3 July 2018

CG-M-29-2017 non-confidential

Final non-confidential minutes of the 29th meeting of the Coordination Group (CG)

31 May-1 June 2018

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the twenty ninth CG meeting (CG-29). 31 members and experts from 23 Member State Competent Authorities (MSCAs) and CH participated in the meeting. Three representatives from DG SANTÉ and three representatives from ECHA were present in the meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-29-2018) and invited participants to add any items under AOB. Two agenda points were added to the agenda: i) cases where an applicant is unable to find a reference MS (refMS) and, ii) update from the Standing Committee meeting. The agenda was agreed with these additions.

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. Draft minutes from CG-28

The Chair explained that the draft confidential CG-28 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. The draft confidential CG-28 minutes were agreed.

Actions:

SECR: to upload the CG-28 minutes into the relevant folders in the CG CIRCABC.

5. Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

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

Actions:

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

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

The Chair informed the meeting that 23 referrals had been closed via written procedure after the CG-28 meeting. An agreement by consensus was reached for all cases and the products can be authorised.

One referral was briefly introduced. The referral concerned a PT18 product and the point of disagreement was related to the need of additional data for the characterisation of the active substance. The discussion will be continued during the CG-30 meeting.

Actions:

All: To provide comments on the referral by 8 June 2018.

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

6.1 Issues identified in the context of UA

The SECR presented an updated list of issues identified in the context of UA applications (CG-29-2018-15). The intention of publishing this list is to allow eCAs of national authorisations of products based on the same active substance to be informed about the issues identified in UA applications.

The SECR commented that also the Working Groups (WG) Chairs are informed about the discussions in the CG.

The Commission encouraged ECHA to involve refMSs for MR procedures in the discussions between eCA for UA. Similarly, CG members were also encouraged to communicate internally with members of WGs about the conclusions reached by the CG (e.g. CG agreements, outocmes of e-consultations or other agreed ways formward).

Actions:

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

SECR: To provide an updated list for the next CG meeting.

6.2 Post-authorisation conditions in product authorisation

The SECR presented a proposal on how to address post-authorisation conditions for product authorisations. The aim of the proposal was to have a common understanding of MSs on the exceptional situations where a post-authorisation condition could be acceptable. This would avoid the submission of referrals to the CG on that matter. The discussion will be continued during the CG-30 meeting.

Actions:

SECR: To amend document considering the comments received during the meeting ASAP and open a newsgroup for comments.

All: To comment (2 weeks) after opening the newsgroups.

7. Any Other Business (closed session)

7.1 Late procedures

COM presented the overview of late procedures and stressed the need to comply with the 30-day deadline to finalise the national authorisation of the products after the mutual recognition phase.

Actions:

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

7.2. Feedback on e-consultations

Two e-consultations were tabled for discussion:

1) Efficacy of a professional dishwashing product and the applicability of guidance and legal aspects.

A member introduced an e-consultation on the efficacy requirements concerning a biocidal product family (BPF) authorisation application for disinfection of dishwashing systems. A discussion was initiated on whether a deviation from the standard efficacy test method defined is the efficacy guidance was acceptable for this application. The commenting period is still ongoing for this e-consultation and the discussion will be continued during CG-30 meeting.

Actions:

1) All: To comment in the newsgroup by 14 June.

2) Data requirements for storage stability for simplified authorisation (SA).

A member introduced an e-consultation on data requirements for storage stability concerning an application for simplified authorisation. CG members initiated a discussion on whether for simplified authorisations efficacy data could be submitted instead of chemical stability data. The commenting period is still ongoing for this e-consultation and the discussion will be continued during CG-30 meeting.

Actions:

2) All: To comment in the newsgroup by 12 June.

7.3 Risk assessment of PT19 products for animals

ECHA received a question from a MS evaluating a biocidal product intended to be used as a repellent for humans and for animals. A pre-meeting consultation was launched where the input from MSs was requested on how to evaluate biocidal products and treated articles having a primary biocidal function for use on animals.

A proposal from ECHA considering the received comments was prepared and presented during the meeting (CG-29-2018-13). Where the risk assessment for animals is not covered by the risk assessment for human health, ECHA proposes to use existing BPR guidance on performing the exposure assessment as well as guidance available from other regulatory frameworks (e.g. veterinary medicinal products).

