP is for the time being the only available source of information and that is why it is important that the information available in the system is accurate and up to date.

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 proposed to have a conference call with the MSs which had commented on the initial document (CG-9-2015-01) in order to clarify some of the issues included in that first proposal and to identify the items that could be forwarded to the *ad hoc* Human Exposure Working Group, such as points on reduction of uncovered skin surface and avoidance of oral and inhalation exposure. The proposal was to organize the conference call by end August.

The Chair invited any other member interested in participating in the conference calls to communicate with the CG SECR in order to be informed about the next steps in the proposal.

Actions

SECR: To communicate with MSs in order to organize the conference call.

7.3 Feedback from e-consultations

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

7.4 Expiry date for authorisations of products containing an AS that is a candidate for substitution

The Commission introduced document CG-12-2015-04, which is a follow-up of the discussion that took place at the 60th CA meeting. The document contained an analysis of the relevant provisions in the BPR for this case and a way forward on how to handle the changes to wrong expiry dates via national administrative laws. The Commission also thanked those members having contributed withy written comments before the meeting.

At the end of the discussion, the Chair person concluded that the analysis and way forward presented in the document of the Commission was supported by the majority of MSs but it could not be agreed by consensus. Two MSs expressed reservations as they could not support some of the elements in the document.

Actions

Affected **rMSs**: to use the measures available to amend the product authorisations in accordance with national administrative laws as soon as possible.

Affected **CMSs**: to use the measures available to amend the product authorisations in accordance with national administrative laws and to align the expiry dates to the expiry date in the rMS.

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

Due to time constraints, the issue was not discussed at the meeting. Written comments can be submitted after the meeting.

Actions

SECR: To set up a Newsgroups discussion on CIRCABC.

All: to comment on the Newsgroups by 21 August.

7.6 Classification of a change for a wood preservative

Due to time constraints, the issue was not discussed at the meeting. Written comments can be submitted after the meeting.

Actions

SECR: To set up a Newsgroups discussion on CIRCABC.

All: to comment on the Newsgroups by 21 August.

Open session

9. Welcome to the open session

The Chair welcomed ASOs to the open session and reiterated the welcome to the Serbian CA to the Coordination Group meeting as an observer. Four observers from two 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-12-2015) 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 on the organization of CG meeting January 2016 and the communications from the rMS in accordance with Article 48(3) of the BPR.

The Chair remarked that version 2 of the revised agenda and the documents for AP 14.3 (CG-12-2015-19), 14.5 (CG-12-2015-18) and 16.6 (CG-12-2015-20) 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-11

The SECR explained that the draft non-confidential CG-11 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-11.

Actions

SECR: to upload the CG-11 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

13.1 Election of Chair and Vice-Chair

After 1.5 years as Chair of the Coordination Group, this was the last meeting chaired by the current Chair. For the election of the new Chair, a nomination letter had been received for nominating a CG member as new Chair of the CG. The CG members agreed to elect the nominee as Chair for the next period, starting with CG-13.

Regarding the vice-Chair position, since no nomination had been received, it was

proposed to have a rotating vice-Chair position, based on the EU presidency. It was mentioned that the vice-Chair position supports the Chairperson and contributes to the preparations of the meeting. For the second semester of 2015, the Luxembourgish Contact Point accepted the vice-Chair post, and was elected as vice Chair for the period of their presidency.

13.2 Secure CIRCABC

The SECR informed the meeting about the deployment of the new platform Secure CIRCABC that will host all the ECHA interest groups (IG) in CIRCABC. It was clarified that the environment of the site will be identical and the major change to the new platform is the need to authenticate via username and password as done until now plus a challenge code which will be sent to the mobile device. The login is valid per application; therefore it will be possible to work on several IGs simultaneously with one pin code.

A question was raised on the use of the same phone number for several users in the same IG. The CG SECR will double-check internally and inform the CG members accordingly.

