13 March 2019

CG-M-33-2019 non-confidential

Final non-confidential minutes of the 33rd meeting of the Coordination Group (CG)

14-15 January 2019

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chair thanked ANSES on hosting CG-33 meeting in their premises. The head of the department of regulatory product assessment welcomed the participants to the meeting and remarked an importance to have a discussion on product related topics among the Competent Authorities in context of the Biocidal Products Regulation.

The Chairman welcomed all participants to the thirty-third Coordination Group meeting (CG-33). 46 members and experts from 19 Member State Competent Authorities (MSCAs), Norway and 5 participants from 4 Accredited Stakeholder Organisations (ASOs), participated in the meeting. One representative from DG SANTÉ and two 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-33-2019) and invited participants to add any items under AOB. The agenda for the closed session was agreed with the addition of one point on ECHA's opinions on the classification of changes.

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-32

The Chair explained that the draft confidential CG-32 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. The draft confidential CG-32 minutes were agreed.

Actions:

SECR: to upload the CG-32 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-33 meeting, three referrals were discussed during a teleconference on 5 December and five referrals were discussed during a teleconference on 18 December. An agreement by consensus was reached for six products and the products can be authorised. The outcomes were agreed by written procedure.

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

Four referrals were tabled for discussion, and two referrals that were still under commenting were briefly introduced.

1) A referral was discussed related to a PT8 product containing Cypermethrin, tebuconazole, IPBC and Propiconazole as active substances. The disagreement was related to the acceptability of the long term stability data of the product. The applicant provided additional data during the referral period and CG members agreed by consensus that the provided data was acceptable to confirm the shelf life of the product.

2) A referral was discussed concerning a PT2 product containing copper sulphate pentahydrate as active substance. The product is to be used in combination with an oxidizer product and the disagreement was related to the validity of the efficacy data to support the use in swimming pools to prevent the growth of bacteria.

   Although the refMS still supported the conclusion of their assessment, considering that the applicant was willing to remove the claim against bacteria in order to proceed with the authorisation of the product, the refMS joined the majority to reach a consensus agreement and agreed that the product should only be authorised for prevention of growth of green algae.

   CG members agreed by consensus that the efficacy data was sufficient to demonstrate that the product was sufficiently effective to prevent growth of green algae only. The product can be authorised for this use, and an application for a major change will need to be submitted to claim control of bacterial growth.

3) 4) Two referrals were discussed concerning two similar PT8 products from the same applicant containing IPBC as active substance. The refMS had not provided answers to the comments during the mutual recognition phase and, therefore the referrals were initiated. CG members agreed by consensus on how to provide the missing information in the PAR and the SPC, and to include several RMMs in the SPC. The referrals were closed and the products can be authorised.

5) A referral was briefly introduced concerning a PT18 product containing transfluthrin as active substance. The point of disagreement was related to the validity of the submitted efficacy data. The commenting period of the referral is still ongoing and the discussion will take place by teleconference.

6) A referral concerning a PT2 product containing copper sulphate pentahydrate as active substance that was still under commenting and was only briefly introduced. The point of disagreement was related to the efficacy data of the product. The refMS informed the meeting that they could already agree with the proposal of the icMS and amend accordingly the efficacy claims of the product. In case that no further comments are received during the commenting period, the referral will be closed by written procedure.

Actions:

1), 2), 3), 4) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

5) SECR: To organise a follow up teleconference after the commenting period.

5), 6) All: To provide comments by 28 January.

6) SECR: Where no additional comments are received, to initiate agreement of the outcome by written procedure.

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-33-2019-16). 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.

CG member: To provide information to the SECR on an issue raised for UA of lactic acid products.

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

One e-consultations was discussed:

1) **Post approval requirements at product authorisation**

A CG member presented an outcome of an e-consultation on post approval requirements for the active substance at product authorisation (CG-33-2019-14).