The NL CA informed that for a risk assessment for animals an existing EFSA guidance (2009) can be used and reference to this guidance should be given in the proposal.

The Commission commented that already available guidance under other regulatory framework should be considered and used for exposure assessment of biocidal products, especially guidance used under the veterinary medicinal products framework. In this way a harmonised approach and consistency could be followed performing exposure assessment for animals.

The CG was invited to consider whether development of guidance addressing the risk assessment for animal health should be prioritised, and to provide feedback about the number of products on the market authorised or under evaluation for their use on animals.

The document will be updated and tabled for discussion during the CG-30 meeting.

Actions:

All: to provide feedback on the number of products affected by this topic.

IE: to give feedback on the example of horse rugs.

7.4 Update on questions forwarded from the CG to ECHA

The SECR presented an overview of the status of the questions referred from the CG to be addressed by ECHA (CG-29-2018-05).

The SECR informed that, in general, for the discussion of the different topics in the WG, the WG Chair would contact the MS that initiated the request and invite it to provide a discussion paper for the WG.

The SECR proposed to update the overview table presented in the meeting on a regular basis for information purposes.

In order to help to set priorities for the discussion of the different topics in the WGs, and in order to estimate the impact of each topic, feedback from MSs was requested to estimate the number of cases affected by each issue, the date when an answer from the WG would be needed, and a justification of the proposed date.

Actions:

SECR: to produce an updated table for the next CG meeting.

All: to provide feedback on the priorities.

7.5 Update on the WP on Biocidal Product Family concept-Extension of WP

The SECR explained that the deadline of the WP on the BPF concept expired in May 2018. Current discussions in the WP were focusing on two topics related to the clarification of the concept of similarity and grouping of co-formulants. The topics on definition of ranges for physico-chemical parameters, clarification on whether the assessment of BPFs should be based on the BPF or meta SPC level, and the establishment of clear rules for the identification of the worst case scenario, were also to some extent addressed as part of the discussion of the two main topics.

CG members agreed to extend the deadline to 31 December 2018 and to prioritise the discussions already on-going.

The SECR also informed that the representatives of Industry, considering the lack of resources in both MSs and Industry, had offered to hire a consultant financed by Industry that could lead the discussions on the similarity concept in cooperation with MSs. CG members agreed that MSs should take the lead in the discussion of the topic.

Actions:

SECR: To update the WP on the conclusions of the CG.

7.6 Cases where an applicant is unable to find a refMS

A discussion was initiated on whether MSs can refuse acting as refMS for applications submitted for national authorisation and mutual recognition. The Commission will provide clarification on this matter during the CG-30 meeting.

Actions:

COM: To provide clarification on the matter.

7.7 Update from the Standing Committee meeting

The Commission updated the CG on the discussions during the May Standing Committee meeting related to two Article 36 decisions.

One proposal concerned how to express the content of the AS in the SPC, which received a favourable opinion by unanitmity. The Commission decision clarifies the legal aspects regarding the interpretation of the definition of an active substance under the BPR and of a substance under REACH. However, in order to further clarify this matter and ensure a common understanding of MSs at product authorisation, the Commission will also propose an update of Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content). The updated Q&A pair will be tabled for discussion at the July meeting of the CG for discussion and agreement, with a view to further update the CA document as soon as possible.

The second proposal concerns two referrals on PT19 products that were referred to the Commission under the provisions of Article 36. The decision will be voted during the next meeting of the Standing Committee that will take place in July since a few MSs wanted to further consider the impact that the proposal could have on already authorised PT19 products.

8. Agreement of the action points and conclusions

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

Open session

9. Welcome to the open session

The Chair welcomed ASOs to the open session. 4 observers from 3 ECHA accredited stakeholder organisations (ASOs) were present for the open session of the meeting.

10. Agreement of the agenda for the open session

The Chair introduced the draft agenda (CG-A-29-2018) and invited CG members and ASOs to propose any other items under AOB. No additional items were proposed and the agenda was agreed.

