26 September 2017

CG-M-24-2017 non-confidential

Final non-confidential minutes of the 24th meeting of the Coordination Group (CG)

10 – 11 July 2017

Part I - Summary Record of the Proceedings

Closed session

1. Welcome to the closed session

The Chairman welcomed participants to the twenty fourth CG meeting. 27 members and experts from 21 Member State Competent Authorities (MSCAs), NO, CH and an observer from Serbia participated in the meeting. One representative from DG SANTÉ and three representatives from ECHA were present in the meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-24-2017) and invited participants to add any items under AOB. Three agenda points were added to be discussed in the closed session. The fist point was related to the authorisation of products containing creosote, the second point was related to the status of attractants in PT18 products and the third point was on how to address provisional authorisations considering the BPC opinion on chlolecalciferol. The agenda was agreed with the addition of these points.

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 participants to declare any potential conflict of interests. There were no potential conflicts declared.

4. The draft minutes from CG-23

The Chair explained that the draft confidential CG-23 minutes had been uploaded for commenting via Newsgroups. Comments were received from a CG member and the minutes were updated accordingly. The CG members agreed on the updated confidential draft minutes from the CG-23.

Actions:

SECR: to upload the CG-23 minutes into the relevant folders in the CG CIRCABC.

5. Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

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

Actions:

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

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

The Chair informed the meeting that six referrals had been closed via written procedure after the CG-23 meeting. No agreement by consensus was reached for one of the referrals and this case will be referred to the Commission under the provisions of Article 36. An

agreement by consensus was reached for all the other five products (i.e they meet the conditions in Article 19(1) for granting an authorisation).

Three formal referrals were tabled for discussion and one recently submitted referral (7 July) was briefly introduced.

1) CG members discussed one formal referral concerning a PT 18 product. The disagreement concerned efficacy, human health and environmental risk assessment, physico-chemical characteristics and RMMs. Several points of disagreement were previously discussed and closed during the teleconference taking place prior to the meeting. The remaining open points were discussed. The CG members reached an agreement by consensus on all points of disagreement.

   The product meets the condition for granting an authorisation in Article 19(1) and the referral has been closed.

2) CG members discussed another formal referral concerning a PT 18 product. The disagreement concerned classification and labelling, efficacy, human health and environmental risk assessment, physico-chemical characteristics, packaging size and RMMs. Several points of disagreement were previously discussed and closed during the teleconferences taking place prior to the meeting. The remaining open points were discussed. The CG members reached an agreement by consensus on all points of disagreement.

   With the agreed changes, the product now meets the condition for granting an authorisation in Article 19(1) and the referral was closed.

3) One formal referral concerning a PT2 product family was discussed related to a disagreement on the classification and labelling. The CG members reached an agreement by consensus on the classification of the product. The product meets the condition for granting an authorisation in Article 19(1) and the referral was closed.
4) A formal referral was introduced concerning a PT18 product family. The points of disagreement concerned the composition of the family, several RMMs, efficacy and shelf life of the products. The discussion will take place by teleconference and will be finalised by written procedure.

Actions:

1-3) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

4) All: To provide comments by 28 July 2017.

4) SECR: to arrange a teleconference for discussion of the referral after the commenting phase.

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

6.1 Issues identified in the context of UA

The SECR presented an updated list of issues identified in the context of UA applications (CG-24-2017-15).

During the meeting the CG members requested the CG SECR to provide the outcome of the closed points to the CG members.

Actions:

MSs: To take note of the information provided in the table.

SECR: To provide the outcome of the closed points to CG members.

6.2 Iodate used as stabilizer

The SECR informed the meeting about the discussions that had been taking place in the APCP WG related to the question on when iodate/iodide should be considered as a stabiliser in iodine or iodine/PVP containing products (CG-24-2017-23). No conclusion was

reached during the APCP WG-III-2017 and discussions will continue during the WG-IV-2017.

Actions:

SECR: To communicate to the chair of the WG the urgency on having the conclusions of this issue.

6.3 Practical considerations for the renewal of PT8 products

A CG member introduced the topic regarding the renewal of PT8 products authorised under the BPD containing substances considered as candidates for substitution (CG-23-2017-07). The member proposed that the renewal for PT8 products authorised under the BPD containing different combinations of the active substances IPBC, propiconazole and tebuconazole should be done at the same time as the renewal of the active substances (2020).

The CG member pointed out that many issues would be avoided if the renewal of these products would be postponed after the renewal of the active substances. Several CG members supported that proposal.

The Commission indicated that the BPR does not provide for a legal basis in order to grant an administrative renewal as suggested by the CG member. The only legal basis that could be used is Article 31(7) of the BPR, which already requires the submission of an application for renewal, its validation and the start of its evaluation.

