14 March 2016

CG-M-15-2016 FINAL public

Final minutes of the 15th meeting of the Coordination Group (CG)

20-21 January 2016

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Director General in the Ministry of Health welcomed the participants to the meeting and remarked the impact of the items to be discussed in the meeting and the relevance of the implementation of the biocidal Products Regulation for the ES Competent Authority.

The Chairman welcomed participants to the fifteenth CG meeting. 41 members from 22 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and one representative from ECHA were present for the full meeting. The Chair asked the CG members their agreement that participants from the ES CA attending the meeting as observers.

The Chair thanked the ES CA for hosting the meeting and for their support in the organization of the meeting.

The list of attendees is given in Part III of the minutes.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-15-2016) and invited participants to add any 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.

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-14

The SECR explained that the draft confidential CG-14 minutes had been uploaded for commenting via Newsgroups. No comments had been received on the confidential minutes. No comments were received during the meeting and the CG members agreed on the draft minutes from CG-14 meeting.

Actions

SECR: to upload the CG-14 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 two informal referrals submitted just before the meeting were to be taken as formal referrals since the deadline of 90-days for the mutual recognition was already over. These two referrals were presented in the agenda item 5.3.

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

There was a discussion on a formal referral.

1) Several CG members had commented on this formal referral after CG-14 meeting and a conference call with the rMS and concerned MSs took place, where further clarification was requested to the rMS on the use pattern and the field of use of the biocidal product.

Since an agreement was not reached during the meeting and taking into account that the 60-day period has already expired, the rMS was requested to refer the disagreement to the Commission according to Article 36(1) of the BPR.

Two formal referrals submitted immediately before the CG meeting were just introduced. Further discussions will follow as stated in the Working Procedures for the Coordination Group.

2) An introduction was provided by the rMS and the initiating MSs. The documents will be distributed after the meeting and further discussions will follow via written procedure and during the Coordination Group meeting in March.

3) An introduction was provided by the rMS and the initiating MSs. The documents will be distributed after the meeting and further discussions will follow via written procedure and during the Coordination Group meeting in March.

Actions

SECR:

2) Distribute the referral document and follow-up the discussion as stated in the Working Procedures
3) Distribute the referral documents and follow-up the discussion as stated in the Working Procedures

All:

2) To provide comments on the formal referral by 11 February

3) To provide comments on the formal referral by 11 February

6. Any Other Business (closed session)

6.1 Late procedures

The Commission briefly introduced the reports prepared by ECHA. Regarding pending applications submitted under the BPD, the Commission encouraged MSs to continue with the update of the information available in R4BP. This involves as a priority closing obsolete cases and cases where the product authorisation has been already granted but the asset in R4BP has not been created yet.

Actions

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

6.2 Revision of LoEPs in connection with new data becoming available at the product authorisation stage

As a follow-up of the discussion during last CG meeting, the Commission explained its views regarding the implementation of Article 15 of the BPR and the revision of LoEPs.

The Commission informed CG members that Article 15 has not to be applied to amend the LoEP. Article 15 of the BPR has to be applied only in those cases foreseen in Article 15, i.e. where there are significant indications that:

- the conditions in Art 4(1) are no longer met: in practice, it should only be used if the substance had to be banned;

- the conditions in Art 5(2) are no longer met: in practice, it should only be used if the substance had to be banned;

- the use of the AS in biocidal products and/or TA raises significant concern about the safety of those products and/or TA: in practice, it should only be used if a use had to ban.

Therefore, unless a MS demonstrates that the above conditions are met, the Commission would not re-open an AS approval.

Regarding the revision of the LoEP, the Commission considers that as they are not explicitly mentioned in the approval Regulation, they should just be considered as a compilation of the peer reviewed scientific information to be used in the assessment of biocidal products. When it comes to a potential legal basis to support the update of a given EP, a link could be made with paragraph 8 in annex VI to BPR. As the evaluating CAs shall make use of the latest available information, where the new information affects an EP of the AS, it sounds sensible that the new information is peer reviewed (and agreed by all MSs) before it is used by all the eCAs dealing with a class of products. Otherwise each eCA would consider different information or in a different way, which would certainly be a chaos for MR and even result in unequal treatment to applicants. In any case, the Commission made clear that the review of the agreed LoEP should be limited to very exceptional cases, as it might trigger in the end the review of all existing authorisations (e.g. as for the imidacloprid case).

