**7 July 2015**

**CG-M-11-2015 FINAL PUBLIC**

# Final minutes of the 11th meeting of the Coordination Group (CG)

**19 May 2015**

# Summary Record of the Proceedings

## Closed session

## 1. Welcome and apologies to the closed session

The Chair welcomed participants to the eleventh meeting. 34 members from 25 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and two from ECHA were present for the full meeting. The list of attendees is given in Part III of the minutes.

A special welcome was made to the Swiss representatives attending the Coordination Group meeting for the first time after the adoption of the agreement on mutal recognition between the European Community and the Swiss Confederation.

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

The Chair introduced the draft agenda (CG-A-11-2015) and invited any items under AOB. The agenda was agreed with the inclusion of a agenda item about the expiry dates of authorisation for products containing a.s. meeting the substitution criteria under AOB.

The Chair remarked that the documents (CG-11-2015-18&19) for AP 7.1 had been 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-10

The SECR explained that the draft confidential CG-10 minutes had been uploaded for commenting via Newsgroups. No comment had been 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-10.

The Chair informed the meeting that currently the meeting minutes are anonimyzed (i.e. no mention of names of MSCA is made). The Chair mentioned the possibility for MSs and ASOs to have explicit mention of the name of their MSCA in the non-confidential minutes if this is requested for a specific discussion.

**Actions**

**SECR:** to upload the CG-10 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

No new referrals have been brought up for discussion at CG level, and an update was provided to two informal referral discussed at CG-10 meeting.

For one of them, the initiating cMS informed that they would move forward the referral to the formal phase before next meeting.

For the second referral, the rMS informed that they had not receive the additional information requested to the authorisation holder. As a consequence the rMS (and the initiating CMS) will consider further actions to the product authorisations.

**Actions**

**The 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 were discussed and an update was provided by the relevant MS on a formal disagreement discussed during CG-9.

For the first one, the rMS and the initiating cMS confirmed that the authorisation holder had withdrawn all the applications for mutual recognition in all cMSs and the referral is therefore closed. The rMS will also cancel the authorisation.

For the second referral, the discussion took place on the identity of the biocidal product and whether the carrier of the product should be considered part of the mixture or an article. The applicant attended the meeting and provided clarifications to questions by MSs. Further discussions and a written procedure will be established to try to reach an agreement.

For the third formal referral, the discussion took place on the idenfitication of substances of concern for the environment and for human health, and on the validity of the leaching studies in order the conduct the risk assessment. The applicant attended the meeting and provided clarifications to questions by MSs. Further discussions will follow via Newsgroups and the referral will be included in the agenda of CG-12 meeting for discussion.

A MS updated the meeting on a referral discussed at CG-9 to be submitted to the Commission under Art. 36.

A general discussion took place on the overview document prepared for the CA meetings. Members requested that this document includes the name of the product, to be available to the CG meeting, under the closed session.
It was also agreed that for formal referrals on which the CG has reached an agreement, the SECR should prepare a short summary document with the main points of disagreement discussed and the agreed outcome, excluding the name of the product. This document could be made publically available, which could be useful in different regulatory processes by MSs, Commission and Industry.

**Actions**

2) **SECR:** To move on the preparatory activities an accordance with the working procedures, and then to initiate a written procedure for reaching agreement.

3) **All MSs and applicant:** to comment on one of the referrals via Newsgroups by 2 June.

**SECR:** to prepare the different documents

to check with the IT team if the R4BP3 supports the task for the rMS to record a CG agreement.

## 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

The Commission introduced the reports prepared by ECHA, which aim to monitor the performance of the authorisation system at EU and at MS level.

CG members made several comments and were invited by the Commission to check the content of the reports.

**Actions**

**All MSs:** to check the information in the reports, and where relevant notify the SECR of any discrepancies.

### 7.2 Harmonized RMM for DEET containing products

A member who had presented the proposal of a set of RMM and labelling requirements for non-professional users proposed a way forward consisting on the discussion of the matter in a separate expert group.

Since the issue includes a combination of both technical and policy aspects it was suggested to forward the proposal document (AP 7.2-CG-09-2015-01) and the commenting table from MSs with the replies from the member (AP 7.2-CG-11-2015-09) to the BPC and to the ad hoc Working Group on Human Exposure in order to discuss which group would be best suited for such discussions.

**Actions**

**SECR:** to contact the BPC and ad hoc WG regarding the matter.

### 7.3 Feedback from e-consultations

No closed e-consultations had taken place from the last meeting.

### 7.4 Expiry date for authorisations of products containing an AS that is a candidate for substitution

Some CG members expressed concerns regarding the legal basis for the amendment of the authorisations already granted as requested by the Commission at CG-10.