The Commission also indicated that the approach followed with anticoagulant rodenticides was driven by the objective of renewing all the AS having the same mode of action at the same time, in order to apply new RMMs in a harmonised manner to all products and at the same time. In its opinion, the situation for PT 8 products is not comparable to anticoagulant rodenticides.

On a more general note, the Commission explained the possible consequences of renewing the products before the AS:

- Where the AS meets the substitution criteria after the renewal, the AS will still be renewed and there will be no regulatory consequence (the comparative assessment will be only required at the next renewal of the product).

- Where the AS meets the exclusion criteria after the renewal, the AS will only be renewed if the conditions in Article 5(2) are met. Depending on the properties of the AS, pursuant to Article 19(4) of the BPR some products could no longer be authorised for the general public. However, this matter can be easily dealt with in accordance with document CA-Nov15-Doc.4.1-Final (administrative change). Any other elements arising from the renewal (e.g. new restrictions or RMMs) can be implemented by MSs in accordance with Article 48 of the BPR, as it is going to be done with anticoagulant rodenticides.

Actions:

SECR: To open a newsgroup for comments.

All: To comment on the newsgroup by 1 September.

SECR: To table this point for discussion during the CG-25 meeting.

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

The Commission briefly introduced the topic by referring to some exchanges with a CG member regarding the views of some applicants that disagreed with the actions taken by that member as other MSs had not changed the expiry dates of authorisations of products containing spinosad or borates. It also added that this situation was perhaps not linked to an opposition by MSs to adjust the expiry date, but to the fact that some MSs just waited for the refMS to do so for the sake of consistency (also linked to the comparative assessment issue: 4 vs 5 years).

The Commission asked CG members to provide feedback on the state of play of the modifications agreed in the past concerning the expiry date of the authorisations of products containing spinosad or borates to 5 years.

Actions

COM: to provide the original communication to MSs to the SECR.

SECR: To open a newsgroup for comments including the communication provided by COM.

All: To comment by 1 September 2017.

7. Any Other Business (closed session)

7.1 Late procedures

The Commission presented the overview of late procedures.

Actions

MSs: to review the document and communicate to ECHA any inaccuracies in the data.

SECR: To open a newsgroup for comments from refuses to provide feedback on late applications, and provide a forecast on the completion date of the assessment.

refMSs: To comment by 1 September 2017.

7.2. Feedback on e-consultations

Four e-consultations were presented for discussion and agreement.

1. **Innovative insecticide product**

A CG member presented the conclusion of an e-consultation regarding how to consider biphasic products and products including different formulations (CG-23-2017-04). Different views were expressed. CG members will provide further comments and the discussion will be continued during the CG-25 meeting.

2. **Letter of access requirements for substances of concern**

A CG member presented the conclusion of an e-consultation on the requirement of a letter of access (LoA) for a substance of concern. Different point of views and additional questions were raised during the commenting period, for example on whether a LoA was necessary when the data was to be used by the authorities not in the benefit of the applicant. Another point raised was the need to review other property and copyrights. Considering the complexity of the issue, the CG member proposed to refer this issue to the CA meeting for the preparation of a CA document to clarify the matter. CG members agreed with this proposal.

The commission mentioned that the document will provide a harmonised approach that is legally consistent.

3. **Assessment of a biocidal product containing a combination of an approved active substance and of an active substance "Annex I"**

A CG member presented the document CG-24-2017-20 with the conclusions from an e-consultation on how to address applications for the authorisation of products containing a combination of two active substances with one of them included in Annex I of the BPR. CG members agreed on the proposed way forward in the document with the addition of a clarification regarding "silent active substances". In the case that the Annex I active substance contributes to the efficacy of the product, this substance should be considered as an active substance for the risk assessment. Accordingly, data should be provided by the applicant in order to support the risk assessment. In the case that the Annex I active substance does not contribute to the efficacy of the product, the substance should be considered as a co-formulant (or as a substance of concern when contributing to the classification of the product).

4. Same biocidal product of another same biocidal product

A CG member presented the document CG-24-2017-16 with the conclusions from an e-consultation on applications for a same biocidal product having as reference product another same biocidal product. The Commission indicated that, from a legal point of view, there is no explicit restriction so it is possible to have a same biocidal product application having as a reference product another product that was previously authorised as same biocidal product. The Commission noted though that this approach might represent some practical constraints that should be considered. In other words, it should be highly recommended that all applicants for a SBP in the same MS refer to the initial reference product. The SECR also noted that this procedure is not implemented in R4BP3 at this moment.

