14 March 2017

CG-M-21-2017 non-confidential

Non-confidential minutes of the 21st meeting of the Coordination Group (CG)

19 January 2017

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the twenty first CG meeting. 32 members and advisors from 21 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.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-21-2017) and invited participants to add any items under AOB. Two agenda points were added to be discussed in the AOB part of the closed session. The first point was related to adding additional uses in a creosote based product, and the second point was related to issues when evaluating same biocidal products applications. An additional point related to the concept of "similar uses" in biocidal product families (BPF) was added to be discussed during the open session under the agenda point 14.2. The agenda was agreed with these modifications.

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.

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. Draft minutes from CG-20

The Chair explained that the draft confidential CG-20 minutes had been uploaded for commenting via Newsgroups and that comments were received from a CG member. The minutes were updated with these comments and the CG members agreed on the updated confidential draft minutes from the CG-20.

Actions

SECR: to upload the CG-20 minutes 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.

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

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

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

Nine formal referrals were discussed.

1) A formal referral was introduced concerning a disagreement on the application of the 9th ATP to CLP to a PT14 product. In the opinion of the initiating cMS (icMS), according to Article 19(4) of the BPR the product could not be authorised for the general public. The commenting period for this referral is ongoing and will be further discussed by teleconference.

2-4) Three formal referrals were discussed corresponding to three closely related applications submitted by the same applicant (PT 19). The point of disagreement was the same for the three referrals which was related to the conclusions reached on the human health risk assessment. The icMS argued that the exposure assessment had not been done with the product dose that was used in the efficacy tests.

The CG members agreed by consensus that, in line with the way forward agreed during the CG-16 meeting, changes to the risk assessment of already authorised products in order to take into account any new agreed guidance addressing the dose supporting the efficacy tests will be considered at the renewal stage. It was therefore concluded that the products meet the conditions for granting an authorisation in Article 19(1)(b)(iii) of the BPR.

On a more general note, the CG members discussed that there is a need to address how to perform the risk assessment for PT19 products. ECHA explained that the WGs for toxicology and efficacy will provide a document with the approach to follow for a consistent toxicological and efficacy assessment of PT19 products.

5) A formal referral concerning a PT18 bait product was discussed. The point of disagreement was related to the RMMs specified for the use for non-professional users to prevent exposure of honeybees to the product.

The CG members agreed by consensus that, in the absence of specific guidance, the RMM proposed by the applicant in addition to limiting the use of the product to cracks and crevices were sufficient for granting an authorization. The risk to bees deriving from the outdoor use of insecticide bait products will be addressed at the time of renewal. It was therefore concluded that the product meets the condition for granting an authorisation in Article 19(1)b(iv) of the BPR.

The CG members agreed to refer to the Environmental WG the need to address this topic by next renewal.

6) A formal referral concerning a PT18 product was discussed. The icMS questioned the validity of the efficacy tests submitted by the applicant and the need to address the consumer dietary exposure to the active substance coming from the consumption of poultry. No agreement was reached during the meeting. The referral will be further discussed by teleconference.

7) A formal referral concerning a PT8 product was discussed. The icMS did not agree with the arguments for waiving the use of different standards than those specified in the guidance for testing efficacy. The commenting period will be extended to allow for further input from other MSs. No agreement was reached during the meeting and the referral will be further discussed by teleconference.

8) A formal referral concerning a PT 8, 14 and 18 product was introduced. There were three points of disagreement. The first point was related to the efficacy data submitted which was considered insufficient to prove the efficacy of the product for the use as PT14 and PT18. The second point of disagreement was the type of respiratory equipment to be worn by operators and, the third point of disagreement was related to the threshold value for the concentration of the active substance in the air for re-entering a chamber after fumigation.

The referral will be further discussed by teleconference once the commenting period is finalized.

9) A formal referral concerning a PT19 product was introduced. The icMS was of the opinion that, for this particular case, it should be explicitly indicated in the SPC that the product should not be used to protect plants and plant products. The rMS and cMS agreed on the phrase that could be included in the SPC to address this issue. Other MSs will review the proposed sentence and way forward in order to come to an agreement.

Actions

1) All: To provide comments by 31 January 2017 on the referral.

1) SECR: to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement.

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

2-4) SECR: If finalised by ECHA WGs, to present a document in the CG-22 meeting detailing how to integrate the efficacy and toxicological risk assessment for PT 19 products.

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

5) SECR: to refer to the Env WG the need to address the risk to honeybees of insecticide bait products used outdoors before the next renewal of the authorisations.

6) SECR: to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement.

7) All: To provide comments by 1 February 2017 on the referral.

7) SECR: to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement.

8) All: To provide comments by 30 January 2017 on the referral.

8) SECR: to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement.

9) UK: to send to the SECR the sentence to be added to the label of the product.

9) SECR: to upload the sentence provided by UK in the newsgroup for comments for this referral.

9) All: To provide comments by 3 February 2017 on the referral.

