14 April 2015

CG-M-10-2015 PUBLIC

Final minutes of the 10th meeting of the Coordination Group (CG)

17 – 18 March 2015

Summary Record of the Proceedings

1. Welcome and apologies to the closed session

The Chair welcomed participants to the tenth meeting. 33 members from 23 Member State Competent Authorities (MSCAs) participated in the meeting. Two representatives from DG SANTÉ and from ECHA were present for the full meeting. The list of attendees is given in Part III of the minutes.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-10-2015) and invited any items under AOB. The agenda was agreed with moving AP 7.4 to the open session and adding two new items under AOB.

The Chair remarked that the compilation of comments received for AP 7.2 for harmonised RMMs for DEET containing products; two executive summaries on an informal and a formal referral by the initiating cMS; and a summary of a conference call on another formal referral were uploaded to CIRCABC at a later stage.

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 agenda

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

4. Agreement of the draft minutes from CG-9

The SECR explained that the draft confidential CG-9 minutes were uploaded for commenting via Newsgroups. Two comments were received and incorporated into the current draft.

No further comments were received during the meeting and the CG members agreed on the draft minutes from CG-9.

Actions

SECR: to upload the CG-9 minutes into the relevant folders in the CG CIRCABC.

5. Formal and informal referrals to the CG

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

The discussion took place on three informal referrals:

1) For the first one, an agreement has been found and is now closed within the CG.

2) For the second informal referral, as there are outstanding issues, it was suggested that this one should be taken further as a formal referral by one of the current cMSs.

Actions

Any current cMS: to take the informal disagreement forward as a formal referral.

3) For the third informal referral, the rMS and the initiating cMS have found a way to go forward. The discussion is now considered to be closed within the CG. Another cMS has submitted a formal referral for one of the involved products.

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

The discussion took place on three formal referrals:

1) The first formal referral is linked to the above-mentioned third informal referral. New data have been submitted by the applicant, and will be evaluated by the rMS and taken into account in the context of this formal referral.

Actions

rMS: to evaluate the new data.

SECR: to set up a Newsgroup discussion once the evaluation of the rMS is available.

all MS: to comment on the evaluation by rMS in order to conclude at CG-11.

2) For the second formal referral no agreement has been reached. This one will be referred further to the COM under Article 36 by the rMS.

Actions

rMS: to refer the disagreement to the COM under the Article 36 procedure.

3) For the third formal referral an agreement has been reached. The referral is closed within the CG.

Some members provided updates on previous formal referrals.

For the first one the rMS is still waiting for the applicant to submit supplementary documentation in order to conclude.

For the second one the rMS referred the case to the COM in accordance with Article 36.

Actions

2nd rMS: to forward the documentation submitted to the COM to all cMS and the applicant.

6. Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/ EC (closed session)

Two rMSs that decided to take formal actions concerning some first authorisations subject to Article 4(4) notifications submitted under the BPD updated the meeting on the current status of such actions.

7. Any Other Business (closed session)

7.1 Late procedures

ECHA informed that the report is being refined and will be provided to all MS at the next meeting.

Actions

SECR: to produce the report on late procedures.

7.2 Harmonized RMM for DEET containing products

A member who presented the proposal of a set of RMM and labelling requirements for non-professional users informed that the commenting deadline expired shortly before the CG meeting. Some issues that are discussed at ECHA's WG level have also been raised.

Actions

A member: to look at the comments and present a revised document for the next meeting.

SECR: to check ongoing discussion at the WG and liaise with the member.

7.3 Feedback from e-consultations

CG members were updated regarding the follow-up of two closed e-consultations.

On the derivation of M-factors for an insecticide, members are invited to comment on the proposed way forward by a CG member within 2 weeks.

Regarding the e-consultation on whether products consisting of some plant blossoms should be considered as falling within the scope of the BPR, the Commission informed the meeting that a paper had been tabled for discussion at the 59th CA meeting (agenda item 8.2).

Actions

SECR: to re-open the Newsgroup discussion on the M-factors.

All: to comment by 1 April.

7.4 Residue analytical method in air (moved to the open session)

7.5 Expiry date for authorisations of products containing AS that are candidate for substitution

The Commission informed the meeting that some product authorisations containing an AS that qualifies as a candidate for substitution (i.e. meeting the P&T criteria) have been granted under the BPR for longer than 5 years. MSs were invited to amend the expiry date of the affected authorisations accordingly.

Upon request from a CG member, it was clarified that product authorisations granted under the BPD (i.e. having the same expiry date as the AS approval) do not need to be amended. However, MR or SBP authorisations linked to those authorisations can only be granted under the BPR for a maximum of five years (see document CA-Sept14-Doc.5.7–Final on "Harmonised approach to the consideration of the expiry dates of new product authorisations linked to other authorisations through certain authorisation procedures").