Actions

SECR: to double check whether or not one phone number is acceptable for several users and to inform the CG members accordingly.

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

14.1 Clarifications on some SPC sections

The Commission presented an updated version of the Q&A on the listing in the SPC of filling operation sites (document CG-12-2015-09). This updated version takes into account the discussion held at the last CG meeting as well as the comments received afterwards from 4 CG members.

The proposed Q&A considers that sites where filling operations are carried out should not be listed in the SPC as manufacturing sites, but they should be notified by the authorisation holder (AH) to a CA upon request (e.g. for enforcement purposes) and be subject to the relevant requirements in Article 65(2) of the BPR.

Upon request from a member, it was clarified that the reference in the third paragraph of the answer to national legislation may affect the products placed on the market of a MS in accordance with Article 89(2) of the BPR or the BPR in those cases where a MS has such national legislation (as the BPR does not address the registration/authorisation of manufacturers, retailers, etc.).

Some members mentioned that operations other than mixing could be carried out when manufacturing the final biocidal product. The question whether dilution also was regarded as mixing was also raised.

The answer was agreed with a proposed rewording in the first paragraph in order to clarify that sites where any manufacturing processes leading to the final biocidal product (e.g. mixing or others) are carried out, except filling operations, should be listed in the SPC.

The final wording will be circulated for agreement before referring the Q&A for formal endorsement at the 61st CA meeting.

Actions

COM: to update the document according to the discussion.

SECR: to circulate the final wording for agreement before next CA meeting.

COM: when agreed by the CG, refer the Q&A for formal endorsement at the 61st CA meeting.

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

The Commission introduced document CG-12-2015-10, which takes into account the discussion held at the last CG meeting as well as the comments received afterwards from 4 CG members. The Commission briefly explained the changes introduced in the document and the reasons why some comments were not taken on board. On the lack of rMS for administrative changes, the Commission mentioned that where a MS rejects a notification, the rejecting MS has the duty to inform the other MSs where the notification has been submitted. Therefore the changes Regulation already ensures a robust degree of coordination where something is wrong.

A member expressed some concerns regarding the reference to Article 48 of the BPR in paragraph 12, which should be deleted. Otherwise, this might send a signal to AHs indicating that even if they do not apply for the required consequential changes, the CA would amend the product authorisations without submitting any data and without paying any fees. The Commission referred first to paragraph 9 in the document, which clearly mentions the responsibilities of the AH. Article 48 is only mentioned as a safety net where the AH fails to fulfil his obligations. In addition, Article 48 allows the CA to amend the product authorisation to introduce a condition to apply for the missing change within a given deadline. In so doing, the CA will receive a fee for the work to be done. The Commission was willing to include this clarification in the document (e.g. as a footnote).

On case 3 in the Annex, some MSs considered that the removal of a user category referred to in the 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) but not where it must be removed as a result of a regulatory measure, which might deserve some assessment. 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 (i.e. the user category is removed from the label of the products placed on the market from the date of the implementation of the new C&L) even if the SPC has not been updated by the CA yet. Taking into account that the Annex to the changes Regulation does not make any explicit distinction and for the sake of simplicity, the Commission would give an equal treatment in both cases so that the notification to implement the new C&L and the notification to remove the user category can be grouped. The Commission also noted that no assessment would be needed to delete a user category (in accordance with the definition of an administrative change).

Regarding case 2 in the Annex, upon request of a member the Commission clarified that this example covers cases where evidence was available in the initial risk assessment and that there might have some other situations to be addressed on a case by case basis. In addition, the notification submitted by the applicant could also clarify or refer to the relevant sections in the PAR where the information supporting his decision to not remove the non-professional user category is available. The Commission was willing to include this clarification in the document (e.g. as a footnote).

Due to time constraints and since an agreement was not reached, the Chair invited CG members and ASOs to submit further comments in writing with a view to present an updated version of the paper at the next CG meeting in September.

