CG-M-1-2013 FINAL PUBLIC

Agreed at CG-2

10 December 2013

Final minutes of the 1st meeting of the Coordination Group (CG)

24 September 2013

Part I - Summary Record of the Proceedings

1. Welcome and apologies

One of the members acted as a Chair of the Coordination Group (CG) until an interim Chair was elected under item 4.2. The acting Chair welcomed participants to the first meeting.

The Chair informed the meeting of the participation of 30 members from 22 Member State Competent Authorities (MSCAs) and one observer country. Apologies were received from three MSCAs and participants from three MSCAs did not attend. A representative of the European Commission and three observers from ECHA accredited stakeholder organisations (ASOs) were present for the full meeting and the open session of the meeting, respectively. The Chair also introduced the ECHA Secretariat. 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-1-2013) and invited any items under AOB. The agenda was agreed subject to agenda items 8.5 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. Tour de table

The Chair invited the representatives of the MSCAs (referred to hereafter as 'members') to introduce themselves and the MSCA they represent.

4. Administrative issues

4.1. Housekeeping issues

The acting Chair informed participants that reimbursement is not available for travel and accommodation from the Agency. The acting Chair also noted that MSCA Contact Points have been appointed at the request of the Member States instead of fixed term members of the CG. The Contact Points act as a single point of contact for the Agency in communicating with MSCAs on matters relating to the CG. It also allows MSCAs the flexibility to nominate the most appropriate participants for each meeting of the CG.

4.2. Election of an interim chair

The Secretariat introduced paper CG-1-2013-01 and one of the members of the CG chaired the meeting for this item. A member had been nominated for the position of the Interim Chair of the CG. The nomination was unanimously supported by the members of the CG and therefore the member was duly elected Interim Chair during the establishment period of the CG until and including the meeting scheduled for 15 January 2014.

4.3 Participation of applicants and stakeholders in the CG

The Secretariat (SECR) introduced paper CG-1-2013-02 in which it was proposed that ASOs should be allowed to participate in meetings of the CG unless applicants provide a justified objection based upon confidential business information (CBI) to their attendance for their agenda item; there should be a balanced representation of the interests of those ASOs invited to meetings; and applicants are only invited to participate for their case.

These proposals were agreed by members subject to the addition of the following: members may request a closed session for a particular item, either before a meeting of

when agreeing the agenda; and before each case is discussed by the CG, members will have the opportunity to have a closed session discussion.

Actions:

The SECR was to invite ASOs and applicants to attend future meetings of the CG, but to clearly explain the agreed approach. In addition, the approach for the participation of ASOs and applicants in written procedures was to be clarified by the SECR.

4.4 Managing conflicts of interest

The SECR introduced paper CG-1-2013-03 by explaining the importance of considering any conflicts or perceived conflicts of interest of members of the CG to ensure the impartiality and objectivity of discussions and decision-making by the CG. It was proposed that the Agency's policy on conflicts of interest should be applied to CG in a manner that is proportionate and consistent with its role and that minimises the administrative burden. Accordingly, at the start of each meeting, CG members would be required to make a declaration of any potential conflicts of interest in relation to the agenda and the Chair will apply appropriate mitigating measures e.g. removal of voting rights for a particular agenda item. Members of the CG agreed to this proposed approach.

4.5 CG Rules of Procedure

Draft CG Rules of Procedure (RoPs) were presented by the SECR in document CG-1-2013-04. It was explained that the Biocidal Products Regulation (BPR)[1] requires the CG to prepare its own RoPs and that these provide a framework by which all of the activities of the CG are governed.

A discussion took place article-by-article in which members broadly supported the draft RoPs but several areas needed clarification. In particular, Article 2 of the RoPs should 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 decision-making making should be on the basis of two thirds majority. A number of detailed comments were also made on the draft including the need to reflect relevant implementing legislation in Article 1.

Actions:

Members were invited to provide any further comments in the dedicated CIRCA BC newsgroup by Friday 18 October. The SECR to revise the draft RoPs on the basis of the discussion and any further comments for possible agreement at the next meeting.

