24 May 2016

CG-M-16-2016 non-confidential

Final non-confidential minutes of the 16th meeting of the Coordination Group (CG)

14 March 2016

Part I - Summary Record of the Proceedings

Closed session

1. Welcome and apologies to the closed session

The Chairman welcomed participants to the sixteenth CG meeting. 32 members from 24 Member State Competent Authorities (MSCAs) participated in the meeting. One representative from DG SANTÉ and two representatives from ECHA were present for the full meeting.

The Chair thanked the BE CA for hosting the meeting and for their support in the organization of the meeting.

2. Agreement of the agenda for the closed session

The Chair introduced the draft agenda (CG-A-16-2016) and invited participants to add any items under AOB. The agenda was agreed without changes.

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

Actions:

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

3. Declaration of interest in relation to the agenda

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

4. Agreement of the draft minutes from CG-15

The Chair explained that the draft non-confidential CG-15 minutes had been uploaded for commenting via Newsgroups. No comments had been received on the confidential minutes. No comments were received during the meeting and the CG members agreed on the draft minutes from CG-15 meeting.

Actions

SECR: to upload the CG-15 minutes into the relevant folders in the CG CIRCABC.

5. Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

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

Actions

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

5.2 Informal referrals on mutual recognition disagreements before Article 35 of the BPR

The Chair informed that no informal referrals had been notified, so there were no formal referrals for discussion.

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

Four formal referrals were discussed.

1) The applicant attended the meeting. For this formal referral, an agreement was reached by consensus on all the points of disagreement of the formal referral. As a result, the product was considered to meet the conditions for granting an authorisation in Article 19(1)b of the BPR. This formal referral is therefore closed.

2) For this formal referral, an agreement was reached by consensus on the point of disagreement. As a result, the product was considered to meet the conditions for granting an authorisation in Article 19(1)b of the BPR. This formal referral is therefore closed.

3) The applicant attended the meeting. For this formal referral on a biocidal product family, an agreement was reached by consensus on the points of disagreement of the formal referral. As a result, the product was considered to meet the conditions for granting an authorisation in Article 19(1)b of the BPR. This formal referral is therefore closed.

4) The applicant attended the meeting. For this formal referral, an agreement was reached by consensus on the point of disagreement of the formal referral. As a result, the product was considered to meet the conditions for granting an authorisation in Article 19(1)b of the BPR. This formal referral is therefore closed.

Actions

SECR: to follow-up the outcome of the referrals as stated in the Working Procedures

6. Any Other Business (closed session)

6.1 Late procedures

The Commission briefly introduced the reports prepared by ECHA (documents CG-16-2016-02&03).

Regarding the still on-going BPD procedures, the Commission encouraged MSs to continue with the priority actions: to close obsolete cases and cases for which the product authorisation has already been granted, provided that the CA has checked before closing the case that: i) the case type is correct and ii) the case is correctly linked to the right reference case (for MR-P) or reference asset (for MR-S).

Regarding the applications submitted under the BPR, particular attention was paid to the role of the refMSs, as it has a wider impact on the procedures in the CMSs. The Commission encouraged MSs to undertake the relevant actions, as the number of applications is expected to significantly increase in the near future as a consequence of the higher number of active substance approvals per year (e.g. from 10-15 to 50).

Actions

All MS: to undertake the relevant actions.

6.2 – Insect repellents

6.2.a) Policy and regulatory considerations

The Commission introduced this agenda item by stressing that the recent developments with the Zika virus have put insect repellents under the spotlight of both public health authorities and the media. On account of this situation, the Commission decided to become more pro-active on this subject since the last CG meeting in order to find a way forward.

The Commission made a presentation, which has been uploaded on S-CIRCABC by the CG SECR after the meeting, aiming at setting the scene for the discussion on the three main identified topics:

i) the feedback received from ECHA's Human Exposure Working Group and the associated open question: are some RMMs expected to be observed by the general public?;

ii) the exposure assessment model used by a member, on account of the comments made by CG members after CG-15, the draft SPCs and PARs made available to all MSs and the impact of discussion point i), and

iii) a regulatory way forward to close as soon as possible the still on-going procedures (most of which are linked to that member acting as refMS), also without triggering a significant number of referrals to the CG.

6.2.b) Harmonized RMMs for DEET containing products

ECHA briefly introduced document CG-16-2016-15, which was a follow-up of previous discussions within the CG (from CG-9 to CG-13) on a proposal from one of the member states on RMMs for DEET containing products.

The discussion focused on whether a number of RMMs are expected to be observed in all MS or to be effective for products to be used by the general public and therefore, whether they are acceptable to be used within the assessment to lead to an acceptable risk.

