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

MINUTES

89th 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

24-25 September 2020

1. Adoption of the agenda	For adoption *CA-Sept20-Doc.1*	

On suggestion from one Member State, an additional point was added to the agenda, related to request from applicants for flexibility of deadlines in mutual recognition procedures due to the Covid-19 pandemic. The agenda was then adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Sept20-Doc.2*	

The minutes of the previous meeting were adopted.

3. Draft delegated acts		
3.1. Draft delegated act to include citric acid into Annex I to the BPR	For discussion *CA-Sept20-Doc.3.1*	

The Commission services presented the draft delegated regulation proposing to include citric acid into Annex I to the BPR, following a recent interest from industrial stakeholders and following past CA discussions of 2018. In particular, citric acid was approved as an active substance for use in biocidal products of product-type 2 by the Commission Implementing Regulation (EU) No 2016/1938. The BPC opinion also concluded that citric acid is eligible for inclusion in Annex I to the BPR. Such inclusion would facilitate the placing on the market of biocidal products containing citric acid.

One Member State remarked that lactic acid and potassium sorbate were also identified as candidates for inclusion in Annex I during the CA discussion in 2018. The Commission services informed that no formal enquiry for the inclusion of those substances in Annex I has been received from the applicant or Member States, but indicated their willingness to proceed with such an inclusion at the request of Member States. Several Member States indicated their interest to have also these active substances included into Annex I[1].

The Commission services also clarified that there is no need to modify or cancel the approval decision on citric acid because of the inclusion of the substance in Annex I.

Finally, the Commission services explained that the minimum purity requirements of the substance was found useful because of the different alternative suppliers mentioned in the Article 95 list . For product authorisation, the applicants should enquire whether the substance contained in their product meet the already adopted specifications for citric acid.

The CA meeting supported the draft delegated act proposing the Annex I inclusion of citric acid, and the Commission will therefore proceed with the adoption process.

3.2. Draft delegated act to include carbon dioxide generated from propane, butane or a mixture of both by combustion into Annex I to the BPR	For discussion *CA-Sept20-Doc.3.2*	

[1] After the CA meeting, the Commission checked the classification of lactic acid that has evolved, and lactic acid is longer eligible for Annex I inclusion.

The Commission services presented the draft delegated regulation proposing to include this active substance into Annex I to the BPR. The BPC opinion of June 2020 concluded that this active substance does not give rise to concern and is eligible to Annex I inclusion. It was therefore decided to propose a Delegated act and not an approval Regulation, in line with the CA agreement of 2018 on Annex I inclusions. A decision not approving carbon dioxide as an active substance for use in biocidal products of product-type 19 will be submitted to the Standing Committee on Biocidal Products as the non "in-situ" carbon dioxide (ex: supplied in canisters) is no longer supported in the Review Program. Similarly to the food and feed substances included recently in Annex I, a date of approval of carbon dioxide generated from propane, butane or both by combustion for product-type 19 is set, and will be 1st July 2022. In accordance with Article 89 existing products containing this substance will have to be authorised within three years of the date of the approval.

A Member State expressed concerns about the risks for end-users losing consciousness during the use of the substance and proposed a restriction for use in PT 19 products (repellents and attractants) only in order to ensure that end-users are not exposed to a high concentration of CO2. The Commission services answered that the BPC has not considered it necessary to introduce restrictions for specific uses. Furthermore, the approach to follow on Annex I inclusion is included in the document "CA-Nov18-Doc.5.3 - Final - Management of Annex I to BPR.doc" and it was concluded that no restriction should normally be introduced to not create barriers to innovation and as concerns can be dealt with during the product authorisation stage. Another Member State expressed sympathy for the concerns expressed by the other Member State about the risk of using biocidal products containing carbon dioxide generated from propane, butane or a mixture of both.

Another Member State asked whether other in situ substances for which a CLP classification is not possible could be also eligible for Annex I inclusion. The Commission services answered that the examination of the Annex I inclusion conditions will be made case by case and will be based on a BPC opinion.

ECHA confirmed that the current technology is mainly used to attract mosquitoes with carbon dioxide. There is no indication that the current technology could be used for other PTs.

The Commission services concluded that another discussion on the proposal will take place at the next meeting and called Member States to contribute to the newsgroup by 23 October 2020 inviting Member States to check the past 2018 CA agreement on the management of Annex I inclusions, and those Member States would like to introduce in Annex I restrictions measures for use of the active substance in specific product type(s), to make text proposals and provide justifications. The Commission services added that a rejection of an application for the inclusion of CO2 under the PPP basic substances list is being discussed with the Member States. The two Member States proposing to include a restriction in Annex I seems to support the inclusion of the active substance in the basic substances list of the PPPR.