Finally, the Commission pointed out that what is still missing is a clear working procedure to do so by the relevant WGs, with a final endorsement by the BPC. In this context, the procedure described in document BPC-8-2014-03 should be agreed and implemented as soon as possible, as the information becoming available form third party dossiers is just one scenario out of the seven identified in that paper.

The chairman noted that CG members encouraged the development and finalization of the BPC document on the new data becoming available after approval of active substances.

Actions

SECR: to convey the message to BPC SECR.

6.3 How to deal at Product authorisation with reference sources with a higher purity than the minimum purity in the implementing regulation

The SECR informed that during last CG meeting and the commenting period several MSs had suggested referring this point to the Analytical Methods and Physico-Chemical Properties WG for a technical discussion on whether the technical equivalence should be requested to the applicant. This discussion had been included in the agenda for the WG meeting taking place in the last week of January.

After the discussion at the ECHA APCP WG and depending on the outcome of the discussions, it should be clarified whether further discussions at regulatory or policy level are needed on this point, within the Chairs of the CG and APCP WG.

6.4 Feedback from e-consultations

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

6.5 In-can preservatives in rodenticides and other PTs

The Commission briefly reminded MSs about the task referred to in paragraph 22 and footnote 4 in document CA-Sept14-Doc.5.5 – Final.

Actions

rMSs: to submit the relevant information to the CG SECR.

6.6 Evaluation of a BPF

A member presented the document regarding the evaluation of a biocidal products family. Different views were provided on whether one of the meta-SPCs should be included in the biocidal product family, due to the differences in the composition. MSs were invited to submit written comments on the two questions raised by the member in their document.

Actions

SECR: to set up a Newsgroups in CIRCABC

All: to comment by 11 February.

6.7 DEET Exposure Assessments

A member presented the document regarding the approach followed in the exposure assessment for DEET containing products. It was also raised the issue on whether a harmonization approach should be used and how to handle the mutual recognition applications where a different exposure assessment method has been used.

The Commission welcomed that this issue is brought to the CG for discussion as it might have relevant implications in terms of MR procedures. However, it noted too that the technical discussion, which is in the origin of the potential regulatory issues, should have been taken place earlier, taking into account that the deadline in Article 89(3) of the BPR to have DEET products authorised in all the MSs is already over since July 2015.

The Commission supported the views that the HH exposure WG should address this problem as a matter of priority not only because of the identified issue for DEET products, but mainly to avoid the same problem with applications for products containing similar repellents (e.g. IR 3535).

The Commission also mentioned that in the absence of a harmonised methodology, what is important is that the assessment carried out by the refMS shows that the conditions in Article 19 of the BPR are met and CMSs should have some flexibility to accept the refMS's model.

The Commission added that without having a clear certitude for a date by when the HH exposure WG would have solved the matter and on account of the already existing delays, the on-going applications for MR cannot be put on hold *sine die*. If a solution cannot be found in the short-term, MR disagreements should in principle be referred to the CG to decide whether or not a product meets the conditions in Article 19 of the BPR. If a CG agreement is not found, then a Commission decision would have to settle the matter.

MSCAs were invited to submit comments on both the regulatory elements regarding the mutual recognition process and a description of which technical issues should be discussed within the Human Exposure WG, both regarding DEET and other actives substances (i.e. repellents) with a similar use pattern.

Actions

SECR: to set up a Newsgroups in CIRCABC

All: to comment by 11 February.

SECR: to forward the elements to the discussed to the Human Exposure Working Group

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 three 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-15-2016) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed with the inclusion of one item under AoB regarding the antifouling issues raised by CEPE.

