

CG-M-2-2013 FINAL PUBLIC
Agreed via written procedure
14 February 2014

**Final minutes of the 2nd meeting of the
Coordination Group (CG)**

10 December 2013

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair welcomed participants to the second meeting.

The Chair informed the meeting of the participation of 33 members from 23 Member State Competent Authorities (MSCAs). Two representatives from DG ENV and one from DG ENTR from the European Commission and the ECHA Secretariat, and three observers from ECHA accredited stakeholder organisations (ASOs) were present for the full meeting and the open session of the meeting, respectively, two of which had experts accompanying them, were present for the open session of the meeting. An applicant also attended for one of the disagreements under item 6 of the agenda. The list of attendees is given in Part III of the minutes.

2. Agreement of the agenda

The Chair introduced the revised draft agenda (CG-A-2-2013) and invited any items under AOB. The agenda was agreed subject to modifications, agenda items 8.1 and 9.1 being dealt with in the closed session and the addition of two further items (9.2 and 9.3) under AOB.

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

3. Declaration of interest in relation to agenda

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

4. Agreement of the draft minutes from CG-1

The Chair proposed that the minutes would only make reference to 'a member', rather than naming countries or individuals, unless a member specifically requests their contribution to be attributed to them. This approach will protect the independence of CG members and would be consistent with the approach taken in the Biocidal Products Committee. Applicants will be referenced as such in the minutes and by their company name in Part III - List of Attendees; further details will be provided in a confidential annex to the minutes. The revised draft minutes were agreed.

Action:

The Secretariat to finalise the minutes and upload to CIRCABC.

5. Administrative issues

5.1. Housekeeping issues

The SECR explained the idea behind the closed and open sessions and that CG-2 is still to be considered a "transitional" meeting with regard to properly distinguishing between open and closed sessions. The SECR also pointed out that the 10 day deadline before the CG meeting needs to be respected when circulating meeting documents.

It was commented by a member and agreed that the current classification of the documents, i.e. "Internal" will be changed in the future into either "Confidential" or "Non Confidential".

Members also commented on the current upload of the documents on CIRCA BC and would wish to have all meeting documents in the same folder on CIRCA BC.

Action:

All: respect the 10 day deadline for circulating meeting documents.

SECR: to use classification "confidential" and "non-confidential" for the future documents (instead of current "internal").

SECR: all meeting documents to be stored in the same folder in the CG CIRCA BC.

5.2. Election of the Chair and Vice-Chair

The Secretariat introduced paper CG-2-2013-01. A member had been nominated for the position of the Chair of the CG, and another member for the position of the Vice-Chair. The nominations were unanimously supported by the members of the CG and therefore the members were duly elected as Chair and as Vice-Chair.

Action:

SECR and Chairs: to define the role of Chair and Vice-Chair for discussion at a future meeting.

5.3 CG Rules of Procedure

The revised draft CG Rules of Procedure (RoPs) were presented by the SECR in document CG-2-2013-02.

The SECR explained that following the previous discussion at CG-1, a number of changes had been made in the revised draft. In particular, Article 2 of the RoPs to specify only one representative per MSCA should be permitted to attend the CG, but advisers could accompany the representative. Article 13 should be clarified to ensure that voting could be carried out by proxy and that decision-making should preferably be by consensus, but if that fails be on the basis of a two thirds majority approach, which is more stringent than that originally proposed.

A discussion followed in which the following issues were raised. Several members proposed that Article 1(c) should be amended to better describe that when the CG discusses scientific and technical issues, these should be discussed at a level that is appropriate to address to specific issues arising in the context of mutual recognition of national product authorisation. While issues requiring a more policy or scientific consideration can be referred to other fora, the CG may discuss other technical issues related to product authorisation in order to avoid future disagreements. In relation to Article 2 several members proposed that there be sufficient flexibility to allow the MSCA Contact Points to be backed up in times of absence or holidays. The SECR proposed therefore that an alternate Contact Point be permitted. These aspects were agreed in principle and the RoPs were to be revised accordingly.

A more substantial discussion took place in relation to the basis for agreement as described in Article 13. Several members expressed the view that the CG does not have a mandate to make decisions and noted that there is no scope for appeal following agreement at the CG. The basis for agreement therefore should be consensus alone. COM agreed that there is no basis for appeal, but was concerned that if consensus is the only basis for agreement at the CG, this could result in Member States taking nation positions with the consequence that disagreements are frequently dealt with by the Commission.

