15 May 2017

CG-M-22-2017 non-confidential

Final non-confidential minutes of the 22nd meeting of the Coordination Group (CG)

14/15 March 2017

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the twenty second CG meeting. 37 members from 25 Member State Competent Authorities (MSCAs) participated in the meeting. Two representatives from DG SANTÉ and three representatives from ECHA were present for the full meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-22-2017) and invited participants to add any items under AOB. Four agenda points were added to be discussed in the closed session. The first two points were related to an update on new data generated for transfluthrine and permethrin. The third point was related to a clarification needed for the agreement reached during the CG-16 meeting for PT 19 products, and the fourth point was related to the dietary risk assessment of PT 19 products. One agenda point was added to the AOB of the open session regarding an update from the Efficacy Working Group (WG) on the e-consultation on use classes for PT8. The agenda was agreed with these modifications.

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. The draft minutes from CG-21

The Chair explained that the draft confidential CG-21 minutes had been uploaded for commenting via Newsgroups and that comments were received from a CG member. The minutes were updated with these comments and the CG members agreed on the updated confidential draft minutes from the CG-21.

Actions

SECR: to upload the CG-21 minutes into the relevant folders in the CG CIRCABC.

5. Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

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

Actions

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

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

The Chair informed that no informal referrals had been notified, so there was no informal referral for discussion.

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

The Chair informed that three formal referrals had been closed by written procedure during the discussions that took place after the CG-21 meeting via teleconference. An agreement by consensus was reached by the CG members on the conditions for the authorisation of these products.

Five formal referrals were discussed during the meeting and one formal referral submitted on 13 March 2017 was briefly introduced.

The Chair explained that two additional referrals were pending acceptance due to a procedural issue. This issue would be discussed during the meeting. The Chair further explained that the acceptance by the CG of a referral previously introduced during the CG-21 meeting had been questioned by the Commission. This referral was submitted under the provisions of Article 27(2) for simplified authorisation and it was not clear whether the subject of the disagreement would fall under the scope of this Article. The Agenda Point 6.3 related to the scope of referrals for simplified authorisations under Article 27 of the BPR would therefore be discussed first and, depending on the outcome, it would be decided whether this referral would need to be addressed by the CG.

1), 2) Two formal referrals were discussed concerning PT 19 products which had a common point of disagreement. The two referrals were treated as one issue. The cMS argued that the exposure assessment of the products had not been carried out using the application rate that was proven to be efficacious. An additional point of disagreement concerning whether a co-formulant should be considered as a substance of concern was discussed. No consensus was reached and the referral will be further discussed by teleconference. The newsgroup on this referral will be re-opened for written comments for MSs to reflect on the discussions held during the meeting.

3) A formal referral concerning a PT19 product was discussed. The icMS and the refMS agreed on a way forward for the points of disagreement during the referral commenting period. The outcome of the referral was presented and the CG members agreed on the outcome by consensus. The risk of secondary inhalation exposure will be refined to demonstrate an acceptable risk and the PAR and SPC will be amended to account for the comments of the cMSs.

It was concluded that the product meets the condition for granting an authorisation in Article 19(1)(b)(iii) of the BPR and this formal referral is therefore closed.

4) A formal referral concerning a PT8, 14 and 18 product was discussed. A few major points of disagreement related to the necessary PPE and human exposure were resolved in a discussion during a preliminary teleconference. An open point was discussed related to a disagreement on the efficacy studies necessary for the product authorisation. The CG members agreed by consensus that for this exceptional case it was justified to add a post authorisation condition for submission of additional efficacy data.

It was concluded that the product meets the condition for granting an authorisation in Article 19(1) of the BPR.

5) A formal referral concerning a PT18 product was discussed. The point of disagreement was related to the validity of the efficacy data submitted by the applicant. In the meantime, the applicant has submitted a new efficacy study. The CG members agreed by consensus that the data in this new study was sufficient to prove the efficacy of the product. An additional point remains open related to a disagreement on the data needed for a field study. The referral will be closed by written procedure once this point is resolved.

6) 7) The acceptance of two referrals was discussed. The Chair explained that there was a procedural issue related to the timelines of submission of the referrals that needed to be

discussed by the CG in order to decide whether the referrals should be accepted. The CG members decided to accept only one of the referrals.

The point of disagreement was related to how to report the concentration of the active substance in the SPC.

8) Based on the agreement reached in the discussion of the agenda point 6.3, the CG members agreed that the conditions in article 27(2) for referring this disagreement to the CG were not met. This disagreement was therefore not accepted as a referral by the CG.

9) A formal referral was introduced concerning a disagreement on the environmental exposure assessment of a PT 8 product consisting of 3 different active substances. The discussion will be finalised during the CG-23 meeting.

Actions

1-2) SECR: to open a newsgroup for comments on the still open points.

1-2) All to comment on the newsgroup by 28 March.

1-2) SECR: to organize a teleconference in April with the objective of finding a way forward for an agreement by consensus.

3) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

4) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

5) All: To provide comments by 15 March 2017 on the referral.

5) cMS with the open point and rMS to communicate the agreement via the newsgroup in S-CIRCABC.

5) SECR: to follow-up the outcome of the referral by written procedure.

6-7) SECR: To remove the referral from the referral list.

8) SECR: To initiate the referral as stated in the Working procedures.

9) All: To provide comments by 3 April 2017 on the referral.