9) SECR: In case that other MSs object the outcome as proposed by UK and DE, to organize a meeting teleconference with all MSs in February for each of the referrals with the objective of finding a consensus agreement

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

6.1 Issues identified in the context of UA

The SECR presented a list of issues identified in the context of UA applications (CG-21-2017-28), which will be updated and made available to the CG members every meeting. The intention of publishing this list is to allow eCAs of national authorizations of products based on the same active substance to be informed about the issues identified in UA applications.

A CG member commented that eCAs evaluating similar products to those discussed in the UA applications would be interested in participating in the discussions of the issues, since these issues would be also applicable for applications at at national level.

Actions

MSs: To take note of the information provided in the table.

SECR: To update the table, where relevant, for upcoming CG meetings.

6.2 Iodate used as stabilizer

The SECR introduced the document CG-21-2017-15 in which it was described the issue related to iodine and iodine/PVP containing products in which iodate is used as a stabilizer. The issue of concern was whether iodate should be regarded as a stabilizer or as an active substance in these products. This topic was previously discussed in the APCP WG-V in 2015 and the conclusion was that if the concentration of iodine would increase more than 10% in the product during its lifetime, the iodate should be treated as an active substance. If the increase in concentration would be below 10%, iodate could be treated as a stabilizer.

A few member states had noted the need to reconsider this issue since a considerable number of applications are affected. Four options were discussed:

a) Treat iodate as a special case and include all iodine containing species in the risk assessment while ensuring that the level of iodine remains within the ranges set by the FAO/WHO.

b) Submit applications according to Article 93 of the BPR resulting in iodine being considered as an in-situ generated active substance for iodate, iodine and hydronium.

c) Apply Article 15(a) of the Review Program Legislation providing that a misleading advice was given to applicants that resulted in the treatment of iodate as a stabilizer.

d) Reformulation of products.

Related to option (b), the CG members agreed that article 93 is not applicable since iodine generated from iodate/iodide/hydronium cannot be considered as an in situ generated active substance.

Further information is needed in order to make an informed decision on the best way forward to address this issue.

Actions

MSs: To check whether a misleading written advice was given in the past to applicants that resulted in considering iodate not as an active substance and communicate the outcome to the SECR by 3 February.

MSs: to contact applicants to enquire about technical feasibility, and timelines for option (d) taking into account the legal deadlines and communicate the outcome to the SECR by 9 February.

SECR: To open a Newsgroup forum for written comments.

MSs: to comment in the Newsgroup including a reflection on the implications of option (d) and the timeline needed for reformulation in case this option was followed by 9 February.

7. Any Other Business (closed session)

7.1 Late procedures

The Commission introduced the reports prepared by ECHA (CG-21-2017-06 & CG-21-2017-07 & CG-21-2017-08). A new report was introduced on late cases in the rMSs for MRP procedures.

Actions

MSs: to review the document and communicate to ECHA any inaccuracies in the data.

SECR: To open a Newsgroup forum for written comments.

rMSs: (from document CG-21-2017-08) to provide details on the delay of all mentioned cases via the newsgroup by 9 February

All: to provide comments in the newsgroup on the format of report CG-21-2017-08 by 9 February.

7.2. Feedback on e-consultations

Three e-consultation were presented for discussion.

1. A CG member presented the results of an e-consultation related to a question on how different formulation types should be grouped in the same biocidal product family (CG-21-2017-25). Most CG members supported the view that solid formulations should be in different BPFs than liquid formulations. Different opinions were expressed whether liquid formulations based on different solvents could be included in the same BPF.

   The Commission mentioned that the BPF concept guidance could be reviewed in the light of experience. CG members should also consider the impact of a too restricted approach on the fees to be paid by applicants and the overall additional workload for CAs during the lifecycle of the BPF(s) (authorisation, changes and renewals).

   A few CG members were of the opinion that at this moment there was little experience on this area and argued that, making unjustified restrictions (where the risk assessment is possible) should not be the way forward. Therefore, a case by case approach would be needed. On the other hand, other CG members indicated that this approach might result in unequal treatment of applicants and, therefore, a clearer guidance was needed. A CG member proposed that a possible way forward could be to organize a working party to address this topic.

   Another aspect mentioned was that a more clear definition and criteria for similar uses were needed.

   The chair proposed to reopen the newsgroup forum on this topic and invited the CG members to provide written comments in the light of the discussion in the meeting.

2. A CG member presented the results of an e-consultation related to the interpretation of the efficacy guidance for PT8 (use class 2), which were summarized in document CG-21-2017-26. Different opinions were given. While a few CG members agreed that it is not possible to claim a use class 2 (or higher) when a product has not demonstrated efficacy against rotting fungi, a CG member argued that it is possible to claim use class 2 as long as the product is only approved for use in dry or occasionally humid locations.

   The CG members agreed that the discussion of this topic should be referred to the efficacy working group, who should consider if the exception mentioned to claim use class 2 in this consultation would be acceptable.

3. A CG member introduced an e-consultation on the requirements of a letter of access (LoA) for substances of concern (SoC) as described in document CG-21-2017-13. The CG member explained the difficulties found for MSs to know whether the information given for a SoC was protected or not and therefore if a LoA was needed in those cases.

   The Chair indicated that the commenting period for this e-consultation was still open until 26 January and invited the CG members to comment on this topic. The Commission indicated that it will also contribute with some proposals.