After further discussion, it was agreed that the basis for agreement on disagreements in mutual recognition at the CG would be by consensus. However, all members were requested to use their best endeavours to reach consensus and minimise the number of disagreements referred onwards to the Commission. In the event that one or several members disagree with the majority view, the minority position would be communicated to the Commission and recorded in the minutes of the meeting. It was also agreed that procedural matters could be agreed by the CG by two thirds majority of members with the right to vote.

Actions:

SECR to revise the RoPs on the basis of the discussion with a view to reaching agreement at the next meeting. Alternate Contact Points were to be granted access to CIRCABC.

5.4 Working procedures and templates

The SECR introduced documents CG-2-2013-03, 04 & 05 and explained that following the previous discussion at CG-1, the whole working procedure document (CG-2-2013-03) has been re-worked.

Several members commented that the document should emphasise more that the informal exchange should always take place between the concerned and reference Member States (cMS; rMS) and COM also recommended the involvement of all other concerned Member States. This informal discussion should exhaust all possibilities for finding an agreement. This comment is also relevant to the templates for submitting disagreements to the SECR. Members commented that the templates should also be signed off not only by the cMS but also by the rMS.

Several members commented on the timelines for the formal disagreement. While it was recognised that the timeline for a formal referral is 60 days, the timelines for commenting and addressing the comments foreseen in the draft working procedures were found to be too short.

The CIRCA BC structure was also commented on. Several members would prefer to have all documents relevant to the CG meetings in one folder.

With regard to the templates several comments were made and additional fields were proposed by members of the CG (adding R4BP2 Reference Number, reference to the SPC section, possibility to indicate whether the referral should be discussed in an open or closed session of the CG).

Actions:

SECR to revise the working procedures and templates on the basis of the discussion with a view to reaching agreement at the next meeting.

6. Disagreements on mutual recognition

Referral 1 was discussed. The applicant represented by 2 people attended the meeting. The concerned MS introduced the disagreement. The applicant submitted a new study when commenting on the disagreement.

The rMS questioned why the formal disagreement was initiated while their experts were still engaged in the discussion about the product authorisation. They also questioned why the cMS disagrees with the toxicological assessment while during their discussion it seemed like an efficacy issue.

The cMS argued that the problem was the doses given that would also need to be considered in the environmental and human health risk assessment. They also said that in the new field study that was just submitted by the applicant, some details, i.e. the area where the product is applied, are missing.

In agreement with the COM, it was decided that as the bilateral discussions were still on-going between the concerned and reference MS, the disagreement will be taken back to the "informal" stage and the MS will be asked to continue with their bilateral discussions. As it was also pointed out by several members during the general discussion on agenda point 5.4, the bilateral informal discussion is essential before initiating the formal stage. It was also emphasised that it is one of the very first disagreements and the procedures are not yet agreed on.

Referral 2 was discussed. The applicant did not attend the meeting for this agenda point. The cMS explained that they had three points for disagreement and two out of those three have already been settled between the concerned and reference MS. The discussions are on-going to agree on the remaining point.

In agreement with the COM and in line with the previous disagreement it was decided also for this case, to take the disagreement back to the informal stage and let the cMS and rMS to continue with the dialogue.

Actions:

cMS and rMS: to discuss further keeping in copy all other concerned MS.

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

The Commission informed the meeting on the state of play of the on-going notifications as reported in document CG-2-2013-10. For the following notifications, additional information was provided:

1.- Notifications on chlorophacinone containing products: the notifying MS is reconsidering the notifications in the light of a Commission decision taken a few months ago on a similar notification sent by The Netherlands (click [here](#)). Taking into account of the comments received for those notifications, The Commission is going to propose to ECHA to launch a review of the TNG on efficacy of rodenticides. This will enable an open discussion on whether a further consideration of the type and bait composition might be suitable in the context of reading-across for efficacy data. The RefMS for the contested products also supported this approach.

