3 July 2019

CG-M-35-2019 non-confidential

Final non-confidential minutes of the 35th meeting of the Coordination Group (CG)

13-14 May 2019

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman and the Vice-Chairman welcomed all participants to the thirty-fifth Coordination Group meeting (CG-35). 29 members and experts from 21 Member State Competent Authorities (MSCAs), Norway, Switzerland, Serbian Observer and 2 participants from 2 Accredited Stakeholder Organisations (ASOs), participated in the meeting. Five representatives from DG SANTÉ and three representatives from ECHA were present in the meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-35-2019) and invited participants to add any items under AOB. The agenda for the open session was agreed with the addition of one point on PT8 environmental exposure assessment for service life.

Actions:

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

3. Declaration of interest in relation to the agenda

The Chair invited the representatives of the MSCAs (referred to hereafter as 'members') to declare any potential conflict of interests. The Chair declared a conflict of interest for two products, as the same MS is the refMS. The Vice-Chair replaced the Chair for discussion of this topic.

4. Draft minutes from CG-34

The Chair explained that the draft non-confidential CG-34 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. The draft confidential CG-34 minutes were agreed.

Actions:

SECR: to upload the CG-34 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-35 meeting, four referral were discussed during teleconferences on 10 April, 30 April and 7 May. An agreement by consensus was reached for four products and the products can be authorised. The outcomes were agreed by written procedure.

The Chair informed that a new referral for a product was recently submitted and invited to provide comments by 31 May.

Actions:

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

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

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

1) A referral was discussed concerning a PT18 product containing permethrin as active substance. The disagreement was related to the acceptability of the risk mitigation measures (RMM) and an environmental exposure assessment. The applicant provided additional information for exposure assessment and the PAR will be updated with the relevant information. As regards to the point of disagreement related to the RMMs all MSs, except the icMS, agreed that the proposed RMMs are acceptable. The icMS was requested to discuss this point internally further and inform all CG members on the outcome of the discussion. This point will be further discussed.

2) A referral was discussed concerning a PT18 product containing s-methoprene as active substance. The disagreement was related to the used input parameters for the MEDRice model and consequent identified an unacceptable risk, as well as on exposure assessment of bees for inland water and flooded area. The revised assessment was provided by the refMS. Thus CG members agreed on the uses which can be authorised. Considering that the use for inland water and flooded area will not be authorised, the point of disagreement for exposure assessment of bees was not relevant. The referral was closed and the product can be authorised.

3) A referral was discussed concerning a PT19 product containing DEET as active substance. The point of disagreement was related to the identified unacceptable risk, i.e., spray product is classified as H318 and authorised for general public. Due to the classification of the product (H318 - Eye Dam. 1.), the risk for ocular exposure by spray application, CG members agreed by consensus that this product could not be authorised in accordance with Article 19 (1) of the BPR. The referral was closed.

4) A referral was discussed concerning PT8 product containing tebucanazole, basic copper carbonate, propiconazole as active substances was presented during the CG-35 meeting. The disagreement was related to a co-formulant to be identified as possible substance of concern (SoC). Considering that different views were expressed by the MSs on the interpretation of the definition of SoC, the Commission services was requested to provide a legal advice whether a co-formulant can be consider as a SoC. An agreement was not reached on the point of disagreement and this point will be further discussed after receiving clarification from the Commission services.

5) A referral concerning a PT18 product containing *Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52* and *Bacillus sphaericus 2362, strain ABTS-1743* as active substances was discussed. The disagreement was related to the indication of biopotency and content for each active substance, as well as on the necessity on the method for the determination of content of each microbial active substance in the biocidal product. CG members agreed by consensus that applicant should provide a global minimal biopotency of the product and the calculated content of each active substance. The product will be authorised with the post authorisation condition, i.e., an analytical method which quantifies each active substance in the product should be provided by the applicant. The referral was closed and the product can be authorised.

6) A referral was briefly introduced concerning a PT8 product containing tebucanazole, basic copper carbonate, propiconazole as active substances. The points of disagreement were related to the physical chemical part of evaluation and a lack of the secondary poisoning assessment for environmental part. The commenting period of the referral is still ongoing and the discussion will take place by teleconference.