On a more general note the CG member presented an explanation about different information in the BPC opinion, assessment report and implementation regulation as regards to the identified data gaps:

a) Data gaps identified during the evaluation of active substance dossier, could be addressed by post-approval data request and, if relevant, are included in Section 2.5 of the BPC opinion and have to be submitted at the latest 6 months before approval of the active substance (in case of existing active substance) or until approval (for active substances not falling under the transitional rules).
b) The data gaps identified for the representative biocidal product(s) are only relevant for the representative biocidal product and are specified only in the CAR under section "requirement for further information related to the (reference biocidal) product". The BPC does not include them in its opinion as this is only relevant for the evaluated representative product and, possibly, for very similar biocidal products.

Those data requests (a, b) are never included in the active substance approval Regulation by the Commission as only Section 2.3 of the BPC Opinion is the basis to phrase the specific conditions.

For specific case, CG members discussed whether a post-approval condition included in the CAR of active substance was applicable for a particular product authorisation. The CG members agreed that the clarification from the applicant should be submitted and the APCP WG would need to be consulted in order to decide whether a requirement would be applicable for the particular product.

Action points:

SECR: To inform ECHA about the need to follow up on this topic by the APCP WG.

SECR: To publish the outcome on the confidential S-CIRCABC IG space.

CG member: To provide a discussion paper for the APCP WG.

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-33-2019-15).

7.4 Update on dissemination

The SECR provided an update on the status of the dissemination platform for product information.

7.5 Election of the vice-Chair of the CG

The representative from the PL CA was elected as vice-Chair of the CG.

7.6 Availability of comparative assessment reports

During the CG-31 meeting it was agreed that ECHA should investigate how to store comparative assessment reports in R4BP3. The possibility to create a document type "Comparative assessment report" in R4BP3 will be further investigated by the IT team.

For time being the comparative assessment reports have been uploaded by the CG SECR in the confidential S-CIRCBC IG. CG SECR proposed a procedure where MSs can directly upload comparative assessment reports in S-CIRCBC. In order to ensure that comparative assessment reports can be found easily, the database will be organised by PTs.

CG members agreed on such proposal.

7.7 Classification of changes

During the CG-33 meeting, the Commission reminded that, in accordance with Article 2(2) of the Changes Regulation (EU) 354/2013, the authorisation holder may request ECHA to provide an opinion on the classification of changes. This would avoid lengthy discussions between authorisation holders and MSs, and it would avoid that the same question is asked to different MSs in parallel, as well as the risk of dis-harmonised answers. CG members were invited to provide comments on how the classification of changes is handled by MSs.

This topic will further be discussed during the CG-34 meeting.

Action points:

SECR: To open a newsgroup

All: To provide comments by 5 February on how classification of changes are handled in MSs.

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. Five 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-32

The Chair explained that the draft non-confidential CG-32 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period, but CG SCER included some clarification in the final version. CG members agreed with the non-confidential draft minutes from the CG-32.

Actions:

SECR: to upload the CG-32 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

No administrative issues were tabled for discussion.

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

The SECR updated the meeting on the progress of the items referred to the WGs related to the second renewal of AVK rodenticides. In particular, CG members were informed that (1) a CG member will provide a discussion document for dermal absorption for the HH WG (another CG member will provide support); and (2) the ENV WG agreed that a recent study concerning risk to surface water would need to be considered at the renewal of the active substance in order to agree on a harmonised approach. Since the renewal of products will take place before the renewal of the active substance, CG members will provide comments on how to address the timelines related to products concerning this issue.

On a more general note, the Commission commented that it could be also discussed whether, overall, a full evaluation of the PT14 products should be done as the renewal of PT14 products will take place before the renewal of active substances.

CG members were invited to provide comments on this aspect and also whether the conclusions of the ENV WG should be applicable for the second or the third product renewal.

Actions:

SECR: To open a newsgroup.

All: To provide comments by 5 February on whether the conclusions of the ENV WG should be applicable for the second or the third product renewal.

14.1.2 PT14 – Harmonisation for reporting packaging size and material

A CG member presented an updated proposal to harmonise the reporting of packaging size and material during the second renewal of AVK PT14 products (CG-33-2019-19). 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.

CG members in general supported the proposal.