4. Biocidal products

4.1. Covid-19 survey on the need of disinfectants	For discussion	

The Commission services indicated that two Member States provided input in the newsgroup which pointed out not to have quantitative information on the need of disinfectants.

4.2. Addressing the need of disinfectants: Active chlorine released from hypochlorous acid and active chlorine generated from sodium chloride by electrolysis	For information	

The Commission services informed that one Member State asked which regulatory option could be used to make products containing active chlorine released from hypochlorous acid for PT1 available on the market.

The Commission services explained that the transitional provisions set up under Article 89(2) of the BPR are not applicable to active chlorine released from hypochlorous acid and biocidal products containing it, as this substance is not in the review programme for existing active substance set up under Regulation (EU) No 1062/2014 for product-type 1.

However, Article 55(1) of the BPR can be applied to any biocidal product containing a non-approved active substance, which is not being evaluated in the review programme for the concerned PT. Therefore, the competent authority of the Member States may permit the making available on the market and use of a biocidal product containing the biocidal active substance active chlorine released from hypochlorous acid for PT1 using the provisions of Article 55(1) of the BPR.

Please note that the ECHA guidance on advice for companies on making disinfectants available on the EU/EEA market address this point (See Q&A pair N° 3).

4.3. Article 55(1) permits for disinfectants	For information	

The Commission services pointed out that in most of the Member States the granted permits will expire soon. Taking into account the emergency situation and that the drafting of Article 55(1) does not explicitly specify that Member States may not grant a permit having the same or a similar content as a former permit, another permit may be granted for 180 days. Member States can also ask the Commission to extend the permit. Such an extension request should include evidence that the authorisation holders cannot meet the demand for disinfectants. Member States should also consider that the Commission needs 2-3 months to process such requests.

4.4. Report from Coordination Group	For information	

The Commission services debriefed the meeting on the main points discussed at the Coordination Group meeting held on 6,7 July 2020.

Six formal referrals were discussed and one was briefly introduced.

- Five referrals were discussed concerning PT 14 products containing alphachloralose as an active substance. Those referrals were triggered by the amendment of the authorisations in accordance with provisions of Article 48 of the BPR. Two MSs disagreed with another two MSs´ amendments. The disagreement is related to amendment of authorisations considering information provided by the national

institutions in relation to poisoning cases of cats (secondary poisoning) and dogs (primary poisoning). The referrals were closed after the CG meeting with Article 36 of the BPR, i.e., the points of disagreement will be referred to the Commission.

- A referral was discussed concerning a PT 14 product containing difenacoum as an active substance. The disagreement was related to the missing ED assessment for non-active substances and the missing environmental exposure assessment for some uses. MSs agreed that for this particular case an ED-assessment of the non-active substances of the product is not necessary since the criteria were not applicable yet at the during the renewal phase. In relation to the second point of disagreement, MSs agreed that based on the expert judgment it is not expected that unacceptable risk will be identified for the environment. Thus, this referral is closed.
- A referral was briefly introduced concerning a PT10 product containing Pythium oligandrum, Chromista - Stramenopila as an active substance. Several points of disagreement were raised related to the environmental (ENV) and the human health (HH) risk assessment. This referral was discussed after the CG meeting and closed.

The Commission services presented to the CG the document 'Practical considerations for authorisation procedures made through mutual recognition in sequence, application for changes (major, minor) and renewals due to the UK withdrawal from the EU'. The MSs raised several practical questions, e.g., in relation to fees. However, the main discussion was on the need to find the way forward how to deal with the renewal of products of which the UK was the evaluating Member State. This document was agreed by the CG members. However, it was also noted that the document will be tabled for final agreement during the CA meeting in September.

Related to legal discussions:

- The Commission services informed the CG, following internal consultation, on the topic "Interaction between Article 52 (Period of grace) of the BPR and Article 6 (Period of grace) of Commission Delegated Regulation (EU) No 492/2014 on the renewal of authorisations". The Commission services noted that those two Articles (Article 6 of Renewal Regulation and Article 52 on the BPR) contradict each other thus, the amendment of Regulation No 492/2014 will be triggered.
- The Commission services provided the document onscope issues raised during the mutual recognition period. This document clarifies whether, i.e., if in the context of a mutual recognition procedure the cMS considers that the biocidal product cannot be authorised because it should not be considered a biocidal product in the context of the BPR, the question of disagreement should be resolved in accordance with Article 35 of the BPR, i.e. through a referral to the CG. The document notes that the question whether a product is a biocidal product or not is a precondition for the application of the conditions of authorisations set out in Article 19 of the BPR. If agreement is not reached by the MSs in the context of the referral, this point of disagreement should be referred to the Commission in accordance with Article 36 of the BPR.
- The Commission services presented the note to the CG clarifying which MSs should be considered as the reMSs for referrals submitted based on Article 48 of the BPR. It was noted that the competent authority of a Member State that cancelled or amended their national authorisation becomes the refMS for the referrals submitted under provisions of Article 48 of the BPR.