7) A referral was briefly introduced concerning a PT3 product containing iodine as active substance. The point of disagreement was related to the dietary risk assessment. The commenting period of the referral is still ongoing and the discussion will take place by teleconference.

Actions:

1) The icMS: to provide a clarification whether they would agree with the proposed RMMs by 21 May.

2), 3), 5) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

4) The COM: to provide clarification on legal interpretation for one point of referral.

6), 7) MSs: to provide comments by 27 May.

6), 7) SECR: To organise a follow up teleconference after the commenting period is finalised.

5.3. Clarification points for submission of formal referral

The CG SECR reminded MSs that:

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

a) in accordance with Working procedure for resolving of disagreements:
    a. during the referral discussion time all discussions (comments and received documents) should be posted on CIRCABC so that every MS is aware of the ongoing discussions,
    b. the refMS is responsible for informing an applicant or authorisation holder about the progress and on-going discussion of the referral. The SECR explained that only following documents are sent to the relevant applicant/authorisation holder by the CG SECR, i.e., the referral document during the launching of the referral, the brief summary of the discussion points (discussion tables) before teleconference and meetings, discussion tables with conclusions after teleconference and meetings, agreed outcomes of the referral for confidentiality check. All other communication should be done by the refMS.

On a more general note, the SECR explained that access to CG S-CIRCABC is granted to the MS experts only if the CG Contact point (CG CP) agrees with that request. However, the comments in the Newsgroups of S-CIRCABC should be posted only by CG CPs.

Actions:

MSs: To take note of the information.

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

6.1 Issues identified in the context of UA

The SECR presented an updated list of issues identified in the context of UA applications (CG-35-2019-08). 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 Issues identified in the context of NA

The SECR introduced a new agenda point and invited to report issues identified in the context of National Authorisation (NA) that might be relevant for other NA or for UA.

MSs: To take note of the information and to report relevant issues.

7. Any Other Business

7.1 Late procedures

The Commission briefly invited MSs to take note of the reports and proposed that the information on late procedures could be prepared once or twice per year. ECHA and the Commission will further discuss this point.

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:

1) Complete quantative composition

A CG member presented the outcome of an e-consultation on a complete quantitative composition for the mixture(s) in a mixture of biocidal product (CG-35-2019-04), i.e., a complete quantitative composition of mixtures are not required as a default, but only on a case-by-case decision. A CG member provided several examples and noted that not always the applicant knows the "complete quantitative composition" of this mixture. However, concerning the perfumes, a composition certificate with the allergenic components is always required as this could be relevant for the identification of SoC and product classification.

2) Interpretation of SoC criteria in BPR guidance (MEA)

A CG member presented the outcome of an e-consultation on interpretation of substance of concern criteria in BPR guidance a complete quantitative composition for the mixture(s) in a mixture of biocidal product (CG-35-2019-05). The discussion will be continued during the CG-36 meeting.

3) Co-formulant as potential active substance

A CG member presented the outcome of an e-consultation on a co-formulant as potential active substance (CG-39-2019-22). MSs supported a proposal that particular substance should not be considered as a potential active substance. However, a general discussion on this topic will be continued during the CG-36 meeting.

4) ED assessment of co-formulants by MS

One of leading CG members presented the outcome of an e-consultation on ED assessment of co-formulans by MS (CG-35-2019-26, CG-35-2019-27, CG-35-2019-28).

The CG member noted that during the written commenting period MSs generally supported:

- in case there are indications of ED properties for a co-formulant, transfer the ED assessment from the BPR CA to REACH CA;
- in case ED assessment under REACH is necessary, the product authorisation is granted in order to prevent delays;

- where the co-formulant is identified as ED in the frame of REACH, applicant must inform eCA/rMS;
- ECHA should coordinate work-sharing among all MSs.

MSs also requested for alignment of the proposal with the prepared document "Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants".

A leading MS presented three step-wise proposals for assessment of ED for co-formulants:

1) refer to REACH each time where there is an indication of ED properties for co-formulant. This approach would ensure a high level of harmonisation among eCAs/refMSs. However, there could be cases when such approach could not be followed, as it is not applicable for REACH CAs, e.g., no registration dossier available etc.