Different views were expressed on the question of whether the owner of the reference same biocidal product could act on behalf of the owner of the original product to grant a letter of access. The CG members will consult their experts on this matter and the Commission will provide further comments.

Actions:

1) All: To comment by 1 September 2017.

1) MS to update the document accordingly after the commenting phase and forward it to the SECR.

1) SECR: To table this e-consultation for discussion/agreement during the CG-25 meeting.

2) COM: To table this e-consultation for discussion in the CA meeting.

3) MS: To provide an updated document to the SECR.

3) SECR: To upload the updated document in the relevant S-CIRCABC space.

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

4) All: To comment by 1 September 2017.

4) COM: To provide written comments

4) MS to update the document accordingly after the commenting phase and forward it to the SECR.

7.3 Conclusion on the pilot testing of the SoP of MR

The SECR presented a proposal to amend the SoP of the mutual recognition phase on account of the results of the pilot testing initiated early this year. CG members agreed to change the current procedure (i.e. 60+30 days) to the new one, which includes the seven steps covered in the pilot test. The document will be further discussed and the details in terms of timelines will be agreed in the CG-25 meeting.

Actions

SECR: To update the SoP proposal and open a newsgroup for comments.

All: To comment on the newsgroup by 1 Sept.

SECR: To launch a pre-meeting consultation with an updated proposal based on the comments before CG-25.

SECR: To communicate the ECHA IT the need to adapt R4BP 3 to support the new procedure for the mutual recognition phase.

7.4 Harmonisation of the assessment of insect repellents

The SECR introduced the discussion and explained that, after the CG-22 meeting, the proposal from ECHA for the harmonisation of the assessment of insect repellents was amended and circulated for comments. Based on the comments received, the final

proposal (CG-24-2017-21) was presented for discussion. The comments received were addressed by ECHA in document CG-24-2017-22.

The discussion concluded with no consensus on accepting the proposal from ECHA. The chair noted that, while new efficacy testing methods are developed, for current applications, a case by case approach will be followed. Recently the referrals of two PT19 products were referred to the Commission under the provisions of Article 36. A BPC opinion will be requested for these two cases that may be taken into consideration for a possible way forward for the harmonisation of the assessment of insect repellents.

Actions

SECR: To communicate the EFF WG on the urgency of having test methods for field studies and laboratory tests adapted to dose used in the exposure assessment.

7.5 Consultation on dietary risk assessment for PT 19 products

A CG member presented the conclusions of the consultation on the need to conduct a dietary risk assessment for PT19 products (CG-24-2017-28). Different opinions were expressed with a few members being in favour of performing a dietary risk assessment while others considering that RMMs could be sufficient to ensure a safe use. The CG members agreed with the proposal of forwarding the discussion to ECHA to be further elaborated in an appropriate forum.

Actions

SECR: To refer the discussion to ECHA to be further elaborated in an appropriate forum.

7.6 Technical equivalence of Aluminium phosphide

A CG member introduced the topic by reference to document CG-24-2017-14. A change in classification of an impurity in aluminium phosphide according to the 9th ATP would result in some alternative sources not being considered as technical equivalent. The SECR clarified that, where the classification of a component of an active substance changes and affects the classification of an alternative source of the substance, it is the responsibility of the eCA and the applicant to re-evaluate whether the technical equivalence assessment is still valid.

Actions

MSs: To check if they have any ongoing applications or authorised products with aluminium phosphide containing the sources that are affected by the new 9th ATP.

DE: To provide MSs with a list of affected products for which DE is the refMS.

7.7 Election of vice-Chair of the Coordination Group

The CG Chair informed the meeting that no candidatures were received for the post of vice-Chair of the CG. According to the RoP of the CG, until a vice Chair is appointed, the SECR would replace the Chair in case of need.

7.8 Approval of creosote

A CG member informed the meeting that it will send a letter to all cMSs on creosote containing products in order to collect information on how the authorisations have been granted in those MSs.

7.9 Status of attractants in PT18 products

A CG member asked how PT18 products containing an attractant in the formulation should be addressed.

The Commission clarified that this topic had been previously discussed and that the guidelines described in document CA-Sept13-Doc.6.2.b Rev.1-Final should be followed.

The attractant present in the product as well as the PT18 active substance should be considered as active substances.

7.10 BPC opinion on cholecalciferol and provisional authorisations

A CG member asked the Commission whether the latest discussions in the BPC meeting (where cholecalciferol was considered to be a candidate for substitution according to Article 10(1)(e) of the BPR), have any impact on the on-going applications for provisional authorisations under Article 55(2) of the BPR in terms of comparative assessment.

