

1 June 2018
CG-M-28-2017 non-confidential

**Final non-confidential minutes of the 28th meeting of the
Coordination Group (CG)**

13-14 March 2018

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the twenty eighth CG meeting (CG-28). 38 members and experts from 25 Member State Competent Authorities (MSCAs), NO and CH participated in the meeting. Two representatives from DG SANTÉ and three representatives from ECHA were present in the meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-28-2018) and invited participants to add any items under AOB. The Chair informed the meeting that due to the high number of referrals tabled for discussion, the open session of the meeting had been cancelled. Four agenda points were added to the agenda: i) update on the progress of the WP-BPF-3 meeting, ii) update on the agreement reached by the BPC on iodate used in iodine containing products, iii) how to perform a risk assessment of PT19 products for use for domestic animals, and iv) harmonisation of instructions of use for PT19 products. The agenda was agreed with these additions.

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

Actions:

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

3. Declaration of interest in relation to the agenda

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

4. Draft minutes from CG-27

The Chair explained that the draft confidential CG-27 minutes had been uploaded for commenting via Newsgroups. Comments received from a CG member were discussed and the final version of the draft CG-27 minutes (confidential and non-confidential) was agreed.

Actions:

SECR: to upload the CG-27 minutes into the relevant folders in the CG CIRCABC.

5. Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

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

Actions:

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

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

The Chair informed the meeting that ten referrals had been closed via written procedure after the CG-27 meeting. An agreement by consensus was reached for all ten products (i.e. they meet the conditions in Article 19(1) for granting an authorisation) and the products can be authorised.

Twenty five formal referrals were tabled for discussion. Fifteen referrals corresponded to PT14 products and were related to the renewal of anticoagulant rodenticides. One referral corresponded to a PT8 product, two to PT2 products, three to PT18 products and four to PT19 products. An agreement was reached by consensus for seven referrals and the authorisation of these products can be granted. Three teleconferences have been scheduled to continue the discussion of the remaining open points of the different referrals.

- 1) The outcome of a referral concerning a PT14 product related to the shelf life of the product was formally agreed by the CG members. An agreement on a way forward had been reached during a teleconference prior to the meeting. The product meets the condition for granting an authorisation according to Article 19(1)(d). This formal referral was therefore closed.
- 2) to 6), 9), 10), 12) and 13) Nine referrals corresponding to PT14 products with a similar point of disagreement related to the shelf life of the products were discussed. CG members confirmed that the agreement reached during the CG-20 meeting should be applied, however, there were uncertainties on the information that was required on degradation products and efficacy for aged bait. A follow up meeting by teleconference will be organised on 10 April in order to agree on a way forward that can be generally applied to the resolution of this issue.
- 7) A referral was discussed concerning a PT14 product containing bromadiolone as active substance. The point of disagreement was on the classification of the product. Information provided by the applicant on the composition of the product will be considered by CG members to decide on the classification. The discussion will be continued by teleconference.
- 8) A referral was discussed concerning the shelf life of a PT14 product containing difenacoum as active substance. Considering additional data provided by the applicant on the stability of the product, CG members agreed on the shelf life of the product. The product meets the condition for granting an authorisation according to Article 19(1)(d). This formal referral was therefore closed.
- 11) A referral was discussed concerning the validity of the efficacy data of a PT14 product containing difenacoum as active substance. CG members considered that the efficacy data was sufficient to support the use of the product. The product meets the condition for granting an authorisation according to Article 19(1)(i). This formal referral was therefore closed.
- 14) A referral of a PT8 product was discussed related to the values for dermal exposure to be used in the assessment considering the use of new gloves. CG members agreed on a way forward on the values to be used similar to that agreed in a previous referral. The product meets the condition for granting an authorisation according to Article 19(1)(iii). This formal referral was therefore closed.
- 15) , 16) Two referrals of two related PT2 products from the same applicant containing hydrochloric acid as active substance were discussed. CG members agreed that the additional environmental exposure assessment included in the revised PAR by the refMS was acceptable. The products meet the condition for granting an authorisation according to Article 19(1)(ii). These formal referrals were therefore closed.
- 17) A referral of a PT18 product containing bendiocarbe as active substance was discussed. Multiple points of disagreement were raised in all areas. The refMS will provide an updated PAR addressing the comments.