2) refer to REACH when there is a high level of indication of ED properties for co-formulant and the list of co-formulants with lower concern/less priority would be prepared for REACH future assessment. This approach would allow some prioritisation and would be more acceptable for REACH CA workload. However, it should be also considered that there is a possible lack of expertise in some eCA/rMS and this approach would not allow harmonisation of an assessment as expert judgment without peer review would be used. A question was also raised how to manage co-formulant with high indications of ED properties that will not be assessed under REACH?

3) use already available assessments made by a public authority, but not peer-reviewed. If there is conclusion that a co-formulant is considered as ED, it was proposed to have a formal agreement on the risk assessment in the ED WG. Refer to REACH if WG cannot conclude on ED properties of co-formulant.

Several MSs supported proposal 1 and 2. However, a concern was expressed for proposal 2 on how to define "high" and "low" level of indication of ED properties. MSs asked ECHA urgently to establish a coordination mechanism for co-formulant assessment. ECHA commented that tools are under developing in order to start an inventory of the co-formulants from IUCLID dossiers and to link those co-formulants with other processes under REACH and CLP.

The Commission services commented that an update of the BPR Annexes as regards data requirements for ED assessment should be considered as the current text will affect the proposed CG approach. It seems appropriate not to conclude this discussion in the CG as it is expected that discussions in the expert group will be concluded September 2019. The Commission also expressed their concerns on the proposal that MSs always should follow REACH way for assessment of co-formulants as such an approach is not in line with the agreed CA document and the BPR.

The discussion will be continued during the CG-36 meeting.

One e-consultation was briefly introduced.

5) Anti-allergen claim

One e-consultation as regards to anti-allergen claim (CG-35-2019-03) was briefly introduced as the e-consultation is under commenting and will be further discussed during the CG-36 meeting.

A MS is asking whether (a) MSs consider "anti-allergen claim" falls into the BPR, (b) efficacy data to support such claim should be provided and assessed in the frame of this dossiers, (c) the use of Article 72(3) of the BPR is justified in this case.

Action points:

1) MS: to provide a public version of the agreed document by 3 June.

1) SECR: to upload a provided public version of the document in the relevant CIRCABC space.

2), 3), 4), 5) SECR: To open Newsgroup for comments.

2), 3), 4), 5) MSs: To provide comments by 3 June.

7.3 Update on questions forwarded from CG to ECHA

The SECR briefly presented an updated overview of the status of the questions referred from the CG to be addressed by ECHA (CG-35-2019-09).

7.4 Update of the Working Procedure for resolving of disagreements

The CG SECR presented an updated Working Procedure for resolving of disagreements. MS agreed to include the following clarification among some editorial changes:

- In the case that an applicant decides to withdraw an application for authorisation from cMS during the 90 days period MR phase, the cMS should inform the SECR that will forward this information to the CG Contact Points via email. Afterwards, those comments can be taken over by another cMS with on-going mutual recognition procedure for the product and those comments may be referred to the CG by another cMS. Where no other cMS takes over comments, those comments will be considered as closed.
- The acceptance of the formal referral template marks the start of the 60-day process.
- The icMS responsibility was clarified, i.e., to clearly identify the contact details of the applicant, to whom the referral document will be sent, to ensure that the referral documents do not contain any confidential information which cannot be shared with the applicant/authorisation holder. If the authorisation holder and the applicant are different legal entities, this is up to the icMS, in corporation with the refMS, to prepare a referral document with the points of disagreements which can be shared with the applicant/authorisation holder.

An updated working procedure was agreed and is applicable from 13 May.

Action points:

MSs: To take note of the information.

SECR: To upload agreed document in the relevant CIRCABC space.

7.5. Mutual recognition (MR) of a mutual recognition of a National authorisation (NA)

A MS invited to discuss a topic whether mutual recognition of a mutual recognition (MR) of a NA is possible (CG-35-2019-24) in accordance BPR provisions.

The MS introduced the case where the mutual recognition on sequence was submitted based on the MR asset in R4BP3.

The Commission services commented that after legal analysis it could be confirmed that in general the BPR does not foresee MR based on other MR of a NA.

Several MSs supported that such application, i.e., MR on MR of a NA should be rejected.

ECHA commented that it should be considered that MR on SBP application is possible.

On a more general note, MSs raised question if MR on MR of a NA is accepted how to deal with the product renewal.

