**20 September 2016**

**CG-M-18-2016 non-confidential**

# Final non-confidential minutes of the 18th meeting of the Coordination Group (CG)

**7 July 2016**

# Part I - Summary Record of the Proceedings

## Closed session

## 1. Welcome and apologies to the closed session

The Chairman welcomed participants to the eighteenth CG meeting. 24 members from 17 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and two representatives from ECHA were present for the full meeting. A representative from DG SANTÉ was present during the items 1-5 of the agenda.

## 2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-18-2016) and invited participants to add any items under AOB. The agenda was agreed without changes.

The final agenda is included in Annex II of the minutes.

**Actions:**

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

## 3. Declaration of interest in relation to the agenda

The Chair invited the representatives of the MSCAs (referred to hereafter as 'members') to declare any potential conflict of interests. There were no potential conflicts declared.

## 4. Agreement of the draft minutes from CG-17

The Chair explained that the draft confidential CG-17 minutes had been uploaded for commenting via Newsgroups. A minor comment was received during the meeting that will be incorporated to the final minutes. The CG members agreed on the confidential draft minutes from CG-17.

**Actions**

**SECR:** to amend the minutes and upload the CG-17minutes into the relevant folders in the CG CIRCABC.

## 5. Formal and informal referrals on mutual recognition disagreements

### 5.1 Overview of the referrals discussed at the Coordination Group

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

**Actions**

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

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

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

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

Three formal referrals were discussed.

1. The first formal referral concerned a biocidal product family authorisation via the simplified procedure. Thirteen points of disagreement on efficacy had been raised in the referral process by several MSs. The MSs having submitted comments agreed on 12 of the points in a conference call prior to the meeting and the outcome was explained during the meeting and further agreed by all the CG members. The point of disagreement still open was related to the presence of a co-formulant in the product at a low concentration which could in principle potentiate the activity of the relevant product(s). If it were established that the substance was active, the product family could not be authorised under the simplified procedure. The applicant informed that the substance would be removed from the product family composition. Some CG members mentioned that, even though the applicant was willing to remove the co-formulant from the family, the assessment of the efficacy role of every substance that might be an AS for the same PT should not be taken as a wide precedent under the SAP.

Having solved this point, an agreement was reached by consensus on all the points of disagreement. It was then concluded that the conditions for granting an authorisation in Article 25 of the BPR were met and the referral is now closed.

On a more general note, the Commission mentioned that it is particularly important under the SAP to check the efficacy role of any co-formulant that is also an AS for the same PT as a confirmation of such efficacy role might make the product non-eligible under the SAP (i.e. an AS not listed in Annex I to the BPR). Therefore, it is the applicants' responsibility to choose the right co-formulants and where relevant, to justify the absence of any efficacy role (which might be waived if the concentration in the product is far from the assessed efficacy range of the substance).

The Commission also clarified that according to Article 9 of the changes Regulation, the authorisation holder (AH) has the obligation to notify each MS, on the territory of which the biocidal product is made available, of notifications or applications made to the eCA via R4BP3 (see also section 5 "changes to product authorisations" in Annex I to document CA-March16-Doc.4.6 – Final.rev1).

2. The second formal referral was introduced in closed session. This formal referral was related to an insecticide product. According to the initiating concerned MS (iCMS) the submitted efficacy data did not allow to validate the efficacy against ants either as a granular solid bait for direct application or when applied diluted as a liquid drench. Related to efficacy of the aged product, the iCMS considered that palatability of the aged product was not proven and suggested amending the target species in the SPC to make it more specific for *Lasius niger*, since efficacy against other species had not been proven.

After the introduction, the discussion proceeded in the presence of the applicant. A few members considered that the field data submitted by the applicant was valid. With regards to the palatability, a few MSs argued that, considering the composition of the product it was highly unlikely that the palatability of the aged product would be compromised and, therefore, no additional data was required.

The CG members noted that the renewal of this product would need to be submitted in a short time, and that the applicant was preparing the data set for the renewal stage. The Commission noted that in the context of any application for renewal, the applicant has to submit "its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information" (see Article 31(3)(b) of the BPR and Article 2(1)(f) of Regulation 492/2014). Therefore, this provision already addresses the principle that "its assessment" should demonstrate that those conclusions are still valid when the product is assessed according to the guidance that is applicable at the time of the submission of the application for renewal. In this context, the introduction of a specific condition in the current authorisations to consider some new additional data at the renewal stage would not be essential.

Considering this, the CG members agreed by consensus that the current data set was sufficient for this authorisation. However, these points of disagreement will have to be further considered at the renewal stage, in accordance with the latest applicable guidance on data requirements at the time of renewal.

CG members also agreed that regarding the target species, the SPC and, if relevant, the PAR should be amended to indicate: "*Lasius niger* (black garden ant) only" instead of "ants including *L. niger*".

With this agreement, it was concluded that the product meets the conditions for granting an authorisation in Article 19(1)b(i) and the referral is now closed.