The Commission replied that there is no consequence, as document CA-March15-Doc.4.3-Final (paragraphs 10 & 11) clarifies that the products can be authorised for 3 years without carrying out a comparative assessment.

8. Agreement of the action points and conclusions

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

Open session

9. Welcome to the open session

The Chair welcomed ASOs to the open session. Three 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-24-2017) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed

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

Actions

SECR: to upload the final 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-23

The Chair explained that the draft non-confidential CG-23 minutes were uploaded for commenting via Newsgroups and no comments were received. The CG members agreed on the draft minutes (non-confidential part) from the CG-23 meeting.

Actions

SECR: to upload the CG-23 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

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

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

The SECR presented an updated version of the mandate for the Working Party on the biocidal product family concept (CG-24-2017-27). The main changes included in the updated version were the following:

- Revision of the mode of operation of the Working Party with a detailed procedure to address technical questions to ECHA to be considered for discussion in the WGs.
- Introduction of the possibility of adding additional discussion topics during the operation of the Working Party.
- Provisions to allow discussions of confidential items in a closed session during meetings and through the CIRCABC platform.

CG members agreed to maintain in the list of objectives the point related to the application of paragraph 77 of Annex VI to the BPR in relation to BPFs. For the time being, the impact of the concentration of substances of concern (SoC) in families was not considered to be necessary as a discussion topic.

The SECR presented in the screen the draft mandate including the agreed modifications. The CG members agreed on the document. The SECR will initiate the setup of the Working Party and call for the nomination of members and volunteers to lead the discussion of the different topics.

Actions

SECR: To initiate the setup of the Working Party as detailed in the mandate.

All: To nominate members for the WP and volunteers to lead the different topics in the objectives.

SECR: To inform the CG members ASAP on the organisation of the first meeting of the WP.

14.2 Anticoagulant rodenticides

14.2.1. Consolidated version of the AR for anticoagulant renewal

The Commission introduced this agenda item by referring to the pre-meeting consultation held before CG-24 (see documents CG-24-2017-12 and CG-24-2017-13). In order to steer the discussion, the Commission guided CG members with some slides where the main open discussion points were included (*post-meeting note: the presentation has been uploaded in Circabc now*):

- 1. Overall approach: "Full consolidation" vs "addenda"

All MSs that commented during the pre-meeting consultation supported the "addenda approach" as a compromise for PT 14 products. CG members agreed to produce a consolidated PAR based on addenda to the initial PAR and not a fully consolidated PAR after the renewal.

- 2. Structure of the PAR: following some discussions on the comments made by two CG members during the pre-meeting consultation, and in order to keep the document as simple as possible, the following structure (in chronological order) was agreed:

Section 1: At the beginning of the PAR (e.g. 2nd page), a list indicating, in chronological order, the assessment of any minor or major changes, as well of any renewal procedure. The list should refer to the relevant section and addenda to the initial PAR; see example below:

Application type	**refMS**	**Case number in the refMS**	**Decision date**	**Assessment carried out (i.e. first authorisation / amendment / renewal)**	**Chapter / page**
NA-APP	*UK*		xx.xx.xxxx	Initial assessment	
NA-AAT	*UK*		xx.xx.xxxx	*Change of expiry date to 31.08.2020*	
NA-MAC	*IT*		xx.xx.xxxx	*Addition of the target organism house mouse (Mus musculus)*	
NA-MIC	*UK*		xx.xx.xxxx	*Extension of shelf-life (24 to 48 months)*	
NA-RNL	*UK*		xx.xx.xxxx	*Renewal of the authorisation*	

Section 2: Consolidated version of the PAR chapter "Summary of the product assessment" (to be updated after each change).

Section 3: assessment carried out for the first authorisation;

Section 4: assessment of any minor or major changes that have been agreed since the first authorisation;

Section 5: assessment of the application for renewal of the authorisation. For PT 14 products, this corresponds to the template (proposed by DE) agreed by CG members in the CG-24 meeting.

- 3. Case of a different refMS for changes or at the renewal: for PT14, CG members agreed that the consolidated PAR with the addenda will be produced by the refMS dealing with the renewal application, as it has received the fees to compensate the associated workload and has the latest and more recent information on the product.

- 4. Applicability to other PTs: Some CG members considered that the agreed approach for PT 14 was a compromise solution in order to deal with the matter under some time pressure. Under different circumstances, a full consolidation of the initial PAR would be the ideal solution. Therefore, CG members agreed to have some further discussions at CG-25 in order to decide whether the agreed approach for PT 14 should be followed for other PTs (e.g. PT 8). A CG member indicated that MSs will also gain experience with the agreed approach for PT 14 by the end of the year, which can be used to better inform this decision on the applicability to other PTs.

