

EUROPEAN COMMISSION

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

MINUTES

93rd 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

28-29 September 2021

1. Adoption of the agenda For adoption CA-Sept21-Doc.1

The agenda was adopted with an AOB point suggested by one Member State on incidents involving phosphine-releasing products, one point concerning an update on a Court case and three AOB points for the closed session.

2. Adoption of the draft minutes of the previous CA meeting	For adoption <i>CA-Sept21-Doc.2</i>	
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One Member State requested the addition of one sentence in the section related to future Article 65 reporting. The minutes of the previous meeting were then adopted.

3. Draft delegated acts

Regulation (EU) No 1062/2014 C	For discussion CA-Sept21-Doc.3.a CA-Sept21-Doc.3.b
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The Commission introduced the draft delegated Regulation amending the Annex II to the Review Programme Regulation and explained that the aim of the revision is to reflect the actual state of the Review Programme. It was further explained that the changes in Annex II derive from: removal of the active-substance/product-type combinations no longer supported, of those for which a Commission approval or non-approval decision, as well as of those which were included into Annex I to the BPR following the adoption of several delegated acts. In addition, three active substances were redefined, leading to the inclusion of new entries corresponding to the new identities. Also two active substances that benefitted from the food and feed derogations and for which the notifications were recently found compliant by ECHA have been included, as well as one entry following a redefinition, which was omitted in the previous amendment of the Review Programme Regulation.

The Commission mentioned that for one of the entries related to the notifications for food and feed (brandy PT19) there was a need to identify the rapporteur Member State (point 5.3 on the agenda).

4. Biocidal products

4.1. Risk mitigation measu products and treated a	1

The Commission introduced the item and invited the Member State who submitted the document provided for the meeting to introduce the document. This Member State mentioned that the document was submitted in response to various questions posed by the Commission in the past months and discussed at the CA meetings. The paper addresses the issue of setting

specific conditions of use of treated articles at active substance approval stage. The position of this Member State is that the conditions of approval must specify which categories of uses are acceptable. In their view there are too many treated articles on the market whose use has not been assessed for risks or efficacy, but exposure - of humans and environment - continues. The proposal is to reverse the regulatory approach, from specifying forbidden use categories to specifying allowed use categories. Evaluations of active substances already include use categories in the assessments. In the view of this Member State referring problems to the product authorisation stage is ineffective, which brings a discrepancy of treatment between treated articles produced in the EU and those which are imported, which are a big proportion of treated articles on the market. The approach suggested by this Member State would also bring benefits for the enforcement activities, since inspectors would have clarity on the permitted uses.

The Commission indicated that at the moment internal reflections are ongoing on what could be the general conditions to be included at active substance approval and that the Commission is ready to work with competent authorities and stakeholders in order to get more clarity regarding treated articles. The Commission had a question on the part in the document mentioning that the defining of use categories is already ongoing and asked the Member State who prepared the document to clarify this. The Member State stated that examples of such work ongoing are the evaluation of silver where uses were sorted in different exposure categories, the case of creosote (in this case the use categories are not triggered by exposure but by consideration of the necessity of the use) and the environment use categories for treated wood. The Commission also remarked, as already discussed in the past, that it is not to be expected that in dossiers already submitted applicants provided information on all possible use categories where substances may be used in treated articles. The Member State states that this might not be true for most of the cases, as already the Biocidal Products Directive included data requirements for use in treated articles, which were then called 'treated materials'.

The Commission added that problems arise from the fact that at active substance approval stage companies are requested to provide only one representative product and not an exhaustive list of possible uses of the active substance in treated articles. Reference was also made to the work performed by ECHA and some Member States in the context of the FAST project, where more targeted assessments are performed. ECHA indicated that for active substances used in treated articles it seems is not possible to apply the targeted assessment approach.

One Member State mentioned they welcome the document and acknowledged the difficulty of grasping all use categories at active substance approval stage. Another Member State indicated they support the approach suggested in the document and stressed that a better and clearer legal framework for treated articles is needed; however, finalising the Review Programme is the first priority under the BPR, therefore attentions should be paid so that the work on treated articles does not jeopardise the completion of the Review Programme. Another Member State also welcomed the proposal, but mentioned that it brings some challenges related to the increased workload during the active substance assessment.

One Member State stated that the implementation of the proposed approach will probably take place in the more distant future, as the concept needs further refinement and might be firstly implemented in the context of renewals. It also concurred that additional work that would slow down the active substance approval process must be avoided. This Member State suggested in would be beneficial to develop a notification system as set out in Article 58(7), so that persons placing on the market a treated article would have to notify it and thought that the making available and use of treated articles cannot be properly addressed under the current provisions of Article 58. Another Member State supported the idea of applying the

new approach in the context of renewals and flagged one element that could not addressed at active substance approval level, namely mixture toxicity in the case of multiple active substances contained in treated articles (like for instance in the case of wood preservatives).

The Commission concluded the discussion noting the willingness of many Member States to continue working on this topic and informing that a newsgroup will be opened to collect comments of Member States. The Commission also highlighted that work on this topic should not be detrimental to the work for the completion of the Review Programme.

