14 May 2019

CG-M-34-2019 non-confidential

Final non-confidential minutes of the 34th meeting of the Coordination Group (CG)

12-13 March 2019

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman and the Vice-Chairman welcomed all participants to the thirty-forth Coordination Group meeting (CG-34). 28 members and experts from 21 Member State Competent Authorities (MSCAs), Norway, Serbian Observer and 4 participants from 4 Accredited Stakeholder Organisations (ASOs), participated in the meeting. Four 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-34-2019) and invited participants to add any items under AOB. The agenda for the closed session was agreed with the addition of one point on how to deal with case for which MR process has been started before SoP for MR (point added by ECHA).

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. The Chair declared a conflict of interest for three formal referrals, as the same MS is the refMS. The Vice-Chair replaced the Chair for discussion of those topics.

4. Draft minutes from CG-33

The Chair explained that the draft confidential CG-33 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period, but during the CG-34 meeting MS proposed minor changes. CG members agreed with the confidential draft minutes from the CG-33.

Actions:

SECR: to upload the CG-33 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 uploaded as well to the Disagreements folder in S-CIRCABC.

The Chair informed that, prior to the CG-34 meeting, two referrals were discussed during a teleconference on 14 February, two referrals were discussed during a teleconference on 5 March and two referrals were also discussed during a teleconference on 6 March. An agreement by consensus was reached for one product and the product can be authorised. The outcome was agreed by written procedure.

Another referral was closed by written procedure and the product can be authorised as the refMS and icMS agreed on the open points and no comments were received during the commenting period.

The Chair informed that four referrals were recently submitted on 6 and 7 March.

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

Five referrals were tabled for discussion, and one referral that was still under commenting was briefly introduced.

1) 2) Two referrals were discussed concerning two similar PT18 products from the same applicant containing alpha-cypermethrin as active substance. The points of disagreement were related to the different areas: efficacy, physical chemical parameters, risk assessment of human health and environment, instruction for safe disposal of the product. CG members agreed by consensus on the way forward on the points of disagreement and agreed that the final PAR and SPC will be provided by the refMS by 31 March. The referrals were closed and the products can be authorised.

3) A referral was discussed concerning a PT18 product used in aircrafts containing 1R-trans phenothrin as active substance. Most of the points of disagreement were discussed during the teleconference on 6 March. The remaining points were discussed during the CG-34 meeting and agreement was reached that (a) MMAD data inclusion will be recorded in the PAR, (b) WHO guidance 243 should be followed for the risk assessment of human health for this particular case, (c) RMM should be indicated in SPC to exclude several exposures per day of the cabin crew, (d) considering the used propellant gas, the authorisation shall be subject to the post-authorisation condition. An agreement was not reached on one of the points of disagreement related to dermal exposure assessment and relevant risk mitigation measures. This point will be further discussed.

4) A referral was discussed concerning a PT18 product containing permethrin as active substance. Most of the points of disagreement were discussed during the teleconference on 6 March. The remaining points were discussed during the CG-34 meeting and agreement was reached that the studies provided by the applicant for quantitative analysis of the generated smoke and analytical method for the determination of each substance of concern are acceptable. An agreement was not reached on one of the points of disagreement, i.e., since an unacceptable risk for environment was identified, locations for which the product can be allowed to be used, where no wet cleaning is expected, should be clarified. This point will be further discussed.

5) An outcome of the referral of the PT18 product containing transfluthrin as active substance was presented during the CG-34 meeting, since the refMS and the icMS found an agreement before the meeting. CG members agreed by consensus on the efficacy of the product and the application dose. The referral was closed and the product can be authorised.

6) A referral concerning a PT8 product containing IPBC as active substance was only briefly introduced considering that it is still under commenting. The points of disagreement are related to the product classification and labelling, physical chemical properties, and environmental risk assessment considering an identified substance of concern, as well as to the fact that SPC has not been provided. The MSs are invited to provide comments on the points of disagreement by 29 March.

Actions:

1), 2), 5) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

4) The icMS: To provide an additional information by 15 March.

3), 4) The refMSs: To provide an additional information by 18 March.

3), 4) MSs: To review the refMS provided information by 20 March.

6) MSs: to provide comments by 29 March.