- The Commission services presented the note concerning questions raised on the legal status of the consortium as authorisation holder. The document clarifies two questions: 1) shall the consortium be a legal entity in order to be an authorisation holder, 2) who should be the beneficiary of a letter of access provided by the applicant:- the consortium, the member-companies of the consortium that will place products on the market, or both? Some MSs expressed their reservations in relation to the response provided for the second question. Particularly, that it should be examined on a case-by-case basis who is the beneficiary of the letter of access when the authorisation holder is the consortium, but the products will be placed on the market by its members. The discussion on this topic will continue in the CG of September.
- The Commission services presented the proposal how to proceed with the renewal of the products containing creosote. The Commission services proposed two options: 1) proceed with the product renewals following the time lines set in the procedure with the current conditions in the active substance approval; 2) prolong the authorisations of products containing creosote, to allow that the renewal of these products takes place after the approval of the active substance. During the meeting MSs supported option 2. However, considering the nature of the substance the CG considered that this should be further discussed and agreed at CA level.
- A MS presented an outcome of the e-consultation in relation to the details to be included in the SPC for SoC The discussion will continue in September at the CA level.

4.5. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-Sept20-Doc.4.5*	

The meeting was invited to take note of the document distributed in CIRCABC.

4.6. List of pending Article 36 requests	For information *CA-Sept20-Doc.4.6*	

The Commission services presented an overview of pending Article 36 request with an indicative timeline.

4.7. Monitoring report on mutual recognition procedures	For discussion *CA-Sept20-Doc.4.7*	

The Commission services presented the report on monitoring delays in mutual recognition procedures. The report gives an overview of the delays in all applications submitted from 01/01/2010 until 20/08/2020 (included) for 5 case types: National Authorisation, Mutual Recognition in parallel, Mutual recognition in sequence, Simplified Authorisation and Union Authorisation.

Delays were represented in the graphs in percentage, the number of cases delayed/on time are represented in the graphs as numbers. The total number of authorisations (total workload per MSs) was also provided. The main conclusions from the report were presented: differing situations between MSs on the percentage of delays and workload, 17 MSs have a high percentage of delays on almost all the procedures, Member States with higher percentage on

delays are also the ones that have processed more applications. The worst average (combining the procedures for all MSs) delay figures are for case type 'mutual recognition in parallel' and the best average (all MSs) delay figures are for case type 'Union Authorisations'. The main delays occurred in almost all the procedures in the acceptance stage of the dossier.

Some Member State enquired on the calculation method for the delays, as the figures presented do not match with the delays that they calculated themselves. Clarification on the method for the extraction of the data and the calculation of the delays was provided by ECHA. It was clarified that a strict criteria was chosen to calculate the delays (one day of delay is considered as a delay in the process). The Commission services pointed out that the figures on delays are quite high in most MSs and a change of the applied methodology would not trigger a substantial change of the results and conclusions. It proposed to focus the discussion on analysing the causes for the occurrence of the delays in the mutual recognition procedure in the next CA-meetings, as these procedures show the higher delays.

A MS proposed that an action plan to address delays in product authorisation is develop, once the analysis on each procedure is finished. The Commission services agreed on this proposal.

4.8. Monitoring report on mutual recognition procedures	For discussion *CA-Sept20-Doc.4.8*	

This point was addressed under agenda item 4.7.

4.9. Non-active substances contained in biocidal products having indications for ED properties: prioritisation under REACH	For discussion *CA-Sept20-Doc.4.9*	

ECHA provided an extensive presentation how REACH and BPR could interact on the determination of the ED properties of non-active substances. ECHA will propose for the December CA-meeting a document specifying the procedures.

4.10. Non-active substances contained in biocidal products having indications for ED properties	For discussion *CA-Sept20-Doc.4.10*	Closed session

This item was discussed in closed session.