The Commission also reminded CG members that, in accordance with Article 23(2) of the BPR, MSs having carried out a comparative assessment have to send the results of such comparative assessment to the CG SECR. Then ECHA will make these results available to all the MSs through Circabc (confidential folder).

Actions

All MSs:

- to review the expiry date of such product authorisations;
- where a comparative assessment has been performed for products authorised under the BPR, forward them to ECHA in accordance with Article 23(2).

7.6 Question on a new BP Family application for UA

A member presented their question with regard to a new BP Family application for Union Authorisation and asked for the opinion of other CG members. As the question was only presented at the meeting it was agreed that the member would send the question in written to the CG Secretariat. The SECR will then make it available for all CG members for commenting via a CIRCABC Newsgroup Forum.

Actions

A member: to send a written question.

SECR: to create a Newsgroup on the issue.

All: to comment.

7.7 AS definition for a Wood preservative

A member presented their problem with regard to the definition of an active substance for a wood preservative product and asked for the opinion of other CG members. The member has a different view on what the active substance is than what the applicant claims. The applicant also referred to an already authorised product that some members tried to find but could not. Many members commented on how to define what the AS is. It was also added that there is an ongoing HELPEX question (with the deadline of 31 March) initiated by another MS. Another member pointed out that there is a non-inclusion decision for a similar substance and gave the reference to it.

Actions

A member:

- to get additional information from the applicant;
- to contribute to the HELPEX discussion.

16.4 Questions regarding R4BP / IUCLID (partial discussion)

Before the arrival of the ASOs, CG members had the possibility to raise issues with regard to the R4BP3 system.

The below issues were raised:

- Since Skeleton/minimum SPC are currently being used, the R4BP3 database is filled in with incomplete information. ECHA acknowledged the concern and reminded the MSCAs that at some point the SPCs should be filled with actual information and that this will represent an effort for MSCAs and industry and requires policy decision and if possible harmonised approach between MSCAs. COM was concerned about the position expressed by some CG members regarding change applications and called for enforcing, where relevant, the SPC requirement for change applications.
- One member raised an issue with workaround suggests asking the company to re-apply in R4BP 3 (e.g. for SBP) since the migrated application is for a national authorisation. Several members were calling for the possibility for the MSCA to change the type of authorisation instead. ECHA replied that this is a question of principle in order to ensure the stability of the database and that such changes require manual intervention by ECHA.
- It was originally indicated that the multilingual SPC would become available within 3 months. ECHA informed the members that the checking of translations has now started but was delayed by the time it took to have the beta version available for checking the translations in context.
- Another member asked about the impact on dissemination of the use of skeleton SPCs and questioned the requirement of SPC for product authorisations granted under the BPD without SPC. ECHA answered that the migration platform which will disseminate information taken from R4BP3 will only become available at some point in 2016. COM indicated that, where required by the changes Regulation, the change applications are an opportunity to request draft SPC in the new format from the authorisation holder. Not all members agreed to this proposed way forward.
- A member highlighted the issue of requesting a draft SPC for products authorised under the BPD and for which there has never been any discussion between the authorisation holder and the MSCA on what the SPC should contain. This is also in connection with an agenda item at the 59th CA meeting (CA-March15-Doc.4.11). The Commision mentioned that, if necessary, this topic could be tabled for discussion at the next CG meeting.
- A member expressed the wish that the SPC is in the future less strongly linked to a specific product in order to facilitate the re-use of an SPC. ECHA indicated that this is coming soon in an update of the SPC editor
- Another member pointed out that there are links that are wrongly migrated. And incorrect numbers of authorisations/mutual recognitions that would be subject to renewal deadlines had been reported in the previous CG meeting.
- Some members have IT problems, and difficulties with using R4BP 3 and the SPC editor. ECHA indicated that there soon will be video tutorials to provide additional guidance and mentioned the general issue of browsers compatibility which can be the source of many problems.

ECHA took note of the issues raised and the discussion then continued in the open session with the participation of the ASOs.

9. Welcome to the open session

The open session first started without the participation of the ASOs.

The Chair welcomed ASOs to the open session. Five observers from three 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-10-2015), mentioning that agenda item 7.4 was moved form the closed to the open session under AoB, and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed without changes.

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. Agreement of draft minutes (non-confidential part) from CG-9

The SECR explained that the draft non-confidential CG-9 minutes were uploaded for commenting via Newsgroups. No comment was received on the non-confidential minutes. No comments were received during the meeting either and the CG members agreed on the revised draft minutes from CG-9.

Actions

SECR: to upload the CG-9 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

13.1 Housekeeping issues

The SECR informed the meeting that the ECHA hosted part of the current CIRCABC will be transformed into Secure-CIRCABC. The main change will be the 2-factor identification system which means that members will need to provide a mobile number where a single use PIN code will be sent. The phone number will not be visible for ECHA and will only be used for sending the PIN code. The migration will take place by the end of July, at the latest. ECHA will provide instructions on how to log in to the new platform. The SECR also informed the meeting that there are currently discussions between ECHA and DG DIGIT on how to provide user support.