2.- Notifications on wood preservatives involving automated dipping application: a draft decision based on the agreement reached at CG-1 has been tabled for the CA meeting covering all the notifications received. The Commission stressed that this decision is the first one taken according to the BPR legal basis (Article 36), so addressed to all MSs. In this context, The Commission further explained some general aspects regarding the impact of Commission decisions taken in the context of MR disagreements:

- Decisions are addressed to all MSs (and not only to the CMSs involved in the specific MR procedure that triggered the Decision). Therefore, the provisions in a given Decision shall apply to:

a) the product(s) authorised by the RefMS,

b) to any product in any CMS which has been already authorised, or is going to be authorised, through MR of the product authorisation(s) in the RefMS. That is why the application reference code in the RefMS provided by the R4BP2 has been chosen as the common identifier of the product authorisations in any MS, even if the application for MR was submitted by another applicant or under a different product name.

Those provisions will have also an effect on subsequent applications for MR in sequence, and vice versa, a decision taken on an application for MR in sequence in a new CMS can affect products already authorised in other MSs. Thus, The Commission encouraged all MSs to closely follow the discussions on MR disagreements in order to raise any comments or concerns at the right moment (i.e. CG discussions).

- The provisions in a Decision (e.g. amending the terms and conditions of an existing authorisation) have to be implemented by MSs within 30 days of notification of the decision (which takes place at an earlier stage than the publication in the official journal).

- Article 52 of the BPR also applies for the disposal, making available on the market and use of existing stocks of the products affected by the Commission decision.

The notifying MS mentioned that two of notifications addressed by the draft decision do also cover additional issues (e.g. spraying outdoors). In order to avoid applicants to change the labelling of their products twice, a single decision covering all the issues for each specific product would be suitable. The Commission agreed on this approach and mentioned that the current proposal is based on the possibility that the other issues were

solved during the commenting period. If not, the two products will be removed from this draft decision and be addressed separately.

3.- Notifications on wood preservatives classified as skin sensitizers: The Commission briefly described the grounds for the draft decision tabled for the CA meeting and mentioned that the notifying MS accepts to authorize the products as proposed by the Decision, but still disagrees on the pack size issue. A MS submitted comments before the CA meeting and expressed its concerns on this specific case, as it can set a precedent in terms of authorisation of skin sensitizers for non-professional users.

In connection with these comments and concerns, some technical aspects linked to the assessment performed by the RefMS leading to a safe use of the products without any PPE will be further discussed at the next CG meeting in January.

4.- Notification on a wood preservative (efficacy issue): the notifying MS informed the meeting that such notification had been withdrawn on the basis of the explanations provided by the RefMS during the commenting period.

Actions:

COM: to forward documents (PAR and comments submitted by MSs) on two of the 4(4) notifications to the CG (via the SECR) for the CG to assess the technical and scientific grounds for the risk assessment.

SECR: to include the point in the agenda of the January 2014 CG meeting.

8. Transitional item: harmonisation of scientific and technical issues in relation to product authorisation

8.1.a TM discussion on dermal absorption value for products containing bromadiolone

A MS introduced document CG-2-2013-21. Another MS raised the issue of the potential impact of the proposed approach for already authorised products. The Commission clarified that the adoption of the document does not mean a retrospective application of its content and that document CA-July12-Doc.6.2d-Final on "Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products" applies. Where appropriate, the proposed approach could be applied at the renewal stage.

The meeting concluded to accept the outcome from discussions at TM III and IV and utilise the amended dermal adsorption default value, where appropriate, for similar formulations containing bromadiolone. The point was considered closed.

Actions:

SECR: to include outcome for consideration in updates to technical guidance documents.

8.1.b TM discussion on effect values for imidacloprid and questions from TM to the CG

A MS introduced this agenda item and reminded that TM concluded that the new data on aquatic ecotoxicity by Roessink *et al.* (2013) are valid and reliable and should therefore be considered for risk assessment. New data on this topic is also expected to be available in another MS by the end of 2013, and the applicant was committed to submitting a new study to that MS and the rapporteur MS in order to show that the existing information in the CAR is compatible with the abovementioned findings.

Concerning the question from TM to know in which way the CAR had to be updated, the meeting considered that the rapporteur MS for the active substance should take into account the new information generated or to be generated by the applicant and where appropriate, request the Commission to review the approval in accordance with Article 15 of the BPR. The meeting considered that further discussions on this issue, if necessary, should be referred to the BPC.

On the implications of the new data at the product authorisation stage, the meeting supported the Commissions' recommendation that evaluation should be based on the currently available and agreed data. Where appropriate, the product authorisation can be granted subject to a condition to present new data in a given period of time or give the applicant the possibility to apply for a change.