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. Agreement of draft minutes (non-confidential part) from CG-14

The SECR explained that the draft non-confidential CG-14 minutes were uploaded for commenting via Newsgroups. No comment had been received on the non-confidential minutes. No comments were received during the meeting and the CG members agreed on the draft minutes from CG-14.

Actions

SECR: to upload the CG-14 minutes into the relevant folders in the CG CIRCABC.

12. Administrative issues

12.1 Revision of Rules of Procedure & Working procedures

The SECR informed the meeting about the revision of the Rules of Procedure to take into account the agreement during CG-14 meeting on the publication in the public CIRCABC platform of the non-confidential documents discussed at CG together with the minutes of non-confidential sections of CG meetings. It also addresses a previous agreement during CG-11 that executive summaries of formal referrals on which the CG has reached an agreement, after confidentiality check with the applicant, should be made publically available. The Commission proposed to include Working Parties meetings within the Article in the Rules of Procedure on the role of the CG SECR. It was suggested to prepare a proposal on this point for next meeting and agree on the current version.

The revision of the Working Procedures for resolving disagreements of the Coordination Group takes into account in Annex I the update of the "R4BP3 MANUAL for authority users; How to run BPR processes with R4BP 3 in Member State competent authorities" and in Annex II includes the meeting dates for the Coordination Group in 2016 and the timelines for disagreements, including the preferred submission.

Both Rules of Procedure and Working Procedures were agreed.

Actions

SECR: to upload the updated and agreed version of the Rules of Procedure and Working procedures onto S- CIRCABC.

12.2 Code of Conduct for applicants

The SECR presented the Code of Conduct submitted to applicants attending Coordination Group meetings for discussion of formal referrals. The proposed version included in this document had been updated and adapted to the Rules of Procedure and practices of the Coordination Group.

Several general remarks were made by MSCAs and stakeholders, and it was proposed that CG members and stakeholders could provide further comments in writing.

Actions

SECR: to set up a Newsgroups in CIRCABC.

All: to comment by 11 February.

12.3 Election Vice-Chair of the Coordination Group

The Chair thanked the Vice-Chair for the job done during the last months and support during the last CG meetings preparation. The Chair informed the meeting that a nomination had been received for the position of Vice-Chair of the Coordination Group and asked for the CG meeting agreement. Since the CG members agreed to the election, the nominee was elected as new Vice-Chair of the Coordination Group for the next one year period.

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

13.1 Q & A document on the simplified authorisation procedure

The Commission introduced document CG-15-2016-02 as a follow-up of the discussions at the last CG meeting and thanked those MSs having contributed during the commenting period.

CG members welcomed the paper as a good starting point for the discussion and raised a number of questions. The Commission addressed the following issues discussed at the meeting:

- LoA (Q1): a LoA for an AS in category 6 of Annex I is only needed for an application for product authorisation under the normal procedure but not under the SAP.

- Producing a PAR (Q3): even if a PAR template has not been agreed yet, nothing prevents the eCA to produce a document summarising the assessment of the application.

- SoC guidance (Q9): A CG member asked whether this guidance (only addressing HH issues) would be suitable for the SAP. The Commission asked CG members to make any alternative proposal.

- C&L information on the AS (Q9): additional information on the AS can only be considered for the purpose of amending entries in Annex I; at the product authorisation stage, the As being in Annex I is sufficient.

- Authorisation number (Q 13): several MSs mentioned that they would not feel comfortable having on the labels the authorisation number of the MS of the eCA. Other MSs would have no problem with this.

  The Commission clarified that as the products are only authorised by the eCA, the products in the other MSs are not authorised but only notified. Hence, they cannot have an additional authorisation number in the notified MSs.

  Still those MSs would like to have a kind of "national registration" number available for inspectors, who would not have access to R4BP and to whom training on the specificities of the SAP would be almost impossible.

