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

MINUTES

82nd 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

13-15 March 2019

1. Adoption of the agenda	For adoption *CA-March19-Doc.1.rev2*	

The following points were added to the agenda under AOB: item on the developments at IMO level on cybutryne and one item to be discussed in a closed session. The Chair also informed that some of the items of the agenda will be postponed to the next meeting, more specifically items 4.4.(b), 4.8 and 7.8.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-March19-Doc.2*	

The draft minutes of the 81st CA meeting were adopted.

3. Draft delegated acts		
3.1. Draft proposals including certain food and feed active substances into Annex I to the BPR	For discussion *CA-March19-Doc.3.1.a* *CA- March19-Doc.3.1.b* *CA- March19-Doc.3.1.c* *CA- March19-Doc.3.1.d* *CA- March19-Doc.3.1.e* *CA- March19-Doc.3.1.f* *CA- March19-Doc.3.1.g*	

The Commission services presented the revised proposals for delegated acts including certain food and feed active substances into Annex I to the BPR, following the positive opinions from ECHA and the previous discussions in the CA meeting. In particular, compared to the previous versions, specific conditions concerning the specification of certain of these active substances have been included to make reference to the fact that these must correspond to the legal definition of food and feed, and that they must meet, or have met in an earlier point in time, the conditions for food and feed safety. This condition is functional, for instance for honey, as honey made out of certain plants is not safe for human consumption.

One Member State identified the need for an editorial correction in the explanatory memorandum. Another Member State requested clarifications on the applicable transition period for existing products on the market following the Annex I inclusion, and questioned the absence of reference to the possibilities to apply for authorisation via the simplified authorisation procedure in recital 7. The Commission services indicated that recital 7 makes reference to the text set in Article 89 of the BPR, which does not make reference to the simplified authorisation procedure: however, in practice, similarly to applications to Union authorisation which are also not specifically mentioned in Article 89, applications via the simplified authorisation procedure can be considered as applications for authorisation as included in Article 89(3). It was also clarified that applications for authorisation of existing products must be submitted before the date set in Article 2 of the delegated acts, i.e. 1st June 2021. On the timing for adoption, the Commission services explained the time constraints as

these acts must be in force before September 2019 for legal certainty and thus will avoid the need for submission of applications for approval for the related substances, as discussed previously in the CA meeting.

On D-fructose, one Member State questioned the limited inclusion of D-fructose, as there will be products consisting of a complex mixture which might contain other type of fructoses, or inverted sugar, and this Member State would have preferred a more open inclusion. This Member State indicated that D-fructose is rather limited but other substances have a rather wide scope. The same Member State also pointed out that the Biocidal Products Regulation should support sustainability and a limited scope of an Annex I does not provide an incentive for industry to apply for simplified procedure. The Commission services indicated that the same comment was raised by that Member State at the BPC level and in that meeting it was clarified that the BPC made a recommendation covering D-fructose, considering that the notification was made only for that specific active substance. The Commission services underlined that companies can submit an application to include in Annex I other types of fructose. The relevant procedure is included in Commission Implementing Regulation (EU) No 88/2014. When confronted to particular cases at product authorisation, for example on the identity of a substance, the Commission services reminded that Member States may consult the Coordination Group on specific cases in order to find a harmonised approach between Member states.

On powdered egg, one Member State questioned whether the powdered egg made out of the white part of the egg was covered, to which ECHA gave a confirmation.

On vinegar, one Member State would prefer, if possible, to avoid the reference to a technical standard in the act, due to previous issues at national level where it was considered that the reference to a standard raised accessibility issues to the persons concerned by decisions if it is not available in the relevant languages. Another Member State proposed to add a restriction that the intended uses shall not exceed the Acceptable Operator Exposure Concentration of 1 mg/m3 as was recommended by EFSA when vinegar was considered for approval as a basic substance under the framework for plant protection products.

The draft delegated acts were agreed by the expert group as presented. For vinegar, the expert group agreed that the Commission services will check whether the reference to the technical standard needs to be modified (if it is removed, the same provisions on the reference to food and feed as in the other acts would be added), and will also check whether the introduction of a limit of 1 mg/m3 is required and, if necessary, will make modifications to the act.

4. Biocidal products		
4.1. Report from Coordination Group	For information	

The point was not discussed.

4.2. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-March19-Doc.4.2*	

The meeting participants were invited to take note of the report uploaded in CIRCABC.

4.3. Executive report on product authorisations	For information *CA-March19-Doc.4.3*	

The meeting participants were invited to take note of the report uploaded in CIRCABC.