4.11. Non-active substances contained in biocidal products having indications for ED properties: whether including the name in BPC opinion and authorisations	For discussion and agreement *CA-Sept20-Doc.4.11*	

The Commission services provided a presentation on non-active substances for which it was not possible to conclude whether those meet the scientific criteria for the determination of endocrine-disrupting properties within the period for the evaluation of the application,

including a proposal on how to manage such non-active substances in authorisations. It was proposed to include a recital in the authorisation specifying the name of the non-active substance(s) having indications of ED properties. One Member State asked which criteria would be used to determine whether indications exist of ED properties and referred to discussions being held in the coordination group about the screening of ED properties and on whether indications are significant or not. The Commission services referred to the agreed CG document on the determination of non-active substances having indications of ED properties. Another MS pointed out that for CMR substances the proposed approach is not being applied. The Commission services pointed out that the criteria for the determination of ED properties only allow to identify EDs. Currently it is being investigated to have a classification for EDs under CLP. In that case also 'suspected' EDs may have a classification. One MS indicated that it does not in favour including a recital indicating the names of the non-active substances having ED properties. Another Member State stated that it does not include a recital of such non-active substances in national authorisations The Commission services indicated that a newsgroup will be opened in which CA-participants can point out whether the proposal of the Commission is supported or not and their considerations for this position.

4.12. Change of classification of active substances and the consequences on biocidal product procedures	For discussion	

The discussion on this item was postponed for the CA meeting in December.

4.13. Simplified procedure for products containing active substances newly included into Annex I	For discussion and agreement *CA-Sept20-Doc.4.13a* *CA-Sept20-Doc.4.13.b*	

The Commission services proposed an addition to the Q&A annex of *CA-March16-Doc.4.6 Final - note for guidance Q&A on simplified procedure* that explains which product authorisation procedures are available for products containing active substances listed in Annex I to the BPR.

The proposal was endorsed, and the updated document will be made available on Circabc.

4.14. Details of concentration of substances of concern n SPC	For discussion and agreement *CA-Sept20-Doc.4.13.a*	

The Commission services presented a document clarifying that the exact concentration of substances of concern need to be indicated in the SPC, as confidentiality for this cannot be claimed. The issue was discussed previously in the Coordination Group in the context of an e-consultation. Member States agreed on the conclusion reflected in the document.

4.15. Borderline biocides and cosmetics for hand sanitizers	For information *CA-Sept20-Doc.4.15*	

The Commission services updated the CA meeting on the activities on-going on the demarcation between cosmetic hand-gels and disinfectants. A survey was run among Member

States' cosmetic authorities on the presence and status of hand gels on the market and the preliminary findings were presented. It is the intention to provide an extensive list of non-allowed claims on the label of hand gels in order to distinguish clearly cosmetics from disinfectant products. This will be elaborated in a paper to the Cosmetics Borderline Working group. The CA meeting will be kept informed about the developments.

4.16. Risk mitigation measures	For discussion *CA-Sept20-Doc.4.16*	Closed session
4.17. Renewal of creosote containing products	For discussion and agreement *CA-Sept20-Doc.4.17*	

The Commission services presented a document, based on discussions in the in the Coordination Group, proposing two options to proceed with the renewal of the products containing creosote: 1) proceed with the product renewals following the time lines set in the renewal procedure and considering the current conditions in the active substance approval; 2) after receiving requests for renewal of products to prolong the authorisations of products containing creosote, to allow that the assessment for the renewal of these products takes place after the approval of the active substance. The majority of MSs supported option 2, and therefore this approach was agreed for proceeding with the renewal of these products containing creosote.

4.18. Legal status of consortium	For discussion and agreement *CA-Sept20-Doc.4.18*	

The Commission services presented a document concerning questions raised on the legal status of the consortium as authorisation holder. The document clarifies two questions: 1) Should the consortium be a legal entity in order to be an authorisation holder? 2) who should be the beneficiary of the letter of access provided by the applicant- the consortium, the member-companies of the consortium that will place products on the market, or both? Some MSs expressed their reservations in relation to the response provided to the second question. Particularly, that it should be examined on a case-by-case basis who is the beneficiary of the letter of access when the authorisation holder is the consortium, but the products will be placed on the market by its members.

4.19. Amendment of (Article 6) Regulation No 492/2014	For discussion *CA-Sept20-Doc.4.19*	

The Commission services indicated that on the topic "Interaction between Article 52 (Period of grace) of the BPR and Article 6 (Period of grace) of Commission Delegated Regulation (EU) No 492/2014 on the renewal of authorisations" that that the period of grace cannot be automatically granted. The Commission services noted that the two Articles (Article 6 of Renewal Regulation and Article 52 on the BPR) are not fully aligned thus an amendment of Regulation No 492/2014 will be triggered.

Member States are invited to provide their views on this issue and to put forward other possible amendments to this Regulation No 492/2014.

