EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Food and feed safety, innovation
Pesticides and Biocides

MINUTES

77th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

14-16 March 2018

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 2 299 11 11
E-mail: SANTE-BIOCIDES@ec.europa.eu

1. Adoption of the agenda	For adoption *CA-March18-Doc.1*	

Three points were added to the agenda under AOB: grouping of antifouling products, state of play of Research use only (RUO) products and in vitro diagnostics for veterinary use and OECD meeting of Working Group on Biocides. The agenda was adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-March18-Doc.2*	

The draft minutes of the 76th CA meeting were adopted.

3. Draft delegated acts

3.1. Draft Delegated Regulation amending Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products (Review Programme Regulation)	For discussion *CA-March18-Doc.3.1a&b*	

The Commission services introduced the topic and explained that the aim of this revision exercise, similarly to the one conducted in 2016, is to clarify in the Annex II of the Regulation which active substance/product-types are actually supported. It was mentioned that the changes to the Annex II ensue mainly from (i) *in situ* redefinitions, with the former identity being replaced by the new agreed one and other additional identities for which compliant notifications were submitted; (ii) active substance/product-type combinations for which the Commission adopted an approval or non-approval decision (which will be removed from the Annex); (iii) active substances/product-type combinations for which no compliant notifications were submitted following the withdrawal of participants; (iv) compliant notifications submitted for substances that had benefitted from the derogation for food and feed. It was also indicated that a mirroring non-approval implementing decision will be adopted for those active substance/product-type combinations that will be removed from Annex II.

One Member State (MS) asked clarification on the transitional period for the labelling of products following the redefinition of an active substance. It was agreed that the Commission services will provide an answer on this topic at a later stage.

Following the question from a MS concerning the consistency between the Annex and the active substances suppliers list, especially concerning the redefinition of active substances, ECHA clarified that the Article 95 list is aligned with the redefinitions and it indicates those identities that were redefined.

MSs were invited to check in detail the Annex II and provide their comments by 6 April 2018.

4. Biocidal products

4.1. Renewal of PT 8 products	For discussion and agreement *CA-March18-Doc.4.1*	

The Commission services briefly introduced document CA-March18-Doc.4.1 and thanked those MSs having submitted comments after the last meeting. The main elements raised during the discussion were the following:

- Paragraph 8(c) should make clear that it refers to biocidal products, since it could be seen as contradicting paragraph 16, which refers to the active substance renewal process.

- Several steps are missing from the timeframes presented in Annex I sections A and B.

- The proposed dates for the extension of the current validity of the authorisations in Annex 1 should really represent a worst case scenario, also considering the stop of the clock and longer timelines in case of referrals to the Coordination Group. The assessment of the new ED criteria could also be considered when estimating that worst case.

- Following the discussions held in the Coordination Group concerning the submission of a consolidated product assessment report at the renewal stage, section 3.3 of the document should include a paragraph about that.

- There is no legal basis to organise the renewal process of products in such a way that some applications would be treated earlier than other in order to distribute the workload in a more balanced manner over the time.

- A MS suggested moving paragraph 13 at the beginning of section 3.1.

- Industry supported the overall approach in the document and called upon MSs in order to allow a flexible approach for applicants in terms of fee payment and reimbursement. Depending on the outcome of the AS renewal, some products will no longer be supported.

- Upon request from Industry, it was clarified that the 6-month period referred to in paragraph 20 starts counting as from the entry into force of the Implementing Regulation on the renewal of the approval of the relevant AS(s). Therefore, from a practical point of view applicants will have more time to prepare the applications since the relevant BPC opinions will be known a few months earlier.

The Chair noted the broad support for the approach described in the document. The Commission services will therefore address the above comments in a revised version, which will be tabled for agreement at the May CA meeting.

4.2. Report from Coordination Group	For information	

The Commission services briefly informed the meeting of some issues discussed at the 28th coordination group (CG) meeting:

i) In terms of MR disagreements, CG members discussed 25 formal referrals. A consensus agreement was reached in 7 cases and for the other cases (18) the discussions are still on-going. The Commission services underlined the support provided by the CG Secretariat and the Chair of the CG in order to facilitate the agreement-reaching process. On a more general note, MSs

were further encouraged to improve the bilateral discussions within the MR phase in order to limit the number of referrals being submitted to the CG.

ii) The CG working party on biocides families has held its third meeting. The main elements under discussion were 1) the approach to consider similarity of uses based on a matrix including the uses specified in Annex V to the BPR; ii) the approach to consider similarity of composition;

iii) and some general aspects related to similarity: the need for an explanatory document on the rationale behind the family structure, how to improve and optimise pre-submission discussions and meetings and how to deal with ongoing applications when there is a change in the consideration of similarity during evaluation, mutual recognition or peer review.

