17 September 2019

CG-M-36-2019 non-confidential

Final non-confidential minutes of the 36th meeting of the Coordination Group (CG)

2-3 July 2019

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chair welcomed all participants to the thirty-sixth Coordination Group meeting (CG-36). 28 members and experts from 22 Member State Competent Authorities (MSCAs), Switzerland, Serbian Observer and 4 participants from 4 Accredited Stakeholder Organisations (ASOs), participated in the meeting. Four 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-36-2019) and invited participants to add any items under AOB. The agenda for the closed session was agreed with the addition of one point on the CG meetings and teleconferences.

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. No declarations of conflicts of interest were made.

4. Draft minutes from CG-35

The Chair explained that the draft non-confidential CG-35 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. The draft confidential CG-35 minutes were agreed.

Actions:

SECR: to upload the CG-35 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 the CG level. This overview is uploaded as well to the Disagreements folder in S-CIRCABC.

The Chair informed that, prior to the CG-36 meeting, four referrals were discussed during the teleconferences on 12 June and 14 June. An agreement by consensus was reached for three products and the products can be authorised. The outcomes were agreed by written procedure.

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

Five referrals were tabled for discussion and one, which was still under commenting, was briefly introduced.

1) A referral was discussed concerning a PT19 product containing DEET as an active substance. The disagreement was related to the human health risk assessment, acceptability of the risk mitigation measures (RMM) and calculations for emission estimation for environment. The PAR will be amended by the refMS clearly identifying the conclusions from the risk assessment and a clarification will be included in the annex of the PAR that all uses are authorised under Art 19(5) of the BPR. The MSs will review an updated PAR. This point will be further discussed.

2) A referral was discussed concerning a PT2 product containing nonanoic acid as an active substance. Since an unacceptable risk for environment was identified, the limitations for maximum packaging size was proposed and inclusion of additional RMMs. It was also requested to include additional information on the application rate and more detailed instructions for use. Since commenting period for this referrals finished a day before the CG meeting, no agreement was reached on the points of disagreement. This referral will be further discussed by teleconference.

3) A referral was discussed concerning a PT8 product containing tebucanazole, basic copper carbonate, propiconazole as active substances. The disagreement was related to a co-formulant to be identified as a possible substance of concern (SoC). The COM provided a legal clarification on the interpretation of the definition of a SoC during the referral period. Considering that, during the teleconference the MSs agreed that the particular co-formulant should be considered as a SoC. An updated risk assessment was provided by the refMS. An agreement was reached on the point of disagreement by consensus. This referral is therefore closed.

4) A referral was discussed concerning a PT8 product containing tebucanazole, basic copper carbonate, propiconazole as active substances. The points of disagreement were related to the physical chemical part of the evaluation and the secondary poisoning assessment for environmental part. The applicant submitted the additional requested information during the referral period, which was incorporated in the updated PAR accordingly. An agreement was reached on the points of disagreement by consensus. This referral is therefore closed.

5) A referral was discussed concerning a PT8 product containing tebucanazole, basic copper carbonate, propiconazole as active substances. The points of disagreement were related to a co-formulant to be identified as a possible substance of concern (SoC), environmental risk assessment, i.e., the leaching rate/amount estimation; necessity to include an identified SoC in the mixture toxicity assessment as well as inclusion of the additional RMMs. The refMS provided the updated PAR where the identified SoC was included in the risk assessment which was agreed by the CG members. The CG members also agreed on inclusion of the icMS proposed RMMs, clarification of the wording on the use class as well as, that in this particular case, a mixture toxicity assessment is not necessary. One point of disagreement is still open and it will be clarified whether this point can be considered as eligible for the referral in accordance with Article 36 of the BPR.

6) A referral was briefly introduced concerning a PT19 product IR3535 as an active substance. The points of disagreement are related to the efficacy. The commenting period of the referral is still ongoing and the discussion will take place by teleconference.

Actions:

1) The refMS: to provide an updated PAR by 10 July.

1) The COM: to provide a legal clarification for one point of the referral by 10 July.

2) The icMS: to provide a view on open point of disagreement by 10 July.