- 18) , 19) Two related referrals from the same applicant concerning two PT18 products were discussed. Multiple points of disagreement were raised in all areas and an agreement was reached for the majority of the points. The discussion will be continued by teleconference.
- 20) A referral of a PT19 product containing ethyl butylacetylaminopropionate as active substance was discussed. Multiple points of disagreement were raised in all areas. An agreement was reached for several points and the discussion of the remaining open points will be continued by teleconference.
- 21) A referral of a PT19 product containing DEET as active substance was discussed. A point of disagreement related to the percentage body surface to be used in the dermal exposure assessment to use against ticks was not agreed. On 16 March it will be decided whether this disagreement will be referred to the Commission under the provisions of Article 36 of the BPR.
- 22) A referral of a PT19 product containing DEET as active substance was discussed for which points of disagreement were raised in all areas. The refMS will provide an updated PAR for agreement.
- 23) The outcome of a referral of a PT19 product containing imidaclorid and pyriproxyfen was formally agreed by the CG members. A way forward had been previously discussed in a teleconference prior to the CG meeting addressing the efficacy of the product. The product meets the condition for granting an authorisation according to Article 19(1)(b)(i) of the BPR. This formal referral was therefore closed.

The discussion of two additional PT14 referrals which were still under the commenting period was postponed. These referrals will be discussed during a teleconference on 11 April.

Actions:

SECR, COM: To propose a way forward to facilitate reaching an agreement for referrals on shelf life of PT14 products.

SECR: To organise a follow up teleconference on 10th April to discuss with CG members (only) how to address open points of disagreement related to shelf life of PT14 products.

1), 8), 11), 14), 15), 16), 23) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

2), 3), 4), 5), 6), 9), 10), 12), 13) refMS: To update the PAR by 27 March.

2), 3), 4), 5), 6), 9), 10), 12), 13) SECR: To organise a follow up teleconference on 11th April to discuss the open points of disagreement related to shelf life of PT14 products (including applicants).

7) MSs: To provide comments by 19 March on the dedicated newsgroups considering the comments provided by the applicant.

7) SECR: Depending on the comments from MSs, a) organise a teleconference for a follow up discussion on 11 April or b) initiate the procedure for closing the referral by written procedure.

10) refMS: To contact the applicant to check whether additional data is available to support the application.

12) All: To provide comments by 19 March in the dedicated newsgroups.

13) All: To provide comments by 20 March in the dedicated newsgroups.

17) refMS: To provide the response to the open points and the updated PAR and SPC by 23 March.

18), 19) SECR: To clarify the applicable guidance related to the open point of disagreement as soon as possible and organise a follow up teleconference to discuss this point of disagreement.

20) FR, IT, ES: To inform the SECR by 16 March on whether they support the majority opinion of the CG on a point of disagreement.

20) refMS: To cross check the PAR concerning the point of disagreement on phys chem properties and inform the CG members.

20) All: To provide comments by 21 March on a point of disagreement related to human health.

20) SECR: To organise a teleconference for 28 March to continue the discussion.

21) FR, IT, ES: To inform the SECR by 16 March on whether they support the majority opinion of the CG on the remaining open point of disagreement.

21) SECR: Depending on the feedback from FR, IT and ES, to organise the agreement of the referral by written procedure.

21) refMS: Depending on the feedback from FR, IT and ES, to refer the referral to COM under the provisions of Article 36 of the BPR.

22) icMS: To clarify several open points related to human health risk assessment.

22) refMS: Once the points of disagreement are clarified by the icMS, to provide an updated PAR by 27 March.