Actions

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

All: to comment by 21 August.

14.3 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-12-2015-11, to which supportive comments were received from one member during the commenting period. The Commission also thanked IND representatives for their comments, which would need some additional discussions with MSs.

A few members commented on paragraph 14, suggesting that the current practice should be maintained, particularly when the models or drafts are requested before the procedure is closed. The Commission clarified that the current wording is open to one option or the other, and clarified that in any case the request should not affect the authorisation decision within the legal deadlines. A member also pointed out that where a label is not submitted in due time or it is not in accordance with the agreed SPC, enforcement activities could also play a role.

A discussion took place regarding the comments submitted by IND on paragraph 12:

- 12(a): The Commission explained that the example label of one individual product could be acceptable if all the intended uses in the meta-SPC are mentioned, in line with the spirit in Article 69(2)(g) of the BPR. A member suggested that this approach, if agreed, should also be applicable to applications for single biocidal products.

-12(b): As explained in paragraph 6 of the document, the information available in the draft SPC does not replace what is required in Annex III. These instructions as they will be reflected in the labels, leaflets, etc., while being in accordance with those in the SPC, might be formulated in a different manner that is more meaningful and comprehensible to the final user.

IND representatives mentioned that taking into account that this information is supplied in the draft SPC, the submission of the document referred to in this paragraph would create extra workload and work duplication. The ASO mentioned that they foresee to have the same wording in the SPC and on the label, and that submitting a draft label and use instruction for all uses would be a duplication of work. A member expressed some sympathy with these views, as the AH has in any case the responsibility to label the product in accordance with the SPC.

The Commission responded that the requirement in Annex III regarding these instructions for use are already mandatory in addition to the draft SPC, and that the current proposal for BPF applications just wants to reduce workload by submitting in the application dossier just one single document per meta-SPC instead of multiple documents (i.e. one for each individual product in the family).

-12(c): The Commission also pointed out that, to be acceptable, the SDS of one individual product should also contain the relevant information for all the intended uses in the meta-SPC.

A member mentioned that paragraph 12 should remain as it is and that paragraph 15 should also refer to paragraph 12.

Due to time constraints and since an agreement was not reached, the Chair invited CG members and ASOs to submit further comments in writing with a view to present an updated version of the paper at the next CG meeting in September.

Actions

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

All: to comment by 21 of August.

14.4 Proposal for a harmonized labelling of (anticoagulant) rodenticides

The Commission introduced this agenda item. As a follow-up of the discussion held at the last CG meeting, and taking into account:

- The overall support from MSs to have this sentence in the SPC and then on the label,

- Some concerns expressed by a CG member and the Commission in terms of to what extent the implementation of such proposal might affect first authorisations already granted which will be subject to MR in sequence, and

- That the CG will produce a set of harmonized phrases for the different sections of the SPC of AVKs to be implemented at the renewal stage,

The Commission proposed the following two-step approach:

1. As a transitional, short-term measure until the renewal process is finished and in order to avoid conflicts with those MSs having not applied the phrase in first authorisations, it is proposed to address this issue through Article 37 of the BPR. In fact, the sentence is more linked to the general properties of the AVKs than to a specific risk in one individual product. Commission decisions approving restrictions of products to professionals referred to the inclusion directives, which oblige MSs to ensure, when granting product authorisations, that primary as well as secondary exposure of humans, non-target animals and the environment is minimised, by considering and applying all appropriate and available risk mitigation measures. This reasoning could be applied by analogy here and some MSs might consider this phrase as an additional RMM to protect wildlife, even if it was not considered essential by the rMS because there is another instruction or recommendation aiming at the same purpose.

Therefore, those MSs wanting to introduce this sentence (or another similar as mentioned by a CG member during the commenting period) could do so on the grounds of Art. 37(1)(a) or (c), and where the applicant so agrees, there is no issue with the rMS. Those MSs could also apply the sentence to purely national authorisations or SBP authorisations.