The SECR also explained that the non-confidential minutes will be made available on a public CIRCABC site where also people without access rights to the CG Interest Group can consult the document.

Finally, the SECR announced that they will organise the forthcoming new election of the Chair and Vice-Chair. The appointment for the Chair and Vice-Chair was for a

period of 1.5 years. Since that period started with the March 2014 meeting, this means that the current period will end with the July 2015 meeting. The next Chair and Vice-Chair will start their work with the September 2015 meeting.

SECR will send out the invitations to nominate Chair and Vice-Chair after this meeting.

Actions

SECR:

- to keep the members informed about the progress with regard to the migration and access to secure-CIRCABC;
- to create the public CIRCABC site for the non-confidential minutes;
- to invite members to nominate Chair and Vice-Chair for the CG for the next 1.5-year term starting from the September meeting.

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

14.1 BP Families – draft Q&A document from BPF workshop

The Chairperson informed the meeting that two documents were uploaded for this agenda item, one including the list of Q&A and another one compiling some more general topics discussed at the workshop. Therefore, it was proposed discussing both documents separately.

1.- Q&A (document CG-10-2015-01)

A member shared some comments to a few questions that had been already submitted in writing. CG members and ASOs were invited to submit further comments to the draft Q&A.

The Commission also invited those members having launched helpex consultations dealing with the implementation of the new BPF concept to forward their outcome to the CG SECR with a view to be agreed by the CG and included in Annex IV to the note for guidance.

2.- Other issues (document CG-10-2015-02)

2.1.- IT issues.

ECHA informed the meeting that the IT team is working on a temporary work around to adapt the current family SPC template to the new BPF concept. It has been already sent to the IT Key Users Group for comments. Further developments would be needed to accommodate other needs, such as the search function based on the uses within each meta-SPC.

2.2.- Additional technical guidance.

Some CG members and ASOs commented on paragraph 6(c). A CG member explained further the idea behind this paragraph, aiming at avoiding the assessment of worst case products that will never be placed on the market. ASOs shared these views and mentioned that formulator chemists would never propose some co-formulant combinations at extreme concentrations. They also added that further information from the applicant can also help the evaluating CA to assess the maximum risk level proposed in the application.

The CG requested the Commission amending paragraph 6(c) according to the above discussion.

2.3.- Submission of example labels within the application.

A member mentioned that sometimes assessors also use labels for the evaluation, as the product information is presented in the same way as it is provided to the final user.

The Commission noted that under the BPR the core document for the assessment and to be agreed on is the SPC and not the labels. Requiring example labels in accordance with a number of intended uses that might not be authorised would lead to unnecessary workload both for applicants and CAs. Several members and ASOs shared the views of the Commission and supported the idea of postponing the submission of example labels to a later stage in the authorisation procedure (i.e. once the SPC has been agreed).

If time allows, the Commission will draft a document addressing the submission of draft labels for the next CG meeting.

Actions

SECR: to set up a Newsgroups discussion for commenting on the draft Q&A document by 10 April.

All MS having HELPEX discussions: to forward them to SECR.

COM:

- to clarify the wording of paragraph 6(c) and provide with some examples.
- If possible to draft a document addressing the submission of draft labels.

14.2 Applications for a same BP of an individual product of a BPF

The Commission introduced document CG-10-2015-03, which takes into account the discussion at CG-9 and the comments submitted after the meeting. The updated version is proposed for agreement by the CG as the approach provided therein is compatible with the current text of the SBP Regulation.

Regarding the possibility of allowing different application routes for the BPF (e.g. UA) and the SBP of an individual product of a BPF (e.g. at national level), the Commission informed the meeting that a paper has been tabled for the 59th CA meeting concerning the amendment of the SBP Regulation (agenda item 4.7.a).

On document CG-10-2015-03, a member suggested a clarification in paragraph 11(c). The Commission clarified that the suggested approach is a matter of proportionality and that, as mentioned in footnote 14, the PAR should clearly indicate which data has been used to support each meta SPC.

Another member asked how a CA would be able to judge that the addition of a manufacturer of the SBP can be dealt with as an administrative change (i.e. provided that the product composition and the formulating process remain unchanged). It has to be noted that the description of the manufacturing process is not a data requirement for biocidal products. The Commission proposed addressing this point outside the scope of the paper under discussion. However, it was suggested as a possible way forward that, where relevant, the applicant for the SBP could submit to the CA a self-declaration (ideally co-signed by the manufacturer of the reference product) stating that the formulating process remains unchanged.

A member suggested a clarification in the wording of footnote 9, so that it is made clearer that the second sentence refers to other administrative changes.

The meeting agreed to the document subject to the above-mentioned clarification in footnote 9 and will therefore be proposed for formal endorsement at the 59th CA meeting.