The CG members also indicated the need to get clear guidance on efficacy testing of drench applications.

3. The third formal referral concerned a disagreement on the risk mitigation measures of a rodenticide product. The reference MS (rMS) was not present in the meeting. The disagreement was related to technical/organisational measurements to have priority over personal protective equipment in accordance with Dir 98/24/EC.

The Commission noted that despite that several MSs seem to have also authorised rodenticides in the past with pack sizes higher that 10 kilos and including the RMM to wear RPE, Directive 98/24/CE applies without prejudice of the BPR and therefore, where a risk is identified, the STOP principle should be applied. Thus, the Commission proposed applying such principle: i) in this case, which would set a precedent for products to be authorised from now on and ii) in the context of the renewal of the existing product authorisations, particularly through the harmonised sentences in the SPC template of products to be authorised for professional users.

CG members supported the way forward as proposed by the Commission and considered that in this case, a restriction of the packaging size should be implemented before imposing the use of a respiratory mask. The CG members agreed to apply this agreement for upcoming authorisations or at the renewal stage for already authorised products. It was also clarified that the restriction of the packaging size should only be implemented when unacceptable risks are identified.

With this agreement it was concluded that the product meets the conditions for granting an authorisation in Article 19(1)b(iii) and the rMS will be informed about the outcome. Since an agreement was reached by consensus the referral is now closed.

The CG members requested forwarding to the Human Exposure Working Group whether there is a need to revise the HEEG opinion N12 regarding the possible need to also assess exposure by inhalation when handling products with a pack size below 10 kilos.

**Actions**

**1-3)** **SECR:** to follow-up the outcome of the referral as stated in the Working Procedures

1) **SECR:** to update the CG members on how to notify changes in products authorised under the simplified procedure in R4BP3.
2) **SECR:** to forward the evaluation of drench application to the efficacy WG for discussion before the renewal of the product.
3) **SECR:** to forward to the HH WG whether there is a need to revise the HEEG-12 opinion on the assessment on AVKs.

## 6. Any Other Business (closed session)

### 6.1 Late procedures

The Chair announced that no report was made available for this meeting due to some internal checks concerning the data quality and consistency.

The Commission made a presentation (see document CG-18-2016-09), which was a follow-up of the discussions held at the CG and CA meetings in May. It focused on the different components of a "multifactorial problem" (as identified by the CA meeting) and on the

remedial actions to be considered, particularly those that can be undertaken at the EU level. CG members were invited to provide some preliminary contributions at the meeting and to submit written comments in order to better prepare a policy discussion at the September CA meeting.

The Chair invited CG members to submit written comments by 19 August.

**Actions**

**MSs:** to undertake the relevant actions

**SECR:** to open a Newsgroups forum for written comments

**All:** to comment on the Newsgroups by 19 August

**SECR:** to communicate the IT group about issues with IUCLID 6.

## 6.2. DEET products: progress report

A CG member presented a detailed progress report of the still on-going procedures.

Regarding products classified with "H315" and the follow-up action from CG-17, the Commission informed the meeting that this issue was subject to an e-consultation launched by a MS in January 2014. Although an agreed conclusion from that e-consultation was not made available, a number of MSs clearly stated that they would not authorise these products, and two MSs mentioned that they would only do so if product specific data were provided. Therefore, there was clear feedback in the past that those MSs would raise objections to mutually recognise H315 products if finally authorised (as also indicated by two different MSs at CG-17).

The Chair noted that this agenda item will no longer be tabled at future meetings and would only be discussed in the context of product-specific referrals, if any.

## 6.3 Feedback on e-consultations

An e-consultation was presented for agreement of the CG members. A member presented the conclusions of the e-consultation regarding the evaluation of similar products with a different mode of application (CG-18-2016-18). This consultation was related to the efficacy data necessary when two products with the same composition are marketed as separate single products. In particular, the question referred to the case where one of the products is advised to be used in combination with the other. The CG members agreed that, since the two products are marketed as separate single products, efficacy data should be available for both products for authorisation.

The CG members noted that there is currently no standard for testing the application method of injection in wood boring insect holes. This question should be referred to the efficacy working group for further guidance.

**Actions**

**SECR:** to communicate this issue to the efficacy WG

## 6.4 Renewal of anticoagulant rodenticides

The Commission made a presentation which provided an overview of the renewal process and the next key milestones. It focused on the need to meet the agreed deadlines, to address the technical issues already identified by the BPC (e.g. assessment of dermal absorption and issues regarding storage stability), as well as other elements identified by CG members during a pre-meeting consultation. Finally, the presentation opened a discussion on the key elements that might need to be addressed by the relevant ECHA WGs at the September meetings.

The following elements were discussed:

***1) Technical matters:***

1.1.- Dermal absorption: CG members agreed to ask the WG on which read across between formulations containing the same or a different AS is possible.