The Commission reminded the legal basis in the BPR establishing that products containing an AS meeting the substitution criteria shall only be authorised for a

maximum of 5 years (i.e. Articles 23 and 91). Taking into account the legal text and that the AS at stake was known to meet two out of the PBT criteria since the AS approval, decisions to grant authorisations for a period longer than 5 years can only be considered as an error which needs to be corrected.

Regarding the legal basis for the amendment of the affected authorisations, the Commission referred to Article 48 as the tool which can be used in the BPR to cancel or amend existing product authorisations.

No conclusion was reached and CG members and the Commission were invited to further reflect on the matter for further discussion.

## Open session

## 9. Welcome to the open session

The Chair welcomed ASOs to the open session and reiterated the welcome to the Swiss CA to the Coordination Group. 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-11-2015) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed without changes.

The Chair remarked that the revisions of documents for AP 14.3 and 14.6, including additional comments from MSs had been 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.

## 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-10

The SECR explained that the draft non-confidential CG-10 minutes were uploaded for commenting via Newsgroups. A comment had been 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-10.

The Chair informed the meeting that currently the meeting minutes are anonimyzed (i.e. no mention of names of MSCAs or ASOs is made). The Chair mentioned the possibility for MSs and ASOs to have explicit mention of the name of their MSCA or ASO in the non-confidential minutes if this is requested for a specific discussion.

**Actions**

**SECR:** to upload the CG-10 minutes into the relevant folders in the CG CIRCABC.

## 13. Administrative issues

### 13.1 Election of Chair and Vice-Chair

The SECR informed the meeting about the election of Chair and vice-Chair. Invitations had been sent to nominate Chair and Vice-Chair for the CG and one nomination had been received for Chair. CG members were invited to nominate candidates for Chair and especially for Vice-Chair by informing the CG SECR.

CG members were informed that the election of the new Chair and Vice-Chair will take place in the July meeting and the next Chair and Vice-Chair will start their work with the September 2015 meeting. The Chair of the CG remarked the relevance of the Vice-Chair in the preparatory phase of the meetings and during consultations via emails and teleconferences with the ECHA SECR, COM and MSCAs.

**Actions**

**All MSs:** to nominate candidates for Chair and Vice-Chair.

### 13.2 Revision of RoP (inclusion of Switzerland)

The SECR informed the meeting about the revision number 4 of the Rules of Procedure for the inclusion of Switzerland as a member of the Coordination Group as a result of the agreement on mutual recognition between the European Community and the Swiss Confederation.

The revised Rules of Procedure incorporate now in Article 2 the Swiss CA as a member of the Coordination Group.

CG members agreed on the revision of the Rules of Procedure.

**Actions**

**SECR:** To upload the agreed RoP to the "general & procedural documents" folder in the CG CIRCABC IG.

### 13.3 CG July meeting

The SECR informed the meeting that the facilities in ECHA are available to host the CG meeting in July. The suggested date for the meeting, Tuesday 7 July at the ECHA premises in Helsinki, was agreed by the CG members.

**Actions**

**SECR:** To organise the meeting at ECHA and inform accordingly CG members and ASOs.

*[Post-meeting note: After the meeting it was decided that the next meeting will be held in Brussels instead in order to be held back-to-back with the meeting of the Standing Committee.]*

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

### 14.1 Biocidal Product Families

### 14.1.a Draft Q&A document from BPF workshop

The Commission presented the revised version of the document after the commenting period (CG-11-2015-02), which included some additional Q&As arising from bilateral discussions between ECHA and prospective applicants for UA, from some evaluating CAs or from previous discussions in HelpEx.

Regarding the latest, the Commission informed the meeting that for questions related to the new BPF concept discussed in HelpEx, once the discussion is closed, the proposed way forward will be sent to the CG for agreement and further incorporation into Annex IV to the note for guidance in a Q&A format. The CG secretariat will report back to HelpEx on the agreed answer so that the HelpEx database is updated accordingly.

A member proposed including a clarification in the answer for Q11, regarding that different uses should preferably be included in different meta-SPCs if included in the same BPF.

Another member made a comment on answer to Q26, but it was not supported by CG members. Concerning the answer to Q15, that member also suggested noting in the minutes that the IT tools should be further developed to allow the allocation of the relevant manufacturer(s) to the product-specific SPCs in an automatized way.

The meeting agreed to the document subject to the above-mentioned clarification and will therefore be proposed for formal endorsement at the 60$^{th}$ CA meeting.

**Actions**

**COM:** to update the document for endorsement at 60th CA meeting.

### 14.1.b Updated SPC template for a BPF

The Commission presented the revised version of the document after the commenting period (CG-11-2015-03). The template aims to facilitate a common understanding of the three-level information within the SPC of a BPF. On the other hand, it will enable companies to submit information in a coherent and harmonised way in the context of the pre-submission phase of applications for UA or presubmission meetings with evaluating CAs.

