11 July 2017

CG-M-23-2017 non-confidential

Final non-confidential minutes of the 23d meeting of the Coordination Group (CG)

10 May 2017

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed the participants to the twenty third CG meeting. 33 members from 24 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and two representatives from ECHA were present for the full meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-23-2017) and informed the meeting that, due to the large number of items for discussion and the limited available time, priority would be given to the discussion of referrals and three items of the open session (agenda points 13.1, 14.2 and 15.1). An agenda point was added to the AOB of the closed session concerning the reports from MSs on the authorisation of creosote containing products. The agenda was agreed with this modification.

The list of meeting documents and the final agenda are included in Part IV of the minutes.

Actions:

SECR: to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.

3. Declaration of interest in relation to the agenda

The Chair invited the representatives of the MSCAs (referred to hereafter as 'members') to declare any potential conflict of interests. There were no potential conflicts declared.

4. The draft minutes from CG-22

The Chair explained that the draft confidential CG-22 minutes had been uploaded for commenting via Newsgroups and that comments were received from a CG member. The minutes were updated with these comments and the CG members agreed on the updated confidential draft minutes from the CG-22.

Actions

SECR: to upload the CG-22 minutes into the relevant folders in the CG CIRCABC.

5. Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

The Chair presented the overview table of the referrals discussed so far at CG level. This overview is as well uploaded to the Disagreements folder in S-CIRCABC.

Actions

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

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

The Chair informed that no informal referrals had been notified, so there was no informal referral for discussion.

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

The Chair informed that one formal referral had been closed by written procedure during the discussions that took place after the CG-22 meeting via teleconference. An agreement by consensus was reached by the CG members on the conditions for the authorisation of this product.

The Chair invited the SECR to explain a proposal for the organisation of the teleconferences to discuss referrals in between CG meetings. The SECR proposed to have a fixed time slot every two weeks. The CG members agreed on the proposal and fixed the time slot on Wednesday morning every two weeks.

Eight formal referrals were discussed during the meeting and three formal referrals submitted on 3rd, 4th and 5th of May respectively were briefly introduced.

1) A formal referral concerning a PT8 product was discussed. The validity of efficacy data and use of a dermal absorption value were discussed in a teleconference prior to the meeting. The outcome of the referral which was acceptable for both icMS and rMS was presented during the meeting. A clarification will be added to the PAR on the validity of the efficacy data. The dermal absorption value used in the risk assessment is acceptable given the date at which the application for authorisation was submitted. The CG members agreed on the outcome by consensus.

It was concluded that the product meets the condition for granting an authorisation in Article 19(1) of the BPR.

2) A formal referral concerning a PT18 product was discussed. The referral concerned a general issue on the inclusion of the active substance concentration in the SPC. A way forward was presented encompassing a short term solution and as a long term solution to forward the matter to the CA meeting. The CG members will decide in writing after the meeting.

3) A formal referral concerning a PT18 product was discussed. The referral was about whether the data confirmed efficacy against all claimed organisms in all use patterns. The CG members agreed to take some additional data as provided by the applicant into consideration before deciding on the outcome of the referral.

4) A formal referral concerning a PT18 product was discussed. The referral was about whether the data confirmed efficacy against all claimed organisms in all use patterns. For a part the CG members agreed to proceed as for the previous referral. For other open points a teleconference will be scheduled.

5), 6) Two formal referrals were discussed concerning PT 19 products which had a common point of disagreement. The two referrals were treated as one issue. In the previous CG meeting and during a teleconference these referrals were already discussed, but no consensus could be found during those discussions. During the meeting the matter was further discussed with the intention to find a way forward for these specific products.

No agreement was reached by the CG members for the resolution of the referrals. The two cases will be referred to the Commission.

7) A formal referral concerning a PT8 product was discussed. The icMS and rMS had agreed on a way forward on the need to perform a mixture toxicity assessment during a teleconference prior to the meeting. The PAR and SPC had already been updated accordingly at the time of the meeting.

It was concluded that the product meets the condition for granting an authorisation according to Article 19(1)(b)(iv) of the BPR.

8) A formal referral concerning a PT18 product was discussed. Shortly before the meeting additional data regarding shelf life had become available. The rMS and icMS agreed that these data provided sufficient evidence for the claimed shelf life.