4.20. EBPF position on the renewal of anticoagulant rodenticides	For discussion *CA-Sept20-Doc.4.20*	

The Commission services introduced this agenda item and the three possible options for a way forward. One Member State indicated to be in favour of option 3 (products renewal would be postponed and approval and the authorisation time lines would be aligned). The difference in the approval and authorisation period could be accepted for the last time but should be aligned in the future.

Two Member States asked the Commission to further investigate the possible delays because of the need to perform an ED assessment. Another Member State stressed that under option 1 (prolong the authorisations until the active substance renewal) the postponement of payments could not be accepted and called for an industry commitment to monitor alternatives and inform in due time the Member States. One Member State mentioned to be in favour of option 2 (products would be renewed as scheduled). Another one indicated to hesitate between option 1 and 3 but rejected option 2 because it would entail a revision of the authorisation if the conditions of the approval would be amended.

Industry representative favoured option 1 and indicated that non-chemical alternatives are not available with the same level of efficacy as anticoagulant rodenticides. A Member State pointed out that the BPR requirements specify that sufficient efficacy of alternatives must be demonstrated not the same level of efficacy.

The Commission services pointed out that it is recommended to agree on an option in the December 2020 meeting because of the legal deadlines for the renewals. The Commission services indicated that a newsgroup will be open in which CA-participants can indicate which option of the Commission is supported with a justification for it. Member States were also invited to inform about their position on the performance of an EU comparative assessment and in particular on the type of questions that should be addressed, and whether postponement of fees could be take place or not.

4.21. Dioxins emissions from the use of the biocidal product family (BPF) "CMIT/MIT SOLVENT BASED" in fuels used in road and ship transport	For information *CA-Sept20-Doc.4.21*	

The Commission services informed on an Article 75(1)(g) request to ECHA concerning a CMIT/MIT based product family which is used as fuel preservative. The issue with this product is that during combustion of the fuel containing this product dioxin will be formed, for which no risk assessment has been performed in the PAR. The Agency is requested to submit the opinion to the Commission before the end of this year.

4.22. Derogations for the use of the biocidal product Biobor JF	For information	

The Commission services informed that 15 Member States and the UK have granted derogations for the use of Biobor JF and that three Member States submitted a request to the Commission for the extension of the temporary permit. The Commission services also informed that two extensions decisions were presented for information and discussion the day before in the meeting of the Standing Committee. The Commission services mentioned that

they are aware that the manufacturer of the product had discussions with some competent authorities with a view to identifying a an evaluating competent authority for the prospective application for active substance approval.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-Sept20-Doc.5.1*	

The meeting was invited to take note of the document distributed in CIRCABC.

5.2. Progression of the renewal process of approval of active substances	For information *CA-Sept20-Doc.5.2*	

The meeting was invited to take note of the document distributed in CIRCABC.

5.3. ECHA Active Substance Action Plan	For information *CA-Sept20-Doc.5.3*	

ECHA presented its progress report on the implementation of the ECHA Action plan on active substances. In particular, ECHA indicated to have asked feedback from Member States about their work plan to conclude the assessment of their dossiers by 2024. Furthermore, ECHA called for volunteering Member States to reflect on how to simplify the assessments of active substances.

5.4. Progression of evaluation of applications for approval as regards to the determination of ED properties	For information *CA-Sept20-Doc.5.4*	

The Commission services indicated that ECHA will submit a paper for the next meeting that will highlight the challenges it faces in the Review Programme in relation to EDs. The Commission services informed the meeting that it has submitted to ECHA two Article 75(1) requests on two active substances asking ECHA to clarify the ECHA opinion on the risk assessment of substances considered to have ED properties.

5.5. Status of an active substance containing an impurity identified as an endocrine disruptor	For discussion *CA-Sept20-Doc.5.5*	

The Commission services introduced the document underlining that not all relevant Directorate General Commission services had the opportunity to provide their views. Therefore the document is only preliminary. However, this was found already as a good basis for initiating the discussion in the CA-meeting.

It was indicated that this document should be considered as an addition to the agreed CA-notes on on-going procedures and approved active substances agreed in March and September 2018, respectively. In short, it is considered in the note that an impurity is part of the active substance and if this impurity is identified as an ED, the active substance should be identified as an ED.

One Member State pointed out that the coherence with REACH should be ensured but reminded that substances having ED properties should be considered as non-threshold substances as highlighted in the CA documents of 2018. Another Member State asked about the impact of an impurity having only indications of ED properties.
The Commission services indicated it will open a newsgroup for comments from Member States by 23 October. The intention is to conclude the discussion in the December CA-meeting.