ECHA also acknowledged the added value of the template for the adaptation of the SPC editor to the new BPF concept, particularly to integrate the "meta-SPC" concept.

ASOs mentioned that they hope it will be possible to make revisions of the SPC template in necessary based on the experience developed with the current and future applications for family authorisations. ECHA noted this opinion and stated that a certain degree of stability is needed to not impact IT development.

CG members agreed on the template.

**Actions**

**COM:** to present the document for endorsement at 60th CA meeting.

## 14.2 Harmonized way to deal with alternative party dossiers during PA

ECHA presented the revised version of the document to incorporate the comments received after CG-9 and Newsgroups discussions. One of the main changes in the document regards the implications of Technical Equivalence at the different tiers on the possibility to change the agreed list of endpoints from the reference source.

ECHA clarified that the data included in the alternative source dossier considered technically equivalent at Tier II are not necessarily relevant for the reference source (i.e. due to the presence of a new impurity in the alternative source).

MSs considered that the Technical equivalence assessment should include which data have been evaluated when perfoming the equivalence assessment. MSs also asked how the product authorization procedure should be dealt with if there is a need to change the agreed list of endpoint as a consequence of new data. The Commission considered that on-going procedures, as they take into account the agreed list of endpoints, should not be put on hold when an Article 15 request is launched by a rMS. In case a change in the agreed list of endpoints would be needed, this would affect any authorisations of products containing the active substance (and not only those containing the alternative source). Therefore, all the authorisations should be amended in accordance with Article 48 of the BPR.

ECHA also clarified upon request from a MS that if a dossier submitted for Technical Equivalence is deemed to be equivalent at Tier II, it does not imply that the dossier is considered complete for further authorisation steps and there is no link between both steps.

Regarding the inclusion on Article 95 list ECHA proposed that an applicant can be included in that list not only by applying to Article 95 directly, but also by submitting an alternative dossier in the context of a product authorisation application. In the first situation, the compliance check of the Article 95 dossier would be performed by ECHA, while the validation of the alternative dossier in the context of a product authorisation would be conducted by the rMS.

Industry supported the approach that the agreed list of endpoints is used for the products authorised unless there is an Article 15 procedure. Industry considered that in an Article 15 procedure, the original participants in the Review Programme should be involved in the discussions. It was also noted that in case of protected studies contaninig data submitted to refine an endpoint, the data protection should be further considered for the other involved applicants (such as those of Article 95). Otherwise, protected data would be used for refinement by companies without access to those data.

A member asked how "significant changes" to the agreed list of endpoints should be understood. The Commission considered that, in order to make the best use of available resources, only those changes significantly affecting the conclusions of the reference source peer-reviewed should be considered under Article 15 requests (e.g. leading to the non-approval of a use for the active substance). Otherwise, the identified elements should be addressed at the renewal of the active substance approval.

Regarding the coordination mechanism between MSs, the Commission suggested clarifying in the document how several rMSs having received the same third party dossier at the same time would decide which MS carries out the validation and evaluation of the dossier.

The Chair suggested that, since some issues still need further dicussions, MSs can provide further comments via Newsgroups and if possible, a preparatory conference call could be held, involving the commenting parties prior of presenting the document at the CG meeting.

**Actions**

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

**All:** to comment by 12 June

### 14.3 Clarifications on some SPC sections

The Commission presented a document for discussion regarding filling operations. This paper included a proposal supported by a few members suggesting that filling operations should not be considered as part of the manufacturing process.

The Commission mentioned that this proposal goes beyond the original discussion on whether or not these contract manufacturers should be listed in the SPC, as filling operators would be then exempted from the obligations in Article 65(2) of the BPR. The Commission and several MSs considered that filling operations are part of the manufacturing process and that the reference in the BPR to "manufacture of the biocidal product" is too unspecific to make a distinction between formulators and filling operators.

A member mentioned that sometimes the filling operator is the only manufacturer in the CMS, as the product can be supplied in bulk by the manufacturer of the mixture in another MS, and that it is important for the CA to know who is the manufacturer to ensure traceability and for enforcement purposes. This member introduced the idea of distinguishing between a "main manufacturer" and other manufacturers having a contract with the main manufacturer to carry out filling or other kind of operations. It should be further consider whether only the main manufacturer should be listed in the SPC while maintaining for the contract manufacturers the obligations referred to in Article 65 of BPR.

The issue of batch number assignation was discussed. ASOs informed the meeting that current practice is that batch number assignation and storage of samples is done at mixture level, and not at the level of batches of a certain pack size as produced by the filling operator(s). Industry mentioned that in any case, the AH is fully responsible of the product as it is placed on the market.

