21 November 2018

CG-M-31-2018 non-confidential

Final non-confidential minutes of the 31st meeting of the Coordination Group (CG)

25-26 September 2018

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the thirty-first Coordination Group meeting (CG-31). 35 members and experts from 24 Member State Competent Authorities (MSCAs) and 3 Accredited Stakeholder Organisations (ASOs), a Serbian observer and Norway participated in the meeting. Two 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-31-2018) and invited participants to add any items under AOB. The agenda for the closed session was agreed with the addition of one agenda point on the initiation of the commenting phase on the MR-S procedure.

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. No declarations of conflicts of interest were made.

4. Draft minutes from CG-30

The Chair explained that the draft confidential CG-30 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. The draft confidential CG-30 minutes were agreed.

Actions:

SECR: to upload the CG-30 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 a referral was closed via written procedure prior to the CG-31 meeting. An agreement by consensus was reached and the product can be authorised.

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

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

1) A referral was discussed related to a PT18 product containing synthetic amorphous silicon dioxide as active substance. The point of disagreement was related to the validity of the analytical data submitted for some properties of the active substance in the product. CG members agreed by consensus on a way forward. The product was considered to meet the condition for granting an authorisation according to Article 19(1)(d), of the BPR. This formal referral was therefore closed.
2) A referral was discussed concerning a PT19 product containing citronellal and peppermint oil as active substance. No agreement was reached and the discussion will be continued by teleconference.
3) A referral was discussed concerning a PT8 product containing 3-iodo-2-propynylbutylcarbamate as active substance. CG members agreed by consensus to include several risk mitigation measures (RMMs) in the SPC. The product was considered to meet the condition for granting an authorisation according to Article 19(1)(c), Article 19 (1)(b)(iii) and Article 19 (1)(b)(iv) of the BPR. This formal referral was therefore closed.
4) A referral was discussed concerning a PT14 product containing brodifacoum as active substance. CG members agreed by consensus that, considering the composition of the product, additional efficacy data was not needed. The product was considered to meet the condition for granting an authorisation according to Article 19 (1)(b)(i) of the BPR. This formal referral was therefore closed.
5) A referral was discussed concerning a PT18 product containing a micro-organism as active substance. No agreement was reached and the discussion will continue by teleconference.
6) A referral was discussed related to a PT18 product containing transfluthrin as active substance. CG members agreed by consensus that the product should be considered as a carrier based product and physico chemical characteristics should be carried out with the product without carrier. The product was considered to meet the condition for granting an authorisation according to Article 19(1)(c) of the BPR. This formal referral was therefore closed.
7) , 8) CG members agreed that two referrals concerning two PT8 products were not eligible to be submitted to the CG. The point of disagreement was not related to the assessment report of the MAC application and, therefore, the two referrals were rejected.
9) A referral concerning a PT18 product containing permethrin as active substance was briefly introduced. Several points of disagreement related to efficacy, surface tension, classification and exposure were raised. The discussion will continue by teleconference.
10) A referral was discussed related to a PT18 product containing imidocloprid as active substance. The point of disagreement concerned the need of additional phys chem data. CG members agreed on the way forward. The product was considered to meet the condition for granting an authorisation according to Article 19(1)(d) of the BPR. This formal referral was therefore closed.

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-31-2018-18). 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.

6.2 Post-authorisation conditions in product authorisation

The SECR presented an updated proposal (CG-31-2018-03) on how to address post-authorisation conditions for product authorisations. The SECR will prepare an updated proposal with the majority opinion of the CG for agreement during the CG-32 meeting.

Actions:

SECR: To provide an updated version of the document for the CG-32 meeting considering the comments received and the majority opinion

SECR: To table the document for agreement at CG-32.

7. Any Other Business

7.1 Late procedures

The Commission 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

Three e-consultations were discussed and one e-consultation was briefly introduced:

1) RMM for PT18 products for industrial textile treatment

A CG member presented the outcome of an e-consultation on RMMs for PT18 products for industrial textile treatment (CG-31-2018-02). CG members discussed on RMMs that could be applied to PT18 products where a risk is identified for the environment during application of the product and the service life of a treated article.

CG members will provide further comments on how to address a risk when a product is used to treat articles, and whether the risk can be managed. The discussion will continue during the CG-32 meeting.

Actions:

COM: To provide comments on how to proceed with the labelling of treated articles when there is a risk identified in the biocidal product.

