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

MINUTES

92nd 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

1-2 June 2021

1. Adoption of the agenda	For adoption *CA-June21-Doc.1-rev1*	

One Member State proposed the addition of two items, regarding (i) the early review of iodine, PVP-iodine and zineb and (ii) impact analysis for antifouling products. The agenda was adopted with the proposed additions.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-June21-Doc.2*	

The minutes of the 91st CA meeting were adopted.

3. Draft delegated acts
No item for information or discussion

4. Biocidal products

4.1. Second renewal of AVK rodenticides products	For discussion and agreement *CA-June21-Doc.4.1*	

The Commission services introduced a CA document proposing an extension of the date of authorisation of anticoagulant (AVK) biocidal products until December 2023 for completing the evaluation. This would allow Member States to take into the BPC conclusions on the application of dermal absorption values as well as the outcome of the future comparative assessment at EU level in the evaluation of the renewal applications for biocidal products,

Two Member States supported the document as presented by the Commission services.

Five Member States requested further clarifications on how the competent authorities should handle the future applications for renewals of AVK rodenticides.

The Commission services explained that the provisions of the Biocidal Products Regulation (BPR) and the Commission Delegated Regulation (EU) No 492/2014 apply. The moment when the competent authority accepts the application the evaluation should start. At a later stage the outcomes of the comparative assessment at EU level could be added. As to the fees, the Commission services explained that applicants have to pay the relevant fees, as it is a condition for the authority to accept the application.

One Member State asked whether the wording of paragraph 17 could be simplified by indicating that Member States are allowed to postpone the expiry date of the current authorisation instead of 'granting a renewal'. According to that Member State, the current wording seems to suggest that a decision on a renewal needs to be taken and that another application needs to be submitted before the competent authorities can grant the final authorisation. The Commission services clarified that the wording of paragraph 17 is based on the provisions of article 5(4) of the Renewal Regulation. Member States would need to receive an application for renewal and may grant a renewal for an authorisation for the period

necessary to complete the evaluation. Several Member States supported the views of the initial Member State and requested the inclusion of a footnote explaining the exact meaning of the wording 'granting a renewal for the relevant authorisation'.

Following these initial discussions and based on a proposal from one Member State, the CA proposed to include the following paragraph in the minutes of the meeting to ensure that a coordinated approach will be followed at the renewal of the AVK products:

> *Instead of finalising the submitted renewal application in R4BP3, Member States can initiate a national authorisation (NA-AAT) application before the expiry date (i.e. within 550 days). A NA-AAT application initiated by a Member State would allow to amend the authorisation, if necessary. After having uploaded the formal decision ("grant") to postpone the expiry date and changing the expiry date to 1st July 2024 in the system, the NA-AAT application can then be finalised by the Member State. It is important that Member States change the expiry date, as, otherwise the case will disappear from the system. The process for the renewal application (the NA-RNL) shall continue as usual under the status 'in progress'. A decision on the renewal of the national authorisation shall be taken before 1st July 2024.*

Further to several requests from Member States and industry representatives highlighting the tight deadline to finalise a full evaluation of the applications before the proposed deadline in the draft CA document, the Commission proposed to extend the expiry date of the current authorisations until 1st July 2024 to ensure that Member States can take into account the results of the EU comparative assessment and finalise their evaluations. The CA meeting decided to amend the date for extending the authorisations from 31 December 2023 to 1st July 2024 in the CA document and agreed to the amended CA document.

4.2. Risk mitigation measures for products and treated articles	For discussion and agreement *CA-June21-Doc.4.2.a* *CA-June21-Doc.4.2.b*	

The Commission services provided feedback on the discussions held with Member States on previous disagreements for setting risk mitigation measures (RMMs) for treated articles at product authorisation stage in the CG-46 (April 2021). The first topic discussed was on the applicability and controllability of the RMMs. The conclusions from the discussions in the coordination group (CG) and the feedback provided by Member States is the following. The applicability of RMMs needs to be assessed on a case by case basis, and the decision taken is based on expert judgment. The decision on whether the RMMs can be applied and controlled realistically is decisive for including the RMM in the authorisation and whether authorising the use. Equal treatment of applicants needs to be guaranteed. It was proposed that the RMMs agreed in the CG are included in the list of frequently used sentences in the SPC.

The second item discussed in the CG was on the possibilities to laid down RMMs that are detailed enough at the approval of the active substance. All Member States that replied considered this not to be realistic. Member States consider that it should be possible to accept more stringent measures than the ones set in the active substance approval, but asked for legal assurances from the Commission services that this is possible. Other issues presented in the CG meeting were the applicability to the downstream users of RMMs and on the concept of treated article.

One Member State asked what about approved biocidal active substances as those approvals do not contain specific conditions for treated articles. Another Member State put forward the position of imported treated articles.

The Commission services pointed out that it is reflecting on having a general condition for treated articles in approval regulations.

The Commission services requested Member States to further reflect on these issues.

A newsgroup will be opened so that Member States can provide comments (until 30 June 2021).

4.3. Categorisation of a biocidal product containing a non-active substance meeting the criteria for being PBT or vPvB	For discussion and agreement *CA-June21-Doc.4.3*	

One Member State pointed out still have a concern on the release of PBT substances in the environment, however, it could support the generic limit proposed. The Member State stressed that agreeing to this approach does not imply that it considers that a safe threshold exists for PBT substances. This Member State proposed to apply the generic limit in relation to relevant group of the non-active substances in the product. Another Member State considered that the use of PBT substances should be discouraged and proposed that applicants should provide a justification at applications.

