14 January 2018

CG-M-32-2018 non-confidential

Final non-confidential minutes of the 32nd meeting of the Coordination Group (CG)

20-21 November 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-second Coordination Group meeting (CG-32). 36 members and experts from 22 Member State Competent Authorities (MSCAs), Norway, Switzerland and Serbia, and 4 participants from 4 Accredited Stakeholder Organisations (ASOs), participated in the meeting. One representative 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-32-2018) and invited participants to add any items under AOB. The agenda for the closed session was agreed with the addition of two points. The first point was on the update of the Working Procedure for resolving disagreements and the second one on the reports of products containing creosote.

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-31

The Chair explained that the draft confidential CG-31 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. The draft confidential CG-31 minutes were agreed.

Actions:

SECR: to upload the CG-31 minutes into the relevant folders in the CG CIRCABC.

5. Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

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

The Chair informed that, prior to the CG-32 meeting, two referrals were discussed during a teleconference on 12th October and closed via written procedure. An agreement by consensus was reached for one referral and the product can be authorised. For the second referral, no agreement was reached for one point of disagreement and the reference MS (refMS) will refer this point to the Commission under Articles 36(1) of the BPR.

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

Three referrals were tabled for discussion and five referrals that were still under commenting were briefly introduced.

1) A referral was discussed related to a PT2 product containing nonanoic acid as active substance. The disagreement was related to whether the proposed RMMs were sufficient to control the risk to the environment. No agreement was reached and the discussion will continue by teleconference.
2) A referral was discussed concerning a PT14 product containing difenacoum as active substance. The disagreement was related to the validity of the dermal absorption value used in the exposure assessment. No agreement was reached and the discussion will continue by teleconference.
3) A referral was discussed concerning a PT8 product containing permethrin as active substance. The point of disagreement was related to the classification of the product and to the need to provide additional physico chemical data. CG members agreed by consensus on the classification of the product and the need to provide additional physico chemical data as a post-authorisation condition. The product was considered to meet the condition for granting an authorisation according to Article 19 of the BPR. This formal referral was therefore closed.
4) 5), 6), 7) and 8) Five referrals that were currently under the commenting period were very briefly introduced. The products corresponded to four PT8 products and one PT2 product. The discussion of these referrals will take place after the commenting period in December by teleconference.

Actions:

1), 4) and 5) SECR: To organise a follow up teleconference on 5 December.

1) Applicant: To provide information on possible instructions of use for MetaSPC 2 by 28 November.

2) RefMS and icMS: To evaluate the impact of the dermal absorption values to non-professional users by 10 December.

2), 6), 7) and 8) SECR: To organise a follow up teleconference on 18 December.

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

4) All: To provide comments by 23 November.

5) All: To provide comments by 23 November.

6) All: To provide comments by 5 December.

7) All: To provide comments by 5 December.

8) All: To provide comments by 6 December.

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-32-2018-09). 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 introduced the discussion and summarised an updated proposal with relevance to MSs related to having a harmonised way on the application by MSs of post-authorisation conditions (CG-32-2018-16).

The proposal considered the majority opinion of the CG expressed during the CG-31 meeting and included a proposal on how to follow up on post-authorisation conditions according to Article 48 of the BPR. The proposal was agreed considering a few points discussed and agreed during the meeting.

Minority positions on the agreement of the document were expressed on one point by 3 CG members and on a second point by 4 CG members.

Actions:

SECR: To incorporate the amendments to the document as agreed and publish the document in the relevant S-CIRCABC interest group.

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

Four 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-32-2018-01). CG members discussed the RMMs that could be applied to PT18 products where a risk would be identified for the environment during both, application of the product, and the service life of a treated article with that product.

Considering all comments received the following approach was proposed by the CG member:

a) Concerning the application of the product –products could be authorised with the following RMM "Application solutions must be collected and reused or disposed as a hazardous waste. They may not be released to soil, ground, surface water or any kind of sewer".