5.3. Clarification points for submission of formal referral

The CG SECR reminded MSs that in accordance with provision of Article 35 (2) of the BPR, only those points of disagreement shall be referred to the CG, for which the cMS considers that a biocidal product assessed by the refMS does not meet the conditions laid down in Article 19 of the BPR.

On a more general note, the CG SECR reminded that in accordance with Working procedure for resolving of disagreements all discussions (comments and received documents) should be posted on CIRCABC so that every MS is aware of the ongoing discussions.

Actions:

MSs: To take note of the information.

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-34-2019-07). The intention of publishing this list is to allow refMSs of national authorisations of products based on the same active substance to be informed about the issues identified in UA applications.

Actions:

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

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

7. Any Other Business

7.1 Late procedures

The SECR and the Commission briefly presented the overview of late procedures.

Actions:

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

7.2. Feedback on e-consultations

One e-consultations was briefly introduced:

1) **Complete quantative composition**

A CG member, briefly introduced a recently launched e-consultation regarding complete quantitative composition for a product. The discussion will be continued during the CG-35 meeting.

Action points:

MSs: to provide comments by 27 March

7.3 Update on questions forwarded from CG to ECHA

The SECR briefly presented an updated overview of the status of the questions referred from the CG to be addressed by ECHA (CG-34-2019-06).

8. Agreement of the action points and conclusions

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

Open session

9. Welcome to the open session

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

10. Agreement of the agenda for the open session

The agenda for the open session was agreed with the addition of one point on MR of individual products in a family (point added by MS).

Actions:

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

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

The Chair invited the participants to declare any potential conflict of interests. No declarations of conflicts of interest were made.

12. Draft minutes (non-confidential part) from CG-33

The Chair explained that the draft non-confidential CG-33 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period, but during the CG-34 meeting MS proposed minor changes. CG members agreed with the confidential draft minutes from the CG-33.

Actions:

SECR: to upload the CG-33 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 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

The SECR updated the meeting on the progress of the items referred to the WGs related to the second renewal of AVK rodenticides. In particular, CG members were informed that a CG member would provide a discussion document for dermal absorption for the HH WG (another CG member will provide support).

As regards to a surface water study, the ENV WG agreed that the recent study should only be taken into account at the next active substance renewal stage (in order to agree on a harmonised way forward on how to take the outcome of the study into account). Since the renewal of products will take place before the renewal of the active substance, during the CG-33 meeting CG members were invited to provide comments on whether the conclusions of the ENV WG should be applicable for the second or the third product renewal.

The CG members agreed that a recent study concerning risk to surface water should be considered at the next (2nd) renewal of the active substance in order to have a harmonised approach. This decision was also made taking into account that the risk assessment for AVK rodenticides is unacceptable and the overall conclusion of the environment risk assessment will not be changed even when considering the recent study and all AVK rodenticides are authorised through Article 19(5) of the BPR.

The CG member commented that in this particular study, results were reported that significant residues of AVK substances were identified in freshwater fish species across several rivers in MS. Considering that a research project has been started and the results will be presented for future discussion.

Actions:

All: To take note on the information.

14.1.2 PT14 – Harmonisation for reporting packaging size and material

A CG member presented an updated proposal to harmonise the reporting of packaging size and material during the second renewal of AVK PT14 products (CG-34-2019-18). The proposal was updated with the comment from the Commission on the specific case of product to be used by general public against mice and rats. In the document it was clarified that in accordance with active substance renewal approval conditions, the maximum quantity of bait per pack indicated in all tables of use for the general public should be one proposed "for rats, only or mice and rats". In MSs where some uses against rats are not allowed for the general public, maximum pack size can be adjusted pursuant to Article 37 of the BPR.

CG members agreed with the document.

Actions:

MS: to provide a final public version of the document by 22 March.

SECR: To upload document in into the relevant folders in the CG CIRCA BC.

14.2 Harmonised approach for filling in the PAR template

During the CG-33 meeting MSs were invited to volunteer to lead the revision of the different sections of the PAR in order to avoid some duplications and make the PAR shorter and more user friendly. The SECR informed CG on volunteers to lead the revision of the physical chemical and analytical properties, efficacy, environment and general sections of the PAR.

The SECR asked whether any other CG member would be willing to volunteer to review human health section of PAR template. Considering that there were no volunteers to lead this section, it was agreed that SECR will contact a particular CG member to clarify about possible volunteers.