4.4. Union authorisation		
(a) Executive report on applications for UA	For information *CA-March19-Doc.4.4.a*	

The meeting participants were invited to take note of the report uploaded in CIRCABC.

(b) Executive report on delays for UA applications	For discussion *CA-March19-Doc.4.4.b*	Closed session

This item was postponed to the next CA meeting.

4.5. Management of product authorisations for *in situ* cases	For discussion and agreement *CA-March19-Doc.4.5*	

The Commission services announced that substantial amendments were made to the last version of the CA document. The meeting discussed the revised text section by section to identify possible remaining concerns.

The most important comments received are listed below:

In relation to section 3.2, paragraph 9, an example of the generation of one or more in situ active substances involving one or more precursors was removed and the other example was clarified. One Member State asked to clarify that IGS should not cover dosing systems that could manage the ratio of precursors.

In relation to section 3.3 point 13(c), the meeting agreed that a variable concentration of the precursors should be allowed.

At the request of two Member States, the Commission services clarified that, according to Article 17(6), each member of the family will have to be identified at the level 3 of the SPC. Those Member States argued that for some specific cases under the second indent of the definition of biocidal products (i.e. ozone) it will not be possible to identify an exact concentration of the in situ active substance generated and thereby to identify each member of the biocidal product family. The Commission services acknowledged that the legislation has some limitations to address the specific characteristics of in situ generation system, in particular those under the second indent, where the active substance is the biocidal product and may vary within a range (see Annex V of the CA document). In practice, this limitation could lead to the obligation to authorise an infinite number of in situ biocidal products. The Commission services proposed that in such cases, the authorisation does not specify the member of the family but that the authorisation is granted at the level of the meta-SPCs. From the risk and efficacy assessments point of view this provides no problem as the whole range of concentrations of

the active substance will be covered at that level which will constitute a family (see Annex V of the CA note). One Member State asked to adapt in relation to this approach the paragraphs 27 and 36.

The meeting agreed that the Commission develops a Q&A item in the Annex of the CA-document to address this point. The Commission services will consult the Coordination Group as well as the Legal Service of the Commission for their opinion before the Q&A is presented to the CA in advance of the May meeting.

In relation to section 3.4, paragraph 19(b), a Member State asked how technical equivalence could be verified. The Commission services replied that, as for normal active substance, the applicant would have to provide a certificate of technical equivalence delivered by ECHA.

In relation to section 3.5, paragraphs 26 and 27, it was discussed which information on the composition of the active substance should be available in the SPC. In connection with the obligation to inform the consumer about the composition of the in situ active substance, a Member State enquired whether a 5-batch analysis should be requested in order to inform the users about the presence of impurities. The Commission services clarified that the need for a 5-batch analysis of the in situ generated active substance could be further discussed in the development of ECHA's technical guidance but that this is not a requirement specified in the BPR. One Member State indicated that for case type 3 in paragraph 26 it is not correct to refer to the paint as precursor.

In relation to recital 29, it was clarified that for cases falling under the second indent that the Hazard and Precautionary statements of the precursor(s) should be mentioned in a relevant part of the SPC if appropriate.

4.6. Disinfecting by-products	For discussion *CA-March19-Doc.4.6*	

The Commission services reminded the context of this note prepared by the UK, where in essence the question asked to the CA meeting is whether the issues related to disinfecting by-products (DBPs) should be dealt with already now at the authorisation of products, or whether the issue should be dealt with at the renewal of approval stage in those cases where guidance is not available.

The UK competent authority presented a note describing the challenges ahead in assessing the impacts on human health and the environment of substance's metabolites, breakdown and reaction products (DBPs). The issue was discussed in two relevant Coordination Group meetings and a written consultation took place between those two meetings. No clear consensus emerged during these consultations but the Coordination Group agreed that this issue should be treated as a matter of urgency.

The UK CA put forward four proposals for consideration by the CA in order to make progress on this long lasting issue.

Four Member States commented that the assessment of DBP is a complex matter that would require setting priorities for identifying when a full environmental and/or human health risk assessment is needed of DBPs. It was highlighted that some DBPs are not identified as an issue and would therefore not be relevant for assessment.

One Member State disagreed and argued that this option would require too much time while urgent action is needed as many Member States are already involved in product authorisation.

A lack of harmonisation on the assessment of DBPs could lead to an increasing number of referrals at the product authorisation stage.