For further information, the Commission services referred the meeting to the list of conclusions and actions arising from the CG-28 meeting, which will be made available on the dedicated CG CIRCABC interest group.

4.3. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-March18-Doc.4.3*	

The Chair invited the CA meeting to take note of document *CA-March18-Doc.4.3.*

4.4. Executive report on product authorisations	For information *CA-March18-Doc.4.4*	

The Chair invited the CA meeting to take note of document *CA-March18-Doc.4.4.*

4.5. Union authorisation		
(a) Executive report on applications for UA	For information *CA-March18-Doc.4.5.a.1* *CA-March18-Doc.4.5.a.2*	

The Chair invited the CA meeting to take note of documents *CA-March18-Doc. 4.5.a.1&2.*

(b) Template for Implementing Regulations granting UA	For information *CA- March18-Doc.4.5.b.1* *CA- March18-Doc.4.5.b.2* *CA- March18-Doc.4.5.b.3*	

The Commission services briefly introduced the updated version of the documents, which took into account the comments made at the last meeting and those submitted later on during the commenting period. It was also clarified that these documents could still be subject to some changes during the inter service consultation of the draft Implementing Regulations for the first Union authorisations.

(c) Checking of the translations of the SPC in UA SBP procedures	For discussion	

The Commission services briefly introduced the topic by indicating that, from the Commission's perspective, what is important is that every single Union authorisation (UA) has a SPC with correct translations in all languages. That SPC will be in the end the basis for the authorisation holders to create the labels in each language and for the enforcement authorities to check compliance.

The Commission services pointed out that the SPC will be an annex to the Implementing Regulation (IR) granting the UA, so MSss will have to check in any case the SPC in their official languages as part of the consultation of the Standing Committee. In that context, checking the translations at an earlier stage would i) give more time to MSs to identify any possible issue and ii) avoid the negative consequences that a late identification would involve (i.e. the adoption of the IR would be delayed until the translation issues have been solved).

ECHA made a presentation including some proposals to address the concerns expressed by MSs in terms of workload and the need to further optimise the process for SPCs that should be identical to those of the reference products (except for very limited information that should have been identified by the applicant in a supporting document and checked by ECHA during the validation of the application).

Industry representatives indicated that the applicants for the reference product have no interest in any possible change in the drafting of the SPC and that they use to support applicants for same products in the translation of the SPCs.

ECHA will further elaborate the above-mentioned proposals in the form of a document to be discussed in the May CA meeting.

4.6 Management of product authorisations for *in situ* cases	For discussion *CA- March18-Doc.4.6*	

The Commission services briefly introduced the topic by a presentation. Given the high number of *in situ* generation systems (IGS) already on the market (some of them were not covered by the BPD), the Commission proposed an approach that would allow manufacturers to group similar IGS under a IGS Biocidal Product Family.

A MS proposed to align the wording used in the note to the one used in the presentation because it is, according to this MS, closer to the legal requirements of the BPR ('realistic limited use conditions' versus ‘realistic worst case conditions’).

Another MS (supported by another one) indicated to support the general principles in the note, however, it had many technical questions. This MS noted that the definition of precursors mentioned in the note should be aligned to the definition of precursors agreed in previous CA documents. In particular catalysts should not be considered as precursors. The same MS mentioned that flexibility should be given to industry to shape the content of the IGS biocidal product family. The reference to the authorisation of room disinfectants as mentioned in point 4.5 of the note does not seem appropriate in this regard. The Commission services will check the coherence of agreed CA and ECHA documents. A MS supported the pragmatic approach but considered that his approach should be tested by looking at examples.

Another MS highlighted the issue of orphan IGS that are on the market but for which the manufacturers are no longer commercially active. The Commission acknowledged this issue and indicated that users can only use authorised IGS under the BPR. A MS pointed out a mismatch in the draft note and the BPC recommendations of 2017 on the data requirements for precursors; should the requirements be as for products or active substances. According to the latter,

precursors and active substances should be evaluated in accordance with the provisions of Annex II. The Commission stated it would check the approach proposed by ECHA. The MS asked whether generated active substances will also be subject to EDs assessment.