   CG members agreed by majority on the proposed approach. One CG member expressed a minority opinion and did not agree that this RMM was sufficient to control the risk to the environment. In its opinion, the product should only be authorised according to Article 19(5) of the BPR (where applicable).

b) Concerning the service life of treated fabrics, products could be authorised considering the following:
   - According to Article 19(1) for the treatment of non-washable wool against mites, with a restriction that would need to appear on the label of the product such as "for production of non-washable wool only" or "Not to be used for production of washable textiles.

     CG members agreed by majority with the proposed way forward under this sub-point. The approach will be applied for "target organisms" in general and not restricted to mites. A minority opinion was expressed by a CG member who considered that this use should only be authorised through Article 19(5) or 2(8) of the BPR (where applicable).

   - According to Article 19(5) or 2(8) for the treatment of textiles against mosquitos.

     CG members agreed by consensus with the proposed way forward under this sub-point.

However, if those uses included in subpoint b) are authorised Article 58(3) and Article 58(4) of the BPR should apply.

CG members agreed on the way forward by majority with a minority opinion expressed by a CG member on several points as indicated above. The agreement reached would be without prejudice of any further consideration on whether these treated articles might have a primary biocidal function and therefore become biocidal products.

2) Definition of Substance of Concern (SoC)

A CG member presented the outcome of an e-consultation on the definition of a SoC (CG-32-2018-02).

CG members agreed that the approach followed for simplified authorisation presented in the document CA-March16-Doc.4.6, point 13 could be also applicable for the normal authorisation procedure.

In accordance to document CA-Nov14-Doc.5.11-Final, co-formulants that are evaluated as active substances and for which the draft final CAR is available, should be considered as SoCs. However, CG members agreed that, in line with the document CA-March16-Doc.4.6, the eCA/refMS may consider, on a case-by-case basis that, where these co-formulants do not to lead to classification of the biocidal product, nor lead to potential systemic/local risks, these co-formulants may not be considered as SoCs, since the definition of the Article 3(1)(f) of the BPR of SoC would not be met.

Further guidance would need to be developed in order to have a harmonised approach on how to address these situations on a case-by-case basis. The DE CA volunteered to prepare a discussion document for the Human Health Working Group.

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-32-2018-06). This use often results in a risk for the terrestrial environment that is controlled by imposing a RMM stating to use a plastic sheet to cover the soil while applying the product.

CG members agreed by majority that the RMM to cover the soil with a plastic sheet is effective to control the risk to the environment provided that the SPC contains clear instructions to safely dispose off the plastic sheet. It was considered that this RMM would be effective independently of the PEC/PNEC value calculated for the risk to the environment.

A CG member expressed a minority opinion indicating that they considered that the effectiveness of the RMM would depend on the severity of the risk, that is, the PEC/PNEC value. Therefore, the proposed RMM would not be generally applicable. This point of view was not supported by other CG members.

4) Renewal of SBP of anticoagulant (AVK) PT14 products

A CG member presented the conclusions of the e-consultation on the renewal of same biocidal product (SBP) authorisations of AVK PT14 products in different MSs (CG-32-2018-22).

CG members agreed that, where products are identical, those MSs were a SBP is authorised would be willing to cooperate during the renewal of their national authorisations. However, it would be important to make sure that products to be assessed remained identical over time.

It was also indicated by one CG member that, even though sharing of work was supported, a fee reduction for the evaluation of the dossier would not be possible at the moment.

The Commission indicated that this topic could be included in the SBP guidelines that are currently being developed by ECHA.

5) Post approval requirements at product authorisation

A CG member introduced an e-consultation on post approval requirements of the active substance at product authorisation (CG-32-2018-10). CG members initiated a discussion on whether a post-approval condition included in the CAR of an active substance was applicable for a particular product authorisation.

On a more general note, the Commission explained that, where post-approval conditions are to be generally applicable to all products, these conditions should be stated in the BPC opinion of the active substance approval.

The e-consultation was still under the commenting phase and the Chair invited CG members to provide further comments in writing.

Action points:

1), 3) and 4) MS: To provide a final public version of the document.