A MS indicated that concerning the confidentiality check of the information contained in the initial PAR, it has requested the applicants to indicate which information should be considered as confidential. In the absence of any input from the applicant with an adequate justification, the initial PAR will be included as it is in the consolidated PAR for dissemination.

Actions

SECR: To open newsgroup for comments.

All: To comment by 1 September 2017 on the applicability of this approach to PTs other than PT14.

14.2.2. Dermal absorption of anticoagulant rodenticides

A CG member proposed to use the dermal absorption values used for the first authorisation for the dermal absorption assessment in the renewal of the PT14 products (see document CG-24-2017-07).

The Commission indicated that at CG-21, CG members agreed on a document prepared by ECHA regarding the assessment of dermal absorption for anticoagulant rodenticides at the renewal stage. The paragraph on "Read-across and worst-case approach for dermal absorption" indicated that "As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iii) remain valid, applicants will have to address the dermal absorption issue according to document CA-July13-Doc.6.2.b – Final".

The CA document of 2013 was known well in advance, so applicants should have addressed the dermal absorption issue in the application for renewal according to it. They already knew that where no product specific data was available or no LoA is granted to data from another similar formulation, then the default values in the EFSA guidance would apply (with some margin of discretion for expert judgement).

The Commission considered that, timely wise, any pending discussions in the WG, workshops and follow up regulatory discussions in the CG are not compatible with the current renewal procedure as the evaluations are already on-going and the refMSs will have to send the AR and draft SPC to cMSs by the end of August.

In terms of equal treatment of applicants, the Commission indicated that each application has to be considered on its merits. What needs to be ensured is that MSs follow a common approach in terms of how to assess the applications (i.e. the CA document), but then each application may contain different information.

In order to avoid MR disagreements, MSs would have to accept that different default values may be used by different refMSs on account of the information available in the application. Referrals should only be sent to the CG when there is a clear evidence that the conditions in Article 19(1)(iii) are not met, and not just because the refMS used a different default value based on the available data and the judgement of their experts on that specific product. The Commission referred to some recent referrals for which the expert judgement of different refMSs was considered to be valid when using lower values than the default values in the EFSA guidance.

Several CG members supported the views of the Commission. One CG member also mentioned that applying the CA document to MAC applications or to new products and not to renewals would not make any sense. This would certainly create an unequal treatment of applicants.

Although industry representatives supported the proposal of the CG member, the Chair noted that CG members did not support the proposal.

Actions

SECR: To open a newsgroup for comments.

All: To comment by 1 September 2017 on the applicability of this approach to PTs other than PT14.

14.3 The list of existing national registrations (and new products) prepared in the context of a Union Authorisation

The SECR presented a proposal for a template to be used as supporting document to list the existing and new products for Union and National authorisation procedures.

The Commission indicated that this matter was already addressed in document CA-March14-Doc.5.1-Final on the transition between national schemes and BPR-authorisations following active substance approvals. Paragraph (8) clearly says that for the purpose of enforcement, the approach in the paper was subject to the condition that the application for authorisation of the new product contains a clear identification and a short description of the existing product(s) to be linked to such application. The Commission also noted that the need to provide such approach is equally valid for Union and national authorisation procedures.

MSs were invited to provide comments on the proposed template. The template will be tabled for agreement in the CG-25 meeting.

Actions

SECR: To open a newsgroup for comments.

All: To comment by 1st September 2017 on the template.

15. Feedback from working parties

15.1 Update on the publication of the outcome of the WPs

The CG SECR informed the CG members that the translation of the SPC template for anticoagulant rodenticides in all EU languages as well as the list of frequently used sentences in the SPC (including their translation) had been published in the ECHA website.

16. Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the reports in documents CG-24-2017-02 and CG-24-2017-03, 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-24-2017-01, 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 (CG-24-2017-11) includes changes concerning some approved active substances.

Actions

Rapporteur MS: to check the new information and report to CG SECR by 18 July.

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

16.4.1. R4BP 3.9 new features

The SECR presented the new features that have been introduced in R4BP 3.9 (CG-24-2017-24). The new main new features include new case types, improved search and notifications, extension of grouped submissions and an improvement in process flows.

A CG member noted that in those cases where an applicant withdraws an application, no notification is sent to the eCA. This matter will be referred to the ECHA IT team.

Actions

SECR: To provide an update to the CG on the notification process for withdrawal of applications by the applicant.

16.4.2. R4BP 3.10 MR synchronisation schema

The SECR presented the new synchronisation schema to be incorporated in R4BP 3.10 for the mutual recognition procedure (CG24-2017-26).

