9 January 2017

CG-M-20-2016 non-confidential

Final non-confidential minutes of the 20th meeting of the Coordination Group (CG)

15 November 2016

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the twentieth CG meeting. 32 members from 25 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and four 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-20-2016) and invited participants to add any items under AOB. An agenda point was added to be discussed in the open session related to the document agreed by the CG on label claims during the CG-19 meeting. The agenda item 6.3 from the closed session was moved to the open session as agenda item 13.8. The agenda was agreed with these modifications.

The final agenda are 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. The draft minutes from CG-19

The Chair explained that the draft confidential CG-19 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-19.

Actions

SECR: to upload the CG-19 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.

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

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

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

Three formal referrals were discussed. The three referrals corresponded to three closely related DEET products coming from the same applicant. The point of disagreement was identical for all cases and therefore the three referrals were treated as one issue. The referrals were only submitted one week before the CG-21 meeting, on 8 November, and the commenting phase was still ongoing. The intention at this point was to introduce the disagreement during the CG-20 meeting, with the objective of reaching an agreement by the next CG meeting in January (CG-21).

The point of disagreement was related to the discrepancy on the values with which the efficacy and the human health toxicological assessments were performed.

The commenting period is opened until 25 November and a meeting by teleconference will be organised in December with all MSs to further discuss the referrals.

Actions

All: To provide comments by 25 November on the referrals.

SECR: to organize a teleconference with all MSs in December with the objective of finding a way forward for an agreement by consensus for the 3 formal referrals.

5.4 Proposal to amend the RoP

During the CG-19 meeting, a CG member presented a proposal to amend the rules of procedures (RoP) for formal referrals related to the point of reaching an agreement. The proposal was to move from an agreement by consensus to an agreement by majority.

The Commission confirmed that from a legal point of view this is consistent with Article 35 of the BPR, as the CG is in charge of establishing its own rules of procedures. It was also indicated that the approach of making a decision based on majority is already followed by the BPC for the approval of active substances and is well accepted by all the BPC members. An agreement by majority would not prevent that, for very controversial cases where the CG members are not able to find an agreement, the issue is referred to the Commission according to Article 36 of the BPR.

A few CG members expressed their disagreement to change the rules of procedures. They highlighted that the decision making process by consensus is working well as 24 referrals out of 27 have been solved by consensus and only 3 were referred to the Commission.

The CG members agreed not to change the rules of procedures.

6. Any Other Business (closed session)

6.1 Late procedures

The Commission introduced the report prepared by ECHA (CG-20-2016-08).

Actions

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

ECHA: to provide a report for the CG-21 meeting with detailed information on delays.

6.2. Feedback on e-consultations

One closed e-consultation was presented for discussion and agreement.

A CG member presented the comments of the e-consultation related to the practical implementation of a specific concentration limit set up in the 9th ATP for anti-coagulant rodenticides (ARs). In order not to classify a product with reproductive toxicity 1B, the maximum concentration of active substance (AS) permitted in an AR powder product is 30 ppm. During the manufacturing process, the concentration of the AS in the biocidal product can vary with the possibility that the specific concentration limit set in the 9th ATP regulation is exceed. In order to avoid this and account for tolerance in the analytical method, the CG member proposed to set a maximum concentration limit of 27 ppm based on its national experience. The concern raised was to have products on the market that may not be safe to the general public. The CG member therefore proposed to request from the applicant a five batch analysis to demonstrate that the final concentration of the AS in the biocidal product was not exceeded.

The CG members considered the question outside the scope of the CG. The CG members agreed that compliance with the classification and labelling according to the CLP Regulation is relevant for all biocides, including ARs, and that the maximum concentration of an AS should be the one stated in the CLP regulation. Regarding the requirement of requesting an additional five batch analysis to demonstrate that the final concentration in the biocidal product was not exceeded, it was mentioned that this is not possible, since it is not specified in the EU legislation.

An additional question was raised regarding whether the authorisation of products containing 50 ppm AS should be cancelled if efficacy with less than 30 ppm is demonstrated, as per the principles in Annex VI to the BPR. The CG members agreed to wait for field experience on efficacy and any possible impact on resistance by practical use of the low concentration products before considering further action.

6.3 Renewal of anticoagulant rodenticides

Agenda item moved to the open session (Agenda point 13.8):

6.3.(a) Regulatory questions

6.3.(b) Update from questions forwarded to the WG

6.4 Implementation of the procedure for alternative dossiers

The SECR presented the update list of alternative dossiers (CG-20-2016-13) which is taking into consideration the comments received on the initial draft list presented during the CG-19 meeting.

Clarification is needed on the column referring to the "Evaluation step (life cycle)" whether this column refers to the check carried out by ECHA in the context of Article 95 or to the evaluation carried out by the refMS.

The Commission highlighted the importance of keeping this list updated and communicating to ECHA the progress on the evaluation of alternative dossiers in order to avoid duplication of work.

The document was agreed with the provision that the column on the "Evaluation step (life cycle)" will be reviewed.

Actions

SECR: Check consistency of the data provided by one of the MS.

SECR: upload and regularly update the document in CIRCABC

ALL: To provide relevant information to ECHA as detailed in the procedure described in the document CG-17-2016-13

6.5 – 9th ATP and MR in sequence

The Commission thanked CG members for the input provided during the commenting period after the last CG meeting.