4.2.	. 1	For discussion and agreement <i>CA-Sept21-Doc.4.2</i>	
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The Commission presented key principles to agree on to manage new data on an active substance presented in the context of an application for product authorisation, and how to manage the Listing of endpoints (LoE). These principles build on existing procedures defined in BPC and CG relevant documents that would need to be revised, as well as the previous discussions in the past CA meetings. Once agreed, ECHA will be requested to develop the corresponding procedures within its BPC and in collaboration with the CG.

One Member States considered that a specific procedure "AS-UPD" should be used in R4BP in order to manage these data, that the Member States who was responsible for the assessment of the active substance (eCA) should be responsible to assess also these new data as they would have to assess them in the future being also normally responsible for the assessment of the renewal, and that reference Member State for the product should be allow to suspend the evaluation of the dossier pending the common conclusion of the validity of these data and the whether the corresponding endpoint value needs to be modified. The Commission responded that this proposal was difficult to follow as this is not foreseen in the Articles of the BPR related to the assessment of product authorisation, and there would be also a fee issue as only the reference Member State (and concerned Member State in case of mutual recognition) receive a fee to assess the application for product authorisation, and by extension, the data submitted in this context, and not the former eCA on the active substance.

Another Member State considered that the endpoint value in the LoE should be modified only when it has an impact on the outcome of the risk assessment; in other cases, it should not be modified, and it would be studied later in the context of the renewal of the approval of the active substance.

Another Member State had concerns concerning the capacity of the BPC to cope with the potential workload, and would propose that only discussions in the relevant BPC working groups would be sufficient. That Member State would expect also that new/additional data of on the active substance would be submitted to assess additional uses not seen at the approval stage, considering the FAST project on-going at ECHA level which aims at limiting the number of uses assessed. It enquired whether a letter of access would be needed by subsequent applicants for such data.

Another Member State would welcome streamline with a procedure in R4BP and the possibility to stop the clock and have deadlines. The Commission clarified that it would not expect to request a new BPC opinion on the approval the active substance, as the substance is approved and no early review under Article 15 is made, but rather an addendum of the assessment report on the active substance to reflect the common on the new data to help product authorisation and avoid disagreement in the mutual recognition phase.

Another Member State expressed concerns about the workload while not making proposals on how to deal with the new data.

Another Member State would also like to know how to deal with the cases which are pending. ECHA expressed concerns on the additional coordination mechanism referred in the presentation on the workload and on the timelines will have to be carefully assessed and that the mechanisms might have to be streamlined, for instance promoting direct communication between Member States without always involving ECHA (for monitoring or recording) and avoiding discussion in the BPC or WG when the reference Member State considers the new information provided not relevant.

Another Member State asked whether a letter of access would be needed in case environmental data for outdoor use is presented during in product authorisation from another applicant, and these data were not provided at the approval stage as only an indoor use was supported as reference use. The Commission replied that, in that case and as indicated in the presentation, a letter of access to these additional data, or their own data on the environment, would be have to be submitted by other prospective applicants, as they have to submit a complete data package (ie. data on the environment would be missing otherwise from their dossier if they request an outdoor use, as data on the environment were not originally included in the data package submitted for the approval of the active substance).

Member States are invited to provide further comments in the newsgroup that will be open by 27 October 2021.

auth		For discussion and agreement <i>CA-Sept21-Doc.4.3</i> .	
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The Commission presented an amended version (CA-Sept21-Doc.4.3) of the document that was discussed in the CA meeting of June 2021 (CA-June21-Doc.4.5). The document has been amended taking into account the comments submitted by the Member States and ECHA. A newsgroup will be opened to provide Member States the opportunity to submit comments to this version.

The document summarises how to manage different types of relevant information that becomes available during the procedure for granting an authorisation of a biocidal product or once the authorisation has been granted, and that may impact the fulfilment of the conditions of Article 19 or Article 25 of Regulation (EU) No 528/2012 (the 'BPR').

The cases included in this document were already addressed in the past, and a way forward was developed and agreed in previous CA documents, namely CA-May13-Doc.5.4 - Final.rev1 - Classification and labelling of biocidal products.doc, CA-March16-Doc.4.15-Final - cut off dates para. 8a annex VI.doc; CA-Nov15-Doc.4.1 - Final - Handling changes to C&L and consequences.doc.

The document CA-March16-Doc.4.15-Final on the possibility to apply cut-off dates for the application of paragraph 8a of Annex VI to the BPR is considered not correct, and therefore it is proposed to repeal that document.

The Commission clarified that the BPC procedure to decide on the status of an active substance as regards P/B/T or ED status is to be established by the BPC. ECHA confirmed that a procedure will be developed and that it will be kept as pragmatic and simple as possible. The Commission will reflect internally on the procedures to consider the change of status of an active substance in ongoing and already granted Union authorisations.

A Member State enquired about the consistency with the approach followed for the plant protection products as regards changes in CLP. The Commission confirmed that the same approach as proposed in the document is being applied in plant protection products.