Actions

1) NL to provide an updated document ASAP after the meeting with the comments provided during the CG-21 meeting.

1) SECR: to open a Newsgroup forum for written comments on the updated version of the document.

1) All: to comment on the Newsgroup (3 weeks).

2) SECR: to refer the e-consultation to the Efficacy working group to take into consideration the comment by a member state on possible exceptions.

3) All: to comment on the Newsgroup by 26 January.

7.3 Working procedure for the pilot test on the MR phase

The SECR presented a proposal for the pilot testing of the standard operation procedure (SoP) for the MRP process (CG-21-2016-16). Three MSs had volunteered as rMS for testing the procedure. All cases proposed related to PT8 products. The SECR asked whether other product types could also be tested and if possible, whether a BPF could be also identified for the test.

The CG members agreed on the proposal presented with the following amendments:

1) Addition of the details of all the cases involved in the testing.
2) Step 4 in the table should refer to a reply within 5 days.
3) Replies from the cMSs will be addressed to the case of the rMS (NA-APP).

The CG members agreed to start the pilot test directly after the CG-21 meeting, as soon as the draft PAR and draft SPC are uploaded in R4BP3 by the rMS for the different cases.

Actions

UK and DK: to provide details on the cases to be tested.

SECR: to amend the proposal for the pilot testing of the MR SoP and upload it in S-CIRCABC in the corresponding space.

Volunteering rMSs and involved cMSs: to initiate the pilot test according to the agreed procedure.

7.4 Election of vice-Chair of the Coordination Group

Vasilis Vagias was re-elected as vice Chair of the CG.

7.5 Additional uses in a creosote based product

A CG member presented a case where additional information for a use is being assessed by the rMS in order to be included in the PAR, as it needs to be authorised in other cMSs by MR-S.

In order to do so, the appropriate regulatory procedure is needed to provide legal certainty to the involved parties (applicant, rMS and cMSs).

The Commission emphasised the legal obligation for MSs, when having authorised a creosote containing biocidal product, to send to the Commission a report as outlined in Directive 2011/71/EU.

Actions

rMS: to evaluate the most suitable regulatory procedure to reopen the case.

7.6 Issues when evaluating same biocidal products

A CG member presented a case where an application for a same BPF cannot be considered to be identical to the reference BPF (different composition of individual products).

The Commission referred to Article 2(b) of the SBP Regulation, which states that evidence should be provided by the applicant that the products are identical (except differences that can be the result of administrative changes). The CG members agreed on this comment. The Commission further mentioned that CG members should reflect on this issue in the context of the agenda item concerning the need for additional guidance on the SBP Regulation.

Actions

SECR: to communicate to ECHA the necessity to clarify this concept in the guidance on same biocidal products.

8. Agreement of the action points and conclusions

The list of action points and conclusions for the closed session will be agreed by written procedure.

Actions

SECR: To circulate the list of action points and conclusions for agreement ASAP after the meeting.

All: to send comments by 27 January.

Open session

9. Welcome to the open session

The Chair welcomed ASOs to the open session. Five 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 Chair introduced the draft agenda (CG-A-21-2017) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed.

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.

11. 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.

12. Draft minutes (non-confidential part) from CG-20

The Chair explained that the draft non-confidential CG-20 minutes were uploaded for commenting via Newsgroups and no comments were received. The CG members agreed on the non confidential draft minutes from the CG-20 meeting.

Actions

SECR: to upload the CG-20 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

13.1 Clarification in the RoP

Following a question raised by a CG-member, the SECR informed that there was a mistake in the document "Rules of procedure for the Coordination Group (CG) under Regulation EU n°528/2012" (RoP).

ECHA informed that the RoP for the CG will be corrected to indicate that the agreements of items not related to formal referrals should be by majority of two thirds of votes when a consensus agreement is not found.

A revised version of the RoP will be tabled for the next CG meeting for discussion and agreement.

Actions

SECR: To correct the RoP and schedule the updated document for agreement during next CG meeting.

13.2 Working procedure for the linguistic review in UA

The SECR presented a proposal for the linguistic review process of the translations of the SPC by the MSs for UA (CG-21-2017-22). This proposal follows up from the CA meeting proposal discussed in July 2012 on this topic (CA-July12-Doc.5.2.g). During the commenting phase several CG members had expressed their concern about the resources that would be needed for this process. The timelines were also considered to be very short and, in order to have a more efficient process, it was proposed to try to initiate the review process before the submission of the opinion. A CG member proposed to have a simplified version of the

procedure which would not include a final review of the translations by the applicant. ECHA and industry did not support this option since they considered that a final review by the applicant was necessary in order to ensure that the changes in the translation did not change the actual meaning of the SPC instructions.

Several CG members and industry mentioned that a tool that could track changes in the SPC text was needed to facilitate the review of the translations, especially considering the tight timelines set for this process. The use of the SPC comparison tool for this purpose would not allow to detect the exact changes introduced in the revised text, which would result in a loss of time for all parties. The SECR explained that at this moment this tool is not available and the issue will be communicated to the IT group in ECHA in order to find a solution.