It clarified that Article 19(4) is one of the legal conditions for granting an authorisation, which applies to any new authorisation to be granted (including those by MR in sequence). The Commission further clarified that derogation according to Article 37 is not needed here. Article 37 is intended to allow MS to derogate according to some national specificity, which is not the case for an EU directly applicable requirement in Article 19(4) of the BPR.

The Commission referred to Article 23(6) of the BPR as a similar example, which imposes that the authorisation of a product containing a candidate for substitution can only be 5 years under the BPR, even if the reference product was authorised by the refMS under the BPD for 10 years.

With this clarification, the Chair noted agreement from CG members and considered this agenda item as closed.

6.6 – Additional data for Permethrin

A member provided an update on the consultation regarding the new Permethrin soil invertebrate effects data to ongoing product authorisation applications. The general consensus was that the new PNEC soil value was a data gap and would need to go through the procedure described in the document "Procedure for the submission, evaluation and dissemination of data generated after active substance approval" agreed during the BPC-15 meeting. A proposal was made for a harmonised way forward, also to be applied for similar cases (document CG-20-2016-20).

If the endorsed new PNEC value is not available as of 3 months before the finalization of the assessment by the reference MS, then it is proposed to use the current LoEP and the EPM applied. If the BPC endorsed PNEC value is available after the eCA evaluation has been closed, then Article 47(1)(a) of the BPR would apply to the applicant as necessary, and Article 47(2) by the rMS or ECHA. Article 48 of the BPR would be actioned if applicable.

The e-CA for the additional data for permethrin noted that the new value provided was not considered to be significantly different than the original value. A member commented that the data would be reviewed by the BPC but that the commenting for the post approval data had not been initiated yet by ECHA. Concerning transfluthrin, no data gap for the active substance had been identified which would make it a different case than the one of permethrin now under consideration.

As the cut off period of 3 months referred to in document CA-March16-Doc.4.15-Final allows MS to make use of a case by case approach, the Commission suggested a certain degree of flexibility in order to use the newly agreed values in the final risk assessment (e.g. if they are available two months before the end of the assessment phase by the refMS).

The CG members agreed with the way forward proposed, including that a certain level of flexibility regarding the 3 month cut off period should be allowed.

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. Six observers from three 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-19-2016) and invited CG members and ASOs to propose any other items under AOB. Agenda item 6.3 from the closed session was moved to agenda item 13.8 of the open session. The agenda was agreed with the inclusion of two items regarding the document agreed by the CG on label claims and the location of the CG-21 meeting.

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. Draft minutes (non-confidential part) from CG-19

The Chair explained that the draft non-confidential CG-19 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 the CG-19 meeting.

Actions

SECR: to upload the CG-19 minutes into the relevant folders in the CG CIRCABC.

12. Administrative issues

12.1 Working Procedures

The SECR presented an updated version of the proposal on the operational steps of the mutual recognition (MR) process (CG-20-2016-02). A proposal to initiate the commenting phase during the evaluation period at the same time that the applicant was reviewing the draft SPC and draft PAR was not supported. From a legal point of view, the proposal is not in line with the BPR as it would be mixing the evaluation and the MR phase. From a practical point of view, the MS CAs could be reviewing a version of the PAR and the SPC which is not finally proposed for MR, resulting in a loss of efficiency. Furthermore, the procedure would not be applicable to MR in sequence (MRS).

Another proposal was related to increase in a few days the last steps of the procedure. This would result in a total of 97 days, which would not be in line with what is required in the BPR. On this point, the BPR estates that at the end on the 90 day period the agreed final SPC and final PAR has to be uploaded in R4BP.

The updated version of the proposal allows for flexibility in some of the shortest timelines in cases where the period falls for example on weekends, holidays or if there are some kind of technical IT issues.

Further, the SECR presented a proposal for a pilot testing in case of agreement that would comprise testing 3 MRS and 3 MRP processes.

A member argued that the procedure did not seem to be applicable to MRS since the agreed final PAR and SPC would be already uploaded before the mutual recognition phase is initiated. The procedure would need to be updated to account for this. The Commission clarified that even though the evaluating phase would differ, the distribution of the 90 day period would be the same for MRP and MRS processes and therefore the timelines would be still applicable.

The Commission clarified that discussions should not take place during the 10-day period for notification of referrals. This period is meant as an administrative step to prepare the necessary documents. The intention to submit a referral to the CG should be made before the end of the 90 day period of the MR phase. Ten days would be an interpretation of the phrase in the BPR "without delay."

The Commission explained that the new procedure for Union Authorisation also includes very tight timelines as those proposed in this procedure. A CG member mentioned that the proposed timelines are not compatible with the frequency of meetings of the national body looking at the SPCs for agreement. The Commission reminded that, as discussed in the 66th CA meeting, the internal administrative procedures of MSs would need to take into consideration the timelines defined in the BPR procedures and, if necessary, be adapted to them.

The CG members agreed on the timelines proposed for the purpose of conducting a pilot test for 3 MRP procedures. Based on this, if the pilot test would be successful, the procedure could be adapted as necessary to fully accommodate the MRS procedures. In case the pilot test showed that the procedure was not workable, a new proposal would be made.