The Commission services explained that taking decisions whether a full environmental and/or human health risk assessment of DBPs should be a high or low priority, would be time-consuming. The Commission services proposed an alternative approach combining prioritisation and use of existing guidance in particular for the assessment of some disinfectant active substance/ use combinations for swimming pools. The final option should also take into account the lack of resources in the Member States, ECHA and the Commission.

The Commission services concluded by asking the participants to send their comments in writing and identify clearly their favoured option by Friday 5th April via the dedicated CIRCABC newsgroup.

4.7. CG-WP's recommendations regarding BPFs: outcome and applicability	For discussion *CA-March19-Doc.4.7*	

ECHA recalled the objective of the Coordination Group (CG) Working Group (WG) on the implementation of the Biocidal Product Family (BPF) concept. Article 3(1)(s) specifies under which conditions several biocidal products could be grouped within a biocidal product family. The document CA-Nov14-Doc5.8-Final.rev3 outlined a practical approach for the implementation of this article but some of the elements of the former document of 2014 required further clarification and updates. The CG mandated a dedicated WG to address those concerns and illustrate the approach with relevant examples.

ECHA mentioned that the CG already agreed on several deliverables last year and that a last deliverable on similarity issues was adopted on 12 March 2019. When one of the similarity criteria is not met, the applicant will be required to redefine the structure of the proposed BPF. In the future a pre-submission meeting between applicant and competent authority would help in understanding the structure of the proposed BPF. In the last CG meeting a document was agreed with proposals to update the policy in relation to BPF.

The Commission services explained that, according the CG document, the MS CA could accept three refinements of the family (via subsets and extensions) under certain conditions in order to avoid redundant applications while keeping a manageable size of the BPF.

The Commission services further explained that, based on the consensus reached by the CG, the document CA-Nov14-Doc5.8-Final.rev3 will be revised and, if possible, a new paper will submitted to the next CA meeting for discussion and possible agreement.

On the question of the applicability of the revised CA document, the Commission services explained that a majority of CG members supports an early entry force of the new guidance, even if a cut-off date of two years is the standard transitional period for the applicability of new guidance for biocidal products. This shorter transition period is proposed because a lot of applications for BPF authorisation are already under discussion and the revised CA note will help the MS CA in their decision making process. However, a large majority of MS CA in the CG agreed that the new rules should only apply to applications for products submitted after the date of entry into force of the revised CA document. Only three delegations were in favour of requiring the applicability of the new guidance to already submitted applications.

ECHA commented that the overall objective is that MSCAs act in a harmonised way and that therefore the existing applications should as far as possible be considered in line with what has

been agreed. The Commission services reminded of the importance of a level playing field for companies.

4.8. Guidance on same biocidal products (SBP)	For information *CA-March19-Doc.4.8*	

This item was postponed to next CA meeting.

4.9. Reports from Member States on the authorisation of creosote containing products	For information	

The Commission services informed that the reports forwarded by the Member States having authorised products containing creosote have been published on DG SANTE's webpages (https://ec.europa.eu/health/biocides/creosote_en) and invited those Member States that have not yet forwarded their reports to the Commission to do so.

4.10. Applicability of transitional period in relation to Union authorisations	For information	

The Commission services indicated that the Coordination Group agreed that, in the situation the new BPF-family guidance would require to split on-going applications for families, all the existing products initially covered by that BPF, notwithstanding the necessary split of the family in separate families, can still benefit from the provisions of Article 89 of the BPR regarding the transitional period. The Commission services proposed to apply this principle also to products originally covered by a Union authorisation family and at a later stage transferred in national products. This proposal triggered many questions of Member States and it was agreed to submit a document setting out the details for the next CA meeting.

4.11. French provision on the restriction of use and placing on the market of treated wood	For information *CA-March19-Doc.11.b.1* *CA-March19-Doc.11.b.2*	Closed session

The discussion took place in a closed session.

4.12. Article 47 notification	For information	Closed session

The discussion took place in a closed session.

4.13. Biocidal products containing chromium	For information	Closed session

The discussion took place in a closed session.

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

The Commission services presented the annual report for 2018 on the review programme and reminded that Member States should organise their work along the priority lists, invited them to submit the delayed reports of the 1st, 2nd and 3rd list of the review programme, and insisted that the backlog reports must be finalised by the concerned Member States.

5.2. Progression of the renewal process of approval of active substances	For information *CA-March19-Doc.5.2*	

The Commission services presented the status report on the applications for renewal of approval, and reminded the concerned Member States to inform Commission and ECHA of their choice to perform a limited or full evaluation within 90 days of the acceptance of the dossier by ECHA.