- "Wear long-sleeved shirts and trousers": As pointed out in the presentation by the Commission, the use of long clothing was identified as one of the most controversial RMMs regarding the provisions in the BPR (Art. 19 and Annex VI), as these clothing requirements could be seen as the only mean to reduce exposure to acceptable levels (i.e. like PPE in paragraph 63 of Annex VI).

CG members expressed different views on the acceptability of this RMM. Several CG members argued that this RMM is not likely to be observed under realistic conditions of use of insect repellents. It was also mentioned that this RMM would not be effective to protect the users since some mosquito species can even bite through clothes, unless they meet some given standards. Therefore long clothing was not considered to be an acceptable RMM and the 37% value identified in the Head hoc recommendation cannot be used in the assessment.

- "Not to apply on clothes": Where a product is intended to be used on clothes, the penetration factor proposed by the Human Exposure Working Group (50%) should be used. CG members agreed that, where an unacceptable risk is identified for such a product, then this RMM ("Not to apply on clothes") is acceptable to reduce that risk to an acceptable level.

- "Application only once a day": CG members agreed that this RMM is acceptable within the approach recommended by the Human Exposure Working Group; i.e. the protection time of the product (as determined in the efficacy assessment on a case-by-case basis) should provide evidence that this RMM is likely to be observed.

- "Not to use with sun creams": CG members expressed different views on the acceptability of this RMM. Since use of sun creams is highly recommended for other public health reasons (e.g. sunburn, skin cancer), particularly in regions and seasons with high uv radiation index, CG members agreed that it is not an acceptable RMM.

- "Use only in situations of risk for vector-borne diseases": CG members discussed the implications of this proposal. Taking into the limited knowledge of the general public about the relevant vector-disease combinations, presence of the vector in the visited area, etc… and some other complex implications affecting the supply chain (e.g. supply restricted to pharmacies only), CG members agreed that a distinction between comfort and vector control product should not be made.

As the Human Exposure Working Group requested some feedback from the CG on the acceptability of these RMMs, CG SECR will report the output of the CG discussion back to the WG.

Actions

SECR: to report the output of the CG discussion back to the Human Exposure Working Group.

6.2.c) DEET Exposure Assessment

The Commission thanked a member for having distributed the PAR and draft SPC of three concrete examples in which their model was applied. The Commission also thanked all the MSs having sent comments to these documents or just shared other issues identified in the context of the assessment of applications of DEET containing products within such short notice. The discussion was split in three parts:

1. Human exposure assessment model

The Commission pointed out that, where a RMM is the only mean to reduce exposure to an acceptable level and such RMM is not expected to be observed by the users under realistic conditions of use, then the result of the assessment is that there is an unacceptable risk. CG members agreed that RMMs that are not likely to be observed by the general public in all MS (e.g. use of long clothing – see the conclusion under agenda item 6.2.b) are not applied in the assessment in order to lead to an acceptable risk.

CG members agreed that CG SECR will report the output of the CG discussion on acceptable RMMs back to the Human Exposure Working Group so that the discussions on a harmonised exposure assessment model for insect repellents held in December 2014 can re-start. This agreed model could then be used for other insect repellents (e.g. icaridine, IR 3535) and also at the renewal of DEET products.

Regarding the model used by a member, as the wearing of long-sleeved shirts and trousers (i.e. the 37% value identified in the Head hoc recommendation) cannot be used as an acceptable RMM to reduce exposure, then there is an unacceptable risk for a given age group (children) and the condition in Article 19(1)(b)(iii) is not met.

Finally, the Commission encouraged representatives from MSs and ECHA in the WGs to early identify any issues that might pose regulatory issues at product authorisation and MR, so that those issues are properly addressed within the CG well in advance of the relevant deadlines for product authorisation.

2. Regulatory way forward

The Commission presented a regulatory way forward to speed up the authorisation of the pending applications of DEET products. This way forward has to be seen as a transitional approach for those pending applications until a harmonised exposure assessment model for insect repellents is agreed at the EU level.

The two main purposes of such way forward are: i) to address the needs of MSs where a product is really needed for some age groups (e.g. children) and ii) neither to block MR procedures nor trigger too many referrals to the CG.

In that context, Article 19(5) of the BPR provides MSs with the legal basis to authorise products in cases where not authorising the product would result in disproportionate negative impacts for society when compared to the risks to human health arising from the use of the biocidal product. This condition is MS-specific (like for derogation under Article 5(2) of the BPR), and the authorisation should contain appropriate RMMs to ensure that human exposure is further minimised, including the wearing of long-sleeved shirts and trousers. Other RMMs could be specific labelling requirements (e.g. warning that deviating from the instructions for use would led to a risk) or supplying additional information to the users (e.g. additional leaflet). A reduction of the validity of the authorisation could also be proposed. The Commission clarified that, when available, the above-mentioned harmonised, agreed EU guidance would be applied at the renewal stage.