5) All: To provide comments in the dedicated newsgroup by 29 November.

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-32-2018-03).

7.4 Election of the Chair and vice-Chair of the CG

The representative from the EL CA was re-elected for a second term as Chair of the CG.

The SECR invited CG members to nominate candidates for the post of vice Chair of the CG.

Actions:

All: To consider nominations for the post of vice Chair of the CG.

7.5 Update of the Working procedure for resolving disagreements

The SECR informed that the Working Procedure for resolving disagreements was updated considering the timelines agreed in the SoP for the MR phase, as agreed during the CG-28 meeting.

CG members also agreed to incorporate in the Working Procedure the amendment marked in bold text below related to one of the points agreed during the CG-28 meeting: *"in order to increase efficiency, for all procedures in parallel, the SECR will launch all referrals on the same product the **working** day after the deadline for submitting a referral. This date will be considered as the referral submission date"*

CG members agreed with the update of the Working Procedure.

The SECR reminded that, where a point of disagreement is not raised within 40 days after the start of the commenting phase, the referral of that point would not be accepted by the CG Secretariat.

Actions:

SECR: To publish the updated working procedure in the corresponding S-CIRCABC IG.

7.6 Products containing creosote

The Commission reminded those MSs that have authorised creosote containing products that a report should be submitted to the Commission as soon as possible. This point was also tabled for the 81st CA meeting.

Actions:

All: To check whether a report needs to be sent to COM and if not sent yet, to send it as soon as possible.

8. Agreement of the action points and conclusions

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

Open session

9. Welcome to the open session

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

10. Agreement of the agenda for the open session

The agenda for the open session was agreed.

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-31

The Chair explained that the draft non-confidential CG-31 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. CG members agreed with the non-confidential draft minutes from the CG-31.

Actions:

SECR: to upload the CG-31 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

No administrative issues were tabled for discussion.

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

The SECR updated the meeting on the discussions currently taking place in the WGs on AVK PT14 products. Related to assessment of resistance, the SECR informed that the Chair of the BPC had indicated that this aspect should need to be addressed at active substance level.

- APCP WG.

  The discussion concerning analytical requirements considering the matrix effect on the active substance concentration during storage has been finalised. Analytical data to quantify the active substance is required. It is necessary to develop a new analytical method to extract the Active substance from the matrix. Based on feedback from MSs, it has been reported that applicants have already provided improved methods that can be used for this purpose.

  The discussion concerning bridging of storage stability data between 25 ppm and 50 ppm products has been finalised. Read across of data is possible in both directions (25 to 50 or 50 to 25 ppm) as long as it is scientifically justified.

  On the point on data requirements for stablishing the shelf life for products showing degradation above 10%, the WG concluded that it is unlikely that the active substance

in this type of products would degrade, since the decrease in active substance is believed to be due to absorbance to the matrix. Once a reliable analytical method for quantitation of the active substance is used, this point should not be of any concern. However, should there be any degradation products, these should be identified an analysed using a validated method following the applicable current guidance.

- HH WG

  The discussion on harmonisation of dermal absorption values will be introduced during the HH WG in December 2018.

- ENV WG

  The ENV WG will initiate a discussion in December 2018 on the assessment of surface water for AVK PT14 products.

14.1.2 PT14 - Physical hazards and respective characteristics

A CG member informed the meeting that, after discussion with the SECR and the Chair of the APCP WG, it was considered that this item should better be discussed within the APCP WG.

14.1.3 PT14 – Harmonisation for reporting packaging size and material

A CG member presented a proposal to harmonise the reporting of packaging size and material during the second renewal of AVK PT14 products (CG-32-2018-14). It included a proposal on the information that would be necessary to describe the packaging size and material for the "primary" and "secondary" packaging (where applicable), for the different types of products.

The following points were raised:

- A CG member commented that, related to the need of providing information on the pack size, this information would need to be indicated. The CG member considered that this was necessary since the use of gloves would depend on the size of the product blocks.
- A CG member indicated that for products used by non-professionals for both mice and rats, in their MS the size of the packaging is different.