5.3. Approach on some in-situ active substances	For discussion *CA-March19-Doc.5.3*	

ECHA presented its document on the management of chlorine dioxide related substances in the review programme, and proposed to specifically review each second precursor already at the approval stage and in situ active substances to define by reference to the precursors and the active substance generated, leading to the need to perform re-definitions. It is necessary to clarify this situation as ECHA has received three notification falling under the general entry of 'chlorine dioxide generated from sodium chlorite by acidification/oxidations'. ECHA pointed out that lack of assessment at approval stage of the second precursor will probably lead to many referrals at product authorisation stage. The Commission services expressed its preliminary reservations on such an approach, as the decision reached in 2015 was a compromise considering the potential high number of additional entries which would be added to the review programme. In 2015 it was estimated that more than 100 entries may occur to the Review Programme by a redefinition. The Commission services called for the views of the other Member States, inviting them to consider the pros and cons of both approaches.

Seven Member States took the floor to support the ECHA proposal or a variation of it, with the view to already assess at the approval stage the second precursors and specify them in the approval decisions. One of these Member States, supported by a few of them, proposed not to make a re-definition but to already identify and list the second precursors in the future approval decision based on the second precursors currently present in the applications under assessment by Portugal. Another Member State expressed it concerns on all options. It was also mentioned that the discussion on chlorine dioxide could have an impact on other similar cases in the Review Programme which have unspecific entries.

CEFIC, represented by the current participant for the dossiers submitted in Portugal, supported to maintain the approach agreed in 2015 to keep flexibility and assess the second precursors at the product authorisation stage. One Member State questioned why so many different second

precursors would be needed and asked to CEFIC whether there are specific technical reasons behind, like whether it would be important to use the second precursor A or B specifically. CEFIC mentioned that the using of the second precursors A or B has, a priori, only limited relevance as it is used mainly for its function as a "proton donor".
It was clarified that including the name of the second precursors in the approval decision would *de facto* mean that only the specific precursors listed in the approval decision could be allowed at product authorisation stage.

The Commission services invited Member States to send their comments by Friday 5th April via the dedicated CIRCABC newsgroup.

5.4. CLH status of biocidal active substances	For information *CA-March19-Doc.5.4*	**Closed session**

The discussion took place in a closed session.

6. Treated articles

No item for information or discussion

7. Horizontal matters		
7.1. ECHA communications		
(a) Biocides dissemination: updates on the new dissemination website	For information	

ECHA gave a presentation on the Workshop organised on 12-13 February on the active substance process in ECHA, reporting on the main discussion points, proposals and conclusions. ECHA indicated that more details on undertaken follow-up actions and proposals will be presented at the next CA meeting.
ECHA also informed on the status of the dissemination website. Following the issues related to the disclosure of confidential documents after the release of the new website, Member States competent authorities were requested to review all the documents in the assets by end-January. The gradual publication of documents related to products authorisations will resume at the end of March.

7.2. ECHA guidance		
(a) State of play ECHA guidance (on-going consultation, finalised guidance)	For information *CA-March19-Doc.7.2.a*	

(b) Priority setting for developing ECHA guidance	For discussion *CA-March19-Doc.7.2.b*	

Items 7.2.a and 7.2.b. were discussed jointly.

The Commission services introduced the topic by referring to the document prepared by ECHA and distributed in advance of the meeting.

ECHA indicated that the document is meant to provide an overview of all the identified guidance needs in various areas and what is foreseen for them. ECHA pointed out that, while there is an overall steering for topics of general relevance or particular importance, prioritisation mostly takes place area per area as the majority of the topics are very specific. Since in most of the cases the initial drafting is provided by Member States' experts, there is to some extent an implicit prioritisation (i.e. the absence of volunteers from Member State imply a de-prioritisation of certain topics). Several Member States expressed that the document should better clarify what are the priorities. One Member State pointed out that several groups should put forward their views and ECHA needs to perform a horizon scanning. Two Member States indicated that it is important to know the risks of the lack of guidance. ECHA asked the Member States to send the topics that are lacking and information to determine the timeline by which the corresponding guidance should be developed.

(c) Draft guidance on data requirements and assessment of applications for renewal of active substances	For discussion *CA-March19-Doc.7.2.c*	

ECHA presented a draft guidance document on the data requirements for the application for renewal of approval, which included several specific questions asked to Member States. The Commission emphasised that renewal of approval should be managed properly to avoid ending up assessing dossiers for 10 years like in the review programme.

One Member State indicated that it did not send comments, but will do so. It enquired if and how data coming out from third party dossiers and Article 95 dossiers stage could be considered at the renewal of approval. It supported the idea of a "renewal document" as presented in the draft guidance, and wondered whether an updated consolidated CAR was needed.