5.6. Status of an active substance generating disinfection by products identified as an endocrine disruptor	For discussion *CA-Sept20-Doc.5.6*	

The Commission services introduced the document underlining that not all relevant Directorate General Commission services had the opportunity to provide their views. Therefore the document is only preliminary. However, this was found already as a good basis for initiating the discussion in the CA-meeting..

One Member State wanted to know the background for the difference in approach between disinfection-by-products and PBT-substances, as ,according to this Member State, in the PBT assessment, a substance containing residues identified as a PBT is considered itself as being a PBT substance.

The Commission services indicated it will open a newsgroup for comments from Member States by 23 October. The intention is to conclude this discussion in the December CA-meeting.

5.7. Status of C(M)IT as a new or existing active substance	For discussion and agreement *CA-Sept20-Doc.5.7*	

The Commission services explained that it was necessary to clarify whether the substance C(M)IT should be considered as a new or existing substance according to the BPR, following a question raised at one of the BPC meeting in June, which is also important in the context of the assessment of an application for provisional authorisation. The information collected tend to show that the only mixture CIT/MIT was present on the market before 14 May 2000, but no conclusive information was collected that would show the substance C(M)IT was placed on the market alone before that date.

Based on the collected information, it was concluded that the active substance C(M)IT should be considered as a new active substance and should benefit from the advantages granted by the BPR to genuinely new active substances and products containing them.

5.8. Early review of iodine, PVP iodine and zineb	For information	

The Commission services updated the meeting on the state of play of the early review, indicating the publication of the contributions of applicants on DG SANTE website had been delayed because of discussions on the confidentiality of certain documents.

6. Treated articles

No item for information or discussion

7. Horizontal matters

7.1. ECHA guidance		

(a) Status update on the development of ECHA guidance	For information *CA-Sept20-Doc.7.1.a*	

ECHA introduced the document and underlined that also Spain volunteered to participate in the development of pollinators guidance. One MS asked an amendment of paragraph 2.7 of the document. Another MS requested whether it would be possible to amend CA-document on in situ in relation to pure and technical substance. The Commission services pointed out not to favour to open this document, however, the MS was invited to submit its comments. On the request of ECHA the Netherlands volunteered to participate in developing guidance for disinfection-by-products.

(b) Draft guidance on relevant renewal data under Article 95	For discussion and agreement *CA-Sept20-Doc.7.1.b*	

ECHA presented its revised draft guidance document. The draft guidance was endorsed by the CA meeting.

On the question of a Member State, it was clarified that the agreed guidance will be published on the website of ECHA.

(c) Progress of BPC WG discussions on risks assessment of skin sensitizers active substances	For discussion *CA-Sept20-Doc.7.1.c-1* *CA-Sept20-Doc.7.1.c-2*	

The Commission services recalled previous discussions in the CA meeting on this issue, and referred to the notes prepared by ECHA and by industry representatives. It reminded that CEPE and AISE requested the development of a Quantitative Risk Assessment (QRA) for skin sensitisers contained in paints and detergents. These representatives also stressed that a sufficiently broad portfolio of preservatives should be maintained.

In February 2020, the CA meeting asked ECHA to assess whether a QRA methodology could be developed and to report back to the CA meeting before the end of 2020.

Several Member States indicated that this is a very sensitive topic for human health and that they do not have a clear position on this issue. Industry called for the possibility to establish a QRA methodology and the active substance approval should provide the opportunity to demonstrate a safe use/exposure at product authorisation stage. Therefore industry asked the Commission and the Member States not to introduce restrictions on the use of preservatives in treated articles at the approval stage that would exclude demonstrating safe use at product stage.

ECHA stated that no robust methodology for QRA can be expected for the coming years. It is also currently impossible to describe which type of data will be requested for such QRA. The Commission asked ECHA to continue working with other Agencies and scientific groups on the development of QRA.

The Commission services indicated it will open a newsgroup and asked for input on a possible approach on how to address the risks to skin sensitizers as the Commission services would like to explore the proposals in the next meeting. One option is to explore the possibilities, for ensuring a proper availability of preservatives, to reopen the Note for Guidance of 2013 on the authorisation of biocidal products classified as skin sensitisers (CA-Sep13-Doc.6.2.a).

7.2. Temporary maximum levels of chlorate in food	For information *CA-Sept20-Doc.7.2*	

The Commission services informed the meeting that temporary MRLs are set for chlorate in Commission Regulation (EU) 2020/749.