Based on the discussion the CA document was amended in paragraphs 40 and 41 (amendments are in italic):

(40) For reasons of coherence, the same concentration limit should also be applied for the determination of whether a substance identified as PBT and vPvB and contained in a biocidal product is a SoC. This implies that the concentration of a substance identified as PBT and/or vPvB, and contained in a biocidal product, should be higher than or equal to 0.1% w/w for triggering the identification as SoC for the assessment of this biocidal product. However, where a biocidal product contains a high number of substances in individual amounts <0.1% (w/w) *which are identified as PBT or vPvB,* the concentration limit is considered to apply *for the group of substances identified as PBT or vPvB.*

(41) The authorisation holder should try to substitute the substance identified as PBT or vPvB and contained in a biocidal product regardless whether the concentration above or below 0.1% w/w. This effort shall be proven at the authorisation process.

The CA-meeting agreed to the document with the exception of one Member State which proposed to include the following in the minutes: *'The Netherlands does not agree with the proposed concentration limit because a limit of 0.1% is not necessarily safe for the environment. The Netherlands refers to the Green Deal and Zero pollution, which aim at a strong reduction of persistent and bioaccumulative substances in the coming years'.*

4.4. Management of data on an active substance in an application for a biocidal product	For discussion and agreement *CA-June21-Doc.4.4*	

The Commission informed the meeting of the comments received after the last CA meeting on the questions referred to Member States. Only 5 Member States contributed to the newsgroup. All replying Member States agree that the current CG and BPC documents in relation to data submitted on active substances during product authorisation need to be updated/further developed, and prefer that the Listing of endpoint (LoE) stays connected to the assessment report (AS AR) on the active substance. However, the replying Member States had various and diverging views on the situations that should lead to a modification of the harmonised listing of endpoint. The Commission services also requested Member States to provide their legal analysis related to their position not to accept in an application for product authorisation a mix of a letter of access and data, as well as on their position to not take into account certain data on active substance that would be submitted by an applicant.

One Member State considered that only data on active substance set at the approval and agreed endpoint values should be used at product-authorisation stage. However, this Member State acknowledged that the submission of additional data on active substance at product authorisation cannot be prevented. It considered that the LoE should not be modified unless the conclusions of the risks assessment of the product are affected. It considered that new data should normally only be looked in the context of the renewal of approval of the active substance.

Another Member State indicated that data are often submitted at product authorisation for having refined values for PNEC for the active substance and would prefer to consider them only at the active substance renewal stage.
ECHA considered that the LoE should also be connected to the assessment report of the active substance, and expressed concerns to modify the assessment report outside the active substance renewal processes. The Commission services reminded that LoE has been amended in the past by the BPC when missing data referred in section 2.5 of the BPC opinion were submitted prior to product authorisation, in accordance with the current BPC procedures.

The Commission services concluded that there is a need to develop a common view on how to manage additional data on active substance submitted during product authorisation, and asked Member States to provide their comments on the questions included in the two last slides of the presentation made during the meeting. Member States were also asked to provide their legal analysis on the controversial points referred in the presentation. A newsgroup will be opened so that MSs can provide comments (until 30 June 2021).

4.5. Change of classification of substances and the consequences on biocidal product procedures	For discussion and agreement *CA-June21-Doc.4.5*	

The Commission services presented the document CA-June21-Doc.4.5. that aims to address what are the consequences for authorisations of biocidal products when new information on the substances contained in the product becomes available. The document summarises how to manage different types of new information that becomes available on a substance contained in a biocidal product during the evaluation of an application for authorisation by the reference Member State, during the discussion phase between Member States in the context of mutual recognition, and when the product is already authorised.

The cases included in this document were already partly addressed in the past, and a way forward was developed and agreed in previous CA documents. However, some amendments

have been introduced. The document does not address new information on the listing of end points of the active substance, as this will be addressed in a different document.

The document contemplates two different situations depending of the moment in time when the new information becomes available: before the authorisation is granted, and after the authorisation is granted.

Two Member States asked at which moment new information has to be taken into account for product evaluation. The Commission services pointed out that new, valuable information has to be taken into account and it has to be decided whether it is relevant for the product authorisation. It will reflect on the advice of expert groups. One Member State pointed out that this document implies that Member States have to apply Article 48 and cannot require a change of the authorisation holder. Guidance on this issue would be appreciated. The Commission services indicated that the Commission has not laid down detailed rules in accordance with Article 51 up to now. This article provide legal base to lay down detailed rules for the application of Article 48. ECHA indicated that this document would imply that procedural timelines could not be respected and refers to point 8 of Annex VI stating that at the evaluation of product shall be considered scientific information which is reasonably available.

The Commission services indicated that a newsgroup would be opened for the contributions of the members of the CA meeting.

4.6. Report from the Coordination Group	For information	

The Commission services provided feedback on the CG-46 meeting.

In the CG-46 meeting one formal referral was discussed and agreement was reached for it. The Commission services presented the revised document concerning the distribution of the renewal cases where the UK was the refMS. Revision was carried out due to the fact that for some cases feedback was provided that an agreement between the applicant and a MS different than the one nominated.

A Member State presented a proposal for the revision of the CA document in relation to handling carriers (CA-Nov16-Doc.4.3 - Final). Discussion will continue at the next CG meeting. Mutual recognition phase of a non-authorisation decision was discussed.