Another Member State questioned the criteria leading to a full evaluation, and also noted that sometimes additional data is needed which should be assessed. According to this Member State a renewal does not imply a re-evaluation of all data previously submitted for the approval would be needed. One Member State suggested that the need for an Article 5(2) assessment should be added to the list of criteria for deciding when to conduct a full evaluation.

Another member state commented that the preferred approach is that dummy products are not accepted at the stage of renewal, but this might lead to practical problems: it might be that some a.s. suppliers do not have real products approved. In that case no data are available to them on the uses of real products and dummy products may still be a solution.

Another Member State raised its doubts on the need to submit the old data package from the previous approval, noted that a reference product would be needed if a risk assessment is needed, and considered that the renewal in most cases will not be a "limited" evaluation. It was also mentioned that, in certain situations, having a reference product may be difficult. One Member State raised its doubts that data for a reference product are needed as authorised and assessed products are still on the market. One Member State underlined the link between the

renewal and CLP and Article 95. This Member State pointed out that renewal may trigger a proposal for a modified classification. Another Member State raised a more general question on how to bring new information on an active substance one may become aware (ex: via national authorisations, monitoring, etc.) to the knowledge of other Member States, so that it is considered at the occasion of the renewal of approval. ECHA pointed out to liaise with CLP colleagues to clarify the situation.

One industry representative asked to have the document as it was only distributed to Member States.

It was agreed that the draft document will be provided to stakeholders for comments. The Commission services invited Member States and stakeholders to send their comments by Friday 5th April.

7.3. Technical equivalence assessment and Good Laboratory Practice	For discussion and agreement	

The industry representative that had brought this item for discussion indicated that they agreed with the comments provided by the two Member States after the September CA meeting. It was therefore concluded that the technical guidance of ECHA (including the GLP requirement) should be continued to be adhered to.

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

The Commission services reported on the discussions in the last Technical Seminar related to UK's withdrawal held on 15 March.

7.5. EU-wide forecasting of applications	For discussion *CA-March19-Doc.7.5*	

The Commission services introduced the topic by mentioning the comments received from four Member States after the last meeting and highlighted that any further investigation as to whether to put in place such system and to the modalities to do so should continue only if there is adequate support from Member States. One Member State indicated that it is difficult for Member States to commit further before having more clarity on what such system would achieve and the modalities to do so. Two Member States expressed their support for a forecast system because of the advantages of such a system and suggested to try to develop a simple version that would at least indicate the main trends. One industry representative expressed support for the idea in general but pointed out that a margin of flexibility is needed for companies to adapt their planning and such a system should not become a mandatory pre-registration tool. According to this industry representative, formulators rely on the Work Programme of the BPC which is changing very often and provides limited visibility. The same representative enquired whether an extrapolation from the various national systems in place in some Member States would be possible. The Commission services underlined that, in order to have an effective forecast system in place, commitment from both applicants and authorities is needed. A Member State indicated that a forecast system could focus on finding out the trends.

ECHA expressed strong reservations for the development of such system and questioned its real benefits and underlined the difficulty to have reliable forecast beyond the time span of several months, also bearing in mind that the timeline for national authorities to increase their resources is approximately two years. One Member State echoed the reservations expressed by ECHA and mentioned that, since national forecast systems are difficult to implement, the implementation of a EU-wide system would be even more difficult. Another Member State stressed that there is a need for a forecast system with a timeline of at least 12 months.

One Member State indicated that they have an informal tool which provides good forecasting for a two-year time span. ECHA mentioned that there are already forecast systems in place for active substance applications and Union authorisation applications, based on the input received from Member States.

The Commission services invited Member States to send their comments by Friday 5th April via the dedicated CIRCABC newsgroup.

7.6. Amendment of Annexes II and III to the BPR	For discussion *CA-March19-Doc.7.6*	

The Commission services explained the progress made since the last CA meeting. A meeting was organised by ECHA with technical national experts to discuss the outstanding issues. At this meeting most of them were solved but no consensus could be found on the proper wording for the testing on reproductive toxicity and the ED assessment of biocidal products. According to ECHA-EFSA guidance having proper information on reproductive toxicity is key for determining ED properties of a substance. The Commission also clarified its intention to have a transitional period of 12 months for active substances and 24 months for products for the implementation of the new rules.