An industry stakeholder asked to clarify the distinction between releasers and *in situ* generation. Another industry stakeholder indicated that the Commission note goes into the right direction but stressed the urgency to come up with an agreed position on IGS authorisation. In relation to Annex II of the note, the association questioned the legal basis for making a distinction between simple and complex devices.

The Commission concluded by thanking the participants for their general support on the way forward and promised to revise the note following the information received during the meeting and after the consulting period (with a deadline of 6 April). The Commission highlighted that additional work will be required to clarify open technical questions with ECHA and that the position of the Commission Legal Service may be sought on certain issues.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-March18-Doc.5.1*	

(a) Specific discussion on the progression of the review of active substances, on the progress on the 1st and 2nd priority lists, and on new active substances	For discussion and agreement *CA-March18-Doc.5.1.a*	

The Commission services presented an overview of the progress of the work performed in 2017 on the review programme. It was noted that less progress has been made compared to 2016 and efforts must be made to meet the objectives commonly set in the BPR. In particular, MSs have to accelerate delivering decisions on active substances in the review programme to ensure safety and a fair competition on the market (by having all substances and products reviewed and subject to the same requirements). The Commission services underlined it is possible to respect the deadlines in the review programme as some MSs managed to respect the deadline for all their active substances (everything is 'green' in the document).

In that context, the actions for improvement presented at the last CA meetings were reiterated. An industry representative highlighted that several processes are being managed now in parallel (approvals, renewal of approvals, authorisations, renewal of authorisations) which generates workload and noted that prioritisation and application of revised/new guidance must be discussed. This stakeholder also emphasised the need to improve communication. It is essential that applicants and authorities communicate immediately if issues develop.

A MS noted that approving 50 active substances per year is a high figure, which also generates a cascade of workload for product authorisations. MSs may have difficulties to cope with the workload and proposed to postpone the deadline of 2024 of the review programme. The Commission services highlighted that the objective of finalising by 2024 the review programme, which started in 2004, must be achieved and there is no intention to postpone it. For this MSs need to allocate sufficient resources to the competent authority. MSs have the tools available to increase the capacity by setting proper fees according to the BPR to finance this activity. The

Commission services also underlined the role of guidance. ECHA should prioritise the existing requests for guidance based on what is really critical for the evaluation process. Also the timing for applicability of new guidance may also have to be reconsidered. Another MS asked for the cooperation of applicants, as some applicants trigger legal actions on their case, delaying the review process.

The actions for improvement of the review programme were agreed.

(b) Overview of expected applications in the context of redefinitions made on *in situ* generation in March 2015	For information *CA-March18-Doc.5.1.b*	

The Commission services informed that, following the request made by certain MSs, some applications that should be submitted in 2018/2019 in the context of re-definitions made on *in situ* generation in March 2015 will be re-allocated to other evaluating MSs compared to the current allocation set in Annex II to Regulation (EU) No 1062/2014. The re-allocation, agreed between the previous eCAs and the new eCAs, will be reflected in the update of the Annex II of the Review Regulation. One MS asked what would happen if no application is finally submitted. The Commission services answered that a non-approval decision will be adopted, and the relevant products will have to be removed from the market in according with the provisions of Article 89 of the BPR.

5.2. Inclusion of corn cob into Annex I to the BPR	For discussion and endorsement *CA-March18-Doc.5.2*	

The Commission services informed of the receipt of the ECHA BPC opinion on a possible inclusion of corn cob into Annex I to the BPR, following the process agreed during the 70th CA meeting of March 2017. In accordance with the agreed process, the Commission services informed that they intend to propose a draft delegated act to include this substance into Annex I to the BPR.

A MS considered that the BPC did not perform an appropriate methodological analysis of the requirements for including a substance in Annex I and expressed its concerns about the data at the basis of this inclusion. To its view, the requirements were different under the BPD and it wanted to have clarification on the level of data required to get an Annex I inclusion under the BPR. According to this MS, companies must be treated with fairness and consistency. Supported by another MS, the Commission services replied that the approach on corn cob has been discussed and agreed during the 70th CA meeting of March 2017 and is linked to the specific situation of this substance explained in the CA meeting of March 2017. The Commission services emphasised that a full dossier was submitted under the BPD, assessed and considered acceptable by MSs under the BPD, as the substance had been included into Annex I and IA under the BPD in 2013. ECHA's BPC has therefore considered this assessment, and verified if the conditions set in Article 28 of the BPR were fulfilled. As regards other companies interested to submit applications for inclusions into Annex I of other active substances, the data requirements are those set in Regulation (EU) No 88/2014.