For this particular application, it was agreed that the cMS will contact the applicant to clarify situation and ask to resubmit an application from the reference asset.

The general approach will be further discussed during the CG-36 meeting.

Action points:

SECR: To open Newsgroup for comments.

MSs and the COM: To provide comments by 3 June.

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. Two observers from two ECHA accredited stakeholder organisations (ASOs) were present for the open session of the meeting.

10. Agreement of the agenda for the open session

The agenda for the open session was agreed with the addition of one point on PT8 environmental exposure assessment for service life (point added by ECHA).

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-34

The Chair explained that the draft non-confidential CG-34 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-34.

Actions:

SECR: to upload the CG-34 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

No administrative issues were tabled for discussion.

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

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

Actions:

All: To take note on the information.

14.2 Update of the PAR template

During the CG-33 and CG-34 meetings MSs were invited to volunteer to lead the revision of the different sections of the PAR in order to avoid some duplications and make the PAR shorter and more user friendly. The SECR informed CG on volunteers to lead the revision of the physical chemical and analytical properties, efficacy, environment, human health and general sections of the PAR.

The SECR proposed to have a one PAR template with all updated sections for MSs commenting. Thus leading MSs were invited to provide their proposals by 15 September.

Actions:

SECR and MSs (leading the update of the PAR template sections): to provide proposal for update of the PAR template by 15 September.

SECR: To open Newsgroup for comments.

All: To provide comments on proposal (2 weeks).

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

The Commission briefly updated the CG members that considering the received feedback from the CG members, the revised version of the CA document has been prepared for the May CA meeting. Additional comments on the tabled proposal were received from two MSs.

Actions:

All: To take note of the information.

15 – Feedback from working parties

15.1 BPF WP recommendations - update from the CA meeting

The Commission updated the CG members that the revised version of the CA document has been prepared for the May CA meeting, considering the CG agreed document for assessment of similarity in biocidal product families.

The CG members asked the COM to communicate their decision from CG-34 on the applicability of the WP recommendation, i.e., CA note should be applicable for the new applications submitted after CA agreement.

Actions:

All: To take note of the information.

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

The SECR briefly presented a status of the update of the list of frequently used sentences for the SPC including on the timelines, indicating that the second commenting period has been initiated for the updated list of sentences. The CG were invited to provide further comments.

Actions:

MSs: to provide comments on the proposal and the prepared documents by 24 May.

16 – Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting participants to take note of the reports in the documents CG-35-2019-20 and CG-35-2019-25, which were made available for information.

16.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-34-2019-17, which was made available for information.

16.3 List of active substances meeting the exclusion or substitution criteria

The Chair invited the meeting participants to take note of the updated version of the list of active substances meeting the exclusion or substitution criteria (CG-35-2019-21).

On a more general note, the CG were informed about changes to be introduced in the report:

- In order to have a better overview on all active substances, two tables (review of active substances and new active substances) will be merged in one Excel sheet,
- If there will be an active substance approved this will be added to the list and changes will be recorded in the Excel sheet - "changes" .
- The product type will be removed from the Excel sheet.

Actions:

Rapporteur MS: To check the new information and report to CG-SECR by 27 May.

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

ECHA presented the new structure of the ECHA website and how to easily find the information needed (CG-35-2019-23).

On a more general note, as regards to the dissemination of the product assessment reports, MSs were invited to black out names of authors for all studies for the next public PARs.

16.5 Feedback on e-consultations

No e-consultations have been tabled for discussion.

The SECR informed CG about a new structure of S-CIRCABC IG for e-consultations.

Actions:

All: To take note of the information.

16.6 PT8 residue migration into food commodities

One CG member presented the document that was discussed during the previous CG meetings and updated the CG about any changes introduced (CG-34-2019-02).

On a more general note, the member explained that the document includes proposals about consumer safety and MRL exceedance in connection with PT8 products. For the case of a possible MRL exceedance, a risk mitigation measure was proposed to be introduced as well as the precautionary statement proposed as necessary to inform that existing MRLs must not be exceeded.