The Chair invited those CG members that would like to volunteer for the test to communicate this to the CG SECR. The pilot test would be initiated after the CG-21 meeting and would be coordinated by ECHA. It would be desirable to include a biocidal product family in the test and cases with a relevant number of concerned MSs. The volunteer MSs, ECHA and the Commission will discuss the communication and monitoring tools to be used during the pilot phase, which will be presented during the CG-21 meeting for agreement.

On a more general note, Industry encouraged MSs to involve the applicant during the bilateral discussions also during the pilot test. This will be added as a footnote in the procedure for the pilot test.

Actions

SECR: To open a Newsgroup forum to request volunteers for participating in the pilot test.

All: Volunteers rMSs to communicate to the SECR by 29 November their willingness to participate in the pilot test.

SECR/COM/rMSs: Once volunteers have been confirmed, define the communication and monitoring procedure for conducting the pilot test with a view to be agreed at CG-21.

12.2 Amendment of the working procedures

The SECR presented a revised version of the working procedure for resolving disagreements (CG-20-2016-01). This revision includes the action point agreed at the 66th CA meeting related to referrals not being accepted when communicated after the end of the 90 day period for the mutual recognition phase.

The SECR indicated that the amendment concerned step 2 of the procedure: "*Receipt of formal referral by SECR,*" where the following sentence was added: "*Formal referrals to the CG will only be accepted within 10 days following the expiration of the 90-day period for agreement on the SPC"*.

The CG members agreed on the document, with the addition of a footnote providing exceptions to the timeline in case of holidays or unforeseen technical issues. The new rule will not apply to referrals that might currently be under preparation and that should be submitted before 1st January 2017.

Actions

SECR: To include the footnote in the document. Upload the revised version in CIRCABC.

12.3 Election of the Chair and Vice Chair of the CG

Joost van Galen, from the Dutch CA, was re-elected as Chair of the CG and Jolanta Stasko, from the Latvian CA, was elected as vice Chair of the CG for the next term.

12.4 Location CG-21

The next CG-21 meeting will be hosted by The Netherlands CA (Ctgb) located in EDE (The Netherlands).

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

13.1 Guidance on carrier-based biocidal products

The Commission presented the revised version of the guidance on carrier-based biocidal products (document CG-20-2016-17) for discussion and agreement.

The document was updated taking into consideration the comments received during the commenting period after the CG-20 meeting. The major change in the revised version relates to the removal of the two subcategories within "Type B" products that was introduced in the previous version. A new section has been included related to physical and chemical properties.

The CG members agreed on the document and it will be tabled for endorsement during the 67th CA meeting.

Actions

COM: To table the document for formal endorsement at the 67th CA meeting

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

A CG member presented the document CG-20-2016-10 with a proposal on how to approach the pigments, perfumes and dyes (PPD) concept for biocidal product families (BPF).

The proposed way forward is to amend the Q&A pair (25) in Annex IV of the document on the biocidal family concept (CA-Nov14-Doc.5.8 – Final) and include two new Q&A pairs. The proposal also addresses the need of a definition of PPDs that includes mixtures and not only single substances, since a mixture can also function in a product as a PPD.

The variation of a PPD in a product will in most of cases also affect other components, for example solvents. It was proposed that PPDs should be allowed to vary within the authorised composition ranges as well as those solvents and components that are associated to that variation in the PPD concentration. The changes should not affect the concentration of other components or co-formulants in the product. The required level for information of the composition of PPD mixtures would need to be agreed.

A CG member commented that it might be worthwhile to go further considering changes for the Q&A 28 in the document on the BPF concept related to changes in composition of PPDs and how to minimize the work load for MSCAs and industry. A CG member commented about the need to prepare a presentation to illustrate with practical examples how the grouping of components can be done.

The CG members were invited to comment on the Q&A presented. A position document from the SME UEAPME on this subject was forwarded to the Commission but it was not considered

for the current proposal. This proposal suggested a modification of the Q&A 25 by adding the text "excluding the main solvent." This document will be made available to the CG members to be considered during the commenting period. Industry representatives and those MSs having contributed to the document will also consider the UEAPME paper when preparing the updated proposal for next CG meeting.

The Commission also encouraged the MSs having made the proposal to further illustrate how it would work in practice with some examples or slides, as it was done for the currently agreed principle at the Prague workshop (COM presentation).

Actions

SECR: to make available to the CG members the document prepared by UEAPME on this topic.

SECR: To open a Newsgroup forum for written comments on the document presented on the PPD concept.

All: to comment on the Newsgroup by 6 December

13.3 Q&A for the biocidal product family concept

The Chair indicated that COM will prepare a document with some proposals addressing the questions provided in this agenda point (CG-20-2016-10) and other Q&A pairs discussed during the meeting. MSs are invited to provide new Q&A pairs that should be added to the document.

Actions

SECR: To open a Newsgroup forum for CG members to provide additional Q&A pairs to be included in the Annex IV of the TNG.

All: to comment on the Newsgroup by 6 December

COM: to prepare a document for discussion for the CG-21 meeting with all Q&A pairs addressing the topics presented during the CG-20 meeting and those proposed via the Newsgroup.