9) A formal referral concerning a PT 18 product was briefly introduced. The icMSs explained the major points of disagreement which related to the efficacy of the product, determination of safe uses, packaging sizes, dermal absorption and preventing resistance of the product. The referral will be discussed by teleconference and during the CG-24 meeting.

10) A formal referral concerning a PT 18 product was briefly introduced. The icMSs explained the major points of disagreement which related to the efficacy of the product and instructions of use. The referral will be discussed by teleconference and during the CG-24 meeting.

11) A formal referral concerning a PT 18 product was briefly introduced. The icMSs explained the major points of disagreement which related to the packaging sizes of the product. The referral will be discussed by teleconference and during the CG-24 meeting.

Actions

1) SECR: to follow-up the outcome of the referral as stated in the Working Procedures.

2) SECR: to upload the draft outcome in the newsgroups in S-CIRCABC.

2) All: To review the draft outcome and comment in case of disagreement by 12/05/2017 (17:00 pm CET).

2) SECR: In case of agreement, to follow-up the outcome of the referral as stated in the Working Procedures.

3) SECR: to prepare and upload the draft outcome in the newsgroups in S-CIRCABC.

3) All: To review the draft outcome and comment in case of disagreement.

3) SECR: In case of agreement, to follow-up the outcome of the referral as stated in the Working Procedures.

4) SECR: to schedule a teleconference for discussion of the referral.

5-6) rMS: to refer to COM (SECR in cc) the open point from these referrals following the provisions in Article 36 of the BPR.

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

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

8) SECR: to prepare and upload the draft outcome in the newsgroups in S-CIRCABC.

8) All: To review the draft outcome and comment in case of disagreement.

8) SECR: In case of agreement, to follow-up the outcome of the referral as stated in the Working Procedures.

9) All: To provide comments by 25 May 2017 on the referral.

9) SECR: to schedule a teleconference for discussion of the referral.

10) All: To provide comments by 29 May 2017 on the referral.

10) SECR: to schedule a teleconference for discussion of the referral.

11) All: To provide comments by 29 May 2017 on the referral.

11) SECR: to schedule a teleconference for discussion of the referral.

6. Harmonisation of technical and regulatory issues in relation to product authorisation

6.1 Issues identified in the context of UA

Due to time constraints this point was not presented.

Actions

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

6.2 Iodate used as stabiliser

Due to time constraints this point will be discussed during the CG-24 meeting.

Actions

SECR: To table the topic for discussion for the CG-24 meeting.

6.3 Practical considerations for the renewal of PT8 products

Due to time constraints this point will be discussed during the CG-24 meeting.

Actions

SECR: To table the topic for discussion for the CG-24 meeting.

6.4 Validity of the product authorisations for spinosad and borates-containing products

Due to time constraints this point will be presented during the CG-24 meeting.

Actions

SECR: To table the topic for information for the CG-24 meeting.

7. Any Other Business (closed session)

7.1 Late procedures

Due to time constraints this point will be presented during the CG-24 meeting.

Actions

SECR: To produce a revised document for the CG-24 meeting.

7.2. Feedback on e-consultations

Due to time constraints this point will be discussed during the CG-24 meeting.

The e-consultation on the "BPF concept and formulation types" will be further discussed within the working party that will be set up for issues related to the Biocidal product family concept.

Actions

SECR: To table the topic for discussion for the CG-24 meeting.

7.3 Update on the pilot testing of the SoP of MR

Due to time constraints this point will be discussed during the CG-24 meeting.

Actions

SECR: To table the topic for discussion for the CG-24 meeting.

7.4 Harmonisation of the assessment of insect repellents PT19

Due to time constraints this point will be discussed during the CG-24 meeting.

Actions

SECR: To table the topic for discussion for the CG-24 meeting.

7.5 Consultation on dietary risk assessment for PT 19 products

Due to time constraints this point will be discussed during the CG-24 meeting.

Actions

SECR: To table the topic for discussion for the CG-24 meeting.

7.6 Election of the Chair of the CG

The CG representative from Greece was elected as the Chair of the CG.

A call for candidates for the position of vice Chair will be initiated.

Actions

SECR: To initiate the call for candidates for the vice Chair position.

7.7 Reports from MSs on the authorisation of creosote containing products

The Commission reminded those MSs having authorised creosote containing products about the submission of the reports required in the inclusion Directive.