The proposal will be updated taking into consideration the comments received.

Actions

SECR: To prepare an updated proposal and open a newsgroup for comments.

All: to comment on the Newsgroup (3 weeks).

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

14.1 Impact on family sizes for PT 8 due to tinting paste issue – BPF approach for PPD concept (pigments, perfumes and dyes)

A CG member introduced an updated version of the document on how to approach the PPD concept for biocidal product families (CG-21-2017-14). Different opinions were given during the commenting period and a harmonised approach was not found.

In order to reach a harmonized approach, the opinion of all MSs would be needed. Due to the lack of time during the meeting for further discussion, the Chair proposed to have an updated document and to open a Newsgroup forum for further comments.

Actions

DK: To provide an updated version of the document ASAP after the meeting.

SECR: To open a Newsgroup forum for written comments on the updated version of the document.

All: to comment on the Newsgroup (3 weeks)

14.2 New Q&A pairs for Annex IV to the note on the biocidal product family concept

The Commission briefly introduced document CG-21-2017-23. Due to the lack of time during the meeting for further discussion, the Chair proposed to open a Newsgroup forum for further comments on this paper.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 9 February

14.3 Template to describe the biocidal product family structure

A CG member presented an updated version of the template to provide an overview of the biocidal product family structure.

Industry suggested that the document should not give too much information since the purpose was to give an overview of the BPF and not full details. Industry proposed that it should be possible to adapt the template case by case when necessary.

The CG members agreed on the template that should be used as a supporting document in the application, but not be part of the PAR.

Due to lack of time, the CG members were invited to further reflect on other elements regarding the practical use of the agreed template and how to present it to the applicants.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 9 February.

14.4 Grouping of ingredients in biocidal product families

A CG member briefly presented the updated version of the document related to grouping of ingredients in BPFs (CG-21-2017-03) which takes into account the comments received during the commenting period. The document includes examples on how the grouping could be done.

The Commission commented that the grouping of ingredients would need to be decided on a case by case approach and that, in any case, the exact composition of the products would need to be given at the product level.

Due to the lack of time during the meeting for further discussion, the Chair proposed to open a Newsgroup forum for further comments.

Actions

AT: To provide ASAP an updated version of the document including the comments made at CG-21.

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup (3 weeks).

14.5 Renewal of anticoagulant rodenticides

14.5(a) IT issues with non-linked applications for renewal (difenacoum and difethialone containing products): Options for a suitable way forward.

ECHA (by WebEx conference) presented a proposal with the actions to overcome the IT issues with R4BP3 related to the completion of the existing applications for the renewal of AVK rodenticides (CG-21-2017-29 and CG-21-2017-27).

ECHA explained that due to the capabilities of R4BP at the time of submission of the applications, those cases submitted from September 2013 to the end of November 2014 for MR process did not have a link in the IT system between the rMS and the cMSs. This issue affected approximately 700 cases. Other cases submitted after this date did not present this issue; the grouping information was available either in the form of a document that was attached to the application or, for applications submitted after April 2015, in the case itself in R4BP3. ECHA clarified that, even if the cases that were not connected, the assets derived from these cases did have the link.

ECHA will be contacting the applicants for the 700 products affected by this issue by adhoc communication in R4BP3 to request to fill in a form to provide the information to allow to link the rMS and the corresponding cMSs. A CG member informed that they had already performed this task and therefore the cases linked to their MS could be excluded from the list. The communication will be done by 31st January at the latest and a response from the applicant would be required in 10 days.

Industry noted that there were cases submitted after December 2014 that were also affected by this issue. ECHA advised that in these cases where applicants were aware that the grouping of the rMS and the corresponding cMSs was not done, the applicant should communicate the problem to the rMS.

For submitting the pending information by 28 February 2017 by the applicant, the CG members agreed that once the grouping information is received, the rMS will send one adhoc communication to request the pending information needed to complete the renewal of the product and another separate adhoc communication to request the draft SPC. This action

can be directly started for those cases submitted from December 2014. The cMSs will have access to the data collected by the rMS through R4BP3. For this purpose, the communications related to this topic should be clearly identified.

The Commission undertook to prepare a summary of the conclusions reached during the meeting and the actions to be taken by the different actors with the relevant deadlines. Once agreed by CG members, the SECR will make it available to MSs and ASOs shortly after the meeting.

Actions

COM: To summarize in a document the conclusions of the discussion and the agreed actions to be taken by the different actors.

SECR: To distribute those conclusions and actions for final agreement ASAP.

All: to comment on the conclusions by 23 January.

SECR: To distribute the final version of the conclusions and agreed actions to ASOs and MSs.

SECR: To clarify the IT implications for PTs other than rodenticides.

14.5(b) Actions by MSs in R4BP3 to allow applicants the submission of the pending information by 28/02/17

This agenda point was covered under agenda point 14.5(a)

14.5c Feedback from WGs on "ground water assessment" and "dermal absorption assessment"

The SECR presented an update from the environmental WG on how to perform the ground water assessment for the renewal of AVK rodenticides and from the toxicology WG on how to address the dermal absorption assessment (CG-21-2017-20).