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

Actions:

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

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

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

12. Draft minutes (non-confidential part) from CG-28

The Chair explained that the draft non-confidential CG-28 minutes had been uploaded for commenting via Newsgroups and no comments were received during the commenting period. The CG members agreed with the non-confidential draft minutes from the CG-28.

Actions:

SECR: to upload the CG-28 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

No administrative issues were tabled for discussion.

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

14.1 Guideline on the handling of SBP applications

The SECR presented an update on the work carried out on the SBP guidelines (CG-29-2018-23 and CG-29-2018-24).

A pre-meeting consultation was launched to collect proposals or additional topics to be addressed in the SBP guideline. The SECR explained that the concept paper was a preliminary proposal that would be used to further elaborate on the SBP guidelines. Therefore, it was not the intention to discuss the paper during the meeting.

The SECR proposed to agree on the objectives of the guideline as listed below:

a) *Harmonise the validation and assessment of SBP applications among MS and ECHA.* - This will ensure that the same approach on handling SBP applications will be applied among MSs and ECHA for national and Union SBP applications, respectively.
b) *Give guidance to applicants in terms of requirements.*
c) *Optimise the workload and resources on handling SPB applications* - During the commenting phase CG members expressed a concern about the renewal of SBP authorisations and possible duplication of work.

CG members agreed on the objectives.

During the meeting the table of contents of the preliminary concept paper was presented and supported by the CG members. CG members will provide written comments on the concept paper provided by the SECR and on the table of contents. The discussion will be continued during the CG-31 meeting.

Actions:

SECR: To open a newsgroup for comments.

All: To provide comments on the table of contents of the document and on the text of the concept paper by 22 June.

SECR: To table this item for discussion for the CG-31 meeting.

All: To communicate to ECHA whether they will be willing to write any chapters of the guidelines.

14.2 Assessment of PT21 products – New assessment tool

A CG member presented an updated proposal on how to address the environmental assessment of PT21 products using the new assessment tool developed for the saltwater scenarios (CG-29-2018-22). The CG member volunteered to perform the evaluation of the impact of applying the new model compared to the current model and invited CG members to contribute to the generation of data.

Three CG members acting as refMS for MR applications expressed their willingness to contribute to provide the necessary data for the assessment of saltwater scenarios using both, the current method and the method based on the new tool. The data would in principle be available by September 2019.

A CG member mentioned that the Annex 3 of the proposal had to be amended, since an assessment is not required for vessel category 4. In all cases the PT21 assessment guidance should be followed.

On the point on applicability of Article 37 of the BPR, the Commission commented that, for this type of products, Article 19(5) (i.e. in case of unacceptable risks for the environment but need to keep a minimum tool box available on the market) and Article 37 (in case of derogation from MR) could be relevant. Regarding "overeffective" products, the Commission referred to the provisions in point 77 of Annex VI to the BPR as the legal basis for any decision on that respect.

The document will be amended to take into consideration the comments provided during the meeting. The three CG members participating in the generation of data will indicate whether it could be possible to have the environmental assessment data before September 2019.

The SECR mentioned that CEPE had provided a position document related to this topic. The UK CA will answer directly to CEPE.

Actions:

DE, NL, and FR: To indicate when the evaluation of PT21 products will be available for this scenario by 14 June

UK: to provide answer to CEPE directly on their position paper.

UK: To update the document once feedback is received from MSs and considering the comments in the meeting.

SECR: to open a newsgroups for agreement on the updated document.

All: To indicate in the newsgroups in case a MS does not agree with the document.

SECR: If the document is agreed, to publish the document in S-CIRCABC.

14.3 Date of applicability of Technical Agreements of Biocides (TAB) entries and conclusions of the WGs on the technical questions referred from CG

The SECR presented a proposal in order to clarify the date of applicability of Technical Agreements of Biocides (TAB) entries related to product authorisation processes and the date of applicability of conclusions of the WGs on the questions referred from the CG (CG-29-2018-02).