The CG Secretariat briefly introduced a document with proposals for the next steps in light of the CA document CA-March21_Doc.4.3_Final regarding the bridging of ED-assessment of biocidal co-formulants with REACH screening and assessment. The points for CG discussion were on: inventory list of co-formulants generated from IUCLID, MSs' list of co-formulants, review and revision of existing CG documents CG-34-2019-02 and CG-41-2020-03. No conclusion was reached and discussion will continue at the next CG meeting. (Closed session discussion and open session for information).

Other topics discussed were RMMs for treated articles.

A Member State drew the attention of stakeholders to the fact that in general the renewal application for PT14 products should be submitted by the end of June, as the deadline is drawing near and applications has not been submitted for all PT14 products where that is the deadline, in that Member State.

The main CG agreements reached during the CG-46 meeting:

- e-consultation in relation to Refinement of PNECsoil for a particular product dossier.
- e-consultation in relation to a co-formulant potential having ED properties.

- e-consultation in relation to RMM by using personal protective equipment for persons applying the biocidal product against oak processionary caterpillar.
- Substances of concern (SoC) and active substance Annex I of the BPR. The MS informed the CG that they did not wish to continue the discussion further, this would be addressed in the frame of a general revised SoC guidance. The CG agreed by consensus that the topic was closed and that the presented document would be the final document.

The secretariat of the CG updated the CG on the started maintenance of the list of frequently used sentences in the SPC and presented a document containing several amended or new sentences related to the updated list of frequently used sentences in the SPC where opposing comments had been received during the commenting. The reached agreements were recorded in the revised document and will be taken into consideration for the update of the list.

The CG agreed on the updated templates for referral submission and processing, as well as on a template for Member States to submit the detailed statement to the Commission in accordance with Article 36 of the BPR, on the updated Working Procedure for resolving of disagreements, on that e-consultations would be conducted via Interact instead of S-CIRCABC, on a revised document in relation to questions raised by the working group on environment of the BPC on how and which types of entries need to be assigned for particular TAB entries.

Topics where further discussion will take place were: consultation in relation to topic – PT1 hand disinfectant packaging and labelling. Member States will provide further feedback. A Member State briefly presented an outcome of an e-consultation in relation to topic – Splitting of applications of biocidal product families. It was agreed that the initiating Member State of the e-consultation would provide a revised document and Member States would provide further feedback. However, following the meeting the initiating Member State provided a revised document and withdrew the e-consultation considering it closed.

4.7. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-June21-Doc.4.7*	

The document was uploaded for information. The Secretariat of the Coordination Group asked MSs if this report is useful. The CA meeting concluded that, as a similar report is made for the CG meetings, there is no need to duplicate the task. From now onwards, the Secretariat of the Coordination Group will provide only the version of the document prepared for the CG meetings.

4.8. Guidance on Biocidal product family-2nd revision	For discussion and agreement *CA-June21-Doc.4.8*	

The Commission services explained that two modifications to the CA-July19-Doc.4.2 on the implementation of the concept of biocidal product family have been proposed by ECHA. The changes provide clarification on the definitions of the function of co-formulants (see paragraph 42) and a harmonised approach to determine a worst-case test product to be taken into account for the efficacy core assessment of a disinfectant BPF.

A Member State made an editorial comment which was accepted. Another Member State asked whether it would be up to an evaluating Member State to decide whether the applicant

needs to split a BPF if the conditions of similarity would not be met. The Commission services confirmed (see section 3.3 of the CA document).

The CA meeting agreed with the changes proposed by the Commission services.

4.9. Food flavourings contained in biocidal products and the evaluation of ED properties	For information	

The Commission services explained that food flavourings can be considered food under Regulation 178/2002. This is relevant for the application of the document 'Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment' (CA-March21-Doc.4.3).

4.10. CA-March16-Doc.4.6 – Final.rev3 Q&A pairs concerning the practical implementation of the simplified authorisation procedure (SAP)	For discussion and agreement *CA-June21-Doc.4.10.a* *CA-June21-Doc.4.10.b*	

The Commission services presented a revised version of CA-March16-Doc.4.6, that includes a new Q&A (number 30), to clarify that Member States that received notifications for individual products belonging to that family are entitled to raise formal referrals in accordance with Articles 35 and 36 of the BPR, only for the products for which they have received a notification. The CAs agreed on the proposed modification of the CA-document.

4.11. Use of aircraft insecticides	For information	Closed session

This item was discussed in closed session.

4.12. Mutual recognition of same biocidal product authorisations	For discussion and agreement *CA-June21-Doc.4.12*	

The Commission services presented a document addressing the question on whether a same biocidal product authorised in accordance with Commission Implementing Regulation (EU) No 414/2013 can be subjected to mutual recognition. The issue was raised by Germany during the 91st meeting of the Competent Authorities for biocidal products. The position of that Member State is reflected in the document CA-March21-Doc 4.16-Mutual recognition of same biocidal products. In the opinion of that Member State mutual recognition should be restricted to national authorisations in strict sense only, and therefore, same biocidal product authorisations can be subjected to changes but cannot be mutually recognised.

Similar discussions on whether is it possible that a same biocidal product authorisation is recognised in other Member States by mutual recognition in sequence, have taken place in the past, and specifically in the meeting of the coordination group of September 2015 (CG-13 agenda point 14(6)), in the 61st meeting of the Competent Authorities for biocidal products (agenda point 4.1) and the 62nd meeting of the Competent Authorities for biocidal products (agenda point 4.2).

