17 November 2016

CG-M-19-2016 non-confidential

Final non-confidential minutes of the 19th meeting of the Coordination Group (CG)

20 September 2016

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the nineteenth CG meeting. 31 members from 26 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-19-2016) and invited participants to add any items under AOB. Two items were added to the agenda. The first one related to the implementation of the 9th ATP regulation for anti-coagulant rodenticides and the mutual recognition in sequence, and the second one related to the additional data available for permethrin. An additional item was proposed to be added for the open session related to Article 93, however, this topic was finally discussed under agenda point 6.5 and therefore does not appear in the AOB section of the agenda. The agenda was agreed with these additions.

The final agenda are included in Annex II of the minutes.

Actions:

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

3. Declaration of interest in relation to the agenda

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

4. Agreement of the draft minutes from CG-18

The Chair explained that the draft confidential CG-18 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period or during the meeting. The CG members agreed on the confidential draft minutes from CG-18.

Actions

SECR: to upload the CG-18 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 were no informal referrals for discussion.

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

Two formal referrals were discussed. These referrals corresponded to two applications submitted by the same applicant for two closely related insecticide products (PT 18). The points of disagreement for the two referrals were very similar and therefore were discussed at the same time. In both cases, the disagreement was concerned with the data submitted to prove the efficacy of the products.

Related to the first point of disagreement, the initiating concerned MS (icMS) was of the opinion that the available field test data was not sufficient to establish the efficacy of the product for the uses and target species claimed in the authorisation. The field test data available had been performed without including the bait box. This, in the opinion of the icMS, did not follow the directions given in the applicable guidance, where it is mentioned that testing should be performed with the bait box. On the contrary, the reference MS (rMS), based on expert judgement and considering the shape of the bait station in this case, was of the opinion that the tests performed without the bait station would be sufficient to prove the efficacy of the product.

Related to the second point of disagreement, the icMS considered that efficacy data should be submitted on aged bait product. In the opinion of the rMS, considering the composition of the product, the submission of these data was not necessary.

The CG members expressed different opinions and did not reach an agreement during the meeting. A follow up discussion will take place by teleconference with the objective of reaching an agreement by 22 October.

Actions

1-2) SECR: to organize a teleconference with all MSs with the objective of finding an agreement by consensus for the 2 formal referrals

5.4. Proposal to amend the RoP

A CG member presented a proposal to amend the rules of procedures (RoP) for formal referrals related to the point of reaching agreement by consensus. This point will be further discussed in the next CG meeting.

SECR: Open a newsgroup in CIRCABC to provide comments on the proposal to amend the RoP.

All: To provide comments by 12 October.

6. Any Other Business (closed session)

6.1 Late procedures

ECHA presented the report on timelines for cases finalised and in progress (CG-19-2016-16). The Commission updated the CG members on the discussion to be held at the next CA meeting.

Actions

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

6.2. Feedback on e-consultations

An e-consultation was presented for agreement of the CG members related to the "Data used for classification and labelling of biocidal products". It concerned the applicability of data protection as described in Article 59 of the BPR in the case of using protected data without a letter of access for the purpose of classification and labelling. Different opinions were expressed by the CG members. In order to get clarification on this matter, it was agreed to consult the Commission services.

Actions

SECR: Forward e-consultation to COM.

COM: To provide feedback at the next CG meeting.

6.3 Renewal of anticoagulant rodenticides

SECR explained that the Chairs of the Working Groups in collaboration with the Commission had reviewed the technical questions gathered related to the renewal of anticoagulant rodenticides. The list of questions to be discussed is summarised in the meeting document CG-19-2016-10.

Two additional questions of a regulatory matter were received during the consultation and introduced by the Commission:

(a) *Products showing degradation above 10% during storage and for which efficacy tests of aged bait are not available. Possibility of authorisation with a condition of submission of efficacy data at the next renewal*.

(b) *Efficacy data requirements on aged bait applicable for the renewal of AVK rodenticides considering the differences between the new unpublished PT14 guidance and the current TNG*.

