15 July 2016

CG-M-17-2016 non-confidential

Final non-confidential minutes of the 17th meeting of the Coordination Group (CG)

24 May 2016

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the seventeenth CG meeting. 31 members from 25 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and three 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-17-2016) and invited participants to add any items under AOB. The agenda was agreed after the inclusion of a formal referral for introduction to the CG members.

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-16

The Chair explained that the draft confidential CG-16 minutes had been uploaded for commenting via Newsgroups. The comments that had been received on the confidential minutes had been incorporated to the revised draft minutes. No comments were received during the meeting and the CG members agreed on the confidential draft minutes from CG-16.

Actions

SECR: to upload the CG-16 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 formal referrals for discussion.

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

A formal referral was discussed. The referral was related to risk mitigation measures and the CG members agreed that only a general sentence on the use of protective chemical resistant gloves should be included as a RMM in the SPC of the product.

Since the CG reached an agreement on this point of disagreement for the formal referral, this disagreement was considered as closed. The product meets the conditions laid down in Article 19(1)b(iii) of the BPR and the biocidal product authorisations can be granted.

Two formal referrals submitted immediately before the CG meeting were presented to the members. A first discussion will take place via written procedure in the next weeks with a view to discuss and agree on a possible way forward during the CG meeting in July 2016.

For the first one, the points of disagreement relate to the efficacy claims of the product. Additional open issues related to the same product will be raised and discussed during the commenting period in view of reaching an agreement in the next CG meeting in July.

For the second one, the points of disagreement relate to the validity of the efficacy data. CG members were invited to contribute during the commenting period in view of reaching an agreement in the next CG meeting in July.

Actions

1) **SECR:** to follow-up the outcome of the referral as stated in the Working Procedures
2) **MSs:** to comment by 1 June
3) **MSs:** to comment by 13 June

6. Any Other Business (closed session)

6.1 Late procedures

The Commission briefly introduced the reports prepared by ECHA and made a presentation, which has been uploaded on S-CIRCABC by the CG SECR after the meeting.

Regarding the applications submitted under the BPD, the Commission encouraged MSs to continue with the previously indicated priority actions.

Regarding the late applications submitted under the BPR, ECHA reports show that during the last year the system is no longer delivering new authorisations as in previous years because of delays. The Commission stressed the serious consequences of this situation for the whole EU system, MSs and Industry, and called for immediate action as the number of applications is expected to significantly increase in the near future (e.g. AS approvals per year from 10-15 to 50).

Following the contributions from several CG members, a number of factors were identified as contributing to this multifactorial problem.

A CG member explicitly supported to move towards a tacit agreement approach as mentioned in the presentation of the Commission, reflecting a stronger MR spirit and avoiding a re-assessment of the application by the cMSs. This re-assessment makes impossible meeting the MR deadlines and may also result in repeated referrals to the CG, etc...

The Commission is very concerned with these developments and will also make this presentation in the CA meeting for a more policy oriented discussion.

Actions

MSs: to undertake the relevant actions

6.2. DEET products: progress report

A CG member presented a detailed progress report and it is expected that all the pending assessments would be concluded by the end of June and be ready to go through the MR process, in most cases under MR-S.

Some MSs expressed serious concerns that the way forward proposed by the Commission and supported by the CG in March would create a precedent for similar cases in future, deviating from the normal Article 35 and 36 procedures. The Commission stated that it was not intended to set any precedent, but to address this specific situation under these specific circumstances.

The Commission would expect that a similar situation does not happen in future, as the three-year period in Article 89(2) of the BPR should be sufficient for the refMS to early identify any technical issue, have an early discussion in EU fora if needed and finalise the assessment within 365 days (clock stop excluded). Then, there should also be time enough to address any technical disagreement via the normal Article 35 and 36 procedures and have products authorised in time in all MSs.

Regarding products classified with "H 315", several CG members mentioned that they have not been able to find any previous conclusions from the CG stating that "H 315" products cannot be authorised. The Commission requested the CG SECR to double check the previous CG discussions on this matter and share any findings with CG members.

Two CG members explained that they would not authorise "H 315" products and that MR applications of those products would trigger a referral to the CG.