All: To provide comments in the dedicated newsgroups for this e-consultation by 18 October.

2) Definition of SoC

A CG member presented the outcome of an e-consultation on definition of SoC (CG-31-2018-15). CG members discussed whether the approach followed for simplified authorisation presented in the CA-March16-Doc.4.6 Final.rev1 document, point 13 could be also applicable for other types of authorisations. In this case, an active substance which is present in a product as a co-formulant at a concentration above 0.1% (but below a specific or generic concentration limit), could on a case-by-case basis be considered not to be a SoC.

Different views were expressed by the CG members. CG members will provide further comments in writing on this topic.

3) RMMs for PT8 products for in-situ applications

A CG member presented the conclusions of the e-consultation on risk mitigation measures (RMMs) for PT 8 products for in-situ application brushing treatments for Use Class 3 (CG-31-2018-16). When this use results in a risk for the terrestrial environment it is controlled by imposing a RMM stating to use a plastic sheet to cover the soil while applying the

product. A discussion was initiated on whether this RMM is acceptable for all cases and whether it could be enforced, in particular for use by the general public.

The Commission proposed to initiate a commenting period to focus the discussion on two points:

(a) Likelihood that the general public will observe the RMM to cover the soil with a plastic sheet during application of the product.
(b) The need to include a clear instruction on how to handle the cover after the use.

CG members will provide written comments addressing these two points.

4) Renewal of SBP of AVK PT14 products

The Chair informed the meeting that the commenting period of this e-consultation was still ongoing. CG members were invited to provide comments by 28 September. The discussion of the e-consultation will take place during the CG-32 meeting.

The Commission indicated that this topic could be included in the SBP guidelines that are currently being developed by ECHA. Additionally, the Commission commented that, in principle it could be possible to have synergies for the renewal of the reference product and the SBP where both applications would be in the same MS. For example, where the SBP remains identical to the reference product, the CA might consider that a full evaluation is not needed and take a more administrative approach for the renewal of the SBP and, where possible, also apply a reduced fee. However, where the applications would correspond to different MSs, coordination would be more complicated.

Action points:

1) COM: To provide comments on how to proceed with the labelling of treated articles when there is a risk identified in the biocidal product.

1), 2) All: To provide comments in the dedicated newsgroups for this e-consultation by 18 October.

2) MS: To provide an updated document with a proposal considering the comments for the CG-32.

3) All: To provide comments in the dedicated newsgroups for this e-consultation by 18 October in particular on whether the proposed RMM is expected to be followed by the general public and on how to handle a cover after use.

4) All: To provide comments by 28 September.

7.3 Update on questions forwarded from CG to ECHA

The SECR presented an updated overview of the status of the questions referred from the CG to be addressed by ECHA (CG-31-2018-17).

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

Actions:

SECR: To open a newsgroups.

All: To provide feedback on the impact of the issues listed in Table 1 of the meeting document (cases affected and timelines) by 18 October.

7.4 Comparative assessment

The Commission reminded CG members that comparative assessment reports need to be submitted for all product authorisations including a substance that is a candidate for substitution. The SECR will communicate to the ECHA IT team the need to develop

adequate searching capabilities in R4BP 3 and the new dissemination tool in order to assist MSs with the tasks related to comparative assessment.

The SECR will provide a proposal with a way forward on how to share and store comparative assessment reports in R4BP.

Actions:

SECR: Prepare proposal on how to store in R4BP 3 comparative assessment reports.

7.5 Implementation of conclusions of the Commission decision on PT19 products

The Commission informed the meeting that the CA meeting in September will be discussing the consequences of a decision of the Standing Committee related to PT19 products and the need to submit additional efficacy data where the application rate used in the efficacy studies does not correspond to the application rate used for the human health risk assessment. The impact on already authorised PT19 products will be discussed.

7.6 Organisation of CG-33 meeting

The Chair requested volunteers for organising the CG-33 meeting.

Action points:

All: To inform the SECR in case of volunteering to host the CG-33 meeting.

7.7 Initiation of the commenting phase on the MR-S procedure

Due to time constraints this agenda point was not discussed.

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. Three observers from three 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.

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-30

The Chair explained that the draft non-confidential CG-30 minutes had been uploaded for commenting via Newsgroups. Comments were received from one CG member and the minutes were updated considering the comments. CG members agreed with the non-confidential draft minutes from the CG-30.