13.4 Developments of dissemination with regard to products

ECHA presented via video conference an update on the developments of dissemination with regard to biocidal products (document CG-20-2016-03). The new tools related to searchability, comparison tools and an overview of the SPC viewer were presented.

Confidentiality was noted as a concern. ECHA mentioned that documents tagged as confidential in R4BP3 would not be disseminated. Information in the SPCs is considered as not being confidential and in principle would be disseminated. A member commented that regarding decisions, these data should not be published, since these could contain confidential information. ECHA mentioned that the intention would be to publish the terms and conditions of the authorisation according to Article 67(2) of the BPR. The Commission noted that the MSs should consider the inclusion of confidential information when drafting the terms and conditions of the product authorisation.

Related to the comparison tool, in principle, when a country is specified, the SPC corresponding to that country would be selected. If not specified, the newest SPC would be taken for comparison. A member mentioned that there would also be a need to publish information coming from old SPCs for enforcement purposes.

Even though the tool appeared to be very helpful, Industry showed a concern about the tool being publicly available on its current form. The visual representation of the market area was pointed out as a point of concern. Related to this point, the Commission commented that even though in a different format, this data was already publicly available.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 6 December

13.5 Template in the PAR to describe the biocidal product family structure

A CG member presented a template document that could be used as part of the PAR to give an overview of the structure of a biocidal product family (BPF). The information is structured in the template on three levels: family level, meta-SPCs and the individual products.

In general, CG members recognised the usefulness of the document to better understand the structure of the BPF and, particularly, the grouping of co-formulants. Some improvements were suggested, for example adding information such as formulation types.

Industry indicated that this document is very useful to summarise what the applicant wants to authorise. Industry expressed some reservations regarding the sections to record uses and the description of uses, and proposed some options for improvement to make the document easier to read.

The Chair invited the members to comment on the template and to indicate where they would like it to be placed in a dossier.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 6 December

13.6 Definition of a BPF based on physical characteristics – Q&A for Annex IV of the TNG

A member presented the document (CG-20-2016-04) with a proposal for a Q&A pair related to the use of physico-chemical parameters for defining a biocidal product family. The proposal was to include ranges of critical physico-chemical parameters with an impact on efficacy or risk assessment to delimit the Meta SPCs of families. An example would be the pH at which it is known that an active substance is active.

The proposal was that the applicant would need to justify the physico-chemical characteristic range at the time of notifying a product belonging to the family. The Commission clarified that justifying the physico-chemical characteristics during notification would not be appropriate, since notification is an administrative task and does not involve evaluation of the data. A member proposed that the physico-chemical ranges might better be defined at the family level instead of being define at the meta SPC level.

The Chair invited the CG members to provide comments on the proposal. The comments will be reviewed by the Commission, who will prepare a document with Q&A pairs for discussion during the CG-21 meeting.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 6 December

COM: To include this topic in the document with the Q&A pairs to be presented in the CG-21 meeting.

13.7 Grouping of ingredients in biocidal product families

A CG member presented a proposal (document CG-20-2016-15) for grouping co-formulants with the same function in biocidal product families in order to avoid the creation of an excessive number of meta-SPCs. An example would be emollients, thickeners or wetting agents. At this moment the co-formulants are listed in the BPF with a concentration of 0% to a certain value. It would be desirable to have a defined range for the functional group

instead of having the co-formulants listed individually. The functional group could also be linked to a physico-chemical parameter for example surface tension in the case of wetting agents.

A few CG members where in favour of the proposal, however a few points of attention where mentioned. Industry mentioned that the changes in the classification are the boundaries of the meta-SPCs and therefore the concentration ranges for the co-formulants when grouped cannot be too wide. A CG member mentioned that grouping co-formulants could result in changes in physico-chemical characteristics that could be difficult to control if the co-formulants are grouped. This is especially a concern when looking at an administrative notification step.

It was clarified that the proposal mentions that classification should not change due to the grouping in a meta-SPC.

The Commission indicated three main concerns regarding the proposal. The first point was to ensure that, despite the grouping of co-formulants by function at meta-SPC level, at the 3rd information level, the applicant provides the exact composition of the product and mentions which of the possible co-formulants is used in that particular product.

The second point was related to the concentration of co-formulants, as it was indicated that only co-formulants which have no effect on risk or efficacy should be allowed to be at 0%. It was clarified that the current legal requirement is that the active substances that cannot be at 0%. Any other co-formulant can be at 0%.

The third point mentioned was that the proposal of grouping co-formulants might trigger some different views and some disagreements within the different MSs; for example, clear guidance would be needed to clarify which co-formulants having the same function are eligible to be grouped.

The Commission reiterated that notifications in accordance with article 17(6) have to be kept as a purely administrative task, where the agreed information to be notified is kept to a minimum.

The Chair invited CG members to submit written comments by 6 December.

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 6 December

13.8 Renewal of anticoagulant rodenticides

(Agenda point 6.3 from the closed session)

13.8 (a). Regulatory questions

A CG member presented the updated version of the document addressing regulatory questions on the renewal of AVK rodenticides (CG-20-2016-19). The comments received during the consultation were incorporated in the document, which included two additional questions for further discussion.