Actions

SECR: to check with previous discussions regarding H315 at CG level.

6.3 Feedback on e-consultations

Five e-consultation were presented for the consideration of the CG members.

A member presented the outcome of an e-consultation regarding the generation of new data on the active substances during product authorisation stage.

Another CG member presented a summary document (CG-17-2016-12) with the outcome of an e-consultation regarding the data set to be requested for the assessment of substances of concern. This proposed way forward was supported by the CG members.

A member presented the conclusions of an e-consultation on the simplified authorisation of the pressurised CO2 disinfestation process. The document (CG-17-2016-24) has been uploaded in S-CIRCABC by the CG SECR after the meeting. The CG members supported the proposed way forward.

A member presented the conclusions of an e-consultation regarding the definition of a BPF based on physical characteristics. A new proposal including a Q&A pair for the Note of Guidance on the BPC concept (Annex IV) will be provided by the MS. The CG members supported the proposed way forward.

A member introduced an e-consultation on two similar products with different mode of application. CG members are requested to provide comments on this consultation.

On a more general note, the Commission noted that it is important to avoid parallel discussions in different fora, such as helpex and CG e-consultations (e-Cs). It also referred to document CA-May16-Doc.7.3, in which it is mentioned that for questions that are outside ECHA's remit , the question owners (national biocides helpdesks) should decide on and take care of the appropriate follow-up action (e.g. whether a question needs to be taken forward to the Coordination Group). It is therefore up to the MSs to decide whether to follow this two-step approach or directly launch the e-C within the CG.

The Commission also stressed the relevance of some of the issues discussed in e-C and the need

to have a clear conclusion on whether a way forward can be supported by all CG members. In that respect, it was also suggested that in order to make e-Cs more useful, the current working practice should be improved so that: i) the above-mentioned parallel discussions within helpex are avoided; ii) CG members launching an e-C, will have to produce a document summarising the views of the contributors and proposing a way forward; iii) this way forward is discussed at least in a physical meeting, so that it can be concluded whether or not it is acceptable for other MSs (and recorded in the minutes); iv) e-Cs are properly filed in S-CIRCABC for archive purposes.

The CG SECR informed that an overview table with the e-consultations discussed so far at the CG will be prepared for next meeting and will be updated regularly. Also the filling structure will be modified in S-CIRCABC for better tracking of the e-consultations.

Actions

SECR: to prepare an overview table of on-going and closed e-consultations

1) **MS:** to provide a summary document with the outcome of the e-consultation
   SECR: to distribute the summary document to CG members

4) **MS**: to provide a proposal of Q&A pairs on the BPF document for next CG meeting
   SECR: to open a Newsgroups for other MSs to propose additional Q&A pairs
   MSs: to provide proposals for Q&A pairs
5) **All:** to comment by 9 June

6.4 Label claim for disinfectants

A CG member presented the summary document (CG-17-2016-02) of the comments received in the S-CIRCABC newsgroup discussion over label claims for disinfectants. No agreement was reached on what exact information should be included in the SPC and on the label claims. Different opinions were raised related to the precision of the data needed for the label claims. The general opinion was that label claims should not be part of the SPC, however, the SPC should indicate to some extent what can be claimed so that inspectors can check if the label is in agreement with the SPC.

Additionally, a member mentioned that there was a need to clarify whether some non-biocidal claims should be considered within the SPC. This is the case for example for products in which a non-biocidal action is needed for the active substance to reach the target organism.

CG members agreed that there are two aspects to consider (1) Which label claims can be supported based on the efficacy data submitted and (2) the regulatory aspects related to how and where to introduce information in the SPC supporting a label claim and the level of freedom allowed in label claims.

Related to the first point, it was proposed to discuss this matter in the efficacy Working Group to provide a guidance on which claims can be supported depending on the outcome of the risk assessment. This guidance would be then discussed by the CG members.

Related to the second point, the Commission volunteered to provide a document with the regulatory aspects to be discussed during the CG meeting in July 2016.