2) The refMS: to provide a view on open point of disagreement by 10 July.

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

3) The SECR: to forward one topic for discussion to ECHA.

1), 2) SECR: To organise a follow up teleconference on 17 July.

6) SECR: To organise a follow up teleconference after the commenting period is finalised.

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

6.1 Issues identified in the context of UA

The SECR presented an updated list of issues identified in the context of UA applications (CG-36-2019-14). The intention of publishing this list is to allow the refMSs of national authorisations of products based on the same active substance to be informed about the issues identified in the UA applications.

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

7.2. Feedback on e-consultations

Two e-consultations were discussed and one e-consultation was briefly introduced

1) Interpretation of SoC criteria in BPR guidance (MEA)

A CG member presented the revised outcome of an e-consultation on interpretation of substance of concern criteria in BPR guidance (CG-36-2019-09) for a particular case.

The CG members did not find an agreement on the questions raised by the MS. It is up to the initiating MS now to decide whether this point should be discussed at the CA level.

2) ED assessment of co-formulants by MS

One of the leading CG members presented an updated proposal on a practical approach how to perform an ED assessment of co-formulants by the MS (CG-36-2019-05, CG-36-2019-06).

As no agreement was reached, the discussion will be continued during the CG-37 meeting.

3) Submission of information in accordance with requirements of Article 89(3)

A CG member briefly introduced an e-consultation on a matter in relation to Article 89 (3) of the BPR (CG-36-2019-7). Since this e-consultation is under commenting, the discussion will be continued during the CG-37 meeting.

Actions:

2) SECR: To open Newsgroup for comments.

2) MSs: To provide comments by 30 July.

3) MSs, ECHA and the COM: To provide comments by 15 August in the already opened Newsgroup.

7.2. Update on questions forwarded from CG to ECHA

The SECR briefly presented an updated overview of the status of the questions referred from the CG to be addressed by ECHA (CG-36-2019-11).

Actions:

MSs: To take note of the information.

8. Agreement of the action points and conclusions

The list of action points and conclusions for the closed session were agreed by the CG meeting.

Open session

9. Welcome to the open session

The Chair welcomed ASOs to the open session. Four observers from four ECHA accredited stakeholder organisations (ASOs) were present for the open session of the meeting.

10. Agreement of the agenda for the open session

The agenda for the open session was agreed with the addition of two points (a) trade name for national authorisation and (b) information from BPC-31 meeting.

Actions:

SECR: to upload the final 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 participants to declare any potential conflict of interests. No declarations of conflicts of interest were made.

12. Draft minutes (non-confidential part) from CG-35

The Chair explained that the draft non-confidential CG-35 minutes had been uploaded for commenting via Newsgroups. No comments were received during the commenting period. CG members agreed with the non-confidential draft minutes from the CG-35.

Actions:

SECR: to upload the CG-35 minutes into the relevant folders in the CG CIRCABC.

13. Administrative issues

No administrative issues were tabled for discussion.

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

The SECR updated the meeting on the progress of the items referred to the WGs related to the second renewal of AVK rodenticides. In particular, the CG members were informed that a MS would provide a discussion document for dermal absorption for the HH WG (another MS will provide support).

Actions:

All: To take note on the information.

15 – Feedback from working parties

15.1 BPF WP recommendations - update from the CA meeting

The SECR updated the CG members that the revised version of the CA document has been prepared for the July CA meeting, considering the CG agreed document for assessment of similarity in biocidal product families.

The Commission informed on the proposal as regards to the applicability of the WP recommendation to be discussed during the following CA meeting.

Actions:

All: To take note of the information.

15.2 Follow up on the WP on frequently used sentences in the SPC

The SECR briefly presented a status of the update of the list of frequently used sentences for the SPC including the timelines, indicating that the third commenting period has been initiated. The CG members were invited (a) to provide comments on the previously commented/opened points and on the revisions of these points proposed by the SECR, (b) indicate a proposal on the additional sentences with regards to the PTs and the SPC field.