Actions:

SECR: to agree on timelines with topic leading MSs.

MSs (leading the update of the PAR template sections): To provide proposals for update of the PAR template.

SECR: To open Newsgroup for comments.

All: To provide comments on proposal.

14.3 Authorisation of products with in situ active substances: some discussion points

The Commission briefly updated the CG members that considering the received feedback from the CG members, CA members and ASOs, the revised version of the CA document has been tabled for discussion and agreement for the March CA meeting.

The Commission invited MSs to provide sufficient input for the development of the technical guidance for in-situ products as soon as update of the Recommendation of the BPC Working Groups for in situ generated active substances will be started.

14.4 Products currently on the EU market and new products linked to applications for UA-BBP

The SECR introduced the topic and informed that during the CG-25 meeting the template for applicants to give an exhaustive list of products (including those currently on the EU market and new ones) for which a National authorisation or Union authorisation is being applied for, was agreed. This template is available in ECHA webpage (LINK). During the Business Rule Check (BRC) step in R4BP3 ECHA checks whether this document is included in the UA applications.

The SECR commented that the same approach will be followed also for UA-BBP applications in order to support MSs that every MS will not need to request such information separately. ECHA will check during the BRC step for all new UA-BBP applications whether this template is included. For already submitted UA-BBP applications, ECHA will request to submit the template if it has not been included.

15 – Feedback from working parties

15.1 Agreement on WP recommendations

The SECR presented (CG-34-2019-09, CG-34-2019-12, CG-34-2019-13) agreed WP recommendations in a nutshell and all WP agreements related to the similarity concept (similar composition, similar level of risk and efficacy, similar uses) consolidated in one document (CG-34-2019-12, CG-34-2019-13).

Some open points in the document were presented to the CG members for discussion and agreement:

- During the WP-BPF-8 meeting WP experts agreed by consensus on the document concerning criteria to assess similarity of uses. However, the experts were asked to provide comments on the use object/pattern category. The document tabled for CG meeting included received proposals for the use object/pattern category list. The SECR presented the CG member's proposal with justification for change. The CG members agreed with the proposed changes. The SECR informed CG members that IND identified inconsistencies in the matrix of uses and these will be corrected in the revised tool.
- The general principles described in the document on how to address similar level of risk and efficacy were agreed by consensus by the WP experts. However, during the WP-BPF-8 it was agreed that additional examples should be included in the Annex of the document to further illustrate the concept. The CG member presented the question how to manage paragraph 77 of Annex VI of the BPR in concept of similar level of efficacy? An example was given if the core composition 5-10% is supported by both the efficacy data and the risk assessment the question was raised whether more flexible approach would be supported by the CG members and allow to keep the core with 5-10% active substance concentration, if the efficacy is already proven for products with active substance concentration 5%, or core should be restricted to 5% of the active substance.

  Several CG members expressed opinion that they would support more flexible approach and could accept the core composition with 5-10%.

During the CG-34 meeting for discussion of this agenda point there were no comments from ASOs.

The CG members agreed on the document for assessment of similarity in biocidal product families. This document and the question of how to manage paragraph 77 of the Annex VI of the BPR in the context of the BPF have been forwarded for further consideration for the CA level.

Actions:

COM: To take note of the agreement.

SECR: to update an automated tool for uses in the form of matrix considering the agreement on "use object, pattern category".

15.2 Applicability of the WP recommendations

The SECR introduced the topic (CG-34-2019-01) and invited CG members to discuss the date of applicability of the document for assessment of similarity in biocidal product families agreed by the WP. Two options were proposed for discussion as regards the document: Option 1 – an approach agreed in the CA document (CA-July12-Doc.6.2.d-Final) should be followed, i.e., the 2 years cut of date would apply, Option 2 – earlier applications of the documents to BPF applications.

In general, CG members supported by consensus an earlier application of the WP recommendation (Option 2). However, CG members expressed different views whether WP recommendation should be applied for applications under evaluation (e.g., "X" month before the draft PAR is sent to the applicant) (a) or only for the new applications submitted after CA agreement on earlier applications (b). Option 2 (b) was supported by the majority of the MSs.

In support of the Option 2 (a) MSs commented that there are very complex BPF applications already submitted by the IND and in the evaluation stage and applying recommendation for on-going cases would harmonise an approach among MSs.