The Commission clarified that, when a disagreement is referred to the Commission under Article 36, those cMSs agreeing with the refMS may authorise the product. The cMSs would wait in this case for the refMS to authorise first the product in order to ensure that the same expiry date is recorded for all authorisations.

A CG member noted that R4BP 3 should allow some flexibility with the deadline for submitting a referral as stated in the working procedure in those cases where the deadline is affected by holidays or other unforeseen events. The SECR confirmed that this provision will be incorporated in the process.

Regarding the step for the agreement of the SPC and PAR at the end of the mutual recognition phase, several CG members noted that agreement should be actively expressed and not by tacit agreement. This is in line with the BPR where it states that cMSs "shall record the agreement in RRBP". The Commission explained that cMSs are required to actively communicate their agreement with the PAR and the SPC, however, in those cases where a MS does not record the agreement within the deadlines, in order to be able to move forward to the next step, it is necessary to assume that that MS agrees with the documents. This is in line with the discussion in the CA meeting where it was agreed that where a MS does not submit a referral at the latest 10 days after the 90 day period of the mutual recognition phase, it is understood that that MS agrees with the PAR and SPC even if the MS has not explicitly communicated the agreement.

Actions

SECR: To inform the ECHA IT team about the discussion and points to be incorporated in the procedure.

16.5 Feedback on e-consultations

A CG member presented the conclusions of the e-consultation on clarification on applications for a change (CG-24-2017-19). CG members agreed on the document which will include a clarification in the last paragraph.

Actions

SECR: To publish the document on the relevant CIRCABC space.

SECR: To update the CG members on the possibility to produce and publish a template supporting document for changes in the ECHA website.

17. Agreement of the action points and conclusions

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

o0o

Part II - MAIN CONCLUSIONS & ACTION POINTS

24th meeting of the CG

10-11 July 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 with the addition of 3 points for the AOB of the closed session.	**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-23	
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-23 meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-23 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed about the update of the overview table of the referrals discussed so far at CG level.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
The Chair informed that six referrals had been closed via written procedure since the previous CG meeting (CG-23). Three formal referrals were discussed 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) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. 3) An agreement was reached by consensus and this referral is therefore closed. The outcome of the	**1-3) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **4) All**: To provide comments by 28 July 2017. **4) SECR:** to arrange a teleconference for discussion of the referral after the commenting phase.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
referral was agreed by the CG members One referral was introduced 4) The refMS introduced the referral. This referral will be closed by written procedure.	
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA – The SECR presented the list of issues identified in the context of UA.	**MSs:** To take note of the information provided in the table. **SECR:** To provide the outcome of the closed points to CG members.
6.2 - Iodate used as stabiliser The SECR informed the meeting about the discussions that took place during the APCP WG-III related to the use of iodate as stabiliser in iodine and iodine/PVP containing products.	**SECR:** To communicate to the chair of the WG the urgency on having the conclusions of this issue.
6.3 - Practical considerations for the renewal of PT8 products A member introduced the topic regarding the renewal of PT8 products authorised under the BPD containing substances considered as candidates for substitution.	**SECR:** To open a newsgroup for comments. **All:** To comment on the newsgroup by 1 September. **SECR:** To table this point for discussion during the CG-25 meeting.
6.4 Validity of the product authorisations for spinosad and borates-containing products COM introduced the topic and asked CG members to provide feedback on the state of play of the modifications agreed in the past concerning the expiry date of the authorisations of products containing spinosad and borate to 5 years.	**COM:** to provide the original communication to MSs to the SECR. **SECR:** To open a newsgroup for comments including the communication provided by COM. **All:** To comment by 1 September 2017.
7 – Any Other Business	
7.1 – Late procedures	
COM presented the overview of late procedures.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data. **SECR:** To open a newsgroup for comments from refMSs to provide feedback on late applications, and provide a forecast on the completion date of the assessment. **refMSs:** To comment by 1