Actions

COM: to clarify the wording of footnote 9 and present the document at the CA meeting.

14.3 Harmonized way to deal with 3rd party dossiers during PA

The SECR explained that comments were received on the document via the Newsgroup discussion after CG-9 but haven't had time yet to produce a new version of it. The SECR committed to provide with the updated document for CG-11.

Actions

SECR: to provide with the updated document for CG-11.

14.4 Clarifications on some SPC sections

The Commission briefly introduced document CG-10-2015-04 and focused on those questions deserving further discussion.

Members and ASOs commented on several questions, such as:

- Q6: Upon request of a member, it was clarified that a new manufacturer cannot be added within the MR procedure in a CMS.

- Q7: Industry showed concerns with the proposed Q&A in terms of confidential business information, burden and cost linked to administrative changes and length of the SPC. Only mixing operations should be included; this would be the case for most of the BPD authorisations.

The Commission mentioned that this information cannot be considered as confidential under the BPR. In addition, it is important to track all the manufacturing sites for control purposes; Filling operations, as the last manufacturing step, could also be at the origin of safety issues. The fee for administrative changes in MSs ranges from 500 to 800 euros, approximately.

While some members supported the proposed Q&A or did not express a preference, a few members did not support the need to state such information in the SPC.

Members and ASOs were invited to provide comments on this question and COM will present it for discussion at the next CG meeting.

-Q8: Members agreed keeping this Q&A in the document, as well as introducing a similar one under heading 1.3 for the manufacturing sites of biocidal products.

- Q9: Upon request of a member, it was agreed including a footnote saying that the PAR should indicate the detailed description of the identity of the substance as in the AS approval.

- Q11: Upon request of a member, it was agreed deleting "environmental and human health", so that the answer widely refers to "risk assessment" and therefore, including the evaluation of the phys-chem properties too.

- Q13: Members agreed keeping this Q&A in the document.

- Q17: On account of the on-going discussions for anticoagulant rodenticides, it was decided to change the PT 14 example by another one (e.g. PT 18). Upon request of ASOs, it was clarified that PT 8 products can be placed on the market both for professional and non-professional users where the pack size is the same and there is no contradicting instruction for use or RMM between the two user categories (e.g. wearing of gloves, etc..).

- Q18: A member proposed that for MR in sequence, the CMSs could also consider the SPC agreed under the first round of MR in parallel. The Commission clarified that Article 33 clearly refers to the SPC in the authorisation of the refMS. In addition, this approach would not work for first authorisations not granted through MR in parallel.

Taking into account the implications that this element might have in terms of choice of a refMS by applicants and on the other hand, the need to share the workload of first authorisations between MSs, it was finally agreed to restrict the scope of the proposed Q&A to applications for MR in parallel.

-Q 19: It was agreed to be deleted until the outcome of the CA discussion is available.

The agreed questions will be moved to the 60th CA meeting for formal endorsement.

Actions

SECR: to set up a Newsgroups discussion for commenting on Q7.

All: to comment by 10 April.

COM: to produce an updated version of Q7 for CG-11.

14.5 PAR template for national authorisation

The SECR explained that two documents were uploaded onto CIRCABC for this meeting. Document No. 7 is the template previously provided by DE and where comments received after CG-9 have been incorporated. Document No. 11 is the template provided by ECHA, based on the Union Authorisation PAR template.

The Commission suggested agreeing on using the PAR template provided by ECHA, as both evaluating CAs and applicants should get used to work with a similar template under the two procedures. CG members supported this approach but several members commented that the current UA template would need to be further improved.

Further discussion will be scheduled at CG-11.

Actions

SECR:

- to set up a Newsgroup discussion for commenting on the ECHA NA PAR template.
- To discuss with the BPC SECR the possibilities for improvement for the UA PAR template.

All: to comment on the ECHA NA PAR template by 10 April.

14.6 RMMs for PT18

A member presented the outcome of the survey and stated that more comments from members and ASOs would be welcome.

The Newsgroup discussion will be re-opened.

Actions

SECR: to set up a Newsgroups discussion on the CIRCABC.

All: to comment by 10 April.

14.7 Handling of changes to the C&L of authorised products

A member presented the issue and several other members supported the concern (changes in C&L does not always qualify as administrative changes).

Another member referred to the discussions that took place in the context of the changes Regulation and to the reasons why it was decided to consider changes to the C&L as administrative ones. However, they should be restricted to cases where the compliance with the newly applicable C&L requirements do not have other consequences (e.g. wearing of PPE or classification as reprotox 1A/B for products authorised for the general public).

The Commission took note of the expressed concerns for certain cases and explained that for the time being an amendment of the Changes Regulation is not foreseen. It was also mentioned that where a MS considers that a change to the C&L should not have been considered as purely administrative, the CA can always take formal actions at any time in accordance with Article 48 of the BPR.