Related to question (a), the Commission mentioned that it would be difficult for the applicant to generate the data on aged bait in time and supported to accept the authorisation with the condition mentioned above. The Commission considered that applicants should follow the new guidance for providing the required field data at the next renewal, provided that the guidance is published by the end of the year (because of the two-year cut off).

A member commented that the claim on the period of storage stability (and efficacy) for products with higher than 10% degradation should be based on available data at the time of the renewal of the authorisation. A change could be then introduced once additional data would be available, after the renewal of the authorisation, to demonstrate stability during a longer period of time.

Related to question (b), a member explained that the new unpublished guidance is relaxing the efficacy data requirements for aged bait compared to the current guidance (e.g. 24 months of shelf life where the product contains an in-can preservative and 12 months without it) and that this point is very unlikely to be changed. Allowing the applicants to refer to the new guidance would simplify the data requirements for the applicant.

The Chair proposed to have a proposal drafted by DE for these two questions based on the discussion and open this for comments via a newsgroup in CIRCABC. In case of all members would agree with the proposal, this would be adopted as the position of the CG in this matter as way forward.

Actions

DE: Produce a document with a way forward for the 2 questions, including the case where the new TNG requires less data than the current TNG and submit to SECR.

SECR: Open a newsgroup in CIRCABC to provide comments on the proposed way forward.

All: To provide comments by 12 October.

6.4 Major changes to authorisations to reduce the active substance concentration

The Commission briefly informed the CG of the latest developments regarding the applicability of the CMR additivity principle to anticoagulant rodenticides with a combination of two active substances (ASs) below the specific concentration limit (SCL). According to the feedback received from the Commission services responsible for the CLP Regulation, it seems that MSs supported the views that the CMR additivity principle would apply to those products and it is expected that those views would be formally endorsed at the October Caracal meeting. If so, then ECHA will amend the relevant guidance documents accordingly.

From the biocides perspective, the Commission mentioned that this means in practice that the above-mentioned rodenticides would also be classified and as a consequence, they could not be authorised for use by the general public. In other words, the option of mixing two substances below the SCL would no longer be possible as a major change to the current authorisations in order to keep the general public as a user category.

CG members did not report any specific issue linked to major changes to authorisations to reduce the active substance concentration.

6.5 Implementation of the procedure for alternative dossiers

As part of the procedure described in the document CG-17-2016-13, ECHA was required to create and maintain a list of alternative dossiers. The list created was presented by ECHA. It was suggested to include the list of products that have included an alternative dossier and clarify the information given in a few columns. The CG members were requested to provide written comments for improvement related to the format and the type of information included in the table. ECHA will update the table according to the comments received.

A member inquired how to address the dossiers for national authorisations coming from Article 93. ECHA explained that the dossiers coming from Article 93 or 94 will appear in the Article 95 list once the evaluating CA will have finished the validation of the dossier.

This point (initially added as AoB to the agenda) was closed and as not reopened as AoB.

Actions

SECR: Open a newsgroup in CIRCABC to provide comments on the list presented.

All: To provide comments by 12 October.

6.6 Conflict between Article 35/36 procedures and MR derogations according to Article 37

The Commission briefly introduced this topic, which was tabled for discussion at the CA meeting. While taking a particular case as an example, the discussion would focus on the possible conflict between Article 35/36 procedures and Article 37 derogations from a broader perspective.

6.7 – 9th ATP and MR in sequence

The Commission informed the meeting of a question from a MS regarding the implementation of the 9th ATP Regulation to authorisations granted via MR in sequence. The Commission referred to document CA-May16-Doc.4.1–Final, in which it was agreed that new products must be classified and labelled according to the 9th ATP as from its date of entry into force (i.e. mid-August 2016).

The Chair invited CG members to submit written comments with their views on this topic by October 12th.

Actions

SECR: Open a newsgroup in CIRCABC to provide comments on the topic.

All: To provide input by 12 October.