The SECR proposed that, in general, the reference date of a TAB entry for product authorisation would be the date of publication of the TAB entry on the ECHA website. The date of applicability of a TAB entry would depend on the type of entry:

- Editorial changes of the existing guidance and clarification/interpretation of the existing guidance would be applicable as of the reference date,
- New entries related to new guidance or technical scientific advice would be applicable considering the approach agreed in the CA-July12-Doc.6.2d-Final (CA document).

The SECR also proposed that, for existing TAB entries, after incorporation in the guidance document, the date of applicability of the TAB entry would remained unchanged. This would be in line with the procedure for active substances.

Regarding the date of applicability of the conclusions of the WGs on questions referred from the CG, it was proposed that, where relevant, the CG would decide on the date of applicability of the conclusions of the WG on a case by case basis. Where applicable, the provisions in document CA-July12-Coc.6.2d-Final should be considered.

CG members commented that, regardless of the type of TAB entry, where further data requirements would be triggered by a new entry, or where the outcome of the assessment might be significantly impacted, the approach agreed in the CA document should be followed.

A CG member commented that, on a case by case basis, it should also be possible to apply WG agreements as from the reference date in order to have a harmonised approach during the assessment of applications.

It was also pointed out, that, when a TAB entry is incorporated in the guidance document, ECHA should ensure that it is clearly indicated in the guidance document the date of applicability of each entry.

On a more general note, the Commission expressed the importance of having a good cooperation between the WG Chairs and the BPC Chair, as technical agreements reached by the limited number of the experts in WGs might have important policy or regulatory consequences.

The discussion will continue during the CG-30 meeting.

Actions:

SECR: to open a newsgroups for comments on the proposal.

All: To comment on the document by 14 June.

14.4 Date of applicability of EN standards

The SECR presented a proposal to clarify whether the CA-July12-Doc.6.2d-Final document is applicable to new EN standards (CG-29-2018-01).

It was clarified that the CA-July12-Doc.6.2d-Final document does not specifically define the term "new guidance". However, it is considered that "new guidance" could be understood as any written document (either first drafted or updating a previous version) establishing new clarifications or recommendations on different aspects related to product authorisation. New guidance also has a clear date of adoption/publication as from which

its content is definitive (no longer a draft) and can therefore be followed by applicants with full predictability.

Considering this, new EN standards should be considered in the scope of the CA-July12-Doc.6.2d-Final document. In any case, an applicant may use a new EN standard on a voluntary basis before the two year cut-off date.

The Commission clarified that Section 3.2. of the CA-July12-Doc.6.2d-Final document is applicable in those cases where not applying the new guidance would result in a serious concern. However, in those cases, a request to apply a new guidance would also trigger the revision of existing authorisations, i.e., application of Article 48 of the BPR.

The Commission mentioned that, where additional data has to be generated during the evaluation of an application (i.e. under the stop of the clock), MS can *encourage* the use of a new EN standard, but the applicant would not be obliged to do so.

CG members agreed that the CA-July12-Doc.6.2d-Final document on applicability of new guidance is applicable to new EN standards.

14.5 Preparation of the second renewal of AVK PT14 products

The SECR introduced the topic. During the first renewal of AVK PT14 products, it was noticed a lack of harmonisation in several aspects that derived in numerous referrals being submitted to the CG.

In order to timely prepare for the second renewal of these products, the SECR provided a proposal with a list of topics that would need to be addressed (CG-29-2018-18). Considering the deadlines for submission of applications for renewal and the two year cut off for application of new guidance, these items would need to be addressed by October 2019. CG members were invited to indicate whether additional items should be added to the list.

The following comments were received during the meeting:

- Guidance on requirements for data related to resistance should be developed.
- Clarification is needed on data or information requirements where the long term storage stability data show above 10% degradation of the active substance. It should be clarified whether an expert statement should be accepted as justification for a decrease in active substance related to absorption of the active substance to the product matrix. A CG member mentioned that Industry and the APCP WG should be consulted in this matter.
- Guidance on the evaluation of risk assessment for surface water is needed.
- Guidance on dermal absorption assessment should be developed.

Industry emphasised the importance of involving the applicants in the discussions. It was suggested that it might be necessary to establish a working party in order to address the issue of the storage stability of this type of products.

CG members were invited to provide written comments to identify additional items to be addressed for the second renewal of AVK PT14 products.