On the issue of reproductive toxicity, the Commission services stressed the relation with REACH and PPPR, where similar information requirements are applicable, and informed about the recent conclusions of the Council working party of 5 March 2019 that called for a more coherent approach across different legislation with regard to the assessment of ED properties of chemical substances. A common approach for the EOGRTS under the three legislations BPR, REACH and PPPR is therefore most welcome.

Five Member States supported the alignment of the data requirements for reproductive toxicity under REACH, BPR and PPPR. One Member State added that the current triggering system under REACH for the Extended One Generation Test (EOGRTS) has shown its limitations and should be replaced. According to this Member State the two-generation study (OECD TG 416) could be an alternative to the EOGRTS in some conditions and if appropriately justified by the applicant. The Commission services indicated that triggering certain cohorts in the EOGRTS is one of the main issue for discussion and acknowledged that the triggering system provides implementation challenges under REACH.

One Member State underlined that for non-active substances, additional information is not always needed. This implies that the text should make use of the wording ‘may’, even if the Commission proposes the wording “shall” concerning the points 8.7 and 9.2 of Annex III. However, the current wording of points 8.7 and 9.2 is very different, the current wording of 8.7 is “may be required”, the wording of 9.2 is “shall be carried out”.

Four other Member States informed they will send comments in writing. The Commission services invited all delegations to clarify their positions in writing before 5 April. A robust

justification of their choices would be appreciated. Once the final views of the Member States are known, the Commission will organise a meeting with other DGs and Agencies involved in the matter in order to agree on a way forward and possibly propose a new wording for the next CA meeting in May. A few Member States commented on other parts of the Appendix I of the CA document and were also invited to provide their comments in writing for the sake of completeness.

On the ED assessment of products a Member State expressed strong concerns about the fact that the current wording seems to imply that all non-active substances would have to be assessed following the BPR route. According to that Member State, flexibility should be given to the Member State to choose the REACH procedure to assess the ED properties of non-active substances.

In Commission's view both the routes under BPR and REACH are possible to identify ED properties of non-active substances. The Commission added that the current wording of point 8.7 in Annex III of the BPR is very similar to the proposed wording. It was clarified that the provisions are primarily addressed to applicants and describe how the information should be compiled and presented to a competent authority. A too lenient wording could lead to insufficient submitted data for allowing the Member States to carry out a proper assessment. The wording aims at identifying with non-active substance should be considered as Substance of Concern (SoC) based on available information.

Another Member State argued that EDs must be substituted and therefore biocide formulators should preventively use non-active substance that have no identified ED properties. According to this Member State the REACH process for determination of ED properties could be done in parallel to the authorisation process of biocidal product.

Two Member States asked if harmonised information on EDs could be easily accessible in order to avoid referrals at the product authorisation stage. Two Member States proposed to include a systematic review of literature as general data requirement. The Commission services explained that such requirement of a systematic literature review exists under the PPPR, but only for active substance contained in PPP, and proposed to have a look at the situation under the PPPR. Another Member State underlined the additional work for applicants and competent authorities and questioned the added value of the evaluation of existing literature.

A Member State asked whether under the current review programme of active substances, an evaluating authority could request a reproductive study in order to assess the EDs properties of a given substance. The Commission services replied that such authority is entitled to request such data if considered necessary for the assessment while keeping in mind animal welfare.

Under point 8.7, ECHA proposed to modify the last paragraph of the right column as the current drafting is unclear. The modification was accepted and will be inserted in a revised draft.

7.7. Update on EC policy on EDs		
(a) BTSF training on EDs on 6-7 February 2019	For information	

The Commission services indicated that the feedback received from the experts who attended the training on 6-7 February was positive and that a second training will take place later this year. At the same time the Commission services are investigating whether it is possible to extend the scope of the BTSF trainings, including other topics related to biocides.

(b) Use of Activities Coordination Tool (ACT) as coordination platform between eCAs	For information	

The Commission services mentioned that, in relation to the ED assessment, the coordination tool is meant to provide information to Member States as to which of them is assessing what non-active substance and also to provide the results of the assessment, when available.

ECHA indicated that the PACT tool is a public tool accessible on the ECHA website and providing information on the REACH and CLP processes. The ACT tool is restricted to authorities and is the full tool supporting the REACH activities. Internal discussions are ongoing regarding the access of biocides competent authorities to the tool and which BPR processes should be included in the tool. ECHA also indicated that they are exploring the possibility to make an inventory of all co-formulants contained in all product authorisation applications, which could facilitate the work of Member States.