A MS noted that rodenticide products based on corn cob have not yet been authorised due to lack of sufficient efficacy data, and noted that sufficient data must be submitted to obtain a product authorisation, even under the simplified authorisation procedure. The Commission services

echoed this point, and noted that it was an element already stated clearly in the final assessment report made under the BPD.

It was concluded that there is a general support of the CA meeting to prepare a draft delegated act to include corn cob into Annex I to the BPR, which will be presented in a subsequent meeting.

5.3. Process for food and feed substances under Article 15(b) of Reg. 1062/2014	For discussion and endorsement *CA-March18-Doc.5.3*	

The Commission services informed of the receipt of the ECHA BPC opinion on a possible inclusion of certain food and feed active substances into Annex I to the BPR, following the process agreed during the 66th CA meeting of September 2016. Following that process, the Commission services informed that they intend to further investigate the possibility to prepare a draft delegated act to include some of these substances into Annex I to the BPR. In particular, the interaction with Article 89 of the BPR (transitional period) needs to be further investigated. The Commission services indicated that for the substances found not eligible for Annex I inclusion, a 'normal' application for approval should in any case be submitted by applicants. For all the active substances referred to in the document MSs were invited to indicate their willingness to become evaluating MS, which needed be appointed and listed into Annex II to Regulation No 1062/2014; although one MS noted specification of an eCA was a requirement under the notification procedure (Art17(2)).

Two MSs informed that they are willing to act as eCA for some of these active substances. A MS asked in which category of Annex I the substances could be included. The Commission services clarified that these substances could possibly be listed into category 4 of Annex I as "Traditionally used substances of natural origin", based on information presented in the ECHA BPC opinion. Two MSs regretted that the possible entries covered by these substances may be limited or restrictive, as entries in Annex I could be more general on these types of substances. The Commission services noted that ECHA's BPC based its opinion on the notifications and information provided by industry. The identification was therefore highly dependent on industry's submissions and ECHA's BPC's consideration of these elements when delivering its opinion. One MS asked to clarify the link between Annex I listing and Article 95 obligations. The Commission services pointed out that only substances listed in category 6 of Annex I, and products containing them, are subject to Article 95 obligations. In response to one MS, The Commission confirmed that national procedures for handling during transition should continue. ECHA informed the CA meeting that an appeal procedure is currently on-going for two substances for which the notification was not considered compliant by ECHA. Those two substances are not included in the document discussed.

It was agreed to proceed as agreed at the 68th CA meeting of September 2016. The Commission services will therefore further investigate the possibility to include these substances into Annex I to the BPR, and check the interactions with Article 89 of the BPR.

5.4. Renewal of approval of active substances which are both approved and listed in Annex I to the BPR	For information	

The Commission services informed that a few legal questions still need further analysis, and it is the intention to have a discussion at the next CA meeting. They invited MS and stakeholders to refresh their knowledge about this topic by reading the previous CA documents from 2016 and 2017 on this topic, in order to be ready to have a discussion at the next CA meeting.

5.5. Opinion on a declaration of interest to notify under article 15(a) of Reg. 1062/2014	For discussion and endorsement	**Closed session**

A discussion took place in closed session.

5.6. Availability of MSs to act as eCA for new active substances	For discussion	**Closed session**

A discussion took place in closed session.

6. Treated articles

6.1 (a) Scope issues related to the enforcement project	For information and discussion *CA-March18-Doc.6.1*	

The Commission services introduced this agenda item, that was discussed together with agenda item 6.1(b). A MS uploaded in the relevant newsgroup an additional document related to the enforcement of the provisions on treated articles. According to the Commission services two questions were raised: (i) How should a MS handle a non-compliant treated article which has been made available on the market in that specific country, and (ii) the language on the label of a treated article. In relation to the first question the Commission services indicated that the BPR contains provisions in relation to the placing on the market of treated articles. If a treated article is made available on the market the enforcement should consider other relevant EU rules (for example on market surveillance) or national rules. The Commission services indicated that existing CA guidance seems not to address the second question. It will investigate whether a draft view can be prepared for the next meeting.