The Commission services recalled that the note on the establishment of maximum residue levels (MRLs) for residues of active substances contained in biocidal products (CA-Sept09-Doc.3.4.a) has not identified PT8 substances as an area where such levels should be described as a matter of priority. As maximum residue limits for active substances contained in biocidal products in contact with food and feed have to be established in accordance with other EU legislation, a broader reflection is required. The Commission services also noted that defining the type of food in contact with the PT8 products would be an important prerequisite before setting the MRLs.

Several MSs commented that the proposed precautionary statement would not be considered as useful to inform the users of the treated wood about the existence of MRL and should not be included on the label of the product.

The Chair informed if agreement will not be reached for this topic will be referred to the CA level discussion.

Actions:

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

All: To provide comments by 3 June.

16.7 Harmonisation of the documents for changes applications

The SECR presented a proposal how to harmonise the submission of the documents and IUCLID for changes application (CG-35-2019-11) particularly also for UA applications. In general MSs supported a proposal:

- to include the proposed history-table at the beginning of the PAR to clearly identify the changes compared to the previous version(s), as well as to have an overview of the changes history compiling all changes done to the PAR since the initial approval,
- a consolidated PAR with highlighted changes is provided by applicants,
- a IUCLID file (only) needs to include data relevant for the change,
- the respective supporting document should be included in the application.

However, additional questions, mainly related to the consolidated version of PAR, were raised. Therefore, this agenda point will be further discussed during the CG-36 meeting.

Actions:

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

All: To provide comments by 3 June.

16.8 Definition of the function of co-formulants

The SECR informed the CG members that considering that there were initial discussion on the definition of the function of the co-formulants in the APCP WG. This topic will be further discussed in the above mentioned WG and CG members will be informed on the agreement.

Actions:

All: To take note of the information.

16.9 Article 89 and a change from an UA procedure to a NA procedure

The Commission services briefly introduced a topic to be discussed during the May CA meeting and on the proposal included in the CA document:

There three different cases for which the question has been raised to clarify whether the biocidal products available on national markets of Member States can benefit of the transitional rules set out in Article 89 of the Biocidal Products Regulation (BPR). These three cases are described below.

1. Case 1: Splitting a Biocidal Product Family (BPF) into different BPFs

During the evaluation process, the evaluating competent authority may conclude that a biocidal product family application needs to be split in order to be compliant with the definition of a biocidal product family as included in Article 3(1)(s) of the BPR (i.e. the company submitted a too large application with some products not being similar). The first application will continue to be processed, but only with the products having similar uses, composition and levels of risk and efficacy.

For the other products no longer part of this family, one or more new product(s) or product family application(s) for authorisation should be submitted to address that part(s) of the original BPF that are no longer under the initial application. Those applications will de facto be submitted later than the date of approval of the last existing active substance for that product type.

2. Case 2: Transferring a national single product application to a same single biocidal product application, based on an individual product of a BPF

An application ("first application") was submitted to an eCA for a national authorisation of a single biocidal product based on Letter of Access (LoA) to an individual product of a Union authorisation BPF. At that time, it was not possible to apply at a national level for a same biocidal product referring to only an individual product of a BPF authorised at Union level (or subject of an on-going application for Union authorisation). While this national authorisation application was under the evaluation phase, the situation changed and it became possible to make such an application because of becoming applicable the Commission Implementing Regulation (EU) 2016/1802. For administrative and efficiency reasons, the relevant competent authority suggested to the applicant to withdraw its "first application" and to submit instead, in accordance with Article 3 of Commission Implementing Regulation (EU) No 414/2013, a new application for a same biocidal product at national level referring to the same reference individual product authorised by the BPF at Union level. This application will de facto be submitted later than the date of approval of the last existing active substance for that product type.

3. Case 3: Transferring a product covered by a same single biocidal product Union authorisation to a same single biocidal product national authorisation

An application for a same biocidal product Union authorisation was submitted referring to an individual product covered by a BPF application for Union authorisation. The company would like to withdraw this application and to submit one or more application(s) for a same biocidal product at national level referring to the same reference product as the previous application. This application will de facto be submitted later than the date of approval of the last existing active substance for that product type.

Actions:

SECR: All: To take note of the information.

16.10 State of play of revision of Annexes in relation to ED assessment of non-active substances

The Commission services briefly update CG indicating that updated version of Annexes will be discussed during the next CA meeting.

Actions:

All: To take note of the information.

16.11 Linking of PAR and SPC documents

This topic was postponed to CG-36 meeting.