Actions:

SECR: to open a newsgroups for comments on the document.

All: To comment on the document by 14 June.

14.6 Possibility of bridging 25 and 50 ppm shelf life data for PT14

A CG member presented the topic on whether bridging 25 and 50 ppm storage stability data for AVK PT14 products was acceptable (CG-29-2018-26). In the opinion of the CG member, considering the low concentration of active substance in the products, 25 or 50 ppm, and the minimal change in the composition of the product matrix, bridging these data should be acceptable.

The SECR mentioned that this topic had been already discussed during the APCP-WG-II meeting in 2016. During this meeting, the WG agreed that a new storage stability test is needed for the lower active substance containing products in order to check that the decrease of the active substance is still acceptable after storage. A CG member noted that they had already applied the agreed APCP-WG-II 2016 approach to relevant authorisations and that it was likely that generation of these data were already underway.

A CG member commented that bridging data from 50 ppm products to 25 ppm products was in their opinion not acceptable. However, bridging from 25 to 50 ppm might be possible.

CG members agreed that this was a technical issue and the discussion should be referred to the APCP WG.

The CG member initiating the consultation will prepare a document to be considered by the APCP WG Chair. The SECR mentioned that the document should include any relevant new aspects to justify re-opening this issue for discussion.

Actions:

IE: To prepare a document and to refer the issue to the APCP WG.

15 – Feedback from working parties

15.1 WP on the biocidal product family concept

The SECR updated the meeting on the discussion that took place during the fourth meeting of the WP on the BPF concept that took place on 31 May. The following points were discussed and agreed:

- The WP agreed on uses that should be considered as similar related to PT1 and PT5 in the uses matrix.
- The WP agreed that two exceptions could be applied to uses not considered as similar in the matrix. One exception would allow to have in the same family products with the same composition that are used for uses considered as not similar in the matrix. The second exception would allow to have in the same family uses that are considered as not similar, but can be covered by the same risk and efficacy assessment. The limitations and exact scope of the exceptions would be discussed during the WP-BPF-5 meeting.
- The WP agreed on the following documents: (a) how to deal with splitting of families, (b) grouping of co-formulants, and (c) best practices for pre-submission discussions.

The documents agreed by the WP will be circulated for the consideration of CG members and to be agreed during the CG-30 meeting.

Actions:

SECR: to open a newsgroups to distribute the documents agreed in the WP.

All: To consider the documents for agreement during the CG-30 meeting.

SECR: To table for the CG-30 meeting the agreement of the documents.

16 – Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the reports in document CG-29-2018-09 & CG-29-2018-12, which were made available for information.

16.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-29-2018-08, which was made available for information.

16.3 List of active substances meeting the exclusion or substitution criteria

The Chair invited the meeting to take note of the updated version of the list of active substances meeting the exclusion or substitution criteria (CG-29-2018-07).

Actions:

Rapporteur MS: to check the new information and report to CG SECR by 8 June 2018.

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

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

16.4 IT issues

16.4.1 Introduction to R4BP 3.11

The SECR gave an update on the new release of R4BP 3.11 and the SPC editor 2.2 and presented the new capabilities of the SPC comparison tool (CG-29-2018-28).

In order to prepare for the renewal of PT8 and PT18 products, the Commission invited MSs to check that for these products all procedures are correctly linked in R4BP 3.

16.5 Feedback on e-consultations

Two e-consultations were tabled for discussion:

1) **Use of the same trade name in two products of different PTs**

A member presented the conclusions of an e-consultation on the use of the same trade name in two products of different PTs (CG-29-2018-16). The topic was previously discussed during the CG-26 and CG-27 meetings and no consensus was found on a way forward. During the CG-27 meeting it was agreed to have a final discussion in open session in order to have the feedback from Industry in this matter.

The Commission provided some clarifications about a few points mentioned in the document:

- The requirement in the Changes regulation for avoiding confusion when adding or changing a trade name in the context of an administrative change to an existing authorisation underlines a general principle that trade names of authorised products should not lead to confusion.
- The Changes regulation only foresees merging products into a family as an administrative change in the case that the products were authorised as part of the same frame formulation under the BPD.