Actions

All: To check back home and where relevant, send the report to COM as soon as possible.

8 – Agreement of the action points and conclusions

The list of action points and conclusions for the closed session will be agreed by written procedure.

Actions

SECR: To circulate the list of action points and conclusions for agreement ASAP after the meeting.
All: to send comments by 19 May.

Open session

9. Welcome to the open session

The Chair welcomed ASOs to the open session. Six 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-23-2017). The chair informed that due to the large number of items for discussion and the limited available time, any additional items would be tabled for discussion for the next CG meeting. The agenda was agreed.

Actions

SECR: to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.

11. Declaration of interest in relation to the agenda, open session

The Chair invited the members to declare any potential conflict of interests. There were no potential conflicts declared.

12. Draft minutes (non-confidential part) from CG-22

The Chair explained that the draft non-confidential CG-22 minutes were uploaded for commenting via Newsgroups. A few minor comments were received prior to the meeting upon which the draft minutes were updated. The draft CG-22 minutes were agreed.

Actions

SECR: to upload the CG-22 minutes into the relevant folders in the CG CIRCA BC.

13. Administrative issues

13.1 Update of the "Working procedures for resolving disagreements"

The SECR presented the updated document of the "Working procedures for resolving disagreements" (CG-23-2017-10). The document was updated taking into consideration the experience gained so far in the process of mutual recognition. The main changes in the document were related to the following points:

- The preferred submission window concept has been removed in order to align with the submission deadline of 10 days after the 90 day period of the mutual recognition procedure.
- The procedure related to informal exchange of information mentioned in Step 1 has been simplified. On this point, it was questioned whether informal referrals should be still considered in the procedure.
- Additional points added to the referral should be considered as a referral and follow the same timelines as those defined for the initial referral, that is, communication of the referral to the SECR before the expiration of the 90 day period of the mutual recognition phase, and submission of the documentation 10 days after at the latest.
- Only points of disagreement raised by the icMS(s) during the first 60 days of the 90-day period of the mutual recognition phase would be accepted.
- An additional step has been added concerning the acceptance of the referral.

The following comments were received to be incorporated in the procedure:

- The Commission proposed to restructure Steps 2 and 3 into three steps: submission of the referral by the icMS, acceptance and distribution of documents.
- The involvement of the applicant in the preparatory phase (Step 5) should be optional since there are occasions were the disagreement is of a regulatory nature where the applicant is not required to give an opinion.
- Disagreements on the new aspects introduced in the updated PAR or SPC arising after the first 60 day commenting period of the mutual recognition phase should be accepted.
- A deadline for acceptance of referrals should be added in Step 3.
- All MSs should be invited to participate in the preparatory teleconferences.
- The referral document should have as reference the product name as mentioned in R4BP3 in the rMS.

The SECR clarified that the referral template should be used for all referrals submitted on the same product. In the case of MR-S procedures, the possibility of combining all referrals would need to be evaluated on a case by case basis.

A CG member mentioned that it would be useful to have the outcomes with a reference number in order to easily make reference to these documents. The Chair suggested to include a number in the overview of the referrals that is distributed for the CG meeting. All cMSs that have raised points of disagreement in the referrals will be listed in the overview table.

A newsgroup will be opened with an updated version of the working procedure taking in consideration the comments received. The document will be agreed by written procedure.

Actions

SECR: To update the Working Procedure document and open a newsgroup for comments and agreement on the updated version.

All: To comment or agree on the newsgroup in 3 weeks after the upload of the revised document.

SECR: If agreed, to upload the new version on S- CIRCABC.

13.2 Working procedure for the linguistic review of the SPC translations in UA

The SECR presented a revised version of the working procedure for the linguistic review of the SPC translations in UA with the agreements reached during the CG-23 meeting (CG-23-2017-01). A paragraph in the document is still under discussion related to the provisions for Icelandic and Norwegian.

The CG members agreed that, where relevant, in cases where more than one MS share the same language, there will be a cooperative approach among the MSs to ensure that the translation is acceptable in all MSs sharing the language. A footnote will be added to the document to clarify this aspect.

The CG members agreed on the document, excluding the paragraph concerning the provisions for Norwegian and Icelandic. This paragraph will be amended once the legal provisions with Norwegian and Icelandic are clarified. A footnote will be added mentioning that, where relevant, MSs sharing the same language should have a collaborative approach.