For MR in parallel, all the MSs should in principle apply the sentence. However, the approach under Article 37 would also solve some cases where the rMS would still not propose this sentence in the SPC (e.g. for consistency with other national authorisations granted beforehand).

2.- In the mid-long term, to harmonise the standard sentences in the SPC sections for anticoagulant rodenticides, so that a more harmonised labelling is achieved after the renewals (see agenda item 14.5).

The above-mentioned proposal was agreed by the CG members.

Actions

COM/SECR: to properly reflect the agreed way forward in the draft minutes of the meeting.

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

The Commission briefly introduced this agenda item through a presentation (see document CG-12-2015-18), underlining the main points for discussion in the last slide. The Commission would be in favour of the contribution and participation in the project of IND, taking into account their knowledge of the products and the different practice in MSs. The Commission also informed the meeting that the rodenticides WP of Cefic would be willing to prepare a proposal to be discussed in the CG working party (WP).

A member informed the meeting that they are working in a project at national level including a labelling working group aiming at similar objectives and also involving IND. The first meetings of that working group will be held in August with a view to conclude by March 2016.

A few members referred to other similar national initiatives carried out in the past, which could be useful to consider, particularly when it comes to the national specificities (e.g. professionals vs. trained professionals, etc.).

CG members also supported a wide membership in the WP and an efficient work organisation at WP level, which should report back to the CG.

The CG agreed to create an ad hoc Working Party, including MSs and ASOs.

All participants were invited to submit suggestions for the mandate, objectives and functioning of the WP before the next CG meeting. A proposal for the mandate, objectives and functioning of the WP will be discussed at CG-13.

Actions

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

To check with the ECHA IT team the implementation into a future revision of the SPC editor.

All: to comment on the Newsgroups by 21 August.

To provide information on previous and ongoing projects at MS level on this issue and any proposals on the set up of the Working Party.

SECR/COM: to prepare a proposal for the mandate, objectives and functioning of the Working Party taking into account the input provided during the commenting period.

14.6 SBP authorisations and applications for MR in sequence

The Commission introduced this topic by referring to a question sent by IND to a CA, which suggested having a discussion at EU level (CG or CA meeting).

The Commission explained that:

- A SBP authorisation is an independent national authorisation, which can be subject to MR-S in accordance with Article 33 of the BPR.

- ECHA colleagues have confirmed that this procedure is supported in the R4BP3. SBP cases result in a NA asset and as such MRS cases can be started if the AH so

wishes. Every asset still got the source case linked to it. Hence, the CA user can find the original national authorisation and all documents that are part of the asset.

The Commission also pointed out some other operational elements which might deserve some consideration by MSs:

- Whether, from a practical point of view, the MR should be done at the reference product level rather than at the SBP level.

- Any MSs might become rMS for a MR-S procedure of a SBP, while this rMS has not assessed the dossier of the relevant reference product.

CG members and ASOs were invited to submit comments with a view to discuss this topic at CG-13.

Actions

COM: to properly describe the issue in the draft minutes of the meeting.

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

All: to comment on the Newsgroups by 21 August.

15. Feedback from working parties

No update from the last meeting.

16. Any other business (open session)

16.1 Trends in PA

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 PA

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 three 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 Products under the simplified procedure according to Article 25 BPR

A member presented a proposal for removing several active substances from Annex I to the BPR since the classification of the substance is triggering some issues during the assessment of products. The products in question can only be authorised with PPE due to the classification triggered by the active substance, and therefore these products are not eligible for the simplified procedure.

The Commission briefly explained the relevant provisions in the BPR to remove substances from Annex I (i.e. Article 28(3) of the BPR). This proposal was supported by some CG members. Taking into account the possible policy implications, it was agreed that the member would refer the topic to the CA meeting for further discussion. The document for the CA meeting could also refer to the discussion held at the CG meeting.