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	September 2017.
7.2 – Feedback on e-consultations	
Four closed e-consultations were presented: 1) A member presented the conclusion of an e-consultation regarding how to consider biphasic products and products including different formulations. Different views were expressed. 2) A member presented the comments of an e-consultation regarding the need of a letter of access for substances of concern. The CG members agreed to refer this discussion to the CA meeting. 3) A member presented the comments of an e-consultation regarding the assessment of a biocidal product containing a combination of an approved active substance and an active substance of Annex I. The CG members agreed on the document with the addition of a clarification regarding the reference to silent active substances. 4) A member presented the comments of an e-consultation regarding applications of a same biocidal product having as reference another same biocidal product. The item will be further discussed during the CG-25 meeting.	**1) SECR:** To open a newsgroup for comments on the document provided for discussion. **1) All:** To comment by 1 September 2017. **1) MS** to update the document accordingly after the commenting phase and forward it to the SECR. **1) SECR:** To table this e-consultation for discussion/agreement during the CG-25 meeting. **2) COM:** To table this e-consultation for discussion in the CA meeting. **3) MS:** To provide an updated document to the SECR. **3) SECR:** To upload the updated document in the relevant S-CIRCABC space. **4) SECR:** To open a newsgroup for comments on the document provided for discussion. **4) All:** To comment by 1 September 2017. **4) COM:** To provide written comments **4) MS** to update the document accordingly after the commenting phase and forward it to the SECR.
7.3 Conclusion on the pilot testing of the SoP of MR	
The SECR presented the results of the pilot testing of the SoP for the mutual recognition phase. The CG members agreed to change the current procedure including the steps tested in the pilot test. The exact details of the steps will be agreed in the CG-25 meeting.	**SECR:** To update the SoP proposal and open a newsgroup for comments. **All:** To comment on the newsgroup by 1 Sept. **SECR:** To launch a pre-meeting consultation with an updated proposal based on the comments before CG-25. **SECR:** To communicate the ECHA IT the need to adapt R4BP 3 to support the new procedure for the mutual

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	recognition phase.
7.4 Harmonisation of the assessment of insect repellents	
The SECR presented an amended proposal for the harmonisation of the efficacy and exposure assessment of PT 19 products. The CG members did not agree by consensus on accepting a discrepancy between the application rate used in the efficacy testing and that used in the exposure assessment.	**SECR**: To communicate the EFF WG on the urgency of having test methods for field studies and laboratory tests adapted to dose used in the exposure assessment.
7.5 Consultation on dietary risk assessment for PT 19 products	
A CG member presented a proposal to address the dietary risk assessment of PT 19 products. The CG members agreed to refer the discussion to ECHA to be further elaborated in an appropriate forum.	**SECR:** To refer the discussion to ECHA to be further elaborated in an appropriate forum.
7.6 Technical equivalence of Aluminium phosphide	
The SECR clarified that MSs should communicate with applicants regarding changes in classification of components or impurities in a product affecting the technical equivalence of alternative sources	**MSs**: To check if they have any ongoing applications or authorised products with aluminium phosphide containing the sources that are affected by the new 9th ATP. **DE**: To provide MSs with a list of affected products for which DE is the refMS.
7.7 Election of the vice-Chair of the CG	
No candidatures were received for the post of vice-Chair of the CG. The Chair informed the meeting that, according to the RoP of the CG, until a vice Chair is appointed, the SECR would replace the Chair in case of need.	
7.8 Approval of creosote	
A CG member informed the meeting that it will send a letter to cMSs in order to see how the authorisations have been granted.	
7.9 Status of attractants in PT18 products	
The approach discussed in the latest CA document on multi PT active substances should be used for addressing these products.	
7.10 BPC opinion on cholecalciferol and provisional authorisations	
No comparative assessment will be needed for the provisional authorisations.	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Item 8 – Agreement of the action points and conclusions	
The list of action points and conclusions for the closed session was agreed by the CG meeting.	
OPEN SESSION	
9 –Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.
11 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-23	
There were no comments on the draft non confidential minutes of the CG-23 meeting. The non-confidential minutes were agreed.	**SECR:** to upload the CG-23 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 Mandate for the Working Party on the biocidal product family concept	
The SECR presented an updated version of the mandate for the Working Party on the biocidal product family concept. The CG members agreed not to include as an objective the impact of substances of concern. The document was agreed with this modification.	**SECR:** To initiate the setup of the Working Party as detailed in the mandate. **All**: To nominate members for the WP and volunteers to lead the different topics in the objectives. **SECR**: To inform the CG members ASAP on the organisation of the first meeting of the WP.
14.2 Anticoagulant rodenticides	
14.2.1. Consolidated version of the AR for anticoagulant renewal	
The CG members agreed to produce a consolidated PAR based on addenda to the initial PAR and not a fully consolidated PAR after the renewal for PT14. The PAR will include a section with the latest consolidated summary of the assessment of the product.	**SECR:** To open a newsgroup for comments. **All:** To comment by 1 September 2017 on the applicability of this approach to