9) SECR: to organize a teleconference in April, if needed, with the objective of finding a way forward for an agreement by consensus during CG-23.

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-22-2017-13).

The SECR briefly informed the meeting regarding an additional point that was not included in the table and was raised in the EFF WG-II-2017. This point was related to an EN standard method to test the efficacy of iodine and the acceptability of the Phase 2 Step 2 in the method.

Actions

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

6.2 Iodate used as stabilizer

The SECR presented the document CG-22-2017-15 with a proposal including two different approaches to solve the issue of iodate acting as stabiliser in iodine or PVP iodine containing products. The SECR explained that, as follow up from the discussion during the CG-21 meeting, written comments were received from several MSs on the approaches presented on the document CG-21-2017-15. Based on the comments an updated proposal was prepared including two different approaches to be discussed:

(a) Consider iodate as a stabiliser in products when the increase in iodine overtime stays within a specified range. This range could be discussed by the APCP WG.

(b) Consider iodate as a new substance independently of the increase of iodine over time in the product.

The CG members agreed that clarification was needed from the APCP WG on the technical question about what exact use of iodate/iodide could be regarded as stabiliser. The decision on what approach to follow (a) or (b) would then be taken once the technical questions have been addressed by the WG.

Actions

SECR: to refer the issue to the APCP WG to decide under what conditions iodate can be considered as a new active substance.

6.3 Scope of referrals for simplified authorisations under Article 27 of the BPR

The Commission briefly introduced this agenda item by referring to document CG-22-2017-23, which was also subject to a pre-meeting consultation. The Commission also referred to the comments submitted by two CG members concerning whether scope issues concerning Article 2(2) of the BPR are also covered by Article 27(2) of the BPR.

On a more general note, the Commission mentioned that Article 35 of the BPR presupposes that the concerned product for which the conditions in Articles 19 or 25 are questioned, as evaluated and/or authorised by a MS, is a biocidal product falling under the scope of the BPR. Concerns related to scope issues should be identified at an earlier stage by the MS carrying out the assessment of the application of MR-P, UA or the SAP. If so, the agreed procedure in document CA-March14-Doc.7.5 should be followed and where relevant, it might conclude with the submission of a request to the Commission to take an Article 3(3) decision. The Commission referred to several previous Article 3(3) requests.

Upon request from a MS, the Commission also clarified that disagreements on the wording of some instructions for use or RMM would not be "scope issues" within the meaning of Article 2(2), as they are intended to adapt or to improve some parts of the SPC biocidal product and not to contest that it falls under the scope of the BPR.

Regarding whether Article 88 of the BPR could be used to prohibit the making available of products for reasons not covered under Article 27(2) of the BPR (e.g. risk for the environment or human health), the Commission responded that:

- It would deviate from the objectives and spirit of the BPR if the notified MSs made a risk assessment of products notified under the SAP in order to identify such risks,

- It could be perceived as a disproportionate decision to consider that a product authorised under the SAP and notified in other MSs "constitutes a serious immediate or long-term risk to the health of humans, particularly of vulnerable groups, or animals, or to the environment".

In order to get support from all CG members the Commission agreed deleting paragraph 11 of the document, as such deletion does not change the key criteria for the eligibility of referrals under Article 27(2) in the document and the proposed way forward.

The CG members agreed with the document with the deletion of paragraph 11. Two CG members noted though that they still understand that scope issues under Article 2(2) are legally covered by referrals to the CG according to Article 27(2).

Actions

COM: To provide an updated version of the document.

SECR: To upload the amended document in the relevant folder in S-CIRCABC

7. Any Other Business (closed session)

7.1 Late procedures

The Commission presented the overview of late procedures and focused the attention of CG members on the report concerning the delays in the refMSs.

Actions

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

7.2. Feedback on e-consultations

Three e-consultations were presented for discussion and agreement. A fourth e-consultation on the BPF concept and formulation type was postponed to be discussed during the CG-23 meeting.

1. Sodium Potassium hydroxide in biocidal products

A CG member presented the comments received on the e-consultation related to the possible influence of the co-formulants sodium hydroxide or potassium hydroxide on the efficacy of products (CG-22-2017-06). The SECR informed the CG members that discussions were held in the EFF WG-I-2017 and EFF WG-II-2017 related to this issue for product types 1-5. The CG members agreed that the conclusions reached by the EFF WG will be followed.

2. Innovative insecticide product

An e-consultation was presented on whether the different components of multiconstituent products could be grouped as a single product or should be regarded as separate products.

The Commission will provide written comments to the MS initiating the e-consultation. A final document will be presented in the CG-23 meeting for agreement.

3. Letter of access requirements for substances of concern

A CG member presented the outcome of the e-consultation (CG-22-2017-28) regarding the letter of access (LoA) requirements for substances of concern (SoC).

A CG member noted that when an applicant submits data, a LoA is only required if that data is owned by another party.

It was clarified that it is possible that data could be used by an eCA which would not be in the benefit of the applicant. This would be the case for example of using data available for a SoC that would result in a more restrictive use of a product.

The Commission was of the opinion that, in principle, an eCA using data protected through another regime should make sure that using those data would not be in conflict with the data protection provisions in this other regime.

Comments will be provided by 2 MSs to the MS initiating the e-consultation. With these comments, the document will be updated and tabled for agreement during the CG-23 meeting.