16.12 Accordance check template for UA

The SECR presented an accordance check template to be used for UA applications (CG-35-2019-18). MSs were invited to provide comments on the document.

The SECR informed that this extended accordance check can also be used by eCAs as a checklist before submission of the UA dossier to ECHA.

The SECR invited to provide feedback on the template and also on the following questions:

- If ECHA fails the accordance check:
    - What kind of support would the eCA like to receive when going back to evaluation?
    - Would the eCAs be willing to provide also a revised draft Product Assessment Report (PAR) in "track changes", to limit and thereby speed up the second accordance check?

This agenda point will be further discussed during the CG-36 meeting.

Actions:

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

MSs: To provide comments by 3 June.

16.13 CG-36 and CG-37 meeting organisation

The SECR informed that CG-36 meeting will be organised in Helsinki if CA meeting will not take place in Brussels and the CG-37 will be organised in Brussels on 16 September (afternoon) and 17 September (full day).

Actions:

All: To take note of the information.

16.14 PT8 environmental exposure assessment for service life

The SECR reminded the CG members to contact their experts and inform that assessment performed for active substances or in the frame of national authorisation in PT8 including the new TIME 2 should be posted in the ENV WG Newsgroup for basic impact assessment.

Actions:

All: To take note of the information.

17. Agreement of the action points and conclusions

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

Actions:

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

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Part II - MAIN CONCLUSIONS & ACTION POINTS