7.3. Non chemical alternatives for control of rodents	For information	

The Commission services informed that a first draft of the guidance document on rodent traps testing should be ready before the end of the year. The guidance will provide a tool to assess the efficacy and humaneness of rodent traps. The Commission services indicated that with ECHA was discussed the possibility for the BPC to peer-review the guidance to ensure that the guidance is sufficiently robust to generate relevant data for a comparative assessment with anticoagulant rodenticides. ECHA pointed out that it could agree to provide an opinion provided that some elements of the guidance where ECHA has no specific expertise are not subject to the Commission request.

7.4. The use of biocides in plastic Food Contact Materials	For information	(scheduled timing 25 September 9:30)

The Commission services provided a presentation how a Specific Migration Limit (SML) could be set for biocides used in Food Contact Materials (FCMs). The presentation indicated three possible options for setting a SML: during approval of the active substance, after approval and before product authorisation application, or during product authorisation. The meeting was informed that EFSA has specific guidance on data requirements for assessing FCMs. One Member State favoured the setting of a SML before product authorisation. The Commission services informed that an applicant could provide the relevant information during active substance approval. However, it is unclear whether a proper legal base exists for this. Another Member State pointed out that the SML will depend on the material being used and also asked whether SMLs would apply to imported treated articles. The Commission services pointed out that the assessment for SMLs depends on the material being used and SMLs apply to imported articles. The EFSA guidance on SMLs will be available on biocides' CIRCABC. The Commission services indicated it will open a newsgroup for comments.

7.5. ECHA communications	For information *CA-Sept20-Doc.7.5*	

The meeting took note of the information provided by ECHA.

7.6. Update on Court cases	For information	

This item was not discussed.

7.7. UK's withdrawal from the EU: refMSs for authorisations where the UK was the refMS	For discussion *CA-Sept20-Doc.7.7*	

The Commission services presented for discussion a document on how to deal to with procedures of mutual recognition in sequence, major changes, minor changes and renewals for ongoing cases for which the UK was the reference Member State. For mutual recognition in parallel procedures an agreement was already established between Member States. The Commission services also clarified that the UK cannot act as reference Member State since its withdrawal from the EU. Therefore, it is not possible - if no Member State is taking over the role of reference Member State - to refer points of disagreement to the Coordination Group for procedures in which the UK was acting as reference Member State. For the ongoing cases of mutual recognition in sequence for which a new reference Member State is needed in order to be able proceed, a proposal was made to the CA-meeting. For cases having only one concerned Member State it was proposed that this Member State takes over the role of reference Member State. When there are several concerned Member States, a new reference Member State was selected among those. For minor changes, major changes and renewals the UK also cannot longer act as reference Member State. A table is provided for the on-going cases for which there is a need to establish a new reference Member State. For 'new' cases the applicant would have to find itself a new reference Member State at this moment. ECHA indicated that the document will be discussed in detail in the CG-meeting next week.

The Commission services noted that there are many ongoing cases in R4BP3 that should have been closed and requested Member States to check their cases in R4BP3 and close the finalised cases. It was underlined that applications for mutual recognition and changes submitted after the withdrawal of the UK, and having the UK as reference Member State, have to be rejected.

7.8. UK's withdrawal from the EU: refMSs for authorisations subject to renewal	For discussion *CA-Sept20-Doc.7.8*	

The Commission requested feedback from Member States on how to assign the remaining UK assets to a new reference Member State. Two options were proposed: either to distribute the assets by product-type, or to extract the assets by chronological order of upcoming renewals and distribute them among Member States. Depending on Member States' preferences, a proposal to reassign these assets will be made in the next CA meeting.

The file with the remaining UK assets will be distributed to MSs in advance to facilitate their decision-making.

7.9. UK's withdrawal from the EU: Exposure scenarios for PT21	For discussion	Closed session

This item was discussed in closed session.

7.10. Data protection period for active substances	For discussion *CA-Sept20-Doc.7.10*	

The Commission invited Member States to reflect on the second case presented in the document, pointing out that Article 95(5) limits the data protection period of active substances which had been included in the Review programme on 1st September 2013.

The Commission services asked for comments from Member States by 23 October 2020.

7.11. Use of falsified data in an application	For information	Closed session

This item was discussed in closed session.

8. Scope matters	

8.1 Scope issues identified during the drafting of PT 11-12 efficacy guidance	For discussion and agreement *CA-Sept20-Doc.8.1.a* *CA-Sept20-Doc.8.1.b*	

The Commission services recalled that most of the points of the document were supported at the last meeting. However, an agreement was not reached regarding the preservation of air washer systems and sump water in air conditioning systems, and claims against Legionella. A new version of the document was uploaded on Circabc based on the inputs received from the newsgroup on those pending issues to accommodate the concerns of the Competent Authorities. EBPF also introduced additional clarifications regarding the allocation of PTs for preservatives used in oil recovery.