Regarding MR, the uses authorised by the refMS in accordance with Article 19(5) (e.g use on children) are only mutually recognised in those cMSs where the conditions in Article 19(5) are also met. Where these conditions are not met, cMSs may derogate from MR in accordance with Article 37(1)(c) of the BPR (e.g. not authorise the use on children; see the examples in the presentation of the Commission).

Upon request of a CG member the Commission clarified that, in the context of a MR procedure, a CMS cannot make use of Article 19(5) to authorise a use that has not been authorised by the refMS (e.g. use on children).

It was also clarified that already authorised products (including those requiring the wearing of long clothing as a RMM) have not to be reviewed as a result of the above-mentioned way forward. This does not prevent though that a particular product can be subject to a referral to the CG in the context of MR-S, and where relevant, be subject to some amendments.

A CG member asked the Commission whether more detailed guidance was going to be produced. The Commission responded that on account of the above-mentioned policy and regulatory considerations (i.e. time constraints and urgency to close the pending DEET cases as soon as possible), quick action is required from MSs and that the normal guidance development process (i.e. drafting by COM, CG discussions and CA endorsement) would postpone those actions for some time, which is not available. It was also mentioned that the minutes of the meeting will also record the discussion and clarifications made by the Commiision.

CG members supported the way forward presented by the Commission as a suitable approach under the current circumstances, allowing MSs to close the still on-going DEET applications as soon as possible. CG members also agreed that already authorised products should not be reviewed.

3. Other identified technical issues

The Commission listed in its presentation a number of issues identified by some MSs. Regarding those that had already been discussed within the CG, CG members agreed that the previously reached agreements on these issues should be taken into account.

Concerning products with "H 315", a CG member mentioned that i) this might affect a high number of products (around 50%); ii) a non-authorisation decision might have to be checked with the public health authorities and iii) time would be needed to provide data showing that the products are not skin irritant via a condition in the products authorisation. The Commission responded that the BPR already provides for a clock stop in order to allow the applicant to provide further data (Article 30(2) of the BPR), but it seems that this step is already over. Regarding the possibility to conditionally authorise H 315 products, the Commission mentioned that MSs should perhaps consider whether this would lead to an unequal treatment of applicants, as there might be alternative DEET products without that controversial H statement (if some applicants have already produced the required data).

For those HH or ENV issues that have not been discussed yet within the CG, as they do not seem to be of a major nature compared to those already discussed, the Commission encouraged CG members to discuss any identified issue with the involved refMS and only when it cannot be addressed bilaterally, refer the matter to the CG.

On a more general note and looking at future cases, the Commission also clarified that for MR procedures (particularly for MR-P), the refMS plays a role of evaluating body (similarly to the eCA for UA applications). Therefore, the assessment of the application, which will be reflected in the PAR, should also take into account that the product is going to be authorised and used in other MSs and not only in the territory of the refMS.

Actions

SECR: to report the output of the CG discussion on acceptable RMMs back to the Human Exposure Working Group so that the discussions on a harmonised exposure assessment model for insect repellents can re-start.

COM: inform the CA meeting of the CG conclusions and the next steps forward.

6.2.d) Workshop proposed by AT on the assessment on PT19 products.

Austria presented the proposal to organise a workshop on the assessment of PT 19 repellents.

As the Workshop is going to be organised in June 2016, Austria was invited to coordinate the dates with ECHA in order to avoid overlapping with the BPC and WGs meetings.

The Commission noted that the Workshop will be a key opportunity to identify any outstanding issue on the assessment of insect repellents (either on human health, environment or efficacy areas) to be addressed by ECHA's WGs.

CG members were invited to provide comments on the subjects and proposals to be discussed at the workshop.

Actions

SECR: To set up a Newsgroups discussion.

All: to comment by 4 April.

6.3 Feedback from e-consultations

Four e-consultations were presented for MSs consideration.

1) A member presented the e-consultation regarding generation of new active substance data and asked MSs to provide comments via Newsgroups by 25 March.
2) A member presented an e-consultation regarding the data set to be request for the assessment of substances of concern. The member asked for MSs views in a Newsgroups discussion by 29 March.
3) A member reported on the outcome of an e-consultation on a simplified authorisation application containing lactic acid.
4) A member presented an e-consultation on the pH parameter for a biocidal product family. The member requested MSs to provide their views in the consultation via Newsgroups by 1 April.

Actions

1) All: to comment by 25 March
2) All: to comment by 29 March

4) All: to comment by 1 April

6.4 Evaluation of a BPF

A member presented a document on how diverse the composition of the products can be to still be part of the same BPF. CG members agreed that the structure regarding the composition of the family members should be decided on a case-by-case basis.