The SECR updated the meeting on the TOX WG-IV-2016 conclusions with reference to a former e-consultation on SoC. The WG considered the current concentration limit of ≥0.1 % to be a reasonable cut-off for SoC identification for those active substances that act as a co-formulant in a biocidal product. The WG members also supported the current guidance in that a full quantitative risk assessment should be performed for active substances acting as co-formulants and identified as SoCs.

4. BPF concept and formulation types

This e-consultation will be discussed during the CG-23 meeting.

Actions

2) COM: to provide comments to the document

2) MS to update the document accordingly

2) SECR: To table the document for agreement for the CG-23 meeting.

3) 2 CG members: to provide comments to the document

3) Initiating CG member: to update the document accordingly

3) SECR: To table the document for agreement for the CG-23 meeting.

4) SECR: To table the topic for discussion for the CG-23 meeting.

7.3 Update on the pilot testing of the SoP of MR

The SECR briefly updated the meeting on the pilot test of the Standard Operations Procedure (SoP) for the MR procedure. The test had been started for three cases and three other cases were pending.

7.4 Update from Toxicology and Efficacy Working Groups on assessment of insect repellents

The SECR presented the document CG-22-2017-11 prepared by the Chairs of the EFF and TOX WGs. The document presented a way forward for harmonisation of the assessment of PT19 products based on the conclusions reached by the EFF and TOX WGs.

The CG members did not agree on the document. The document will be forwarded to the WG to clarify the points raised during the meeting.

Actions

SECR: To forward the document to the relevant WGs.

7.5 Application of Article 19(5) of the BPR

A CG member asked the meeting whether a cMS could mutually recognise pursuant to Article 19(5) a product which has not been authorised by the refMS (no authorised use).

CG members agreed that where there is no product authorisation in the refMS, there is no product authorisation that could be mutually recognised according to article 32 of the BPR.

On a more general note, the Commission referred to the CA document on Article 19(5) and MR (CA-Nov16-Doc.4.2 – Final), in which it is emphasised that: i) Article 19(5) applies only when the exceptional circumstances laid down in it are met and ii) it is a right of a MS to authorise a use/product that would be essential in its territory in order to avoid or mitigate "disproportionate negative impacts for society". Therefore, it is a tool aiming at filling a need identified by the MS and not at giving the applicant an additional opportunity to demonstrate that the conditions in Article 19(5) are met in order to authorise a given use/product that failed to pass the risk assessment.

7.6 Election of vice-Chair of the Coordination Group

The CG Chair announced that he will have to renounce to chairing the CG by end of May 2017. MSs were invited to appoint candidates for the post.

Actions

All: To communicate to the SECR candidatures for Chair of the CG by 15 April.

SECR: To table the election of the Chair of the CG for the CG-23 meeting.

7.7 Consultation on dietary risk assessment for PT 19 products

A CG member briefly introduced the topic about the dietary risk assessment approach for PT19 products used by non-professionals on skin application. A harmonised approach is necessary for the assessment of this application as several different approaches are used currently in the EU. An e-consultation will be opened in order to have the feedback from the CG members.

Actions

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

All: To comment on the newsgroup by 6 April.

7.8 Clarification on the agreement on DEET issues reached during the CG-16 meeting

A CG member asked the SECR to share with all the CG members the bilateral discussions on this topic held with the Chair, the Commission and the SECR. The discussions were related to a requested clarification on the agreement reached during the CG-16 meeting for PT 19 products.

Actions

SECR: To distribute the email with the clarification to all CG members.

7.9 Newly generated data on transfluthrine

A CG member informed the meeting about additional data assessed in the context of product authorisation that is currently under review by the BPC for transfluthine.

Actions

Two CG members: to communicate with each other on the matter and inform CG members during the CG-23 meeting.

7.10 Newly generated data for permethrin

A CG member informed the meeting about the conclusions on the additional PNEC soil data for permethrin.

Actions

Member: To provide the information on writing to the CG members.

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. Five observers from two 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-22-2016) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed with the inclusion of one item regarding un update on a previously discussed e-consultation on use classes for PT8.

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-21

The Chair explained that the draft non-confidential CG-21 minutes were uploaded for commenting via Newsgroups. Written comments were received from a MS prior to the meeting, upon which the draft minutes were updated. An ASO made a comment on AP 14.5 regarding the IT implications for PTs other than rodenticides. With those comments, the draft CG-21 non confidential minutes were agreed.

Actions

SECR: to upload the CG-21 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

13.1 Clarification in the RoP

The SECR presented the amended "Rules of procedure for the Coordination Group (CG) under Regulation EU n°528/2012" (RoP) of the CG. The document included a correction related to the adoption of decisions by majority of votes for issues other than referrals.

The CG members agreed on the document.

Actions

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

13.2 New template for submissions of referrals

The SECR presented a revised version of the template to be used for submitting referrals to the CG. In the new format, the icMS should indicate during the submission of a referral whether (a) the point of disagreement has already been discussed with the refMS and the issue remains unsolved within the 90-day period or (b) the point relates to an issue where the response of the refMS has not been provided within the 90-day period.

The Commission emphasised that referrals must be initiated during the 90 day period even if the answers of the refMS have not been provided (or provided late). A CG member indicated that the template should clearly state that it is the responsibility of the refMS and not the icMS to involve the applicant in the discussions of the open points for the referral.