Some members expressed that, taking into account the "single batch number" practice, filling operations should not be considered as part of the manufacturing process nor listed in the SPC.

On account of the different views expressed by CG members on the subject, the Commission requested further comments both from MS and ASOs with a view to discuss the matter at the CG July meeting.

**Actions**

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

**All:** to comment by 12 June.

### 14.4 PAR template for national authorisation

ECHA presented the revised PAR template for NA after the conference call with the MSs having commented in the Newsgroups and the Commission.

ECHA reported the main issues revised in the new proposal. As agreed during the conference call, the SPC should be considered a separate document of the PAR. However, the initial summary assessment would be kept in the section " Summary of Product Assessment" containing all the headings of the SPC template and should include the information submitted by the applicant during the application.

For the revisions of the PAR, it was agreed keeping the original version of the PAR and, when revisions are needed, to include the revised chapters as addenda, together with the date of the latest update in the front page. At the beginning of the PAR a list shall explain what changes and when they have been incorporated. Administrative changes would not be included in the list, but only those affecting the assessment and a consolidated version would be created at the renewal of the product authorisation.

As the wording "Authorised uses" and "Intended uses" refers to different stages of the assessment, the wording "Intended uses" will be kept in the tables for the assessment sections of the PAR, while the "Authorised uses" will be included in the tables part of the Summary. A short Conclusion chapter will be kept at the beginning of the document.

Regarding the full composition of the family in the confidential annex of the PAR, it was suggested including in the confidential annex the full composition only when a single bp is assessed, while for a bp family the range of composition is included. The full composition of each individual member of a bp family should be reported in a separate excel file embedded in the confidential annex of the PAR. The confidential annex of the PAR shall be uploaded to R4BP. The initial proposal of uploading the full composition to R4BP as separate excel files was not supported by the Submission Manual for application of National authorisation and was then disregarded.

Some minor comments were provided to the PAR template for NA, regarding section 2.1.1. (to remove the trade names) and 2.1.6. and the PAR template was agreed with no further comments from MSs.

ECHA indicated that this template should be used also for Union authorisation (with the necessary specific additions) and the BPC will be informed accordingly.

It was clarified that, in order to avoid unnecessary work duplication, applicants having already prepared their draft risk assessment under the old template may still submit that template within the application and that CAs receiving a draft risk assessment under the old template may still produce the draft PAR with the old template; an adaptation to the new template remains voluntary.

Applicants should use the new template when the preparation of a draft risk assessment starts after the publication of the new template in the ECHA website.

**Actions**

**COM:** to update the document for endorsement th 60$^{th}$ CA meeting.

**SECR:** if endorsed at the CA meeting, to invite the BPC to take note of the new template, and to adapt, where relevant, the PAR template of Union Authorisation accordingly.

### 14.5 RMMs for PT18

A member informed the CG members about the status of the development of the draft guidance.

Several MSs and ASOs expressed their intention to provide further comments to the initial proposal.

**Actions**

**SECR:** to reopen the Newsgroups discussion on CIRCABC

**All:** to comment by 12 June

### 14.6 Handling of changes to the C&L of authorised products

The Commission introduced document CG-11-2015-06.rev1, which included a minor amendment in the title of the annex to the document.

Some members raised the issue of the time constraints (30 days) to handle the notifications of administrative changes (i.e. invoicing and checking of the notification).

The Commission clarified that the deadlines set by the changes Regulation aimed to treat the notifications as something really administrative without any communication back and forth with the applicant. Should the notification not be correct, the CA shall reject it and inform the other CMSs accordingly. The Commission suggested that where a CA is not able to react within the 30 days and the notification should have been rejected, that CA can always amend or cancel the authorisation in accordance with Article 48 of the BPR. At the same time, the CA could also inform the CA for the implementation of the CLP Regulation or even the control authorities.

Upon request of CG members, the Commission clarified that:

- The application for a change referred to in paragraph 17 has to be read as "in addition" to the notification of the administrative change.

- The changes limited to the new C&L requirements (e.g. pictograms, etc..) can be implemented by the AH, even if other non-administrative changes being a direct consequence of the new classification have not been agreed yet by the CA.

A member wondered how these non-administrative changes being a consequence of the new C&L requirements should be handled, if they can be implemented only after an approved application for such changes.

The Commission invited CG members and ASOs to submit further comments in writing with a view to present an updated version at the next CG meeting in July.

**Actions**

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

**All:** to comment by 12 June.

### 14.7 Submission of example labels, instructions for use, safety data sheets and models or drafts of the labelling within an application for product authorisation

The Commission introduced document CG-11-2015-06. Due to time constraints, the chairperson invited CG members and ASOs to submit further comments in writing so that the Commission can present an updated version at the next CG meeting in July.