The SECR also informed that additional product types could be added in the document by extended Working Party on "Frequently used sentences in the SPC". However, it was reminded that during the CG-25 meeting the CG members agreed to postpone the extension of the Working Party so that the MSs could gain additional experience related to other product types.

In addition, the SECR commented that a comprehensive review of existing product types of existing sentences, agreed previously at the Working Party, could be performed during the next review of the list or in the scope of the extended Working Party.

Actions:

MSs: to provide comments on the proposal and the prepared documents by 12 July.

16 – Any Other Business (open session)

16.1 List of active substances meeting the exclusion or substitution criteria

The Chair invited the meeting participants to take note of the updated version of the list of active substances meeting the exclusion or substitution criteria (CG-36-2019-08).

Actions:

Rapporteur MS: To check the new information and report to CG-SECR by 12 July.

SECR: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an updated version for next CG meeting.

16.2 IT issues

The SECR briefly informed the CG members on the IT issues occurred in May 2019.

The SECR also explained that ECHA is preparing for the next IT-user group meeting which will take place in November. It was agreed that one CG member will present issues and needs from the MSs point of view in this meeting. Therefore, the MSs were invited to provide feedback, which will be collected and first presented in the September CG meeting for further discussion.

Actions:

SECR: To open a Newsgroup for feedback.

MSs: To provide feedback by 15 August.

SECR: To table this topic for discussion during the CG-37 meeting.

16.3 Feedback on e-consultations

Two e-consultations were tabled for discussion.

1) Co-formulant as potential active substance

A CG member presented the outcome of an e-consultation on a co-formulant as a potential active substance (CG-36-2019-01). The CG members had firstly a general discussion whether for the substances identified (included Annex I of Reg. 2032/2003) but not notified (Annex III of the Reg. 2032/2003), the non-biocidal effects should be supported by a literature review or testing data. Secondly it was discussed whether a structural similarity of the known active substance has to be taken into account in a context of possible biocidal effect.

On a more general note, ASOs reminded that a topic as regards to the co-formulant contribution to a product efficacy was discussed at the CA level (CA-Jan18-Doc.4.2.) and expressed their concerns that small separate discussions take place on the similar topics in several fora.

A MS commented that in the CA document the issues addressed the situation if the substance is included in the notified active substance list, but did not address the issue if a product contains an identified co-formulant.

During the meeting for the first question, the CG members agreed that a case by case approach could be followed by the MSs, i.e., MSs can accept expert justification, literature data or in case of concerns request for an additional testing. As regards to the second question, the MSs did not support that assessment of structurally related compounds should be carried out. However, the MSs need to be aware of some obvious aspects of similarity, e.g., acids. The outcome of this e-consultation was agreed by the CG members.

2) Anti-allergen claim

Due to the absence of the leading MS, the discussion on this e-consultation (CG-36-2019-2) was postponed to the CG-37 meeting. The MSs and ASOs were invited to provide their comments to the SECR. This e-consultation will be tabled for discussion at the CG-37 meeting.

Actions:

1) MS: to provide a public version of the agreed document by 30 August.

1) SECR: to upload a provided public version of the document in the relevant CIRCABC folder.

2) SECR: To open Newsgroup for comments.

2) All: To provide comments by 15 August.

16.4 Harmonisation of the documents for changes applications

The SECR presented a revised proposal how to harmonise the submission of the documents and IUCLID for changes application (CG-36-2019-13) particularly also for UA applications.

In general MSs supported a proposal:

- to include the proposed history-table at the beginning of the PAR to clearly identify the changes compared to the previous version(s), as well as to have an overview of the changes history compiling all changes done to the PAR since the initial approval,
- a IUCLID file needs to be provided including only data relevant for the change,
- the respective supporting document should be included in the application.

As regards a point whether changes should be introduced in the consolidated PAR or via an addendum different opinions were expressed by MSs and ASOs. However, the following compromise agreement was reached:

- for national authorisations the CG members agreed that changes should be introduced in the PAR via an addendum. However, at the renewal stage the PAR should be consolidated.
- for Union authorisation the CG members provided a recommendation which should be forwarded to BPC, i.e., all changes would be necessary to introduce in a consolidated PAR.