22) SECR: If necessary, depending on whether MSs agree with the updated PAR, to organise a follow up teleconference to discuss the remaining open points of disagreement.

5.3 Clarification points for submission of formal referrals and updated submission template

The SECR presented a proposal to improve the efficiency of the submission of referrals.

The SECR presented an updated version of the referral submission template considering the new agreed SoP for the mutual recognition process and including a few additional clarifications. The template will be updated to include a few minor comments from CG members.

CG members agreed that (a) in order to increase efficiency, for all procedures in parallel, the SECR will launch all referrals on the same product the day after the deadline for submitting a referral. This date will be considered as the referral submission date; (b) the refMS will inform the applicant about the progress and ongoing discussions of the referral; (c) applicants will be invited to teleconferences relevant to their product.

Action points:

SECR: To provide an updated template addressing the comments received by MSs.

SECR: To open a newsgroup to comment on the updated template.

MSs: To comment of the updated template (within 1 week from the opening of the newsgroup).

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

6.1 Issues identified in the context of UA

Due to time constraints, this agenda point was not presented.

Actions:

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

SECR: To provide an updated list for the next CG meeting.

7. Any Other Business (closed session)

7.1 Late procedures

Due to time constraints, this agenda point was not presented.

Actions:

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

7.2. Feedback on e-consultations

An e-consultations on harmonisation of instructions of use for PT19 products was tabled for discussion.

Due to time constraints, this agenda point has been postponed for discussion to the CG-29 meeting.

Actions:

1) SECR: to table this item for discussion for the CG-29 meeting.

7.3 Update on iodate used as stabiliser in iodine containing products

Due to time constraints, this agenda point was not presented.

7.4 Risk assessment of PT19 products for companion animal protection

Due to time constraints, this agenda point has been postponed for discussion to the CG-29 meeting.

7.5 Update on the activities of the WP on the BPF concept

Due to time constraints, this agenda point was not presented.

8. Agreement of the action points and conclusions

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

Actions:

SECR: To upload the list of conclusions and action points in S-CIRCABC.

All: To comment (1 week)

SECR: To upload the agreed list of conclusions and action points in the relevant S-CIRCABC space.

Part II - MAIN CONCLUSIONS & ACTION POINTS

28th meeting of the CG

13-14 March 2018

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
CLOSED SESSION	
1.- Welcome	
2 – Agreement of the agenda.	
The agenda for the closed session was agreed with the addition of four agenda points for updating the CG on: i) the progress of the WP-BPF-3 meeting, ii) the agreement reached by the BPC on iodate used in iodine containing products, iii) how to perform a risk assessment of PT19 products for use for domestic animals, and iv) harmonisation of instructions of use for PT19 products.	SECR: to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.
3 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
4 – Draft minutes from CG-27	
The draft confidential minutes of the CG-27 meeting were agreed with the comments provided by a CG member.	SECR: to upload the CG-27 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed about the update of the overview table of the referrals discussed so far at CG level.	SECR: to produce a revised overview table for next CG meeting.
5.2 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
The Chair informed that ten referrals had been closed via written procedure since the previous CG meeting (CG-27) for which an agreement by consensus was reached. Twenty three formal referrals were discussed corresponding to thirteen PT14, one PT8 product, two PT2 products, three PT18 products and four PT19 products. Related to disagreements on shelf life of PT14 products, CG members agreed that the agreement reached during the CG-20 meeting should be applied. 1) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. 2) The discussion of the referral will be finalised by teleconference on 11 th April.	SECR, COM: To propose a way forward to facilitate reaching an agreement for referrals on shelf life of PT14 products. SECR: To organise a follow up teleconference on 10 th April to discuss with CG members (only) how to address open points of disagreement related to shelf life of PT14 products. 1), 8), 11), 14), 15), 16), 23) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures. 2), 3), 4), 5), 6), 9), 10),