Related to the ground water assessment, a CG member commented that the reference to the guidance was misleading and a footnote should be added to clarify this aspect. The footnote would direct the applicant to the correct source of information. The document will be amended accordingly.

Industry mentioned that for the active substance approval, the requirement of the groundwater assessment had been postponed to the renewal of the substance. The necessity to provide these data for the product renewal was a concern for applicants.

Related to the dermal absorption, the SECR explained that according to the feedback from the WG, it was not possible to establish a worst-case formulation type in order to allow for read across. On the other hand, pending legal consideration, it was discussed that it might be possible to develop specific default values per each formulation type. The Commission commented that the initial question from the CG to the WG was answered: "It was not possible to establish a worst-case formulation for read across" and questioned whether resources should be spared to develop specific default values given the unclear legal situation. The Commission view was that if a MS or the WG develop default values by using data submitted in individual applications for authorisation, they should realise that it would be in conflict with Article 59(1) of the BPR .

A few members mentioned that, in any case, if the establishment of default values would be only agreed in May 2017 at the earliest, this would be too late to be considered for the renewal of the AVK rodenticides.

The CG members agreed on the document with the addition of an explanatory footnote for the groundwater assessment.

Actions

SECR: To amend the document with the footnote proposed by a CG member and distribute to ASOs and MSs to make it publicly available.

14.5d What to do with the current authorisations if the pending information is not submitted by 28/02/17

The Commission introduced document CG-21-2017-20.

On a more general note, a CG member mentioned that where there is no application for renewal, the products should be allowed to stay on the market until the the expiry date in the authorisation. The Commission agreed with that statement, but it clarified that here we are not talking about of a case of "non-application" for renewal as the applications were already submitted in the past. Here, it is about the lack of submission of pending information, which would allow MSs to conclude the on-going procedure with a non-renewal decision.

Upon request from a MS, the Commission clarified that the first sentence of Article 6(a) of Regulation 492/2014 is not correct, as it would contradict the BPR. Article 52 does not apply where there is no application for renewal as the period of grace has to be linked to a decision by the CA "not to renew".

Industry representatives proposed agreeing on a common date so that all MSs adopt the non-renewal decisions for these products at the same time, and suggested the 1st March 2018. The Chair noted that CG members did not support such proposal.

On amore general note, some CG members indicated that they did not request the fee to applicants at the time of the submission of the application. The Commision clarified that fees is a national issue and that MSs might have followed different approaches, so they should address the payment of the relevant fees (e.g. rMS/cMS) with the applicants on a bilateral basis.

14.6 Guidance for the implementation of the amended SBP Regulation

Following the implementation of the amended SBP Regulation, ECHA has updated the support documents which are available on the ECHA website. The SECR presented a document (CG-21-2017-24) that summarizes the available guidance documents related to the SBP Regulation with the appropriate links on the ECHA website.

MSs were invited to check the already available guidance and to see whether additional guidance is still needed. They should consider as an example the case mentioned by a CG member as an AoB of the closed session.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 9 February

15. Feedback from working parties

15.1 Frequently used sentences for the SPC

15.1a List of frequently used sentences for the SPC

The SECR informed the CG members on the activities of the working party. The list of frequently used sentences had been finalized by the WP and was available for information (CG-21-2017-12). The SECR clarified that all MSs were invited to nominate experts for the WP, and, therefore since the WP experts had already performed the review of the list, the list had not been opened for comments by the CG members.

This work concludes the first objective of the WP.

15.1b Frequently used sentences for the SPC- next steps

Related to the second objective of the working party on the establishment of the responsibilities for the translation of the list of frequently used sentences, the SECR informed that ECHA would undertake the translation of the sentences of the list. Further, outside of the remit of the WP, a proposal with the next steps for the review of the translations by the MSs was presented (CG-21-2017-11).

A newsgroup forum will be opened to comment on this proposal

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 9 February

16. Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the report in document CG-21-2017-02 and CG-21-2017-04, which was 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-21-2017-05, which was made available for information.

16.3 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.

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.

16.4 IT issues

The Chair informed that no additional IT issues had been tabled for discussion.

16.5 Feedback on e-consultations

The Chair informed that no e-consultations had been tabled for discussion for the open session of the meeting.

16.6 Confidentiality on comparative assessment reports

A CG member presented the document with the conclusions of the consultation on the confidentiality on comparative assessment reports (CG-21-2017-17). The document included further questions for clarification.

The Commission referred to Article 23(2) of the BPR and concluded that 1)The MSs should forward the complete comparative assessment report to the CG SECR according to Article 23(2) of the BPR as soon as it is available and 2) The version of the comparative assessment to be included in the PAR should not contain confidential information.

The CG members agreed with the conclusions of the Commission. A document will be prepared with the conclusions reached during the meeting and will be tabled for agreement in the CG-22 meeting.

Actions

FR: To provide the SECR with an updated document with the conclusions from the CG discussion.

SECR: To table the document for agreement in the CG-22 meeting.

17. Agreement of the action points and conclusions

The list of action points and conclusions will be agreed by written procedure.

Actions

SECR: To circulate the list of action points and conclusions for agreement ASAP.