Actions:

RMS: to use currently available and agreed data to grant the product authorisation subject to a condition or give the applicant the possibility to apply for a change.

8.2 Paper on the impact on product authorisation of the new BPR requirements linked to active substances meeting the exclusion or substitution criteria (and the availability of a common source of information – list)

A member introduced documents CG-2-2013-13 & 18. Some MSs supported the general approach suggested by the member due to the existing constraints to perform a comparative assessment. A MS supporting the approach wanted to seek confirmation that such an approach is legally consistent.

Regarding the availability of the list of active substances meeting the exclusion or substitution criteria, the Commission introduced the latest version made available by ECHA which contains the active substances on which a decision has been taken. The Commission stressed that the list includes the key criteria agreed in Document CA-Sept13-Doc.3.0-Final on "Principles for taking decisions on the approval of active substances under the BPR". In addition, the list will be also improved in the short term by ECHA as follows:

- There will be three independent P/B/T columns. In addition, it will be also indicated if the substance potentially fulfils the criterion (e.g. potentially P). It will be also clarified whether the P/B/T status was established by using the old TGD or the REACH rules.
- It will be clarified that the CMR properties refer to the proposal for revision of harmonised classification.
- There will be conclusion columns (Yes/No) on interim ED criteria, exclusion criteria and substitution criteria.

Members of the CG asked about the timelines for that improved version as well as about the maintenance and publication of the list. The Commission clarified that the list will be maintained by ECHA and be considered as the relevant source of information to make a harmonised decision on whether an active substance meets or not the exclusion or substitution criteria.

In this respect, The Commission proposed the following approach:

- ECHA to check the information contained in the list in the short term (i.e. before the January CG meeting). For that purpose, it was agreed to focus first on some priority active substances (e.g. those meeting the exclusion/substitution criteria or those on which MSs have to make a decision in the context of applications for product authorisation under Art. 91 of the BPR, SBP applications, etc.).
- Once the updated priority list is distributed to the CG, rapporteur MSs for those priority substances should double check the info on the list.
- If needed, the list will be discussed/refined again at the March CG meeting.
- The list will be endorsed at the March CA meeting for its use in the context of product authorisation and made publicly available.

Concerning the UK proposals and the legal concerns raised by a MS, the Commission mentioned that BPR establishes comparative assessment as an obligation without any general transitional period; therefore, The Commission cannot support such proposals. On the other hand, Article 23(4) of the BPR should only be applied on a case by case approach but not to all on-going applications which might require a comparative assessment. Where such a comparative assessment would be required and Article 23(4)

is not applicable, The Commission has made a proposal that will be discussed at the CA meeting (document CA-Dec13-Doc.5.1.k).

The Commission also clarified that the validity of product authorisations under the BPR is not linked anymore to the expiry date of the active substance approval and recommended, for MR authorisations, to give the same validity as in the RefMS in order to have common renewal deadlines.

Actions:

SECR: to review the status of the priority substances (where the authorisation decisions are foreseen next year) and to provide it to the MSCAs by the end 2013, if possible.

Relevant eCAs: to cross-check by the January 2014 CG meeting, if possible.

Members are invited to comment on the paper in preparation for the January meeting in a dedicated CIRCA BC newsgroup.

All to provide a list of priority substances to SECR and COM.

8.3 Note for Guidance on comparative assessment: next steps forward

The Commission briefly referred to document CG-2-2013-19. This paper will be subject to a policy discussion at the CA meeting, where MSs will be invited to endorse Section 2.1 of the paper (General considerations and proposed approach).

9. Any other business

9.1 Late procedures

The Commission briefly introduced document CG-2-2013-16. Members were invited to provide any comments or proposals for updating the document to the Commission and SECR in cc.

9.2 Trends in PA

The Commission briefly introduced document CG-2-2013-17, underlining the fact that more than 3 000 authorisations have been already granted.

9.3 Article 91 applications

The Commission briefly reported on the latest information on this topic sent to MSs. This refers to a new feature that has been added to the R4BP2 for uploading the draft AR and draft SPC. Some guidance on this feature has been also distributed to MSs.

A MS referred to how a CMS can become aware of these documents being available, in connection with the 90-day period to submit comments. The Commission clarified that an automatic e-mail will be sent by the R4BP2 to all CMSs when those documents have been made available by the RefMS.