4.6 Working procedures and templates

The SECR introduced document CG-1-2013-05 that proposed the basis for working procedures (WPs) for the CG as well as document management. It was explained that the draft WPs at this stage are high level, rather than specifying a detailed approach and would be refined in the light of operational experience. Three main WPs were described: a formal referral according to Article 35 of the BPR, an informal referral i.e. to request a discussion at the CG before a formal referral is made ('upstream discussion') and for carrying out written procedures. Documents CG-1-2013-06 and 07 provided draft templates for formal and informal referrals, respectively.

A discussion took place in which the broad approach proposed in documents CG-1-2013-05, 06 and 07 was supported subject to clarification of the following aspects: the template in CG-1-2013-07 should specify that the rMS (reference Member State) is satisfied that discussions have taken place and unsolved issues remain; the consequences of an agreement reached between a cMSs (concerned Member States) and

[1] Regulation (EU) No 528/2012.

the rMS for the other relevant MSCAs; and the timing of the informal discussion by the CG. A number of detailed comments were also made on the documents.

The SECR explained that documentation relating to the business of the CG will be distributed by the SECR via CIRCA BC, rather than group emails. Documentation for the CG will be uploaded to the dedicated CIRCA BC Interest Group that has been established for the CG and to which all Contact Points have access.

In addition, the Commission clarified that the 60 day period to resolve disagreements by the CG as specified in the BPR, starts when a cMS has formally referred the disagreement to the CG.

Actions:

Members were invited to provide any further comments in the dedicated CIRCA BC newsgroup by Friday 18 October. COM was to clarify consequences of an agreement reached between a cMSs and the rMS for the other relevant MSCAs for the next meeting. The SECR to revise documents CG-1-2013-05, 06 and 07 on the basis of the discussion and any further comments for possible agreement at the next meeting.

5. Issues arising from mutual recognition discussions

The Chair explained that this item would usually be to consider any referrals (formal or informal) to the CG for discussion. No such items had been received in advance of this meeting.

6. 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 following document CG-1-2013-08 and its annexes. Due to time constraints, the Commission proposed to focus the discussions on the new notifications submitted after the July PA&MRFG meeting and on the automated dipping issue.

One member introduced their new notifications, and the rMSs mentioned that they will continue the bilateral discussions and provide comments in writing during the commenting period. Other members were also invited to send comments on these notifications.

The applicant for one product attended the meeting and shared his views on their two notifications with CG participants. The applicant was to submit the comments in writing.

With regard to the on-going notifications for wood preservatives involving automated dipping application, members unanimously supported the proposal from one member presented at the July PA&MRFG meeting, with the needed refinement to take into account the discussion held in TM III 2013. The TM endorsed the HEEG[2] opinion on exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping (which was based on the above-mentioned proposal).

Members also agreed on the phrase to be included on the label of products to be applied by automated dipping as proposed by the above mentioned member.

One member mentioned that for the products affected by the on-going notifications, due to the number of products affected and the resources it would require, they do not propose to amend the certificates for any products involved at this point. If the applicants submit their products for any other amendments then they will be updated with regard to the automated dipping at that point, or if not then it will be included at renewal of authorisation.

[2] Human Exposure Expert Group.

Actions:

Members were invited to continue bilateral discussions on the notifications and to send any further comments to the Commission on the notifications during the commenting period. The Commission was to update document CG-1-2013-08 where appropriate for the next CG meeting.

7. Feedback to the Stakeholders on the outcome of item 4.3

The Chair summarised the outcome of the discussion that took place under agenda item 4.3. The ASOs present at the meeting thanked members for their consideration of the matter and welcomed the outcome.

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

8.1 Draft Guidance document on "Authorisation under the Biocidal Products Regulation of products containing more than one existing active substance or belonging to more than one product-type"

The Chair introduced the document, which was not endorsed in July, so MSCAS had been invited to send comments by the end of August. Comments were received from two members. The updated version takes into account some clarification from those comments and for scenario 1 (one product type (PT), several existing active substances contributing to the biocidal function), it is proposed to consider that where the product is supplied with a purpose defined by one PT only (PT 18), even if it contains several active substances contributing to that purpose (PT 18 + PT 19), the product has to be only authorised under that PT (insecticide). The paper was to be tabled at Biocides CA meeting for endorsement.