**Actions**

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

**All:** to comment by 12 June.

### 14.8 Residue analytical method in air

A member presented the document including the requirement of a residue analytical method in air for several active substances. The CG agreed on the approach and considered that the data requirement should be applied first at renewal of the active substance and consequently at renewal of the product authorisations or, for new products, after the renewal of the relevant active substances.

**Actions**

**SECR:** To inform the BPC about the CG agreement, so that can be taken into consideration in context of the active substance renewals.

### 14.9 Proposal for a harmonized labelling of (anticoagulant) rodenticides

A member presented a proposal for a harmonized risk mitigation phrase in the SPC and on the label for (anticoagulant) rodenticides regarding the risk for wildlife. The proposal included the inclusion of the safety instruction "Hazardous to wildlife" to the SPC and labels of all (anticoagulant) rodenticides.

Several CG members supported the proposal, but no conclusion was reached on how to address this during the authorisation process. The Commission noted that in the context of the agreed strategy for the renewal of anticoagulant rodenticides, the CG will be responsible to produce a harmonised set of sentences for the different sections of the SPC. Therefore, this aspect could be addressed in that context and allow MSs to implement it in a harmonised way and at the same time in all product authorisations. Otherwise, it should be further discussed how the proposed sentence could be implemented in the context of MR procedures, namely mutual recognition in sequence.

MS and ASOs were invited to submit further comments in writing with a view to continue the discussion at the next CG meeting in July.

**Actions**

**SECR:** to set up a Newsgroups discussion on CIRCABC

**All:** to comment by 12 June

### 14.10 Opinion from MS regarding CA document on dermal absorption assessment for biocidal product authorisation

A member presented a proposal of allometric scaling to be used as a refinement to derive the AEL. This approach could result in a higher AEL value.

CG members did not support this approach as it is linked to the established list of endpoints for the approved active substances that have followed a peer-review process. It was agreed that this type of refinement is not possible at the product authorisation stage.

### 14.11 Storage stability test for product containing in-situ generated active substances

ECHA presented the question originally received from HelpEx on the storage stability test for biocidal products containing in situ generated active substances and invited CG members to agree on the answer.

The proposed approach is that a confirmation is needed that the concentrations of needed precursors are sufficiently high to generate the in situ active substances in such a concentration that proves to be efficacious. Therefore, it would be reasonable to provide information on the storage stability of the precursors necessary to generate the in situ active substances.

The CG meeting agreed on the answer, which will be recorded in the minutes and reported back to HelpEx to keep track of the agreement.

**Actions**

**SECR:** to inform HelpEX about the outcome of the discussion.

## 15. Feedback from working parties

No update from the last meeting.

## 16. Any other business (open session)

### 16.1 Trends in PA

The Commission briefly introduced the new reports produced by ECHA. Regarding document CG-11-2015-15 (product authorisations), the Commission noted that the figures are not up to date, as 4560 authorisations had been already granted on 13 May 2015 according to ECHA's website. The idea is to include in the report three histograms showing:

- The total number of product authorisations per MS,

- The number of product authorisations per MS indicating the different asset types (purely national, first authorisations linked to MR-P, MR-S, SA, SBP, etc…),

- The trend over time of the total number of product authorisations in the EU indicating the different asset types (purely national, first authorisations linked to MR-P, MR-S, SA, SBP, etc…)

Regarding document CG-11-2015-15, it aims to provide an overview at EU and at MS level (split by case types) of the number of on-going applications submitted under the BPR.

**Actions**

**All MSs:** To check the information in the reports, and where relevant notify the SECR of any discrepancies.

### 16.2 Deadlines for application for PA

The Commission briefly introduced the new report produced by ECHA (document CG-11-2015-17), which essentially maintains the same structure as the document that the Commission used to prepare under the BPD.

### 16.3 List of substances meeting the substitution criteria

The SECR explained that there has not been updates to the list from the previous meeting. A link to the version presented during CG March had been made available.

**Actions**

**SECR**: If relevant, to produce an updated version for the next CG meeting.

## 16.4 Questions regarding R4BP / IUCLID

### 16.4.a. Adaptation of the SPC editor to the new BPF concept

ECHA updated the meeting on the adaptation of the SPC editor to the new BPF concept. CG members were informed that new instructions are being developed for the applications in relation to the meta-SPC and the preparation of documents for their applications. These instructions would be circulated within the R4BP key users in order to receive their inputs and then would be make publicly available at the beginning of June.

**Actions**

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

## 16.5 Feedback on e-consultations

A member provided a summary of the outcome of the e-consultation on "Analytical methods for AS in BP". The comments received by MSs supported the approach regarding the possibility to read-across the validation of analytical methods. MSs also considered that room for expert judgement is needed.

The proposal of the conclusions will be circulated among the Coordination Group members.