The Commission commented again that PT14 products renewal will be before the renewal of active substances. Consequently, the packaging size should be compliant with the current conditions of the active substance approval. The Commission will check the current active substance approval conditions for products intended for "mice and rats". CG members will be invited to provide comments on the feedback from the Commission.

Actions:

COM: To check the active substance approval conditions for products intended for "mice and rats" by 2 February.

SECR: To open a newsgroup for comments on the feedback from COM.

All: To provide comments (2 weeks).

14.2 Harmonised approach for filling in the PAR template

The SECR informed the meeting about some elements to be addressed in the current structure of the PAR in order to avoid some duplications and make the PAR shorter and user friendlier. However, no volunteer was received to lead this topic.

A CG member proposed work-sharing among several MSs and volunteered to provide a proposal for the update of PAR section related to environmental and (or) human health.

The Commission welcomed this proposal and invited ECHA to consider to volunteer to review the general part of PAR. The Commission asked whether any other CG member would be willing to volunteer to review APCP and EFF parts of PAR template.

Actions:

SECR: To open a newsgroup.

All: To volunteer to lead the update of the sections on EFF and APCP of the PAR by 5 February.

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

During the discussion of the document in CG-32 meeting the Commission commented that the proposal regarding the applicability of TAB entries under category d) 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 forwarded the document to the CA meeting for discussion.

The Commision informed that in the 81st CA meeting it was agreed that the applicability of TAB entries under category d) which should follow the 2 year cut-off rule (CG-33-2019-07). However, deviation from this standard approach would be possible for some cases, if it would be agreed by the CG.

Actions:

SECR: To publish the document in the relevant CIRCA BC space.

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

With the support of a power point presentation (CG-33-2019-01) sent to CG members and ASOs before the Christmas break, the Commission introduced several points for discussion concerning the authorisation of biocidal products involving in situ generated active substances. The objectives of having such discussion in the CG were to discuss key elements (principles rather than details); to request written feedback from CG members as experts on product authoriation after CG-33; with a view to update draft CA note for discussion in the March 2019 CA meeting. As indicated by some MSs at the last CA meeting in November 2018, the Commision suggested focus first on general aspects (i.e. for single biocidal products) and then address the specificities of biocidal product families.

The Commission added that in both cases a (draft) SPC has to be filled in as part of the (application for) product authorisation. Therefore, CG members were invited to look at the examples tabled for the 81st CA meeting as supporting information (CG-33-2019-02) and to submit written comments about this matter.

Follwing the introduction of each discussion point, CG members were asked to provide their views:

1) Definition of in situ active substance: CG members agreed that the definition of an active substance under the BPR and the definition of a substance under REACH apply (along the lines of Commission decision (EU) 2018/1305).
2) Definition of biocidal product (for in situ generated AS): CG members agreed that according to the definition of a biocidal products (BP) under Article 3(1) of the BPR:

   - first indent: the biocidal product is the precursor;

   - second indent: the biocidal product mainly involves the in situ generated AS.
3) Case-types: CG members had a common understanding of the three case-types currently described in the draft note of the CA, which consider the whole IGS (precursor(s)/device parameters/in situ genetared AS) that is relevant for the biocidal product subject to authorisation.

Regarding coating technologies, since there is no mixing of precursors nor device involved, CG members were asked to comment on whether a 4th case should be indicated in the note in order to cover this technology generating free radicals. If so, it could perhaps be accommodated under case-type 2, where the paint would be the biocidal product, which subject to uv light, would generate the in situ AS (free radicals).

4) Authorisation of the BP (first/second indent) vs. having information on the whole IGS: CG members agreed that even if only the BP (e.g. the precursor or the insitu generated AS, for the first and second indent, respectively) is authorised, information on the whole IGS is needed to have a complete assessment of the BP and fill in the SPC of the authorised BP (instructions for use, etc..).

CG members also had common understanding that devices are NOT authorised as biocidal products. However, their role (and whole IGS) has to be considered since i) it affects the "output" of the IGS (i.e. the in situ AS) and whether it meets the specifications in the AS approval, is safe and efficacious and ii) to fill in the SPC of the biocidal product (instructions for use, maintenance, checks, etc..).