In the last meeting it was agreed that MSs would submit examples that could be considered in the context of the existing guidance on treated articles. Several MSs and a third country included several examples in the relevant newsgroup. A stakeholder provided its views on this issue. The Commission services looked at these examples and the questions raised in relation to upcoming activities of the Biocidal Products Regulation Subgroup of the Forum (BPRS) and concluded that, based on the existing CA guidance, one is able to decide whether a product can be considered a biocidal product or a treated article.

One MS stated that several of the uploaded examples do not provide sufficient information to conclude on the status and suggested to set the minimum information required. Another MS proposed to further discuss this issue as the authority receives signals that it is really difficult to work in practice with the CA guidance. A MS underlined that the CA members do not have a harmonised interpretation of the guidance. Following this discussion the Commission services

proposed to develop a document based on the provided examples of the MS. In this document all CA-members will be invited to include their assessment. The three examples with the most diverging views will be discussed in the next CA meeting.

6.1 (b) Questions relating to the enforcement	For information and discussion	

See point 6.1 (a).

7. Horizontal matters		

7.1. ECHA communications	For information	

ECHA made a brief presentation on the confidentiality claims check, indicating that an in-depth discussion is foreseen for the May CA meeting and that MSCAs should prepare for it.

7.2. ECHA guidance		
(a) Priority setting for developing ECHA guidance	For information	

This agenda item will be discussed in next CA meeting.

(b) State of play ECHA guidance (on-going consultation, finalised guidance)	For information *CA-Jan18-Doc.7.2.b*	

Regarding the EFSA – ECHA guidance on endocrine disruptors, ECHA indicated that as part of the formal consultation procedure, the members of the BPC will have a two weeks period in mid-April for providing written comments and similarly the MS competent authorities will have the possibility to provide written comments in mid-May. ECHA highlighted that in view of the earlier opportunities to provide input and comments and considering the extremely tight timeline for the finalisation and publication of the guidance in early June, only limited comments are expected from the BPC members and CA members.

7.3. Endocrine disruptors		

(a) The implementation of scientific criteria for the determination of ED properties in the context of active substances	For discussion and agreement *CA-March18-Doc.7.3.a*	

The Commission services introduced the revised CA document by a presentation. The revised document is based on the discussion in the January CA meeting and the received contributions. One MS could agree in general with the document and proposed to clarify the sentence concerning 'applying scientific guidance' in paragraph 10. In particular this MS indicated that the current drafting implies that the scientific guidance would obtain an obligatory character. ECHA clarified that the use of ECHA guidance is not mandatory but is recommended. Another MS pointed out not to favour to disconnect the scientific guidance of the decision whether a substance is an ED. This MS proposed to use 'recommend' in relation to the scientific guidance. One MS suggested to include in the BPC opinion, concerning active substances for which the rapporteur MS submitted its assessment report before 1 September 2013, a sentence on whether the substance would meet the interim criteria. The Commission services clarified that the interim criteria will not anymore apply from the moment the scientific criteria will become applicable.

One MS raised a question on the use of data submitted in other regulatory fora referring to the paragraphs 21 and 22. Another MS proposed to delete in paragraph 21 the last sentence 'it must not be used to replace data …'. This view was supported by another MS as the use of data is considered a horizontal issue. A MS indicated that paragraph 22 implies that a competent authority has to assess whether a company could benefit from the use of the data. An industry stakeholder indicated the importance to address data sharing and data protection. The Commission services stated that it is important to separate the concepts of data protection, data sharing and confidentiality of data. It was also pointed out that in the BPC regularly data is being used not submitted by the applicant. One MS asked a clarification of footnote 22. The Commission services clarified that the ED criteria of an active substance do not have to be determined if the BPC would propose to have a non-approval of the active substance because of non-ED properties. In such a case, it is better not to delay the non-approval process. However, if during the discussion in the Standing Committee appears that one of the conditions set out in Article 5(2) could be met and the Standing Committee may support an approval, the Commission will return the opinion to ECHA to determine the ED properties. The reason for this return of the opinion is that the information whether a substance is considered to have endocrine-disrupting properties may affect the position of a MS in the Standing Committee. So, it is important that the evaluating competent authority estimates whether the non-approval opinion of the BPC will lead to a non-approval decision in the Standing Committee. ECHA pointed out to be pleased with paragraph 10. According to ECHA the working groups should assess whether a substance meets the criteria in section A and/or B of the Annex of Regulation (EU) 2017/2100 and pointed out it would be useful to have a finalised document for the next BPC meeting. A third country proposed to change the reference in footnote 9 to Article 5(3) into the Commission Delegated Regulation 2017/2100. An industry stakeholder indicated to appreciate the pragmatic approach in the document and asked clarification of the sentence in paragraph 11 on the non-approval if the required data were not provided. The Commission services indicated that an applicant should be allowed a reasonable period to submit data and confirmed that the failure to submit the required information in the set timeframe, and in the absence of valid justifications, can lead to a non-approval.

