20 November 2019

CG-M-37-2019 non-confidential

Final non-confidential minutes of the 37th meeting of the Coordination Group (CG)

16-17 September 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-seventh Coordination Group meeting (CG-37). 29 members and experts from 21 Member State Competent Authorities (MSCAs), Norway, Switzerland, Serbian Observer and 3 participants from 1 Accredited Stakeholder Organisation (ASO), participated in the meeting. Three 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-37-2019) and invited participants to add any items under AOB. Two agenda points were added to the AOB of the closed session on product authorisation with high concentration of active substance and stability test for mosquitos nets. The agenda was agreed with this modification.

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-36

The Chair explained that the draft non-confidential CG-36 minutes had been uploaded for commenting via Newsgroups. Comments were received from one CG member during the commenting period and the minutes were updated considering the comments. CG members agreed with the confidential draft minutes from the CG-36 meeting.

Actions:

SECR: to upload the CG-36 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-37 meeting, four referrals were discussed during the teleconferences on 17 July and 28 August, and two referrals were discussed via CIRCABC only. An agreement by consensus was reached for five 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

Six referrals were tabled for discussion.

1) A referral was discussed concerning a PT18 product containing imidacloprid as an active substance. The disagreement was related to the technical content of the active substance, specific instruction for use, risk mitigation measures (RMM) and on the validity of the submitted efficacy data against certain target organisms. The SPC was amended by the refMS. An agreement was reached on the points of disagreement by consensus. This referral is therefore closed.

2) A referral was discussed concerning a PT19 product containing IR3535 as an active substance. The disagreement was related to the expression of the application rate for non-professional users in a manner which would avoid over or under application. The CG agreed how to express the application rate for this particular product. An agreement was reached on the point of disagreement by consensus. This referral is therefore closed.

3) A referral was discussed concerning PT18 product containing permethrin as an active substance. The disagreement was related to a particular use of the product. The other points of disagreement were related to the human health exposure assessment (use of scenario and migration rate value) and the environmental risk assessment. The CG agreed by consensus on the use of the scenario for human health exposure assessment. No agreement reached on three other disagreement points. This referral will be further discussed at the teleconference.

4) A referral was discussed concerning PT19 product containing IR3535 as an active substance. The disagreement points were related to the appropriateness of the study to demonstrate the efficacy, and classification and labelling of the product. The CG members agreed by consensus on the point of disagreement in relation to the classification and labelling. No agreement was reached on a disagreement point on the appropriateness of the data package to demonstrate the efficacy. The latter will be referred to the Commission by the refMS. This referral is therefore closed.

5) A referral was discussed concerning PT19 product containing IR3535 as an active substance. The disagreement points were related to the appropriateness of the studies to demonstrate the efficacy. The CG members agreed by consensus that the product is sufficiently effective against particular target organism and authorisation can be granted for this use. No agreement was reached on a disagreement point on the appropriateness of the data package to demonstrate the efficacy for other target organisms. The latter point of disagreement will be referred to the Commission by the reference Member State. This referral is therefore closed.

6) A referral was discussed concerning a PT18 product containing S-Methoprene as an active substance. The points of disagreement were related to the human dietary assessment, the refinement of the environmental risk assessment through modelling and the human health risk assessment in relation to the dermal absorption. The CG agreed by consensus on the points of disagreement related to the human health risk assessment. The point of the environmental risk assessment will be further discussed at the teleconference.

Actions:

1), 2), 4), 5) SECR: to follow-up the outcome of the referrals as stated in the Working Procedures.

3) The icMS: to provide input on one point of disagreement by 24 September.

5), 6) The refMS: to refer the points of disagreement to the COM.

3), 6) SECR: To organise a follow up teleconference tentative on 26 September.

6) The refMS: to provide information by 20 September.

6) All MSs: to cross check the refMS provided information by 25 September.

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-37-2019-14). 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

7.1. Late procedures

The SECR briefly invited MSs to take note of the reports and reminded that proposed that the information on late procedures will be prepared twice per year.

Actions:

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

7.2. Feedback on e-consultations

Two e-consultations were discussed.

1) ED assessment of co-formulants by MS

A MS presented an updated proposal of the outcome of e-consultation related to ED assessment of co-formulants (CG-37-2019-11). The Commission, MSs and ECHA discussed the revised document and since there were still some deviating views of the document between the Commission, MSs and ECHA, it was concluded that an additional commenting period is necessary. The discussion will continue at the CG-38 meeting.