Considering the time limits for the submission of referrals, the cMS will not need to ask confirmation from the refMS that the open issues were discussed and remained unsolved.

It was also questioned the level of detail necessary in the referral scope section in the form if the commenting table is included in the attachment.

During the discussion, the Commission proposed some changes to the document: (a) a footnote would be necessary in order to clarify that, for MRS procedures, the date of acceptance of the application by the icMS must be indicated (b) for MRS procedures, a list of MSs where the application is already authorised should be given.

Actions

SECR: To amend the document and open a newsgroup for agreement of the revised version.

ALL: To agree in 3 weeks after upload of the document.

SECR: Once the document is agreed to upload the document in the relevant CIRCABC folder.

13.3 Working procedure for the linguistic review in UA

The SECR presented the comments received to the proposal for the linguistic review by the MSs of the translations of the SPC for UA (CG-22-2017-10). One comment was received from a MS, which proposed to adopt a simplified version of the Option 2 described in the document. The MS proposed to eliminate the step where the applicant makes comments to the review provided by the MS. The CG members agreed with this proposal.

The procedure will be adapted with the comments received in writing from NO in order to extend the review procedure to EEA MSs.

Actions

SECR: To prepare an updated version of the document including provisions for EEA countries.

SECR: To table the document for agreement during the CG-23 meeting.

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

14.1 New Q&A pairs for Annex IV to the note on the biocidal product family concept

The Commission introduced this agenda item by referring to the comments submitted after the last CG meeting by industry and some MSs. The Commission would like to discuss with CG members some relevant elements raised in those comments before moving forward with the drafting of any new Q&A pair.

To steer that discussion, the Commission made a presentation addressing the main points raised by MSs and industry and proposing some points for discussion on the BPF concept based on current experience. The Commission apologised for not having shared the presentation with CG members before the meeting (*post-meeting note: it has been uploaded on circabc as document CG-22-2017-32)*.

Following the discussion, the CG members agreed that it would be suitable to organize a working party (WP) on this topic, which would also need some input from experts in the WGs. In this context, ECHA mentioned that in order to help, WGs might need some data to consider (e.g. from the already submitted applications). The Commission added that this input from WGs on technical concepts (e.g. "similar uses", etc.…) should be used to inform the more general regulatory or policy discussion aiming at finding a right balance between flexibility and complexity/feasibility for BPFs.

The Chair invited CG members and industry to provide feedback on the questions in the presentation. On account of that feedback, SECR will prepare a draft document with the objectives and mandate of the above-mentioned WP so that it can be discussed and if possible agreed at the next CG meeting.

Actions

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

All: To comment on the newsgroup by 6 April.

SECR: To table for discussion in CG-23 meeting a draft document with the objectives and mandate of the WP.

14.2 Impact on family sizes for PT 8 due to tinting paste issue – BPF approach for PPD concept (pigments, perfumes and dyes)

A CG member presented the document CG-22-2017-12 with an updated proposal on how to approach the pigments, perfumes and dyes (PPD) concept for biocidal product families (BPF).

The proposal listed three options to address the problem of the notification system.

From the three options presented, related to Option A1 where it was proposed to change the legal text, the Commission explained that this would be difficult to achieve, at least in the short-term. The second option (A2) giving some flexibility on the ranges specified for solvents was considered as the most pragmatic option, however, it was acknowledged that this option was in conflict with the BPR legal text. Considering the conclusions on Options A1 and A2, the CG members agreed that Option A3 was the only viable option at this moment that is in line with the BPR and, therefore, it should be followed. Consequently, only changes

in the main solvent content within the PPD mixture would be allowed without requiring the notification of a new BPF member.

The CG members agreed that PPDs could be considered as mixtures.

14.3 Grouping of ingredients in biocidal product families

The CG members agreed to refer this issue to the general discussion to be handled by the new Working Party for resolving issues related to biocidal product families.

14.4 Template to describe the biocidal product family structure

This item will be discussed during the CG-23 meeting. CG members willing to use the template should use the document CG-22-2017-03.

Actions

SECR: To table this item for discussion for the CG-23 meeting.

14.5 Anticoagulant rodenticides

14.5a Update on points for discussion at the 70th CA meeting

The Commission briefly informed the meeting of a number of points related to anticoagulant rodenticides tabled for discussion at the 70th CA meeting.

14.5b Translations of the SPC templates for anticoagulant rodenticides

The SECR informed the meeting that the harmonised sentences in the SPC templates for anticoagulant rodenticides have been translated into all the EU languages. The CG members agreed to review the translations.

Actions

All: to review the translations by 6 April 2017

SECR: to upload the document with the translations on ECHA website.

14.6 Guidance for the implementation of the amended SBP Regulation

The SECR informed that no comments had been received from MSs on the need of further guidance for the implementation of the amended SBP Regulation.

14.7 Residue analytical methods in water Permethrin

A CG member presented the document (CG-22-2017-26) about the residue analytical methods in water (including drinking water) for Permethrin. In the active substance approval procedure a PNEC value of 0.047 ng/l for permethrin was derived for water. For analysis of residues of permethrin in drinking water and surface water a method was accepted, but the limit of quantification of this method is 50 ng/l. Therefore, this method cannot be considered sensitive enough for the measurement of permethrin residues.