Further, the Commission proposed a way forward for the 2 products mentioned in the e-consultation belonging to the same AH and havng identical composition. For merging the products and having one authorisation covering the two uses under the same trade name, instead of initiating a major change application, the change could be dealt via an administrative change prior classification by ECHA. A CG member however noted that, considering the amount of work necessary for such a change and the ability to include cMS in the process, a minor change procedure would be more suitable.

CG members agreed to have a general discussion on this topic in the CA meeting.

Actions:

COM: To table this topic (trade names in general) for discussion for the next CA meetings.

ASOs: To provide comments to SECR by 10 July.

SECR: To open a newsgroups for suggestions for the discussion in the next CA meetings.

All: To provide suggestions by 10 July.

2) How to indicate in the SPC the application rate for RTU spray products in an understandable manner

A member introduced an e-consultation on how to indicate in the SPC the application rate for ready to use (RTU) spray products in an understandable manner for the consumers (CG-20-2019-06). During the commenting period, MSs that provided comments agreed with the general principle of indicating in the SPC for non-professionals for PT18 and PT19 products the number of sprays and/or the duration of spraying per treated surface/volume. For professional users, this information would not be required in the SPC.

ASOs asked about when the proposed approach could be implemented, since this might have consequences on the stocks of the labels. The Commission suggested that in order to minimise those effects, this principle could be implemented for new authorisations, for existing products during the renewal procedure, or as part of a applications for changes that would also affect the content of the labels.

CG members supported in general the proposal in the document. The information on the number of sprays should be included in the section "instructions of use" of the SPC.

The standard sentences to be used were not agreed and comments will be submitted to address this aspect.

A discussion was initiated on the distinction between professional and trained professional use for these products, since in some MSs this distinction is not available. The document will be revised and CG members will reflect on how to address the distinction between professional and trained professional use. The document will include a paragraph on how to implement the conclusions for new authorisations.

Actions:

SECR: To open a newsgroups for comments on the standard sentences to be used.

All: To comment on the sentences by 14 June.

CG member: To prepare an updated document addressing the comments in the meeting and the standard sentences.

17. 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

29th meeting of the CG

31st of May- 1st of June 2018

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 two agenda points on refusal of MSs to act as refMS for applications for National authorisations, and an update on the latest SC discussion.	**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-28	
The draft confidential minutes of the CG-28 meeting were agreed without modifications.	**SECR:** to upload the CG-28 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed about the update of the overview table of the referrals discussed so far at CG level.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
The Chair informed that 23 referrals had been closed via written procedure since the previous CG meeting (CG-28) for which an agreement by consensus was reached. One referral recently submitted was briefly introduced. The discussion will continue during the CG-29 meeting.	**All**: To provide comments on the referral by 8 June 2018.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA – The SECR presented the list of issues identified in the context of UA.	**MSs:** To take note of the information provided in the table. **SECR:** To provide an updated list for the next CG meeting.
6.2 - Post authorisation conditions in product authorisation	
The SECR presented a proposal on post authorisation	**SECR:** To amend document