6.5 Label claims for disinfectants

A member introduced the discussion on how to include in the SPC a link to label claims for disinfectants. Due to time constrains, CG members were asked to provide written input via Newsgroups by 4 April.

Actions

CG SECR: to set up a Newsgroups discussion on S-CIRCABC

All: to comment by 4 April

7. Agreement of the action points and conclusions

Due to time constraints, the list of action points and conclusions was agreed by the CG meeting via written procedure.

Open session

8. Welcome to the open session

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

9. Agreement of the agenda for the open session

The Chair introduced the draft agenda (CG-A-16-2016) and invited CG members and ASOs to propose any other items under AOB. The agenda was agreed without changes.

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

Actions

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

10. Declaration of interest in relation to the agenda, open session

The Chair invited the members to declare any potential conflict of interests. There were no potential conflicts declared.

11. Agreement of draft minutes (non-confidential part) from CG-15

The Chair explained that the draft non-confidential CG-15 minutes were uploaded for commenting via Newsgroups. No comment had been received on the non-confidential minutes. No comments were received during the meeting and the CG members agreed on the draft minutes from CG-15.

Actions

SECR: to upload the CG-15 minutes into the relevant folders in the CG CIRCABC.

12. Administrative issues

12.1 Code of Conduct for applicants

The CG SECR informed the meeting about the revision of the Code of Conduct to be submitted to applicants attending CG meetings. This revised version includes the comments received from CEFIC.

The Code of Conduct for applicants was agreed and will be distributed from now onwards to applicants attending CG meetings.

Actions

SECR: to distribute this Code of Conduct to applicants attending CG meetings.

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

13.1 Q&A document on the simplified authorisation procedure

The Commission introduced document CG-16-2016-08, which is a follow-up version of the document discussed in the last CG meeting. The Commission thanked those MSs having contributed during the commenting period (DE, FR, NL, ES, BE, DK, EE & SE) and Cefic. With a view to double check whether those comments were addressed in the revised version, a pre-meeting consultation was carried out with those MSs and Cefic.

The updated document, which is tabled for final discussion and agreement, included some comments in balloons to further explain the new additions and changes compared to the version discussed at CG-15.

Upon request from CG members, the Commission clarified the following elements:

- Q&A 4: the crossed reference into brackets to Q&A 13 "for in-can preservatives" should read "for some co-formulants".

- Q&A 11: A CG member questioned its relevance, as Article 95 compliance is neither a data requirement for the SAP nor for normal authorisation procedures. The Commission clarified that, as Article 95 compliance is a requirement for legal making available on the market, and the product authorisation (whatever the authorisation procedure is) is a pre-requisite for the making available of a product on the market, then the authorisation procedure is the best place to check Article 95 compliance.

- Q&A 12: for better accuracy, while making the answer shorter, it was proposed to refer both in the question and the answer to "in-can preservatives active substances". The Commission clarified that, where the biocidal product to be authorised under the SAP is manufactured in the EU, the PT6 biocidal product incorporated in it has also to be authorised in the MS where such "SAP product" is manufactured.

- Q&A 17: a reference to the additional labelling requirements laid down in Article 69(3) of the BPR has been already included as an example.

- Q&A 18: there is no need for granting an "extra national authorisation" in order to have a SPC in the official language(s) of the notified MS, as it is already a requirement for the notification through R4BP3.

- Q&A 25: Where the disagreement concerns the quality of the translation only, it is proposed that it is not referred to the CG. However, if the notified MS wants to provisionally prohibit the placing on the market, this has to be formally notified to the AH via R4BP3 within the 30 days of the notification.

- Q&A 27: the answer should be amended to refer to disagreements "which are referred to the CG".

- Q&A 28: the reference in the answer to "until a decision pursuant to Articles 35 and 36 has been taken" should be deleted as in cases of poor quality of the translation the disagreement will not be referred to the CG.

- Q&A 32: where relevant, a notified MS is expected to replace in R4BP3 the SPC of a product by an updated SPC notified as a consequence of a change agreed by the eCA. The notified MS may charge a fee for such a task in accordance with its national fee legislation.

The Chair noted that with the proposed changes on Q&A pairs number 4, 12, 27 and 28, the document was agreed by the CG, with a reservation from a CG member on Q&A pair 11 (Article 95 check for category 6 substances).

Actions

COM: to forward the document, taking into account the changes agreed at the CG meeting, to the CA meeting for endorsement.

13.2 Evaluation of alternative dossiers during product authorisation

ECHA presented the revised document after CG-14 meeting and provided clarifications to the comments by CG members.

CG members commented on section 3.c of the document, considering that Annex VI of the BPR enforces MSCASs to take up the new information available. Another member commented that the check of the adequacy of the quality or adequacy of the data or justifications provided in the alternative dossiers should not be left as an option but as an obligation for the refMS.