The CG member asked that should be clarified (a) what will be authorised if there is no specification of the output of IGS given in AS approval and only specification for precursors (example, active chlorine) is incuded in the BPC opinion; (b) what information should be included in the SPC?

5) Composition of the biocidal product (section 2 of the SPC): CG members acknowledged the complexity of this issue. A CG member committed to provide some examples after the meeting in order to better inform the discussion. Regarding the example at slide number six, where two precursors are involved, that CG member indicated that perhaps a case by case approach would be needed in order to decide if the 100% accounts for each precursor or for each of them.

6) Hazard & precautionary statements (section 3 of the SPC): for biocidal products falling under the first indent (case-types 1 and 2), a CG member considered that the H&P statements of the in situ generated AS should always be indicated. Another CG member suggested being indicated under another section of the SPC (e.g. section 6).

For biocidal products falling under the second indent (case-type 3), a CG member indicated that the H&P statements of the precursor (e.g. table salt) should not be indicated under section 3. If needed, a general instruction for use could be added to the SPC, but this should not be checked by the evaluating CA since the precursor is not placed on the market for biocidal purposes nor authorised as a biocidal product.

7) May a BP generate more than 1 in situ AS?: CG members did not oppose to this possibility, since it is explicitly covered by the definition in Article 3(1) of the BPR (..”generating one or more active substances…”). A CG member suggested finding another example because of the on-going discussions regarding chloraine dioxide. CG members were invited to provide other relevant examples.

8) Specificities for in situ BPFs: CG members were asked to provide input on:

i) how to establish the composition range for in situ families (particularly for families under the first indent);

ii) for families under the second indent (i.e. when a device is involved), which value should be indicated in the SPC for in situ AS concentration (the "output" of the IGS, or the "in use" concentration?). A CG member indicated that some times it is very difficult to know the precise contentration of the AS as such.

iii) wheter individual products should only have a specified/fixed composition, or generate a "range of concentrations" of the in situ AS, taking into account the overall concept of a BPF (for non-in situ products); in other words, whether we could be talking about a "family of families".

CG members and ASOs were invited to identify any generic issue for discussion and submit it together with any comments after the CG meeting (e.g. about the filling in of the fields "application rate and frequency", "instructions for use", in the SPC, etc…).

Actions:

SECR: To open a newsgroup for comments on the presentation provided by COM.

All: To provide comments by 5 February.

DE: To provide examples on the composition of IGSs.

14.5 Unique Formula Identifier (UFI) required for authorised biocidal products

The Commission briefly updated the CG about the use of UFI for biocidal products, since this matter was subject to a number of questions from a few MSs.

No derogation applies for biocidal products in relation to Commission Regulation (EU) 2017/542 of 22 March 2017 (modifying Regulation (EC) No 1272/2008). This implies that as from 1 January 2020, any business operator placing on the market biocidal products (i.e. the authorisation holder under the BPR or the relevant importer or downstream user under the national systems of MSs referred to in Art. 89 of the BPR) for consumer use shall comply with the new requirements (i.e. including the generation of UFI). Please note that those operators (i.e. the authorisation holder under the BPR or the relevant importer or downstream user under the national systems of MSs referred to in Art. 89 of the BPR) having submitted information relating to the affected biocidal products to a body appointed responsible for receiving information relating to emergency health response (‘Poison centres’) have to comply with the new requirements as from 1 January 2025 only.

The Commission also informed the meeting that colleagues from DG GROW will attend and address further questions in the March CA meeting. In this context, it was clarified that i) for same biocidal products, companies should also generate an independent UFI and ii) for Biocidal Product Families, UFIs have to be generated for the different family members. It was noted though that, apparently, the UFI could be generated for a range of a concentration

of a chemical. The Commission would need to be further investigate whether this approach could be used for (some) family members.

Upon request from two CG members, the Commission clarified the following:

- The UFI has not to be indicated in the SPC (i.e. not linked to Article 22(2) of the BPR);
- The generation of the UFI does not involve any action by the biocides CA, since it is a labelling requirement that follows from the CLP Regulation (to be observed by the AH according to Article 69(1) of the BPR). It will also be subject to checks in the context of CLP enforcement.