Similar issues were discussed in the past for DEET and IR3535 residue analytical method in air. For these cases, it was agreed (CG-M-11-2015) that *"the data requirement should be applied first at renewal of the active substance and consequently at renewal of the product authorisations or, for new products, after the renewal of the relevant active substances."*

The CG members agreed to follow the same approach for permethrin as for DEET and IR3535. Appropriate analytical methods shall be requested at the renewal stage of active substance and consequently at renewal of the product authorisations in accordance with the approach agreed on CG-11 (May 2015).

Actions

Rapporteur MS: To report to the applicant the agreed way forward.

15. Feedback from working parties

15.1 Frequently used sentences for the SPC – Next steps

The SECR informed the meeting that the frequently used sentences in the free text of the SPC have been translated to all EU languages. The CG members agreed to review the translations.

Actions

All: to review the translations by 26 April 2017

SECR: to publish the document in the ECHA website.

16. Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the report in document CG-22-2017-19 and CG-22-2017-20, which was 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-22-2016-22, which was made available for information.

16.3 List of substances meeting the exclusion or substitution criteria

The Chair informed the meeting that the updated version of the list includes changes concerning some approved active substances.

Actions

Rapporteur MSs: to check the new information

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

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

16.4 IT issues

Several issues were discussed:

a) The Commission asked the meeting regarding the SPC editor for BPF families whether the table describing a given use within a meta SPC should allow to choose more than one PT from those PTs allowed in that meta SPC. The Commission clarified that it would be the applicant choice to (a) use PT specific uses description in the SPC (available now in the SPC editor) or (b) include several PTs in one metaSPC (proposed amendment in the SPC editor) and afterwards have different PTs in one label.

The CG members agreed that it should be possible.

b) A point of concern was raised related to the pdf version of the SPC. The field "application method" is not displayed in the pdf version. The SECR will refer this issue to the IT team.

c) A CG member indicated that there were connectivity issues regarding R4BP 3. The system was also reported to be slow. The SECR invited the CG members to refer the specific questions to the IT Helpdesk.

d) Several CG members indicated that the authorisation number (also for national authorisation) in the SPC appeared as asset number and *vice versa* after the printing of the SPC. The CG members stressed that MSs are issuing the national authorisations and that the authorisation numbers should be accepted and considered in R4BP 3. The SECR pointed out that the asset and authorisation numbers should be clearly indicated in the SPC. The IT team will be informed about this issue.

Actions

SECR: To inform the ECHA IT team about the discussion and the additional open issues.

16.5 Feedback on e-consultations

One e-consultations was discussed. Additionally one update from the EFF WG was provided by the SECR.

1. a) A CG member presented the conclusions of an e-consultation (CG-22-2017-14) related to applications for a change in concerned MSs. It was indicated that, due to the changes applied, there can be situations where the product in the refMS differs significantly from the product in the cMS. The CG member commented that especially in cases where there is a different authorisation holder in the cMS this can be problematic. Discussions took place on related issues regarding the changes Regulation (EU No 354/2013).

The Commission apologised for not providing the comments in writing. However, two main issues were clarified by the Commission during the discussions (a) the Changes Regulation allows for the authorisation holder to have a representative to submit the application for the changes on his behalf (b) the aim of the Changes Regulation is to try to avoid work duplication and benefit from synergies. The assessment made by the refMS should be accepted by other cMSs.

The Commission also indicated that it should be possible to request from the applicant a supporting document stating that the conditions of the authorisation in the members remain the same at the submission of the application for a change. This would be in line with the approach in Regulation 492/2014, which sets the precondition that the terms and conditions should be the same in the MSs in order to benefit from the renewal under a coordinated approach.

The CG members were invited to participate in the preparation of a supporting document in which the applicant states that, for the purpose of an application for a change, the conditions are the same in all the cMSs involved in the procedure.

A CG member commented that there are situations where the authorisation holder would like to submit the application for a change for an authorisation issued through the mutual recognition process, but without the consent of the first authorisation holder. Related to this point, the Commission explained that the Changes Regulation allows that the application for a change can be done only in one MS. However, the consequence could be that at the time of the renewal, the authorisation in this MS would need to be done as a national authorisation pursuant to Article 31 of the BPR.

b) During the discussions several issues regarding the need of a LoA were raised. The Commission clarified that when the same applicant submits an application to different MSs, a LoA would be necessary in the refMS but not in all MSs. If the authorisation holder can act as an applicant in another MS, it is not necessary to request a LoA in accordance with Article 59 of the BPR. Several MSs commented that they consider that if the company in the concerned MS is different from that in the refMS, a LoA is necessary. Different views were expressed by the CG members regarding the request of the LoA and it was indicated that a general discussion would be necessary.

c) A concern was raised regarding the tracking of changes with the IT tools. R4BP 3 is tracking the changes for the relevant authorisations, however, it is not easy to find what was exactly changed in each case.

d) Following the discussion, possible synergies for the evaluation of SBPs were also raised. In SBP applications, the same changes are initiated in several MS, that means that each MS needs to evaluate the changes separately. The proposal was to discuss (i) whether there could be an agreement among MSs where one MS evaluates the application for a change on behalf of all MSs and (ii) whether that could also be applied for the renewal of the SBPs in different MSs.

The Commission indicated that an SBP authorisation is purely a national authorisation and, therefore, it should be renewed in accordance with Article 31 of the BPR. The CG members were invited to think whether it could be possible to have an agreement among MSs to look for synergies for the evaluation of renewals or the same changes for SBPs in several MSs.