In support of the Option 2 (b) MSs commented that in order to comply with the legal BPR deadlines and give predictability for applicants, the new BPF concept should be only applicable for the new applications submitted after CA agreement on earlier applications.

The Commission informed that the CA document (CA-Nov14-Doc.5.8-Final.rev3) will be upated to include the recommendations of the WP and will be tabled for discussion and possible agreement on the May CA meeting.

This information was forwarded for consideration at the CA meeting.

Actions:

COM: To take note of the CG view and inform CA meeting accordingly.

15.3 Follow up on the WP on frequently used sentences in the SPC

SECR updated the CG on the update of the frequently used sentences for the SPC.

CG members agreed that the sentences developed for PT14 would not be included in the list of frequently used sentences. Furthermore, regarding the proposal to include P18 sentences in the list it was agreed that SECR would consult the MS in order to provide further clarification. The CG will be invited to provide further comments.

Actions:

SECR: to open Newsgroup for commenting on the necessity to include PT18 sentences.

All: to provide further comments when the Newsgroup is opened.

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-34-2019-16 and CG-34-2019-20, 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-34-2019-14, which was made available for information.

16.3 List of active substances meeting the exclusion or substitution criteria

SECR presented the report and informed the CG about the updates introduced in the table. Furthermore the SECR informed the CG that for certain active substances no application was submitted for renewal.

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-34-2019-11).

Actions:

Rapporteur MSs: To check the new information and report to CG-SECR by 26 March.

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

There were no topics tabled for discussion

16.5 Feedback on e-consultations

One e-consultation was discussed.

1) **ED potential of co-formulants in BPs**

The lead CG member introduced this topic and the changes that have been made to the document regarding ED potential of co-formulants (CG-34-2019-02).

In addition, the Chair reminded the CG that the document was already discussed twice during previous meetings.

It was clarified during the discussions that the document to be agreed upon includes instructions for the applicants.

The steps included in the decision tree for assessing ED properties of co-formulants in biocidal products was discussed and agreed upon.

In addition, CG members discussed any possibility for a harmonized approach for the assessment when it comes to the same co-formulants. In relation to this, several CG members expressed concern about finalising the assessment of the product authorisation applications in the legal timelines of the BPR and duplication of the work for the same co-formulants.

One CG member indicated that if a co-formulant has any indications to have ED properties, this has to be referred to and evaluated under the provisions of the REACH Regulation.

The Commission reminded the CG about the discussion, that it is up to the evaluating MS to decide to take into account the assessment of REACH or assess a co-formulant within the remit of the BPR. Furthermore, the Commission indicated that in order to avoid duplication of work, as indicated in document (CA-March18-Doc.7.2.b-final) a coordination and information exchange mechanism should be developed.

It was highlighted by one ASO member, that in case the possibility for further testing is removed from the last step, the applicants will not be able to submit any more tests if there is an uncertainty regarding the ED properties for certain co-formulants. This view was supported by one MS.

The document was agreed by the majority.

The minor revisions agreed at the meeting will be updated by the lead CG member.

Actions:

UK: to provide the final public version of the document by 19 March.

SECR: to upload document into the relevant folders in the CG CIRCABC.

16.6 How to deal with ED assessment for co-formulant when in the context of changes application co-formulant exchange is proposed by the applicant?

The SECR presented an approach on how to deal with ED assessment for co-formulants in the context of changes application, a co-formulant exchange is proposed by the applicant. SECR commented that in the context of an application for a change, the evaluating body (e.g. refMS or eCA) should only assess the information related to the change. The applicant has to justify in the application whether the new co-formulant(s) have to be assessed in accordance with CA document (CA-March18-Doc.7.3.b-final), i.e. whether there are indications that the involved co-formulant(s) may have ED properties. The evaluating body, on the basis of the information provided by the applicant or available to it, decides whether there are indications that the involved co-formulant(s) may have ED properties. Where relevant, it may ask additional information to the applicant for the appropriate assessment.

The CG member commented that in practice this approach could be difficult to follow as a supplier of the biocidal product does not have full information on the co-formulants.

The CG members also expressed the following concerns: (a) how the assessment of the co-formulant can be finalised in the legal timelines included in the Commission Implementing Regulation No 354/2013, (b) if there is indication that a co-formulant has ED properties, the pathway followed under the REACH Regulation should be followed for an assessment of ED properties as biocides experts still have a limited experience in such assessment and this can affect the outcome of the evaluation.