15 – Feedback from working parties

15.1 Update on the WP on the BPF concept

The SECR informed the CG that the documents on similarity of uses, similar level of risk and efficacy and similar composition were agreed by the WP experts. The documents will be tabled for agreement during the CG-34 meeting. ECHA will prepare a non-confidential presentation for the CG-34 meeting summarising the recommendations of the WP. This presentation can be publically used for information purposes.

On a more general note, the Commission commented that CG members nominated experts for WP in order to discuss technical details. Therefore, it would be expected that the documents agreed by the WP should not be discussed in detail.

After agreement by the CG, the Commission would update the document CA-Nov14-Doc.5.8-Final.rev3 including the recommendations of the WP. This document would then be presented to the CA meeting. The CA would need to decide on the date of applicability of the new guidance document. In order to better inform such decision, the CG will also be consulted on the matter during CG-34.

Actions:

SECR: To open a newsgroup for comments on when the WP recommendations should be applicable.

All: To provide comments by 5 February.

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-33-2019-09 and CG-33-2019-10, 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-33-2019-08, which was made available for information.

16.3 List of active substances meeting the exclusion or substitution criteria

The Chair invited the meeting to take note of the updated version of the list of active substances meeting the exclusion or substitution criteria (CG-33-2019-18).

Actions:

Rapporteur MS: To check the new information and report to CG-SECR by 25 January.

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 provided an update on the status of the dissemination platform for product information. ASOs indicated their concerns that confidential information had been made publically available during dissemination.

ASOs requested ECHA to plan a test period to prevent any release of confidential information before any product related documents are made publically available.

ASOs will provide written feedback on their concerns.

Actions:

ASOs: To provide written feedback on incidents related to dissemination of confidential data in the dissemination platform.

SECR: To forward the feedback to the ECHA IT team.

16.5 Feedback on e-consultations

Two e-consultations were discussed.

1) ED potential of co-formulants in BPs

The CG member leading this topic indicated that, due to the large amount of comments received, it was not possible to provide a discussion document for this meeting. The discussion was therefore postponed to the CG-34 meeting.

2) Disinfectant by-products

A CG member presented the updated conclusions of the e-consultation on the assessment of disinfectant by-products (DBPs) during the product authorisation stage (CG-33-2019-03). A discussion took place on whether evaluation of DBPs should be done at product authorisation level or at active substance level. The CG member asked the opinion of the CG on the following:

a) deferring the assessment of DBPs for products in product types (PTs) other than PT2 until PT- specific guidance is available.

b) 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 ten MSs provided comments. Different opinions were expressed, however, considering a majority opinion the CG member proposed:

- for point a) the assessment of DBPs for products in PTs other than PT2 should be deferred for both human health and the environment until PT-specific guidance is available,
- for point b) for human health - the assessment of DBPs for products in PT2 for human health should be carried out particularly for swimming pools. Where disinfectant DBPs have already been identified (i.e. chlorate, bromate, trihalomethanes) a preliminary risk assessment could be carried out. Also, since guidance gives some indication on how to deal with chlorine, DBPs of these could be assessed, considering also available public literature. However, more discussion are needed to ensure that harmonised approach applied. For environment - the assessment of DBPs for products in PT2 should be deferred until information on DBPs is provided by active substance notifiers at renewal.

During the meeting CG members provided comments as follow:

- For point a) at least preliminary human health risk assessment of DBPs should be carried out. Some concerns were expressed, particularly about chlorates. A CG member pointed out that the general approach from existing PT2 guidance could be adapted to another non-PT 2 products. This opinion was supported by another CG member.

- In addition, the assessment of the DBPs had been already postponed from the active substance approval stage to the product authorisation phase by the CAs. Applicants were already working on the generation of the necessary information and dossiers have been submitted recently. Therefore, the CG member did not support deferring the assessment. If the assessment of DBPs will be postponed it should be ensured that guidance are developed urgently to address this point. The CG member also considered that in principle available guidance are sufficient to make an assessment for DBPs at least for environment.
- Another CG member commented that DBPs assessment could be focused for the more relevant uses.
- A CG member commented that in practice there are difficulties to assess DBPs in existing on-going applications.