The first question was related to the first discussion point about products showing degradation above 10%. It was questioned whether a minimum shelf life was required to grant an authorization. The CG members agreed that according to Article 19 of the BPR, there was not a legal basis for requiring a minimum shelf life. It was also agreed that, unless there is a good justification, those products for which a degradation below 10% cannot be demonstrated at any time, should not be authorised.

The second question was related to the second point of discussion, about the efficacy data for aged bait. The question was whether the conclusions of the document should be applied to all PT 14 products. The CG members agreed that the conclusions should be applicable to all PT14 products.

The CG members agreed with the conclusions from the document presented. A revised version will be provided addressing the two open questions incorporating the conclusions agreed during the meeting.

Actions

DE: To prepare an updated version of the document based on the conclusions reached during the meeting.

SECR: To upload the document into the relevant folder in the CG CIRCA BC.

13.8 (b). Update from questions forwarded to the WG

The SECR presented an update on the discussions that took place during the Working Group (WG) meeting in September 2016 (CG-20-2016-11).

As a general comment, the CG members expressed their concern about the timelines and whether the WG would be able to find a conclusion to the open questions in time for the applicants to better prepare the submission of the pending information for the renewal of AVKs by the end of February 2017.

Not related to the renewals, but to applications for major changes for the reduction in the level of AS, the CG members agreed with the way forward proposed in the document by the efficacy WG. In short, if a complete efficacy data package for the formulation at 50 ppm was submitted for the first authorisation, including at least 20% of palatability in the lab tests, it is assumed that the level of palatability remains the same in the new product at < 30 ppm and hence only new field tests should be required for the application for a major change.

Related to the update on the question of the environmental working group, the Commission mentioned that the update regarding the environmental questions on the assessment of groundwater was addressing the case of a first authorisation. Clarification was needed whether the conclusions reached were also applicable to the renewal of products, as according to Article 31, the data requirements are different. The applicant has to provide any data that has been generated since the first authorisation and the assessment of whether the conclusions of the first assessment remain valid.

A CG member mentioned that the groundwater assessment had not been performed for the initial assessment for authorisation. Clarification is therefore needed whether there was a commitment that applicants should perform this assessment for the renewal stage. It was also mentioned that a new model for assessing ground water was discussed during the WG-IV meeting in September. Clarification is needed whether this model should be applied now for the renewal of AVK rodenticides. In case that a model already approved is available, there is a need to look at the two year cut off to evaluate if this can be applied at the renewal stage.

Related to the update on the question to the toxicology working group on read-across and worst-case approach for dermal absorption, the CG members expressed the urgency in reaching a conclusion by the working group meeting in November. This is necessary in order to allow the applicants to take these conclusions into consideration for the submission of the above-mentioned pending information in the renewal dossiers.

Actions

SECR: To communicate to the WG chairs the need of reaching an agreement during WG-V on the initial toxicology questions and those raised at CG-20 regarding the environmental assessment.

14. Feedback from working parties

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

The Commission informed CG members that following the pre-meeting consultation, a few clarifications were added to the cover note. The Commission also corrected some typos and

a mistake in the document for professional users (adaptation of the sentence regarding personal protection equipment (PPE) as in the document for trained professionals).

With these clarifications, the Chair noted that document CG-20-2016-22 AP 14.1.rev1 was agreed by the CG meeting and it will be tabled for endorsement during the 67th CA meeting.

The Commission thanked the working party members both from MSs and industry for their valuable contributions, as well as the CG SECR for its support during the last 11 months.

Actions

COM: To table the document for formal endorsement at the 67th CA meeting

14.2 Frequently used sentences for the SPC

The CG SECR informed the CG members on the activities of the working party. The phase of identifying sentences was finalised and the sentences identified were reviewed by the WP experts. A consolidated list is currently under preparation and will be distributed for further comments and agreement.

Industry commented that there might be product names that need to be taken out of the list. Some sentences were long and complex and it might be better to remove these sentences from the final list. Industry suggested limiting the sentences per field to approximately 10.

15. Any Other Business (open session)

15.1 Trends in product authorisation

The Chair invited the SECR to present the reports in documents CG-20-2016-06 and CG-20-2016-07, which were made available for information.

The SECR indicated that in the reports in document CG-20-2016-06 a new section corresponding to the values of total number of products in progress was added.

The Commission indicated that between Q4 this year and Q4 last year only 300 product authorisations had been granted.

15.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-19-2016-08, 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.

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 IT issues

ECHA provided a presentation (document CG-20-2016-28) to give an update from the annual IT-expert user group meeting.

From the end of October, new versions of R4BP3 (3.8) and the SPC editor (2.0) are online.

A few capabilities have been added to R4BP3 related to the amendment of the same biocidal product Regulation. Other processes have been added as well related to the handling of the assets for Union Authorisations. A new functionality was introduced to enable the notification of a family member in a MS starting from a family authorised through the simplified authorisation procedure in another MS.

The new product family structure with the 3 levels of information has been implemented in the version 2 of the SPC editor. The old SPC files for families have been automatically migrated in the new format. Other new features were presented and are detailed in the document CG-20-2016-28.