The conclusion that was reached in those discussions is that the BPR does not contain any provision restricting mutual recognition of same biocidal products authorisations. Some Member States suggested to introduce such a provision, preventing that same biocidal products authorisations could be mutually recognised in the draft of the Commission Implementing Regulation (EU) No 414/201 ('SBP Regulation') that was being discussed at the time. During these discussions it was clarified that such a restriction could only be made by modifying the BPR as such.

The Commission services concluded that same biocidal product authorisations granted in accordance with Regulation (EU) No 414/2013, can be recognised in other Member States subjected to mutual recognition procedures, as established in Chapter VII of the BPR.

Article 3(1)(m) of the BPR provides the definition of national authorisations. There is no distinction in the concept of 'national authorisation' under Article 3(1)(m) as to the procedure under which the national authorisation was granted (whether it was granted through full application of Chapter VI of the BPR or with some derogations from that Chapter). Therefore, there is no legal reason to distinguish national authorisations of 'same biocidal products' from other national authorisations, as both fulfil the definition of 'national authorisation' under Article 3(1)(m).

Article 32(1) of the BPR establishes that applications for mutual recognition of a national authorisation can be made. Since there is no distinction in the concept of 'national authorisation' under Article 3(1)(m) as to the procedure under which the national authorisation was granted, any national authorisation as defined in Article 3(1)(m) of the BPR can be recognised in other Member States.

The Member State that raised the question does not share this analysis, as in their view same biocidal products authorisation are mere administrative acts in which no assessment takes place. This Member States also pointed out that chapter VI of the BPR addresses national authorisations and chapter IV same biocidal products. Also, they see practical problems, as they think it will not be easy to trace back the authorisation of the reference product in R4BP3 of a same biocidal product. This position was supported by several other MSs, although it was pointed out by one of these MSs that this situation will not happen in reality due to the need for the applicant to have a letter of access to the data of the reference product. Additional questions were raised by Member States on the consequences of this interpretation. The Commission services asked Member States to submit their questions in written, and they will try to provide clarification, and update the document accordingly, if needed. ECHA intervened to clarify that arrangements were done in the past to trace back the authorisation of the reference product in R4BP3.

Another Member State asked to address the situation in the document that a mutual recognition of a same biocidal product is requested and the reference product is not authorised for this Member State.

The issue will be discussed in the next CA meeting. A revised version of the document will be uploaded in CIRCABC, as some editorial mistakes were detected after uploading.

The Commission services are reflecting on drafting a document compiling all the clarifications made on mutual recognition procedures, maybe as a Q&A document. Some Member States welcomed the initiative.

4.13. Clarification: mutual recognition in case non-authorisation decisions	For information *CA-June21-Doc.4.13.a* *CA-June21-Doc.4.13.b*	

The Commission services informed that document CA-June21-Doc 4.13.a will not be presented in the meeting, as internal discussions are still ongoing.

The Commission services presented the document CA-June21-Doc 4.13.b, that intends to clarify that in the context of a minor or major application for changes (MIC or a MAC) the concerned Member States are entitled to provide comments to the decision of a reference Member State that decided not to authorise an application for changes (major or minor).

Regulation No (EU) 354/2013 establishes a procedure for resolving disagreements on the assessment by the reference Member State on changes applications, in Article 7(4), Article 7(6), Article 8(4), Article 8(6) and Article 10. Therefore, even in case of non-authorisation of the changes, the concerned Member States have the right to comment on the conclusions of the assessment report or, where relevant, on the revised summary of the biocidal product characteristics of the refMS.

The discussion will continue in the next CA meeting. A revised version of the document will be uploaded in CIRCABC, as some editorial mistakes were detected after uploading.

4.14. List of pending Article 36 requests	For information *CA-June21-Doc.4.14*	Closed session

The Commission services informed on the state of play and the progress of the pending Article 36 requests from Member States. It was reminded that the timelines included there are indicative.

4.15. Designation of the biocidal product when free radicals are generated from a polymer	For discussion *CA-June21-Doc.4.15*	

The Commission services explained that the topic was introduced at the request of a Member State who sought clarity on the identification of the biocidal product when free radicals are generated from a catalyst in a polymer matrix. The polymer is in the form of granules that are extruded to provide an ‘object’ or an ‘article’ that is placed on the market. The catalytic effect is always present and free radicals are generated when the object comes into contact with moisture.

This initiating Member State proposed two options. Either the object could be considered the biocidal product, as this is the product placed on the market (see case-type 3 of the CA document on the management of product authorisation in case of in-situ), or the free radicals generated would be regarded as the biocidal product (under case-type 4 of the CA document on the management of product authorisation in case of in-situ). In that latter case, the polymer matrix could be considered a device, as it aims to distribute the catalyst through the object.

Just before the CA meeting, another Member State argued that this case should be considered under case type 3. To support its opinion, that Member State made reference to CA-Sept15.Doc.5.2 on master batches in which is defined a master batch as a pre-dispersed concentration of additives allowing the user to use such additive accurately into a batch product. In the specific case at hand, the master batch would be considered as a biocidal product and the object would be regarded as a treated article.

The initiating Member State supported case-type 3 and indicated that the wording of case-type 3 in the note on in-situ should be adapted to clarify what is the biocidal product (preferably either the object or the master batch).

Another Member State expressed the view that the free radicals generated would be the biocidal product but as it is not a physical object, it was proposed to leave the possibility to the applicant to choose what is the biocidal product (i.e. either the master batch, the catalyst or the object) to be labelled with a primary biocidal claim. The case-type 3 option was therefore not supported by that Member State as it would imply that the object placed on the market is sold with a biocidal claim. As it is unclear whether this will be the case, this Member State proposed to refer to case-type 4. If this option is supported, the CA-note will have to be amended as it currently includes only a reference to a device. Another option would be to create a specific case-type 5 that would cover the case at hand.