Actions:

SECR: to upload the CG-30 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 Date of applicability of Technical Agreements of Biocides (TAB) entries

The SECR presented an updated proposal for discussion to clarify the type of entries and date of applicability of TAB entries related to product authorisation (CG-31-2018-20). The document was modified considering the discussion during the CG-30 meeting and the comments received after the meeting.

In the proposal the types of entries in the TAB as well as applicability of those TAB entries were clarified. During the meeting the SECR proposed that for a type (d) entry - new guidance as new or updated technical scientific advice is given in order to have a harmonised approach on how the assessment should be done (without new data requirements) - new guidance should be applied for product authorisation where the reference date of the TAB entry is at least 6 months before the submission of the authorisation application.

This approach was supported by the majority of the CG members. The Chair invited ASOs to comment the proposal. No comments were provided by the ASOs during the CG-31 meeting.

The SECR will inform the CG about new TAB entries directly after publication and ECHA will implement a process to include the date of applicability of TAB entries for product authorisation.

The Commission commented that this proposal could be in conflict with the agreed way forward presented in document CA-July12-Doc.6.2d for applicability of new guidance. In order to ensure consistency, the Commission will forward the document to the CA meeting for discussion.

Actions:

SECR: To update the final document and publish it in the relevant S-CIRCABC space.

COM: To forward the discussion to the CA meeting.

14.2 Preparation for the second renewal of AVK PT14 products

The SECR presented the document CG-31-2018-06 which included a summary of the items to be addressed before the second renewal of PT14 AVK products. The following points were discussed:

- Storage stability data – The APCP WG has initiated the discussion on how to apply the 2014 guidance. Related to this point, the following will be discussed: (a) analytical requirements concerning the matrix effect on the concentration of active substance, (b) bridging data from 25 to 50 ppm products and (c) data requirements for products showing degradation above 10%.
- Physical hazards and respective characteristics – Considering the CLP regulation it is needed to agree on whether it is needed to re-assess the information related to this area. This item will be discussed by the CG. The DE CA agreed to take the lead on this topic.
- Dermal absorption values harmonisation – The discussion will take place in the human health (HH) WG. CG members were invited to consult with their HH experts and propose a volunteer to prepare a discussion document to initiate the discussion in the HH WG as soon as possible.
- Surface water assessment – The Environmental (ENV) WG will initiate a discussion on whether there could be any potential issues to be addressed in the second renewal of AVK products related to surface water assessment as indicated in a publication by Kothoff et al.[1]
- How to address resistance – The SECR informed that, due to other priorities, the efficacy (EFF) WG would initiate work on the guidance on how to address resistance at the earliest by end of 2019. This guidance will therefore not be available for the second renewal of AVK PT14 products. The Commission commented that it should be clarified to what extent information on resistance should be requested to individual authorisation holders, since resistance is not related to a specific formulation of the product, but rather to the active substance and local population of rodents. The SECR will discuss with the Chair of the BPC in order to decide how resistance should be addressed.
- Submission of the PAR – CG members agreed to initiate a general discussion on the requirements related to the PAR to be submitted for the renewal. The SECR will take the lead on this item.
- Packaging- the CG will initiate a discussion to agree on a harmonised approach on how to report package size and material. The FR CA agreed to take the lead on this topic.

CG members proposed to lead the CG discussions will provide a discussion document for the CG-32 meeting.

Actions:

[1] Kotthoff, M., Rüdel, H., Jürling, H. et al. Environ Sci Pollut Res (2018). Available at : https://doi.org/10.1007/s11356-018-1385-8

Proposed volunteers: To confirm to the SECR whether they can lead the topics and to provide a discussion document for the CG-32 meeting.

14.3 Revised Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content)

The Commission presented an updated version of the document related to the update of the Q&A pair number 10 in document CA-May15-Doc.4.4 (CG-31-2018-19). In the context of a disagreement referred to the Commission, a decision was adopted that the active substance content in the SPC should be reported taking into consideration the definition of active substance in the BPR, which refers to the definition of substance in the REACH regulation. This means that the concentration of active substance in the SPC should not be reported as pure active substance, and, consequently, the guidance in the Q&A pair number 10 would need to be adapted in order to be consistent with that decision.