Another MS briefly referred to document CA-Dec13-Doc.5.1.t. on a proposal for a workaround for the submission of certain applications in R4BP3. The Commission clarified that the document will be further discussed at the CA meeting but is not intended to be used as an open door for companies that were late in the submission of applications for product authorisation.

All: contact COM in relation to any trouble associated with the making available the draft SPC or assessment report under R4BP2.

10. Conclusions and action points

Members of the CG agreed the main action points and conclusions of the meeting which are included in Part II of these minutes. The SECR was to upload the action points and conclusions to CIRCA BC after the meeting.

Main conclusions and action points

Agreed at the 2nd meeting of the CG

10 December 2013

Agenda point	
Conclusions / decisions / minority positions	Action requested after the meeting (by whom/by when)
2 – Agreement of the agenda	
The agenda was agreed with <ul style="list-style-type: none"> - Having a closed session Referrals 1 & 2; - Adding under AP 7 a paper on skin sensitisation; - Adding under AP 9, AoB a paper on Article 91 applications. 	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 – Agreement of draft minutes from CG-1	
The minutes were agreed subject to including a reference to action point 9.3, that CG Contact Points will be the first contact point for authorisations.	SECR: to finalise the minutes and upload to the CG CIRCA BC.
5 – Administrative issues	
5.1 – Housekeeping	
	All: respect the 10 day deadline for circulating meeting documents. SECR: to use classification “confidential” and “non-confidential” for the future documents (instead of current “internal”). SECR: all meeting documents to be stored in the same folder in the CG CIRCA BC.
5.2 – Election of the Chair and Vice-Chair	
It was agreed that two members were duly elected as Chair and Vice-Chair, respectively of the CG for a term of 1,5 years starting from the March 2014 meeting.	SECR and Chairs: to define the role of Chair and Vice-Chair for discussion at a future meeting.
5.3 – Draft CG Rules of Procedure (RoPs)	
Significant changes were discussed in relation to Articles 1, 2 and 13 as below: <ul style="list-style-type: none"> • Article 1(1)(c) to reflect the CG will discuss issues in relation to product authorisation and mutual recognition; • Article 2 to reflect an alternate Contact Point may be appointed; • Article 13 to reflect agreement is by 	SECR: to revise the RoPs with a view to reach agreement at the next meeting. SECR: to grant access to CIRCA BC for any alternate Contact Points proposed to the SECR.

Agenda point	
Conclusions / decisions / minority positions	Action requested after the meeting (by whom/by when)
<p>consensus, except for procedural matters and to strengthen the wording in relation to the need whenever possible to reach consensus.</p> <p>Several detailed changes were also proposed.</p>	
5.4 – Working procedures and templates	
<p>Comments were made as follows:</p> <p>Working procedures:</p> <ul style="list-style-type: none"> - To emphasise the importance of the informal discussion involving all cMS; - Timelines being too short for commenting and addressing comments; - To streamline document management on CIRCA BC. <p>Templates:</p> <ul style="list-style-type: none"> - cMS and rMS to declare that they have exhausted the informal route of disagreement; - Which chapters of the SPC the disagreement refers to. <p>Several detailed changes were also proposed.</p>	<p>SECR: to revise the working procedures and the templates with a view to reach agreement at the next meeting.</p> <p>All: to provide comments by end 2013.</p>
5.5 – Feedback on test Web conferencing & future application	
<p>Members supported the idea of discussing real cases of disagreement via web conferencing.</p>	<p>SECR: to</p> <ul style="list-style-type: none"> - Prepare updated instructions on how to use the web conferencing tool; - Set up another meeting to carry out a full scale test including, where possible, those members and ASOs not involved earlier.
6 – Disagreements on mutual recognition	
<ul style="list-style-type: none"> • Referral 1 – applicant present <p>It was <u>agreed</u> to take the disagreement back to the informal stage and encourage the rMS and cMS to further discuss the issue with a view to reach an agreement.</p>	<p>cMS and rMS: to discuss further keeping in copy the other concerned MS.</p>
<ul style="list-style-type: none"> • Referral 2 – applicant not present. <p>cMS and rMS had reached agreement with the exception of one point. It was <u>agreed</u> to take the disagreement back to the informal stage for the outstanding point and encourage the rMS and cMS to further discuss the issue with a view to reaching an agreement.</p>	<p>cMS and rMS: to discuss further on the outstanding point.</p>
7 – Transitional item: Article 4(4) notifications under the BPD	
<p>Main issues identified:</p> <ul style="list-style-type: none"> - Need to review the Technical Guidance on Efficacy of rodenticides; - Need to look at the technical and scientific grounds for the risk assessment of two wood preservatives; 	<p>COM: to forward documents (PAR and comments) on two of the 4(4) notifications to the CG (via the SECR) for the CG to assess the technical and scientific grounds for the risk assessment.</p>