Actions

SECR: To forward the discussion to the EFF WG to provide technical input on the label claims

COM: to prepare a proposal on the regulatory discussion for next CG meeting

6.5 Major changes to authorisations of anticoagulant rodenticides to reduce the active substance concentration

The Commission informed that a number of major change applications have been already submitted to MSs. CG members were encouraged to ensure that these applications already

submitted are handled in time, as otherwise the general public would have to be removed from the authorisation by the end of the transitional period provided for in the 9th ATP Regulation. The Commission also invited those MSs acting as refMS to follow a harmonised approach in the assessment in order to avoid referrals being sent to the CG.

In that respect, the Commission informed the meeting of some contacts with the ECHA colleagues responsible for the efficacy working group (EFF WG). It seems that some discussions on how to assess these applications were held in the past, but they were inconclusive because of the lack of information on what information would be included in the applications. As the applications have been already submitted, CG members were also encouraged to liaise with the EFF WG member in their CA and raise any relevant technical issue at the September meeting of the EFF WG.

The Commission also reminded that some discussions took place regarding data waving (e.g. new bait choice tests would not be needed), and that it is important that this is communicated to prospective applicants in order to avoid unnecessary animal testing and costs.

A CG member mentioned that for those changes consisting in including a combination of two ASs below the SCL, the BPR requires a cumulative risk assessment. In this respect, the Commission informed the meeting of the content of document CA-May16-Doc.4.1.a, which is linked to the possible applicability of the additivity principle to these products and therefore, could result in a classification as toxic for reproduction too. The Commission also mentioned that it has requested the opinion of the legal services and that once available, the conclusion will be communicated to MSs and stakeholders.

Actions

MSs: to liaise with the EFF WG member in their CA.

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-17-2016) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed with the inclusion of an item on the clarification of a Q&A pair in the Q&A document on SAP on the identification of active substances in Annex I to the BPR.

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-16

The Chair explained that the draft non-confidential CG-16 minutes were uploaded for commenting via Newsgroups. The comments received on the non-confidential minutes had been incorporated to the revised draft minutes. No comments were received during the meeting and the CG members agreed on the draft minutes from CG-16.

Actions

SECR: to upload the CG-16 minutes into the relevant folders in the CG CIRCABC.

12. Administrative issues

12.1 Revision of the Working Procedures

The CG SECR informed the meeting about the revision of the Working Procedures to state that MSCAs that not contributed during the initial commenting period of a referral are assumed to support the position of the rMS during this phase. This does not prevent MSCAs to provide opinions on the referral during a later stage of the process. The revised version of the Working Procedures also mentions that, as previously agreed, the product name will be part of the title of the public document of the outcome of a referral. The revision of the Working Procedures was agreed.

After the agreement of the document, a CG member proposed considering a future revision of the document to revise the 90-day period for the Mutual Recognition phase (currently split in 60days for the cMSs to check the dossier and if necessary send comments on the evaluation made by rMS, and 30 days for the bilateral exchange) into two periods of 45 days each. It was agreed to open this proposal for comments from other MSs via Newsgroups in order to decide whether this revision is considered necessary by the Coordination Group.

Actions

SECR: to upload the revised Working Procedures to the S-CIRCABC.

To open a Newsgroups discussion on the revision of the 90-day period

All: to comment by 15 June

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

13.1 Evaluation of alternative dossiers during product authorisation

ECHA presented the final document (CG-17-2016-13&14) and acknowledged the comments received by MSs during the commenting phase after CG-16 meeting.

ECHA presented an overview on the BPC and CG documents dealing with the evaluation of new data after active substance approval. In both documents the approach proposed is the use of the List of Endpoints agreed by the BPC for the evaluation of product authorisation applications.

The new information available has to be peer-reviewed and agreed by the BPC before the List of Endpoints is amended. For that amendment of the LoEP, Article 15 of the BPR can be applied when well justified significant concerns exist about the safety of the biocidal product. When new technical or scientific information is available after the finalisation of the assessment and it is expected to significantly modify the conclusions of the assessment, Article 75(1)g of the BPR can be applied to amend the LoEP.

A CG member expressed their reservation on the need of a BPC agreement on the revised List of Endpoints before it can be used on the evaluation of product authorisation applications. In that respect, the Commission noted that if a MS decided to use new information for on-going applications as refMS, for consistency reasons that MS would also have to review all already granted authorisations in accordacen with Article 48 of the BPR. This would lead to a significant workload, which might be of little added value if afterwards the BPC considers the new information during the peer review as not relevant or relevant but not sufficient to justify the amendment of the existing endpoints.