ASOs acknowledged that there might be some more controversial cases and that for those cases, applicants would in principle not submit the change as an administrative one.

Actions

COM: to reflect on what kind of changes of C&L can be applied as administrative changes in the context of the Changes Regulation and if this can be further clarified.

SECR: to set up a Newsgroups discussion on the CIRCABC.

All: to comment by 10 April.

15. Feedback from working parties

15.1 WP on comparative assessment

The Commission introduced document CG-10-2015-06, which took into account the 2nd round of comments within the WP on comparative assessment. The Commission thanked WP members for their valuable contributions.

The Commission provided an overview of those comments, starting by those of a more general nature:

- Some MSs raised the lack of experience and expertise within the CAs in terms of assessment of economic or practical disadvantages, non-chemical alternatives or even chemical diversity. Some of them proposed postponing these tasks until

further experience has been gained. The Commission clarified that they cannot be postponed as they are elements required in Article 23 of the BPR. In terms of expertise, CAs would have to further develop these fields of expertise to meet the duties agreed during the BPR negotiations. In addition, further experience will be acquired with time and also by looking at the work done by other MSs, which will be shared in accordance with Article 23(2) of the BPR.

- A MS considered that more detailed guidance should be provided. The Commission clarified that the proposed document is consistent with the CG agreement at CG-8, which considered that the level of detail in the draft TGN was appropriate.

- Finally, Industry claimed that efficacy should always be considered when comparing biocidal products. The Commission reminded the agreement reached in document CA-March14-Doc.5.4-Final, so that every authorised biocidal product is considered to be sufficiently effective.

A member considered that more detailed guidance should be provided and that, for some aspects, this document would not fulfil the mandate in Article 24 of the BPR. The member suggested moving footnote number 2 to a specific paragraph within the body text. In the future, expert groups (e.g. the current WP or others) should be able to develop more detailed guidance.

The Commission referred to the above-mentioned CG agreement and stated that the document provides a harmonised framework while maintaining some room for manoeuvre for the evaluating CA (e.g. use of expert judgement) and being feasible within the product authorisation or renewal deadlines. The Commission agreed to upgrade footnote 2 into the text, which clearly indicates that the document can be improved in the light of experience.

With this change regarding footnote 2, the chairperson noted support from the rest of CG members to the arguments provided by the Commission.

The Commission also gave an overview of other specific comments presented in track changes, with a particular focus on those in paragraphs 22, 23, 36, 81(c), 82(a), Annex 7.2.1.a and footnote 11. Some members further commented on the document at the meeting and as a result, the following changes were agreed:

- For consistency with paragraph 58(a), all the relevant paragraphs should refer to "hazard or precautionary statements", and not only to P-statements.

- Names of active substances in footnotes will be removed.

- An additional footnote will be added to section 7.2.1.a, to clarify that the example of RMM "Substitution" does not apply to authorised biocidal products.

- Other minor editorial changes.

With the above-mentioned changes, the CG agreed on the document, and to submit it for formal endorsement to the CA meeting.

Actions

COM: to update the document for endorsement at the May CA meeting.

16. Any other business (open session)

16.1 Trends in PA

The SECR informed the meeting that the production of the Trends in Product Authorisation report is being refined by ECHA and will be provided to all MS at the next meeting.

Actions

SECR: to produce the report on trends in PA.

16.2 Deadlines for application for PA

The SECR informed that the production of the Deadlines for application for product authorisation report is being refined by ECHA and will be provided to all MS at the next meeting.

Actions

SECR: to produce the report on deadlines for application for PA.

16.3 List of substances meeting the substitution criteria

The SECR explained that there has been an update to the list and the list was uploaded as meeting document for the current CG meeting.

Actions

COM: to publish the updated version on the public CIRCABC.

SECR: to circulate the information on where this list is to be found and produce the updated version for the next CG meeting.

7.4 Residue analytical method in air (moved from the closed session)

A member presented the document on the requirement of analytical methods to monitor residues in air as part of product application.

The member suggested that these data requirement should not be set for already authorised products but a future date should be set by which it should be required.

It was discussed when this requirement should apply:

- if document CA-July12-Doc.6.2d-Final should be followed or
- if the data requirement should be applied at renewal of PA.

Actions

SECR: to set up Newsgroup for commenting.

All: to comment by 10 April on when the data requirement should apply.

16.4 Questions regarding R4BP / IUCLID

This agenda point was first discussed before the arrival of ASOs and MS raised questions and concerns with regard to R4BP3 to ECHA.