1.2.- Storage stability – shelf-life: CG members agreed that:

- The conclusions in the 2013 Workshop should be followed at the renewal if the guidance referred to in those conclusions is applicable according to document CA-July12-Doc.6.2.d-Final (i.e. 2-year cut-off principle).

- In order to streamline the process, the existing storage stability – shelf-life of products for which efficacy was proven with aged bait should not be reassessed.

1.3.- Efficacy: CG members agreed that according to document CA-July12-Doc.6.2.d-Final, the draft of the revised TNG on efficacy of PT 14 products should not be used in the context of this renewal process. Upon request from a CG member, the Commission clarified that section 3.2 of the above-mentioned document would allow MSs to require alignment with new guidance in cases where reliance on old guidance gives rise to serious concern. Should it be the case, MSs should also trigger the revision of any existing authorised rodenticide (including non-anticoagulants).

Therefore, CG members should focus any request to the EFF WG on elements of the existing and applicable TNG that might need some further harmonised interpretation and have not been addressed in a Commission decision yet.

1.4.- Environmental risk assessment for the terrestrial compartment, including soil & groundwater: CG members were invited to comment on the priority to be given to this point.

***2) Other matters identified by CG members:***

2.1.- C&L - additivity principle: the Commission informed the meeting that a conclusion on this matter is expected to be reached at the September 2016 Caracal meeting.

2.2.- Identification - analytical methods: the Commission clarified that this topic was not linked to the product authorisations renewal in the BPC discussions, as it was identified as a requirement for the next AS renewal. There will be a discussion on this topic at the APCP WG.

2.3- Regulatory - use of Article 19(5): CG members agreed that this Article has to be referred to in the renewal decisions. Where relevant (e.g. the general public is removed as a result of the new CLH), Article 19(4) will have to be referred too.

2.4.- ENV - use of updated ESD (only available by November 2017): CG members agreed that the updated ESDs will become available too late in the process and should therefore not be used in this renewal process (see also the principles in document CA-July12-Doc.6.2.d – Final).

2.5.- Regulatory – harmonised application of the "STOP-principle" as per Directive 98/24/CE: CG members agreed that, where a risk is identified, technical and organizational changes should be considered before imposing the use of PPE as a RMM (e.g. sub-packaging of max. 10 kilos in order to avoid the inhalation risks associated with decanting). CG members agreed addressing this particular measure as a harmonised element in the SPC template applicable to products for professional users.

2.6.- "Minimum" pack size in products for professional users: CG members were invited to consider how best to implement this provision in section 2.4 of the BPC opinions. The Commission expressed some concerns that different approaches by MSs in this respect would not fit with the grounds for derogation in Article 37(1) of the BPR and that a harmonised approach should be found in the context of the SPC template applicable to products for professional users.

The Chair invited CG members to refer to SECR (via Newsgroups in S-CIRCABC) the collected questions to the relevant WGs for discussion at the September meetings by 15 July.

**Actions**

**SECR:** Open a newsgroup in CIRCABC to provide specific questions to refer to the different working groups.

**All:** To provide questions by 15 July.

**SECR:** Refer the collected questions to the relevant WGs for discussion at the September meeting.

### 6.5 Mutual recognition of creosote containing products

The Commission made a presentation which was a follow-up of a previous discussion held at the May CA meeting. The presentation provided an overview of the legal requirements from both the inclusion directive and the BPR, as well as the different tasks for the CMSs. Overall, the Commission referred to the investigation of whether the conditions in Article 5(2) of the BPR are met in the CMS (as per paragraph 10 of annex VI to the BPR) as the key step in the procedure. Only if those conditions are met, then a comparative assessment should be carried out in accordance with Article 23 of the BPR. In these two tasks, the CMSs can check what has been already done by the refMS and where relevant, complement the work done by the refMS with country-specific information.

When it comes to the information to be sent to the Commission before 31 July 2015, the Commission mentioned that a short report summarising the conclusions reached by the MSs having authorised the products would be sufficient. CG members were also reminded that this information will be made publicly available.

The refMS informed CG members that a few minor corrections/changes have been made to the PARs and the Competitive Assessment Report linked to the 4 assets for the creosote biocidal product families in R4BP3. CMSs for MR applications were also invited to check the still on-going cases in R4BP3, as there might be some obsolete MR-P cases linked to the old members of the FF applications submitted under the BPD. In principle, now what should be valid are the applications for MR-S of the 4 BPFs authorised by the refMS.

## 7. Agreement of the action points and conclusions

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

## Open session

## 8. 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.

## 9. Agreement of the agenda for the open session

The Chair introduced the draft agenda (CG-A-18-2016) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed with the inclusion of an item on questions regarding mutual recognition.

The list of meeting documents and the final agenda are included in Part IV of the minutes.

**Actions**

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

## 10. Declaration of interest in relation to the agenda, open session

The Chair invited the members to declare any potential conflict of interests. There were no potential conflicts declared.