The document was agreed by the CG members.

Actions

SECR: to take note of the MS reservation on the minutes

To upload the presentation made by ECHA to S-CIRCABC

13.2 IT development: foreseen implementation for the metaSPC (including the migration of the current BPF SPCs to the new SPC format) and for the new procedures of the amended same biocidal products Regulation

ECHA presented the latest IT developments. The presentation has been uploaded in S-CIRCABC by the CG SECR after the meeting (CG-17-2016-23).

ECHA described the releases planned for 2016 for the IT tools R4BP3 and SPC editor. In July a release will take place to adapt to IUCLID 6 and account for the partial implementation in R4BP3 of some case types for the review Programme. In October the new SPC editor will be released to cover for the Meta SPCs, the changes to the same biocidal product regulation amendments, and the addition of new case types for Union Authorization.

The migration to the new BPF SPC format will be in October.

ECHA has requested to have the input from the MS on two areas:
(1) How to migrate the data from fields at family level to accommodate the data from both the BPF and the member's old SPCs.
(2) How to address the "Formulation type" field at the meta SPC level, since it will only be able to accommodate one formulation type value.

Actions

SECR: to open a Newsgroups discussion

To upload the presentation to S-CIRCABC

All: to provide input by 31 May on the preferred option for the migration

13.3 Guidance on carrier-based biocidal products

A member presented a document (CG-17-2016-05) on how to address the assessment of carrier-based biocidal products. The document aims at clarifying the matter but it does not change existing guidance and does not give further interpretation of critical articles in the Regulation.

An ASO will provide written comments on the efficacy section of the guidance for product types A and B in order to align with the ECHA guidance on efficacy for disinfectants. MSs and ASOs were invited to provide written comments, including how best to describe the carrier and under which section of the SPC. The Commission will take over the drafting of the document, which will be distributed for discussion and agreement during the next CG meeting.

Actions

SECR: to open a Newsgroups discussion

All: to submit comments by 15 June

14. Feedback from working parties

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

The Commission informed CG members that as a follow-up of the commenting period set after the physical meeting of the WP held in Madrid on January 20th, the Commission has updated the two working documents in order to address most of the comments submitted by the WP members. These documents (both the clean version and in track-changes mode) have been uploaded on the S-CIRCABC space of the WP.

Considering that a number of the comments raised were directly linked to some of the proposed RMMs to be included as conditions of the approval of the active substances during the renewal process, any further discussion on these working documents has been postponed until the BPC opinions for the renewal of the active substances are available after the June BPC meeting. As soon as the BPC opinions will become available, the Commission will review the two working documents accordingly and launch a new commenting period within the WP.

At the request of a CG member, the Commission clarified that even if the discussions on the SPC template have been postponed, from the previous discussions it is clear that the wording of some instructions for use or RMMs can be perfectly addressed within this exercise. Therefore, very detailed wording for some of the sections in the AR of the AS renewal and BPC opinions (2.4) could be avoided.

14.2 Frequently used sentences for the SPC

ECHA reported on the status of the activities of the Working Party (CG-17-2016-15). ECHA has initiated the setup of the WP. At this moment, nominations of experts have been received from 8 MS and ASOs. ECHA has distributed the project plan and expects comments from the experts. The next step is to start collecting the sentences.

15. Any Other Business (open session)

15.1 Trends in product authorisation

The Chair invited the meeting to take note of the reports in documents CG-17-2016-06&07, 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-17-2016-10, 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

ECHA informed the meeting about the implementation in R4BP of the notifications of simplified authorisation assets, particularly family members. The questions asked during the commenting period were addressed by ECHA who informed the CG members on when the changes in the IT tools will be implemented (CG-17-2016-11).

15.5 Feedback on e-consultations

Four e-consultations were presented for MSs consideration.