ECHA gave a presentation at the open session (where ASOs were present) that will be uploaded onto CIRCABC for the CG-10 meeting folder. The presentation focused on Helpdesk incidents, key issues and IT activities foreseen for 2015. With regard

to the Helpdesk incidents there was a significant increase in R4BP and SPC editor related incidents. This resulted in using more human resources on ECHA's side than it was originally foreseen. There were several key issues identified with regard to R4BP3 and the SPC editor that require further follow-up. Even though the IT activities are reduced and ECHA is in maintenance mode, the IT tools are being further developed. These include for instance the new emergency patch for the SPC editor, two more releases for R4BP3 (June-July, and early Nov), the migration of the review programme into R4BP3, and further analysis for future development (e.g. for IUCLID 6 development).The BPR IT User Group is foreseen to take place during the autumn.

Industry raised the issue of the current constraints to create an SPC by using the SPC editor, which result in a huge amount of work (about 5 hours/SPC). This is also the case for products authorised under BPD with no agreed SPC. Companies now have to create every SPC from blank, i.e. they have to create SPC specifically for each asset (as part of the authorisation). The Chair mentioned that a similar question with regard to the rodenticides is tabled for the 59th CA meeting (agenda item 4.11) and proposed taking up this issue there.

Actions

SECR: to upload the presentation onto CIRCABC for the CG-10 meeting folder.

All: to make use of the CIRCABC Newsgroup on "R4BP3 issues linked to PA"

16.5 Feedback on e-consultations

No open e-consultations had taken place form the previous meeting, so this point was not discussed.

16.6 CG-12 meeting (July 2015)

The Chair informed the meeting that the CG-12 meeting is foreseen to be held during the week of 6 July and ECHA offered to host the meeting in Helsinki. She also asked members to reflect whether they would like to travel to Helsinki or offer venue to the meeting.

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MAIN CONCLUSIONS & ACTION POINTS

Agreed at the 10th meeting of the CG

17-18 March 2015

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
CLOSED SESSION	
2 – Agreement of the agenda for the closed session	
The agenda for the closed session was agreed with - moving AP 7.4 to the open section and - adding 2 new items under AOB.	**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, closed session	
No declarations of conflicts of interest were made.	
4 – Agreement of draft minutes (confidential part) from CG-9	
No comments were received during the meeting on the CG-9 minutes. The minutes were agreed.	**SECR:** to upload the CG-9 minutes into the relevant folders in the CG CIRCA BC
5 – Formal and informal referrals to the CG	
5.1 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR	
Three informal referrals are on-going. 1) An agreement has been found. 2) It was suggested that as there are outstanding issues this should be taken further as a formal referral by one of the cMS. 3) The rMS and the initiating cMS have found a way to go forward. Another cMS has submitted a formal referral for one of the products.	2) **Any current cMS:** to take the informal disagreement forward as a formal referral.
5.2 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
Three formal referrals are discussed. 1) Linked to the 3rd informal disagreement, new data have been submitted by the applicant, and will be evaluated by the rMS and taken into account in the context of the formal referral. 2) As no agreement has been reached this has to be referred further to the COM under Article 36 by the rMS. 3) An agreement has been found. The referral is closed within the CG.	1) **rMS:** to evaluate the new data **SECR**: to set up a Newsgroup discussion once the evaluation of the rMS is available **all MS**: to comment on the evaluation by rMS in order to conclude at CG-11 2) **rMS**: to refer the disagreement to the COM under the Article 36 procedure.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Some members provided updates on previous formal referrals. - An rMS is still waiting for the applicant to submit supplementary documentation in order to conclude. - Another rMS referred the case to the COM in accordance with Article 36.	**2nd rMS**: to forward the documentation submitted to the COM to all cMS and the applicant.
6 – Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/EC (closed session)	
An update was provided by the COM on outstanding actions on previous notifications.	**rMSs**: to inform the SECR about the actions taken.
7 – AOB	
7.1 – Late procedures	
ECHA informed that the report is being refined and will be provided to all MS at the next meeting.	**SECR:** to produce the report on late procedures.
7.2 – Harmonized RMM for DEET containing products	
A member who presented the proposal of a set of RMM and labelling requirements for non-professional users informed that the commenting deadline expired shortly before the CG meeting. Some issues that are discussed elsewhere (WG) have also been raised.	**A member:** to look at the comments and present a revised document for the next meeting. **SECR:** to check ongoing discussion at the WG and liaise with the member.
7.3 – Feedback on e-consultations	
On the derivation of M-factors for an insecticide, MS are invited to comment on the proposed way forward by a CG member within 2 weeks. Regarding whether products consisting of some plant blossoms should be considered as falling within the scope of the BPR, the COM informed that a CA paper has been tabled for discussion.	**SECR**: to re-open the Newsgroup discussion **All**: to comment by 1 April.
7.5 – Expiry date for authorisations of products containing AS that are candidate for substitution	
The Commission informed that some product authorisations containing an AS candidate for substitution have been granted under the BPR for longer than 5 years.	**MSs:** - to review the expiry date of such product authorisations; - where a comparative assessment has been performed for products authorised under the BPR, forward them to ECHA in accordance with Article 23(2).
7.6 – Question on a new BP Family application for UA	
A member presented the issue and asked for the opinion of other CG members.	**A member**: to send a written question. **SECR**: to create a Newsgroup on the issue.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
	All: to comment.
7.7 – AS definition for a Wood preservative	
A member presented the issue and asked for the opinion of other CG members. There is an ongoing HELPEX question (with the deadline of 31 March) initiated by another MS. Another member pointed out that there is a non-inclusion decision.	**A member**: - to get additional information from the applicant; - to contribute to the HELPEX discussion.
OPEN SESSION	
10 – Agreement of the agenda for the open session	
The agenda of the open session was agreed.	**SECR:** to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.
11 – Declaration of interest in relation to agenda, open session	
No declarations of conflicts of interest were made.	
12 – Agreement of draft minutes (non-confidential part) from CG-9	
No comments were received during the meeting on the CG-9 minutes. The minutes were agreed.	**SECR:** to upload the CG-9 minutes into the relevant folders in the CG CIRCA BC
13 – Administrative issues	
13.1 – Housekeeping issues	
ECHA provided information on: - secure CIRCABC; - public access to non-confidential minutes; - invitations for nominating Chair and Vice-Chair.	**SECR**: - to keep the members informed about the progress with regard to the migration and access to secure-CIRCABC; - to create the public CIRCABC site for the non-confidential minutes; - to invite members to nominate Chair and Vice-Chair for the CG for the next 1,5-year term starting from the September meeting.
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 - Biocidal Product Families – draft Q&A document from BPF workshop	