The Commission noted that it seems that some MSs would like to carry out at the product authorisation stage at least a preliminary assessment of DBPs in order to ensure that the safety aspect is addressed based on the current knowledge. In this context, the Commission asked MSs about the possible consequences of this assessment in terms of RMMs or possible restrictions to the intended uses of the products.

The Commission indicated whether a pragmatic way forward could be established by setting some priorities (e.g. which uses are more relevant and should be assessed first), or by developing a standard set of RMMs to minimise the time invested on every application (provided that that those RMMs are balanced and do not restrict the use of the products unnecessarily).

The CG member indicated that in order develop such generic approach MSs need first to collect information from industry about the use conditions of the products, which could be a long term project.

Since this matter might have significant implications in terms of resources for MSs, delays in product authorisation or implying limiting the scope of the risk assessment, CG members agreed to have a policy discussion during the March 2019 CA meeting.

Actions:

1) All: To provide additional comments as soon as possible.
1) UK: To provide response to comments by 31 January.

1) UK: To provide an updated version of the document by 1 March.

2) UK/COM: Provide a proposal for a policy discussion for the next CA meeting.
2) ASOs: To provide comments on the document before the CA meeting.

16.6 PT8 residue migration into food commodities

A CG member introduced the topic (CG-33-2019-04). As follow up from a PT8 referral, a discussion was initiated concerning the exceedance of maximum residue levels (MRLs) of active substances for PT8 biocidal products intended to be used to manufacture wooden boxes or pallets used to store food commodities and whether it is necessary to set (a) a risk mitigation measure to prevent the residue transfer from treated wood to food and/or (b) set a statement to inform the users about the existence of MRLs.

The Commission referred to the interim approach agreed by the CA meeting. In that approach, PT8 is one of the PTs which in principle should not be considered for MRLs purposes, except if there is clear indications that there are safety issues for consumers. The Commission asked:

1) whether there is a clear evidence on the transfer of residues of active substances between the treated wood and food;
2) why there should be an obligation for the authorisation holder (AH) to inform about MRLs while this information is publicly available;
3) why the AH of biocidal products should have a stricter legal obligation in that respect than AHs for PPPs or medicinal products;
4) whether the proposed RMM is triggered by any risk identified or it is more a precautionary approach which is not based on the risk assessment;

5) whether this information goal cannot be achieved by Article 58(3) and (4) of the BPR, in terms of labelling of treated articles. If the risk is identified with the biocidal product, the person who is placing the treated article on the market should refer to the possible risk on the label of treated articles.

The CG member commented that there was an application in which there was clear evidence about the transfer of residues of the active substance from the treated wood to food.

The discussion will be continued during the CG-34 meeting.

Actions:

SECR: To open a newsgroup for comments.

All: To provide comments by 5 February.

COM: To provide written comments on the topic.

16.7 Automatic generation of study /litereature lists from IUCLID

The SECR informed that ECHA is developing a tool to extract automatically a list of studies/literature from IUCLID that can be included directly in the PAR or used as stand alone document. To ensure that the tool under development is adapted to the practical needs, CG members were asked to provide feedback as soon as the document from ECHA will be provided.

Actions:

SECR: To open a newsgroup for comments on whether this tool would be interesting.

All: To provide comments by 5 February.

16.8 ECHA new structure for Biocides

The SECR informed the meeting about the reorganisation of ECHA (https://echa.europa.eu/about-us/who-we-are/organisation).