  If that national registration number had to be on the label for enforcement purposes, then the Commission referred to the problem identified in the second paragraph of the proposed answer. A CG member having been the eCA for a product, also raised the point that where the product has a multilingual labelling, the latest MS giving the registration number would delay the placing on the market in all the MSs. Industry representatives mentioned that preparing a label would need to have all the information needed available at least three months before the product can be labelled accordingly.

  The Commission underlined that this would be against the spirit of the SAP in the BPR. In this context, a CG member mentioned that the national registration number could be put just on the labels of the batches placed on the market after the national registration number has been given.

- National register of notified products (Q14): the BPR does not explicitly prevents a MS from doing it, but the Commission considers it as not essential (i.e. info available in R4BP) and time consuming (permanent update, copy paste exercise, possible errors, etc.) in a context with other key priorities in terms of AS approval and product authorisation.

- Notification of individual products of a BPF (Q15): several CG members reported issues when the AH wants to notify only one product. The Commission mentioned that according to previous input from ECHA this should be possible. The issue will be forward to ECHA for clarification.

- Placing on the market (Q 16): even if currently the notified MSs have to close the case and upload the SPC of the notified product, the AH could place the product on the market if there is no reaction from the notified MS within the thirty days.

CG members proposed including new Q&A pairs on the following topics:

- In situ products,
- Applications under the SBP Regulation,
- Whether in can preservatives should be regarded as possible SoCs,

CG members were invited to provide written comments with a view to have an updated version of the document for discussion at the next CG meeting.

Actions

SECR: To check with IT colleagues the inclusion of SA assets in ECHA website

to set up a Newsgroups in CIRCABC

All: to comment by 11 February.

13.2 Harmonization of translations in SPC sections

The SECR presented a proposal to establish a working party with industry and MSCAs representatives to work on the identification of common/frequently-used sentences in

SPCs and the development of the translations of these sentences. The establishment of a list of common/frequently-used sentences for the different free text SPC sections and their translations into the official languages would be helpful for industry to simplify the preparation of the SPCs and facilitate their translation and for the MSCAs to check the SPCs and their translations. That list would be particularly relevant for mutual recognitions and Union authorisations but would also be helpful for product authorisations in Member States with several official languages.

Several CG members supported the standardisation and identification of common/frequently-used sentences in SPCs but considered that the translations should be out of the remit of the Working party and be conducted at national level. The Commission supported the proposal and invited MSs to reflect on the priorities for the harmonisation of the SPCs to be developed by the Working party (i.e. starting by a given PT or limited group of PTs (e.g. disinfectants) or having a wider approach valid for any PTs).

Actions

SECR: to set up a Newsgroups in CIRCABC.

All: to comment by 11 February.

13.3 Consideration of cut-off dates for the implementation of paragraph 8(a) of Annex VI to the BPR

The Commission introduced document CG-15-2016-08 as a follow-up of a specific question submitted by a CG member acting as refMS in a MR procedure. The main purpose of the document is to find a balance between the mandate in the BPR to take into account new relevant information while sticking to the mandatory deadlines in the Regulation too.

Overall CG members having taken the floor welcomed the approach in the paper. The following issues were discussed at the meeting:

- New information to be considered by the e-CA (*para. 7*): the document should refer to the excel list compiling information on the approved actives substances and the exclusion/substitution criteria that are met.

- New information becoming available during the MR phase to a CMS (e.g. on a new PNEC value): the new information has to be peer reviewed and agreed by the BPC before the EP is amended and it can be applied to on-going applications and already authorised products (e.g. imidacloprid case).

- Possible unequal treatment of applicants in terms of comparative assessment and validity of the authorisation (*example in Annex I*): so far neither the authorisations grated under the BPD nor authorisations that might have been granted under the BPR before the AS becomes a CFS are reviewed to shorten the validity of the authorisation, and the comparative assessment is postponed to the renewal stage. Therefore, the products would be treated in the same manner as those having been authorised just before the AS becomes a CFS (which is the only way forward compatible with the product authorisation deadlines).

- Consideration of new information in the context of MR disagreements (*section 2.4*): the agreement of the SPC should be based on the PAR proposed by the refMS without considering new information. Where a disagreement is submitted as a formal referral to the CG, the CG will decide on a case by case basis whether or not new information should be considered to reach an agreement (as per the current practice).