During the consultation period, one Member State requested the Commission to propose a procedure under which all the examples of agreed borderline cases could be gathered in one single document. According to this information is currently scattered in different documents, and a single source of information would be of great help.

One Member State requested clarification for the points 2 and 4 of the document where it is stated that 'where food is in direct contact with the treated water, the use shall fall under PT4'.This statement seems to be in contradiction with the current ECHA efficacy guidance. PT 4 addresses surface cleaning and not contact of food with liquids. Following this comment the CA meeting agreed to remove those sentences. The Member State remarked that the issue of the transport of rinsing water in the food industry is unfortunately not addressed in the document.

One Member State proposed some editorial changes and clarifications to items 3 and 11.

Several Member States supported the proposal to gather all the current information on borderline PT cases in one single document. One Member State suggested to discuss this kind of issues in HelpEx and not in the Efficacy Working Group as scope issues are not always related to efficacy. ECHA added that clarification on scope issues are not under the remit of the efficacy working group.

EBPF agreed that the clarification on PTs allocation is very useful and should be made publically available in one document. In the current case, the Efficacy Working Group requested industry to bring the issue of PTs allocation to the CA meeting. EBPF asked to remain involved in the discussion whatever the final means of communication that will be chosen.

The Commission services explained that the former Manual of Decisions (MoD) that contained information on scope and borderline issues was repealed because of the possibility to address them under Articles 3(3) and 36 of the BPR. The Commission services expressed reluctance to re-establish a similar document to the former MoD that could prejudge future Article 3(3) Commission decisions. However, the Commission services acknowledged that the clarification of PTs allocation is of different nature and could be addressed in a more systematic way. The discussions could take place in the HelpEx but it was noted that stakeholders are not involved in this forum. A newsgroup will be open to collect inputs from the CA meeting. A Member State considered that the Efficacy Working Group should be consulted when borderline questions on PT are tabled.

8.2 Bee repellents	For information	

The Commission services indicated that, following a question of a stakeholders on the MRLs for products used as bee repellents, it has to be determined whether bee repellents could be considered in the scope of the BPR. Following internal analysis bee repellents are considered in the scope of the BPR.

9. Enforcement issues	

9.1 Protective masks containing biocidal active substances	For discussion	

The Commission services informed that several cases of face masks treated with biocidal products were brought to their attention and some cases were discussed among competent authorities. The Commission services indicated that the first element to be checked in such cases is whether the masks are medical devices. If they are not medical devices they are in the scope of the BPR and are treated articles. However, if the mask has a primary biocidal function such masks are to be considered biocidal products.

One Member State indicated to consider such face masks medical devices in all cases. On the classification treated articles vs. biocidal products, the views of Member States were diverging. Some of them considered that treated face masks are always biocidal products, while others were of the view that they are treated articles and a case-by-case assessment based on claims and other labelling elements should be performed.

10. International Matters		
10.1 OECD	For information	

The Commission services informed that on 13-14 September a meeting of the working group of biocides took place.

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-Sept20-Doc.11.a*	

(b) Additional active substance data required for biocidal product authorisations	For information *CA-Sept20-Doc.11.b*	

The Commission services referred the meeting to the uploaded document on Circabc. A newsgroup will be opened and members were invited to provide their views.

(c) Discussion on ethanol	For discussion	

A Member State indicated that, in case the outcome of CLP procedure of ethanol would lead to a classification as Carcinogenic category 1A or 1B, this would imply that alcohol-based disinfectants would no longer available for the general public. The evaluating competent authority of the active substance ethanol stated that it is planning to submit its proposal for the classification to ECHA before the end of the year, and that so far the dossier would contain a proposal for classification as Carcinogenic 2.

(d) Face masks with biocidal claims	For discussion *CA-Sept20-Doc.11.d*	Closed session

(e) Biocidal products PT1 vs. medicinal products	For discussion *CA-Sept20-Doc.11.e*	Closed session

Next meetings:

2020 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
-	3-7 Feb	-		
		26-27 March	2-6 March	
-	-	-	-	
	12-15 May	-	-	
-	-	25-26 June	15-18 June	
		-	-	
-	-	-	-	
28-29 Sept	22-25 Sept	-	-	
-	-	29-30 Oct-	5-9 Oct	
			-	
-	8-11 Dec	-	30 Nov - 4 Dec	

2021 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
		-		
	1-5 February			
			1-5 March	
	31 May-3 June			
			14-18 June	
	27-30 September			
			4-8 October	
			29 Nov-3 December	
	6-9 December			