Actions

The member: to bring this issue for discussion at a CA meeting.

16.5 Questions regarding R4BP/IUCLID

The Chair briefly informed the meeting about the release of version 3.3 of R4BP and the multilingual version of the SPC editor. The SECR will distribute further technical details about these tools to the CG members and ASOs via email.

Actions

All: To provide via email to the CG members and ASOs with further information about the new features of the updated versions of R4BP and the SPC editor.

16.6 Feedback on e-consultations

A member provided a conclusion of the outcome of the e-consultation on "Analytical methods for AS in BP" supporting the possibility to read-across the validation of analytical methods. Some additions were made to the proposed conclusion and it was agreed allowing further comments via written procedure to the conclusion.

Actions

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

All: to comment on the Newsgroups by 21 August.

16.7 CG meeting in January 2016

The Spanish CA offered to host the CG meeting in January 2016 in their MSCA facilities during 3rd week of January 2016, which was welcomed and agreed by the CG meeting.

Actions

The member and SECR: to coordinate for the organisation of the meeting and invite MSs and ASOs accordingly.

16.8 Communications in regard to Article 48(3)

The Commission informed that further instructions will be submitted to CAs for the implementation via R4BP of the requirement in Article 48(3) to notify cancellations or amendments of authorisations to the authorisation holder, the competent authorities of other Member States and, where relevant, to the Commission.

Actions

SECR: to provide the CG members with further instructions about the use of R4BP for recording cancellations or amendments of authorisations.

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MAIN CONCLUSIONS & ACTION POINTS