- Information submitted by applicants (*para. 8.b*): the eCA will decide on a case by case basis whether new information should be considered as a result of the consultation with the applicant (e.g. depending on the relevance and extend of such new information, available time to meet the deadlines, etc..).

CG members were invited to provide written comments with a view to have an updated version of the document for discussion at the next CG meeting.

Actions

SECR: to set up a Newsgroups in CIRCABC

All: to comment by 11 February.

13.4 EU statements & hazard statements

The Commission introduced document CG-15-2016-04 as a follow-up of a specific question submitted by a CG member acting as eCA in a BPF application.

The way forward proposed in the document was agreed by the CG, so the Commission will update the two revised documents and table them for endorsement by the CA meeting in March.

As these documents are going to be reviewed, the Commission asked CG members whether they would like to add any new further Q&A pairs, so that they could also be discussed at the next CG meeting and if agreed, also incorporated in the updated versions to be endorsed by the CA meeting.

Actions

SECR: to set up a Newsgroups on new Q&A pair in CIRCABC

All: to comment by 11 February.

COM: To update the revised documents and table it for endorsement at CA level.

If further Q&A pairs are proposed by MSs, these will also be taken up and the documents would be scheduled for next CG and CA meeting.

13.5 Cut-off dates regarding relevance of new guidance

The SECR informed the meeting about the BPC agreement regarding the relevance of new guidance applicable to the active substance approval. In light of the BPC agreement, it was suggested to consult the Coordination Group on the need to revise the applicability of new guidance for the authorisation of biocidal products. It was clarified that ECHA did not suggest changing the cut-off dates but the purpose was to get MSs views on this.

Several MSs expressed that they would not change the cut-off dates and one member considered that a revision could be done in order to reduce the cut-off dates. Upon request of a member, the Commission clarified that paragraph 11 of the current guidance already provides for the possibility of applying new guidance where there is such a level of concern that would also trigger the revision of existing authorisations.

The Industry representatives considered that including a shorter cut-off date would make very difficult for all companies (particularly for SMEs) being aware of the implementation of new guidance.

The Chair suggested a commenting period to collect more MSs views on whether the cut-off dates for product authorisation should be revised.

Actions

SECR: to set up a Newsgroups in CIRCABC.

All: to comment by 11 February.

14. Feedback from working parties

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

The Commission briefly reported on the meeting that took place on January 20th in Madrid. The overall discussion was very positive, with MSs and stakeholders showing a constructive approach to the harmonisation exercise.

Now there will be 3-week commenting period for WP members to submit written comments and then the Commission will have to produce an updated version of the discussion documents. A new meeting could be scheduled back to back to the May CG meeting in Brussels.

15. Any Other Business (open session)

15.1 Trends in product authorisation

Due to time constraints, the Chair briefly introduced the reports prepared by ECHA (documents CG-15-2016-17&18).

15.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-15-2016-19, 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 includes changes concerning some approved active substances.

Actions

Rapporteur MSs: to check the new information

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.

15.4 Questions regarding R4BP 3 / SPC / IUCLID

The Commission presented an issue regarding an extra field in the SPC editor on additional information on packaging material. This extra field will be removed for consistency with the agreed template. However, it was considered interesting asking MSs whether this information should be included in the PAR template and whether the PAR template should be amended accordingly.

MSs supported the use of the current PAR template as this information is only relevant for a few products. Hence, it was agreed not the revise the PAR template as this information can in any case be included in the PAR on a case-by- case basis.

Actions

CG SECR: To give feedback to the BPR IT User Group

15.5 Feedback on e-consultations

Two e-consultations were presented for MSs consideration.