One member requested a clarification on item D of the executive summary to clarify that it refers to applications submitted under the BPR. Another member also suggested a clarification of items E and G of the executive summary to clarify that the general conditions for the non-silent active substances have to be met in any case. A member suggested clarifying the wording of paragraph 12 of the document.

Actions:

The Commission to consider some of the comments made by MSs on a bilateral basis and to amend the document, where appropriate, for endorsement at the next Biocides CA meeting.

8.2 Note on "Authorisation of a biocidal product family for applications submitted under Directive 98/8/EC according to the frame formulation concept"

The Commission introduced the document, which was discussed in July but not endorsed as it was connected to the discussions on Article 91 of the BPR. Since then, one member had submitted comments in relation with the availability of a list to know if the active substance meets the exclusion or substitution criteria, which has an impact on the handling of administrative changes.

One member requested clarification for the cases of pending applications for mutual recognition. The Chair clarified that these applications should be handled according to point 2.1 of the document, as they are also applications submitted under the Biocidal Products Directive[3] for which the authorisation will be granted as from 1st September 2013. The paper was to be tabled at Biocides CA meeting for endorsement.

Actions:

[3] Directive 98/8 EC.

The Commission will send the document for endorsement at the next Biocides CA meeting.

8.3 Note on "Submission in EN of the proposed SPC in applications for mutual recognition in parallel and other regulatory procedures"

The Chair reminded the meeting that MSCAs had been invited to comment in writing on the seven day timeline, taking into account how much time would they reduce from the 30 days to assess the translation and grant the authorisation. No comments were received. The new paragraph 11 as suggested in July by some MSCAs gives now a chance for submitting a draft translation of the SPC at an earlier stage, so a CA can start looking at the translation and have more time to interact with the applicant. The paper was to be tabled at Biocides CA meeting for endorsement.

One member proposed a sentence to be included in paragraph 9 of the document to reflect that, where an MSCA considers the proposed translation is not of the required quality, that MSCA can request the applicant to submit an improved translation as soon as possible. Another member raised concerns about the applicability of the proposed approach in terms of the required resources and skills to judge the quality of translations, taking into account the obligation to meet the 30 day deadline for product authorisation. These concerns were supported by several members.

Actions:

The Commission will amend paragraph 9 and send the amended document to the next Biocides CA meeting for endorsement, indicating that difficulty was found by some MSs with the seven day period for translation and receiving high quality translations.

8.4 Note from the Biocides Technical Meeting on "Authorisation of potential skin sensitiser biocidal products requiring PPE for non-professional users"

The Chair introduced this point for information. In July the Commission services shared their views on this question with MSCAs, which were reflected in the draft minutes of the meeting *("COM considers that wearing PPE is a product specific RMM to reduce exposure and where the product's risk assessment concludes that PPE is not necessary for non-professionals, the PPE requirement cannot be imposed. This requirement would be even less justified if the product only contains skin sensitiser substances but is not classified itself as skin sensitiser*").

MSCAs were invited to react on the Commission position by the end of August. Only one MSCA had submitted comments expressing support to Commission, so a reply was sent to the TM along these lines before the TM III meeting.

8.5 Report from Technical meeting III on follow up issues

Room document CG-1-2013-13 provided by JRC was noted for information.

9. Any other business

9.1 Late procedures

Document CG-1-2013-12 was noted by members and it was agreed that this summary document is useful and that a regular update of progress would be provided by the Commission. Members were invited to provide any comments or proposals for updating the document to the Commission and include a copy in the dedicated CIRCA BC newsgroup. The SECR would provide such updates to members as they become available.