On a more general note, the Commission commented that the second renewal of PT14 products would take place before the renewal of the active substances. Consequently, the packaging size should be compliant with the current conditions following the first renewal of the active substance approvals.

The Commission also proposed to harmonise the nomenclature of the packaging with the one used in other regulations, i.e., to refer to "primary" packaging as that in direct contact with the biocidal product.

Actions:

SECR: To open a newsgroup for comments.

All: To provide comments by 12 December.

14.1.4 PT14 – PAR structure

The SECR introduced the discussion. During the CG-24 meeting, the CG agreed to have a consolidated PAR based on addenda to the initial PAR, but not a fully consolidated PAR. It was also agreed that the PAR would be produced by the refMS evaluating the renewal application.

A discussion was initiated on whether a fully consolidated PAR should be provided for the second renewal.

CG members agreed that, for the second renewal of AVK PT14 products, the preferred option would be to have a fully consolidated PAR. The applicant would be encouraged to cooperate with the refMS to produce the document. In case that it would not be possible to

prepare a fully consolidated version of the PAR, the approach agreed during the CG-24 meeting would still be considered as acceptable.

14.2 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-32-2018-23). The Q&A explained how to report the active substance concentration in the SPC taking into consideration the definition of substance of the REACH regulation.

A CG member proposed to remove the text where it says that efficacy studies are carried out considering the active substance as pure substance. CG members agreed with the document including the change proposed by the CG member.

ASOs requested whether a new pair could be inserted in order to address how the new approach (in line with Commission decision (EU) 2018/1305) would be implemented to on-going applications and already authorised products. By having this information in the same CA document, it would reach applicants in a more efficient manner than through the minutes of the CG. Since CG members agreed with that approach, the Commission will introduce a new Q&A just quoting the content of the agreed minutes of CG-31.

The Commission emphasised the need of good communication with the enforcement authorities and applicants about the changes introduced by the Q&A.

Actions:

COM: To update the Q&A and table the document for discussion in the CA meeting.

14.3 Harmonised approach for filling in the PAR template

The SECR informed that the NL CA would not be able to lead this topic and asked whether any other CG member would be willing to volunteer. CG members were also invited to provide comments on items that would need to be addressed in the current structure of the PAR in order to avoid some duplications and make the PAR shorter and user friendlier.

Actions:

SECR: To open a newsgroup.

All: To volunteer to lead this topic and provide comments on items that should be addressed relating to this topic.

14.4 Assessment of PT21 products – Review of the new assessment tool

During the CG-30 meeting it was agreed that MSs would provide the draft assessment of the salt water scenario for PT21 products using the current OECD model and a new model in order to compare the two methods. Information was provided by two refMSs.

A CG member presented the results of the study comparing the two methods (CG-32-2018-24). The data from five copper/copper thiocyanate based products was assessed. Considering the feedback received from the refMSs, it was noted that the new model was more conservative than the OECD marine scenario model, which was used in the active substance approval process.

Industry expressed some concerns about the calculations used in the new model, where specific values were used in combination with average values, while in the OECD model only average values were used. In the opinion of Industry, the values used in the new model were not acceptable. Following the new model would result in no product being authorised for the Mediterranean region. Industry has contacted DELTARES in order to assess the new model. A report will be available by summer 2019.

For the time being, in the opinion of Industry, only the OECD scenario should be used at the product authorisation stage.

The Commission commented that the comparison is based only on results from five products and thus the results might not be representative enough. Additional data from other refMSs only available late in 2019 would be necessary to reach more significant conclusions.

Actions:

COM: To discuss with UK about reporting to the CA meeting.

14.5 Update of the supporting document for renewal applications

A CG member presented a proposal on an update of the supporting document used for submission of applications for the renewal of product authorisation. It was proposed to include in the supporting document two additional tables: (a) list of all authorised or pending changes for a product (family), following the first authorisation or the last renewal of the reference product (family) and (b) countries where a decision on the change was either taken or is still pending.