Actions

SECR and NO: To agree on the provisions for NO and IS.

SECR: To add a footnote and amend the paragraph related to NO and IS once agreement is reached.

13.3 RoP update related to declaration of confidentiality forms

The SECR presented a revised version of the document "Rules of procedure for the Coordination Group (CG) under Regulation EU n°528/2012" (RoP) of the CG" (CG-23-2017-05). The changes introduced were related to an update of the confidentiality form in the Annex of the document. The CG members agreed on the document.

Actions

SECR: To upload the amended RoP in the relevant CIRCABC space.

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

14.1 Template to summarise the biocidal product family structure

The Chair explained that the template to describe the biocidal product family had already been agreed upon during the CG-21 meeting. The topic for discussion was to decide where the document should be made available.

The CG members agreed that the applicant should include the document in the application for a product authorisation in IUCLID (Section 13) and in R4BP 3 as a supporting document. The document will be available from the ECHA website.

Actions

SECR: To publish the form in the ECHA website

14.2 Renewal of anticoagulant rodenticides: AR to be used in the renewal procedure and possible consolidation of the initial PAR

The Commission introduced this topic by referring to the e-mail sent to CG members and ASOs after CG-23. In this respect, it also proposed to split the discussion on two topics:

1.- How to draft the assessemt report (AR) for the renewal procedure, including the use of a template proposed by a CG member before the meeting (see document CG-23-2017-16), and

2.- Whether or not a fully consolidated PAR should be produced after the renewal (and by whom) with a view to its dissemination through ECHA's website in the future.

On the first discussion point, CG members agreed to use the assessment report template proposed by a CG member in order to reflect the assessment of the applications for renewal of anticoagulant rodenticides. This template will be completed by the refMSs, with no requirement to applicants to submit a draft AR with the agreed template.

Regarding the second discussion point, three CG member indicated that a fully consolidated PAR would provide the latest a clearest picture of the assessment of the products as a stand alone document. On the other hand, MSs would have to do a confidentiality check with applicants, particularly regarding the information that was available in the PAR for the first authorisation. A CG member indicated that this fully consolidated PAR was requested to applicants, while another indicated that it is produced by the CA.

Five CG members indicated though that, on account of the current context of time pressure, workload and available resources for both CAs and applicants, a more balanced and pragmatic solution should be found. A CG member also indicated that for the renewal of the AS approvals a fully consolidated CAR was not produced.

The Chair invited CG members and ASOs to send written comments on the second discussion point, so that it can be further discussed at CG-24.

Actions

SECR: To open a newsgroup for comments on whether a consolidated version of the PAR is needed later in the renewal process.

All: To comment on the newsgroup by 1 June 2017.

15. Feedback from working parties

15.1 Mandate for the Working Party on the biocidal product family concept

The SECR presented the draft mandate for the Working Party on the biocidal product family concept (CG-23-2017-24). The comments gathered during the previous e-consultation in this topic had been taken into account for setting the objectives of the working party. The objectives therefore include the list of issues identified by MSs to be addressed by the working party.

A CG member commented that, on addressing the issues, the financial implications should not be considered by the working party. The Commission and other CG members argued that, even though this could be discussed by the CA, having this aspect already considered by the WP would provide a more balanced view (technical and regulatory) to the resolution of the issues.

A few CG members proposed to include closed sessions in the discussion of the different topics when necessary to allow sharing information of specific examples including confidential information. On this point, the SECR mentioned that, even though closed sessions could be set up, MSs were encouraged to provide discussion documents without confidential information in order to have a more generic open discussion.

The importance of having experts from the WGs participating in the WP was mentioned. Related to the different points listed in the objectives, the Commission suggested the following:

- Points (a) and (g): For addressing these points, the support from the WGs would be necessary.
- Point (h) on the definitions of the boundaries of multi-PT families could be included as part of the point on the concept of similarity of uses.
- Point (j) on the assessment of SoC in the context of product families might not be necessary to be addressed

Considering the timelines for reaching a conclusion in the WP, the Commission invited the CG members to reflect on how to address for the near future the update of Annex IV of the note of guidance. For example, it is necessary to decide on whether more Q&As should be added, and in particular those agreed during the CG-22 meeting. The Commission mentioned that a letter received from a consultant representing SMEs questioned whether adding Q&As was the best way to provide guidance.