Actions:

SECR: to update document in accordance with agreement on the CG meeting.

SECR: to publish the document in the relevant CIRCABC folder.

16.5 Linking of PAR and SPC documents

Due to the absence of the leading MS, the discussion on linking of PAR and SPC documents was postponed to the CG-37 meeting (CG-35-2019-12, CG-35-201913, CG-35-2019-14 and CG-35-201915).

16.6 Accordance check template for UA

The accordance check template for UA, which ECHA had developed for checking the quality of the submitted PARs, was circulated to the CG after the CG-35 meeting for comments. The aim was to collect feedback based on the experience from the MSCAs on the national authorisation evaluation.

During the meeting, the SECR presented a feedback on the comments received and informed that ECHA will take note of the comments received and will start to use this template for the next round of accordance checks for UA submitted in process flow 34. The SECR also encouraged MSs to use this template when finalising the evaluation of their UA applications to confirm whether the PAR is likely to pass the accordance check after submission to ECHA.

Actions:

MSs: to take note of the information.

16.7 AISE organised meeting

AISE representative updated the CG meeting on the AISE organised event which will take place on 18 September.

Actions:

All: To take note of the information.

16.8 Trade names in National authorisation

The CG member asked for a clarification whether trade names are MS-specific as indicated in the CA document (CA-May15-Doc.4.4 – Final.rev4 - Q&A on SPC content.doc) since this would be in conflict with the provisions of the BPR that all MSs during the mutual recognition process need to authorise biocidal products under the same terms and conditions as in the refMS.

Several MSs commented that in accordance with CA document trade names are MS-specific, so that SPC linked to their national authorisation only includes the names authorised in that MS.

Actions:

All: To take note of the information.

7.7 AISE organised meeting

The AISE representative invited the CG members to the event organised by AISE at the local hospital in Brussels on 18 September 2019. Within this event presentations are given (e.g. WHO will give a talk) and a tour in the hospital.

Actions:

All: to take note of the information.

7.8 Information from BPC-31 meeting

The SECR gave feedback from the 31st Biocidal product committee (BPC-31) meeting in relation to an agreement of the developed decision tree for granting shelf life. This decision tree approach is expected to assist the CAs also at the national authorisation level.

In addition, the SECR informed that BPC members agreed on the revised procedure for translation of the SPCs.

Actions:

All: to take note of the information.

17. Agreement of the action points and conclusions

The list of action points and conclusions for the open session was agreed by the CG meeting.

Actions:

SECR: To publish the Action points and conclusions in the relevant S-CIRCABC space.