1) A member reported on the outcome of the Newsgroups discussions on how to deal with applications under Article 55(1) derogation in R4BP. Since the implementation of this process in R4BP is not considered as a priority, it was

considered that applications for Article 55(1) derogations can be submitted outside R4BP for the time being.
The Commission added though that in future, all the applications including Article 55(1) should be dealt with via R4BP for better tracking purposes. In this context the Commission also reminded that what is important in these cases is to properly justify that there is a danger to public health that cannot be controlled by other means and to immediately inform the Commission and the other MSs of such derogation.

2) A member presented an e-consultation on the control of bedbugs resistant to synthetic pyrethroids. The member requested MSCAs and ASOs views on authorized products with active substances other than synthetic pyrethroids that might be available.

Actions

All:

2) to comment by 11 February in the newsgroups in CIRCABC

15.6 BPF concept and tinting pastes

A member presented the follow-up from a consultation regarding the notification procedure for Biocidal Product Families which contain tinting pastes instead of pigments. The CG acknowledged that the limits of the BPR regarding the notification of all products in the composition with the only exception of variations in perfumes, pigments and dyes (PPD) shall be respected.

The Commission also noted that another option to not to have to notify products in accordance with Article 17(6) of the BPR is to have the individual products identified in the authorisation of the BPF.

MSs were invited to propose new Q&A pairs addressing the handling of changes to PPD and tinting pastes with a view to be further discussed at the next CG meeting.

Actions

CEFIC/MSs: to provide proposals for Q&A pairs.

SECR: to set up a Newsgroups in CIRCABC.

All: To comment by 11 February.

15.7 Antifouling issues raised by CEPE

The Chairman informed the meeting that following from the CEPE request during last CG meeting to organize a workshop on the authorisation of antifouling products, a proposal on how to address the different issues in the CEPE proposal had been prepared.

The proposal includes a way forward for the proposed subjects, the scope of the discussions and a suggestion of forum for these discussions. The document will be distributed and will be subject to comments via Newsgroups.

Actions

SECR: to set up a Newsgroups in CIRCABC.

All: To comment by 11 February.

16. Agreement of the action points and conclusions

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

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Part II - MAIN CONCLUSIONS & ACTION POINTS

Main conclusions and action points

(Agreed at 15th meeting of the CG)

(20-21 January 2016)

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
CLOSED SESSION	
2 – Agreement of the agenda for the closed session	
The agenda for the closed session was agreed.	**SECR:** to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.
3 – Declaration of interest in relation to agenda, closed session	
No declarations of conflicts of interest were made.	
4 – Draft minutes from CG-14	
No comments were received during the meeting on the CG-14 minutes. The minutes were agreed.	**SECR:** to upload the CG-14 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	
Two informal referrals received immediately before the meeting were taken out as formal referrals.	
5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
A formal referral was discussed. 1) Since an agreement was not reached, the formal referral will be submitted to the Commission. Two formal referrals were presented. 2) An introduction was provided by rMS and initiating cMS. Further discussions will follow via written procedure and during CG March meeting. 3) An introduction was provided by rMS and initiating cMS. Further discussions will follow via written procedure and during CG March meeting.	**SECR**: 2) Distribute the referral documents and follow-up the discussion as stated in the Working Procedures 3) Distribute the referral documents and follow-up the discussion as stated in the Working Procedures **All MSs**: 2) to provide comments on the formal referral by 11 February 3) to provide comments on the formal referral by 11 February