All: to send comments by 27 January.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

Main conclusions and action points

21st meeting of the CG

19 January 2017

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 2 points for the AOB of the closed session and a point to be discussed as part of agenda point 14.2.	**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-20	
Written comments were received from a MS prior to the meeting upon which the draft minutes were updated. No comments were received during the meeting on the updated version of the confidential minutes of the CG-20 meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-20 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	
Nine formal referrals were discussed 1) Discussions were initiated with a view to reach an agreement in an upcoming teleconference involving all MSs, or at the next CG meeting at the very latest. 2-4) Three referrals were treated as one issue. An agreement was reached by consensus and these referrals are therefore closed. The outcome of the referrals was agreed by the CG members.	**1) All:** To provide comments by 31 January 2017 on the referral. **1) SECR:** to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement. **2-4) SECR:** to follow-up the outcome of the referrals as

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (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) Discussions were initiated with a view to reach an agreement in an upcoming teleconference involving all MSs. 7) Discussions were initiated with a view to reach an agreement in an upcoming teleconference involving all MSs. 8) Discussions were initiated with a view to reach an agreement in an upcoming teleconference involving all MSs 9) Discussions were initiated with a view to reach an agreement in an upcoming teleconference involving all MSs	stated in the Working Procedures. **2-4) SECR:** If finalised by ECHA WGs, to present a document in the CG-22 meeting detailing how to integrate the efficacy and toxicological risk assessment for PT 19 products. **5) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **5) SECR:** to refer to the Env WG the need to address the risk to honeybees of insecticide bait products used outdoors before the next renewal of the authorisations. **6) SECR:** to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement. **7) All:** To provide comments by 1 February 2017 on the referral. **7) SECR:** to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement. **8) All:** To provide comments by 30 January 2017 on the referral. **8) SECR:** to organize a meeting teleconference with all MSs in February with the objective of finding a consensus agreement. **9) UK:** to send to the SECR the sentence to be added to the label of the product. **9) SECR:** to upload the sentence provided by UK in the newsgroup for comments for this referral. **9) All:** To provide comments by 3 February 2017 on the referral. **9) SECR:** In case that other MSs object the outcome as proposed by UK and DE, to organize a meeting

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	teleconference with all MSs in February for each of the referrals with the objective of finding a consensus agreement.
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 update the table, where relevant, for upcoming CG meetings.
6.2 - Iodate used as stabilizer The SECR presented four options to address the issue of iodate used as stabilizer in PT 3 biocidal products. From the options presented, CG members agreed that article 93 is not applicable since iodine generated from iodate/iodide/hydronium cannot be considered as an in situ generated substance. Further information is needed in order to make an informed decision on the best way forward to address this issue.	**MSs**: To check whether a misleading written advice was given in the past to applicants that resulted in considering iodate not as an active substance and communicate the outcome to the SECR by 3 February. **MSs**: to contact applicants to enquire about technical feasibility, and timelines for option (d) taking into account the legal deadlines and communicate the outcome to the SECR by 9 February. **SECR**: To open a Newsgroup forum for written comments. **MSs:** to comment in the Newsgroup including a reflection on the implications of option (d) and the timeline needed for reformulation in case this option was followed by 9 February.
7 – Any Other Business	
7.1 – Late procedures	
COM presented the overview of late procedures. A new report was introduced on late cases in MRP procedures due to delays in the refMS.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data. **SECR**: To open a Newsgroup forum for written comments. **rMSs:** (from document CG-21-2017-08) to provide details on the delay of all mentioned cases via the newsgroup by 9 February **All**: to provide comments in the newsgroup on the format of