The Commission proposed to clarify the text in the introduction section of the supporting document to clearly identify that if an application for renewal is submitted in accordance with the provisions of Article 31 of the BPR, this should be done in one MS only.

CG members agreed with the document with the addition of the comment raised by the Commission.

Actions:

SECR: To publish the document in the ECHA website.

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. Three documents on similarity of uses, similarity of composition, and similar level of risk and efficacy were tabled for agreement during the WP-BPF-7 meeting (21 November). However, the SECR indicated that it was unlikely that all three documents could be agreed. Considering this, the SECR requested whether the mandate of the WP could be extended to 31 January (if necessary) to allow to have an additional discussion back to back with the CG-33 meeting. CG members agreed to extend the mandate of the WP as proposed.

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-32-2018-17 and CG-32-2018-18, 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-32-2018-07, which was made available for information.

16.3 List of active substances meeting the exclusion or substitution criteria

The Chair invited the meeting to take note of the updated version of the list of active substances meeting the exclusion or substitution criteria (CG-32-2018-05).

Actions:

Rapporteur MS: To check the new information and report to CG-SECR by 28 November.

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 briefly informed that the IT User Group meeting was held on 19 November.

16.5 Feedback on e-consultations

Two e-consultations were introduced.

1) ED potential of co-formulants in BPs

A CG member presented the conclusions of the e-consultation on the assessment of Endocrine disrupting (ED) properties of co-formulants in biocidal products (CG-32-2018-12). The CG member proposed a step-wise approach to be followed by applicants when preparing a dossier to assess whether there are indications that a co-formulant in a biocidal product might have ED properties:

a) In step A it is proposed that simple food materials will be excluded from further assessment. CG members in general supported this approach. However, MSs mentioned that it should be considered that there are some food supplements, e.g., cholecalciferol, that have been identified as EDs. Considering this, more detailed definition of the term "simple food materials" would be necessary. This point could also be addressed by establishing a positive list of food materials.
b) In step B it should be checked whether a decision has already been made regarding ED properties within the different EU legislative fields (REACH, PPPs, and BPR). CG members commented that it should be clarified which data bases should be used. The CG member will prepare a consolidated document to address this question.
c) In step C it is checked whether there is existing information suggesting an "indication" of ED properties that may need to be further investigated. In general, it was questioned whether the literature review should be limited to only records from the previous two years and whether it should be limited to non-target organisms. It was also mentioned that, on this step, it should be clarified the data bases that should be applicable.

A CG member commented that it would be necessary to clarify where in the PAR an assessment of ED properties should be included.

In general MSs supported the proposal. CG members will provide further written comments on the document.

As part of this agenda point, ECHA presented the pathway followed under the REACH Regulation that could be followed for an assessment of ED properties. The presentation also included the databases available in the ECHA website which could be used for the purpose of gathering information related to ED assessment (CG-32-2018-25).

A CG member commented that the timelines for product authorisation under the BPR are perhaps not compatible with the timelines used for the substance evaluation process under the REACH regulation. Therefore following this pathway could be challenging.

The Commission indicated that, in order to avoid duplication of work, as indicated in document CA-March18-Doc.7.2.b-Final, ECHA should develop a coordination mechanism (similar to the one already existing for the so-called "third party" dossiers) and an information mechanism to share the outcome of the evaluations. On this point ECHA commented that the number of the assessments for third party dossiers is not comparable with the number of possible co-formulants to be assessed and, therefore, it would be difficult to set up such a system.

CG members also noted that MSs still have limited experience in the assessment of ED properties and this can affect the outcome of the evaluation.

2) Disinfectant by-products

A CG member presented the conclusions of the e-consultation on the assessment of disinfectant by-products (DBPs) during the product authorisation stage (CG-32-2018-13). The CG member asked the opinion of the CG on the following:

1) Deferring the assessment of DBPs for products in product types (PTs) other than PT2 until PT-specific guidance is available.
2) Deferring the assessment of DBPs for PT2 products (including swimming pool disinfectants) until information on DBPs is provided by active substance notifiers at the renewal of the active substance.