## 11. Agreement of draft minutes (non-confidential part) from CG-17

The Chair explained that the draft non-confidential CG-17 minutes were uploaded for commenting via Newsgroups. A minor comment was received during the meeting that will be incorporated to the final minutes. The CG members agreed on the draft minutes from CG-17.

**Actions**

**SECR:** to upload the CG-17 minutes into the relevant folders in the CG CIRCABC.

## 12. Administrative issues

### 12.1 Working instructions of e-consultations

The CG SECR presented a proposal for the working instructions for e-consultations (see document CG-18-2016-03). The instructions formalise the procedure for initiating e-consultations by the CG members. The proposal is that once the e-consultation is finalised, the initiating member will be responsible for providing a summary document with the conclusions of the consultation. This document would be discussed and agreed at the next CG meeting. e-Consultations will be archived in a dedicated space in S-CIRCABC.

The Commission suggested two amendments: (a) The conclusion document should not include confidential information so that this can be made publically available. (b) the complete list of e-consultations should be available in S-CIRCABC while the list distributed for the CG meetings should include the open consultations only.

The CG members agreed to adopt the document with the amendments suggested by the Commission.

**Actions**

**SECR:** to amend the working instructions document.

**SECR/MSs:** to implement the procedure

## 12.2 Working Procedures

The CG SECR presented the outcome of the Newsgroups discussion regarding how to distribute the 90-day period for the mutual recognition (MR) phase. MSs had expressed different views on how this 90-d period should be organized and how other elements such as the communication via R4BP3 and working practices in MSCAs should be taken into account.

In this context, the Commission introduced a proposal to improve the MR phase, including two final steps intended to i) confirm agreement on the latest version of the draft SPC that takes on board the outcome of the bilateral discussions between the refMS and the cMSs and ii) inform the other MSs, where relevant, that some points of disagreement remain and that a formal referral will be sent to the CG. The proposal was as follows:

50 days for cMSs to raise any questions (if not, considered as agreeing),

+ 30 days for bilateral discussions refMS-CMSs (all CMSs in cc),

+ 7 days for cMS(s) having commented to confirm or not SPC agreement,

+ 3 days for:

- refMS to register the agreed SPC in R4BP or

- cMS(s) to submit a formal referral to the CG.

From the discussion held at the meeting, the following elements should be considered for future discussions on this matter:

- MSs were not in favour of reducing the 60-day scrutiny period for the cMS(s) to check the draft SPC against the PAR, particularly taking into account the increasing complexity of the BPF applications.

- MSs considered the two additional steps proposed by the Commission as necessary to improve the MR phase and to know what has been agreed. However, the Commission proposal should be adapted as follows:

  - These two steps should be scheduled within the current 30-day sub-phase (e.g. 20+7+3) in order to preserve the 60-day sub-phase as it is.

  - The 7-day period for confirming agreement on the updated version of the draft SPC should be open to all the CMSs, and not only for those having made comments.

  - Where a cMS still disagrees after the 7-day period, that cMS should inform the refMS and all the cMSs within the 3-day period that a formal referral will be send to the CG. However, the iCMS will need a few days after day 90 to prepare the submission of the formal referral.

- Whatever the final distribution would be, it is very important that the refMS ensures proper tracking of the draft SPC and PAR during the MR phase, so that all CMS are on the same page and working on the same version of the documents (e.g. the draft SPC and PAR are <u>not</u> updated to address bilateral discussions before the end of the 60-day sub-phase).

- The communication tools in R4BP3 should be improved, as already requested by MSs to ECHA at the IT user expert group held in Brussels in November 2015. It is critical that cMSs are informed as soon as the draft SPC and PAR are made available by the refMS for MR-P. ECHA should consider this element as soon as possible.

- A CG member suggested that once there is an agreement on the different steps and other elements in the form of a kind of SOP, a pilot phase could be launched to test how the new approach might work in practice.

- After the pilot phase, the tested approach, if satisfactory, should be implemented in R4BP accordingly, with clear procedural milestones and clear communications each time a subsequent step starts (and the previous is one closed).

The Chair invited CG members to submit written comments by 19 August.

**Actions**

**SECR:** to open a Newsgroups forum for written comments on how to improve the communication tools and how to implement a step to give comments on the updated SPC and eventually starting a referral.

**All:** to comment on the Newsgroups by 19 August.

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

## 13.1 Guidance on carrier-based biocidal products

The Commission introduced document CG-18-2016-12, which is a follow-up of the document presented at the last CG meeting by two CG members. The Commission thanked those MSs and ASOs having submitted comments to the previous consultation and underlined those elements that were new in the document.

The following elements were raised by CG members during the discussion:

- A CG member expressed some reservations on the proposed approach for the description of the composition of the product, even if this is in line with previous CG agreements. The Commission mentioned that the grounds for the CG agreements remain valid, and that considering the carrier component in the weight/weight ratio would significantly affect the AS concentration and the C&L of the product.