A newsgroup will be opened for providing written comments on the document.

Actions

SECR: To open a newsgroup for comments.

All: To comment on the newsgroup by 1 June 2017.

16. Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the report in document CG-23-2017-12 and CG-23-2017-14, which was made available for information.

16.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-23-2017-06, which was made available for information.

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 MS: to check the new information and report to CG SECR by 1 June 2017.

SECR: To transmit the updated version to COM to make it publicly available on CIRCABC.

If relevant, to produce an updated version for next CG meeting.

16.4 IT issues

The SECR informed that the R4BP 3 process for mutual recognition is being adapted to include a few additional key tasks to track different steps in the process. Due to lack of time during the meeting, a document detailing the proposed process will be uploaded in S-CIRCABC for comments.

The Commission informed that a paper was received on 9 May from the rodenticides WG noting that the planned amendment to R4BP 3 to enable the mutual recognition in sequence of same biocidal products is going to be postponed. This delay is related to several points that need to be addressed by ECHA. This issue is directly linked to the renewal of anticoagulant rodenticides and will be discussed during the CA meeting on 11 May 2017.

16.5 Feedback on e-consultations

A CG member presented the conclusions of an e-consultation related to the clarification on applications for a change (CG-23-2017-03).

The CG member explained that changes applied to products in the rMS and cMS are currently not clearly documented in R4BP 3 and a document should be provided by the applicant in which it is clearly indicated the changes made and the sequence in both the rMS and cMS. This document will help to decide whether the new changes can apply to both authorisations.

A second issue on when a letter of access (LoA) is needed was discussed. The CG member explained that it is important to distinguish between asset owner and case owner. A LoA is needed only when the case owner is different in the rMS and the cMS. If the case owner is the same but the asset owners are different, a LoA would not be needed.

In the case that a representative of the case owner is applying for a change, then, in the opinion of the CG member, this representative would not be the case owner and a LoA would be required. A CG member argued that it is very difficult to see in R4BP 3 if the case owner is a representative since this distinction is not available in R4BP 3.

The Commission expressed its views on this matter:

- One fundamental principle in the changes Regulation is to avoid work duplication (i.e. avoid that every MS assesses an application for a change when the product is authorised in more than one MS). This clearly follows from the procedures in Articles 7 and 8, where there is a prominent role of the refMS and from Article 9(a) too, in cases where the same change has been already agreed by another MS.

- It also clearly follows from the changes Regulation that an application for a change can be submitted by the authorisation holder (e.g. Company B, the AH in a cMS), or its representative (e.g. Company A, AH in refMS). As the representative can be the AH of the same product in another MS, the applicant is the same (Company A) in the 2 MSs (refM & cMS). Therefore:

    - Where the applicant (Company A) is the data owner of any data submitted in the application for a change, as this data is <u>not</u> used by the CA in the cMS for the

benefit of another applicant (as Company A is the applicant), no LoA is needed from Company A to Company B.

- Where the applicant (Company A) is not the data owner of the data submitted in the application for a change, as this data will used by the CA in both the refMS and the cMS for the benefit of another applicant (Company A), a LoA is needed from the data owner (Company C) to Company A for the relevant data.

- In order to address whether an application for a change in a cMS is relevant where such change has been already agreed by another MS (as evoked in the initial question of the e-consultation), a similar approach to the one in Regulation 492/2014 could be followed, so that the applicant submits as a supporting document in the application for a change the following:

- Statement/confirmation from the applicant that the change is relevant for the authorisation(s) in the MS(s) where the change is applied for.

- A list including i) the decisions on changes agreed by any Member State before 1 September 2013; ii) the decisions on changes agreed by any Member State in accordance with Implementing Regulation (EU) No 354/2013; iii) the notifications or applications for changes submitted to any Member State in accordance with Implementing Regulation (EU) No 354/2013, which are pending at the time of the submission of the application for a change.

The Commission will send these comments in writing to the CG member, who will provide an updated version of the document at the next meeting.

Actions

CG member: To update the document with the comments from the discussion and forward the document to the SECR.

SECR: To table the document for agreement for the CG-24 meeting.

17. Agreement of the action points and conclusions

The list of action points and conclusions for the open session will be agreed by written procedure.