The Commission questioned that the amendment of the List of Endpoints takes place only via Article 15(1) of the BPR as this article should only be applied in exceptional circumstances. The Commission proposed that Article 75(1) g should also be included as a procedure to be taken by MSCAs to propose a revision of the List of Endpoints, when the proposed amendment does not lead to the review of the active substance approval.

Since this comment was to be addressed in the document, the Chair proposed ECHA and Commission to work bilaterally in the revision of the document and to upload the updated document to S-CIRCABC for MSCAs agreement.

Actions

COM/ECHA: to revise the document by 1 April

SECR: to upload the revised document to S-CIRCABC for agreement

All: to comment by 8 April. CG members not commenting by 8 April are regarded to agree with the revised document.

13.3. Preparatory work to support the preparation of SPCs and the harmonisation of their translation.

The CG SECR informed about the development of the mandate for the Working Party to develop a list of common/frequently-used sentences for the different free text section in the SPC. This mandate includes the objectives and the proposed deliverables and timelines for the Working Party. As requested by CG members during the CG-15 meeting, the translations of the SPC sentences have been taken out of the mandate of the Working Party, as this will be done at a national level.

This list of common/frequently-used sentences would be helpful for industry to simplify the preparation of the SPCs and facilitate their translation and also helpful for the MSCAs to check the SPCs and their translations.

The CG members agreed with the mandate of the Working Party and remarked the limited availability of resources in MSs.

13.4 Consideration of cut-off dates for the implementation of paragraph 8(a) of Annex VI to the BPR

The Commission introduced document CG-16-2016-09, which is a follow-up version of the document discussed in the last CG meeting. The Commission thanked those MSs having contributed during the commenting period (DE, DK & UK). With a view to double check whether those comments were addressed in the revised version, a pre-meeting consultation was carried out with those MSs.

The updated document, which is tabled for final discussion and agreement, includes some comments in balloons to further explain the new additions and changes compared to the version discussed at CG-15. The Commission underlined that a point for discussion was the 3-month period proposed by a CG member for the derogation referred to in paragraph 13 of the document.

Regarding paragraph 13, a CG member expressed some concerns regarding the legal basis for such derogation, but found the three-month period a sensible proposal. Another CG member mentioned in this respect that as this is just a recommendation in a guidance document, the derogation in paragraph 13 could be interpreted on a case by case basis, on account of the relevance of the information becoming available to the refMS/eCA.

A CG member also expressed reservations on some of the examples provided in the annex and proposed that CAs should follow a case by case approach. The Commission noted that what is important in this document are the principles set in the body of the note and that, as in other guidance documents, the list of examples is non-exhaustive and that these examples aim at illustrating how the principles in the paper can be implemented in some identified cases.

The Commission also added that the proposed way forward in most of the examples is based on previous discussions and agreements within the CG (e.g. CG agreement on a formal referral where a co-formulant was considered to become a SoC; approach followed with imidacloprid containing products; general practice under MR procedures that no additional data is considered unless there is a referral to the CG, etc…).

The Chair noted that the document was agreed by the CG, with a reservation from a CG member on some of the examples provided in the annex.

Actions

COM: to forward the document, taking into account the changes agreed at the CG meeting, to the CA meeting for endorsement.

13.5 New Q&A pairs for Annex IV to the note for guidance on the BPF concept

The Chair informed that no proposals for new Q&A pairs had been received from CG members or ASOs arising from the discussion on the BPF concept and the tinting pastes. The annex IV to the note for guidance on the BPF concept remains unchanged until new proposals for Q&A pairs are received.

The ASOs representatives informed that proposals will be discussed bilaterally with some MSCAs and proposed for discussion in an upcoming CG meeting.

13.6 Cut-off dates regarding relevance of new guidance

The Chair informed that following from the Newsgroups discussion after CG-15 different views had been shown on the need to revise the cut-off date for the applicability of new guidance for the applications for product authorisation. On account of these different views, the Chair proposed not to modify the approach and to keep the current cut-off date (2 years) regarding relevance of new guidance.

This proposal was agreed by the CG members.

14. Feedback from working parties

14.1 Development of standardised sentences for the SPC sections of anticoagulant rodenticides

The Commission informed CG members that after the first meeting in Madrid, WP members submitted a number of comments on the proposals made by the Commission. The Commission will prepare an updated version of those proposals and will send them to the WP for further comments in April. A physical meeting could be scheduled in May back to back to the CG meeting if needed.

The Commission also clarified that the final output of the WP needs to be postponed until the BPC opinions will be available in June, in order to ensure consistency with the agreed RMMs attached to the renewal of the anticoagulant ASs.

15. Any Other Business (open session)

15.1 Trends in product authorisation

Due to time constraints, the Chair invited the meeting to take note of the report in documents CG-16-2016-11&12, which were made available for information.