- Upon request of a CG member, the Commission clarified that paragraph 15 only focuses on the concentration of the AS in the final product as it is supplied to the final user and not on the H&P statements. For enforcement purposes, control authorities should know what the AS concentration in the final product is, so that it can be tested in an official laboratory for compliance. Consistently, the AS concentration indicated in section 2.1 of the SPC should be the same.

- A CG member noted that, despite the existing Commission decisions in this respect, treated articles with a primary biocidal function do not meet the definition of a biocidal product and should be considered as a combination of a mixture and an article. Therefore, the concentration of the AS referred to in paragraph 15 should be the one in the mixture/substance used to treat or incorporated in the article. The Commission referred back to previous discussions on the guidance document on TA and the Commission decisions already adopted in this respect.

- A CG member noted that for type B products (para. 17), the description in the IUCLID file would facilitate the inclusion of the information for BPFs at the meta-SPC level and that putting this information in section 6 of the SPC would make this section too long. The Commission invited CG members to reflect on this element and to submit written comments.

The Chair invited CG members and ASOs to provide written comments by 19 August.

**Actions**

**SECR:** to open a Newsgroups forum for written comments

**All:** to comment on the Newsgroups by 19 August

## 13.2 Regulatory issues in the authorisation of PT21 products

The Chair informed that the overview document circulated to the meeting (CG-18-2016-02) contained an update reflecting the outcome of the technical discussions on the authorisation of antifouling products held in the ad-hoc Environmental Exposure Working Group. The majority of the issues raised in the document by the ASOs have been solved in different fora. The protection goal for PT21 products appeared as the only remaining point that could potentially require further discussion.

The Chair proposed to consult the representatives of the CA meeting whether the protection goal should be referred to the CA meeting for further discussion. For this purpose, a Newsgroups discussion will be open for a short consultation with the MSs CA meeting

representatives. If supported by MSCAs, the protection goal will be tabled for discussion at the CA meeting.

The Chair invited CG members and ASOs to provide written comments by 15 July.

**Actions**

**SECR:** to open a Newsgroups forum to consult if this point should be referred to the CA meeting

**All:** to comment on the Newsgroups by 15 July

### 13.3 Linking label claims and the product authorisation

The Commission introduced document CG-18-2016-13, which is a follow-up of the e-consultation discussed at the last CG meeting and focuses on the regulatory aspects only.

The following elements were raised by CG members during the discussion:

- The scope of the document should be restricted to biocidal claims only, as some other non-biocidal claims are also made. The non-biocidal claims do not fall under the scope of the BPR and should only be considered, where relevant, as part of the instructions for use in section 4 of the SPC (e.g. clean before disinfect, etc..).

- A CG member did not consider essential to make a reference in section 6 of the SPC to the section in the PAR where the biocidal claims are assessed. Other CG members considered though that such a reference would help inspectors to find the relevant information in the PAR.

- A CG member asked whether this document should also be checked with the Biocides Enforcement Group (BEG) before it is agreed, as part of it focuses on enforcement.

- A CG member reminded that the technical aspects leading to "which claims can be done" should also be considered by ECHA WGs, as agreed at CG-17.

The Commission agreed to restrict the scope of the document to biocidal label claims only and will consider internally the need for a discussion within the BEG.

**Actions**

**SECR:** to open a Newsgroups forum for written comments

**All:** to comment on the Newsgroups by 19 August

## 14. Feedback from working parties

### 14.1 Development of standardised sentences for the SPC sections of anticoagulant rodenticides

The Commission briefly informed CG members that, now that the BPC opinions for the renewal of the active substances are available, the WP's activity will resume. The Commission will update the working documents accordingly and launch a new commenting period within the WP. If needed, a physical meeting of the WP could be organised in September back to back to the CG meeting. The key objective would be to have the SPC templates endorsed by the CA meeting in November 2016.

### 14.2 Frequently used sentences for the SPC

The CG SECR informed the CG members on the activities of the working party. A total of 18 experts were nominated from 9 CAs and 2 ASOs. The collection of frequently used sentences for the free text of the SPC has been started with closing date of 29 July.

## 15. Any Other Business (open session)

### 15.1 Trends in product authorisation

The Chair invited the meeting to take note of the reports in documents CG-18-2016-14&15, which were made available for information.

### 15.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-18-2016-16, which was made available for information.

### 15.3 List of substances meeting the exclusion or substitution criteria

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

The Chair asked CG members whether the list should be produced only when there is a change in the status of a substance fulfilling the exclusion/substitution criteria or whether it should also reflect the changes of status of CLH dossiers in the RAC committee. CG members expressed that they would prefer to receive the updates including as well changes in the CLH dossier status.

**Actions**

**Rapporteur MSs:** to check the new information

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

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

### 15.4 Feedback on e-consultations

Two e-consultations were presented for CG agreement.