Actions

SECR: To circulate the list of action points and conclusions for agreement ASAP after the meeting.
All: to send comments by 19 May.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

23rd meeting of the CG

10 May 2017

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
CLOSED SESSION	
1.- Welcome	
2 – Agreement of the agenda.	
The agenda for the closed session was agreed. The Commission proposed an AoB concerning the reports from MSs on the authorisation of creosote containing products.	**SECR:** to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.
3 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
4 – Draft minutes from CG-22	
Written comments were received from a MS prior to the meeting upon which the draft minutes were updated. No comments were received during the meeting on the updated version of the confidential minutes of the CG-22 meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-22 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 informed about the update of the overview table of the referrals discussed so far at CG level. The CG members agreed to fix a time slot for teleconferences every two weeks to discuss referrals in between CG meetings.	**SECR:** to produce a revised overview table for next CG meeting. **SECR:** to arrange the organisation of the referrals teleconferences.
5.2 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR	
No informal referrals were discussed.	
5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
The Chair informed that one referral had been closed via written procedure since the previous CG meeting (CG-22). Eight formal referrals were discussed and three referrals were introduced. In order to allow a discussion during the CG-24 meeting, the CG members agreed to extend the deadline of the three new referrals to the 10th July 2017.	**1) SECR:** to follow-up the outcome of the referral as stated in the Working Procedures. **2) SECR:** to upload the draft outcome in the newsgroups in S-CIRCABC. **2) All**: To review the draft

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
1) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. 2) A way forward was proposed for the resolution of the referral. CG members will evaluate a draft outcome reflecting this proposal for agreement via written procedure. 3) A way forward was proposed for the resolution of the referral. CG members will evaluate a draft outcome reflecting this proposal for agreement via written procedure. 4) Discussions were initiated with a view to reach an agreement. Three points of disagreement remain open. Discussions will follow up via teleconference. 5) & 6) Two referrals were covered in one discussion as they had the same point of disagreement. The CG members did not reach an agreement on one point. This unsolved point will be referred to the Commission under Article 36 of the BPR. 7) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. 8) An agreement was reached by consensus. The outcome of the referral will be prepared to be agreed by written procedure. 9) A referral was introduced by the icMSs. The commenting period has been initiated and will be discussed by teleconference with the objective of reaching an agreement during the CG-24 meeting. 10) A referral was introduced by the icMSs. The commenting period has been initiated and will be discussed by teleconference with the objective of reaching an agreement during the CG-24 meeting. 11) A referral was introduced by the icMSs. The commenting period has been initiated and will be discussed by teleconference with the objective of reaching an agreement during the CG-24 meeting.	outcome and comment in case of disagreement by 12/05/2017 (17:00 pm CET). **2) SECR:** In case of agreement, to follow-up the outcome of the referral as stated in the Working Procedures. **3) SECR:** to prepare and upload the draft outcome in the newsgroups in S-CIRCABC. **3) All**: To review the draft outcome and comment in case of disagreement. **3) SECR:** In case of agreement, to follow-up the outcome of the referral as stated in the Working Procedures. **4) SECR:** to schedule a teleconference for discussion of the referral. **5-6) rMS**: to refer to COM (SECR in cc) the open point from these referrals following the provisions in Article 36 of the BPR. **SECR:** to upload the detailed statement from the rMS in S-CIRCABC for information of the other MSs. **7) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **8) SECR:** to prepare and upload the draft outcome in the newsgroups in S-CIRCABC. **8) All**: To review the draft outcome and comment in case of disagreement. **8) SECR:** In case of agreement, to follow-up the outcome of the referral as stated in the Working Procedures. **9) All:** To provide comments by 25 May 2017 on the referral. **9) SECR:** to schedule a teleconference for discussion of