(c) Early review of active substances	For information	

The Commission services indicated that triggering the early review of the three identified active substances has high priority but that, due to resource constraints, the process has not yet been launched but the intention is to launch it soon. In reply to the question of one stakeholder observer on the resources needed for the review of a limited number of substances, the Commission services clarified that, independently on the number of substances to be reviewed, the development of the correct procedure for this new process is where most resources are needed.

(d) Horizon 2020 and Horizon Europe Programmes	For information	

One Member State asked if the outcomes of a former CA document on substitution were taken into account in the current EU research framework programme. The Commission services replied that a topic for biocides used at farm level has been included in Horizon 2020. Other biocide-related topics might be included in the future EU research framework programme Horizon Europe. Discussions with DG RTD and AGRI will start after the summer break and only the most pertinent topics will be included in the programme.

Therefore, the Commission services explained that it would important to show the interests of the Member States and Industry in the development of alternatives to substances of concerns in biocidal products. To that end, the Commission services invited all participants to share any document (conclusions of workshops, studies or description of innovative projects) that could support the request of DG SANTE to include biocide topics of the future programme.

7.8. Application of Unique Formula Identifier (UFI) for biocidal products	For discussion	

This item was postponed to next CA meeting.

7.9. Concerns related to invalid studies	For discussion	Closed session

The discussion took place in a closed session.

7.10. Tattoo inks: update	For information	

The Commission services provided an update of the information presented in May 2017 about the ongoing work under REACH for a restriction proposal of hazardous chemicals in tattoo inks. Tattoos inks are mixtures which contain mainly, pigments, solvents and some additives including preservatives to ensure the integrity of the ink once the bottle have been opened.

The Commission requested in December 2015 the European Chemicals Agency (ECHA) to prepare a possible restriction proposal of the hazardous chemicals present in tattoo inks in the framework of the REACH regulation. ECHA, with the support of the Member States (DK, DE, IT and NO) and in consultation of stakeholders, prepared a restriction proposal on 20/12/2017. The opinion of the Risk Assessment Committee (RAC) was adopted on 20 November 2018. The opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed on 14 March 2019. The final opinion takes into account the comments from the interested parties.

Once the Commission receives ECHA opinions, it has 3 months to prepare the Regulation to amend Annex XVII to REACH. No feedback mechanism will take place because of the extensive consultation that has already took place on these restrictions. The Regulation will be voted by Member States with the scrutiny of the EU Parliament and the Council (3 months). After the 3 months publication in the OJ and enter into effect after 12 months.

The restriction dossier covers all substances listed in the Council of Europe Resolution on this subject and complemented with substances having a harmonised classification as Carcinogenic, Mutagenic and Reproductively toxic (CMR), skin sensitisers, skin or eye irritant, skin corrosive, eye irritant or eye damaging, as well as substances restricted for use under the Cosmetic Products Regulation (EC) No 1223/2009 (CPR), amongst others.

Tattoo inks are not cosmetics, therefore the in-can preservative used in tattoo inks are not subject to the cosmetics regulation and are *de facto* subject to the BPR rules. If a biocide substance is covered by the restriction (example it is irritant if in contact with the skin), then it cannot be used in tattoo inks.

ECHA prepared a table on preservatives which have actually been used in tattoo inks and are already allowed or under evaluation under BPR for PT6.

One Member State asked whether this table can be updated and made available. Another Member State asked what would happen to the inks that are already on the market. The Commission services explained that the final legal text should provide timelines for transitional periods.

Finally, the Commission services informed that close cooperation will take place between the services in charge of the BPR and REACH in the elaboration of the Commission restriction to consider the interactions between both legislation for in-can preservatives. MS were invited to submit information and comments on this topic.

7.11. Integrated strategy for developing and promoting hygiene behaviour change in home and everyday life of the International Scientific Forum on Home Hygiene	For information *CA-March19-Doc.7.11.a* *CA-March19-Doc.7.11.b*	

The participants were invited to take note of the two documents of the International Scientific Forum on Home Hygiene regarding an integrated strategy for hygiene behaviour change in home and everyday life. The Netherlands also made reference to the document that was made available before the meeting upon their request, namely the advisory report of the Health Council of the Netherlands on the careful use of disinfectants, together with its background report on resistance due to disinfectants. Following the concerns in the Netherlands regarding the potential of development of resistance against the active substances used as disinfectants and potential cross resistance to antimicrobials, a thorough study was requested, resulting in the reports distributed for the meeting. The reports were distributed as it is considered that they contain valuable information with respect to the advantages and potential risks of disinfectants, which makes them relevant in the context of disinfectant discussions in the CA. The Netherlands expressed their wish to discuss with the CAs, at a later stage, how to proceed on the need of proper disinfection and how to handle potential resistance during active substance approval and at product level. The scientific information on disinfectants and the resulting message "use disinfectants properly and only when necessary" is a strong message and the Netherlands hopes to discuss how this fits with other strategies, like the targeted hygiene in the strategy of the forum on home hygiene.