15.2 Deadlines for application for product authorisation

Due to time constraints, the Chair invited the meeting to take note of the report in document CG-16-2016-06, which was made available for information.

The Commission pointed out that the ASs were now listed by alphabetic order, while in previous versions they were listed by chronological order regarding the approval date (= deadline for application for product authorisation).

CG members agreed that ECHA should make available a file in excel format so that users can search within the content of the document in order to meet their needs.

Actions

SECR: to produce this report in Excel format

15.3 List of substances meeting the exclusion or substitution criteria

The Chair informed the meeting that the updated version of the list includes changes concerning some approved active substances.

Actions

Rapporteur MSs: to check the new information

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.

15.4 Questions regarding R4BP 3 / SPC / IUCLID

ECHA informed the meeting about the implementation in R4BP of the notification of products ("family members") already authorised under the simplified authorisation procedure.

If a dedicated case type for the notification of family members under simplified procedure cannot be implemented in October 2016, a work around and supporting document will be developed by ECHA to support applicants.

MSs informed of the need of notifications of simplified authorisation assets, particularly family members. The Chair invited MSs to provide the information needs in written, so that ECHA can report back to MSs with the status of the IT developments and the proposed solutions.

Actions

SECR: to set up a Newsgroups discussion

All: to provide the information needs by 4 April

ECHA: to report back to the CG on the proposed solution

15.5 Feedback on e-consultations

Two e-consultations were presented for MSs consideration.

1) A member reported on the outcome of the Newsgroups discussion regarding the control of bedbugs.

2) A member presented the outcome of a survey conducted among MSs regarding the borderline cases between biocidal products and treated articles.

16. Agreement of the action points and conclusions

Due to time constraints, the list of action points and conclusions was agreed by the CG meeting via written procedure.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