The Commission indicated that person who is placing the biocidal product on the market has to follow legal requirements and is responsible to provide all necessary information and demonstrate that products are safe. In accordance with CA document (CA-March18-Doc.7.3.b-final), if the conclusion cannot be made on the ED properties of co-formulant, the post-authorisation condition could be included in the product authorisation. However, the Commission commented that there is necessity to cross check how better deal with ED assessment during the changes application and whether the post authorisation condition can be included there.

The CG member volunteered to prepare a general proposal on how MSs have to assess ED properties of the co-formulants.

Actions:

All: To take note of the information.

MS: To provide a proposal by 3 April.

SECR: To open a newsgroup for comments.

All: To provide comments in the dedicated newsgroup in 3 weeks from Newsgroup opening.

SECR: To table this topic for discussion during the CG-35 meeting (closed session).

16.7 PT8 residue migration into food commodities

One CG member presented the document that was discussed during the previous CG meeting and updated the CG about any changes introduced (CG-34-2019-04). The member explained that the document includes proposals about consumer safety and MRL exceedance in connection with PT8 products. For the case of a possible MRL exceedance, a risk mitigation measure was proposed to be introduced. Furthermore, it was proposed, as post

authorisation condition or for the renewal stage, to request residue trials to prove that the MRL is not exceeded in case of the treated wood.

The member explained that all comments received during and after the CG-33 meeting have been compiled into one document. Most of the commenting MS considered the proposed RMMs as acceptable. The applicability of the precautionary statement introduced for the downstream user of the treated wood was questioned by the commenting MSs. Regarding the proposal to include a precautionary statement, a question was raised how to communicate it to the downstream user. This should be discussed further how to address it in practice and whether any warning should be included in the SPC.

One member pointed out that, based on previous practice, if such a measure is accepted, the labelling elements should be introduced for the treated article at the active substance approval level.

One member asked to clarify whether the precautionary measure would be introduced for all PT8 products or only for products that are intended for treating wood that will come into contact with food. This will be addressed.

The topic will be further discussed. If no agreement is reached the document will be referred to the CA.

Actions:

SECR: To open a newsgroup for comments on the MS proposal.

All: To provide comments by 3 April.

16.8 Automatic generation of study /literature lists from IUCLID

The SECR presented a proposal (CG-34-2019-04) about automatic generation of study/literature list from IUCLID. During the CG-33 meeting SECR asked input from the CG members whether MSs consider such list useful and what information should be included in the list.

Based on the input provided, the CG members supported that study/literature list could be automatically generated from IUCLID in the following format:

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)
3.1 Appearance	Author name	XXXX	Test #1 for…	No

SECR informed that as a second step, further integration between the PAR template and IUCLID is foreseen. Therefore, this study/literature reference will be taken into account during the revision of the PAR template.

16.9 Classification of changes

The SECR presented (CG-34-2019-10) the procedure how classification of changes has been done by ECHA and whether further guidance are needed. The SECR explained that in accordance with the Commission Implementing Regulation No 354/2013 the authorisation holder may request ECHA to provide an opinion on the classification of changes in accordance with provisions of the Article 2 of the the Regulation No 354/2013. ECHA will evaluate an application and deliver an opinion. The SECR informed the CG members that

since 2013, 24 applications for classification of changes have been submitted via R4BP3. However, 20 cases were withdrawn or rejected due to the different reasons and only three cases have been evaluated and opinions have been issued. In all those three applications the label claim extension was included.

The SECR also invited MSs to discuss whether MSs would like to be consulted (by default) in this process.

The CG members commented that there is no necessity to consult with MS for all applications on classification of changes. However, it could be done if there is any concerns or additional questions.

The CG members also commented that they strictly apply the requirements of the Annex of the Regulation No 354/2013, therefore, no additional guidance would be necessary at the moment. If there are concerns on classification of changes, MSs advice applicants to apply to ECHA for classification of changes.

Considering MSs experience in the evaluation of the changes applications, the SECR invited MSs to discuss and provide feedback how to harmonise the submission of the documents and IUCLID for changes applications, particularly also for UA whether:

- MSs would like to receive consolidated PAR or PAR with addenda? Consequently, what should be included into the PAR? MSs were invited to consider also discussion from CG-11 meeting and CG-24 meeting.
- Updated IUCLID file should be submitted or new IUCLID file should be provided only including information relevant for changes application?