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	report CG-21-2017-08 by 9 February.
7.2 – Feedback on e-consultations	
Three closed e-consultation were presented: 1) A member presented the comments received for the e-consultation regarding the "Update Annex IV BPF concept" on the possibility of considering different formulation types within a biocidal product family. CG members had different views on how to group different types of formulations in families. 2) A member presented the conclusions of an e-consultation regarding the "Interpretation of efficacy guidance for PT8 (Use class 2)". The CG members agreed that this issue should be forwarded to the Efficacy WG. 3) A member introduced an e-consultation regarding the "Letter of access requirements for substances of concern".	**1) NL** to provide an updated document asap after the meeting with the comments provided during the CG-21 meeting. **1) SECR:** to open a Newsgroup forum for written comments on the updated version of the document. **1) All:** to comment on the Newsgroup (3 weeks). **2) SECR:** to refer the e-consultation to the Efficacy working group to take into consideration the comment by a member state on possible exceptions. **3) All:** to comment on the Newsgroup by 26 January.
7.3 Working procedure for the pilot test on the MR phase	
The SECR presented a proposal for the pilot testing of the MR SoP. CG members agreed on the document with the following amendments: 1) Addition of the details of all the cases involved in the testing. 2) Step 4 in the table should refer to a reply within 5 days. 3) Replies from the cMSs will be addressed to the case of the rMS. The CG members agreed to start the pilot test directly after the CG-21 meeting, as soon as the draft PAR and SPC are uploaded in R4BP3 by the rMS for the different cases.	**UK and DK**: to provide details on the cases to be tested **SECR**: to amend the proposal for the pilot testing of the MR SoP and upload it in S-CIRCABC in the corresponding space. **Volunteering rMSs and involved cMSs**: to initiate the pilot test according to the agreed procedure.
7.4 Election of the vice-Chair	
Vasilis Vagias was re-elected as vice Chair of the CG	
7.5 Additional uses in a creosote based product	
A CG member presented a case where a product is being re-assessed by the rMS to include additional uses to be authorised in other MSs.	**rMS**: to evaluate the most suitable regulatory procedure to reopen the case.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
A legal basis and an appropriate regulatory procedure is needed to provide legal certainty to the involved parties (applicant, rMS and cMSs). COM emphasised the legal obligation for MSs, when having authorised a creosote containing biocidal product, to send COM a report as outlined in Directive 2011/71/EU.	
7.6 Issues when evaluating same biocidal products	
A CG member presented a case where an application for a same BPF cannot be considered to be identical to the reference BPF (different composition of individual products). CG members agreed that evidence should be provided by the applicant that products are identical according to the SBP Regulation.	**SECR**: to communicate to ECHA the necessity to clarify this concept in the guidance on same biocidal products.
Item 8 – Agreement of the action points and conclusions	
The list of action points and conclusions for the closed session will be agreed by written procedure.	**SECR:** To circulate the list of action points and conclusions for agreement asap after the meeting. **All**: to send comments by 27 January.
OPEN SESSION	
9 –Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.
11 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-20	
The draft non-confidential minutes were agreed.	**SECR:** to upload the CG-20 minutes into the relevant folders in the CG CIRCA BC.
13 – Administrative issues	
13.1 Clarification in the RoP	
The SECR clarified that agreements of discussion items as defined in the RoP in Article 1 (1) c and d should be by consensus and, if this is not possible, by two thirds majority of votes.	**SECR:** To correct the RoP and schedule the updated document for agreement during next CG meeting.
13.2 Working procedure for the linguistic review in UA	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
The SECR presented a proposal for the procedure for the linguistic review in UA.	**SECR:** To prepare an updated proposal and open a newsgroup for comments. **All:** to comment on the Newsgroup (3 weeks).
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 Impact on family sizes for PT 8 due to tinting paste issue – BPF approach for PPD concept (pigments, perfumes and dyes)	
A member briefly introduced an updated version of the document on how to approach the PPD concept for biocidal product families. Due to lack of time, further discussions at the next meeting will be needed.	**DK**: To provide an updated version of the document asap after the meeting. **SECR:** To open a Newsgroup forum for written comments on the updated version of the document. **All:** to comment on the Newsgroup (3 weeks)
14.2 New Q&A pairs for Annex IV to the note on the biocidal product family concept	
COM briefly introduced a document with some new Q&A pairs for Annex IV of the note on the biocidal product family concept. Due to lack of time, further discussions at the next meeting will be needed.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 9 February
14.3 Template to describe the biocidal product family structure	
A member presented the updated version of the template to provide an overview the biocidal product family structure. The CG members agreed on the template and that it should be used as a supporting document in the application and not be part of the PAR. Due to lack of time, CG members were invited to further reflect on other elements regarding the practical use of the agreed template.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 9 February
14.4 Grouping of ingredients in biocidal product families	
A member briefly introduced an updated version of the document on how to approach the PPD concept for biocidal product families. Due to lack of time, further discussions at the next meeting will be needed.	**AT**: To provide asap an updated version of the document including the comments made at CG-21. **SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup (3 weeks).
14.5 Renewal of anticoagulant rodenticides	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
14.5a IT issues with non-linked applications for renewal (difenacoum and difethialone containing products): Options for a suitable way forward.	
ECHA (webex conference) presented a proposal with the actions to overcome the issues with R4BP3 related to the completion of the existing applications for renewal for AVK rodenticides. A number of actions for ECHA, MSs and applicants were agreed, which would also cover agenda item 14.5.b.	**COM**: To summarize in a document the conclusions of the discussion and the agreed actions to be taken by the different actors. **SECR**: To distribute those conclusions and actions for final agreement asap. **All:** to comment on the conclusions by 23 January. **SECR**: To distribute the final version of the conclusions and agreed actions to ASOs and MSs.
14.5b Actions by MSs in R4BP3 to allow applicants the submission of the pending information by 28/02/17	
ECHA (WebEx conference) explained the procedure for submission of information in R4BP3.	See above
14.5c Feedback from WGs on "ground water assessment" and "dermal absorption assessment"	
The SECR presented an update on the questions on ground water assessment and dermal absorption assessment. A footnote will be added to the document to clarify the ground water assessment procedure.	**SECR**: To amend the document with the footnote proposed by a CG member and distribute to ASOs and MSs to make it publicly available.
14.5d What to do with the current authorisations if the pending information is not submitted by 28/02/17	
COM introduced the document on the actions to be followed on this topic.	
14.6 Guidance for the implementation of the amended SBP Regulation	
The SECR informed the meeting about the available guidance documents on the SBP regulation on the ECHA website. MSs were invited to check the already available guidance and to see whether additional guidance is still needed (e.g. see agenda item 7.6)	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 9 February
Item 15 – Feedback from working parties	
15.1 Frequently used sentences for the SPC	
15.1a List of frequently used sentences for the SPC	
The SECR presented the list of frequently used sentences agreed by the experts of the Working Party.	
15.1b Frequently used sentences for the SPC- next steps	
The SECR informed that ECHA will translate the list of frequently used sentences into all EU languages. A proposal was presented for the review of the translations by the MSs.	**SECR:** To open a Newsgroup forum for written comments.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	All: to comment on the Newsgroup by 9 February
16 – Any Other Business	
16.1 - Trends in product authorisation	
The Chair invited the meeting to take note of the document.	
16.2 - Deadlines for application for product authorisation	
The Chair invited the meeting to take note of the document.	
16.3 List of active substances meeting the exclusion or substitution criteria	
The Chair invited the meeting to take note of the document.	**Rapporteur MS:** to check the new information and report to CG SECR by 26 January. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an updated version for next CG meeting.
16.4 IT issues	
The Chair informed that there were no IT issues tabled for discussion.	
16.5– Feedback on e-consultations	
The Chair informed that there were no e-consultations tabled for discussion.	
16.6 – Confidentiality on comparative assessment reports	
A member presented the topic. CG members agreed that: 1) The MSs should forward the complete comparative assessment to the CG SECR according to Article 23(2) of the BPR as soon as it is available. 2) The version of the comparative assessment to be included in the PAR should not contain confidential information.	**FR**: To provide the SECR with an updated document with the conclusions from the CG discussion. **SECR**: To table the document for agreement in the CG-22 meeting.
17 – Agreement of the action points and conclusions	
The list of action points and conclusions will be agreed by written procedure.	**SECR:** To circulate the list of action points and conclusions for agreement asap. **All**: to send comments by 27 January.