During the IT user group meeting it was agreed to increase the IT opening hours. The search functionalities will be restored in R4BP3 and the IT team will look into improvements in the MRP phase process in R4BP3 and the current communications. Two releases are foreseen to take place in 2017.

ECHA provided a presentation (document CG-20-2016-27) related to the major change for the rodenticides (PT 14) in the context of the compliance with the 9th ATP amendment of the BPR and how to manage this process in R4BP3. It was clarified that ECHA is working on a solution by next spring so that MR-S of same products is possible in those MS in which the reference product is also authorised via MR.

Actions

SECR: To upload in CIRCABC the presentations shown during the meeting

15.5 Feedback on e-consultations

Two e-consultations were discussed.

1. A member presented an e-consultation consisting of two questions (document CG-20-2016-24). The first question was related to the use of smoke bombs. The CG member proposed to use wet wipes for cleaning which are disposed of as solid waste as a RMM, although this may not be applicable to large spaces. The second question was related to whether pyrotechnic products should be assessed in the same way as diffusers. The CG members agreed that this type of products should not be assessed as diffusers but rather as smoke generators. The conclusions of the document were agreed by the CG members.

2. The Commission briefly introduced document AP 15.5-CG-20-2016-23. All CG members but one supported the views expressed in the document. The disagreeing member would like to consider whether this matter needed to be further discussed at the 67th CA meeting as an AOB.
   Within the CG, the Chair noted the majority position of the MSs on the topic and considered this agenda item as closed.

Actions

2) COM: After consultation with the disagreeing member, to consider tabling this item for discussion during the CA meeting as AOB.

Post- meeting note*: the disagreeing member decided to not discuss the matter at the 67th CA meeting.*

15.6 Confidentiality on comparative assessment reports

A document was made available on this topic and the Chair invited the CG members to provide comments in writing. This question concerns the confidentiality related to the products that are considered for the comparative assessment and the level of detail that should be included in the PAR.

The Commission mentioned that, at least at Tier I, the information used in the comparison is coming from the SPC. In this case, this information is not considered to be confidential.

On a more general note, the information in the PAR related to the comparative assessment should rather focus on the conclusions (e.g. whether any use is restricted or not authorised as a consequence of the comparative assessment).

Actions

SECR: To open a Newsgroup forum for written comments.

All: to comment on the Newsgroup by 6 December

15.7 Label claims

The Commission briefly informed the CG meeting of the feedback provided by the members of the Biocides Enforcement Group (BEG) at its last meeting on November 11th. They raised some concerns regarding i) where to find the PAR, ii) where to find the information on the efficacy claims within the PAR and iii) the constraints of having this information in English only.

The Commission clarified that the paper was intended to avoid regulatory issues in MR, and that it would be up to each CA to coordinate at MS level with the enforcement authorities how to check if label claims are acceptable (i.e. direct check of the PAR or through the biocides CA). Industry representatives mentioned that the AH might also help to clarify where to find or to provide this information to inspectors.

As this discussion would have some policy implications for the biocides CAs, the CG agreed referring this discussion to the 67th CA meeting.

Actions

COM: To address feedback from BEG during the discussion at the 67th CA meeting.

16. 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.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