**Actions**

**The member:** to submit their proposed way forward to the SECR.

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# MAIN CONCLUSIONS & ACTION POINTS

**Agreed after the 11th meeting of the CG**

**19 May 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<br>- The inclusion of a point on the expiry dates of authorisation for products containing a.s. candidates for substitution | **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-10** | |
| No comments were received during the meeting on the CG-10 minutes.<br>The minutes were agreed. | **SECR:** to upload the CG-10 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** | |
| There was an update on 2 previous informal referrals.<br>For one of them, the rMS did not receive the additional information requested. As a consequence the rMS (and the initiating CMSs) will consider further actions to the product authorisations.<br>For the other referral, there are still some outstanding issues. This will probably be taken forward as a formal referral by a cMS. | **The cMS:** to take the informal referral forward as a formal referral. |
| **5.2 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR** | |
| Three formal referrals were discussed.<br>1) It was confirmed by the rMS and the initiating cMS that the application for MR has been withdrawn. The rMS will cancel the first authorisation.The formal referral is therefore closed.<br>2) The applicant attended the meeting and provided answers to the questions by MSs. A written procedure will be established to try to reach an agreement.<br>3) An explanation of the disagreement was | **2) The SECR:**<br>To move on whith the preparatory activites in accordance with the working procedures, and then to initiate a written procedure for reaching agreement.<br>3) All MSs and applicant: to comment on the referrals via Newsgroups by 2 June.<br>**SECR:**<br>To prepare the different documents.<br>To check with the IT team if the R4BP3 supports the task for the rMS to record a CG |

| Agenda point | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| provided by the initiating cMS. The applicant attended the meeting and provided answers to the questions by MSs. Further discussions will follow via Newsgroups and during CG-12 meeting where an agreement should be reached.<br><br>A MS updated the information on an referral that will be referred to the COM under Art. 36.<br><br>General discussion:<br><br>It was agreed that for formal referrals on which the CG has reached an agreement, SECR should prepare a short summary document with the main points discussed and the agreed outcome, but excluding the name of the product. This document should be made publically available.<br><br>A member requested that the overview document prepared for the CA meetings includes the names of the product. This should be made available to the CG (in closed session). | agreement. |
| **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 Commission on outstanding actions on previous notifications in accordance with the BPD. | |
| **7 – AOB** | |
| **7.1 – Late procedures** | |
| COM presented the reports on timelines for different procedures and invited MSs to check the structure and the content of the reports. | **All MS:**<br><br>To check the information in the reports, and where relevant notify the SECR of any discrepancies. |
| **7.2 – Harmonized RMM for DEET containing products** | |
| A member who had presented a set of RMMs and labelling requirements proposed to further discuss the matter in a separate expert group.<br><br>It was agreed to forward the document to the BPC and the ad hoc HE WG, to decide which group would be best suited for such discussions. | **SECR:**<br><br>To contact the BPC and ad hoc HE WG regarding the matter. |
| **7.3 – Feedback on e-consultations** | |
| No closed e-consultations had taken place since the previous meeting. | |
| **7.4 – Expiry dates of authorisation for products containing a.s. candidates for substitution** | |
| The amendment of the expiry dates for authorisations of products containing candidates for substitution that were granted under the BPR was discussed. No conclusion was reached. | **All MS and COM:**<br><br>To further reflect on the matter, for further discussion. |
| **8.1 – Agreement of the action points and conclusions** | |

| **Agenda point** | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| It was agreed that list of action points and conclusions should be agreed via written procedure after the meeting. | **SECR:** to set up a Newsgroups discussion on the CIRCABC. Deadline for any comments by 22 May. |
| **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-10** | |
| No comments were received during the meeting on the CG-10 minutes.<br>The minutes were agreed. | **SECR:** to upload the CG-10 minutes into the relevant folders in the CG CIRCA BC |
| **13 – Administrative issues** | |
| **13.1 – Election of Chair and Vice-Chair** | |
| ECHA informed about that one nomination for Chair of the CG has been received so far. CG members were invite to nominate for Chair and Vice-Chair.<br>The election of Chair and Vice-Chair will take place at the CG meeting in July. | **All MS:**<br>To nominate candidates for Chair and Vice Chair. |
| **13.2 – Revision of RoP (inclusion of Switzerland)** | |
| ECHA informed about the revision of the Rules of Procedure in order to include Switzerland as Member of the Coordination Group, to reflect the mutual recognition agreement.<br>The revised Rules of Procedure were agreed. | **SECR**: to upload the agreed RoP to the "general & procedural documents" folder in the CG CIRCABC IG. |
| **13.3 – CG July meeting** | |
| ECHA informed that ECHA is able to host the CG meeting in July at their facilities in Helsinki.<br>The suggested data (Tuesday 7 July) was agreed by the CG members.<br>*Post-meeting note: After the meeting it was decided that the next meeting will be held in Brussels instead in order to be held back-to-back with the meeting of the Standing Committee.* | **SECR**: To organise the meeting at ECHA and inform accordingly CG members and ASOs. |