35th meeting of the CG

12th of May – 13th of May 2019

Agenda point **Conclusions / decisions / minority positions**	**Action requested after the meeting** **by whom/by when**
CLOSED SESSION	
1 – Welcome	
2 – Agreement of the agenda.	
The agenda for the closed session was agreed with the addition of one agenda point on how to apply Article 62 of the BPR.	**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	
A conflict of interest was declared.	**SECR:** to record conflict of interest in minutes.
4 – Draft minutes from CG-34	
The draft confidential minutes of the CG-34 meeting were agreed with a minor modification.	**SECR:** to upload the CG-34 minutes into the relevant folders in the CG CIRCABC.
5 – Formal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed that four referrals had been closed before the meeting by written procedure. Agreement by consensus was reached for all four 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 not reached and one point of disagreement will be further discussed. **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 not reached and one point of disagreement will be further discussed.	**1) The icMS**: to provide a clarification whether they would agree with the proposed RMMs by 21 May. **2), 3), 5) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **4) The COM**: to provide clarification on legal interpretation for one point of referral. **6), 7) MSs**: to provide comments by 27 May.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
5) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **6)** The referral was briefly introduced and the discussion will continue by teleconference. **7)** The referral was briefly introduced and the discussion will continue by teleconference.	**6), 7) SECR**: To organise a follow up teleconference after the commenting period is finalised.
5.3 - Clarification points for submission of formal referrals	
ECHA provided clarification as regards of submission of the referrals.	**MSs:** To take note of the information.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA The SECR presented the list of issues identified in the context of UA.	**MSs:** To take note of the information provided in the table. **SECR:** To provide an updated list for the next CG meeting.
6.2 - Issues identified in the context of NA The SECR introduced a topic and invited CG members to report issues identified in the context of NA that might be relevant for other NA or for UA.	**MSs:** To take note of the information and to report relevant issues.
7 – Any Other Business	
7.1 - Late procedures	
COM briefly 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 and one e-consultation was briefly introduced as it is under commenting: *1) Complete quantitative composition.* The outcome of this e-consultation was agreed. *2) Interpretation of SoC Criteria in BPR guidance (MEA)*. SECR provided comment. The discussion will be continued during the CG-36 meeting. *3) Co-formulant as potential active substance*. MS provided additional comment. The discussion will be continued during the CG-36 meeting. *4) ED assessment of co-formulant by MS*. Different opinions were expressed. The discussion will continue during the CG-36 meeting.	**1) MS:** to provide a public version of the agreed document by 3 June. **1) SECR:** to upload a provided public version of the document in the relevant CIRCABC space. **2), 3), 4), 5) SECR:** To open Newsgroup for comments. **2), 3), 4), 5) MSs**: To provide comments by 3 June.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
5) Anti-allergen claim. This e-consultation is under the commenting phase and the discussion will be continued during the CG-36 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.	**MSs:** To take note of the information.
7.4 – Update of the Working Procedure for resolving of disagreements	
SECR presented a proposal for update if the Working Procedure. The proposal was agreed with minor changes. This Working Procedure is applicable as from 13 May.	**MSs:** To take note of the information. **SECR:** To upload agreed document in the relevant CIRCABC space.
7.5 – Mutual recognition of a mutual recognition of a NA	
A MS introduced the topic asking clarification whether the MR application can be submitted based on another MR of a national authorisation.	**SECR:** To open Newsgroup for comments. **MSs and the COM**: To provide comments by 3 June.
7.6 – How to apply Article 62 of the BPR	
A MS asked the other MSs whether they check Article 62 provisions at product authorization phase.	**SECR:** To open Newsgroup for comments. **MSs**: To provide comments by 3 June.
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 with one additional point on PT8 environmental exposure assessment for service life (point added by ECHA).	**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-34	
The draft non-confidential minutes of the CG-34 meeting.	**SECR:** to upload the CG-34 minutes into the relevant folders in the CG CIRCABC.
13 – Administrative issues	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
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 WG (HH) on dermal absorption.	**All**: To take note on the information.
14.2 – Update of the PAR template	
The SECR informed CG on volunteers to lead an update of the APCP, EFF, ENV, HH and general sections of the PAR. CG agreed that the leaders of the relevant PAR template update will provide proposal.	**SECR and MSs (leading the update of the PAR template sections):** to provide proposal for update of the PAR template by 15 September. **SECR:** To open Newsgroup for comments. **All**: To provide comments on proposal (2 weeks).
14.3 - Authorisation of products with in situ active substances: some discussion points	
The COM updated the CG members that considering the received feedback from the CG members, the revised version of the CA document has been prepared for the CA meeting.	**All:** To take note of the information.
Item 15 – Feedback from working parties	
15.1 - Agreement of WP recommendations	
The COM updated the CG members that the revised version of the CA document has been prepared for the CA meeting, considering the CG agreed document for assessment of similarity in biocidal product families. The CG members asked the COM to communicate their decision from CG-34 on the applicability of the WP recommendation, i.e., CA note should be applicable for the new applications submitted after CA agreement.	**All:** To take note of the information.
15.2 – Follow up on the WP on frequently used sentences in the SPC	
The SECR presented a status of the update of the list of frequently used sentences for the SPC including on the timelines, indicating that the second commenting period has been initiated for the updated list of sentences.	**MSs:** to provide comments on the proposal and the prepared documents by 24 May.
16 – Any Other Business	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
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 SECR presented the report, available for information and proposal for changes in the template. The CG members agreed with the proposed changes in the template.	**Rapporteur MS**: To check the new information and report to CG-SECR by 27 May. **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 CG on the topic to be considered for PAR publication. The SECR also presented how to find information in the ECHA Website.	**All:** To take note of the information.
16.5 - Feedback on e-consultations	
No e-consultations have been tabled for discussion for the open session. The SECR informed CG about a new structure of S-CIRCABC IG for e-consultations.	**All:** To take note of the information.
16.6 - PT8 residue migration into food commodities	
A CG member presented the topic with an updated proposal. Different views were expressed. In case that no agreement will be reached this document will be forwarded for discussion at CA level.	**SECR**: To open a newsgroup for comments on the MS proposal. **All**: To provide comments by 3 June.
16.7 – Harmonisation of the documents for changes applications	
The SECR presented a proposal how to harmonise the submission of the documents and IUCLID for changes applications, particularly also for UA.	**SECR**: To open a newsgroup for comments on the document harmonisation. **All**: To provide comments by 3 June.
16.8 – Definition of the function of co-formulants	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
The SECR informed CG on the proposal on development of definition of the function of co-formulants. The discussion will continue in the expert level, i.e., APCP WG. The CG will be informed on the outcome of the discussion.	**All:** To take note of the information.
16.9 – Article 89 and a change from a UA procedure to a NA	
The COM briefly introduced on the topic to be discussed during the next CA meeting.	**All:** To take note of the information.
16.10 – Status of play of revision of Annexes in relation to ED assessment of non-active substances	
The COM update CG indicating that updated version of Annexes will be discussed during the next CA meeting.	**All:** To take note of the information.
16.11 – Linking of PAR and SPC documents	
This item will be discussed during the CG-36 meeting.	
16.12 – Accordance check template for UA	
The SECR presented the accordance check template to be used for UA applications. MSs were invited to provide comments on the document.	**SECR**: To open a newsgroup for comments on the MS proposal. **MSs**: To provide comments by 3 June.
16.13 – CG-36 and CG-37 meeting organisation	
The SECR informed that CG-36 meeting will be organised in Helsinki if CA meeting will not take place in Brussels and the CG-37 will be organised in Brussels on 16 September (afternoon) and 17 September (full day).	**All:** To take note of the information.
16.14 – PT8 environmental exposure assessment for service life	
The SECR reminded the CG members that the assessment performed for active substances or in the frame of national authorisation in PT8 including the new TIME 2 should be posted in the Newsgroup.	**All:** To take note of the information.
17 – Agreement of the action points and conclusions	
The list of action points and conclusions for the open session was agreed by the CG meeting.	**SECR:** To publish the Action points and conclusions in the relevant S-CIRCABC space.