2) Article 20(1)(a)(i) and Article 61 of BPR

A CG member briefly introduced an e-consultation on a matter in relation to Article 20(1)(a(i) and Article 61 of the BPR of the BPR (CG-37-2019-16).

Since this e-consultation is under commenting, the discussion will be continued during the CG-38 meeting.

Actions:

1) SECR: To open Newsgroup for comments.

1) MSs: To provide comments by 8 October.

2) MSs: To provide comments by 4 October in the already opened Newsgroup.

7.3. 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-37-2019-13).

Actions:

MSs: To take note of the information.

7.4. Election of the Chair

The SECR informed that the term of the CG Chair will finish at the beginning of 2020. The CG members were invited to nominate candidates for the CG Chair by informing the CG SECR.

The CG members were informed that the election of the new Chair will take place in the CG-39 meeting.

Actions:

MSs: To nominate candidates for the CG Chair.

7.5. Organisation of CG-39 meeting

The SECR informed that the schedule of the CA meeting will be changed in 2020. It is planned to have the CA meetings in February, May, September and December. Thus, if this schedule will be agreed in the Commission internal services, also CG-39 will take place back to back with the CA meeting at the beginning of February.

The SECR also informed that:

- it will be considered whether it is possible to organise virtual CG meetings in between February – May and September-December. If virtual meetings will take place it should be discussed whether those CG meetings will be dedicated only for discussion of the formal referrals.
- there is a plan to have a CG meeting in July 2020.

The SECR will prepare the provisional CG meeting dates for 2020 and present them to the CG as soon as the CA meeting dates will be confirmed.

Actions:

MSs: to take note of information.

SECR: to prepare the draft plan for the CG meeting on 2020 and provide it for CG-38 meeting.

7.6. Product authorisation with high concentration of active substance

A MS briefly introduced the topic in relation to the authorisation of the product with high concentration of active substance.

A MS was asked to provide a document and to initiate an e-consultation.

Actions:

MS: to provide document to be discussed through an e-consultation.

7.7. Stability test for mosquitos nets

A MS briefly introduced the topic and asked other MSs' view in relation to the stability test for mosquitos nets. This point will be further discussed through e-consultation.

Actions:

MS: to provide document to be discussed through an e-consultation

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. Three observers from one ECHA accredited stakeholder organisation (ASO) 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-37-2019) and invited CG members and ASOs to propose any other items under AOB. No additional items were proposed and the agenda was agreed.

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-36

The Chair explained that the draft non-confidential CG-36 minutes had been uploaded for commenting via Newsgroups. Comments were received from one CG member during the commenting period and the minutes were updated considering the comments. CG members agreed with the non-confidential draft minutes from the CG-36.

Actions:

SECR: to upload the CG-36 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 CG member would provide a discussion document for dermal absorption for the HH WG (another CG member 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 Commission updated the CG members that the CA document in relation to the assessment of similarity in biocidal product families has been agreed during the July CA meeting.

The guidance is applicable for the new BPF applications from October 2019. However, it can be also applied for existing applications if the agreement with applicant is reached.

Actions:

All: To take note of the information.

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

The SECR informed the CG members that all comments for the frequently used sentences have been taken considered and incorporated in the final version of the list. No more comments are expected.

Both lists, a clean version and one with track changes, are available on the CIRCABC Newsgroup. The SECR informed that sentences without any indication for currently available PTs were deleted. The MSs were asked to include the translations on both revised and the newly added sentences. After all translations have been received, the document will be finalised and published on the ECHA website.

The SECR also noted that due to the gathered experiences of the procedure to update the list, the SECR will propose a revision of the procedure on the maintenance of the list and will present it at the next CG meeting.

Actions:

MSs: to provide translations by 30 September into the opened Newsgroup.

The SECR: to prepare the revised proposal on procedure to maintain the list of frequently used sentences in the SPC.

The SECR: To table a revised procedure for discussion during the CG-38 meeting.

16 – Any Other Business (open session)

16.1 Trends in product authorisation

The Chair invited the meeting to take note of the reports in document CG-37-2018-06 and CG-37-2018-07, which were made available for information.