17. Agreement of the action points and conclusions

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

Actions:

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

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Part II - MAIN CONCLUSIONS & ACTION POINTS

33rd meeting of the CG

14th of January – 15th of January 2019

Agenda point **Conclusions / decisions / minority positions**	**Action requested after the meeting** **by whom/by when**
CLOSED SESSION	
1 – Welcome	
2 – Agreement of the agenda.	
The agenda for the closed session was agreed with the addition of one agenda point on request for classification of changes by ECHA.	**SECR:** to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.
3 – Declaration of interest in relation to agenda	
No declarations of cdonflicts of interest were made.	
4 – Draft minutes from CG-32	
The draft confidential minutes of the CG-32 meeting were agreed without modifications.	**SECR:** to upload the CG-32 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 six referrals had been closed before the meeting by written procedure. Agreement by consensus was reached for all cases and the products can be authorised.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
1) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **2)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **3)** An agreement was 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.	**1), 2), 3), 4) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **5) SECR:** To organise a follow up teleconference after the commenting period. **5), 6) All**: To provide comments by 28 January. **6) SECR**: Where no additional comments are received, to initiate agreement of the outcome by written procedure.

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 refMS and icMS agreed on the open point. In case no comments are received during the commenting period, the referral will be closed by written procedure.	
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. **CG member**: To provide information to the SECR on an issue raised for UA of lactic acid products.
7 – Any Other Business	
7.1 - Late procedures	
COM presented the reports related to late procedures.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data.
7.2 - Feedback on e-consultations	
One e-consultation was discussed: Post approval requirements at product authorisation. CG members agreed with the proposed way forward related to a product authorisation. The APCP WG will be consultated on how to address the issue.	**SECR**: To inform ECHA about the need to follow up on this topic by the APCP WG. **SECR**: To publish the outcome on the confidential S-CIRCABC IG space. **CG member**: To provide a discussion paper for the APCP WG.
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 – Update on dissemination	
The SECR updated the meeting on the dissemination	
7.5 - Election of the Chair and vice-Chair of the CG	
The representative from the PL CA was elected as vice-Chair of the CG.	
7.6 – Availability of comparative assessment reports	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
CG members agreed to directly upload comparative assessment reports in S-CIRCABC. The database will be organised by PT.	
7.7 – Classification of changes	
COM introduced the topic on how MSs are deciding on the classification of changes. The discussion will continue during the CG-34 meeting in open session.	**SECR**: To open a newsgroup. **All**: To provide comments by 5 February on how classification of changes are handled in MSs.
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-32	
The draft non-confidential minutes of the CG-32 meeting were agreed.	**SECR:** to upload the CG-32 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 progress of the WGs (HH and ENV) on dermal absorption and application of a study on surface water. The ENV WG agreed that the new study on surface water will be considered for the 2nd renewal at active substance level.	**SECR**: To open a newsgroup. **All**: To provide comments by 5 February on whether the conclusions of the ENV-WG should be applicable for the second or the third product renewal.
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. It was questioned whether it is possible to separate the maximum pack size for products used for "mice and rats".	**COM**: To check the active substance approval conditions for products intended for "mice and rats" by 2 February.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	SECR: To open a newsgroup for comments on the feedback from COM. **All**: To provide comments (2 weeks).
14.2 - Harmonised approach for filling in the PAR template	
A CG member volunteered to take the lead on updating the ENV and/or HH sections of the PAR.	**SECR**: To open a newsgroup. **All**: To volunteer to lead the update of the sections on EFF and APCP of the PAR by 5 February.
14.3 - Date of applicability of Technical Agreements of Biocides (TAB) entries	
COM informed the meeting on the decision of the CA regarding the applicability of TAB entries under category D which should follow the 2 year cut-off rule.	**SECR**: To publish the document in the relevant CIRCA BC space.
14.4 - Authorisation of products with in situ active substances: some discussion points	
COM presented several points that should be addressed for the authorisation of products with in situ generated active substances. CG members will provide comments in written. The discussion will be continued in the CA meeting.	**SECR**: To open a newsgroup for comments on the presentation provided by COM. **All**: To provide comments by 5 February. **DE**: To provide examples on the composition of IGSs.
14.5 - Unique Formula Identifier (UFI) required for authorised biocidal products	
COM briefly updated the CG on this matter. A follow up information will take place in the next CA meeting.	
Item 15 – Feedback from working parties	
15.1 - Update on the WP on the BPF concept	
The SECR informed the CG that the documents on similarity of uses, similar level of risk and efficacy and similar composition were agreed. The documents will be tabled for agreement during the CG-34 meeting.	**SECR**: To open a newsgroup for comments on when the WP recommendations should be applicable. **All**: To provide comments by 5 February.
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
16.2 - Deadlines for application for product authorisation	
The Chair presented the report, available for information.	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
16.3 - List of active substances meeting the exclusion or substitution criteria	
The Chair presented the report, available for information.	**Rapporteur MS**: To check the new information and report to CG-SECR by 25 January. **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 status of the dissemination of biocidal product data.	**ASOs**: To provide written feedback on incidents related to dissemination of confidential data in the dissemination platform. **SECR**: To forward the feedback to the ECHA IT team.
16.5 - Feedback on e-consultations	
Two e-consultations were introduced. 1) ED potential of co-formulants in biocidal products. The discussion will be continued during the CG-34 meeting. 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. CG members agreed to have a policy discussion during the next CA meeting.	**3) All**: To provide additional comments as soon as possible. **1) UK**: To provide response to comments by 31 January. **1) UK**: To provide an updated version of the document by 1 March. **4) UK/COM**: Provide a proposal for a policy discussion for the next CA meeting. **2) ASOs**: To provide comments on the document before the CA meeting.
16.6 - PT8 residue migration into food commodities	
A CG member presented the topic. The discussion will continue during the CG-34 meeting.	**SECR**: To open a newsgroup for comments. **All**: To provide comments by 5 February. **COM**: To provide written comments on the topic.
16.7 - Automatic generation of study/literature lists from IUCLID	
The SECR informed the meeting that the ECHA IT team is looking at providing a list of studies/literature from IUCLID that can be included in the PAR.	**SECR**: To open a newsgroup for comments on whether this tool would be interesting. **All**: To provide comments by 5 February.
16.8 – ECHA new structure for Biocides	