20th meeting of the CG

15 November 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 with the addition of 1 point for the AOB of the open session.	**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-19	
No comments were received during the meeting on the updated version of the confidential minutes of the CG-19 meeting. The draft confidential minutes were agreed.	**SECR:** to upload the CG-19 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 introduced and the chair indicated that they were treated as one issue. 1-3) Discussions were initiated with a view to continue the discussions in an upcoming teleconference involving all MSs with the objective of reaching an agreement at the latest during the CG-21 meeting.	**1-3) All:** To provide comments by 25 November on the referrals. **1-3) SECR:** to organize a teleconference with all MSs in December with the objective of finding a way forward for an agreement by consensus for the 3 formal referrals.
5.4 Proposal to amend the RoP	
CG members expressed their view on changing the RoP for reaching an agreement on a referral from a	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
consensus approach to a majority of votes. It was agreed not to change the RoP. Agreements will continue to be based on consensus.	
6 – Any Other Business	
6.1 – Late procedures	
COM presented the overview of late procedures and reported on the discussion held at the last CA meeting and the action list endorsed by the CA meeting.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data. **ECHA**: to provide a report for the CG-21 meeting with detailed information on delays.
6.2 – Feedback on e-consultations	
One closed e-consultation was presented: A member presented the conclusions of an e-consultation regarding the "Major changes to authorisations to reduce the AS concentration". The CG members agreed that the rules for specific concentration limits are set in the CLP regulation and shall be followed. This applies also to all biocidal products. Regarding whether products containing 50 ppm active should be cancelled if the low concentration products are sufficiently effective, the CG members agreed to wait for experience in efficacy by practical use of the low concentration products before considering further action.	
6.3 Renewal of anticoagulant rodenticides (AP moved to the open session) **6.3.(a) Regulatory questions** **6.3.(b) Update from questions forwarded to the WG**	
6.4 Implementation of the procedure for alternative dossiers	
The SECR presented an updated version of the list of alternative dossiers. The CG members agreed on the document.	**SECR:** Check consistency of the data provided by one of the MS. **SECR**: upload and regularly update the document in CIRCABC **ALL**: To provide relevant information to ECHA as detailed in the procedure described in the document CG-17-2016-13
6.5 9th ATP and MR in sequence	
COM clarified that the new ATP rules should be applied to new authorisations granted including those through mutual recognition in sequence.	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
6.6 Additional data for Permethrin	
A member updated the meeting on the conclusions of the consultation about additional data generated for permethrin. The CG members agreed with the clarification that the 3 month period should be interpreted in a flexible manner in order to take into account the output of the BPC discussions. If confirmed by the BPC the new value should be used.	
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	
9 – Agreement of the agenda	
The agenda for the open session was agreed with the addition of two points.	**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-19	
A minor comment was received on the non-confidential minutes of the CG-19 meeting. The draft non-confidential minutes were agreed with the proposed change.	**SECR:** to upload the CG-19 minutes into the relevant folders in the CG CIRCA BC.
12 – Administrative issues	
12.1 Working procedures for MR	
The SECR presented an updated version of the proposal on the operational steps of the mutual recognition process. A proposal to initiate a pilot testing was presented. The CG members agreed to initiate a pilot test of the proposed procedure for mutual recognition in parallel The timelines presented in the CG document CG-20-2016-02 were agreed for the purpose of the pilot test.	**SECR:** To open a Newsgroup forum to request volunteers for participating in the pilot test. **All:** Volunteers rMSs to communicate to the SECR by 29 November their willingness to participate in the pilot test. **SECR/COM/rMSs**: Once volunteers have been confirmed, define the communication and monitoring procedure for conducting the pilot test with a view to be agreed at CG-21.
12.2 Amendment of the working procedures	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
The SECR presented a revised version of the working procedure for resolving disagreements. The revised version includes the action agreed during the 66th CA meeting related to limit the acceptance of referrals to 10 days after the expiration of the 90 day period for mutual recognition. The CG members agreed on the document, with the addition of a footnote providing for exceptions in case of holidays or unforeseen technical issues. The new rule will not apply to referrals that might currently be under preparation and that are submitted before 1st January 2017	**SECR:** To include the footnote in the document. . Upload the revised version in CIRCABC.
12.3 Election of the Chair and Vice Chair of the CG	
Joost van Galen was re-elected as Chair of the CG Jolanta Stasko was elected as vice Chair of the CG	
12.4 Location CG21	
It was announced that the next CG will be held at the Dutch CA's office in Ede. Information regarding travel and hotels will be provided within two weeks.	
13 – Harmonisation of technical and procedural issues in relation to product authorisation	
13.1 Guidance on carrier-based biocidal products	
COM presented the updated version of the document regarding the guidance on carrier-based biocidal products. The CG members agreed on the document.	**COM:** To table the document for formal endorsement at the 67th CA meeting.
13.2 Impact on family sizes for PT 8 due to tinting paste issue – BPF approach for PPD concept (pigments, perfumes and dyes)	
A member presented a document on how to approach the PPD concept for biocidal product families.	**SECR:** to make available to the CG members the document prepared by UEAPME on this topic. **SECR:** To open a Newsgroup forum for written comments on the document presented on the PPD concept. **All:** to comment on the Newsgroup by 6 December
13.3 Q&A for the biocidal product family concept	
The Chair indicated that COM will prepare a document with the questions provided in this agenda point and all other Q&A pairs discussed during the meeting.	**SECR:** To open a Newsgroup forum for CG members to provide additional Q&A pairs to be included in the Annex IV of the TNG.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	All: to comment on the Newsgroup by 6 December **COM**: to prepare a document for discussion for the CG-21 meeting with all Q&A pairs addressing the topics presented during the CG-20 meeting and those proposed via the Newsgroup.
13.4 Developments of dissemination with regard to products	
ECHA (videoconference) presented an update on the developments of dissemination with regard to biocidal products. The new tools related to searchability, comparison tools and an overview of the SPC viewer were presented.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 6 December
13.5 Template in the PAR to describe the biocidal product family structure	
A member presented a template that could be used in the PAR or as a stand-alone, supporting document in the dossier to provide an overview the biocidal product family structure.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 6 December
13.6 Definition of a BPF based on physical characteristics – Q&A for Annex IV of the TNG	
A member presented a proposal for a Q&A addressing the use of ranges in physical characteristics to define a BPF.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 6 December **COM**: To include this topic in the document with the Q&A pairs to be presented in the CG-21 meeting.
13.7 Grouping of ingredients in biocidal product families	
A member presented a proposal for grouping ingredients in functional groups in biocidal product families in order to avoid the creation of excessive number of meta-SPCs.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 6 December
13.8 Renewal of anticoagulant rodenticides (AP 6.3 from the closed session)	
13.8 (a). Regulatory questions	
A member presented a document addressing two regulatory questions related to the renewal of anticoagulant rodenticides, and two new questions based on the contributions provided during the commenting period. The CG members agreed on the document, with the inclusion of the agreed answers to the two additional questions in the document.	**DE:** To prepare an updated version of the document based on the conclusions reached during the meeting. **SECR:** to upload the document into the relevant folder in the CG CIRCA BC.
13.8 (b). Update from questions forwarded to the WG	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
The SECR presented an update on the questions on the renewal of anticoagulant rodenticides that were discussed during the last Working Group meeting. The members mentioned the need to have the open questions answered by the WG meeting in November to be applied to the renewal of AVK rodenticides. Regarding the feedback from the EFF WG on applications for major changes to reduce the AS concentration, the CG members agreed on the way forward proposed by the EFF WG.	**SECR**: To communicate to the WG chairs the need of reaching an agreement during WG 5 on the initial toxicology questions and those raised at CG-20 regarding the environmental assessment.
14 – Feedback from working parties	
14.1 - Development of standard sentences for the SPC sections of anticoagulant rodenticides	
The Commission presented the note for guidance to which the three documents compiling the harmonised sentences for the SPC of AVKs rodenticides are attached. The CG members agreed on the document.	**COM:** To table the document for formal endorsement at the 67th CA meeting.
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 SECR presented the reports, available for information.	
15.2 - Deadlines for application for product authorisation	
The Chair presented the report, 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.	**Rapporteur MS:** to check the new information and report to CG SECR by 22 November. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an updated version for next CG meeting.
15.4 IT issues	
ECHA updated the meeting on the discussion of the IT expert group meeting. ECHA gave a presentation on how to manage in R4BP3 a major change related to anticoagulant rodenticides.	**SECR**: To upload in CIRCABC the presentations shown during the meeting