Agreed after the 12th meeting of the CG

07 July 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.	**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 – Agreement of draft minutes (confidential part) from CG-11	
No comments were received during the meeting on the CG-11 minutes. The minutes were agreed.	**SECR:** to upload the CG-11 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal and informal referrals to the CG	
5.1 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR	
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 are no informal referral on-going.	
5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
Three formal referrals were discussed. 1) The applicant attended the meeting and provided answers to the questions by MSs. An agreement was reached on all the points of disagreement. 2) The applicant attended the meeting and provided answers to the questions by MSs. An agreement was reached on all the points of disagreement. 3) The applicant attended the meeting and provided answers to the questions by MSs. After the commenting period is expired further consultations will take place between the involved MSs to try to reach an agreement. An update was provided on two previous formal referrals.	On the 1st and 2nd formal referrals: **SECR:** to produce a summary of the referral and the CG agreement to be made publicly available. **rMS:** to register the CG agreement in R4BP3 On the 3rd formal referral: **All:** to comment on the formal referral by 16th July.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
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.	
7 – AOB	
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 and some subsequent procedures (e.g. renewals).	**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 proposed to organize a conference call by end August, to first clarify the issues and decide whether some of the items could be forwarded to the Human Exposure WG.	**SECR:** To communicate with MSs in order to organize the conference call.
7.3 – Feedback on e-consultations	
No closed e-consultation had taken place since the previous meeting.	
7.4 – Expiry dates of authorisation for products containing a.s. candidates for substitution	
The Commission presented an analysis of the legislation and a way forward for the handling of changes to wrong expiry dates via national administrative laws. The above-mentioned analysis and way forward was supported by the majority of MSs and two MSs expressed reservations as they could not support some elements in the document.	Affected **rMSs**: to use the measures available to amend the product authorisations in accordance with national administrative laws as soon as possible. Affected **CMSs**: to use the measures available to amend the product authorisations in accordance with national administrative laws and to align the expiry dates to the expiry date in the rMS.
7.5 – Combination of a reference product and a diluted product in the Product Assessment Report	
The issue was not discussed at the meeting. Written comments can be submitted after the meeting.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to comment on the Newsgroups by 21 August.
7.6 – Classification of a change for a wood preservative	
The issue was not discussed at the meeting. Written comments can be submitted after the meeting.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to comment on the Newsgroups by 21 August.
8.1 – Agreement of the action points and conclusions	
It was decided that list of action points and conclusions should be agreed via written	**SECR:** to set up a Newsgroups discussion on the CIRCABC.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
procedure after the meeting.	**All:** to comment on the Newsgroups by 10 July at 12:00.
OPEN SESSION	
10 – Agreement of the agenda for the open session	
The agenda of the open session was agreed with the inclusion of two items: - CG meeting January 2016. - Communications from the rMS in accordance with Article 48(3) of the BPR.	**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 – Agreement of draft minutes (non-confidential part) from CG-11	
No comments were received during the meeting on the CG-11 minutes. The minutes were agreed.	**SECR:** to upload the CG-11 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
13.1 – Election of Chair and Vice-Chair	
The nominee for the Chair position was elected as Chair. Since there were no candidates for the vice-Chair position, it was agreed that the Vice-Chair will be rotating according to the EU presidency, at least for the first half year starting with Luxemburg.	
13.2 – Secure CIRCABC	
ECHA informed about the migration to S-CIRCABC and the changes in the authentication process.	**SECR**: to double check whether or not one phone number is acceptable for several users and to inform the CG members accordingly.
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 – Clarifications on some SPC sections	
The Commission presented the revised version of the Q&A considering that sites where filling operations are carried out should not be listed in the SPC as manufacturing sites. The content of the answer was agreed with a proposed rewording to clarify that sites where any manufacturing processes leading to the final biocidal product (i.e. mixing or others) are carried out, except filling operations, should be listed in the SPC. The final wording will be circulated for agreement before referring the Q&A for formal endorsement at the 61st CA meeting.	**COM**: to update the document according to the discussion. **SECR**: to circulate the final wording for agreement before next CA meeting. **COM**: when agreed by the CG, refer the Q&A for formal endorsement at the 61st CA meeting.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
14.2 – Handling of changes to the C&L of authorised products	
The Commission presented a revised proposal on how administrative changes to C&L and any consequential changes to the new classification should be handled. Further comments were made on the proposal and since an agreement was not reached, a commenting period will be allowed for MSs.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to comment on the Newsgroups by 21 August.
14.3 – 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 presented the document and asked for the MSs views on the comments presented by IND. Further comments were made by MSs and IND and since an agreement was not reached, a commenting period will be allowed for MSs.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to comment on the Newsgroups by 21 August.
14.4 – Proposal for a harmonized labelling of (anticoagulant) rodenticides	
The Commission proposed a two-step approach consisting on: - As a transitional measure, to make use of the provisions in Article 37 of the BPR to derogate from MR and - in the mid-long term, to harmonise the standard sentences in the SPC sections, so that a more harmonised labelling is achieved after the renewals. The proposal was agreed by the CG members.	**COM/SECR:** to properly reflect the agreed way forward in the draft minutes of the meeting.
14.5 – Development of standardised sentences for the SPC sections of anticoagulant rodenticides	
The Commission presented a proposal for the development of standardised sentences for the SPC sections of anticoagulant rodenticides. The CG agreed to create an ad hoc Working Party, including MSs and ASOs. All participants were invited to submit comments on the mandate, objectives and functioning of the WP before the next CG meeting. A proposal for the mandate, objectives and functioning of the WP will be discussed at CG-13.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. To check with the ECHA IT team the implementation into a future revision of the SPC editor. **All:** to comment on the Newsgroups by 21 August. To provide information on previous and ongoing projects at MS level on this issue and any proposals on the set up of the Working Party. **SECR/COM**: to prepare a proposal for the mandate, objectives and functioning of the Working Party taking into account the input provided during the commenting period.
14.6 – SBP authorisations and applications for MR in sequence	
The Commission presented the issue and asked MSs to submit comments via written procedure.	**COM:** to properly describe the issue in the draft minutes of the meeting. **SECR:** to set up a Newsgroups discussion