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
<p>3) The discussion of the referral will be finalised by teleconference on 11 April.</p> <p>4) The discussion of the referral will be finalised by teleconference on 11 April.</p> <p>5) The discussion of the referral will be finalised by teleconference on 11 April.</p> <p>6) The discussion of the referral will be finalised by teleconference on 11 April. CG members agreed to prolong the deadline of the referral to 18 April.</p> <p>7) The referral is still under commenting. MSs will consider the comments provided by the applicant on the points of disagreement and provide further comments by 19 March.</p> <p>8) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>9) The discussion of the referral will be finalised by teleconference on 11 April.</p> <p>10) The discussion of the referral will be finalised by teleconference on 11 April.</p> <p>11) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>12) The referral is still under commenting. The discussion of the referral will be finalised by teleconference on 11 April.</p> <p>13) The referral is still under commenting. The discussion of the referral will be finalised by teleconference on 11 April.</p> <p>14) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>15) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>16) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>17) CG members agreed to extend the deadline of the referral by 27 April. The refMS will provide the response to the points of disagreement and the updated PAR and SPC by 23 March.</p> <p>18) CG members agreed by consensus on all points</p>	<p>12), 13) refMS: To update the PAR by 27 March.</p> <p>2), 3), 4), 5), 6), 9), 10), 12), 13) SECR: To organise a follow up teleconference on 11th April to discuss the open points of disagreement related to shelf life of PT14 products (including applicants).</p> <p>7) MSs: To provide comments by 19 March on the dedicated newsgroups considering the comments provided by the applicant.</p> <p>7) SECR: Depending on the comments from MSs, a) organise a teleconference for a follow up discussion on 11 April or b) initiate the procedure for closing the referral by written procedure.</p> <p>10) refMS: To contact the applicant to check whether additional data is available to support the application.</p> <p>12) All: To provide comments by 19 March in the dedicated newsgroups.</p> <p>13) All: To provide comments by 20 March in the dedicated newsgroups.</p> <p>17) refMS: To provide the response to the open points and the updated PAR and SPC by 23 March.</p> <p>18), 19) SECR: To clarify the applicable guidance related to the open point of disagreement as soon as possible and organise a follow up teleconference to discuss this point of disagreement.</p> <p>20) FR, IT, ES: To inform the SECR by 16 March on whether they support the majority opinion of the CG on a point of disagreement.</p> <p>20) refMS: To cross check the</p>

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
<p>of disagreement except for one point. The discussion of this point will continue after the CG-28 meeting.</p> <p>19) CG members agreed by consensus on most points of disagreement. The discussion of the remaining two open points will continue after the CG-28 meeting.</p> <p>20) CG members agreed by consensus on several points of disagreement. The discussion of the remaining three open points will continue after the CG-28 meeting. CG members agreed to extend the deadline of the referral to 6 April.</p> <p>21) CG members agreed by consensus on most points of disagreement except for one. The icMS and two CG members will communicate by 16 March whether they support the majority opinion on the remaining open point.</p> <p>22) The PAR of the product will be updated considering the comments provided by the icMS. The referral will be closed by written procedure.</p> <p>23) An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.</p> <p>The discussion of two additional referrals which were still under the commenting period was postponed. These referrals will be discussed during a teleconference on 11 April.</p>	<p>PAR concerning the point of disagreement on phys chem properties and inform the CG members.</p> <p>20) All: To provide comments by 21 March on a point of disagreement related to human health.</p> <p>20) SECR: To organise a teleconference for 28 March to continue the discussion.</p> <p>21) FR, IT, ES: To inform the SECR by 16 March on whether they support the majority opinion of the CG on the remaining open point of disagreement.</p> <p>21) SECR: Depending on the feedback from FR, IT and ES, to organise the agreement of the referral by written procedure.</p> <p>21) refMS: Depending on the feedback from FR, IT and ES, to refer the referral to COM under the provisions of Article 36 of the BPR.</p> <p>22) icMS: To clarify several open points related to human health risk assessment.</p> <p>22) refMS: Once the points of disagreement are clarified by the icMS, to provide an updated PAR by 27 March.</p> <p>22) SECR: If necessary, depending on whether MSs agree with the updated PAR, to organise a follow up teleconference to discuss the remaining open points of disagreement.</p>
<p>5.3 Clarification for submission of formal referrals and updated submission template</p>	
<p>The SECR presented a proposal to improve the efficiency of the submission of referrals.</p> <p>CG members agreed that, with the exception of MR-S procedures, referrals will be launched the day after the referral submission deadline.</p> <p>An updated template for submitting referrals was</p>	<p>SECR: To provide an updated template addressing the comments received by MSs.</p> <p>SECR: To open a newsgroup to comment on the updated template.</p>