1) A member presented the conclusions of an e-consultation regarding the residue assessment of biocidal products. The members agreed that an assessment for all active substances and substances of concern present in the product must be carried out.
2) A member introduced an e-consultation on disinfection products and denaturing substances. Comments from CG members are requested related to the efficacy of denaturing substances and the use of alternative denaturing methods. The Commission implementing regulation describes harmonized approach for denaturing alcohol based disinfectants but also gives an opportunity to use alternative methods. There is a concern that the use of different methods could result in difficulties for mutual recognition.
   The Commission noted that current practice is that when there are co-formulants that are also AS, the applicant must prove that the co-formulant does not contribute to the efficacy of the product.
3) A member presented the outcome of an e-consultation regarding the guidance document on substances of concern. There is a need to clarify the definition of substance of concern where a co-formulant is present at concentrations higher than 0.1% and a full quantitative risk assessment is needed.
4) The same member introduced an e-consultation on follow-up questions for substances of concern.

Actions

1) MS: to provide a summary document with the outcome of the e-consultation
   SECR: to distribute the summary document to CG members
2) MSs: to comment by 9 June
4) MSs: to comment by 2 June

3-4) MSs: to provide a summary document with the outcome of the e-consultation for next CG meeting
SECR: to distribute the summary document to CG members

15.6 Workshop proposed by AT on the assessment of PT 19 products

The CG member presented the agenda (CG-17-2016-16) for the workshop on the assessment of PT 19 products. The workshop will take place in Vienna on 22 and 23 June. The invitations have been distributed. The session on the first day will focus on efficacy of repellents for humans and the session on the second day will be dedicated to efficacy of repellents for animals. A CG member mentioned that it would have been desirable to include a discussion on toxicological issues. This was considered but time and resources constraints limited the scope of the workshop.

15.7 Report from the Ad hoc Environmental Exposure Working Group meeting on the ENV risk assessment for PT 21

ECHA reported on the discussions in the Ad hoc Environmental Exposure Working Group Meeting on the environmental risk assessment of antifouling agents (CG-17-2016-18).

The meeting took place in Amsterdam on 21-22 April. Two agenda items were discussed: The draft manual of product authorization of PT21 products and the release of the software MAMPEC 3.1 presented by Deltares.

Post-meeting note: The CG SECR clarified with Chair of the Ad hoc Environmental Exposure Working Group that the technical issues raised by CEPE had been addressed. The remaining open topics relate to policy and regulatory aspects of the authorisation of antifouling products.

15.8 Identification of active substances in Annex I of the BPR

The Commission reported on the need for revision of a Q&A pair number 1 in the Note of guidance for SAP (Q&A 1). This is due to an omission, as the EC number is not relevant for substances in category 4 of Annex I. The new wording would be as follows:

Q: What is the legal identification of an AS listed in Annex I to the BPR (e.g. category 4: traditionally used substances of natural origin)? It is only the name, or the name in combination with the EC/CAS number, as appropriate?

A: The legal identification of an AS listed in Annex I to the BPR includes both the name and, as appropriate, the EC/CAS number.

CG members agreed with the proposed changes. The Commission will inform the CA meeting of this correction and update the Q&A pair in the document accordingly

Actions

COM: to update the Q&A pair with the revised answer in the next revision of the document.