6.8 – Additional data for permethrin

A member explained that a PNEC value for permethrin during the active substance approval was not accepted. A new PNEC value has been provided and is currently under evaluation by the evaluating MS (eMS). There is a need for a harmonised approach on how to use this new value at product authorisation level. The Chair invited the member to submit this question in writing to the SECR that would then open a newsgroup discussion for comments.

Actions

UK: To submit a description of the topic in writing to SECR.

SECR: Open a newsgroup in CIRCABC to provide comments on the topic.

All: To provide input by 12 October

7. Agreement of the action points and conclusions

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

Open session

8. Welcome to the open session

The Chair welcomed ASOs to the open session. Five observers from four ECHA accredited stakeholder organisations (ASOs) were present for the open session of the meeting.

9. Agreement of the agenda for the open session

The Chair introduced the draft agenda (CG-A-19-2016) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed without changes.

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

Actions

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

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

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

11. Draft minutes (non-confidential part) from CG-18

The Chair explained that the draft non-confidential CG-18 minutes were uploaded for commenting via Newsgroups and no comments were received. The CG members agreed on the draft minutes from CG-18.

Actions

SECR: to upload the CG-18 minutes into the relevant folders in the CG CIRCABC.

12. Administrative issues

12.1 Working Procedures

The CG SECR introduced a proposal prepared in consultation with the Commission (CG-19-2016-06) on how to distribute the 90-day period for the mutual recognition (MR) phase based on the comments provided by the CG members during and after the CG-18 meeting. The proposal contemplates the following phases:

A commenting period of 50 days to raise comments on the draft PAR and SPC, 6 days for the rMS to provide a table summarising those comments, 20 days for bilateral discussions with cMSs, 6 days for the rMS to provide the final PAR and latest version of the draft SPC as well as the final response to the comments, 5 days for the cMSs to indicate agreement to the SPC or the intention to submit a referral to the CG, and 3 days for the rMS to upload the agreed SPC and PAR in R4BP3. It is proposed that the submission of formal referrals would take place no later than 7 days after the 90 day period of the MR phase.

The Commission further explained that the objective of this proposal was to have a more structured procedure that could help to have a more efficient MR process. Related to the step in which the rMS provides the compilation to the comments, the Commission asked the members to reflect whether this step was really essential or if it could be merged with the bilateral discussions.

Members were in favour of having a more structured procedure and to have a pilot test, but stated the importance to have R4BP3 adapted to support this process and the challenge to manage short deadlines of 3 days.

CG members noted that the role of the applicant during the commenting phase should be specified. The Commission explained that Article 30(3)(b)&(c) of the BPR requires the rMS to send the draft SPC and draft PAR to the applicant and that his comments are taken into account when producing the PAR and draft SPC to be sent to the cMSs. Once they are sent to the cMSs, it would be at the discretion of the rMS to organise the interaction with the applicant in order to address the comments raised by cMSs.

CG members raised some points during the meeting and to be considered during the revision of the proposal:

- There might be situations where due to IT problems or particular situations a MS cannot respond in time. Therefore, the mention to tacit agreement of the MS with the draft SPC and PAR should be reconsidered. The Commission referred to the current WP for MR disagreements as a source of inspiration and clarified that what is important is to realise that, if comments are not submitted by a given date (except in the cases expressed above), it has to be understood that there are no comments from the silent cMSs. Otherwise, it would be unfair for the refMS as it would not have sufficient time to address the late comments and this would delay the whole MR phase.
- Specify how to express agreement with the SPC.
- Include a footnote indicating that MSs should make clear if some comments or parts of the comments should not be shared with the applicant by the refMS. In the absence of such indication, it would be understood that the refMS can transmit any comments to the applicant.

Once a final proposal is agreed by the CG, a pilot test could be started with a few cases in order to evaluate the procedure. The communication means during the pilot test would need to be defined, but R4BP3 is not going to be adapted to support the testing phase. In case of a positive outcome of the testing phase, the agreed procedure would then be implemented and work started for the necessary adaptation R4BP3 to support this procedure.

A newsgroup discussion will be opened to receive written comments on the proposal.