The document was updated based on the comments provided during the previous CG meeting. Examples were now included to demonstrate how to calculate the active substance concentration and several footnotes were included for clarification. The following points raised by CG members were discussed:

- The Commission clarified how the new approach should be implemented in on-going applications and on already authorised products. The new approach should be applied to any on-going procedures for UA (i.e. before the BPC opinion is adopted), purely national applications (before the authorisation decision is made) and MR-P (before the agreed SPC is entered in R4BP by the refMS). For MR-S procedures the situation is different, since the product authorisation in the cMS shall be granted under the same terms and conditions as in the refMS.
  For already authorised products, the update of the current SPCs could take place at the renewal stage, but an earlier update could also be possible in connection to other changes affecting the SPC and the information to be put on the label. This would facilitate that existing stocks of labels can be used and unnecessary costs and waste are avoided.

- A CG member commented that this new approach could result in unclear information on the actual content of active substance in products. Issues could be expected with enforcement. The CG member proposed to have both values in the SPC, the active substance as defined by REACH, and the active substance as pure. In this case it would need to be agreed what value should be mentioned in the label. The Commission commented that, in any case, the active substance concentration in the label should be the one to be legally indicated in the SPC, that is, the active substance as defined by REACH. It was open for discussion whether the pure active substance could be reported also in the SPC (Section 6) or would be enough to be reported in the PAR. The Commission indicated that having two values in the SPC would be more confusing for applicants in terms of choosing the right value to be put on the label, as well as for enforcement authorities.

- The data that will soon be disseminated would show inconsistences, since products already authorised would have the active substance content reported as pure active substance. This situation would be especially confusing for the case of a SBPs, where the reference product could appear with a different concentration than that in the SBPs.

  The Commission commented that in this case, since both authorisations would need to have the same terms and conditions, the SBP should always follow the active substance content as reported in the reference product. The concentration in the reference product would only be corrected as indicated above. Since the SBP and the reference product are not linked once authorised, when the active content would be changed in the reference product, it would be possible that for a certain period of time, the concentration of active substance in the two authorisations would differ. This temporary situation in SBPs and MR-S procedures could be acceptable since it does not raise any safety issue.

- The example given on the last table in the document on how to calculate the active substance content where the active substance is supplied as a mixture was discussed. Several CG members considered that the example was not clear since it could be mistaken with other examples in the document. The Commission will change and clarify the example. The Commission further clarified that the examples referred to the minimum active substance purity reported in the CAR and indicated in the AS approval.

- The text in the last sentence in page 1 needs to be clarified.

- A CG member commented that it would be good to clarify the definition of active substance in the SPC in order to avoid confusion. The Commission commented that in a future update of the SPC template, a footnote could be added to the SPC for clarification.

Industry commented that this new approach could result in confusion during enforcement, and questioned the practicality of the approach noting that the risk assessment is based on the pure active substance. Industry representatives also considered why this information should be in the SPC if it is already in the PAR.

The Chair proposed to initiate a commenting period and invited CG members to provide further comments in writing.

Actions:

SECR: To open a newsgroups for comments.

All: To comment by 18 October.

14.4 Harmonised approach for filling in the PAR template

A CG member informed the meeting that in the context of an active substance workshop, in order to facilitate the submission of product applications containing that active substance, they had developed and published in their website a guidance on how to fill in the template of the Product Assessment Report (PAR) for this active substance.

The Commission proposed to initiate a discussion during the CG-32 meeting on how to harmonise the filling in of the PAR and, if necessary, to revise the PAR template in order to make this task less repetitive and more efficient. CG members agreed with this proposal. A CG member will prepare a proposal for discussion for the CG-32 meeting.

ASOs recommended to exclude active substance names from the PAR template in future discussions.

Actions:

CG member: To provide a proposal for a document on recommendations on how to fill in the PAR template for discussion during the CG-32 meeting.

SECR: To table for discussion during the CG-32 meeting a general discussion on a harmonised template to fill in the PAR.

15 – Feedback from working parties

15.1 Update on the WP on the BPF concept

The SECR updated the meeting on the progress of the WP on the BPF concept. Several updated proposals would be discussed in the WP-BPF-7 meeting related to similarity of uses and similar level of risk and efficacy.

15.2 Applicability of the documents agreed by the WP

During the CG-30 meeting, an agreement on the date of applicability of the document on "Splitting of families" was postponed to the CG-31 meeting. A CG member commented that, according to the document CA-Nov14-Doc.5.8–Final.rev3, certain uses in a family

might not be authorised, but it was not possible to split a family. The document on "splitting of families" would therefore introduce a significant change compared to current practice.