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
The Commission presented the two documents on the Q&As and "other issues" to the CG members. Two members commented on the Q&A document. There are also several questions coming from the MS and HELPEX discussions are initiated on this topic. On the "other issues" document, several members and ASO commented on the same point (paragraph 6(c)).	**SECR:** to set up a Newsgroups discussion for commenting on the draft Q&A document by 10 April. **All MS having HELPEX discussions:** to forward them to SECR. **COM:** - to clarify the wording of paragraph 6(c) and provide with some examples. - If possible to draft a document addressing the submission of draft labels.
14.2 Applications for a same BP of an individual product of a BPF	
The Commission presented the revised version of the document after the CG-9. Members were invited to agree on the revised document that is to be presented for endorsement at the CA meeting. The meeting agreed to the document subject to a clarification in footnote 9.	**COM:** to clarify the wording of footnote 9 and present the document at the CA meeting.
14.3 – Harmonised way to deal with 3rd party dossiers during PA	
ECHA gave an update and committed to provide with the updated document for CG-11.	**SECR:** to provide with the updated document for CG-11.
14.4 – Clarifications on some SPC sections	
The Commission explained the structure of the document and gave a brief update on the content. Members and ASOs commented on several questions, such as Q6, 7, 8, 9, 11, 13, 17, 18. Most debate was generated by Q7 on filling operations and sites. The following was decided: - Q7 to be postponed to CG-11 - Q8 to be kept, another Q similar to Q8 to be added in section 1.3, Q9 to be revised (footnote added), Q13 to be kept, Q17 example exchanged, Q18 focus on MRP, Q19 to be deleted. The agreed questions will be moved to CA for endorsement.	**SECR:** to set up a Newsgroups discussion for commenting on Q7. **All:** to comment by 10 April. **COM**: to produce an updated version of Q7 for CG-11.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
14.5 - PAR template for national authorisation	
The SECR explained the documents uploaded onto CIRCABC for this meeting. The Commission suggested agreeing on using the PAR template provided by ECHA (the one that is similar to the UA PAR template). CG members supported this approach but it was pointed out that the current UA template would need to be further improved. Further discussion is scheduled at CG-11.	**SECR:** - to set up a Newsgroup discussion for commenting on the ECHA NA PAR template - To discuss with the BPC SECR the possibilities for improvement for the UA PAR template. **All:** to comment on the ECHA NA PAR template by 10 April.
14.6 – RMMs for PT 18	
A member presented the outcome of the survey and stated that more comments from members and ASOs would be welcome. The Newsgroup discussion will be re-opened.	**SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to comment by 10 April.
14.7 – Handling of changes to the C&L of authorised products	
A member presented the issue and several other members supported the concern (changes in C&L does not always qualify as admin changes). The Commission explained that for the time being an amendment of the Changes Regulation is not foreseen.	**COM:** to reflect on what kind of changes of C&L can be applied as administrative changes in the context of the Changes Regulation and if this can be further clarified. **SECR:** to set up a Newsgroups discussion on the CIRCABC. **All:** to comment by 10 April.
15 – Feedback from working parties	
15.1 – Draft TGN on comparative assessment	
The Commission updated the meeting about the 2nd round of comments in the WP and the changes that were made. Some members further commented on the document at the meeting. As a result of those comments: - Further development of the guidance document will be addressed in a paragraph rather than in a footnote. - Names of active substances will be removed. - Additional footnote will be added to section 7.2.1 Examples. - And several editorial changes will be made. CG agreed on the document, and to submit it for endorsement to the CA meeting.	**COM**: to update the document for endorsement at the May CA meeting.
16 – AOB	
16.1 - Trends in PA	
ECHA informed that the report is being refined	**SECR:** to produce the report trends in PA.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
and will be provided to all MS at the next meeting.	
16.2 - Deadlines for application for PA	
ECHA informed that the report is being refined and will be provided to all MS at the next meeting.	**SECR:** to produce the report on deadlines for application for PA.
16.3 – List of substances meeting the substitution criteria	
ECHA explained that there has been an update to the list and the list was uploaded as meeting document for the current CG meeting.	**COM**: To publish the updated version on the public CIRCABC. **SECR**: to circulate the information on where this list is to be found and produce the updated version for the next CG meeting.
7.4 – Residue analytical method in air (moved from closed session)	
A member presented the document on the requirement of analytical methods to monitor residues in air as part of product application. The member suggested that this data requirement should not be set for already authorised products but a future date should be set by which it should be required. It was discussed when this requirement should apply: - if the document CA-July12- Doc 6.2d-Final should be followed or - if the data requirement should be applied at renewal of PA.	**SECR:** to set up Newsgroup for commenting. **All:** to comment by 10 April on when the data requirement should apply.
16.4 – Questions regarding R4BP3 / IUCLID	
This agenda point was first discussed before the arrival of ASOs and MS raised questions and concerns with regard to R4BP3 to ECHA. ECHA gave a presentation at the open session (where ASOs were present) that will be uploaded onto CIRCABC for the CG-10 meeting folder. BPR IT User Group is foreseen to take place during the autumn.	**SECR:** to upload the presentation onto CIRCABC for the CG-10 meeting folder. **All:** to make use of the CIRCABC Newsgroup on "R4BP3 issues linked to PA"
16.5 – Feedback on e-consultations	
No open e-consultations had taken place from previous meetings.	