The CG member commented that during the discussion of this point it should be also clarified how to deal with the documents if the refMS is not the same as the MS for evaluation of changes.

Actions:

SECR: To open a newsgroup for comments on the document harmonisation.

All: To provide comments by 3 April.

16.10 Function of co-formulants (non-active substances) and grouping

The SECR invited the CG members to discuss whether it is necessary to develop definitions of the function of co-formulants. Particularly considering that as prerequisite for grouping (developed in the context of the BPF concept) a clear definition of the function of the co-formulants is needed.

The CG members supported development of the definitions. Considering that there were initial discussion on the definition of the function of the co-formulants in the APCP WG, the SECR will inform CG members whether this topic should be further discussed in the APCP WG or CG.

Actions:

SECR: to discuss with the APCP WG Chair the document discussed in the WG

16.11 SBP authorisation procedure change from a Union authorisation procedure to a National authorisation procedure

This topic was postponed for the CG-35 meeting.

16.12 MR of individual products in a family

The CG member presented this point and commented that they were informed that some MSs would agree to authorise part of the BPF.

The SECR reminded the CG that it has been clarified during the CG-18 meeting that in accordance with Article 32 of the BPR, MR authorisations are subject to the same terms and conditions.

This also applies to BPFs and one member of the product family cannot be mutually recognised. During the CG-18 meeting it was also clarified that the MR should not be mixed-up with the new cases that the amended SBP Regulation provides for (e.g. SPB application resulting in a "reduced family" or a SPB application of a family member).

Actions:

All: To take note of this information.

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.

Actions:

SECR: To publish the Action points and conclusions in the relevant S-CIRCABC space.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