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	by whom/by when
presented and several comments will be addressed in a revised version.	MSs: To comment of the updated template (within 1 week from the opening of the newsgroup).
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA – Due to time constraints, this agenda point was not presented.	MSs: To take note of the information provided in the table. SECR: To provide an updated list for the next CG meeting.
7 – Any Other Business	
7.1 – Late procedures	
Due to time constraints, this agenda point was not presented.	MSs: to review the document and communicate to ECHA any inaccuracies in the data.
7.2 – Feedback on e-consultations	
An e-consultations on harmonisation of instructions of use for PT19 products was tabled for discussion. Due to time constraints, this agenda point has been postponed for discussion during the CG-29 meeting.	SECR: to table this item for discussion for the CG-29 meeting.
7.3 – Update on iodate used as stabiliser in iodine containing products	
Due to time constraints, this agenda point was not presented.	
7.4 – Risk assessment of PT19 products for companion animal protection	
Due to time constraints, this agenda point has been postponed for discussion during the CG-29 meeting.	
7.5 – Update on the activities of the WP on BPF concept	
Due to time constraints, this agenda point was not presented.	
Item 8 – Agreement of the action points and conclusions	
The list of action points and conclusions for the closed session will be agreed by written procedure	SECR: To upload the list of conclusions and action points in S-CIRCABC. All: To comment (1 week) SECR: To upload the agreed list of conclusions and action points in the relevant S-CIRCABC space.

Due to the high number of referrals scheduled for the CG-28 meeting, the open session was cancelled.

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Part IV - List of Annexes

ANNEX I List of documents submitted to the members of the Coordination Group

ANNEX II Final agenda

ANNEX II

13 March 2018

Final agenda 28th meeting of the Coordination Group (CG-28)

**13-14 March 2018 –
on 13 March 2018 from 9:00 to 17:00 and
on 14 March 2018 from 9:00 to 12:30**

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-28-2018

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 – Draft minutes from CG-27

CG-M-27-2018_Draft confidential

CG-M-27-2018_Draft non confidential

For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-28-2018-07

For information

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

Links to disagreements

For discussion and agreement

5.3 Clarification points for submission of formal referrals and updated submission template

CG-28-2018-09 & CG-28-2018-10

For information

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

6.1 Issues identified in the context of UA

CG-28-2018-06

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-28-2018-08, CG-28-2018-03 & CG-28-2018-05

For information

7.2 Feedback on e-consultations

CG-28-2018-13

Links to e-consultations

For discussion and agreement

7.3 Update on iodate used as stabiliser in iodine containing products

CG-28-2018-12

For information

7.4 Risk assessment of PT19 products for companion animal protection

For discussion

7.5 Update on the activities of the WP on the BPF concept

For discussion

Item 8 – Agreement of the action points and conclusions

For agreement

Due to the high number of referrals scheduled for the CG-28, the open session was cancelled.

The following documents prepared by ECHA SECR are uploaded in S-CIRCABC for information:

- Trends in product authorisation: CG-28-2018-02 & CG-28-2018-04
- Deadlines for application for product authorisation: CG-28-2018-01

- List of active substances meeting the exclusion or substitution criteria: *CG-28-2018-11*

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