During the commenting phase six MSs provided comments. Five MSs supported point 1) of the proposal and four MSs supported point 2) as this would avoid duplication of work and testing in the environment.

During the meeting, three CG members commented that the assessment of the DBPs had been already postponed from the active substance approval stage to the product authorisation phase. Applicants were already working on the generation of the necessary information. Therefore, these CG members did not support deferring the assessment.

CG members commented that more guidance was urgently needed in order to have a harmonised way forward. Clarification was also necessary on how detailed the assessment should be done. A CG member commented that the assessment of DBPs could not be done at active substance level, as the nature of DBPs formed is very dependent of the matrix where the product is applied. For active substance approval not all uses are supported and therefore not all matrixes are considered.

The Commission commented that a pragmatic way forward should be established by setting some priorities and respecting the legal deadlines for the assessment of the products. A scientific discussion at WG level would possibly need to take place prior to a regulatory discussion. A concern was also expressed by the Commission related to the complexity of the assessment of biocidal product families when considering the number of intended uses included in the families and all the possible combinations of matrixes and uses.

CG members will provide further written comments on the document.

Actions:

1) All: To provide comments by 5 December in the dedicated newsgroups.

1) CG member: To provide a revised version of the proposal for discussion in the CG-33 meeting.

1) SECR: To make available the presentation on CIRCABC.

2) SECR: To open a newsgroup.

2) All: To provide suggestions on a more general approach on the handling of the assessment of DBP by 5 December.

2) CG member: To provide a revised version of the proposal for discussion in the CG-33 meeting.