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17 March 2015

CG-A-10-2015

Final agenda
10th meeting of the Coordination Group (CG)

17-18 March 2015

17 March: Starts at 10:30 – ends 18:00
18 March: Starts at 9:00 – ends at 13:00

Venue: Albert Borschette Conference Centre
Rue Froissart 36, 1040 Brussels

CLOSED SESSION

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

CG-A-10-2015 rev1

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-9

CG-M-9-2014_revised-confidential

For agreement

Item 5 – Formal and informal referrals on mutual recognition disagreements

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

Link to disagreements

For information

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

Link to disagreements

For discussion

Item 6 – Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/EC

CG-10-2015-14

For information

Item 7 - Any Other Business

7.1 Late procedures

For information

7.2 Harmonized RMM for DEET containing products

CG-10-2015-18

For discussion

7.3 Feedback on e-consultations

For information

7.4 Residue analytical method in air (moved to the open session)

CG-10-2015-09 & 12

For discussion

7.5 Expiry date for authorisations of products containing AS that are candidate for substitution

For discussion

7.6 Question on a new BP Family application for UA

For discussion

7.7 AS definition for a Wood preservative

CG-10-2015-19, 15, 16 & 17

For discussion

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome and apologies

Item 10 – Agreement of the agenda

CG-A-10-2015

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-9

CG-M-9-2014_revised non-confidential

For agreement

Item 13 – Administrative issues

13.1 Housekeeping issues

For information

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

14.1 Biocidal Product Families – draft Q&A document from BPF workshop

CG-10-2015-01, 21 & 02

For discussion

14.2 Applications for a same biocidal product of an individual product of a biocidal product family

CG-10-2015-03

For agreement

14.3 Harmonised way to deal with 3rd party dossiers during PA

For information

14.4 Clarifications on some SPC sections

CG-10-2015-04

For discussion and agreement

14.5 PAR template for national authorisation

CG-10-2015-07 & 11

For discussion

14.6 RMMs for PT 18

For information

14.7 Handling of changes to the C&L of authorised products

CG-10-2015-10 & 13

For discussion

Item 15 – Feedback from working parties

15.1 Draft TGN on comparative assessment

CG-10-2015-05 & 06

For discussion / agreement

Item 16 – Any Other Business

16.1 Trends in product authorisation

For information

16.2 Deadlines for application for product authorisation

For information

16.3 List of substances meeting the substitution criteria

CG-10-2015-08

For information

7.4 Residue analytical method in air (moved from closed session)

CG-10-2015-09 & 12

For discussion

16.4 Questions regarding R4BP3 / IUCLID

CG-10-2015-20

For information

16.5 Feedback on e-consultations

For information

16.6 CG-12 meeting (July 2015)

For discussion

Item 17 – Agreement of the action points and conclusions

For agreement

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