The Commission services agreed that the way the products are presented to the user would be determinant to define what is the biocidal product.

The initiating Member State excluded the possibility to consider the catalyst as the biocidal product as the catalysts do not generate the free radicals. This position was supported by one Member State. Another Member State disagreed and explained that the document CA-May2016-Doc.5.1[1] specifies that when such free radicals will be generated from systems, such as an electrical device using UV-light, or articles, such as glass, tiles, or panels containing photocatalysts, a case by case analysis will be required to identify the biocidal product to be subject to authorisation.

The discussion will continue at the next meeting and a newsgroup will be opened on CIRCABC to collect the views of the CA on this topic until 30 June 2021.

4.16. Clarification regarding the scope of Regulation No 492/2014	For discussion and agreement *CA-June21-Doc.4.16*	

Item 4.16 was included in the agenda at the request of Germany, that prepared the document CA-June21-Doc.4.16, regarding the clarification of the scope of Regulation 492/2014 on the renewal of authorisation subject to mutual recognition. Germany presented the document, in which two questions are raised on whether authorisations to which major or minor changes have been applied only in the reference Member State or in the concerned Member States fall in the scope of Regulation 492/2014. According to Article 1(3)(a), the application of Regulation No 492/2014 should remain restricted to products having the same terms and conditions or authorisations with differences that fall under the definition of administrative changes. As the removal of a particular claim is considered as an administrative change, Germany would like to have the opinion of the rest of the Member States and the Commission services, on whether authorisations to which administrative changes have been applied to remove claims only in certain Member States, fall into the scope of Regulation 492/2014. According to Germany, in principle those authorisations to which administrative changes have been made, fall into the scope of Regulation 492/2014, but any other change will be out of the scope. This view is supported by one Member State. Another Member State is of the opinion that there is a need to clarify how changes need to be classified, and highlighted that there is no trace in R4BP3 when major or minor changes are applied.

[1] Guidance to specify information requirements for free radicals generated in situ from ambient water or air for substance approval in the context of the BPR.

ECHA highlighted that in accordance with Article 1(2) of Regulation 492/2014, the regulation is only applicable to authorisations granted under the same terms and conditions.

The Commission services pointed out that several derogations to Article 1(2) are provided for in Article 1(3) of Regulation 492/2014, therefore, Regulation 492/2014 is applicable also to authorisations having different terms and conditions, including authorisations granted in accordance with Article 37 of the BPR. The Commission services reminded that there are other aspects of Regulation 492/2014 that need to be updated , and asked Member States to reflect on whether further amendments are needed of this Commission delegated regulation. A newsgroup will be opened to collect the views of the CA on this topic until 30 June 2021.

4.17. Renewal of "Same biocidal products" authorisations	For discussion and agreement *CA-June21-Doc.4.17*	

Item 4.17 was included in the agenda at the request of Germany, that prepared the document CA-June21-Doc.4.17, regarding the renewal of same biocidal product authorisations.

According to Germany, a common understanding and how to handle renewal of same biocidal product authorisations is urgently needed. In the document several questions are raised:

- is the renewal of same biocidal product authorisations possible at all (as this is not mentioned in the relevant legal texts)? If yes,
- should same biocidal product authorisations be handled like national authorisations (even if the reference product was obtained by mutual recognition?)

Two different options are suggested in the document:

1) The renewal of same biocidal product authorisations is not possible. Once the reference product is renewed a new application for a same biocidal product authorisation (of the renewed reference product) should be submitted.
2) All applications for renewal of a same biocidal product authorisation should be handled like the renewal of a national authorisation. The RefMS of the same biocidal product (which is not necessarily the RefMS of the reference product) carries out the assessment for renewal. Data requirements for renewal of national authorisations apply (e.g. IUCLID dossier, draft PAR).

Furthermore, due to the workload exceeding a pure administrative procedure, fees for renewal of a national authorisation could apply.

In any case, in the opinion of Germany, a legal text (procedure) addressing the renewal of same biocidal product authorisations is needed. Germany would like to have the views of the Member States and the Commission services on this matter.

One Member State reminded that this issue was discussed in the context of the first renewal of PT14 products, where it was decided that those would be considered as standalone authorisations not linked to the reference products, but that renewal will be done at the same time. This is reflected in the CA document on renewals of PT14 products. Another Member State confirmed this and added that the issue was also discussed in the coordination group. A third Member State expressed legal concerns on the approach agreed in the past.

ECHA supported the proposition from Germany, and pointed out that further discussions on how to handle all this procedures need to take place. A newsgroup will be opened to collect the views of the CA on this topic until 30 June 2021.

5. Active substances		

5.1. Redefinition of active substances included in the Review Programme	For discussion and agreement *CA-June21-Doc.5.1*	

The Commission services informed that this topic will be discussed at the next CA meeting in September.

5.2. Progression of the review programme on active substances	For information *CA-June21-Doc.5.2*	

The Commission services informed that since the last meeting, no draft assessment report on active substances under the review programme or for new active substances has been submitted by the evaluating competent authorities.

The Commission services reported that only 40% of the review programme has been completed so far and that substantial progress is still required on the priority lists for which assessment reports should have been submitted a long time ago. In addition, the Commission services urged the evaluating Member States to finalise their assessments of the remaining 44 backlog dossiers.