However, it should be noted that disagreements could not be submitted to the CG in this case.

2. The SECR provided a brief update on the interpretation of the efficacy guidance for PT8 products considering the conclusions reached in the EFF WG related to an e-consultation discussed during the CG-21 meeting. The outcome was that the products (PT8) with only insecticide activity can be authorised for preventive use only in UC1. More detailed information is available in the EFF WG draft minutes. After the agreement of the minutes of the WG a summary document will be uploaded in S-CIRCABC.

Actions

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

1) All: To comment on the newsgroup by 6 April.

2) SECR: To upload a summary of the EFF WG conclusions in the relevant S-CIRCABC folder.

16.6 Confidentiality on comparative assessment reports

A CG member presented the updated conclusion on the confidentiality of comparative assessment reports.

The CG members agreed with the proposal in the document.

17. Agreement of the action points and conclusions

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

Actions

SECR: To circulate the list of action points and conclusions for agreement.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

Article I. Main conclusions and action points

22st meeting of the CG

14-15 March 2017

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 4 points for the AOB of the closed session and 1 for the AOB of the open session.	**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-21	
Written comments were received from a MS prior to the meeting upon which the draft minutes were updated. No comments were received during the meeting on the updated version of the confidential minutes of the CG-21 meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-21 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal and informal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed about the update of the overview table of the referrals discussed so far at CG level.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR	
No informal referrals were discussed.	
5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
The Chair informed that three referrals had been closed via written procedure since the previous CG meeting (CG-21). Six formal referrals were discussed 1-2) Two referrals were covered in one discussion as they had the same points of disagreement. Discussions will continue with a view to reach an agreement in an upcoming teleconference involving all MSs. For one product there was an	**1-2) SECR:** to open a newsgroup for comments on the still open points. **1-2)** All to comment on the newsgroup by 28 March. **1-2) SECR:** to organize a teleconference in April with the objective of finding a way