Agenda point	**Action requested after the meeting**
Conclusions / decisions / minority positions	**by whom/by when**
The SECR informed the meeting about the reorganisation of ECHA.	
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

33th meeting of the Coordination Group (CG-33)

14 January – 15 January 2019

on 14 January 2019 from 13:45 to 18:30
on 15 January 2019 from 09:00 to 15:00

Venue:

French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

14 rue Pierre et Marie Curie

94 700 Maisons-Alfort

France

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-33-2019

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-32

CG-M-32-2018_Draft confidential

For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-33-2019-05

For information

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

Links to disagreements

For discussion and agreement

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

6.1 Issues identified in the context of UA

CG-33-2019-16

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-33-2019-11, CG-33-2019-12 & CG-33-2019-20

For information

7.2 Feedback on e-consultations

CG-33-2019-14

Link to e-consultation

For discussion and agreement

7.3 Update on questions forwarded from CG to ECHA

CG-33-2019-15

For information

7.4 Update on dissamination

CG-33-2019-17

For information

7.5 Election of the vice-Chair of the CG

For discussion

7.6 Availability of comparative assessment reports

For information

7.7 Classification of changes

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-33-2019

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-32

CG-M-32-2018_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 – Harmonisation for reporting packaging size and material

CG-33-2019-19

For discussion and agreement

14.2 Harmonised approach for filling in the PAR template

For information

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

CG-33-2019-07

For information

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

CG-33-2019-01 & CG-33-2019-02

For discussion

14.5 Unique Formula Identifier (UFI) required for authorised biocidal products

For discussion

Item 15 – Feedback from working parties

15.1 Update on the WP on the BPF concept

For information

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-33-2019-09 & CG-33-2019-10

For information

16.2 Deadlines for application for product authorisation

CG-33-2019-08
For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-33-2019-18
For information

16.4 IT issues

CG-33-2019-13
For information

16.5 Feedback on e-consultations

CG-33-2019-03 & CG-33-2019-06
Links to e-consultations
For discussion and agreement

16.6 PT8 residue migration into food commodities

CG-33-2019-04
For discussion

16.7 Automatic generation of study/literature lists from IUCLID

For information

16.8 ECHA new structure for Biocides

For information

Item 17 – Agreement of the action points and conclusions

For agreement

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