Part II - MAIN CONCLUSIONS & ACTION POINTS

34th meeting of the CG

12th of March – 13th of March 2019

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 one agenda point on how to deal when MR process has been started before SoP for MR (point added by ECHA).	**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	
The conflict of interest was declared.	**SECR:** to record conflict of interest in minutes.
4 – Draft minutes from CG-33	
The draft confidential minutes of the CG-33 meeting were agreed with a minor modification.	**SECR:** to upload the CG-33 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 informed that two referrals had been closed before the meeting by written procedure. Agreement by consensus was reached for both cases and the products can be authorised.	**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	
1) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **2)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **3)** An agreement was not reached and one point of disagreement will be further discussed. **4)** An agreement was not reached and one point of disagreement will be further discussed.	**1), 2), 5) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **4) The icMS:** To provide an additional information by 15 March. **3), 4) The refMSs:** To provide an additional information by 18 March.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
5) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **6)** The referral was briefly introduced. The discussion will take place by teleconference.	**3), 4) MSs**: To review the refMS provided information by 20 March. **6) MSs**: to provide comments by 29 March.
5.3 - Clarification points for submission of formal referrals	
ECHA provided clarification as regards of submission of the referrals. CG members were reminded that in accordance with Article 35(2) of the BPR, only those points of disagreement shall be referred to the CG, if cMS considers that a biocidal product assessed by the refMS does not meet the conditions laid down in Article 19 of the BPR.	**MSs:** To take note of the information.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA ECHA presented the list of issues identified in Union Authorisations.	**MSs:** To take note of the information provided in the table. **SECR:** To provide an updated list for the next CG meeting.
7 – Any Other Business	
7.1 - Late procedures	
COM presented the reports related to late procedures.	**MSs:** To review the document and communicate to ECHA any inaccuracies in the data.
7.2 - Feedback on e-consultations	
One e-consultation was briefly introduced as it was recently launched: Complete quantitative composition. The discussion will be continued during the CG-35 meeting.	**MSs**: To provide comments by 27 March.
7.3 - Update on questions forwarded from CG to ECHA	
The SECR presented an overview of the status of the questions referred from the CG to be addressed by ECHA.	
7.4 – How to deal when MR process has been started before SoP for MR was agreed	
It was discussed how to deal when MR process has been started before SoP was agreed. CG members agreed on the way forward.	**MSs:** To take note of the information.
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 conclusions and action points were agreed by consensus.	
OPEN SESSION	
9 – Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed with one additional point on MR process of individual products in a family (point added by MS).	**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-33	
The draft non-confidential minutes of the CG-33 meeting were agreed with a minor modification.	**SECR:** to upload the CG-33 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 - Preparation for the second renewal of AVK PT14 products	
14.1.1 Update of WG discussions	
The SECR updated the meeting on the progress of the WGs (HH and ENV) on dermal absorption and application of a study on surface water. The CG agreed that the new study on surface water will be considered for the 2nd renewal at active substance level.	**All**: To take note on the information.
14.1.2 Harmonisation for reporting packaging size and material	
A CG member presented an updated proposal on how to report the packaging size and material. The document was agreed by the CG members.	**MS:** to provide a final public version of the document by 22 March. **SECR**: To upload document in into the relevant folders in the CG CIRCA BC.
14.2 - Harmonised approach for filling in the PAR template	
SECR informed CG on volunteers to lead an update of the APCP, EFF, ENV, general sections of the PAR.	**SECR:** to agree on timelines with topic leading MSs.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
The SECR asked whether any MS would like to volunteer to lead HH section of the PAR. CG agreed that the leaders of the relevant PAR template update will provide proposal.	**MSs (leading the update of the PAR template sections)**: To provide proposals for update of the PAR template. **SECR:** To open Newsgroup for comments. **All**: To provide comments on proposal.
14.3 - Authorisation of products with in situ active substances: some discussion points	
COM updated the CG members that considering the received feedback from the CG members, the revised version of the CA document has been prepared for the CA meeting.	
14.4 - Products currently on the EU market and new products linked to applications for UA-BBP	
The SECR updated the CG that UA-BBP applicants will be requested to provide the list of products currently on the EU market and new products (template agreed during the CG-25).	
Item 15 – Feedback from working parties	
15.1 - Agreement of WP recommendations	
The CG members agreed on the document for assessment of similarity in biocidal product families. This document will be forwarded for consideration in the CA level. The question how to manage paragraph 77 of the Annex VI of the BPR in the context of the BPF will be further discussed during the CA meeting.	**COM:** To take note of the agreement. **SECR:** to update an automated tool for uses in the form of matrix considering agreement on "use object, pattern category".
15.2 - Applicability of the WP recommendations	
CG members were invited to discuss on the date of applicability of the documents agreed by the WP. CG members supported an earlier application of the WP recommendations (Option 2). CG members expressed different views whether WP recommendations should be applied for on-going cases (a) or only for new applications submitted after CA agreement on an earlier applications (b). This information will be forwarded to CA meeting.	**COM:** To take note of the CG view and inform CA meeting accordingly.
15.3 - Follow up on the WP on frequently used sentences in the SPC	
The SECR presented a status of the update of the list of frequently used sentences for the SPC including on the timelines. CG members agreed that sentences developed for PT14 will not be included in the list of frequently used sentences.	**SECR:** to contact MS to submit a clarification on proposal to include PT18 sentences in the list. **SECR:** To open a newsgroup for comments.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	All: To provide comments in the dedicated newsgroup in 3 weeks from Newsgroup opening.
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
16.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	
16.3 - List of active substances meeting the exclusion or substitution criteria	
SECR presented the report, available for information.	**Rapporteur MS**: To check the new information and report to CG-SECR by 26 March. **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	
There were no topics tabled for discussion.	
16.5 - Feedback on e-consultations	
One e-consultation was discussed. ED potential of co-formulants in biocidal products. The document was agreed with minor changes.	**MS**: To provide a final public version of the document by 19 March. **SECR:** To upload document into the relevant folders in the CG CIRCABC.
16.6 - How to deal with ED assessment for co-formulant when in the context of changes application co-formulant exchange is proposed by the applicant?	
The SECR informed on the way forward for this topic. A CG member volunteered to prepare a proposal how to assess ED properties of the co-formulants.	**All:** To take note of the information. **MS:** To provide a proposal by 3 April. **SECR:** To open a newsgroup for comments. **All:** To provide comments in the dedicated newsgroup in 3 weeks from Newsgroup opening.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	SECR: To table this topic for discussion during the CG-35 meeting (closed session).
16.7 - PT8 residue migration into food commodities	
FR CA presented the topic with an updated proposal.	**SECR**: To open a newsgroup for comments on the MS proposal. **All**: To provide comments by 3 April.
16.8 - Automatic generation of study/literature lists from IUCLID	
The SECR presented an updated document. The CG members agreed on (a) the proposal that study/literature list could be automatically generated from IUCLID, (b) the format of the automatically generated study/literature list. This study /literature reference list will be taken into account during the revision of the PAR template.	
16.9 – Classification of changes	
The SECR presented how classification of changes has been done by ECHA and discussed with CG members whether further guidance is needed. The SECR also invited to discuss how to harmonise the submission of the documents and IUCLID for changes application, particularly also for UA applications.	**SECR**: To open a newsgroup for comments on the document harmonisation. **All**: To provide comments by 3 April.
16.10 - Function of co-formulants (non-active substances) and grouping	
The SECR invited the CG members to discuss whether it is necessary to develop definitions of the function of co-formulants.	**SECR:** to discuss with APCP WG Chair the document discussed in the WG
16.11 - SBP authorisation procedure change from an Union authorisation procedure to a National authorisation procedure	
This topic was postponed for the CG-35 meeting.	
16.12. - MR of individual products in a family	
It has been clarified during the CG-18 meeting that in accordance with Article 32 of the BPR, MR authorisations will be subject to the same terms and conditions authorised by refMS across all cMS. This also applies to BPFs.	**COM:** To take note of this information.
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.	**SECR:** To publish the Action points and conclusions in the relevant S-CIRCABC space.