Lastly, the Commission services invited again Member States to use the support provided by ECHA under the Active Action Plan to make progress in the Review Programme.

The CA meeting took note of the information provided by the Commission services.

5.3. Progression of the renewal process of approval of active substances	For information *CA-June21-Doc.5.3*	

The Commission services presented an overview of the renewal applications of active substance/product-type combinations under assessment and the dates of submission of their dossiers. The Commission services recalled the Member States to respect the timelines set under the BPR in particular when additional information is requested from the applicant in order to limit the need for extensions of approvals.

The Commission services drew the attention of the CA meeting on the specific case of carbon dioxide for which recent application for renewal of product authorisation has been submitted for product-type 18, but the product does not comply with the current conditions set in Annex I for this active substance. As carbon dioxide only remains included into Annex I to the BPR, all biocidal products for product-type 18 have to comply with the conditions set Annex I, and, when the general approach on Annex I management was agreed in 2018, it was advised to interested companies to submit applications to modify the conditions of inclusion of carbon dioxide in Annex I. The Commission services invited the Member States that have received such applications to liaise with the applicant to ask them to first introduce a request to modify the conditions set in Annex I. Otherwise it will not be possible to renew the PT18 product authorisations.

5.4. ECHA Active Substance Action Plan – Progress report	For information *CA-June21-Doc.5.4*	

ECHA presented the document where the increase in figures of active substance dossiers was noted. ECHA indicated the intention to launch during the 2nd half of the year a campaign to check whether active substances under evaluation are properly identified. Several actions to streamline the process are tabled for discussion at the BPC-39 meeting. The FAST project is ongoing and will provide the first deliverables by the end of the year. ECHA is working on the analysis of alternatives for hazardous active substances that will continue with the development of guidance and the experience of identification of alternatives for hexaflumuron. As key message, ECHA requested competent authorities to seek support from ECHA early in advance during the evaluation process together with the identification as early as possible of further information needed to perform the assessment. ECHA indicated that the update of the planning for the submission of active substance and Union authorisation dossiers during 2021 – 2024 would be launched shortly after the CA meeting.

6. Treated articles
No item for information or discussion.

7. Horizontal matters

7.1. Risks assessment of skin sensitizers	For information	

The Commission services explained that preliminary discussions with ECHA on the scope of a future mandate on skin sensitisers have just started. The mandate could analyse whether isothiazolinones would meet the conditions for candidates for substitution and if there is a causal link between the development of skin sensitisation and their use in paints and detergents. The mandate could also contain a request to look at the Dutch proposal to use another type of efficacy testing for preservatives that could demonstrate efficacy at a lower concentration.

The Commission services called for volunteering Member States to support ECHA in the preparation of the opinion. Two Member States responded that they could envisage to be involved in the matter but that first the scope of the mandate should be clarified.

An industry association repeated its request for a policy discussion rather than a 'mere technical debate' and recalled that the results of a Dutch research project on alternative methods are expected soon. Two other industry associations expressed also their willingness to be associated in the development of the BPC opinion when the scope of the mandate will be known. The Commission services explained that ECHA is responsible for designating the participants that will be involved in the elaboration of a BPC opinion.

The Agency understood the concerns associated with the use of isothiazolinones but indicated that beyond a technical and scientific mandate, a regulatory/policy discussion would be needed to make progress on this issue.

7.2. The use of biocides in plastic Food Contact Materials	For information	

The Commission services informed the meeting about the state of play of the amendment of the plastics regulation. The intention is to vote on the draft regulation in the relevant Standing

Committee before or after the summer break. Also was indicated that EFSA is concluding their opinion on nanosilver substances to be used in food contact materials.

7.3. ECHA Communications	For information *CA-June21-Doc.7.3*	

ECHA had not specific communications for this meeting.

7.4. Article 65 reporting – Template for future reporting	For discussion and agreement *CA-June21-Doc.7.4*	

The Commission services introduced the proposed updated template for future Article 65 reporting together with a presentation outlining newly added elements and points that were removed compared to the template used for the first reporting of 2020. The Commission services thanked Member States for the comments and suggestions provided and indicated that all the elements that are currently proposed in the template have been used in the first report to the European Parliament and the Council. The elements removed were in fact those which were not included in the first report or for which data can be extracted from R4BP (e.g. products containing active substances meeting exclusion criteria, renewal of authorisations).

In section 1.3.3 (Resources of competent authorities) it was agreed to remove the question on the appropriateness of human resources and the same was agreed for the question on the appropriateness of resources for enforcement.

With respect to section 5 (Poisoning incidents), one Member State strongly supported the differentiation by age group (as included in the harmonised format for poison centres annual reports (Annex II to European Council Resolution 90/C329/03) and the inclusion of one additional category (moderate) in the severity section, alongside severe, fatal and other. Another Member State indicated that the age groups used by their poison centre are different from the ones proposed in the template. It was agreed that two tables will be provided for this section – one without age group differentiation and another one with the differentiation by age group, for those Member States who have these data available. In the same section, one Member State noticed that the distinction between incidents involving humans and incidents involving non-target animals was requested in the template only for pest controls main group and requested that a footnote be added for the other main group clarifying that for those main groups only data related to incidents involving humans was to be reported.

One Member State indicated that they cannot agree with the template at this stage, as they needed to consult other colleagues on some points that were not addressed in the updated template. This Member State agreed to discuss bilaterally with the Commission services the points still pending. This discussion took place and resulted in agreement of the template.