9.2 Meeting dates

The Chair explained that a meeting has been scheduled for 10 December 2013 and a further six meetings in 2014. Generally though meetings would only take place if there are sufficient agenda items to warrant such a meeting. Four of the meetings in 2014 are scheduled to take place immediately before Biocide CA meetings. However, for the other two meetings either a physical or virtual meeting could be considered.

It was agreed that a physical meeting would take place immediately before the December Biocides CA meeting. An exploration of the possibility and a decision would be made on whether a physical or virtual meeting would be more appropriate for the meeting scheduled in mid Jan 2014.

The scheduled meeting dates are as follows (also posted in CIRCA BC):

9 or 10 December 2013 (tbc).	10 July 2014
15 January 2014	16 September 2014
11 March 2014	11 November 2014
13 May 2014	

Actions:

The SECR was to write to Contact Points indicating the necessary requirements for a virtual meeting and establish a dedicated CIRCA BC Newsgroup for comments from members if they can utilise such an approach. Since the meeting it was agreed to test the feasibility of a virtual meeting in early November involving the Chair and several MSCAs.

9.3 Production of a list of active substances that meet the exclusion and substitution criteria

The Chair noted that one MSCA had requested a discussion on the above topic. The Chair acknowledged the usefulness of such a list but recommended that the issue should be better explored at the next Biocides CA meeting.

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.

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Main conclusions and action points

Agreed at the 1st meeting of the CG

24 September 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.	**SECR** to upload the agreed agenda to the CG CIRCABC IG as part of the meeting minutes.
4 – Administrative issues	
4.2 – Election of an interim Chair	
It was agreed that a member was duly elected as interim Chair of the CG until and including the January 2014 meeting of the CG.	
4.3 – Participation of applicants and stakeholders in the CG	
The approach proposed in CG-1-2013-02 was agreed, with the following points clarified: • ASOs and applicants can attend the CG meetings; • There should be a balanced representation of ASO interests in CG meetings; • Before each case MSCAs will have the opportunity to discuss in closed session; • MSCAs may request a closed session for a particular item either before a meeting or when agreeing the agenda; • ASOs can attend the entire meeting of the CG unless an applicant provides a justified objection based upon CBI; • Applicants are invited only for their specific cases; • The approach during written procedures to be clarified.	**SECR** to invite ASOs to attend meetings of the CG but to clearly explain the agreed approach
4.5 – Draft CG Rules of Procedure (RoPs)	
The draft CG RoPs were discussed and a number of detailed and editorial points were made. In addition, the following clarifications to the draft were proposed:	**Members** are invited to provide any further comments in the dedicated CIRCA Newsgroup **by Friday 18 October** **SECR** to revise the draft RoPs according to the

• Article 1 to include reference to relevant biocides implementing legislation and Art 27 of the BPR and the scope of 1b; • Article 2 to specify one representative per Member State and advisers if appropriate to be added to RoPs; • Article 13 to include the possibility of voting by proxy and two thirds majority decision-making.	discussion and comments for the next meeting.
4.6 – Working procedures and templates	
The approach proposed in CG-1-2013-05 and the draft templates in CG-1-2013-06 & 07 was agreed subject to clarification of the following: • The template in CG-1-2013-07 should specify that the rMS is satisfied that discussions have taken place and unsolved issues remain; • Consequences of an agreement reached between a cMSs and the rMS for the other relevant MSCAs; • The timing of the informal discussion by the CG;	**Members** are invited to provide any further comments in the dedicated CIRCA Newsgroup **by Friday 18 October**. **COM** to clarify consequences of an agreement reached between a cMSs and the rMS for the other relevant MSCAs for the next meeting; **SECR** to revise the paper and templates according to the discussion and comments for the next meeting.
6 – Transitional item: Article 4(4) notifications under the BPD	
In relation to document CG-1-2013-08 the following points were agreed: • A member proposal for automated dipping as presented at the PA&MRFG meeting in July with the proposed amendments suggested by TM III 2013; • The applicant for several products will submit comments in writing.	**Members** are invited to continue the bilateral discussions and to send comments on the new notifications during the commenting period. **COM** to update document CG-1-2013-08 where appropriate for the next CG meeting.
8 – Transitional item: harmonisation of scientific and technical issues	
8.1 – Draft guidance on authorisation under BPR of products containing more than one existing active substance or belonging to more than one product type	
	COM to consider some of the comments made by MSs on a bilateral basis and to amend the document, where appropriate, for endorsement at the next Biocides CA meeting.
8.2 – Note of authorisation of biocidal product family for BPD applications according to the frame formulation concept	
	COM to send the document for endorsement at the next Biocides CA meeting.
8.3 – Note on submission in EN of the proposed SPC in applications for mutual recognition in parallel and other regulatory procedures	
• A member proposed sentence to be included in paragraph 9 of the document.	**COM** to send the document to the next Biocides CA meeting for endorsement indicating that difficulty was found by some MSs with the 7 day period for translation and receiving higher quality translations.