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	the referral. **10) All:** To provide comments by 29 May 2017 on the referral. **10) SECR:** to schedule a teleconference for discussion of the referral. **11) All:** To provide comments by 29 May 2017 on the referral. **11) SECR:** to schedule a teleconference for discussion of the referral.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA – Due to time constraints this point was not presented.	**SECR:** to produce a revised overview table for next CG meeting.
6.2 - Iodate used as stabiliser Due to time constraints this point will be discussed during the CG-24 meeting.	**SECR**: To table the topic for discussion for the CG-24 meeting.
6.3 - Practical considerations for the renewal of PT8 products Due to time constraints this point will be discussed during the CG-24 meeting.	**SECR**: To table the topic for discussion for the CG-24 meeting.
6.4 Validity of the product authorisations for spinosad and borates-containing products Due to time constraints this point will be presented during the CG-24 meeting.	**SECR**: To table the topic for information for the CG-24 meeting.
7 – Any Other Business	
7.1 – Late procedures	
Due to time constraints this point will be presented during the CG-24 meeting.	**SECR**: To produce a revised document for the CG-24 meeting.
7.2 – Feedback on e-consultations	
Due to time constraints this point will be discussed during the CG-24 meeting.	**SECR**: To table the topic for discussion for the CG-24 meeting.
7.3 Update on the pilot testing of the SoP of MR	
Due to time constraints this point will be discussed during the CG-24 meeting.	**SECR**: To table the topic for discussion for the CG-24 meeting.
7.4 Harmonisation of the assessment of insect repellents PT19	
Due to time constraints this point will be discussed during the CG-24 meeting.	**SECR**: To table the topic for discussion for the CG-24

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	meeting.
7.5 Consultation on dietary risk assessment for PT 19 products	
Due to time constraints this point will be discussed during the CG-24 meeting.	**SECR**: To table the topic for discussion for the CG-24 meeting.
7.6 Election of the Chair of the CG	
The CG representative from Greece was elected as the Chair of the CG. A call for candidates for the position of vice Chair will be initiated.	**SECR:** To initiate the call for candidates for the vice Chair position.
7.7 Reports from MSs on the authorisation of creosote containing products	
The Commission reminded those MSs having authorised creosote containing products about the submission of the reports required in the inclusion Directive.	**All:** To check back home and where relevant, send the report to COM as soon as possible.
Item 8 – Agreement of the action points and conclusions	
The list of action points and conclusions for the closed session will be agreed by written procedure.	**SECR:** To circulate the list of action points and conclusions for agreement asap after the meeting. **All**: to send comments by 19 May.
OPEN SESSION	
9 –Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.
11 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-22	
Written comments were received from a MS prior to the meeting upon which the draft minutes were updated. The draft CG-22 non confidential minutes were agreed.	**SECR:** to upload the CG-22 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
13.3 Update of the "Working procedures for resolving disagreements"	
The SECR presented an updated version of the document "Working procedures for resolving disagreements". The CG members proposed several amendments.	**SECR:** To update the Working Procedure document and open a newsgroup for comments and agreement on the updated version.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	All: To comment or agree on the newsgroup in 3 weeks after the upload of the revised document. **SECR:** If agreed, to upload the new version on S- CIRCABC
13.2 Working procedure for the linguistic review in UA	
The SECR presented an updated version of the Working procedure for the linguistic review of the SPC translations for UA. The CG members agreed on the document (excluding a paragraph on the provisions for Norwegian and Icelandic). A footnote will be added on a voluntary collaborative approach for MSs sharing a common official language.	**SECR and NO**: To agree on the provisions for NO and IS. **SECR:** To add a footnote and amend the paragraph related to NO and IS once agreement is reached.
13.3 RoP update related to declaration of confidentiality forms	
The SECR presented an updated version of the RoP including a new form to be used for the declaration of confidentiality. The CG members agreed on the document.	**SECR:** To upload the amended RoP in the relevant CIRCABC space.
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 Template to summarise the biocidal product family structure	
The CG members agreed that the form should be submitted by the applicant via R4BP 3 (rMS) and IUCLID 6. The form will be made available in the ECHA website.	**SECR:** To publish the form in the ECHA website
14.2 Renewal of anticoagulant rodenticides: AR to be used in the renewal procedure and possible consolidation of the initial PAR	
The CG members agreed on an assessment report template to be completed by eCAs in order to reflect the assessment of the applications for renewal of anticoagulant rodenticides. The need of a consolidated version of the PAR including the initial PAR will be further discussed at CG-24.	**1) SECR:** To open a newsgroup for comments on whether a consolidated version of the PAR is needed later in the renewal process. **1) All:** To comment on the newsgroup by 1 June 2017.
Item 15 – Feedback from working parties	
15.1 Mandate for the Working Party on the biocidal product family concept	
The SECR presented a draft of the mandate for the Working Party on the biocidal product family concept. The CG members proposed several amendments.	**SECR:** To open a newsgroup for comments. **All:** To comment on the newsgroup by 1 June 2017.
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
16.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
16.3 List of active substances meeting the exclusion or substitution criteria	
The Chair invited the meeting to take note of the document.	**Rapporteur MS:** to check the new information and report to CG SECR by 1 June 2017. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an updated version for next CG meeting.
16.4 IT issues	
The Commission informed the meeting that Cefic has submitted a paper to COM on an IT issue (MR-S of a SBP). As it is related to anticoagulant rodenticides, it is tabled for the 72nd CA meeting. The SECR informed the meeting that there will be some modifications in R4BP 3 related to the mutual recognition process. A document will be circulated for comments.	**SECR:** To open a newsgroup for comments on the document concerning the improvements in MR procedures. **All:** To comment on the newsgroup in 3 weeks after uploading the document.
16.5– Feedback on e-consultations	
A member presented an updated document on the conclusions of an e-consultation related to applications for a change in concerned MSs.	**CG member:** To update the document with the comments from the discussion and forward the document to the SECR. **SECR**: To table the document for agreement for the CG-24 meeting.
17 – Agreement of the action points and conclusions	
The list of action points and conclusions for the open session will be agreed by written procedure.	**SECR:** To circulate the list of action points and conclusions for agreement asap after the meeting. **All**: to send comments by 19 May.