7.5. Assessment of confidentiality claims	For information *CA-June21-Doc.7.5*	

ECHA informed that the first draft of the document had been shared with the Commission services. ECHA is currently taking into account the comments provided by the Commission services. After consolidation, ECHA envisages to make the guidelines available to competent authorities and applicants without delay and to update them in the light of experience. ECHA remarked that the guidelines reflect the experience acquired so far in assessing confidentiality

claims, clarify the general principles and provide practical recommendations. The guidelines do not provide a new interpretation of the obligations under the BPR, therefore further consultation with authorities or stakeholders is not considered as needed.

7.6. ECHA guidance on bees and other non-target arthropod pollinators	For information *CA-June21-Doc.7.6*	

The Commission services introduced the item to the CA meeting and indicated that on 28 June 2021, Ministers in the AGRIFISH Council will discuss the setting of a Specific Protection Goal for honeybees for the risk assessment for plant protection products. This will then be used for the finalisation of the review of the relevant guidance document from the European Food Safety Authority (EFSA). The protection goal will relate to the acceptable impact of the use of plant protection products on honeybee colony size to be measured in field studies.
One Member State expressed its concern on the way forward as it considers that an alignment with an ecosystem services approach as discussed for plant protection products will reduce the level of protection in the assessment of biocidal products. This Member State pointed out that other pollinator species than honeybees could be more vulnerable to chemical exposure.
The Commission services clarified that solitary bees and bumble bees are also addressed in the guidance for plant protection products and that specific protection goals for them will still need to be agreed. The differences between use patterns of biocidal products and plant protection products are acknowledged. For example, the higher tier field studies for plant protection products are not relevant for biocidal products. However, lower tier tests (such as laboratory or semi-filed studies) could be relevant for both plant protection and biocidal products. The target is to align as much as possible the guidance for risk assessment between plant protection products and biocides while being mindful of the objective differences in order to implement the policy of 'one substance, one assessment'. ECHA stated that it is important to have an agreement with regard to protection goals, as this enables them to proceed with the development of the guidance and also allows them to have much clearer objectives in the guidance development.

7.7. Guidance priorities	For discussion and agreement *CA-June21-Doc.7.7*	

One Member State pointed out that it previously suggested to have guidance on performing risk assessment for substances identified as having ED properties. The document does not currently reflect this request. ECHA indicated that it will require time to build some experience on the cases and develop an EU-wide approach, also considering that the JRC is working on this issue. Another Member State pointed out that the Working Group (WG) recommendations on in situ generated active substances do not address efficacy, notwithstanding a task force is dedicated to this. A third Member State asked about ARTFood and the intention to organise meetings in the future. ECHA indicated that the group is finalising one project and one scenario and that discussions are ongoing on enlarging the mandate of ARTFood upon previous request from a Member State.

7.8. Issues identified during the drafting of PT 10 efficacy guidance	For discussion	

The Member State initiating the discussion recapped the outcomes of the newsgroup opened after the last CA meeting to collect the views of the other participants. This Member State concluded that algaecides used for the remedial treatment of construction materials will remain under PT2 and that aesthetical and deterioration claims will be discouraged. On the borderline issue between the Plant Protection Products Regulation (PPPR) and the BPR, it was concluded that the treatment of roots and mosses is in the scope of the PPPR and therefore the BPR is not applicable. Regarding the treatment of artefacts of cultural heritage, the initiating Member State concluded that because of differences in national legislations on the definitions of trained professional and professionals, it was proposed to keep only a reference to professionals. Lastly, on the possibility to exempt the treatment of wood artefact from the scope of PT8 and to assign it to PT 10, it was concluded that the current description of PT10 does not allow this exemption. An Article 55(3) derogation could be a solution if there are not enough products to treat wood artefacts on the national market.

A Member State requested the initiating Member State to provide an updated document with its today's conclusions. The initiating Member State proposed to send its final conclusions in writing after the meeting and recalled that the PT10 efficacy guidance is at its early stage of development and that there will be new opportunities for discussion. The point was considered closed for the CA meeting.

7.9. Allocation of products to another product-type	For discussion	

The Commission services explained that an EBPF document agreed at the CA of September 2020 provided information on the allocation of certain biocidal products to another product-type. However the CA meeting called for the presentation of that document in a more official format i.e. the one that is usually used by the Commission to prepare a CA document and to continue to update this draft with similar information in the future. However, the Commission services informed at the last meeting about its concerns about the potential impacts of such document on the review programme (delays, legal issues, resources…) and the number of cases potentially affected by a change of AS/PT combination while the review programme is far to be completed. The Commission services put forward several questions in a newsgroup for further reflections by the CA.

Following this consultation, the Commission services informed that its concerns have not been alleviated and therefore proposed to not upgrade the EBPF document into a CA format. The EBPF document will remain available for information.

An industry association reminded that the question of reallocation was brought up at the request of the ECHA efficacy working group and wondered now how the position of the Commission services will be communicated to them. The Commission services replied that an analysis of a change of AS/PT combination should be performed on a case by case basis.

A Member State requested whether this point could be covered by the agenda point 5.1 on the redefinition of active substance. The Commission replied that contrary to the change of allocation of PTs, the legal base for the redefinition exercise is clear. The objectives are clearly different as well. The reflection is about the possibility to remove the provisions on taking over under the Review Programme regulation now that the BPR is into force since almost 8 years.

Two other Member States asked how to proceed if a request for a change of PTs is proposed in line with the guidance on efficacy agreed in September 2020. The risks is that the evaluating Member State may choose to not request the relevant efficacy data. It was

proposed to merge the product types 11 and 12 to solve the problem. The Commission services pointed out not having the empowerment to change Annex V.