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

Main conclusions and action points

17th meeting of the CG

24 May 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 with the addition of a formal disagreement for introduction.	**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-16	
No comments were received during the meeting on the confidential CG-16 minutes. The draft confidential minutes were agreed.	**SECR:** to upload the CG-16 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	
A formal referral was discussed and two formal referrals were introduced. 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) The formal referral was introduced. 3) The formal referral was introduced.	**1) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. 2) **MSs**: to comment by 1 June. 3) **MSs**: to comment by 13 June.
6 – Any Other Business	
6.1 – Late procedures	
COM presented the reports on timelines for different procedures and stressed the importance for MSs to comply with the legal deadlines.	**MSs:** to undertake the relevant actions
6.2 – DEET products: progress report	
A member updated the meeting on the status of the applications for authorisation for DEET products. CG members discussed the implications of the H315 phrase in the authorisations in the rMS.	**SECR:** to check the previous discussions regarding H315 at CG level.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Several members voiced their concern that the proposed approach should not create a precedent for future technical disagreements, which should be handled under the normal Article 35-36 procedure.	
6.3 – Feedback on e-consultations	
Five closed e-consultations were presented: 1) A member presented the conclusions of an e-consultation regarding generation of new active substance data during PA. The CG members supported the proposed way forward. 2) A member presented a summary document with the outcome of an e-consultation regarding the data set to be requested for the assessment of Substances of concern. The CG members supported the proposed way forward. 3) A member presented the conclusions of an e-consultation on the simplified authorisation of the pressurised CO2 disinfectation process. The CG members supported the proposed way forward. 4) A member presented the conclusions of an e-consultation regarding the definition of a BPF based on physical characteristics. A new proposal including a Q&A pair for the Note of Guidance on the BPC concept (Annex IV) will be provided. The CG members supported the proposed way forward. 5) A member introduced an e-consultation on two similar products with different mode of application.	**SECR:** to prepare an overview table of on-going and closed e-consultations. 1) **MS:** to provide a summary document with the outcome of the e-consultation **SECR:** to distribute the summary document to CG members 4) **MS:** to provide a proposal for Q&A pairs on the BPF document for next CG meeting. **SECR:** to open a Newsgroups for other MSs to propose additional Q&A pairs. **MSs:** to provide proposals for Q&A pairs. 5) **All:** to comment by 9 June
6.4 – Label claim for disinfectants	
The member presented the conclusions of the consultation. MSs expressed different views on whether label claims should be included in the SPC. Further discussions will follow in next CG meetings.	**SECR:** To forward the discussion to the EFF WG to provide technical input on the label claims **COM:** to prepare a proposal on the regulatory discussion for next CG meeting
6.5 – Major changes to authorisations of anticoagulant rodenticides to reduce the active substance concentration	
COM presented the issues linked to the reduction of active substance concentration for anticoagulant rodenticides, which should be addressed from both a regulatory and technical perspective within the CG and the EFF WG.	**MSs:** to liaise with the EFF WG member in their CA.
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	
9 – Agreement of the agenda for the open session	
The agenda for the open session was agreed with the inclusion of an agenda item on the clarification of a Q&A pair on identification of active substances in Annex I of the BPR in the Q&A document on SAP.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
10 – Declaration of interest in relation to agenda, open session	
No declarations of conflicts of interest were made.	
11 – Draft minutes from CG-16 (non-confidential part)	
No comments were received during the meeting on the non-confidential CG-16 minutes. The draft non-confidential minutes were agreed.	**SECR:** to upload the CG-16 minutes into the relevant folders in the CG CIRCABC.
12 – Administrative issues	
The SECR informed the meeting about revision of the Working Procedures. These WP were agreed by the CG. A proposal was made to revise the 90-day period for the MR into 2 periods of 45 days instead of the 60/30d distribution.	**SECR:** to upload the revised Working Procedures to the S-CIRCABC. To open a Newsgroups discussion on the revision of the 90-day period **All:** to comment by 15 June
13 – Harmonisation of technical and procedural issues in relation to product authorisation	
13.1 – Evaluation of alternative dossiers during product authorisation	
ECHA provided clarifications to the comments by CG members. The document was agreed with a reservation from a MS.	**SECR:** to take note of the MS reservation on the minutes. To upload the presentation made by ECHA to S-CIRCABC
13.2 – IT development: foreseen implementation for the meta SPC (including the migration of the current BPF SPCs to the new SPC format) and for the new procedures of the amended same biocidal products regulation	
ECHA provided a presentation on the implementation of the meta SPC in the IT tools and asked for MSs input on how to proceed with the migration to the new SPC format.	**SECR:** to open a Newsgroups discussion To upload the presentation to S-CIRCABC **All:** to provide input by 31 May on the preferred option for the migration
13.3 – Guidance on carrier-based biocidal products	
A member presented a document on how to address the assessment of carrier-based biocidal products. MSs and ASOS were invited to provide written comments and Commission will take over the drafting of the document for next CG discussion.	**SECR:** to open a Newsgroups discussion **All:** to submit comments by 15 June
14 – Feedback from working parties	
14.1 - Development of standard sentences for the SPC sections of anticoagulant rodenticides	
The Commission reported on the status of the activities of the WP. Further discussions will resume after the release of BPC opinions on the renewal of anticoagulant rodenticide active substances.	
14.2 - Frequently used sentences for the SPC	
ECHA reported on the status of the activities of the Working Party.	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
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 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 updated version for next CG meeting.
15.4 – Questions regarding R4BP3 / SPC/ IUCLID	
ECHA invited CG members to take note of the comments regarding the notification of products under the SAP.	
15.5 – Feedback on e-consultations	
Four e-consultations were presented. 1) A member presented the outcome of an e-consultation regarding the residue assessment of biocidal products. CG members supported the proposed way forward. 2) A member introduced an e-consultation on disinfection products and denaturing substances. 3) A member presented the outcome of an e-consultation regarding guidance document on substances of concern. 4) A member introduced an e-consultation on follow-up questions for substances of concern.	1) **MS:** to provide a summary document with the outcome of the e-consultation **SECR:** to distribute the summary document to CG members 2) **MSs:** to comment by 9 June 4) **MSs:** to comment by 2 June 3-4) **MS:** to provide a summary document with the outcome of the e-consultation for next CG meeting **SECR:** to distribute the summary document to CG members
15.6 Workshop proposed by AT on assessment of PT 19 products	
The member presented the agenda for the workshop. The invitations have been distributed and MSCAs were invited to join the workshop.	
15.7 Report from the Ad hoc Environmental Exposure Working Group Meeting on ENV risk assessment in PT 21	
ECHA reported on the discussions in the Ad hoc Environmental Exposure Working Group Meeting on the environmental risk assessment of antifoulings.	
15.8 Identification of active substances in Annex I of the BPR	
The Commission reported on the need for revision of a Q&A pair on Note of guidance for SAP (Q&A 1). CG	**COM:** to update the Q&A pair with the