16.2 Deadlines for application for product authorisation

The Chair invited the meeting to take note of the report in document CG-37-2018-08, which was made available for information.

16.3 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-37-2019-10).

Actions:

Rapporteur MS: To check the new information and report to CG-SECR by 30 September.

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.

16.4 IT issues

16.4.1 Preparation for the next IT user group meeting

The SECR presented some news which will be introduced in the next version of R4BP3 and SPC, e.g.:

- The new version releases are post-pond and will take place in February 2020,
- The commenting possibility for each field of SPC will be introduced for ad-hoc communications between applicant and MSs. It will be possible to edit comments and delete them in SPC. In R4BP3 for official step only SPC without comments will be possible to upload. Thus, there will be function to delete all comments.
- The MSs will be able to send multiple ad-hoc communications in R4BP3 for which reply is required.
- New automatic messages will be introduced in R4BP3 to inform MSs when task is performed in group submission of mutual recognitions in parallel.

During the CG-36 meeting in preparation for the next IT-user group meeting MSs were invited to provide feedback on the issues and needs from MSs related to the IT tools. The Chair presented a list summarising received feedback. Few new entries were included by the MS during the meeting in relation to the R4BP3.

The list with some additions was agreed by the CG and will be presented in the next IT user group meeting, which will take place in November, by the CG Chair.

Actions:

SECR: To forward a list to ECHA IT colleagues.

16.5 Feedback on e-consultations

Two e-consultations were tabled for discussion.

1) Anti-allergen claim

A MS presented a proposal for the outcome of an e-consultation related to anti-allergen claim (CG-37-2019-02). This e-consultation was previously briefly presented at closed session of the CG-35 meeting and discussed at the open session of the CG-36 meeting.

The Commission and MSs discussed the proposal, the MSs agreeing that this particular an anti-allergen claim is not a biocidal claim. Several MSs remarked that for this reason there is no need to evaluate the anti-allergen claim.

However, the Commission services noted, that there is no provision in the BPR that explicitely prevents the use of such claim and therefore it should be assessed in a casy-by-case basis. Nevertheless, it was concluded that Commission's view is necessary and it will be provided in writing.

This e-consultation will be further discussed at the CG-38 meeting. If this discussion does not lead to an agreement, this matter will be forwarded to a CA level.

Furthermore, the MS informed the CG members that they are preparing a document on non-biocidal claims in general for a submission to CA discussion.

2) Responsibility of submission of information in accordance with requirements of Article 89(3)

A MS introduced the conclusions of an e-consultation on submission of information in accordance with requirements of Article 89(3) of the BPR (CG-37-2019-15). This e-consultation was previously discussed in the CG-35 meeting during the closed session.

The consultation was on the interpretation of Article 89(3) whether it is applicant's responsibility to submit all necessary information about the products that are currently on the relevant MS' market, which are included in the Union or National product authorisation

application, to allow the MS to make all necessary prolongations for the existing authorisations.

The majority of the MSs agreed that where several companies are involved in an application and/or where a company(s) relies on another company or consultant to act as an applicant, it is applicant's responsibility to collaborate and coordinate to ensure that all parties' products are clearly identified in the application.

Some MSs commented that this should be the future authorisation holder responsibility to comply with requirements of Article 89(3) of the BPR.

ASO commented that they would like to review the document and provide comments in writing. The discussion will continue during the CG-38 meeting.

Actions:

1) The COM: to provide clarification in written form by 4 October.

2) SECR: To open Newsgroup for comments.

2) ASOs: To provide comments by 8 October.

1), 2) SECR: to table e-consultations for discussion and agreement during the CG-38 meeting.

16.6 Mutual recognition of a mutual recognition of a NA

A CG member presented the updated document on whether mutual recognition (MR) of a mutual recognition (MR) of national authorisation (NA) is possible in accordance with the BPR provisions (CG-37-2019-01). This document was previously discussed during the CG-35 and CG-36 meeting during the closed sessions.

During the CG-37 meeting, the CG agreed that from the legal perspective BPR does not foresee MR based on other MR of a NA. In case if such application is submitted through R4BP3 it should be rejected by the MS.

One exception was agreed, i.e., MR of MR of a national authorisation can be accepted where the initial authorisation does not exist anymore. However, for these applications an agreement by a MS to act as a new refMS would be necessary.