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
6 – Any Other Business	
6.1 – Late procedures	
COM presented the reports on timelines for different procedures and made a specific reference to the still open cases submitted under the BPD.	**All MSs:** To check the information in R4BP and where necessary, take the relevant actions.
6.2 – Revision of the LoEPs in connection with new data becoming available at the product authorisation stage	
The Commission provided a follow-up of the discussion during last CG meeting on implementation of Article 15 and the revision of LoEPs. CG members encouraged the development and finalization of the BPC document on the new data becoming available after approval of active substances.	**CG SECR:** to convey the message to BPC SECR
6.3 – How to deal at PA with reference sources with a higher purity than the minimum purity in the implementing regulation	
The SECR informed that upon MSs request, the issue has been included in the agenda for next APCP WG. After the technical discussion, further regulatory/policy discussions might be needed within CG/CA meetings.	
6.4 – Feedback on e-consultations	
No closed e-consultation had taken place since the previous meeting.	
6.5 – In-can preservatives in rodenticides and other PTs	
The Commission reminded MSs about their tasks.	**rMSs**: to submit the relevant information to the CG SECR.
6.6 – Evaluation of a BPF	
The member presented the document. Different views were provided and MSs were invited to submit written comments on the two questions raised by the member.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.
6.7 – DEET Exposure Assessment	
The member presented the document. MSs were invited to submit written comments on the regulatory elements regarding mutual recognition and a description of what should be discussed within the Human Exposure WG, both regarding DEET and other substances with similar use pattern. Commission remarked that on-going applications for MR should not be put on hold.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February **SECR:** to forward the elements to be discussed to the Human Exposure Working Group.
7 – Agreement of the action points and conclusions	
The list of action points and conclusions was agreed by the CG meeting.	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
OPEN SESSION	
9 – Agreement of the agenda for the open session	
The agenda for the open session was agreed with the inclusion of an item under AoB regarding the antifoulants workshop.	**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, open session	
No declarations of conflicts of interest were made.	
11 – Draft minutes from CG-14 (non-confidential part)	
No comments were received during the meeting on the CG-14 minutes. The minutes were agreed.	**SECR:** to upload the CG-14 minutes into the relevant folders in the CG CIRCABC.
12 – Administrative issues	
12.1 Working procedures	
The SECR informed the meeting about the revision of the Rules of Procedure and Working Procedures. The Rules of Procedure/Working Procedures were agreed.	**SECR:** to upload the updated and agreed version of the Rules of Procedure and Working procedures onto S-CIRCABC. **COM/ECHA:** to make a proposal for next meeting regarding involvement of CG SECR in WP meetings.
12.2 Code of Conduct for applicants.	
The SECR informed about the revision of the Code of Conduct submitted to applicants attending CG meetings. Members were invited to provide further comments in written.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.
12.3 – Election Vice-Chair of the Coordination Group	
The Chair informed that a nomination had been received for the position of Vice-Chair. CG members agreed and the member was appointed as new Vice-Chair of the CG.	
13 – Harmonisation of technical and procedural issues in relation to product authorisation	
13.1 – Q&A document on the simplified authorisation procedure	
The Commission presented the document. Several remarks were made to the Q&A Annex. A discussion took place on the authorisation number. MSs were invited to provide written comments.	**SECR:** To check with IT colleagues the inclusion of SA assets in ECHA website to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.
13.2 – Harmonization of translation in SPC sections	
The SECR presented the proposal for setting up a working party to harmonize the translations in SPC sections. MSs were invited to reflect on the priorities for harmonization on SPC sections and the availability of resources.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
13.3 – Considerations of cut-off dates for the implementation of paragraph 8(a) of Annex VI to the BPR	
The Commission presented the document. MSs requested some clarification about the document.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.
13.4 EUH statements & hazard statements	
The Commission presented the document and clarified the use of EUH statements. The way forward proposed in the document was agreed by the CG.	**SECR:** to set up a Newsgroups on new Q&A pair in CIRCABC **All:** to comment by 11 February. **COM:** To update the revised document and table it for endorsement at CA level. If further Q&A pairs are proposed by MSs, these will also be taken up and the documents would be scheduled for next CG and CA meeting.
13.5 Cut-off dates regarding relevance of new guidance	
The SECR informed about the BPC agreement regarding the a.s. approval and requested MSs views on whether the cut-off dates for product authorisation should be revised.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.
14 – Feedback from working parties	
14.1 - Development of standard sentences for the SPC sections of anticoagulant rodenticides	
The Commission reported on the outcome of the Working Party meeting.	
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 reports, 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 includes changes concerning some approved active substances.	**Rapporteur MS:** to check the new information **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.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
15.4 – Questions regarding R4BP3 / SPC/ IUCLID	
The Commission presented an issue regarding the extra fields on packaging material in the SPC editor. It was agreed not to revise the PAR template, which can be modified on a case-by-case basis.	**CG SEC:** to give feedback to the BPR IT User Group
15.5 – Feedback on e-consultations	
Two e-consultations were presented. 1) A member reported on a Newsgroup discussion on the applications under Art. 55(1) derogation in R4BP3. Applications can be submitted outside R4BP for the time being. 2) A member presented an e-consultation regarding control of bedbugs.	**All**: 2) to comment by 11 February in the Newsgroups in CIRCABC.
15.6 – BPF and tinting pastes	
The member presented the outcome of the consultation. The CG acknowledged that the limits of the BPR shall be respected. Another way forward was presented. New Q&A pairs will be proposed to be included in the BPF document (Annex IV) addressing the handling of PPD changes and tinting pastes.	**CEFIC/MSs:** to provide proposals for Q&A pairs **SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.
15.7 – Antifoulings issues raised by CEPE	
The Chairman mentioned that a document to address CEPE's requests regarding the authorization of antifoulants will be uploaded for comments.	**SECR:** to set up a Newsgroups in CIRCABC **All:** to comment by 11 February.
16 – Agreement of the action points and conclusions	
CG meeting agreed on action points and conclusions.	