| **Agenda point** | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| **14 – Harmonisation of technical and procedural issues in relation to product authorisation** | |
| **14.1 - Biocidal Product Families** | |
| **14.1.a Draft Q&A document from BPF workshop** | |
| The Commission presented the revised version of the document after the commenting period.<br><br>CG members agreed on the document with the inclusion of a clarification in answer for Q11, regarding that different uses should preferably be included in different meta-SPCs if included in the same BPF. | **COM:** to update the document for endorsement at 60th CA meeting. |
| **14.1.b Updated SPC template for a BPF** | |
| The Commission presented the revised version of the document after the commenting period.<br><br>CG members agreed on the template. | **COM:** to present the document for endorsement at 60th CA meeting. |
| **14.2 Harmonised way to deal with alternative dossiers during PA** | |
| ECHA presented the revised version of the document after the comments after CG-9.<br><br>MS raised further comments and requests for clarification during the meeting.<br><br>Since some points were still under discussion, it was agreed that MSs can provide further comments and, if needed, a preparatory conference call can take place before CG July meeting. | **SECR:** to set up a Newsgroups discussion on the CIRCABC.<br><br>**All:** to comment by 12 June. |
| **14.3 – Clarifications on some SPC sections** | |
| The Commission presented a document for discussion regarding Q7; whether or not filling operations should be considered as part of the manufacturing process and whether or not they should be listed in the SPC.<br><br>CG members expressed different view on the subject, and further comments were requested from both MS and ASOs with a view to propose an alternative wording at the CG July meeting. | **SECR:** to set up a Newsgroups discussion on the CIRCABC.<br><br>**All:** to comment by 12 June. |
| **14.4 – PAR template for national authorisation** | |
| ECHA presented the revised PAR. Some minor comments were provided and MSs agreed on the template. | **COM:** to update the document for endorsement at 60th CA meeting.<br><br>**SECR:** If endorsed at the CA meeting, to invite the BPC to take note of the new template, and to adapt, where relevant, the PAR template of Union Authorisation accordingly. |
| **14.5 - RMMs for PT 18** | |
| A member gave an update on the current status of the project. | **SECR:** to reopen the Newsgroups discussion on CIRCABC.<br><br>**All:** to comment by 12 June. |

| Agenda point | |
|---|---|
| **Conclusions / decisions / minority positions** | **Action requested after the meeting (by whom/by when)** |
| **14.6 – Handling of changes to the C&L of authorised products** | |
| The Commission presented the proposal on this topic of how changes to C&L should be handled.<br>MS and ASOs were invited to submit further comments in writing with a view to present a revised version at the next CG meeting in July. | **SECR:** to set up a Newsgroups discussion on CIRCABC.<br>**All:** to comment by 12 June. |
| **14.7 – Submission of example labels, instructions for use, safety data sheets and models or drafts of the labelling within an application for product authorisation** | |
| The Commission presented the document.<br>MS and ASOs were invited to submit further comments in writing with a view to present a revised version at the next CG meeting in July. | **SECR:** to set up a Newsgroups discussion on CIRCABC.<br>**All:** to comment by 12 June. |
| **14.8 – Residue analytical method in air** | |
| A member presented the document. The CG agreed on the approach and considered that the data requirement should be applied first at renewal of the a.s. and consequently at renewal of PA or for new products after the renewal of the relevant active substances. | **SECR:**<br>To inform the BPC about the CG agreement, so that can be taken into consideration in context of the active substance renewals. |
| **14.9 – Proposal for a harmonized labelling of (anticoagulant) rodenticides** | |
| A member presented a proposal a harmonized risk mitigation phrase in the SPC and on the label for (anticoagulant) rodenticides regarding the risk for wildlife.<br>Several CG members supported the proposal, but no conclusion was reached on how to address this during the authorisation process.<br>MS and ASOs were invited to submit further comments in writing with a view to continue the discussion at the next CG meeting in July. | **SECR:** to set up a Newsgroups discussion on CIRCABC.<br>**All:** to comment by 12 June. |
| **14.10 – Opinion from MS regarding CA document on dermal absorption assessment for biocidal product authorisation** | |
| A member presented the proposal of allometric scaling for refinement of dermal absorption values.<br>CG members did not support this approach as it is linked to the established list of endpoint for the approved a.s. | |
| **14.11 – Storage stability test for product containing in-situ generated active substances** | |
| ECHA presented the HELPEX question and invited CG members to agree on the answer.<br>CG members agreed on the proposal. | **SECR:** To inform HelpEx about the outcome of the discussion. |
| **15 – Feedback from working parties** | |
| No updates on the Working Parties. | |