1. A member presented the outcome of an e-consultation regarding a follow-up questions on substances of concern (CG-18-2016-17). This e-consultation referred to the revision of the HH guidance document on Substances of Concern for those co-formulants that are active substances in another PT, in particular the aspects whether the concentration limit of ≥0.1% is a reasonable cut-off and whether for all active substances a full quantitative risk assessment should be carried out. The CG members proposed to forward this issue to the Human Health Working Group for further discussion.

Another issue raised on this e-consultation regarding the need of a full quantitative risk assessment and the consequent access to data was agreed by the CG members.

2. A member presented the outcome of an e-consultation regarding disinfection products and denaturing substances (CG-18-2016-07a and b). Regarding the question on which denaturing methods were used by the different MSs, some reported to use the harmonised denaturing methods as described in Annex 1 to Regulation 162/2013 while other MSs use alternative methods. The CG members agreed that efficacy without the denaturing substance should be demonstrated. Regarding the use of one or three denaturing substances in Annex 1 the Commission will clarify this at the next meeting. No conclusion was reached.

**Actions**

1) **SECR:** to refer the discussion of the e-consultation to the HH WG
2) **COM:** To clarify if regarding the denaturing substances, one or three denaturing substances should be added to a product.

   **The initiating MS:** to update the conclusion on the second e-consultation once all the data is available.

## 15.5 Questions on MR

A CG member raised two questions regarding mutual recognition:

- ***Applications led by consortia and LoA issues.***

  Some consortia managers consider that, as the consortium as AH of the reference BPF will not place any products on the market but just facilitate the applications for SBPs submitted by consortia members, a LoA to the AS dossier should not be required in the application for authorisation of the reference BPF led by the consortium managers. The Commission clarified that, as any other applicant, the consortium needs to have a LoA from the AS supplier for the whole reference BPF and for all the MSs where an application for MR is submitted. Then at MS level, applicants for a same product of the BPF/family member just need the LoA from the consortium as AH of the reference BPF/family member to all the data supporting the reference BPF/family member (see Article 2(c) of the SBP Regulation). The fact that the consortium will not place products on the market is irrelevant in this respect.

- ***MR of individual products in a family.***

  It seems that some consultants and some MSs believe that MR of family members is possible. The Commission clarified that a family member cannot be mutually recognised. Article 32 of the BPR refers to MR of national authorisations, either in the form of a BPF or a single product. Therefore, MR of a BPF authorisation in the refMS can only result in the cMS in a BPF authorisation under the same terms and conditions. However, nothing forces the AH to place on the market of the cMS all the family members.

  MR should not be mixed-up with the new cases that the amended SBP Regulation provides for (e.g. SBP application resulting in a "reduced family" or SBP application of a family member).

  CG members agreed with the approach mentioned by the MSCA and confirmed by the Commission.

**Actions**

**SECR:** to document the conclusions in the minutes of the CG meeting.

## 16. Agreement of the action points and conclusions

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

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# Part II - MAIN CONCLUSIONS & ACTION POINTS

## Main conclusions and action points

**18th meeting of the CG**

**7 July 2016**

| **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 without changes. | **SECR:** to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes. |
| **3 – Declaration of interest in relation to agenda** | |
| No declarations of conflicts of interest were made. | |
| **4 – Draft minutes from CG-17** | |
| A minor comment was received on the confidential minutes of the CG-17 meeting that will be incorporated in the final version.<br>The draft confidential minutes were agreed. | **SECR:** to amend the minutes and upload the CG-17 minutes into the relevant folders in the CG CIRCA BC. |
| **5 – Formal and informal referrals on mutual recognition disagreements** | |
| **5.1 - Overview of the referrals discussed at the Coordination Group** | |
| The Chair informed about the update of the overview table of the referrals discussed so far at CG level. | **SECR:** to produce a revised overview table for next CG meeting. |
| **5.2 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR** | |
| No informal referrals were discussed. | |
| **5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR** | |
| Three formal referrals were discussed.<br>1) An agreement was reached by consensus and this referral is therefore closed.<br>The outcome of the referral was agreed by the CG members.<br>2) An agreement was reached by consensus and this referral is therefore closed.<br>The outcome of the referral was agreed by the CG members.<br>3) An agreement was reached by consensus by the CG members and this referral is therefore closed. The rMS will be informed about the agreement.<br>The outcome of the referral was agreed by the CG members. | **1-3) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures.<br>1) **SECR**: to update the CG members on how to notify changes in products authorised under the simplified procedure in R4BP3.<br>2) **SECR**: to forward the evaluation of drench applications to the efficacy WG for discussion before the renewal of the product.<br>3) **SECR:** to forward to the HH WG whether there is a need to revise the HEEG-12 opinion on the assessment of AVKs. |