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Part IV - List of Annexes

ANNEX II Final agenda

ANNEX II

10 May 2017

Final agenda
23rd meeting of the Coordination Group (CG-23)

10 May 2017 – From 9.00 to 17:00
Brussels, Centre Borschette

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-23-2017

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-22

CG-M-22-2017_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-23-2017-02

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 and agreement

Item 6 – Harmonisation of technical and regulatory issues in relation to product authorisation

6.1 Issues identified in the context of UA

CG-23-2017-09

For information (postponed)

6.2 Iodate used as stabiliser

For information (postponed)

6.3 Practical considerations for the renewal of PT8 products

CG-23-2017-07

For discussion (postponed)

6.4 Validity of the product authorisations for spinosad and borates-containing products

For information (postponed)

Item 7 - Any Other Business

7.1 Late procedures

CG-23-2017-17, CG-23-2017-18, CG-23-2017-19

For information (postponed)

7.2 Feedback on e-consultations

CG-23-2017-20, CG-23-2017-04, CG-23-2017-22, CG-23-2017-25

Links to e-consultations

For discussion and agreement (postponed)

7.3 Update on the pilot testing of the SoP of MR

CG-23-2017-08

For information (postponed)

7.4 Harmonisation of the assessment of insect repellents PT19

CG-23-2017-23

For discussion and agreement (postponed)

7.5 Consultation on dietary risk assessment for PT 19 products

CG-23-2017-21

For discussion and agreement (postponed)

7.6 Election of the Chair of the CG

For agreement

7.7 Reports from MSs on the authorisation of creosote containing products

For information

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-23-2017

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-22

CG-M-22-2017_Draft non confidential

For agreement

Item 13 – Administrative issues

13.1 Update of the "Working procedures for resolving disagreements"

CG-23-2017-10

For discussion and agreement

13.2 Working procedure for the linguistic review of the SPC translations in UA

CG-23-2017-01

For agreement

13.3 RoP update related to declaration of confidentiality forms

CG-23-2017-05

For agreement

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

14.1 Template to summarise the biocidal product family structure

For discussion and agreement

14.2 Renewal of anticoagulant rodenticides: AR to be used in the renewal procedure and possible consolidation of the initial PAR

CG-23-2017-13, CG-23-2017-15, CG-23-2017-16

For discussion

Item 15 – Feedback from working parties

15.1 Mandate for the Working Party on the biocidal product family concept

CG-23-2017-24

For discussion and agreement

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-23-2017-12, CG-23-2017-14

For information

16.2 Deadlines for application for product authorisation

CG-23-2017-06

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-23-2017-11

For information

16.4 IT issues

For discussion (postponed)

16.5 Feedback on e-consultations

CG-23-2017-03

Links to e-consultations

For discussion and agreement

Item 17 – Agreement of the action points and conclusions

For agreement

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