Actions:

MS: to provide document to be published in the public CIRCABC by 8 October.

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

16.7 Linking of PAR and SPC documents

A CG member presented an approach how to link PAR and SPC documents (CG-35-2019-12, CG-35-201913, CG-35-2019-14 and CG-35-2019-15) in order to prepare a draft PAR template for biocidal product families.

The CG members were invited to take note of this information.

Actions:

MSs: 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.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

37th meeting of the CG

16th of September – 17rd of September 2019

Agenda point Conclusions / decisions / minority positions	Action requested after the meeting by whom/by when
CLOSED SESSION	
1 – Welcome	
2 – Agreement of the agenda.	
The agenda for the closed session was agreed with the addition of two agenda points (a) product authorisation with high concentration of active substance, (b) stability test request for mosquito nets.	**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-36	
The draft confidential minutes of the CG-36 meeting were agreed with minor modifications.	**SECR:** to upload the CG-36 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 five referrals had been closed before the meeting by written procedure. Agreement by consensus was reached for all five 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 reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **2)** An agreement was reached by consensus and this referral is therefore closed. The outcome of the referral was agreed by the CG members. **3)** One point of disagreement was closed. The discussion will be continued by teleconference for the remaining open points. **4)** An agreement was reached on the one point of disagreement. No agreement reached on the one point	**1), 2), 4), 5) SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures. **3) The icMS:** to provide input on one point of disagreement by 24 September. **5), 6) The refMS**: to refer the points of disagreement to the COM.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
of disagreement. This point will be referred to the COM by the refMS. The referral is closed. **5)** An agreement was reached on the one point of disagreement. No agreement reached on one point of disagreement. This point will be referred to the COM by the refMS. The referral is closed. **6)** An agreement was reached by consensus on two points of disagreement. No agreement reached on the one point of disagreement. This will be discussed further via the teleconference.	**3), 6) SECR**: To organise a follow up teleconference tentative on 26 September. **6) The refMS**: to provide information by 20 September. **6) All MSs:** to cross check the refMS provided information by 25 September.
5.3 Clarification points for submission of formal referrals	
The SECR provided clarification as regards of submission of the referrals and organisation of CG meetings.	**MSs:** To take note of the information.
6 - Harmonisation of technical and regulatory issues in relation to product authorisation	
6.1 - Issues identified in the context of UA The SECR presented 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 Late procedures	
The SECR presented the overview of late procedures.	**MSs:** to review the document and communicate to ECHA any inaccuracies in the data.
7.2 - Feedback on e-consultations	
One e-consultations was discussed and one e-consultation was briefly introduced as it is under commenting: *1) ED assessment of co-formulants by MS*. The discussion will be continued during the CG-38 meeting. *2) Article 20(1)(a)(i) and Article 61 of BPR*. This e-consultation is under the commenting phase and the discussion will be continued during the CG-38 meeting.	**1) SECR:** To open Newsgroup for comments. **1) MSs**: To provide comments by 8 October. **2) MSs**: To provide comments by 4 October in the already opened Newsgroup.
7.3 - 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.
7.4 – Election of the Chair	
The SECR informed that the CG Chair term will finish in May 2020. CG members were invited to nominate for the CG Chair.	**MSs:** to nominate for CG Chair.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
7.5 – Organisation of CG-39 meeting	
The SECR briefly updated the CG on the provisional planning of the CG meetings for 2020.	**MSs:** to take note of information. **SECR:** to prepare the draft plan for the CG meeting on 2020 and provide it for CG-38 meeting
7.6 – Product authorisation with high concentration of active substance	
The MS briefly introduced the topic. This topic will be further discussed through an e-consultation.	**MS:** to provide document to be discussed through an e-consultation.
7.7 – Stability test for mosquitos nets	
The MS asked other MSs view in relation to the stability test for mosquitos nets. This point will be further discussed through an e-consultation.	**MS:** to provide document to be discussed through an e-consultation
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.	**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-36	
The draft non-confidential minutes of the CG-36 meeting were agreed with minor modification.	**SECR:** to upload the CG-36 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.	**All**: To take note on the information.
Item 15 – Feedback from working parties	
15.1 - Agreement of WP recommendations	
The COM updated the CG members that the CA document on the assessment of similarity on BPF has	**All:** To take note of the information.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
been agreed during the July CA meeting. The COM informed about the CA document applicability.	
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 translations for new and updated sentences have been requested from the MSs. The SECR invited the CG members to consider whether the procedure to maintain the list of frequently used sentences in the SPC should be revised, considering practical experience. CG members agreed that procedure should be revised.	**MSs:** to provide translations by 30 September into the opened Newsgroup. **The SECR:** to prepare the revised proposal on procedure to maintain the list of frequently used sentences in the SPC. **The SECR**: To table a revised procedure for discussion during the CG-38 meeting.
16 – Any Other Business	
16.1 – Trends in product authorisation	
The Chair presented the reports, available for information.	
16.2 – Deadlines for application for product authorisation	
The Chair presented the report, available for information.	
16.3 - List of active substances meeting the exclusion or substitution criteria	
The Chair presented the report available for information.	**Rapporteur MS**: To check the new information and report to CG-SECR by 30 September. **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.
16.4 - IT issues	
16.4.1 – Preparation for the next IT user group meeting	
The Chair updated CG on the comments received on the issues and needs from MSs related to the IT tools. MSs agreed on information which should be provided in the next IT user group meeting by the CG Chair.	**SECR**: To forward a list to ECHA IT colleagues.
16.5 - Feedback on e-consultations	
Two e-consultations have been tabled for discussion for the open session. 1) *Anti-allergen claim.* The discussion will be continued during the CG-38 meeting. 2) *Responsibility of submission of information in accordance with requirements of Article 89(3).* The discussion will be continued during the CG-38 meeting.	**1) The COM:** to provide clarification in written form by 4 October. **2) SECR:** To open Newsgroup for comments. **2) ASOs**: To provide comments by 8 October.