7.12. AISE –HOPE Healthcare event September 2019	For information *CA-March19-Doc.7.12*	

AISE reported that they are organising an event dedicated to the health care sector, in collaboration with HOPE (the European Hospital and Healthcare Federation) and that the proposed date for the event would be 18 September in in the afternoon, in order to allow both CG and CA members to attend. The confirmation of the date and time will follow later on.

7.13. Article 55(1) notifications	For information	

The Commission services informed that the overview table of the Article 55(1) notifications has been published in the public section of CIRCABC (https://circabc.europa.eu/w/browse/92bd0162-f4b3-49a7-9351-76cf1037287a) and invited Member States to use the agreed template whenever submitting such notifications.

7.14. Overview national and ECHA fees	For discussion	

The Commission services introduced this topic by expressing the view that having a comprehensive overview of the fees in place for active substances- and products-related procedures in the various Member States would be beneficial for the various actors in these procedures in particular SMEs. Member States were asked whether they could agree to provide such overview. Following the positive response from the Member States, it was agreed that The Commission services will circulate an email requesting their input.

7.15. Court cases	For information	

The Commission services informed that the Court rejected the requests for suspension of the approval and non-approval decision on PHMB (1415;4.7) on case T337/18 and T347/18, as well as the second requests for suspension made by the applicants on the same cases. The requests for annulment of the concerned decisions are still on-going in Court.

The Commission services also informed about the reception of a new case T-734/18 submitted by Sumitomo and Tenka Best at the end of December to request the annulment of the non-approval decision on empenthrin. The applicants also requested the suspension of the decision. These requests are still on-going in Court.

7.16. Detection of dimethylsulfamid (DMS) in Danish drinking water	For information	

Denmark informed of the presence of DMS, a degradation on product of dichlofluanid and tolylfluanid, in its ground waters above 0.01 mg/L. Drinking water producing companies are concerned that it may come from plant protection use, but the concerns may also be from biocidal use. Denmark indicated that it will inform the CA meeting of the results of its investigations.
The CA meeting took note of these elements, and the Commission services invited the other Member States to consider including DMS in their own monitoring programmes, if not included already.

8. Scope matters		
8.1 Question raised by Italy	For discussion	

Italy informed that the question is scheduled for discussion in the forthcoming HelpNet meeting at the beginning of April. Should it not be solved in this meeting, it might be brought for further discussion at a subsequent CA meeting.

9. Enforcement issues		
9.1 Fact finding missions: overview report	For information	

The Commission services informed that the internal approval procedures related to the overview report were not yet concluded and the publication of the report is now expected in

June. A workshop with the Member States competent authorities to discuss the main findings in the report will take place in June in Grange; the invitation will be circulated one month before. One Member State asked if the draft report could be shared with the Member States before its publication. The Commission services will check whether this is possible.

9.2 Updates from BPR Subgroup of the Forum (BPRS)	For information	

The item was not discussed.

10. International Matters		
10.1 OECD	For information	

One Member State, who is chairing the OECD Working Group on biocides, reported on the activities of the Working Group and informed that the next meeting will take place on 25-26 September in Seoul (South Korea).

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-March19-Doc.11.a*	

The Commission services invited Member States and stakeholders to inform about any change to the contact points to keep the list up-to-date.

(b) Update on the inclusion of cybutryne into the AFS convention at IMO level	For information	

The Commission services informed about the developments at IMO level on the future inclusion of cybutryne into the AFS convention, with the view to ban it at international level. The EU proposal has been supported by the technical committee in IMO. Transitional provisions would normally foresee that ships should not apply or re-apply paint containing the substance from 3 October 2021, and should either not bear or seal such coatings from 3 October 2026.

(b) Item requested by Belgium	For information	**Closed session**

The discussion took place in a closed session.

Next meetings:

2019 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
-	-	-	26 Feb-1 March	
12-13 March	13-15 March	21-22 March	-	
-	-	-	-	
13-14 May	16-17 May	-	-	
-	-	20-21 June	24-28 June	
3 July	4-5 July	-	-	
-	-	-	-	
17-18 September	19-20 September	-	-	
-	-	-	7-11 Oct	
19-20 November	20-22 November	7-8 November	-	
-	-	-	9-13 Dec	