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Part IV - List of Annexes

ANNEX I List of documents submitted to the members of the Coordination Group

ANNEX II Final agenda

ANNEX II

Final agenda
35th meeting of the Coordination Group (CG-35)

13 May – 14 May 2019

on 13 May 2019 from 09:30 to 18:00
on 14 May 2019 from 09:00 to 16:00

Venue:

13 May
Albert Borschette Conference Centre
Rue Froissart 36
Room 0A
1040 Brussels
Belgium

14 May
Building Belliard 100
Rue Belliard 100
Room 06/026A
1040 Bruxelles
Belgium

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-35-2019
For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-34

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-35-2019-07
For information

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

CG-35-2019-01
Links to disagreements
For discussion and agreement

5.3 Clarification points for submission of formal referrals

For information

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

6.1 Issues identified in the context of UA

CG-35-2019-08
For information

6.2 Issues identified in the context of NA

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-35-2019-16, CG-35-2019-19
For information

7.2 Feedback on e-consultations

CG-35-2019-03, CG-35-2019-04,
CG-35-2019-05 & CG-35-2019-22,
CG-35-2019-26, CG-35-2019-27, CG-35-2019-28
Links to e-consultations
For discussion and agreement

7.3 Update on questions forwarded from CG to ECHA

CG-35-2019-09
For discussion

7.4 Update of the Working Procedure for resolving of disagreements

CG-35-2019-06
For discussion

7.5 Mutual recognition of a mutual recognition of a NA

CG-35-2019-24

For discussion

7.6 How to apply Article 62 of the BPR

For discussion

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-35-2019

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-34

CG-M-34-2019_Draft non confidential

For agreement

Item 13 – Administrative issues

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

For information

14.2 Update of the PAR template

For information

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

For information

Item 15 – Feedback from working parties

15.1 BPF WP recommendations - update from the CA meeting

For information

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

For information

Item 16 – Any Other Business

16.1 Trends in product authorisation

CG-35-2019-20, CG-35-2019-25
Document to be distributed
For information

16.2 Deadlines for application for product authorisation

CG-35-2019-17
For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-35-2019-21
For information

16.4 IT issues

CG-35-2019-23
For information

16.5 Feedback on e-consultations

CG-35-2019-10
For discussion and agreement

16.6 PT8 residue migration into food commodities

CG-35-2019-02
For discussion and agreement

16.7 Harmonisation of the documents for changes applications

CG-35-2019-11
For discussion and agreement

16.8 Definition of the function of co-formulants

For information

16.9 Article 89 and a change from an UA procedure to a NA procedure

For discussion

16.10 State of play of revision of Annexes in relation to ED assessment of non-active substances

For information

16.11 Linking of PAR and SPC documents

CG-35-2019-12, CG-35-2019-13, CG-35-2019-14 & CG-35-2019-15
For discussion

16.12 Accordance check template for UA

CG-35-3019-18

For discussion

16.13 CG-36 and CG-37 meeting organisation

For information

16.14 PT8 environmental exposure assessment of service life

For information

Item 17 – Agreement of the action points and conclusions

For agreement

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