Main conclusions and action points

16th meeting of the CG

14 March 2016

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
CLOSED SESSION	
2 – Agreement of the agenda for the closed session	
The agenda for the closed session was agreed without changes.	**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, closed session	
No declarations of conflicts of interest were made.	
4 – Draft minutes from CG-15	
No comments were received during the meeting on the confidential CG-15 minutes. The draft confidential minutes were agreed.	**SECR:** to upload the CG-15 minutes into the relevant folders in the CG CIRCA BC.
5 – Formal and informal referrals on mutual recognition disagreements	
5.1 - Overview of the referrals discussed at the Coordination Group	
The Chair informed about the update of the overview table of the referrals discussed so far at CG level.	**SECR:** to produce a revised overview table for next CG meeting.
5.2 - Informal referrals on mutual recognition disagreements before Article 35 of the BPR	
No informal referrals were discussed.	
5.3 - Formal referrals on mutual recognition disagreements under Article 35 of the BPR	
Four formal referrals were discussed. 1) An agreement was reached by consensus and this referral is therefore closed. 2) An agreement was reached by consensus and this referral is therefore closed. 3) An agreement was reached by consensus and this referral is therefore closed. 4) An agreement was reached by consensus and this referral is therefore closed. The outcome of all the referrals was agreed by the CG members.	**SECR:** to follow-up the outcome of the referrals as stated in the Working Procedures.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
6 – Any Other Business	
6.1 – Late procedures	
COM presented the reports on timelines for different procedures.	**MSs:** to undertake the relevant actions
6.2 – Insect repellents **6.2.a) Policy and regulatory considerations**	
The COM provided information on recent developments and the status of the PT 19 repellents applications and authorisations.	
6.2.b) Harmonized RMMs for DEET containing products	
The SECR presented the outcome of the technical discussions in the Human Exposure Working Group. The use of long clothing is not considered to be an acceptable RMM, since several member states argued that this RMM is not likely to be observed or to be effective. Therefore long clothing will not be applied in the assessment. CG members agreed that: - the RMM "Not to apply on clothes" is acceptable. If a product is intended to be used on clothes, the penetration factor presented in the Human Exposure Working Group should be used. - the RMM "Application only once a day" can be accepted as a RMM as presented in the Human Exposure Working Group recommendation. Protection time as determined in the efficacy assessment should provide evidence that the RMM is likely to be observed. - a distinction between comfort and vector control product should not be made. - the sentence "not to use with sun creams" is not an acceptable RMM. Regarding a number of issues that had already been discussed within the CG, CG members agreed that the previously reached agreements on these issues should be taken into account	**SECR:** to report the output of the CG discussion back to the Human Exposure Working Group.
6.2.c) DEET Exposure Assessment	
CG members agreed that RMMs that are not likely to be observed by the general public (e.g. use of long clothing) are not applied in the assessment in order to lead to an acceptable risk. The Commission presented a regulatory way forward to close the on-going applications for DEET products in accordance with Articles 19(5) and 37 of the BPR. CG members supported this way forward.	**SECR:** to report the output of the CG discussion on acceptable RMMs back to the Human Exposure Working Group so that the discussions on a harmonised exposure assessment model for insect repellents can re-start. **COM:** inform the CA meeting of the CG conclusions and the next steps forward.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
6.2.d) Workshop proposed by AT on the assessment on PT19 products.	
The member presented the proposal for a workshop on the assessment of PT 19 repellents. MSs will provide comments on the subjects and proposal to be discussed at the workshop.	**SECR:** To set up a Newsgroups discussion **All:** to comment by 4 April
6.3 – Feedback on e-consultations	
Three ongoing and one closed e-consultations were presented: 1. A member presented the e-consultation regarding generation of new active substance data 2. A member presented an e-consultation regarding the data set to be requested for the assessment of Substances of concern 3. A member reported on the outcome of an e-consultation on a SAP application containing lactic acid 4. A member presented an e-consultation on the pH parameter for a BPF	1) **All:** to comment by 25 March. 2) **All:** to comment by 29 March. 4) **All:** to comment by 1 April.
6.4 – Evaluation of a BPF	
A member presented a document on how diverse the composition of the products can be to still be part of the same BPF. It was agreed that the structure regarding the composition of the family members should be decided on a case-by-case basis.	
6.5 – Label claims for disinfectants	
The member introduced the topic for discussion on how to introduce in the SPC a link with label claims for disinfectants. The CG members were asked to provide written input via Newsgroups.	**CG SECR:** to set up a Newsgroups discussion on S-CIRCABC **All:** to comment by 4 April
7 – Agreement of the action points and conclusions	
Due to time constraints, the list of action points and conclusions was agreed by the CG meeting via written procedure.	
OPEN SESSION	
9 – Agreement of the agenda for the open session	
The agenda for the open session was agreed without changes.	**SECR:** to upload the final agenda to the CG CIRCABC IG as part of the meeting minutes.
10 – Declaration of interest in relation to agenda, open session	
No declarations of conflicts of interest were made.	
11 – Draft minutes from CG-15 (non-confidential part)	
No comments were received during the meeting on the non-confidential CG-15 minutes. The draft non-confidential minutes were agreed.	**SECR:** to upload the CG-15 minutes into the relevant folders in the CG CIRCABC.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
12 – Administrative issues	
12.1 Code of Conduct for applicants	
The SECR informed the meeting about revision of the Code of Conduct submitted to applicants attending CG meetings. The Code of Conduct for applicants was agreed.	**SECR:** to distribute this Code of Conduct to applicants attending CG meetings.
13 – Harmonisation of technical and procedural issues in relation to product authorisation	
13.1 – Q&A document on the simplified authorisation procedure	
The Commission presented the revised document after the consultation with CG members and ASOs. The CG members asked for clarifications and comments to the document. With the changes agreed during the CG meeting, CG members agreed with the document, with a MS reservation regarding a Q&A pair (Article 95 compliance check).	**COM:** to forward the document, taking into account the changes agreed at the CG meeting, to the CA meeting for endorsement.
13.2 – Evaluation of alternative dossiers during product authorisation	
ECHA presented the revised document and provided clarifications to the comments by CG members. Since a comment was to be addressed, it was proposed for ECHA and COM to work bilaterally and to upload the updated document to S-CIRCABC for agreement.	**COM/ECHA:** to revise the document by 1 April **SECR:** to upload the revised document to S-CIRCABC for agreement **All:** to comment by 8 April. CG members not commenting by 8 April are regarded to agree with the revised document.
13.3 – Preparatory work to support the preparation of SPCs and the harmonisation of their translation	
The SECR presented the mandate for the WP to work on the frequently used sentences in the SPC. The CG members agreed to set up the WP, taking into account that translations are not in the scope of the Working Party and also noting the limited availability of resources in MSs.	
13.4 – Considerations of cut-off dates for the implementation of paragraph 8(a) of Annex VI to the BPR	
The Commission presented the revised document after consultation with CG members and ASOs. The CG members agreed with the document, with a MS reservation on some of the examples provided in the annex.	**COM:** to forward the document to the CA meeting for endorsement.