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
conditions in product authorisation. The discussion will be continued during the CG-30 meeting.	considering the comments received during the meeting ASAP and open a newsgroup for comments. **All:** To comment (2 weeks) after opening the newsgroups.
7 – Any Other Business	
7.1 – Late procedures	
COM presented the overview of late procedures and stressed the need to comply with the 30 day deadline to finalise the mutual recognition procedure during the national authorisation phase.	**MSs:** to review the documents and communicate to ECHA any inaccuracies in the data.
7.2 – Feedback on e-consultations	
Two e-consultations were presented: 1) A member introduced an e-consultation on the efficacy requirements concerning a BPF for disinfection in dishwashing systems. The discussion will be continued during CG-30 meeting. 2) A member introduced and e-consultation on data requirements for storage stability for simplified authorisation. The discussion will be continued during CG-30 meeting.	**2) All**: To comment in the newsgroup by 14 June. **3) All**: To comment in the newsgroup by 12 June.
7.3 Risk assessment of PT19 products for animals	
The SECR presented the conclusions of an e-consultation on how to address the risk assessment of PT19 products used for animals.	**All**: to provide feedback on the number of products affected by this topic. **IE**: to give feedback on the example of horse rugs.
7.4 Update on questions forwarded from the CG to ECHA	
The SECR presented an overview of the status of the questions referred from the CG to be addressed by ECHA.	**SECR**: to produce an updated table for the next CG meeting. **All:** to provide feedback on the priorities.
7.5 Update on the WP on Biocidal Product Family concept-Extension of WP	
CG members agreed to extend the deadline of the WP to 31 December 2018. CG members agreed that MSs should lead the discussion on the similarity concept.	**SECR**: To update the WP on the conclusions of the CG.
7.6 Cases where an applicant is unable to find a refMS	
ECHA introduced the topic and the discussion will be continued during the CG-30 meeting	**COM:** To provide clarification on the matter.
7.7 Update from the Standing Committee meeting	
COM updated CG members regarding the discussion on Article 36 decisions.	
Item 8 – Agreement of the action points and conclusions	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
The list of action points and conclusions for the closed session was agreed by the CG meeting.	
OPEN SESSION	
9 –Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.
11 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-28	
The draft non-confidential minutes of the CG-28 meeting were agreed.	**SECR:** to upload the CG-28 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 Guideline on the handling of SBP applications	
The SECR presented an update on the work carried out on the SBP guidelines. CG members agreed on the objectives of the guideline.	**SECR:** To open a newsgroup for comments. **All:** To provide comments on the table of contents of the document and on the text of the concept paper by 22 June. **SECR:** To table this item for discussion for the CG-31 meeting. **All:** To communicate to ECHA whether they will be willing to write any chapters of the guidelines.
14.2 Assessment of PT21 products – New assessment tool	
A CG member presented an updated proposal for the application of the new tool/model for assessing PT21 products in saltwater scenarios. CG members agreed on the proposal. A comparison of the results using the old and the new models will be assessed.	**DE, NL, FR:** To indicate when the evaluation of PT21 products will be available for this scenario by 14 June **UK**: to provide answer to CEPE directly on their position paper. **UK**: To update the document once feedback is received from MSs and considering the comments in the meeting. **SECR:** to open a newsgroups for agreement on the updated document. **All:** To indicate in the

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	newsgroups in case a MS does not agree with the document. **SECR:** If the document is agreed, to publish the document in S-CIRCABC.
14.3 Date of applicability of Technical Agreements of Biocides (TAB) entries and conclusion of the WGs on the technical questions referred from CG	
The SECR presented a proposal to clarify the date of applicability of TAB entries and conclusions of the WG to questions raised by the CG related to product authorisation. The discussion will continue during the CG-30 meeting.	**SECR**: to open a newsgroups for comments on the proposal. **All**: To comment on the document by 14 June.
14.4 Date of applicability of EN standards	
The SECR presented a proposal to clarify the date of applicability of EN standards. CG members agreed that the CA document on applicability of new guidance (2 year rule) is also applicable to new EN standards.	
14.5 Preparation of the second renewal of AVK PT14 products	
The SECR introduced the topic to identify issues that should be addressed for the second renewal of AVK rodenticides. The discussion will be continued during the CG-30 meeting.	**SECR**: to open a newsgroups for comments on the document. **All**: To comment on the document by 14 June.
14.6 Possibility of bridging 25 and 50 ppm shelf life data for PT14	
A member presented the topic on whether bridging 25 and 50 ppm shelf life data for PT14 products is acceptable. The discussion will be referred to the APCP WG.	**IE:** To prepare a document and to refer the issue to the APCP WG.
Item 15 – Feedback from working parties	
15.1 WP on the BPF concept	
The SECR updated the meeting on the progress of the WP on the biocidal product family concept. Three documents were agreed in the WP and will be circulated for agreement by the CG.	**SECR**: to open a newsgroups to distribute the documents agreed in the WP. **All**: To consider the documents for agreement during the CG-30 meeting. **SECR**: To table for the CG-30 meeting the agreement of the documents.
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
16.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
16.3 List of active substances meeting the exclusion or substitution criteria	
The Chair invited the meeting to take note of the document.	**Rapporteur MS:** to check the new information and report to CG SECR by 8 June 2018. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an updated version for next CG meeting.
16.4 IT issues	
16.4.1 Introduction to R4BP 3.11	
The SECR gave an update on the new release of R4BP 3.11 and the SPC editor 2.2.	
16.5– Feedback on e-consultations	
Two e-consultations were presented: 1) A member presented the conclusions of an e-consultation on the use of the same trade name in two products of different PTs. CG members did not agree on a harmonised way forward. The discussion will be referred to the CA meeting to address the use of trade names in general. 2) A member introduced and e-consultation on how to indicate in the SPC the application rate for RTU spray products in an understandable manner for the consumers. CG members agreed with the proposal on specifying the number of sprays to be applied and to include this information in the instructions of use in the SPC. The standard sentences will need to be agreed.	**1) COM**: To table this topic (trade names in general) for discussion for the next CA meetings. **1) ASOs**: To provide comments to SECR by 10 July. **1) SECR**: To open a newsgroups for suggestions for the discussion in the next CA meetings. **1) All**: To provide suggestions by 10 July. **2) SECR**: To open a newsgroups for comments on the standard sentences to be used. **2) All**: To comment on the sentences by 14 June. **2) CG member**: To prepare an updated document addressing the comments in the meeting and the standard sentences.
17 – Agreement of the action points and conclusions	
The list of action points and conclusions for the open session was agreed by the CG meeting.	