| | |
|---|---|
| **16 – AOB** | |
| **16.1 - Trends in PA** | |
| COM informed about the new reports produced by ECHA. | **All MS:** To check the information in the reports, and where relevant notify the SECR of any discrepancies. |
| **16.2 - Deadlines for application for PA** | |
| COM informed about the new report produced by ECHA. | |
| **16.3 – List of substances meeting the substitution criteria** | |
| The Chair explained that there has not been updates to the list from the previous meeting. A link to the version presented during CG March had been made available. | **SECR**: If relevant, to produce an updated version for the next CG meeting. |
| **16.4 – Questions regarding R4BP3 / IUCLID** | |
| **16.4.a Adaptation of the SPC editor to the new BPF concept** | |
| ECHA updated the meting on the adaptation of the SPC editor to the new BPF concept. | **All:** to make use of the CIRCABC Newsgroup on "R4BP3 issues linked to PA" |
| **16.5 – Feedback on e-consultations** | |
| A member provided a summary of the outcome of the e-consultation on "Analytical methods for AS in BP". | **The member:** to submit their proposed way forward to the SECR. |
| **17 – Agreement of the action points and conclusions** | |
| It was agreed that list of action points and conclusions should be agreed via written procedure after the meeting. | **SECR:** to set up a Newsgroups discussion on the CIRCABC. Deadline for any comments by 22 May. |

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19 May 2015

CG-A-11-2015

# Final agenda

# 11th meeting of the Coordination Group (CG)

# 19 May 2015
# Brussels (Centre Borschette)

## CLOSED SESSION

**Item 1 – Welcome and apologies**

**Item 2 – Agreement of the agenda**

*CG-A-11-2015*

***For agreement***

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

**Item 4 –Draft minutes from CG-10**

*CG-M-10-2015_draft-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 and discussion***

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**

***For information***

**Item 7 - Any Other Business**

7.1 Late procedures

*CG-11-2015-18 & 19*

***For information***

7.2 Harmonized RMM for DEET containing products

*CG-11-2015-09*

***For discussion***

7.3 Feedback on e-consultations

***For information***

7.4 Expiry date for authorisations of products containing an AS that is a candidate for substitution

***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-11-2015*

***For agreement***

**Item 11 – Declaration of interest in relation to the agenda**

**Item 12 –Draft minutes from CG-10**

*CG-M-10-2015_draft non-confidential_comm*

***For agreement***

**Item 13 – Administrative issues**

13.1 Election of Chair and vice-Chair

***For information***

13.2 Revision of RoP (inclusion of Switzerland)

*CG-11-2015-01*

***For agreement***

13.3 CG July meeting

***For information***

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

14.1 Biocidal Product Families:

14.1.a Draft Q&A document from BPF workshop

*CG-11-2015-02*

***For discussion and agreement***

14.1.b Updated SPC template for a BPF

*CG-11-2015-03 & 04*

***For discussion and agreement***

14.2 Harmonised way to deal with alternative dossiers during PA

*CG-11-2015-14*

***For discussion and agreement***

14.3 Clarifications on some SPC sections

*CG-11-2015-05*

***For discussion and agreement***

14.4 PAR template for national authorisation

*CG-11-2015-12 & 13*

***For discussion and agreement***

14.5 RMMs for PT 18

***For information***

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

*CG-11-2015-06*

***For discussion***

14.7 Submission of example labels, instructions for use, safety data sheets and models or drafts of the labelling within an application for product authorisation

*CG-11-2015-07*

***For discussion***

14.8 Residue analytical method in air

*CG-11-2015-20*

***For discussion and agreement***

14.9 Proposal for a harmonized labelling of (anticoagulant) rodenticides

*CG-11-2015-08*

***For discussion***

14.10 Opinion of MS concerning CA document dermal absorption assessment for biocidal products authorisation

*CG-11-2015-10*

***For discussion***

14.11 Storage stability test for product containing in-situ generated active substance

*CG-11-2015-11*

***For discussion and agreement***

**Item 15 – Feedback from working parties**

**Item 16 – Any Other Business**

16.1 Trends in product authorisation

*CG-11-2015-15 & 16*

***For information***

16.2 Deadlines for application for product authorisation

*CG-11-2015-17*

***For information***

16.3 List of active substances meeting the exclusion or substitution criteria

*Link to document from CG-10 (no update)*

***For information***

16.4 Questions regarding R4BP3 / IUCLID

***For information***

16.4.a Adaptation of the SPC editor to the new BPF concept

***For information***

16.5 Feedback on e-consultations

***For information***

**Item 17 – Agreement of the action points and conclusions**

***For agreement***

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