Actions

SECR: To open a Newsgroup forum for written comments on the proposal

All: to comment on the Newsgroup by 12 October.

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

13.1 Guidance on carrier-based biocidal products

The Commission introduced document CG-19-2016-13, which is a follow-up of the document presented at the last CG meeting. The Commission thanked those MSs and ASOs having submitted comments, including those to the latest version of the document before the meeting. The Commission also underlined those elements that were new in the document, which would deserve a new discussion before the document can be agreed. The Commission also stressed the need to provide clear examples to illustrate the different types of products, which was supported by some CG members.

The main element raised by CG members during the discussion was the distinction within category "Type B". A few CG members expressed that there should only be one category "Type B", where the carrier is not part of the composition. Thus, C&L should be based on the mixture without the carrier, as it was described in previous versions of the document. A member suggested checking this issue with the Reach/CLP experts by CG members when back home.

Another CG member asked for clear guidance on what has to be used for risk and efficacy assessment purposes (mixture vs. final product), as well as for phys-chem testing.

Regarding the proposal in paragraph 22 that a sub-chapter called "carrier" is created under IUCLID section 12.3, a CG member clarified that this would require IT development

by ECHA but that there were other alternatives under the phys-chem properties of the product.

The Chair invited CG members and ASOs to provide written comments by 12 October.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 12 October

13.2 Linking label claims and the product authorisation

The Commission introduced document CG-19-2016-12, which addresses the comments made at the last CG meeting and those submitted during the commenting period. The Commission thanked those MSs and ASOs having submitted comments, including those to the latest version of the document before the meeting.

The following elements were raised by CG members during the discussion:

- A CG member expressed concerns regarding paragraph 13(e), as adding a generic reference to the section of the PAR in which the label claims are addressed would lead in its views to the legal obligation to agree to the PAR as well. As a pragmatic solution, the member proposed that a reference to the PAR is included in the terms and conditions of the national authorisations only.

The Commission clarified that according to the Article 34(5) of the BPR, the terms and conditions should also be agreed during the MR phase and entered in R4BP by the refMS together with the agreed SPC and the PAR. Regarding the reference to the PAR in section 6 of the SPC, it should be understood as a crossed reference for information purposes. What has to be subject to agreement is the wording in section 6 as part of the SPC, which can be agreed under a harmonised wording.

- Upon request from a CG member, it was agreed to amend footnote 4 as follows: "Except where cleaning or other non-biocidal actions are considered in the assessment of the application as a relevant "instruction for use" for the pattern of use of the product and its biocidal efficacy".

- Upon request from some CG members, it was agreed to forward the paper to the Biocides Enforcement Group (BEG) before it is endorsed by the CA meeting. BEG members should have a look at it, particularly at the part which aims at facilitating the enforcement activities. Depending on the input provided by BEG, the paper might need some further discussions in the CG. In this respect, the Commission reminded the comments made by some MSs and reflected in footnote 10, so that it would be up to each CA to coordinate at MS level with the enforcement authorities how to check if label claims are acceptable (i.e. direct check of the PAR by controllers or through the biocides CA).

With the above-mentioned change in footnote 4, the Chair noted that document CG-19-2016-12 was agreed by the CG, with a reservation from a MS.

Actions

COM: to table the document at the next BEG meeting and CA endorsement will be postponed.

14. Feedback from working parties

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

The Commission updated the CG members on the conclusions reached during the 2nd meeting of the WP for the SPC sections of AVKs on September 19th. Most open issues have been closed and the Commission will prepare an updated version of the templates taking into consideration the discussion during the meeting. The updated version will be presented to the WP members for agreement.

As rodenticide experts are part of the WP, it would not be necessary to have a commenting period in the CG or the CA meeting. The Commission will produce a final version of the three documents, which accompanied by a cover note explaining the objective, the content and how to use the templates, will be tabled for agreement by the CG and formal endorsement by the CA meeting in November. Then the note with the annexes will be made available under the folder "documents finalised at CA meetings" of CIRCABC.