An industry association noted that the previous point on the agenda referred also to a possible change of PTs and wondered whether the conclusions of that agenda point should not be amended to take fully into account the concerns expressed here by the Commission services. The Commission services understood that the choice of PT in the document 7.8 is now aligned with the BPR provisions. The point was closed by the CA.

7.10. A.I.S.E. report on targeted hygiene and appropriate use of products	For information *CA-June21-Doc.7.10.a* *CA-June21-Doc.7.10.b*	

A.I.S.E. announced the publication of a joined report carried out by A.I.S.E and IFH which supports the principles of targeted hygiene for EU citizens' health and promote appropriate use of products (cleaning products vs disinfectants where needed). The approach argues that, to be effective, hygiene practices need to be focussed at the times and in the places that matter to break the chain of infection and reduce the risk of exposure to harmful microbes. In the spirit of BPR, this report promotes a sustainable use of biocides.

A.I.S.E also summarised the findings of a consumer survey which indicated that the consumer should better adapt their behaviour towards infection risks. The report called all stakeholders to promote best hygiene practice among consumers.

One Member State stated that other actions than the use of home disinfectants like a reduction of contacts could also be implemented. In general, a reduction of the use of home disinfectants should be recommended. Another Member State stated that the use of disinfectants increased during the pandemic. It is important to turn this trend. A.I.S.E answered that the report does not provide advice on Covid-19 as the project started before the pandemic. The report recommends to use home disinfectants when a risk for public health is identified. The key role of disinfectants in hygiene is demonstrated and industry is fully aware of the importance of their adequate use. A.I.S.E would welcome the opportunity to further discuss the report with Member States authorities.

The Commission services invited the Member States to contact A.I.S.E if they are interested in launching a promotion campaign at national level.

7.11. Revision of the nanomaterial definition: stakeholder consultation	For information *CA-June21-Doc.7.11*	

The Commission services informed the CA meeting of the ongoing revision of the definition of nanomaterials. Contributions are welcome until the end of June under the web link mentioned in the presentation.

7.12. Training: micro-organisms and BPF	For information *CA-June21-Doc.7.12*	

The Commission services informed about the organisation of several training sessions on the risk assessment of micro-organisms. Applications should be sent to the national contact points referred to in the presentation.

The Commission services also informed that one Member State requested the organisation of a training on the concept of BPF. The Commission services informed that it is currently evaluating different possibilities under the existing training tools of DG SANTE. A newsgroup will be open until 30 June to collect information on the number of participants and on their training needs.

7.13. UK's withdrawal from the EU: refMSs for authorisations subject to renewal – final re-distribution table + new assets to be re-assigned	For information and discussion *CA-June21-Doc.7.13.rev1*	Closed session

This item was discussed in closed session.

7.14. Follow-up report on the implementation of the BPR	For information	Closed session

This item was discussed in closed session.

8.	**Scope matters**

8.1 Borderline between Regulation (EC) No 1107/2009 on plant protection products and Regulation (EU) No 528/2012 on biocidal products	For discussion *CA-June21-Doc.8.1*	

The initiating Member State recalled that the document put forward at the December meeting contained a list of 10 possible uses for which it was asked to the competent authorities on plant protection products and biocides to assess which uses would fall under the scope of the BPR or the PPPR. It results from that consultation that at least for 6 uses, the situation was no really clear. The decision tree proposed by the Commission is helpful to determine to which legislation a product would belong based on a claim. However, the tool is not helpful when the intended use is different from the use claimed in the application for authorisation. The question remains on how to ensure that both uses would be identical. The initiating Member State indicated to come back with a revised document for the next CA meeting.

Another Member State questioned the possibility to decide whether a product would fall under the BPR or the PPPR based on a human protection claim as it is suggested in the second row of the presentation. This possibility should be removed as such claims are obviously exclusively covered by the BPR. This Member State also noted that the second row seems to suggest that a tool disinfectant could be considered a plant protection product in the presence of plants. Although, the intention of the tool is supported, these two remarks need to be addressed before it can be endorsed. A list of uses as mentioned by the initiating Member State seems to be more convenient and clearer than a decision tree.

The Commission services indicated that the enforcement authorities could check whether the intended use and the claimed use are similar. It reminded that Article 3(3) of the BPR gives the possibility to the Commission to decide whether a product is biocidal product or not and that when a product is covered by the PPPR, the BPR is no longer applicable for that product.

The decision tree was intended to capture most of the issues relating to borderline cases between the PPPR and the BPR.

9. Enforcement issues
No item for information or discussion

10. International Matters
No item for information or discussion

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-June21-Doc.11.a*	

(b) Update on the early review of iodine, PVP-iodine and zineb		

The Commission services updated the meeting of the state of play of the early review of the substances. A mandate is being submitted to ECHA. On receipt of the opinion the Commission will decide on the proper way forward.

(c) Impact analysis for antifouling products		

The Commission services noted that certain decisions and commitments have been taken in the coordination group and CA meeting in relation to this impact analysis. It is up to the Member States to decide how this relates to the on-going procedures for antifouling products.

Next meetings:

2021
(provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WGs
16-18 February	10-12 March			
		22-23 March	1-5 March	15-26 March
27-29 April				
	31 May-3 June			
29-30 June		22-23 June	14-18 June	2-11 June
1 July				
14-16 September	27-30 September			13-24 September
			4-8 October	
23-25 November		11-12 November	29-30 November	15-26 November
	6-9 December		1-3 December	