| **Agenda point** | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| | To communicate the CG agreement to the rMS. |
| **6 – Any Other Business** | |
| **6.1 – Late procedures** | |
| COM presented the identified issues and proposal for remedial actions. | **MSs:** to undertake the relevant actions<br>**SECR:** To open a newsgroup forum for written comments.<br>**All:** to comment on the Newsgroup by 19 August.<br>**SECR:** To communicate the IT group about issues with IUCLID 6 |
| **6.2 – DEET products: progress report** | |
| A member updated the meeting on the status of the applications for authorisation for DEET products.<br>The Commission updated the meeting about previous discussions within the CG on H315 products. | |
| **6.3 – Feedback on e-consultations** | |
| One closed e-consultation was presented:<br>A member presented the conclusions of an e-consultation regarding the evaluation of similar products with different mode of application. Some elements will be referred to the working group on efficacy.<br>The CG members supported the proposed way forward. | **SECR:** Communicate this issue to the efficacy WG. |
| **6.4 Renewal of anticoagulant rodenticides** | |
| Commission presented considerations and elements to be taken into account at the renewal of AVKs.<br>a) Regulatory approach<br>b) Technical issues<br>- Assessment of dermal absorption<br>- Issues regarding storage stability<br>- Efficacy | **SECR:** Open a newsgroup in CIRCABC to provide specific questions to refer to the different working groups.<br>**All:** To provide questions by 15 July.<br>**SECR:** Refer the collected questions to the relevant WGs for discussion at the September meeting. |
| **6.5 Mutual recognition of creosote containing products** | |
| COM presented the topic | |
| **Item 7 – 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** | |
| **8 –Welcome** | |

| **Agenda point** | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| **9 – Agreement of the agenda** | |
| The agenda for the open session was agreed with the addition of two questions proposed by a MS for the AoB. | **SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes. |
| **10 – Declaration of interest in relation to agenda** | |
| No declarations of conflicts of interest were made. | |
| **11 – Draft minutes from CG-17** | |
| A minor comment was received on the non-confidential minutes of the CG-17 meeting that will be incorporated in the final version.<br>The draft non-confidential minutes were agreed. | **SECR:** to amend the minutes and upload the CG-17 minutes into the relevant folders in the CG CIRCA BC. |
| **12 – Administrative issues** | |
| **12.1 Working instructions of e-consultations** | |
| The SECR presented a proposal for the working instructions for e-consultations.<br>COM proposed a few amendments.<br>The CG members agreed to adopt the document including the amendments proposed by COM | **SECR:** To amend the working instructions document<br>**SECR/MSs:** To implement the procedure. |
| **12.2 Working procedures** | |
| The SECR presented the results of the consultation on the distribution of the 90 d period for mutual recognition phase.<br>COM presented a proposal on the period on MR to move from 60/30 split to 50/30/7/3.<br>Different opinions were expressed on this point and proposals were made on how to improve the communication tool in R4BP3. | **SECR:** To open a Newsgroup forum for written comments on how to improve the communication tools and how to implement a step to give comments on the updated SPC and eventually starting a referral.<br>**All:** to comment on the Newsgroup by 19 August |
| **13 – Harmonisation of technical and procedural issues in relation to product authorisation** | |
| **13.1 Guidance on carrier-based biocidal products** | |
| COM presented the document regarding the guidance on carrier-based biocidal products. A number of comments were raised by several MSs. | **SECR:** To open a Newsgroup forum for written comments.<br>**All:** to comment on the Newsgroup by 19 August |
| **13.2 Regulatory issues in the authorisation of PT 21 products** | |
| All items raised by the ASO have been addressed except one point regarding protection goals. This point might need to be referred to the CA meeting | **SECR:** To open a Newsgroup forum to consult if this point should be referred to the CA meeting.<br>**All:** to comment on the Newsgroup by 15 July |
| **13.3 Linking label claims and the product authorisation** | |
| COM presented the document and MSs provided some questions regarding how to address non-biocidal label claims and the need for discussion at the Biocides Enforcement Group. | **SECR:** To open a Newsgroup forum for written comments.<br>**All:** to comment on the Newsgroup by 19 August |