This would allow the applicants to make use of the harmonised sentences when preparing the draft SPCs in xml format to be submitted in the context of the renewal of the anticoagulant rodenticide products.

14.2 Frequently used sentences for the SPC

The CG SECR informed the phase for identifying other frequently used sentences in the SPC is finalised. Approximately 350 sentences were identified and experts advised to use additionally sentences identified in other harmonization projects. The discussion phase will now start with the objective of harmonizing the sentences provided and agree on the final list.

15. Any Other Business (open session)

15.1 Trends in product authorisation

The Chair presented documents CG-19-2016-14 and 15 and invited the meeting to take note of the reports, which were made available for information.

15.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-19-2016-11, which was made available for information.

15.3 List of substances meeting the exclusion or substitution criteria

The Chair informed the meeting that the updated version of the list (CG-19-1026-08) includes changes concerning some approved active substances. The Commission invited the CG members to review the list and report any inconsistencies.

Actions

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

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

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

15.4 IT issues

The SECR informed the meeting that the comments received related to improvements of R4BP3 were forwarded to the IT team in ECHA and have been noted. These will be discussed in the BPR IT users meeting on 14 November, where it will be discussed which items need to be prioritised.

Feedback was received from the CG members related to IUCLID 6. Some members mentioned that the functionality in general has decreased compared to version 5, for example in terms of searching. Additionally, some issues were reported related to accessibility and slow functioning of the system.

ECHA informed that the release of the new version of the SPC editor and R4BP3 is expected for 27 October. The new features relate to the introduction of the meta SPC

family concept and in R4BP3 the implementation of the amended same biocidal product Regulation. A few more case types will also be available for Union authorisations.

ECHA invited the CG members to provide suggestions via a newsgroup discussion for the IT users meeting in November.

The Commission informed the meeting that the adoption of the amended same biocidal product Regulation will be aligned with the availability of the new IT tools.

A CG member would like to put in practice the submission of "courtesy communications" within R4BP3 each time the refMS makes available the PAR and draft SPC to cMSs, and particularly when the agreed SPC has been entered in R4BP3, as this date triggers the start of the 30-day national authorisation phase and the submission of the translations by the applicants. For the purpose of the translations, the Commission referred to document CA-Sept13-Doc.6.2.d-Final.

Regarding the courtesy communications, the Commission would support this approach until R4BP is further adapted. In this respect, it was noted that priority should be given to the two above-mentioned steps, as well as to the confirmation of SPC agreement by cMSs (as it is explicitly mentioned in Articles 33(2) y 34(5) of the BPR).

Actions

SECR: To open a Newsgroup forum for written comments on IT tools for the BPR IT users meeting in November.

All: to comment on the Newsgroup by 31 October

15.5 Feedback on e-consultations

No e-consultations were tabled for discussion during this meeting.

15.6 Impact on family sizes for PT 8 due to tinting paste issue

The Commission briefly introduced a case where a family would consist of more than 10000 members and the possible challenges to manage this type of applications. The issue originates from the restriction to allow changes in solvents due to variations of pigments, perfumes and dyes, which results either in a high number of products in the initial BPF authorisation or post-authorisation notifications. It was also mentioned that this issue would also arise in future in BPFs of disinfectants.

Industry in cooperation with SE and DK will make a proposal on how to proceed.

Actions

SE, DK and IND: To prepare a document proposal and send to SECR.

SECR: To include Agenda Point for coming CG meeting.

15.7 Procedural issues

The Chair invited the CG members to propose candidates for Chair and vice Chair for the CG as the term for the current Chair will expiry in January next year. Further, the members were invited to volunteer for hosting the CG-21 meeting and The Netherlands expressed their willingness to volunteer.

Actions

MSs: to provide candidature for Chair/ vice Chair

MSs: to volunteer for hosting the January CG meeting.