9 - AOB	
9.1 – Late procedures	
It was agreed that a regular update of progress on late procedures (CG-1-2013-12) is useful for CG members.	**Members** are invited to provide any comments or proposals for updating document CG-1-2013-12 to COM and cc ECHA via a dedicated CIRCA BC newsgroup. **SECR** to circulate updates as they become available.
9.2 – Meeting dates	
It was agreed that a physical meeting would take place back-back with the Dec CA meeting; and consider a virtual meeting in mid Jan 2014.	**SECR** to write to Contact Points indicating the necessary requirements for a virtual meeting and establish a dedicated CIRCA BC Newsgroup for comments from members if they can utilise such an approach.
9.3 – Contact point for an authorisation	
It was agreed that CAs would indicate a contact point for a given authorisation.	**SECR** to consider the most appropriate mechanism proposal to the next meeting.
10 – Conclusions and action points	
CG members agreed these main conclusions and action points of CG-1.	**SECR** to upload the conclusions and action points to the CIRCABC IG after the meeting.

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24 September 2013
Agreed at CG-1
CG-A-1-2013 FINAL

Final agenda

1st meeting of the Coordination Group (CG)

24 September 2013
Brussels (Centre Borschette)
Starts at 9:30 ends at 17:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

CG-1-A-2013

For agreement

Item 3 – Tour de table

Item 4 – Administrative issues (Closed Session)

4.1 Housekeeping issues

4.2 Election of an interim chair

CG-1-2013-01

For agreement

4.3 Participation of applicants and stakeholders in the CG

CG-A-2013-02; Annex 1a & b; Annex 2 & 3

For agreement

4.4 Managing conflicts of interest

CG-1-2013-03; Annex 1a

For information

4.5 Rules of procedures

CG-1-2013-04

For discussion

4.6 Working procedures and templates

CG-1-2013-05 & 06 & 07

For discussion

Item 5 – Issues arising from mutual recognition discussions (Closed session)

For discussion

Item 6 – Transitional item: state of play of notifications made in accordance with Article 4(4) of Directive 98/8/EC (Closed session)

CG-1-2013-08; Annex 1a & b

For information and discussion

Item 7 – Feedback to the Stakeholders on the outcome of item 4.3 (Open session)

For information

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

8.1 Draft Guidance document on "Authorisation under the Biocidal Products Regulation of products containing more than one existing active substance or belonging to more than one product-type";

CG-1-2013-09

For information

8.2 Note on "Authorisation of a biocidal product family for applications submitted under Directive 98/8/EC according to the frame formulation concept";

CG-1-2013-10

For information

8.3 Note on "Submission in EN of the proposed SPC in applications for mutual recognition in parallel and other regulatory procedures";

CG-1-2013-11

For information

8.4 Note from the Biocides Technical Meeting on "Authorisation of potential skin sensitiser biocidal products requiring PPE for non-professional users"

For information

8.5 Report from Technical meeting III on follow up issues (Closed Session) CG-1-2013-13

For information

Item 9 – Any Other Business

9.1 Late procedures (Closed Session) CG-1-2013-12

9.2 Meeting dates

9.3 Production of a list of active substances that meet the exclusion/substitution criteria.

Item 10 – Agreement of the action points and conclusions

For agreement

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