| **Agenda point** | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| **14 – Feedback from working parties** | |
| **14.1 - Development of standard sentences for the SPC sections of anticoagulant rodenticides** | |
| The Commission reported on the status of the activities of the WP, to be resumed after the reception of the BPC opinions on the renewal of AVKs active substances. | |
| **14.2 - Frequently used sentences for the SPC** | |
| ECHA reported on the status of the activities of the Working Party. | |
| **15 – Any Other Business** | |
| **15.1 - Trends in product authorisation** | |
| The Chair presented the reports, available for information. | |
| **15.2 - Deadlines for application for product authorisation** | |
| The Chair presented the reports, available for information. | |
| **15.3 List of active substances meeting the exclusion or substitution criteria** | |
| The Chair invited the meeting to take note of the document.<br>MSs supported to have the list produced every meeting. | **Rapporteur MS:** to check the new information and report to CG SECR.<br>**SECR**:<br>To transmit the updated version to COM to make it publicly available on CIRCABC.<br>If relevant, to produce an updated version for next CG meeting. |
| **15.4 – Feedback on e-consultations** | |
| Two e-consultations were presented.<br>1) A member presented the outcome of an e-consultation regarding the follow-up questions on substances of concern. For one of the topics, CG members agreed to refer the question to the HH WG in order to update the HH guidance document on SoC. The second topic was agreed.<br>2) A member presented the outcome of an e-consultation on disinfection products and denaturing substances. CG members agreed that efficacy without the denaturing substance should be demonstrated. Regarding the use of one or three denaturing substances in Annex 1 to regulation 162/2013, COM will clarify this at the coming meeting. No conclusion was reached. | 1) SECR: Refer the discussion of the e-consultation to the HH WG<br>2) - COM: to clarify if regarding the denaturing substances, one or three denaturing substances should be added to a product<br>- The initiating MS to update the conclusion of the second e-consultation once all the data is available. |
| **15. Questions on MR** | |
| A MSCA raised two questions regarding mutual recognition:<br>- Applications led by Consortia and LoA issues. A LoA is needed for the applicant of the reference product or family. | **SECR:** To document the conclusions in the minutes of the CG meeting. |

| **Agenda point** | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| - MR of single products of family members in a family. COM clarified that a MR of a BPF should result in a BPF under the same terms and conditions.<br><br>CG members agreed with the approach mentioned by the MSCA and confirmed by COM | |
| **16 – Agreement of the action points and conclusions** | |
| The list of action points and conclusions was agreed by the CG meeting. | |

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# ANNEX II

7 July 2016

## Final agenda

## 18th meeting of the Coordination Group (CG)

## 7 July 2016 – from 9:00 to 17:00consid

**Brussels, Centre Borschette**

## CLOSED SESSION

**Item 1 – Welcome**

**Item 2 – Agreement of the agenda**

*CG-A-18-2016*

***For agreement***

**Item 3 – Declaration of interest in relation to the agenda**

**Item 4 –Draft minutes from CG-17**

*CG-M-17-2016_Draft confidential*

***For agreement***

**Item 5 – Formal and informal referrals on mutual recognition disagreements**

5.1 Overview of the referrals discussed at the Coordination Group

*CG-18-2016-01*

***For information***

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

*Links to disagreements*

***For discussion***

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

*Links to disagreements*

***For discussion and agreement***

**Item 6 - Any Other Business**

6.1 Late procedures

*CG-18-2016-09*

***For information***

6.2. DEET products: progress report

***For information/ discussion***

6.3 Feedback on e-consultations

*CG-18-2016-04*

*CG18-2016-18*

*Links to e-consultations*

***For discussion and agreement***

6.4 Renewal of anticoagulant rodenticides

*CG-18-2016-10*

***For discussion***

a) Regulatory approach

b) Technical issues
- Assessment of dermal absorption
- Issues regarding storage stability
- Efficacy

c) Major changes to authorisations to reduce the active substance concentration

***For information***

6.5 Mutual recognition of creosote containing products

*CG-18-2016-11*

***For discussion***

**Item 7 – Agreement of the action points and conclusions**

***For agreement***

## OPEN SESSION

**Item 8 – Welcome**

**Item 9 – Agreement of the agenda**

*CG-A-18-2016*

***For agreement***

**Item 10 – Declaration of interest in relation to the agenda**

**Item 11 –Draft minutes from CG-17**

*CG-M-17-2016_Draft non confidential*

***For agreement***

**Item 12 – Administrative issues**

12.3 Working instructions of e-consultations

*CG-18-2016-03*

***For discussion and agreement***

12.4 Working procedures

*CG-18-2016-08*

***For discussion***

**Item 13 – Harmonisation of technical and procedural issues in relation to product authorisation**

13.1 Guidance on carrier-based biocidal products

*CG-18-2016-12*

***For discussion***

13.2 Regulatory issues in the authorisation of PT 21 products.

*CG-18-2016-02*

***For information***

13.3 Linking label claims and the product authorisation

*CG-18-2016-13*

***For discussion***

**Item 14 – Feedback from working parties**

14.1 Development of standardised sentences for the SPC sections of anticoagulant rodenticides

***For information***

14.2 Frequently used sentences for the SPC

*CG-18-2016-05*

***For information***

**Item 15 – Any Other Business**

15.1 Trends in product authorisation

*CG-18-2016-14 & 15*

***For information***

15.2 Deadlines for application for product authorisation

*CG-18-2016-16*

***For information***

15.3 List of active substances meeting the exclusion or substitution criteria

*CG-18-2016-06*

***For information***

15.4 Feedback on e-consultations

*CG-18-2016-07*

*CG-18-2016-17*

*Links to e-consultations*

***For discussion and agreement***

15.5 Questions on MR

***For discussion***

**Item 16 – Agreement of the action points and conclusions**

***For agreement***

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