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

32nd meeting of the CG

20th of November – 21st of November 2018

Agenda point **Conclusions / decisions / minority positions**	**Action requested after the meeting** **by whom/by when**
CLOSED SESSION	
1 – Welcome	
2 – Agreement of the agenda.	
The agenda for the closed session was agreed with the addition of two agenda points on the information on the authorisation of creosote containing products to be sent to the Commission and on the update of the Working Procedure to resolve disagreements.	**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-31	
The draft confidential minutes of the CG-31 meeting were agreed without modifications.	**SECR:** to upload the CG-31 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 that two referrals had been closed before the meeting by written procedure. Agreement by consensus was reached for one case and the product can be authorised. No agreement was reached for the other case and the disagreement has been forwarded to the Commission.	**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) The discussion will be continued by teleconference. **2)** The discussion will be continued by teleconference. **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)** The referral was briefly introduced. The discussion will take place by teleconference.	**1), 4) and 5) SECR:** To organise a follow up teleconference on 5 December. **1) Applicant:** To provide information on possible instructions of use for MetaSPC 2 by 28 November. **2) RefMS and icMS:** To evaluate the impact of the dermal absorption values to non-professional users by 10 December.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
5) The referral was briefly introduced. The discussion will take place by teleconference. **6)** The referral was briefly introduced. The discussion will take place by teleconference. **7)** The referral was briefly introduced. The discussion will take place by teleconference. **8)** The referral was briefly introduced. The discussion will take place by teleconference.	**2), 6), 7) and 8) SECR:** To organise a follow up teleconference on 18 December. **3) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **4) All**: To provide comments by 23 November. **5) All**: To provide comments by 23 November. **6) All**: To provide comments by 5 December. **7) All**: To provide comments by 5 December. **8) All**: To provide comments by 6 December.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA – ECHA presented the list of issues identified in Union Authorisations.	**MSs:** To take note of the information provided in the table. **SECR:** To provide an updated list for the next CG meeting.
6.2 - Post authorisation conditions in product authorisation	
CG members agreed on the proposal. The document will be amended to include several comments as agreed during the meeting.	**SECR:** To incorporate the amendments to the document as agreed and publish the document in the relevant S-CIRCABC interest group.
7 – Any Other Business	
7.1 - Late procedures	
COM presented the reports related to late procedures.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data.
7.2 - Feedback on e-consultations	
Four e-consultations were discussed: 1) RMM for PT18 products for industrial textile treatment. CG members agreed on a way forward regarding the application of the biocidal product and the service life of some treated articles. 2) Definition of SoC. CG members agreed that the principle applicable for simplified authorisation would also be applicable for other types of authorisations on a case by case basis. Further clarification will be needed from the HH WG. 3) RMMs for PT8 products for in-situ applications.	**1) , 3) and 4) MS:** To provide a final public version of the document. **5) All:** To provide comments in the dedicated newsgroup by 29 November.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
CG members agreed that the RMM to cover the ground is acceptable for professionals and non-professional users as long as the cover is disposed off in a safely manner. 4) Renewal of SBP of AVK PT14. CG members agreed that different MSs can cooperate in the assessment of renewal applications for SBPs as long as the products are confirmed to be identical. One e-consultation was introduced: 5) Post approval requirements at product authorisation. The discussion will be continued during the CG-33 meeting.	
7.3 - Update on questions forwarded from CG to ECHA	
The SECR presented an overview of the status of the questions referred from the CG to be addressed by ECHA.	
7.4 - Election of the Chair and vice-Chair of the CG	
The representative from the EL CA was re-elected as Chair of the CG.	**All:** To consider nominations for the post of vice Chair of the CG.
7.5 – Update of the Working Procedure for resolving disagreements	
The SECR informed that the Working Procedure was updated considering the timelines agreed in the SoP for the MR phase and the agreements from the CG-28 meeting. CG members agreed with the update.	**SECR:** To publish the updated working procedure in the corresponding S-CIRCABC IG.
7.6 – Products containing creosote	
COM reminded MSs of the need to submit a report for authorised products containing creosote.	**All:** To check whether a report needs to be sent to COM and if not sent it yet, to send the report as soon as possible.
Item 8 – Agreement of the action points and conclusions	
The conclusions and action points were agreed by consensus.	
OPEN SESSION	
9 – Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed.	**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-31	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
The draft non-confidential minutes of the CG-31 meeting were agreed.	**SECR:** to upload the CG-31 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
No administrative issues were tabled for discussion.	
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 - Preparation for the second renewal of AVK PT14 products	
14.1.1 Update of WG discussions	
The SECR updated the meeting on the conclusions of the WGs. The discussion on Chemistry and storage stability requirements by the APCP WG was finalised.	
14.1.2 Physical hazards and respective characteristics	
This item will be referred for discussion to the APCP WG.	
14.1.3 Harmonisation for reporting packaging size and material	
A CG member presented a proposal on how to report the packaging size and material. The discussion will continue during the CG-33 meeting.	**SECR**: To open a newsgroup for comments. **All**: To provide comments by 12 December.
14.1.4 PAR structure	
CG members agreed that as first option a fully consolidated PAR should be prepared by the refMS. Should this not be possible, the approach agreed during the CG-24 meeting could be followed as second option. Applicants are encouraged to cooperate with the refMS in the preparation of a fully consolidated PAR.	
14.2 - 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 agreed on the document including a minor change and a section on applicability of the approach to ongoing applications and already authorised products.	**COM**: To update the Q&A and table the document for discussion in the CA meeting.
14.3 - Harmonised approach for filling in the PAR template	
The SECR asked whether any MS would like to volunteer to lead this topic.	**SECR**: To open a newsgroup. **All**: To volunteer to lead this topic and provide comments on items that should be addressed relating to this topic.
14.4 - Assessment of PT21 products – Review of the new assessment tool	
UK presented the results of the study comparing the assessment of the salt water scenario using the new PT21 tool and the current OECD method. The new tool provides more conservative results.	**COM**: To discuss with UK about reporting to the CA meeting.
14.5 - Update of the supporting document for renewal applications	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
CG members agreed with the document with a minor addition.	**SECR**: To publish the document in the ECHA website.
Item 15 – Feedback from working parties	
15.1 - Update on the WP on the BPF concept	
The SECR updated the CG on the progress of the WP. CG members agreed to extend the mandate of the WP until January 2019 if necessary.	
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
16.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	
16.3 - List of active substances meeting the exclusion or substitution criteria	
The Chair presented the report, available for information.	**Rapporteur MS**: To check the new information and report to CG-SECR by 28 November. **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 CG on the conclusions of the IT Users Group meeting.	
16.5 - Feedback on e-consultations	
Two e-consultations were introduced. 1) ED potential of co-formulants in biocidal products. A CG member presented a proposal on how to address information requirements for co-formulants. A revised version of the proposal will be provided for discussion in the CG-33 meeting. Related to this topic, the SECR gave a presentation on relevant pathways under REACH and CLP regulations applicable to co-formulants. 2) Assessment of disinfectant by-products. A discussion took place on whether evaluation of disinfectant by-products should be done at product authorisation level or at active substance level. Different opinions were expressed.	**1) All**: To provide comments by 5 December in the dedicated newsgroups. **1) CG member**: To provide a revised version of the proposal for discussion in the CG-33 meeting. **1) SECR**: To make available the presentation on CIRCABC. **2) SECR**: To open a newsgroup. **2) All**: To provide suggestions on a more general approach on the handling of the assessment of DBP by 5 December. **2) CG member**: To provide a revised version of the proposal for discussion in the CG-33 meeting.
17 – Agreement of the action points and conclusions	