During the meeting a document with track changes was developed addressing the raised comments (in particular paragraphs 10 and 21) and presented to the CA meeting. The Commission services committed to start to develop a horizontal document on data protection to be presented in a future CA meeting. The revised document was agreed by the CA meeting.

(b) The implementation of scientific criteria for the determination of ED properties in the context of biocidal products	For discussion and agreement *CA-March18-Doc.7.3.b*	

The Commission services introduced the revised CA document by a presentation. The revised document is based on the discussion in the January CA meeting and the received contributions. A MS indicated that the Commission services presented a flow diagram for the document discussed under agenda point 7.3.a (implementation of ED criteria for ongoing procedures active substances) and asked whether a similar flow diagram could be provided for the document on biocidal products. The Commission services indicated to have developed such a draft flow diagram for biocidal products. It will be verified whether the draft flow diagram can be improved and provided to the CA meeting. One MS asked clarifications on the drafting of paragraph 23. This MS considered that the four sentences at the bottom of this paragraph were overlapping. Another MS considered the use of 'may' in paragraph 23 not correct. Also it was proposed to change 'indications' to 'evidence' in this paragraph. The proposed amendments received support of one MS. However, another MS did not agree to change 'indications' to 'evidence'. The proposed amendment to 'evidence' triggered a discussion on the definition/meaning of 'evidence' and 'indication'. Also the use of 'evidence' in the Biocidal Products Regulation was analysed. A MS proposed to clarify in a footnote the meaning of 'indications' by referring to 'scientific information available that raises a concern'. The CA meeting also discussed in detail whether the use of 'may' in three places in the paragraph 23 was appropriate. .

Another MS pointed out the strict deadlines for biocidal products authorisations. The Commission services explained that the approach in the draft document is to ensure that the legal deadlines could be respected. One MS considered that no legal basis exists for asking additional data on non-active substances. The Commission services indicated to have analysed the point raised by this MS in a former meeting and that it was concluded that a legal basis exists for asking this type of data. A MS noted that the paragraph on the concentration limit for non-active substances has been deleted and regretted this. One MS indicated in relation to paragraph 28 that downstream users do not have access to the required data on non-active substances by the competent authority.

A MS indicated that in paragraphs 11 and 35 the proposed conclusion on ED properties of a substance in the assessment report is discussed. In its view this paragraph should be aligned with the outcome of the discussion on the document on active substances, for example on the drafting in relation to scientific guidance. One MS indicated that in the footnote 22 the Annex IV of REACH should be Annex XIV.

During the meeting a document with track changes was developed addressing the raised comments (in particular paragraphs 11, 23 and 35) and presented to the CA meeting. The revised document was agreed by the CA meeting. One MS wished their disappointment to be noted in the minutes regarding the removal from the guidance of the paragraph on CLP and concentration limits and their further disappointment that there was no agreement to a compromise to add text to paragraph 9, that account should be taken of when there is evidence that the ED properties of the constituents are not manifested at the concentration at which they are present in the formulation.

(c) The implementation of scientific criteria for the determination of ED properties in the context of already approved active substances	For information / discussion	

The Commission services indicated that it is the intention to discuss this agenda item in the next CA meeting.

7.4. The notification of the United Kingdom pursuant to Article 50 of the Treaty	For information	

The Commission services informed the CA meeting about the results of the 3rd technical seminar. It was indicated that based on the discussed reallocation to another competent authority of active substances of which the UK is currently the evaluating MS, a draft delegated regulation will be prepared. It is the intention to initiate the discussions on this draft act in the next CA meeting. There were also some discussions how to inform applicants about the shift to another eCA in the context of active substance procedures outside the review programme as well as for product authorisations or renewals.

8. Requests for opinions

8.1 Products used to control the size of urban pigeon populations	For discussion *CA-March18-Doc.8.1.a* *CA-March18-Doc.8.1.b*	**Closed session**

A discussion took place in closed session. The status of this kind of product will also be discussed in the relevant EU forum for veterinary medicinal products. The Commission services will update the CA meeting on the outcome of such a discussion.