The SECR clarified the following:

- The current guidance, included in the CA-Nov14-Doc.5.8–Final.rev3 document, does not explicitly prescribe a non-authorisation in case of lack of similarity.
- The paragraph 33 in the CA-Nov14-Doc.5.8–Final.rev3 is only clarifying that a non-authorisation is proposed for some uses if they are not covered by a risk/efficacy assessment.
- Following a "non-authorisation approach" based on lack of similarity would have some disproportionate effects in terms of some uses/products disappearing from the market. This might affect the availability of some products to users and, as a result, have an impact on food safety and/ or public health.
- Taking into account the limited existing guidance so far on how to consider the similarity of uses, where in the context of the evaluation of an application the eCA considers that some uses are not similar, the family could be splitted as suggested in the approach agreed by the WP[2].

A CG member commented that this approach should apply only for new products rather than existing product.

The Commission commented that the objective of the document was to establish what should be done if in the context of the assessment of a biocidal product family it was considered that some uses were not similar. Two possibilities were investigated, a) those uses which are considered as not similar would not be authorised or b) to apply a more flexible approach and allow the applicant to submit a second application for authorisation including the non-similar uses. This document in principle would only be applicable for on-going applications. It would be expected that in the future, a clear guidance on similarity would be available and, therefore, this document would probably not be needed. If during the assessment it would be considered that uses are not similar, those uses would not be authorised since the definition of the biocidal product family (Article 3(s) of the BPR) would not be met.

CG members agreed by majority (with the objection of the UK CA), that the approach in the document on splitting of families provided by the WP on the BPF concept can be applied as of 26 September 2018.

Actions:

SECR: To publish the document in the relevant S-CIRCABC space.

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-31-2018-08 and CG-31-2018-09, 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-31-2018-07, which was made available for information.

[2] This is without prejudice of any further agreement in the future establishing that, once agreed guidance on similar uses is fully applicable, the inclusion of non-similar uses in a family will lead to a non-authorisation of those uses.

16.3 List of active substances meeting the exclusion or substitution criteria

The Chair invited the meeting to take note of the updated version of the list of active substances meeting the exclusion or substitution criteria (CG-31-2018-13).

Actions:

Rapporteur MS: To check the new information and report to CG-SECR by 5 October.

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

The SECR updated the meeting on the progress on the dissemination project and the update of R4BP 3 (CG-31-2018-22).

The SECR reminded the meeting that the new dissemination website will be launched by the end of November 2018. CG members were invited to review the information in R4BP3 and identify and mark as confidential any confidential items that should not be disseminated.

It is expected that requests to access documents will increase in relation to unavailable information (e.g. missing PARs) or information inappropriately identified as confidential. Therefore, MSs were invited to assess correctly the confidentiality claims made by the applicants. The SECR reminded the CG about the built-in R4BP3 capabilities which enable MSs to amend the assets.

The SECR informed that it is expected that in the next six months there will also be an increase of activities related to the UK withdrawal from EU, in particular on communication and data changes in the biocides database R4BP 3. CG members were invited to prepare resources to account for this increase in work load.

The following points were clarified/raised during the discussion:

- A CG member asked whether corrections in notifications of simplified authorisations are possible. The SECR will clarify this item with the ECHA IT team.
- The SECR commented that only documents from active assets will be disseminated. Documents will not be disseminated from cancelled or expired assets. NOTE: This aspect will be consulted and confirmed by the ECHA Dissemination team.
- For old assets from before 1/1/16, even though the SPC will not be disseminated, all other relevant documents not marked as confidential will be disseminated.
- If for a simplified notification the deadline for uploading the SPC is missed, the system automatically creates an asset with the original SPC. In this case it is not possible to make corrections by the MSs themselves. A CG member asked whether it would be possible to consider in a future update of R4BP 3 the possibility to make corrections by MSs themselves for this type of assets.
- Some elements for the dissemination tool will be presented during the Biocides Stakeholder day in October.
- Where the packaging material and the pack size is indicated in the SPC, this information will be disseminated. It was reminded that the SPC is a non-confidential document and that therefore SPCs should not contain any confidential information.

Actions:

All: To review the data to be disseminated related to confidentiality.