Agenda point	**Action requested after the meeting**
Conclusions / decisions / minority positions	**by whom/by when**
The list of action points and conclusions for the 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
32th meeting of the Coordination Group (CG-32)

20 November - 21 November 2018

on 20 November 2018 from 9:30 to 17:30
on 21 November 2018 from 9:00 to 12:30

Venue:
Federal Public Service Health, Food Chain Safety and Environment
Eurostation II
Place Victor Horta, 40
Room: Galilei 06C133 (6th floor)
1060 Brussels Belgium

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-32-2018
For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-31

CG-M-31-2018_Draft confidential
For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-32-2018-08
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-32-2018-09

For information

6.2 Post authorisation conditions in product authorisation

CG-32-2018-16

For agreement

Item 7 - Any Other Business

7.1 Late procedures

CG-32-2018-19, CG-32-2018-20 & CG-32-2018-21

For information

7.2 Feedback on e-consultations

Links to e-consultations

CG-32-2018-01, CG-32-2018-02, CG-32-2018-04, CG-32-2018-06, CG-32-2018-10 & CG-32-2018-22

For discussion and agreement

7.3 Update on questions forwarded from CG to ECHA

CG-32-2018-03

For information

7.4 Election of the Chair and vice-Chair of the CG

For discussion

7.5 Update of the Working Procedure for resolving disagreements

For agreement

7.6 Products containing creosote

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-32-2018

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-31

CG-M-31-2018_Draft non confidential

For agreement

Item 13 – Administrative issues

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

For information

14.1.2 PT14 - Physical hazards and respective characteristics

CG-32-2018-15

For information

14.1.3 PT14 – Harmonisation for reporting packaging size and material

CG-32-2018-14

For discussion

14.1.4 PT14 – PAR structure.

For discussion

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

CG-32-2018-23

For agreement

14.3 Harmonised approach for filling in the PAR template

For discussion

14.4 Assessment of PT21 products – Review of the new assessment tool

CG-32-2018-24

For information

14.5 Update of the supporting document for renewal applications

CG-32-2018-11

For discussion and agreement

15 – Feedback from working parties

15.1 Update on the WP on the BPF concept

For discussion and agreement

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-32-2018-17, CG-32-2018-18

For information

16.2 Deadlines for application for product authorisation

CG-32-2018-07

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-32-2018-05

For information

16.4 IT issues

For information

16.5 Feedback on e-consultations

CG-32-2018-12, CG-32-2018-13 & CG-32-2018-25

Links to e-consultations

For discussion

Item 17 – Agreement of the action points and conclusions

For agreement

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