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
members agreed with the proposed changes.	revised answer in the next revision of the document.
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

24 May 2016

Final draft agenda

17th meeting of the Coordination Group (CG)

24 May 2016 – from 9:00 to 17:30

Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-17-2016

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-16

CG-M-16-2016_revised_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-17-2016-01

For information

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

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

Links to disagreements

For discussion and agreement

Item 6 - Any Other Business

6.1 Late procedures

CG-17-2016-08&09

For information

6.2. DEET products: progress report

For discussion

6.3 Feedback on e-consultations

Link to e-consultations & CG-17-2016-12

For information/discussion

6.4 Label claim for disinfectants

CG-17-2016-02

For information

6.5 Major changes to authorisations of anticoagulant rodenticides to reduce the active substance concentration

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-17-2016

For agreement

Item 10 – Declaration of interest in relation to the agenda

Item 11 –Draft minutes from CG-16

CG-M-16-2016_revised_draft-non-confidential

For agreement

Item 12 – Administrative issues

12.1 Revision of the Working Procedures

CG-17-2016-03

For discussion and agreement

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

13.1 Evaluation of alternative dossiers during product authorisation

CG-17-2016-13&14

For agreement

13.2. IT development: foreseen implementation for the metaSPC (including the migration of the current BPF SPCs to the new SPC format) and for the new procedures of the amended same biocidal products regulation

CG-17-2016-04&19

For information and discussion

13.3 Guidance on carrier-based biocidal products

CG-17-2016-05

For discussion

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-17-2016-15

For information

Item 15 – Any Other Business

15.1 Trends in product authorisation

CG-17-2016-06&07

For information

15.2 Deadlines for application for product authorisation

CG-17-2016-10

For information

15.3 List of active substances meeting the exclusion or substitution criteria

CG-17-2016-17

For information

15.4 Questions regarding R4BP3 /SPC/ IUCLID

CG-17-2016-11

For information

15.5 Feedback on e-consultations

Link to e-consultations

For information

15.6 Workshop proposed by AT on assessment of PT 19 products

CG-17-2016-16

For information

15.7 Report from the Ad hoc Environmental Exposure Working Group Meeting on ENV risk assessment in PT 21

CG-17-2016-18

For information

15.8 Identification of active substances in Annex I of the BPR

For information

Item 16 – Agreement of the action points and conclusions

For agreement

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