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
15.5 – Feedback on e-consultations	
1) A member presented the conclusions of the e-consultation on "Areas for wet cleaning". The CG members agreed on the document. 2) COM updated on the view of the commission related to the confidentiality of the "Data used on C&L of biocidal products". CG members agreed with the document with the exception of one member.	**2) COM:** After consultation with the disagreeing member, to consider tabling this item for discussion during the CA meeting as AOB.
15.6 – Confidentiality on comparative assessment reports	
A member presented the topic.	**SECR:** To open a Newsgroup forum for written comments. **All:** to comment on the Newsgroup by 6 December
15.7 – Label claims	
The Commission updated the meeting on the discussion that took place on this document during the BEG meeting. As this issue involves policy issues regarding support from CAs to enforcement authorities, the matter is referred to the CA meeting.	**COM:** To address feedback from BEG during the discussion at the 67th CA meeting.
16 – 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.

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Part IV - List of Annexes

ANNEX II

15 November 2016

Final agenda

20th meeting of the Coordination Group (CG-20)

15 November 2016 – from 9:00 to 17:00
Brussels, Centre Borschette

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-20-2016

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-19

CG-M-19-2016_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-20-2016-18

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

5.4 Proposal to amend the RoP

For discussion

Item 6 - Any Other Business

6.1 Late procedures

CG-20-2016-08
For information

6.2 Feedback on e-consultations

CG-20-2016-05
CG-20-2016-26
Links to e-consultations
For discussion and agreement

6.3 *Agenda item moved to the open session:*

Renewal of anticoagulant rodenticides
6.3.(a) Regulatory questions

CG-20-2016-19
For agreement

6.3.(b) Update from questions forwarded to the WG

CG-20-2016-11
For information

6.4 Implementation of the procedure for alternative dossiers

CG-20-2016-13
For agreement

6.5 9th ATP and MR in sequence

For discussion

6.6 Additional data for permethrin

CG-20-2016-20
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-20-2016

For agreement

Item 10 – Declaration of interest in relation to the agenda

Item 11 –Draft minutes from CG-19

CG-M-19-2016_draft non-confidential

For agreement

Item 12 – Administrative issues

12.1 Working procedure for MR

CG-20-2016-02

For discussion

12.2 Amendment of the working procedures

CG-20-2016-01

For agreement

12.3 Election of the Chair and Vice Chair of the CG

For agreement

12.4 Location CG-21

For agreement

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

13.1 Guidance on carrier-based biocidal products

CG-20-2016-17

For agreement

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

CG-20-2016-10

For discussion

13.3 Q&A for the biocidal product family concept

CG-20-2016-21

For discussion

13.4 Developments of dissemination with regard to products

CG-20-2016-03

For information and discussion

13.5 Template in the PAR to describe the biocidal product family structure

CG-20-2016-12

For discussion

13.6 Definition of a BPF based on physical characteristics – Q&A for Annex IV of the TNG

CG-20-2016-04

For information

13.7 Grouping of ingredients in biocidal product families

CG-20-2016-15

For discussion

13.8 Agenda point 6.3 from the closed session
Renewal of anticoagulant rodenticides

Item 14 – Feedback from working parties

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

CG-20-2016-22

For agreement

14.2 Frequently used sentences for the SPC

CG-20-2016-14

For information

Item 15 – Any Other Business

15.1 Trends in product authorisation

CG-20-2016-06 & CG20-2016-07

For information

15.2 Deadlines for application for product authorisation

CG-20-2016-09

For information

15.3 List of active substances meeting the exclusion or substitution criteria

CG-20-2016-16

For information

15.4 IT issues

CG-20-2016-27 & CG-20-2016-28

For information

15.5 Feedback on e-consultations

CG-20-2016-23 & GC-20-2016-24
Links to e-consultations
For discussion and agreement

15.6 Confidentiality on comparative assessment reports

CG-20-2016-25
For discussion

15.7 Label claims

For information

Item 16 – Agreement of the action points and conclusions

For agreement

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