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	on the CIRCABC. **All:** to comment on the Newsgroups by 21 August.
15 – Feedback from working parties	
No updates on the Working Parties.	
16 – AOB	
16.1 - Trends in PA	
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 PA	
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 three approved a.s.	**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 – Products under the simplified procedure according to Article 25 BPR	
A member presented a proposal for removing several a.s. from Annex I of the BPR. The COM briefly explained the relevant provisions in the BPR to do so (Article 28(3)). Some CG members supported the proposal but on account of the possible policy implications, it was agreed to refer the topic to the CA meeting for further discussion.	**The Member:** to bring this issue for discussion at a CA meeting.
16.5 – Questions regarding R4BP3 / IUCLID	
The Chair briefly informed the meeting about the latest updates to R4BP and SPC editor. The SECR will distribute further technical details about these tools to the CG members and ASOs via email.	**SECR**: To provide via email to the CG members and ASOs with further information about the new features of the updated versions of R4BP and the SPC editor.
16.6 – 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. Some additions were made to the proposed conclusion and it was agreed allowing further	**SECR:** to set up a Newsgroups discussion on the CIRCABC with the reworded version. **All:** to comment on the Newsgroups by 21 August.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
comments via written procedure to the conclusion.	
16.7 – CG meeting in January 2016	
The ES CA offered to host the CG meeting in January 2016 in their MSCA facilities during 3rd week of January 2016, which was agreed by the CG meeting.	**The member and SECR:** to coordinate for the organisation of the meeting and invite MSs and ASOs accordingly.
16.8 – Communications in regard to Article 48(3)	
The Commission informed that further instructions will be submitted to CAs for the implementation via R4BP of Article 48(3) requirement to notify cancellations or amendments of authorisations.	**SECR:** to provide the CG members with further instructions about the use of R4BP for recording cancellations or amendments of authorisations.
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 on the Newsgroups by 10 July at 12:00.

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7 July 2015

CG-A-12-2015

Final agenda

12th meeting of the Coordination Group (CG)

07 July 2015

CLOSED SESSION

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

CG-A-12-2015

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-11

CG-M-11-2015_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-12-2015-01

For information

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

For information and discussion

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

Link 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-12-2015-02 & 03

For information

7.2 Harmonized RMM for DEET containing products

For information

7.3 Feedback on e-consultations

For information

7.4 Expiry dates of authorisation for products containing a.s. candidates for substitution

CG-12-2015-04

For discussion

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

CG-12-2015-05

For discussion

7.6 Classification of a change for a wood preservative

CG-12-2015-17

For discussion

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome and apologies

Item 10 – Agreement of the agenda

CG-A-12-2015

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-11

CG-M-11-2015_draft-non-confidential

For agreement

Item 13 – Administrative issues

13.1 Election of Chair and vice-Chair

CG-12-2015-06

For agreement

13.2 Secure CIRCABC

CG-12-2015-07 & 08

For information

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

14.7 Clarifications on some SPC sections

CG-12-2015-09

For discussion and agreement

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

CG-12-2015-10

For discussion and agreement

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

CG-12-2015-11&19

For discussion and agreement

14.10 Proposal for a harmonized labelling of (anticoagulant) rodenticides

For discussion

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

CG-12-2015-18

For discussion

14.12 SBP authorisations and applications for MR in sequence

For discussion

Item 15 – Feedback from working parties

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-12-2015-12 & 13

For information

16.2 Deadlines for application for product authorisation

CG-12-2015-14

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-12-2015-16

For information

16.4 Products under the simplified procedure according to Article 25 of the BPR

CG-12-2015-15

For discussion

16.5 Questions regarding R4BP3 / IUCLID

For information

16.6 Feedback on e-consultations

CG-12-2015-20

For information

16.7 CG meeting in January 2016

For information

16.8 Communications in regard to Article 48(3)

For information

Item 17 – Agreement of the action points and conclusions

For agreement

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