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
For PT14, the consolidated PAR will be produced by the refMS dealing with the renewal application. The sections in the PAR will follow a chronological order.	PTs other than PT14.
14.2.2. Dermal absorption of anticoagulant rodenticides	
A CG member introduced a proposal. The CG members did not support the proposal.	
14.3 The list of existing national registrations (and new products) prepared in the context of a Union Authorisation	
The SECR presented a proposal for a template to be used to list the existing national registrations and new products to be used for Union and National authorisation procedures.	**SECR:** To open a newsgroup for comments. **All:** To comment by 1st September 2017 on the template.
Item 15 – Feedback from working parties	
15.1 Update on the publication of the outcome of the WPs	
The SECR informed the meeting that the translation of the SPC template for anticoagulant rodenticides and the list of frequently used sentences including their translation in all EU languages had been published in the ECHA website.	
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
16.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	
16.3 List of active substances meeting the exclusion or substitution criteria	
The Chair invited the meeting to take note of the document.	**Rapporteur MS:** to check the new information and report to CG SECR by 18 July. **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	
16.4.1. R4BP 3.9 new features	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
The SECR presented the new features of R4BP 3.9.	**SECR:** To provide an update to the CG on the notification process for withdrawal of applications by the applicant.
16.4.2. R4BP 3.10 MR synchronisation schema	
The SECR presented the new synchronisation schema in R4BP 3.10 for the mutual recognition procedure.	**SECR:** To inform the ECHA IT team about the discussion and points to be incorporated in the procedure.
16.5– Feedback on e-consultations	
A member presented the conclusions of an e-consultation related to applications for a change in concerned MSs. The CG members agreed on the document with a clarification on the last paragraph.	**SECR:** To publish the document on the relevant CIRCABC space. **SECR:** To update the CG members on the possibility to produce and publish a template supporting document for changes in the ECHA website.
17 – Agreement of the action points and conclusions	
The list of action points and conclusions for the open session was agreed by the CG meeting.	

oOo

Part IV - List of Annexes

ANNEX I List of documents submitted to the members of the Coordination Group

ANNEX II Final agenda

ANNEX II

10 July 2017

Final agenda
24th meeting of the Coordination Group (CG-24)

10-11 July 2017
On 10 July from 13.00 to 17:30 and
On 11 July 9:00-17:00

Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-24-2017

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-23

CG-M-23-2017_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-24-2017-18

For information

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

Links to disagreements

For discussion and agreement

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

6.1 Issues identified in the context of UA

CG-24-2017-15

For information

6.2 Iodate used as stabilizer

CG-24-2017-23

For information

6.3 Practical considerations for the renewal of PT8 products

CG-23-2017-07

For discussion

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

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-24-2017-04, CG-24-2017-05 & CG-24-2017-06

For information

7.2 Feedback on e-consultations

CG-24-2017-17, CG-23-2017-04, CG-23-2017-22, CG-24-2017-20, CG-24-2017-16

Links to e-consultations

For discussion and agreement

7.3 Conclusion on the pilot testing of the SoP of MR

CG-24-2017-09, CG-24-2017-10

For discussion and agreement

7.4 Harmonisation of the assessment of insect repellents

CG-24-2017-21, CG-24-2017-22

For discussion and agreement

7.5 Consultation on dietary risk assessment for PT 19 products

CG-24-2017-28

For discussion and agreement

7.6 Technical equivalence of Aluminium phosphide

CG-24-2017-14

For discussion

7.7 Election of the vice-Chair of the CG

For discussion

7.8 Approval of creosote

For discussion

7.9 Status of attractants in PT18 products

For discussion and agreement

7.10 BPC opinion on cholecalciferol and provisional authorisations

For discussion and agreement

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-24-2017

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-23

CG-M-23-2017_Draft non confidential

For agreement

Item 13 – Administrative issues

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

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

CG-24-2017-27

For discussion and agreement

14.2 Anticoagulant rodenticides

14.2.1. Consolidated version of the AR for anticoagulant renewal

CG-24-2017-12, CG-24-2017-13, CG-24-2017-30

For discussion and agreement

14.2.2. Dermal absorption of anticoagulant rodenticides

CG-24-2017-07

For discussion and agreement

14.3 The list of existing national registrations (and new products) prepared in the context of a Union Authorisation

CG-24-2017-08

For discussion

Item 15 – Feedback from working parties

15.1 Update on the publication of the outcome of the WPs

For information

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-24-2017-02 & CG-24-2017-03

For information

16.2 Deadlines for application for product authorisation

CG-24-2017-01

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-24-2017-11

For information

16.4 IT issues

16.4.1. R4BP 3.9 new features

CG-24-2017-24 & CG-24-2017-25

For information

16.4.2. R4BP 3.10 MR synchronisation schema

CG-24-2017-26

For information

16.5 Feedback on e-consultations

CG-24-2017-19

Links to e-consultations

For discussion and agreement

Item 17 – Agreement of the action points and conclusions

For agreement

o0o