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ANNEX II

20 January 2016

Final agenda

15th meeting of the Coordination Group (CG)

20 January 2016 – from 14:00 to 17:30
21 January 2016 – from 9:00 to 12:30

Madrid. Ministry of Health, Social Services and Equality
Paseo del Prado, 18, 28014 Madrid

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-15-2016

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-14

CG-M-14-2015_draft-confidential

For agreement

Item 5 – Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-15-2016-01

For information

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

For discussion

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

Link to disagreement

For discussion

Item 6 - Any Other Business

6.1 Late procedures

CG-15-2016-15&16

For information

6.2. Revision of LoEPs in connection with new data becoming available at the product authorisation stage

For information

6.3 How to deal at Product Authorisation with reference sources with a higher purity than the minimum purity in the implementing regulation

For information

6.4 Feedback on e-consultations

For information

6.5 In-can preservatives in rodenticides and other PTs

For information

6.6 Evaluation of a BPF

CG-15-2016-10

For discussion

6.7 DEET Exposure Assessments

CG-15-2016-14

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-15-2016

For agreement

Item 10 – Declaration of interest in relation to the agenda

Item 11 –Draft minutes from CG-14

CG-M-14-2015_draft-non-confidential

For agreement

Item 12 – Administrative issues

12.1 Revision of Rules of Procedure & Working Procedures

CG-15-2016-05&06

For agreement

12.2 Code of conduct for applicants

CG-15-2016-07

For agreement

12.3 Election Vice-Chair of the Coordination Group

For agreement

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

13.1 Q&A document on the simplified authorisation procedure

CG-15-2016-02

For discussion

13.2 Harmonization of translations in SPC sections

CG-15-2016-03

For discussion

13.3 Consideration of cut-off dates for the implementation of paragraph 8(a) of Annex VI to the BPR

CG-15-2016-08

For discussion

13.4 EUH statements & hazard statements

CG-15-2016-04

For discussion

13.5 Cut-off dates regarding relevance of new guidance

CG-15-2016-11

CA document CA-july2012-doc6.2d (final)

BPC document BPC-13-2015-07

For discussion

Item 14 – Feedback from working parties

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

For information

Item 15 – Any Other Business

15.1 Trends in product authorisation

CG-15-2016-17&18

For information

15.2 Deadlines for application for product authorisation

CG-15-2016-19

For information

15.3 List of active substances meeting the exclusion or substitution criteria

CG-15-2016-09

For information

15.4 Questions regarding R4BP3 / SPC/ IUCLID

For discussion

15.5 Feedback on e-consultations

Link to e-consultations

For information

15.6 BPF concept and tinting pastes

CG-15-2016-12&13

For discussion

15.7 Antifouling issues raised by CEPE

For information

Item 16 – Agreement of the action points and conclusions

For agreement

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