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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

Final agenda
34th meeting of the Coordination Group (CG-34)

12 March – 13 March 2019

on 12 March 2019 from 09:30 to 17:30
on 13 March 2019 from 09:00 to 13:00

Venue:

12 March
Permanent Representation of the Czech Republic to the EU
15, rue Caroly
1050 - Ixelles Bruxelles
Belgium

13 March
Albert Borschette Conference Centre
Rue Froissart 36
1040 Brussels
Belgium

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-34-2019
For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-33

CG-M-33-2019_Draft confidential
For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-34-2019-05

For information

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

Links to disagreements

For discussion and agreement

5.3 Clarification points for submission of formal referrals

For information

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

6.1 Issues identified in the context of UA

CG-34-2019-07

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-34-2019-15, CG-34-2019-19

Documents to be distributed

For information

7.2 Feedback on e-consultations

CG-34-2019-17

Links to e-consultations

For discussion and agreement

7.3 Update on questions forwarded from CG to ECHA

CG-34-2019-06

For information

7.4 How to deal when MR process has been started before SoP for MR was agreed

For information

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-34-2019

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-33

CG-M-33-2019_Draft non confidential

For agreement

Item 13 – Administrative issues

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

For discussion and agreement

14.1.2 PT14 – Harmonisation for reporting packaging size and material

CG-34-2019-18

For discussion and agreement

14.2 Harmonised approach for filling in the PAR template

For information

14.3 Authorisation of products with in situ active substances: some discussion points

Links to Library

For information

14.4 Products currently on the EU market and new products linked to applications for UA-BBP

For information

Item 15 – Feedback from working parties

15.1 Agreement of WP recommendations

CG-34-2019-09, CG-34-2019-12 &
CG-34-2019-13

For discussion and agreement

15.2 Applicability of the WP recommendations

CG-34-2019-01

For discussion (agreement)

15.3 Follow up on the WP on frequently used sentences in the SPC

For information

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-34-2019-16 & CG-34-2019-20

For information

16.2 Deadlines for application for product authorisation

CG-34-2019-14

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-34-2019-11, CG-34-2019-21

For information

16.4 IT issues

For information

16.5 Feedback on e-consultations

CG-34-2019-02 & CG-34-2019-08

Links to e-consultations

For discussion and agreement

16.6 How to deal with ED assessment for co-formulant when in the context of changes application co-formulant exchange is proposed by the applicant?

CG-34-2019-22

For discussion

16.7 PT8 residue migration into food commodities

CG-34-2019-03

For discussion and agreement

16.8 Automatic generation of study/literature lists from IUCLID

CG-34-2019-04

For discussion and agreement

16.9 Classification of changes

CG-34-2019-10

For discussion

16.10 Function of co-formulants (non-active substances) and grouping

For discussion

16.11 SBP authorisation procedure change from a Union authorisation procedure to a National authorisation procedure

For discussion

16.12 MR of individual products in family

For information

Item 17 – Agreement of the action points and conclusions

For agreement

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