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Part IV - List of Annexes

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

ANNEX II Final agenda

ANNEX II

31 May 2018

Final agenda
29th meeting of the Coordination Group (CG-29)

31 May -1 June 2018 –
on 31 May 2018 from 9:30 to 12:30 and
on 1 June 2018 from 9:30 to 17:00

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-29-2018
For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-28

CG-M-28-2018_Draft confidential
For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-29-2018-03
For information

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

CG-29-2018-20
Links to disagreements
For discussion and agreement

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

6.1 Issues identified in the context of UA

CG-29-2018-15

For information

6.2 Post authorisation conditions in product authorisation

CG-29-2018-19

For discussion

Item 7 - Any Other Business

7.1 Late procedures

CG-29-2018-10, CG-29-2018-11,
CG-29-2018-17

For information

7.2 Feedback on e-consultations

CG-29-2018-04, CG-29-2018-25
CG-29-2018-27
Links to e-consultations

For discussion and agreement

7.3 Risk assessment of PT19 products for animals

CG-29-2018-13

For discussion

7.4 Update on questions forwarded from the CG to ECHA

CG-29-2018-05

For information

7.5 Update on the WP on Biocidal Product Family concept-Extension of WP

CG-29-2018-14

For discussion and agreement

7.6 Cases where an applicant is unable to find a refMS

For discussion

7.7 Update from the Standing Committee meeting

For discussion

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-29-2018

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-28

CG-M-28-2018_Draft non-confidential

For agreement

Item 13 – Administrative issues

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

14.1 Guideline on the handling of SBP applications

CG-29-2018-23, CG-29-2018-24

For discussion

14.2 Assessment of PT21 products – New assessment tool

CG-29-2018-21, CG-29-2018-22

For discussion

14.3 Date of applicability of Technical Agreements of Biocides (TAB) entries and conclusions of the Working Groups on the technical questions referred from CG

CG-29-2018-02

For discussion

14.4 Date of applicability of EN standards

CG-29-2018-01

For discussion

14.5 Preparation for the second renewal of AVK PT14 products

CG-29-2018-18

For discussion

14.6 Possibility of bridging 25 and 50 ppm shelf life data for PT14

CG-29-2018-26

For discussion

Item 15 – Feedback from working parties

15.1 WP on the BPF concept

For information

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-29-2018-09, CG-29-2018-12

For information

16.2 Deadlines for application for product authorisation

CG-29-2018-08

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-29-2018-07

For information

16.4 IT issues

16.4.1 Introduction to R4BP 3.11

CG-29-2018-28

For information

16.5 Feedback on e-consultations

CG-29-2018-16, CG-29-2018-06

Links to e-consultations

For discussion and agreement

Item 17 – Agreement of the action points and conclusions

For agreement

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