16.5 Feedback on e-consultations

No e-consultations were tabled for discussion for the open session

17. Agreement of the action points and conclusions

The list of action points and conclusions 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

31st meeting of the CG

25th of September - 26th of September 2018

Agenda point	**Action requested after the meeting**
Conclusions / decisions / minority positions	**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 the initiation of the commenting phase on the MR-S procedure	**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-30	
The draft confidential minutes of the CG-30 meeting were agreed without modifications.	**SECR:** to upload the CG-30 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed about the update of the overview table of the referrals discussed so far at CG level and informed the meeting that one referral was closed by written procedure before the CG-31 meeting.	**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)** The discussion will be continued by teleconference for the remaining open points. The deadline of the referral has been postponed to 16 October 2018. **3)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral 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)** The discussion will be continued by teleconference for the open point. **6)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the	**1), 3) 4), 6), and 10) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **2) SECR, refMS, icMS**: to clarify whether a co-formulant should be considered a substance of concern by 3 October. **2) refMS**: to provide a clarification of the efficacy of the product by 3 October. **2) All**: To review the data by 9 October. **2), 5) SECR**: To organise a follow up teleconference on 10 October.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
referral was agreed by the CG members. **7)** CG members agreed that the point of disagreement was not eligible to be referred to the CG under the provisions of Article 10(2) of the Changes regulation. **8)** CG members agreed that the point of disagreement was not eligible to be referred to the CG under the provisions of Article 10(2) of the Changes regulation. **9)** The referral was briefly introduced and the discussion will continue by teleconference. **10)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.	**5) refMS**: To clarify what guidance was applicable for the evaluation of this product. **7), 8) SECR**: To remove the referrals from the referral list. **9) All**: To provide comments by 5 October. **3) SECR**: To organise a follow up teleconference after the commenting period is finalised.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA	
The SECR presented the list of issues identified in the context of UA.	**MSs:** To take note of the information provided in the table. **SECR:** To provide an updated list for the next CG meeting.
6.2 - Post authorisation conditions in product authorisation	
The SECR presented an updated proposal in order to decide on what grounds a post authorisation condition could be justified. CG members agreed by majority on the way forward. The final document will be forwarded to the BPC for their consideration for UA.	**SECR:** To provide an updated version of the document for the CG-32 meeting considering the comments received and the majority opinion **SECR:** To table the document for agreement at CG-32.
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	
Three e-consultation were discussed 1) RMM for PT18 products for industrial textile treatment. CG members will provide further comments, in particular on how to address a risk when a product is used to treat articles. 2) Definition of SoC. CG members had different views. The discussion will be continued during the CG-32 meeting. 3) RMMs for PT8 products for in-situ applications. Different opinions were expressed. The discussion will continue during the CG-32 meeting. One e-consultation was introduced 4) Renewal of SBP of AVK PT14.	**1) COM**: To provide comments on how to proceed with the labelling of treated articles when there is a risk identified in the biocidal product. **1) 2) All**: To provide comments in the dedicated newsgroups for this e-consultation by 18 October. **2) MS:** To provide an updated document with a proposal considering the comments for the CG-32. **3) All:** To provide comments in the dedicated