Agenda point	Action requested after the meeting
Conclusions / decisions / minority positions	**by whom/by when**
	1), 2) SECR: to table e-consultations for discussion and agreement during the CG-38 meeting.
16.6 – 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. The document was agreed.	**MS:** to provide document to be published in the public CIRCABC by 8 October. **SECR:** to publish the document in the relevant CIRCBC folder.
16.7 – Linking of PAR and SPC documents	
The CG member presented their experience on how to link PAR and SPC documents.	**MSs:** 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.

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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

Final agenda

37th meeting of the Coordination Group (CG-37)

16 September – 17 September 2019

on 16 September 2019 from 13:30 to 18:00
on 17 September 2019 from 09:00 to 17:00

Venue:

Albert Borschette Conference Centre
Rue Froissart 36
Room 5B
1040 Brussels
Belgium

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-37-2019
For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-36

CG-M-36-2019_Draft confidential
For agreement

Item 5 – Formal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-37-2019-12
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

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-37-2019-14

For information

Item 7 - Any Other Business

7.1 Late procedures

CG-37-2019-04; CG-37-2019-05

For information

7.2 Feedback on e-consultations

CG-37-2019-11

Links to e-consultations

For discussion and agreement

7.3 Update on questions forwarded from CG to ECHA

CG-37-2019-13, CG-37-2019-16

For information

7.4 Election of the Chair

For discussion and agreement

7.5 Organisation of CG-39 meeting

For information

7.6 Product authorisation with high concentration of active substance

For information

7.7 Stability test for mosquitos nets

For information

Item 8 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 9 – Welcome

Item 10 – Agreement of the agenda

CG-A-37-2019

For agreement

Item 11 – Declaration of interest in relation to the agenda

Item 12 –Draft minutes from CG-36

CG-M-36-2019_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 Trends in product authorisation

CG-37-2019-06; CG-37-2019-07

For information

16.2 Deadlines for application for product authorisation

CG-37-2019-08

For information

16.3 List of active substances meeting the exclusion or substitution criteria

CG-37-2019-10

For information

16.4 IT issues

16.4.1 Preparation for the next IT user group meeting

CG-37-2019-03

For discussion

16.5 Feedback on e-consultations

CG-37-2019-02; CG-37-2019-09;
CG-37-2019-15
Links to e-consultations
For discussion and agreement

16.6 Mutual recognition of a mutual recognition of a NA

CG-37-2019-01
For discussion

16.7 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 information

Item 17 – Agreement of the action points and conclusions

For agreement

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