9. Enforcement issues

9.1 Subgroup BPR Forum - Forum/BPRS Action Programme 2019-2023	For discussion *CA-March18-Doc.9.1*	

The Commission services informed the meeting about the last meeting of the Subgroup BPR Forum and indicated that the BPRS discussed the suitability of alert and information exchange systems for BPR, the BPRs enforcement project on treated articles and the BPRS activity Training for Trainers 2018. Also the BPRS noted that 'placing on the market' appears to be translated in different ways.

The Commission services informed that it is planned to have a REACH-CLP-BPR Enforcement Conference on 13 November 2018.

ECHA informed that the current Multiannual Work Programme of the Forum is coming to an end and that the Forum/BPRS installed a Working Group in charge of the preparation of the next strategic document outlining its enforcement priorities and actions for the years 2019-2023. The Competent Authorities are invited to liaise with their BPRS members at the national level and submit information by 20 April 2018 about what in their view should be the BPR enforcement priorities for the coming years.

CA Members are invited to indicate their BRP enforcement priorities for the coming years for the establishment of the Forum Action Programme 2019-2023.

9.2 Fact finding missions	For information	

The Commission briefly informed the CA meeting about the state of play of this project. The fact-finding missions to Hungary, Germany and Spain have been already completed. Belgium and the Netherlands will be visited soon and Poland after the summer break.
Once the overview report of all the fact-finding missions will be ready, Directorate F will organise early 2018 a workshop in order to present that report and spread good practices among MSs.

10. International Matters

10.1 Preliminary process for inclusion of cybutryne into the AFS convention at IMO level	For information	

The Commission services informed about an update on the on-going process to add cybutryne into the Annex of the Anti-Fouling Systems (AFS) Convention, with the view to ban it at international level. The good cooperation of the various EU services (DG Move, DG Sante, ECHA, EMSA) was noted. The Commission services informed that additional work is being performed by EMSA and ECHA to prepare the comprehensive proposal scheduled for discussion in early 2019. In that context, MSs were invited to inform the Commission if they are interested to provide further support in search for additional data on cybutryne effects in other parts of the world.

11. Administrative Matters

8.1. AGM – new electronic system for reimbursement - "AGM"	For information	

The Commission services informed the meeting about the introduction of this new system for reimbursement.

12. AOB

- Grouping of antifouling products

A MS noted that the e-consultation conducted as a follow-up from the last CA meeting on document CA-Jan18-Doc.7.4.a was positive, as only minor editorial comments were made. It enquired if a final version of the document will be forwarded to MSs and stakeholders, and enquired what will be the next steps for this document. The Commission services confirmed that a final version of the document will be made available, and will check if this document will be uploaded or not on the section of CIRCABC with final versions of CA documents as this is a document prepared by a MS and not drafted in the format of aa CA document. In any case, the agreements presented in this document of the CA meeting will have to be reflected into guidance for product authorisation, for transparency to all parties and information of prospective applicants.

- OECD meeting of Working Group on Biocides

The next CA and SC meeting is scheduled at the end of May (week 22). These meetings appear to overlap with the annual meeting of the OECD Working Group on Biocides which is scheduled on 31 May-1 June in Dublin. The Commission services indicated that a room is available for the CA and SC meeting in week 21, however, it has to be checked whether the internal procedures can be concluded on time. The CA meeting was asked to provide their views on the need to reschedule the CA/SC meeting. The Commission services will inform as soon as possible the CA meeting about the planning of the May meeting.

- Research use only (RUO) products and in vitro diagnostics for veterinary use – preservatives

A discussion took place in closed session. MSs were updated on the state of play, in particular on the upcoming meeting in Council.

Next meetings:

2018 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
9-10 January	10-12 January	-	-	I: 16-26/01
-	-	-	-	-
12-14 March	14-16 March	16 March	5-9 March	II: 19-29/03
-	-	-	23-27 April	-
30 May-1 June	28-30 May	-	-	III: 21-31/05
-	-	21 June	24-29 June	-
4 July	5-6 July	-	-	-
25-26 September	26-28 September	-	-	IV: 4-14/09
-	-	12 November	15-19 October	-
19-21 November	21-23 November	-	-	V:?
-	-	-	10-14 December	-