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	newsgroups for this e-consultation by 18 October in particular on whether the proposed RMM is expected to be followed by the general public and on how to handle a cover after use. **4) All:** To provide comments by 28 September.
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. CG members were asked to give feedback on the impact of the issues in order to prioritise the discussion of different questions.	**SECR**: To open a newsgroups. **All**: To provide feedback on the impact of the issues listed in Table 1 of the meeting document (cases affected and timelines) by 18 October.
7.4 - Comparative assessment	
COM reminded CG members of the requirement to provide comparative assessment reports to ECHA for all products containing substances that are candidates for substitution.	**SECR**: Prepare proposal on how to store in R4BP 3 comparative assessment reports.
7.5 - Implementation of conclusions of the Commission decision on PT19 products	
The Commission informed the meeting that a discussion will take place in the next CA meeting on this subject.	
7.6 - Organisation of CG-33 meeting	
The SECR requested volunteers for organising the CG-33 meeting.	**All:** To inform the SECR in case of volunteering to host the CG-33 meeting.
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.	**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-30	
The draft non-confidential minutes of the CG-30 meeting were agreed including the comments raised by a CG member.	**SECR:** to upload the CG-30 minutes into the relevant folders in the CG CIRCA BC.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
13 – Administrative issues	
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 - Date of applicability of Technical Agreements of Biocides (TAB) entries	
The SECR presented an updated proposal to clarify the date of applicability of TAB entries related to product authorisation. CG members agreed on the document. TAB entries that do not require generation of data would be applicable as of 6 months before the submission of the application for product authorisation.	**SECR**: To update the final document and publish it in the relevant S-CIRCABC space. **COM:** To forward the discussion to the CA meeting.
14.2 - Preparation for the second renewal of AVK PT14 products	
The SECR presented the list of issues to be addressed during the second renewal of AVK PT14 products and the status of the discussions currently taking place in the WGs. Volunteers were proposed to lead the different items to be addressed by the CG.	**Proposed volunteers**: To confirm to the SECR whether they can lead the topics and to provide a discussion document for the CG-32 meeting.
14.3 - Revised Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content)	
COM presented an updated proposal for the Q&A pair number 10 in document CA-May15-Doc.4.4-Final. CG members and ASOs will provide further comments on the proposal.	**SECR**: To open a newsgroups for comments. **ALL**: To comment by 18 October.
14.4 - Harmonised approach for filling in the PAR template	
A CG member informed the meeting that in the context of an active substance workshop, they had developed and published in their website a guidance on how to fill in the template of the PAR.	**CG member**: To provide a proposal for a document on recommendations on how to fill in the PAR template for discussion during the CG-32 meeting. **SECR**: To table for discussion during the CG-32 meeting a general discussion on a harmonised template to fill in the PAR.
Item 15 – Feedback from working parties	
15.1 - Update on the WP on the BPF concept	
The SECR updated the meeting on the progress on the WP.	
15.2 - Applicability of the documents agreed by the WP	
CG members agreed by majority that the document on "Splitting of families" can be used as of 26 September.	**SECR:** To publish the document in the relevant S-CIRCABC space.
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
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	
The Chair presented the report, available for information.	**Rapporteur MS**: To check the new information and report to CG-SECR by 5 October. **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	
The SECR updated the meeting of the dissemination of R4BP 3 data. PARs, SPC and authorisations marked as public will be disseminated. The SECR reminded the meeting that all information in the SPC is not considered as confidential. CG members were reminded to check confidentiality of data to be disseminated.	**All**: To review the data to be disseminated related to confidentiality.
16.5 - Feedback on e-consultations	
No e-consultations were tabled for discussion for the open session	
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

31th meeting of the Coordination Group (CG-31)

25 September -26 September 2018

on 25 September 2018 from 9:30 to 17:00
on 26 September 2018 from 9:00 to 12:30

Venue:
Albert Borschette Conference Centre
Rue Froissart 36, 1040 Brussels, Belgium

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-31-2018
For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-30

CG-M-30-2018_Draft confidential
For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-31-2018-01
For information

5.2 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-31-2018-18
For information

6.2 Post authorisation conditions in product authorisation

CG-31-2018-03

For discussion and agreement

Item 7 - Any Other Business

7.1 Late procedures

CG-31-2018-10, CG-31-2018-11 & CG-31-2018-12

For information

7.2 Feedback on e-consultations

CG-31-2018-02, CG-31-2018-04, CG-31-2018-05, CG-31-2018-15, CG-31-2018-14 & CG-31-2018-16

Links to e-consultations

For discussion and agreement

7.3 Update on questions forwarded from CG to ECHA

CG-31-2018-17

For discussion

7.4 Comparative assessment

CG-31-2018-21

For information

7.5 Implementation of conclusions of the Commission decision on PT19 products

For information

7.6 Organisation of CG-33 meeting

For information

7.7 Initiation of the commenting phase on the MR-S procedure

For discussion

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-31-2018

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-30

CG-M-30-2018_Draft non confidential

For agreement

Item 13 – Administrative issues

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

14.1 Date of applicability of Technical Agreements of Biocides (TAB) entries

CG-31-2018-20

For discussion and agreement

14.2 Preparation for the second renewal of AVK PT14 products

CG-31-2018-06

For discussion

14.3 Revised Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content)

CG-31-2018-19

For discussion

14.4 Harmonised approach for filling in the PAR template

CG-30-2018-02

For information

***For discussion* Item 15 – Feedback from working parties**

15.1 Update on the WP on the BPF concept

For information

15.2. Applicability of the documents agreed by the WP

CG-30-2018-05

For discussion and agreement

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-31-2018-08 & CG-31-2018-09

For information

16.2 Deadlines for application for product authorisation

CG-31-2018-07

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-31-2018-13

For information

16.4 IT issues

CG-31-2018-22

For information

16.5 Feedback on e-consultations

Item 17 – Agreement of the action points and conclusions

For agreement

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