o0o

Part II - MAIN CONCLUSIONS & ACTION POINTS

36th meeting of the CG

2nd of July – 3rd of July 2019

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 one agenda point on CG meetings and teleconferences.	**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-35	
The draft confidential minutes of the CG-35 meeting were agreed without modifications.	**SECR:** to upload the CG-35 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 informed that three referrals had been closed before the meeting by written procedure. Agreement by consensus was reached for all three cases and the products can be authorised.	**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	
1) An agreement was not reached and one point of disagreement will be further discussed. **2)** An agreement was not reached and three points of disagreement will be further discussed. **3)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **4)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members.	**1) The refMS**: to provide an updated PAR by 10 July. **1) The COM**: to provide a legal clarification for one point of the referral by 10 July. **2) The icMS**: to provide a view on open point of disagreement by 10 July. **2) The refMS**: to provide a view on open point of disagreement by 10 July.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
5) An agreement was reached on three points of disagreement. It will be cross checked whether another point of disagreement is eligible for the referral. **6)** The referral was briefly introduced and the discussion will continue by teleconference.	**3), 4) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **3) The SECR**: to forward one topic for discussion to ECHA. **1), 2) SECR**: To organise a follow up teleconference on 17 July. **6) SECR**: To organise a follow up teleconference after the commenting period is finalised.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA The SECR will present the list of issues identified in Union Authorisations. CG members are invited to review the list of issues and contact ECHA for further information.	**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 - Feedback on e-consultations	
Two e-consultations were discussed and one e-consultation was briefly introduced as it is under commenting: 1) *Interpretation of SoC criteria in BPR guidance (MEA).* CG members did not find an agreement. It is up to the initiating MS to decide whether this point should be discussed at the CA level. 2) *ED assessment of co-formulants by MS*. The discussion will be continued during the CG-37 meeting. 3) *Submission of information in accordance with requirements of Article 89(3)*. This e-consultation is under the commenting phase and the discussion will be continued during the CG-37 meeting.	**2) SECR:** To open Newsgroup for comments. **2) MSs**: To provide comments by 30 July. **3) MSs, ECHA and the COM**: To provide comments by 15 August in the already opened Newsgroup.
7.2 - Update on questions forwarded from CG to ECHA	
The SECR presented an overview of the status of the questions referred from the CG to be addressed by ECHA.	**MSs:** To take note of the information.
7.3 – Mutual recognition of a mutual recognition of a NA	
The CG member presented an updated document on the topic whether mutual recognition of a mutual recognition on NA is possible in accordance with BPR provisions.	**MS:** to provide document for open session by 30 August. **SECR:** to table this topic for discussion during the CG-37 meeting open session.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
Generally, MR of MR is not legally possible. The discussion will be continued during the CG-37 meeting in open session.	
7.4 – How to apply Article 62 of the BPR	
The CG member presented an outcome of the consultation.	**MSs**: to take note of the discussion.
7.5 – CG meetings and teleconferences	
In general, the CG members supported a proposal to have a fixed time slot on Wednesday morning every week for organisation of teleconferences for discussion of referrals.	**MSs:** To take note of the information.
Item 8 – Agreement of the action points and conclusions	
The conclusions and action points were agreed by consensus.	
OPEN SESSION	
9 – Welcome	
10 – Agreement of the agenda	
The agenda for the open session was agreed with two additional points 1) trade names for National authorisation and 2) information from BPC-31 meeting.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.
11 – Declaration of interest in relation to agenda	
No declarations of conflicts of interest were made.	
12 – Draft minutes from CG-35	
The draft non-confidential minutes of the CG-35 meeting were agreed without modification.	**SECR:** to upload the CG-35 minutes into the relevant folders in the CG CIRCABC.
13 – Administrative issues	
No administrative issues were tabled for discussion.	
14 – Harmonisation of technical and procedural issues in relation to product authorisation	
14.1 - Preparation for the second renewal of AVK PT14 products	
14.1.1 Update of WG discussions	
The SECR updated the meeting on the progress of the WG on dermal absorption and application of a study on surface water.	**All**: To take note on the information.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
Item 15 – Feedback from working parties	
15.1 - Agreement of WP recommendations	
SECR updated the CG members that the revised version of the CA document has been prepared for the CA meeting, considering the CG agreed document for assessment of similarity in biocidal product families.	**All:** To take note of the information.
15.2 – Follow up on the WP on frequently used sentences in the SPC	
The SECR presented a status of the update of the list of frequently used sentences for the SPC including on the timelines, indicating that the third commenting period has been initiated for the updated list of sentences.	**MSs:** to provide comments on the proposal and the prepared documents by 12 July.
16 – Any Other Business	
16.1 - List of active substances meeting the exclusion or substitution criteria	
The SECR presented the report available for information.	**Rapporteur MS**: To check the new information and report to CG-SECR by 12 July. **SECR**: To transmit the updated version to COM to make it publicly available on CIRCABC. If relevant, to produce an updated version for next CG meeting.
16.2 - IT issues	
ECHA informed on preparation for the next IT user group meeting in November. One CG member will present issues and needs from the MSs in the next IT user group meeting.	**SECR**: To open a Newsgroup for feedback. **MSs:** To provide feedback by 15 August. **SECR**: To table this topic for discussion during the CG-37 meeting.
16.3 - Feedback on e-consultations	
Two e-consultations have been tabled for discussion for the open session. 1) *Co-formulant as potential active substance*. The outcome of this e-consultation was agreed. 2) *Anti-allergen claim.* The discussion will be continued during the CG-37 meeting.	**1) MS:** to provide a public version of the agreed document by 30 August. **1) SECR:** to upload a provided public version of the document in the relevant CIRCABC folder. **2) SECR:** To open Newsgroup for comments. **2) All**: To provide comments by 15 August.
16.4 – Harmonisation of the documents for changes applications	