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
13.5 New Q&A pairs for Annex IV to the note for guidance on the BPF concept	
The Chair informed that no proposals had been received from CG members or ASOs arising from the discussion on the BPF concept and the tinting pastes. The document remains unchanged until new proposals for Q&A pairs are received. IND informed that proposals will be discussed bilaterally with MSCAs and proposed for inclusion.	
13.6 Cut-off dates regarding relevance of new guidance	
The Chair informed that different views had been shown on this topic. The Chair proposed to keep the current cut-off date and this proposal was agreed by the CG members.	
14 – Feedback from working parties	
14.1 - Development of standard sentences for the SPC sections of anticoagulant rodenticides	
The Commission reported on the status of the activities of the WP.	
15 – Any Other Business	
15.1 - Trends in product authorisation	
The Chair presented the reports, available for information.	
15.2 - Deadlines for application for product authorisation	
The Chair presented the reports, available for information.	**SECR**: To produce this report in Excel format.
15.3 – List of substances meeting the exclusion or substitution criteria	
The Chair informed the meeting that the updated version of the list includes changes concerning some approved active substances.	**Rapporteur MS:** to check the new information **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.
15.4 – Questions regarding R4BP3 / SPC/ IUCLID	
ECHA presented the status of the IT developments regarding the SAP notifications. MSs were asked to provide the information needs on the notification of SA assets, particularly family members.	**SECR:** to set up a Newsgroups discussion **All:** to provide the information needs by 4 April **ECHA:** to report back to the CG on the proposed solution

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
15.5 – Feedback on e-consultations	
Two e-consultations were presented. 1. A member presented the outcome of the e-consultation regarding control of bedbugs. 2. A member presented the outcome of a survey regarding the borderlines between biocidal products and treated articles.	
16 – Agreement of the action points and conclusions	
Due to time constraints, the list of action points and conclusions was agreed by the CG meeting via written procedure.	

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ANNEX II

14 March 2016

Final draft agenda

16th meeting of the Coordination Group (CG)

14 March 2016 – from 9:00 to 17:30
(open session is foreseen to start at 14.00)

SPF Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement

Salle Ensor 01C264 – 01C271

Eurostation, Place Victor Horta, 40/10

1060 Saint-Gilles – Belgique

CLOSED SESSION

Item 1 – Welcome

Item 2 – Agreement of the agenda

CG-A-16-2016

For agreement

Item 3 – Declaration of interest in relation to the agenda

Item 4 –Draft minutes from CG-15

CG-M-15-2016_draft-confidential

For agreement

Item 5 – Formal and informal referrals on mutual recognition disagreements

5.1 Overview of the referrals discussed at the Coordination Group

CG-16-2016-01

For information

5.2 Informal referrals on mutual recognition disagreements before Article 35 of the BPR

For discussion

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

Links to disagreements

For discussion and agreement

Item 6 - Any Other Business

6.1 Late procedures

CG-16-2016-02&03

For information

6.2 Insect repellents

6.2.a Policy/regulatory considerations

For information

6.2.b Harmonized RMM for DEET containing products

CG-16-2016-15

For discussion and agreement

6.2.c DEET Exposure assessment

For discussion and agreement

6.2.d Workshop proposed by AT on assessment of PT 19 products

Document to be distributed

For discussion

6.3 Feedback on e-consultations

Link to e-consultations

For information

6.4 Evaluation of a BPF

CG-16-2016-10

For discussion and agreement

6.5 Label claim for disinfectants

CG-16-2016-13&16

For information

Item 7 – Agreement of the action points and conclusions

For agreement

OPEN SESSION

Item 8 – Welcome

Item 9 – Agreement of the agenda

CG-A-16-2016

For agreement

Item 10 – Declaration of interest in relation to the agenda

Item 11 –Draft minutes from CG-15

CG-M-15-2016_draft-non-confidential

For agreement

Item 12 – Administrative issues

12.1 Code of conduct for applicants

CG-16-2016-04

For discussion and agreement

Item 13 – Harmonisation of technical and procedural issues in relation to product authorisation

13.1 Q&A document on the simplified authorisation procedure

CG-16-2016-08

For discussion and agreement

13.2 Evaluation of alternative dossiers during product authorisation

CG-16-2016-14&18

For discussion and agreement

13.3 Preparatory work to support the preparation of SPCs and the harmonisation of their translation

CG-16-2016-05

For discussion and agreement

13.4 Considerations of cut-off dates for the implementation of paragraph 8(a) of Annex VI to the BPR

CG-16-2016-09

For discussion and agreement

13.5 New Q&A pairs for Annex IV to the note for guidance on the BPF concept

For discussion and agreement

13.6 Cut-off dates regarding relevance of new guidance

For discussion and agreement

Item 14 – Feedback from working parties

14.1 Development of standardised sentences for the SPC sections of anticoagulant rodenticides

For information

Item 15 – Any Other Business

15.1 Trends in product authorisation

CG-16-2016-11&12

For information

15.2 Deadlines for application for product authorisation

CG-16-2016-06

For information

15.3 List of active substances meeting the exclusion or substitution criteria

CG-16-2016-07

For information

15.4 Questions regarding R4BP3 /SPC/ IUCLID

CG-16-2016-17

For information

15.5 Feedback on e-consultations

For information

Item 16 – Agreement of the action points and conclusions

For agreement

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