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Part IV - List of Annexes

ANNEX II Final agenda

ANNEX II

19 January 2017

Final agenda
21st meeting of the Coordination Group (CG-21)

19 January 2017 – from 9:00 to 17:00
Ctgb, Bennekomseweg 41 Ede, The Netherlands

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-21-2017

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-20

CG-M-20-2016_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-21-2017-09

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

6.1 Issues identified in the context of UA

CG-21-2017-28

For information

6.2 Iodate used as stabilizer

CG-21-2017-15

For discussion

Item 7 - Any Other Business

7.1 Late procedures

CG-21-2017-06 & CG-21-2017-07 & CG-21-2017-08

For information

7.2 Feedback on e-consultations

CG-21-2017-10, CG-21-2017-13, CG-21-2017-25 & CG-21-2017-26

Links to e-consultations

For discussion and agreement

7.3 Working procedure for the pilot test on the MR phase

CG-21-2017-16

For discussion and agreement

7.4 Election of vice-Chair of the Coordination Group

7.5 Additional uses in a creosote based product

7.6 Issues when evaluating same biocidal products

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-21-2017

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-20

CG-M-20-2016_draft non confidential

For agreement

Item 13 – Administrative issues

13.2 Clarification in the RoP

For agreement

13.3 Working procedure for the linguistic review in UA

CG-21-2017-22

For discussion

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

14.1 Impact on family sizes for PT 8 due to tinting paste issue – BPF approach for PPD concept (pigments, perfumes and dyes)

CG-21-2017-14

For discussion

14.2 New Q&A pairs for Annex IV to the note on the biocidal product family concept

CG-21-2017-23

For discussion

14.3 Template to describe the biocidal product family structure

CG-21-2017-18 & CG-21-2017-19

For discussion and agreement

14.4 Grouping of ingredients in biocidal product families

CG-21-2017-03

For discussion

14.5 Renewal of anticoagulant rodenticides:

14.5a IT issues with non-linked applications for renewal (difenacoum and difethialone containing products): options for a suitable way forward

CG-21-2017-27

For discussion and agreement

14.5b Actions by MSs in R4BP3 to allow applicants the submission of the pending information by 28/02/17

CG-21-2017-29

For information

14.5c Feedback from WGs on "ground water assessment" and "dermal absorption assessment"

CG-21-2017-21

For information and agreement

14.5d What to do with the current authorisations if the pending information is not submitted by 28/02/17

CG-21-2017-20

For information/discussion

14.6 Guidance for the implementation of the amended SBP Regulation

CG-21-2017-24

For information

Item 15 – Feedback from working parties

15.1 Frequently used sentences for the SPC

15.1b List of frequently used sentences for the SPC

CG-21-2017-12

For information

15.1b Frequently used sentences for the SPC – next steps

CG-21-2017-11

For discussion

Item 16 – Any Other Business

16.1 Trends in product authorisation

GG-21-2017-02 & CG-21-2017-04

For information

16.2 Deadlines for application for product authorisation

CG-21-2017-05

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-21-2017-01

For information

16.4 IT issues

For information

16.5 Feedback on e-consultations

For discussion and agreement

16.6 Confidentiality on comparative assessment reports

CG-21-2017-17

For discussion

Item 17 – Agreement of the action points and conclusions

For agreement

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