16. Agreement of the action points and conclusions

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

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Part II - MAIN CONCLUSIONS & ACTION POINTS

19th meeting of the CG

20 September 2016

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 2 points.	**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-18	
No comments were received on the confidential minutes of the CG-18 meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-18 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.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR	
No informal referrals were discussed.	
5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
Two formal referrals were discussed. 1) Discussions were initiated with a view to reach an agreement in an upcoming teleconference involving all MSs 2) Discussions were initiated with a view to reach an agreement in an upcoming teleconference involving all MSs	**1-2) SECR:** to organize a teleconference with all MSs with the objective of finding an agreement by consensus. For the 2 formal referrals
5.4. Proposal to amend the RoP	
A CG member presented a proposal to amend the RoP regarding the reaching of agreement by consensus.	**SECR:** Open a newsgroup in CIRCABC to provide comments on the proposal to

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	amend the RoP. **All:** To provide comments by 12 October.
6 – Any Other Business	
6.1 – Late procedures	
ECHA presented the overview of late procedures COM made an overview of the presentation to be given during the CA meeting.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data
6.2 – Feedback on e-consultations	
One closed e-consultation was presented: A member presented the conclusions of an e-consultation regarding the data on C&L for biocidal products. CG members agreed to refer the matter to the Commission services.	**SECR**: Forward e-consultation to COM. **COM**: To provide feedback at the next CG meeting.
6.3 Renewal of anticoagulant rodenticides List of technical issues referred to ECHA working groups	
The SECR presented the list of technical issues that will be discussed in the WGs in September. The Chair presented two questions that were discussed by the CG. It was decided that a CG member would prepare a document with the way forward for the 2 questions. If no objections are found to the way forward the proposal will be considered as agreed upon	**DE**: Produce a document with a way forward for the 2 questions, including the case where the new TNG requires less data than the current TNG and submit to SECR. **SECR:** Open a newsgroup in CIRCABC to provide comments on the proposed way forward. **All:** To provide comments by 12 October.
6.4 Major changes to authorisations to reduce the active substance concentration	
COM made an update on the latest developments regarding the applicability of the additivity principle to some AVK rodenticides.	
6.5 Implementation of the procedure for alternative dossiers	
The SECR presented the list of alternative dossiers for implementing the procedure agreed during the CG-18 meeting	**SECR:** Open a newsgroup in CIRCABC to provide comments on the list presented. **All:** To provide comments by 12 October.
6.6 Conflict between Article 35/36 procedures and MR derogations according to Article 37	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
COM introduced the topic and some CG members provided some comments. Discussion will be followed up during the CA meeting	
6.7 9th ATP and MR in sequence	
COM introduced the topic and some CG members expressed their views briefly.	**SECR:** Open a newsgroup in CIRCABC to provide comments on the topic. **All:** To provide input by 12 October.
6.8 Additional data for Permethrin	
A CG member introduced the topic and will transmit it to the SECR in writing to open a newsgroup.	**UK**: To submit a description of the topic in writing to SECR. **SECR:** Open a newsgroup in CIRCABC to provide comments on the topic. **All:** To provide input by 12 October
Item 7 – 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	
8 –Welcome	
9 – 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.
10 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
11 – Draft minutes from CG-18	
No comments were received on the non-confidential minutes of the CG-18 meeting. The draft non-confidential minutes were agreed.	**SECR:** to upload the CG-18 minutes into the relevant folders in the CG CIRCA BC.
12 – Administrative issues	
12.1 Working procedures	
The SECR presented a proposal on the period of MR based on the comments received from MSs. Members will provide their comments in writing to the proposal.	**SECR:** To open a Newsgroup forum for written comments on the proposal