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
additional point of disagreement that remains open. 3) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referrals was agreed by the CG members. 4) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. 5) Discussions were initiated with a view to reach an agreement. A point of disagreement remains open. As soon as there is an agreement the SECR will prepare an outcome to be agreed by written procedure. 6) The CG members agreed that the conditions in article 27(2) for referring this disagreement to the CG were not met and therefore this disagreement is not accepted as a referral by the CG. 7) The CG members agreed that the conditions in article 35 for referring this disagreement to the CG were not met and therefore this disagreement is not accepted as a referral by the CG. 8) The CG members agreed that the conditions in Article 35 for referring this disagreement to the CG were met. The referral has been accepted by the CG. The acceptance date will be 14/03/2017. 9) A referral was introduced by the icMS. The commenting period has been initiated and will be discussed by teleconference with the objective of reaching an agreement during the CG-23 meeting.	forward for an agreement by consensus. **3) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **4) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **5) All:** To provide comments by 15 March 2017 on the referral. **5)** cMS with the open point and rMS to communicate the agreement via the newsgroup in S-CIRCABC. **5) SECR:** to follow-up the outcome of the referral by written procedure. **6-7) SECR**: To remove the referral from the referral list. **8) SECR:** To initiate the referral as stated in the Working procedures. **9) All:** To provide comments by 3 April 2017 on the referral. **9) SECR:** to organize a teleconference in April, if needed, with the objective of finding a way forward for an agreement by consensus during CG-23.
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.
6.2 - Iodate used as stabilizer The SECR presented two options to address the issue of iodate used as stabilizer in biocidal products. The CG members agreed to forward the matter to the APCP WG in order to have a clear conclusion on whether iodate or the combination iodate/iodide or both shall be considered as an active substance.	**SECR:** To refer the issue to the APCP WG to decide under what conditions iodate can be considered as a new active substance.
6.3 - Scope of referrals for simplified authorisations under Article 27 of the BPR	**COM:** To provide an updated version of the document.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
COM presented a document with a clarification on the scope of referrals submitted under Article 27 of the BPR related to the simplified authorisation procedure. The CG members agreed with the document with the deletion of paragraph 11.	**SECR:** To upload the amended document in the relevant folder in S-CIRCABC
7 – Any Other Business	
7.1 – Late procedures	
COM presented the overview of late procedures.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data.
7.2 – Feedback on e-consultations	
Four closed e-consultations were presented: 1) A member presented the conclusions of an e-consultation regarding the use of sodium/ potassium hydroxide in biocidal products as a co-formulant and its effect in efficacy. The CG members agreed to apply the conclusions reached in the Efficacy Working Group-I 2017. 2) A member presented the comments of an e-consultation regarding how to consider biphasic products and products including different formulations. The COM will provide comments in writing and the CG member will update the document accordingly. The document will be tabled for agreement during the CG-23 meeting. 3) A member presented the comments of an e-consultation regarding the need of a letter of access for substances of concern. Two CG members will provide further input that will be incorporated in the document. The document will be tabled for agreement during the CG-23 meeting. 4) This e-consultation will be discussed during the CG-23 meeting.	**2) COM:** to provide comments to the document **2) MS** to update the document accordingly **2) SECR**: To table the document for agreement for the CG-23 meeting. **3) 2 CG members:** to provide comments to the document **3) Initiating CG member:** to update the document accordingly **3) SECR**: To table the document for agreement for the CG-23 meeting. **4) SECR**: To table the topic for discussion for the CG-23 meeting.
7.3 Update on the pilot testing of the SoP of MR	
The SECR informed the meeting on the progress of the pilot testing of the MR SoP.	
7.4 Update from Toxicology and Efficacy Working Groups on assessment of insect repellents.	
The SECR presented a document with the proposed harmonised approach for the evaluation of the human health exposure of PT 19 products. The CG members agreed that the document should be referred to the EFF and TOX WG for discussion and/or agreement.	**SECR**: To forward the document to the relevant WGs.
7.5 Application of Art 19(5)	
A CG member asked the meeting whether a cMS could mutually recognise pursuant to article 19(5) a product	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
which has not been authorised by the rMS (no authorised use). CG members agreed that where there is no product authorisation in the rMS, there is no product authorisation that could be mutually recognised according to article 32 of the BPR.	
7.5 Election of the Chair of the CG	
CG members were invited to nominate candidates for Chair of the CG. The elections will take place during the CG-23 meeting.	**All:** To communicate to the SECR candidatures for Chair of the CG by 15 April. **SECR:** To table the election of the Chair of the CG for the cG-23 meeting.
7.6 Consultation on dietary risk assessment for PT 19 products	
A CG member introduced the topic.	**SECR:** To open a newsgroup for comments on the document. **All:** To comment on the newsgroup by 6 April.
7.7 Clarification on the agreement on DEET issues reached during the CG-16 meeting	
A CG member asked the SECR to share the bilateral discussions on this topic held with the Chair, COM and SECR with all CG members.	**SECR:** To distribute the email with the clarification to all CG members.
7.8 Newly generated data on transfluthrine	
A CG member informed the meeting about additional data assessed in the context of product authorisation that is currently under review by the BPC.	**Two CG members:** to communicate with each other on the matter and inform CG members during the CG-23 meeting.
7.9 Newly generated data for permethrin	
A CG member informed the meeting about the conclusions on the additional PNEC soil data for permethrin.	**Member**: To provide the information on writing to the CG members.
Item 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	
10 – Agreement of the agenda	
The agenda for the open session was agreed with the addition of one point.	**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	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-21	
Written comments were received from a MS prior to the meeting upon which the draft minutes were updated. An ASO made a comment on AP 14.5 regarding the IT implications for PTs other than rodenticides. With those comments, the draft CG-21 non confidential minutes were agreed.	**SECR:** to amend the minutes and upload the CG-21 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
13.1 Clarification in the RoP	
The SECR presented the amended RoP of the CG related to the adoption of decisions by majority of votes and consensus. The CG members agreed on the document.	**SECR:** To upload the RoP document into the relevant folder in the CG CIRCA BC.
13.2 New template for submissions of referrals	
The SECR presented a revised version of the template to be used to submit referrals to the CG. The CG members proposed several amendments.	**SECR:** To amend the document and open a newsgroup for agreement of the revised version. **ALL:** To agree in 3 weeks after upload of the document. **SECR:** Once the document is agreed to upload the document in the relevant CIRCABC folder.
13.3 Working procedure for the linguistic review in UA	
The CG members agreed on the Option 2 presented in the proposal without the additional step to check the review of the MSs by the applicant.	**SECR:** To prepare an updated version of the document including provisions for EEA countries. **SECR:** To table the document for agreement during the CG-23 meeting.
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 New Q&A pairs for Annex IV to the note on the biocidal product family concept	
COM made a presentation regarding some points for discussion on the BPF concept. The CG members agreed to provide feedback on the questions in the presentation with a view to organize a working party on this topic.	**SECR:** To open a newsgroup for comments on the document. **All:** To comment on the newsgroup by 6 April. **SECR**: To table for discussion in CG-23 meeting a draft document with the objectives and mandate of the WP.
14.2 Impact on family sizes for PT 8 due to tinting paste issue – BPF approach for PPD concept (pigments, perfumes and dyes)	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
A member presented an updated version of the document on how to approach the PPD concept for biocidal product families. CG members agreed on option A3 of the proposal which will be reflected as a Q&A pair in the Annex IV of the note for guidance. CG members agreed that PPDs can be regarded as mixtures if relevant.	
14.3 Grouping of ingredients in biocidal product families	
The CG members agreed to refer this issue to the general discussion to be handled by the new Working Party.	
14.4 Template to describe the biocidal product family structure	
This item will be discussed during the CG-23 meeting. CG members willing to use the template should use the document CG-22-2017-03.	**SECR:** To table this item for discussion for the CG-23 meeting.
14.5 Renewal of anticoagulant rodenticides	
14.5a Update on points for discussion at the 70th CA meeting.	
COM informed the meeting on the points for discussion tabled for the 70th CA meeting related to anticoagulant rodenticides.	
14.5b Translations of the SPC templates for anticoagulant rodenticides	
The SECR informed the meeting that the harmonised sentences in the SPC templates for anticoagulant rodenticides have been translated to all EU languages. The CG members agreed to review the translations.	**All:** to review the translations by 6 April 2017 **SECR:** to upload the document with the translations on ECHA website.
14.6 Guidance for the implementation of the amended SBP Regulation	
The SECR informed that no comments had been received on the need of further guidance for the implementation of the amended SBP Regulation.	
14.7 Residue analytical methods in water Permethrin	
A CG member presented the topic. The CG members agreed that analytical methods would need to be provided at the renewal stage of the active substance.	**Rapporteur MS:** To report to the applicant the agreed way forward.
Item 15 – Feedback from working parties	
15.1 Frequently used sentences for the SPC – next steps	
The SECR informed the meeting that the frequently used sentences identified by the WP had been translated into all EU languages. The CG members agreed to review the translation of the sentences.	**All:** to review the translations by 26 April 2017. **SECR:** to publish the document in the ECHA website.
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
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	
The Chair invited the meeting to take note of the document.	**Rapporteur MS:** to check the new information and report to CG SECR by 26 April. **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	
COM asked the meeting whether the table describing a given use within a meta SPC should allow the choice of more than 1 PT from those PTs allowed in that meta SPC. The CG members agreed that it should be possible. Other CG members introduced other issues to be resolved.	**SECR:** To inform the ECHA IT team about the discussion and the additional open issues.
16.5– Feedback on e-consultations	
1) A member presented the conclusions of an e-consultation related to applications for a change in concerned MSs. Discussions took place on related issues regarding the changes regulation. 2) The SECR informed the meeting about the conclusions reached in the EFF WG related to the e-consultation discussed during the CG-21 meeting on use classes for PT 8.	**1) SECR:** To open a newsgroup for comments on the document. **1) All:** To comment on the newsgroup by 6 April. **2) SECR**: To upload a summary of the EFF WG conclusions in the relevant S-CIRCABC folder.
16.6 – Confidentiality on comparative assessment reports	
A member presented a document with the conclusions agreed during the CG-21 meeting. The CG members agreed on the document.	**SECR:** To upload the document into the relevant folder in CG CIRCA BC.
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 II Final agenda