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
The SECR presented an updated proposal how to harmonise the submission of the documents and IUCLID for changes application, particularly also for UA applications. The CG members agreed on the way forward.	**SECR**: to update document in accordance with agreement on the CG meeting. **SECR**: to publish the document in the relevant CIRCABC folder.
16.5 – Linking of PAR and SPC documents	
This item will be discussed during the CG-37 meeting.	
16.6 – Accordance check template for UA	
The SECR presented a feedback on the comments received on accordance check template to be used for Union Authorisation applications.	**MSs**: To take note of the information.
16.7 – AISE organised meeting	
AISE representative updated CG members on the AISE organised event which will take place on 18 September.	**All:** To take note of the information.
16.8 – Trade names in National authorisations	
The CG member asked the clarification whether trade names are MSs specific.	
16.9 – Information from BPC-31 meeting	
The SECR provided feedback from the BPC-31 meeting.	**All:** To take note of the information.
17 – Agreement of the action points and conclusions	
The list of action points and conclusions for the open session was agreed by the CG meeting.	**SECR:** To publish the Action points and conclusions in the relevant S-CIRCABC space.

oOo

Part IV - List of Annexes

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

ANNEX II Final agenda

ANNEX II

Final agenda

36th meeting of the Coordination Group (CG-36)

2 July – 3 July 2019

on 2 July 2019 from 09:30 to 18:00
on 3 July 2019 from 09:00 to 16:00

Venue:

2 July
Albert Borschette Conference Centre
Rue Froissart 36
Room 4D
1040 Brussels
Belgium

3 July
Commission building DG Education and Culture
Rue Joseph II 70
Room 00/013
1000 Brussels
Belgium

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-36-2019

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 – Draft minutes from CG-35

CG-M-35-2019_Draft confidential

For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-36-2019-10

For information

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

Links to disagreements

For discussion and agreement

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

6.1 Issues identified in the context of UA

CG-36-2019-14

For information

Item 7 - Any Other Business

7.1 Feedback on e-consultations

CG-36-2019-03, CG-36-2019-05, CG-36-2019-06,
CG-36-2019-07, CG-36-2019-09
Links to e-consultations

For discussion and agreement

7.2 Update on questions forwarded from CG to ECHA

CG-36-2019-11

For information

7.3 Mutual recognition of a mutual recognition of a NA

CG-36-2019-04

For discussion and agreement

7.4 How to apply Article 62 of the BPR

For discussion

7.5 CG meetings and teleconferences

For discussion and agreement

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-36-2019

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 – Draft minutes from CG-35

CG-M-35-2019_Draft non confidential

For agreement

Item 13 – Administrative issues

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

14.1 Preparation for the second renewal of AVK PT14 products

14.1.1 PT14 – Update of WG discussions

For information

Item 15 – Feedback from working parties

15.1 BPF WP recommendations - update from the CA meeting

For information

15.2 Follow up on the WP on frequently used sentences in the SPC

For information

Item 16 – Any Other Business

16.1 List of active substances meeting the exclusion or substitution criteria

CG-36-2019-08

For information

16.2 IT issues

For information

16.3 Feedback on e-consultations

CG-36-2019-01, CG-36-2019-02,
CG-36-2019-12
Links to e-consultations
For discussion and agreement

16.4 Harmonisation of the documents for changes applications

CG-36-2019-13
For discussion and agreement

16.5 Linking of PAR and SPC documents

CG-35-2019-12, CG-35-2019-13,
CG-35-2019-14 & CG-35-2019-15
Links to CG-35 meeting folder
For discussion

16.6 Accordance check template for UA

For information

16.7 AISE organised meeting

For information

16.8 Trade names in National authorisation

For information

16.9 Information from BPC-31 meeting

For information

Item 17 – Agreement of the action points and conclusions

For agreement

o0o