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	All: to comment on the Newsgroup by 12 October.
13 – Harmonisation of technical and procedural issues in relation to product authorisation	
13.1 Guidance on carrier-based biocidal products	
COM presented the updated version of the document regarding the guidance on carrier-based biocidal products. Members will provide their comments in writing to the document.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 12 October
13.2 Linking label claims and the product authorisation	
COM presented the updated version of the document regarding linking label claims and the product authorisation. A footnote will be amended following the comments by the members. The document has been agreed with the reservation of a member and will be submitted to BEG for consultation.	**COM**: to table the document at the next BEG meeting and CA endorsement will be postponed.
14 – Feedback from working parties	
14.1 - Development of standard sentences for the SPC sections of anticoagulant rodenticides	
The Commission reported on the discussion during the meeting of the WP on 19 September.	
14.2 - Frequently used sentences for the SPC	
ECHA reported on the status of the activities of the Working Party.	
15 – Any Other Business	
15.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
15.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	
15.3 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. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	updated version for next CG meeting.
15.4 IT issues	
ECHA presented the comments received on how to improve R4BP3 and the feedback from the IT team. The members gave comments on the functioning of IUCLID 6. ECHA updated on the coming IT developments.	**SECR:** To open a Newsgroup forum for written comments on IT tools for the BPR IT users meeting in November. **All:** to comment on the Newsgroup by 31 October
15.5 – Feedback on e-consultations	
No e-consultations were presented.	
15.6 - Impact on family sizes for PT 8 due to tinting paste issue	
COM introduced the issue regarding the size of a PT 8 family for tinting paste products.	**SE, DK and IND**: To prepare a document proposal and send to SECR. **SECR**: To include Agenda Point for coming CG meeting.
15.7 - Procedural issues	
Candidates for Chair and vice Chair to make themselves known before the CG-20 meeting. CG members to inform the SECR for volunteers to host the January CG-21 meeting. NL has already volunteered to host the meeting.	**MSs**: to provide candidature for Chair/ vice Chair **MSs:** to volunteer for hosting the January CG meeting.
16 – Agreement of the action points and conclusions	
The list of action points and conclusions was agreed by the CG meeting.	

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ANNEX II

Final agenda

19th meeting of the Coordination Group (CG)

20 September 2016 – from 9:00 to 17:00

Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-19-2016

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-18

CG-M-18-2016_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-19-2016-01

For information

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

Links to disagreements

For discussion

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

Links to disagreements

For discussion and agreement

5.4 Proposal to amend the RoP

For discussion

Item 6 - Any Other Business

6.1 Late procedures

CG-19-2016-16

For information

6.2 Feedback on e-consultations

CG-19-2016-02 and CG-19-2016-03

Links to e-consultations

For discussion and agreement

6.3 Renewal of anticoagulant rodenticides - List of technical issues referred to ECHA working groups

CG-19-2016-10

For information

6.4 Major changes to authorisations to reduce the active substance concentration

For information

6.5 Implementation of the procedure for alternative dossiers

CG-19-2016-04 and CG-19-2016-05

For discussion

6.6 Conflict between Article 35/36 procedures and MR derogations according to Article 37

For discussion

6.7 9th ATP and MR in sequence

For discussion

6.8 Additional data for Permethrin

For discussion

Item 7 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 8 – Welcome

Item 9 – Agreement of the agenda

CG-A-19-2016

For agreement

Item 10 – Declaration of interest in relation to the agenda

Item 11 –Draft minutes from CG-18

CG-M-18-2016_Draft non confidential

For agreement

Item 12 – Administrative issues

12.1 Working procedures

CG-19-2016-06

For discussion

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

13.1 Guidance on carrier-based biocidal products

CG-19-2016-13

For discussion

13.2 Linking label claims and the product authorisation

CG-19-2016-12

For discussion and agreement

Item 14 – Feedback from working parties

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

For information

14.2 Frequently used sentences for the SPC

CG-19-2016-07

For information

Item 15 – Any Other Business

15.1 Trends in product authorisation

CG-19-2016-14 & CG-19-2016-15

For information

15.2 Deadlines for application for product authorisation

CG-19-2016-11

For information

15.3 List of active substances meeting the exclusion or substitution criteria

CG-19-2016-08

For information

15.4 IT issues

CG-19-2016-09

For information

15.5 Feedback on e-consultations

Links to e-consultations

For discussion and agreement

15.6 Impact on family sizes for PT 8 due to tinting paste issue

For discussion

Item 16 – Agreement of the action points and conclusions

For agreement

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