Agenda point	
Conclusions / decisions / minority positions	Action requested after the meeting (by whom/by when)
- One notification has been withdrawn on the basis of the comments provided by the RMS.	SECR: to include the point in the agenda of the January 2014 CG meeting.
8 – Transitional item: harmonisation of scientific and technical issues	
8.1.a – TM discussion on dermal absorption value for products containing bromodialone	
The conclusion of the meeting was to accept the outcome from discussions at TM III and IV and utilise the amended dermal adsorption default value, where appropriate, from similar formulations containing bromadiolone. The point was considered closed.	SECR: to include outcome for consideration in updates to technical guidance documents.
8.1.b – TM discussion on effect values for imidacloprid and questions from TM to the Coordination Group	
	RMS: to use currently available and agreed data to grant the product authorisation subject to a condition or give the applicant the possibility to apply for a change.
8.2 – Paper on the impact on product authorisation of the new BPR requirements linked to active substances meeting the exclusion or substitution criteria (and the availability of a common source of information – list)	
	<p>SECR: to review the status of the priority substances (where the authorisation decisions are foreseen next year) and to provide it to the MSCAs by the end 2013, if possible.</p> <p>Relevant eCAs: to cross-check by the January 2014 CG meeting, if possible.</p> <p>Members are invited to comment on the paper in preparation for the January meeting in a dedicated CIRCA BC newsgroup.</p> <p>All to provide a list of priority substances to SECR and COM.</p>
9 - AOB	
9.3 – Article 91 application	
	All: contact COM in relation to making available the draft SPC or assessment report under R4BP2.
9.4 – Exchanging information	Members: wherever possible to minimise the use of group emails and instead circulate information via the SECR.
9.5 – CG-3 Meeting in Dublin	SECR: to circulate the preliminary meeting arrangements without delay.
10 – Conclusions and action points	
The conclusions and action points in this document were <u>agreed</u> at the meeting.	SECR: to upload the action points and conclusions to CIRCA BC without delay after the meeting.

Final agenda
2nd meeting of the Coordination Group (CG)

10 December 2013
Brussels (Centre Borschette)
Starts at 9:30 ends at 17:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

CG-A-2-2013
For agreement

Item 3 – Declarations of Interest in relation to the Agenda

Item 4 – Agreement of the draft minutes from CG-1

CG-M-1-2013
For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

For information

5.2 Election of the Chair and Vice-Chair for 2014

CG-2-2013-01
For agreement

5.3 Rules of procedures

CG-2-2013-02
For agreement

5.4 Working procedures and templates

CG-2-2013-03, 04 & 05
For discussion

5.5 Feedback on the test Web conferencing and future application

CG-2-2013-06
For discussion

Item 6 – Disagreements on mutual recognition (closed session)

CG-2-2013-07

6.1 Referral 1

CG-2-2013-08, Annex 1, 2, 3 & 4
For agreement

For agreement

Item 7 – Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/EC (closed session)

CG-2-2013-10

For information

Item 8 – Transitional item: harmonisation of scientific and technical issues in relation to product authorisation

8.1 TM discussion (closed session)

- a) on dermal absorption value for products containing bromodialone
- b) on effect values for imidacloprid and questions from TM to the Coordination Group

CG-2-2013-11, 12, 21

For discussion

8.2 UK paper on the impact on product authorisation of the new BPR requirements linked to active substances meeting the exclusion or substitution criteria (and the availability of a common source of information – list)

CG-2-2013-13, 18, 20

For information

8.3 Note for Guidance on comparative assessment: next steps forward

CG-2-2013-19

For information

Item 9 – Any Other Business

9.1 Late procedures (closed session)

CG-2-2013-14, 15 & 16

9.2 Trends in product authorisation

CG-2-2013-17

For information

9.3 Article 91 applications

Item 10 – Agreement of the action points and conclusions

For agreement

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