ANNEX II

14 March 2017

Final agenda

22nd meeting of the Coordination Group (CG-22)

14-15 March 2017 – from 9.30 to 17:00 on 14 March and from 9.00 to 12.30 on 15 March

Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-22-2017

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-21

CG-M-21-2017_Draft confidential

For agreement

Item 5 – Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-22-2017-04

For information

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

Links to disagreements

For discussion

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

Links to disagreements

For discussion and agreement

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

6.1 Issues identified in the context of UA

CG-22-2017-13

For information

6.2 Iodate used as stabilizer

CG-22-2017-15

For discussion

6.3 Scope of referrals for simplified authorisations under Article 27 of the BPR

CG-22-2017-23

For discussion

Item 7 - Any Other Business

7.1 Late procedures

CG-22-2017-24, CG-22-2017-25, CG-22-2017-27

For information

7.2 Feedback on e-consultations

CG-22-2017-29, CG-22-2017-28, CG-22-2017-08, CG-22-2017-05, CG-22-2017-06

Links to e-consultations

For discussion and agreement

7.3 Update on the pilot testing of the SoP of MR

CG-22-2017-07

For information

7.4 Update from Toxicology and Efficacy Working Groups on assessment of insect repellents

CG-22-2017-11

For discussion and agreement

7.5 Application of Art 19(5)

CG-22-2017-31

For discussion

7.6 Election of the Chair of the CG

For discussion

7.7 Consultation on dietary risk assessment for PT 19 products

CG-22-2017-33

For discussion

7.8 Clarification on the agreement on DEET issues reached during the CG-16 meeting

For information

7.9 Newly generated data on transfluthrine

For information

7.10 Newly generated data for permethrin

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-22-2017

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-21

CG-M-21-2017_Draft non confidential

For agreement

Item 13 – Administrative issues

13.2 Clarification in the RoP

CG-22-2017-02

For agreement

13.3 New template for submissions of referrals

CG-22-2017-16

For discussion and agreement

13.4 Working procedure for the linguistic review in UA

CG-22-2017-10

For discussion

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

14.1 New Q&A pairs for Annex IV to the note on the biocidal product family concept

Link to newsgroup archive

CG-22-2017-32

For discussion and agreement

14.2 Impact on family sizes for PT 8 due to tinting paste issue – BPF approach for PPD concept (pigments, perfumes and dyes)

CG-22-2017-12

For discussion

14.3 Grouping of ingredients in biocidal product families

CG-22-2017-09

For discussion

14.4 Template to describe the biocidal product family structure

CG-22-2017-03

For discussion and agreement

14.5 Anticoagulant rodenticides

14.5a Update on points for discussion at the 70th CA meeting.

Link to the CA documents

For information

14.5b Translations of the SPC templates for anticoagulant rodenticides

CG-22-2017-30

For discussion and agreement

14.6 Guidance for the implementation of the amended SBP Regulation

For information

14.7 Residue analytical methods in water for Permethrine

CG-22-2017-26

For discussion

Item 15 – Feedback from working parties

15.1 Frequently used sentences for the SPC – Next steps

CG-22-2017-17, CG-22-2017-18

For discussion and agreement

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-22-2017-19, CG-22-2017-20

For information

16.2 Deadlines for application for product authorisation

CG-22-2017-22

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-22-2017-21

For information

16.4 IT issues

For information

16.5 Feedback on e-consultations

CG-22-2017-08, CG-22-2017-14

Links to e-consultations

For discussion and agreement

List of the open e-consultations

16.6 Confidentiality on comparative assessment reports

CG-22-2017-01

For agreement

Item 17 – Agreement of the action points and conclusions

For agreement

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