As regards the updating of the list of active substances meeting exclusion or substitution criteria made by ECHA, the Commission proposed that the list is updated after the meeting of RAC committee (4 times per year).

The Commission explained the differences between Article 47 and Article 50 of the BPR. Article 47 establishes an obligation for the authorisation holder to notify unexpected or adverse effects while Article 50 gives opportunity to applicants to request a change in the authorisation.

The document will be tabled for discussion and agreement in the next CA meeting.

4.4. Report from the Coordination Group	For information	
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The Commission made a brief summary of the issues discussed in the CG-47 and CG-48 meetings.

CG-47:

Five formal referrals were discussed and agreement was reached for three of the referrals. The Commission informed the CG on the status of the referrals for which the points of disagreement are referred to the Commission in accordance with Article 36 of the BPR. (Closed session)

A Member State presented a revised proposal for the revision of the CA document in relation to handling carriers (CA-Nov16-Doc.4.3 - Final) on the basis of a referral. The Member States will provide further feedback in writing. The initiating Member State (iMS) will provide a revised document based on the discussion during the meeting and the comments and discussion will continue at the CA. It was noted that the discussions concerning a UA at the last BPC meeting also affecting this CA document were not and will not be taken into consideration for the revision by the CG, as that is not in the remit of the CG. (Closed session)

The SECR presented a revised 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 CG agreed that the inventory list of co-formulants generated from IUCLID will be created and the MSs' list of co-formulants will not be created. Agreement was also reached that CG-34-2019-02 will be reviewed and revised by FR, while CG-41-2020-03 will be recorded obsolete in the minutes and removed from public CIRCABC. Discussion on the inventory list of co-formulants generated from IUCLID will continue at the next CG meeting. (Closed session discussion and open session for information)

The SECR informed the CG that:

- the documents prepared by the CG SECR regarding issues identified in the context of UA and update on questions forwarded from CG to ECHA will only be updated twice/year instead of each CG meeting.
- the documents prepared by the CG SECR regarding the list of active substances meeting the exclusion or substitution criteria will only be updated twice/year instead of each CG meeting.
- the new PAR templates are available on the ECHA website.

The CG SECR reminded ASOs that in case of referrals the contact details in R4BP3 are used, therefore these should be updated if necessary and the provided email address should be checked by the applicant regularly.

The main CG agreements reached during the CG-47 meeting:

- The CG agreed on the amendment of the Rules of the Procedure. Changes included the distinction of regular (previously CG meetings) and additional (previously teleconferences for formal referrals) meetings as well as addressing their differences (e.g. minutes, upload date of documents etc.); amendment of the RoP every 1.5 years and rules on the agreement of amendment of the RoP.
- The CG agreed on the updated Working Procedure for e-consultations. A new concept of informal e-consultations now named informal enquiries has been introduced.
- A Member State presented an outcome of a consultation in relation to topic PT1 hand disinfectant packaging and labelling. The iMS will prepare a public version of the document. Member States will provide further feedback and ASOs were invited to provide comments as well. Discussion will continue in the open session.

A Member State briefly presented an outcome of an e-consultation in relation to topic – RMMs for PT18 products. It was agreed that the iMS would provide a revised document and MSs would provide further feedback.

CG-48

One formal referral was discussed and agreement was not reached.

The Commission informed the CG on the status of the referrals for which the points of disagreement are referred to the Commission in accordance with Article 36 of the BPR. (Closed session)

A Member State introduced a topic in relation to an issue concerning the minimum purity of the AS in a particular biocidal product and asked for the view of the CG members how to proceed if the supplier of the AS confirmed a different minimum purity than any sources' in the CAR and the one's for which he applied for and has been established technical equivalence. The CG members and COM provided their view that an active substance with different minimum purity than any sources' in the CAR and without established technical equivalence could not be used for the authorisation of a product. (Closed session)

The SECR presented a revised document regarding the structure of the inventory list of coformulants generated from IUCLID. The CG agreed on the structure of the list with some minor modifications and that the list would be made available for CG CPs via S-CIRCABC in a dedicated folder. The list will be updated twice every year.

The SECR informed the CG about the publication of the updated list of frequently used sentences in the SPC on the ECHA website.

The Commission gave feedback on the ongoing discussions at the CA meetings on the List of Endpoints for active substances

The main CG agreements reached during the CG-48 meeting:

• The representative from the PL CA was re-elected as the Chair of the CG and her mandate for the second term will begin on 21 November 2021.

- The CG agreed on the amendment of the Standard operating Procedure and process flow for the mutual recognition process in parallel and in sequence, as well as on the amendment of the SoP and process flow for mutual recognition process of minor changes applications Rules of the Procedure. Changes concerned clarifications in the text of the SoP, division of the bilateral discussion step into further substeps and inclusion of the referral submission deadline in the process flow.
- The CG was informed about the coming changes in SPC editor regarding changes to the draft SPC file in Word format (i.e. that R4BP3 asset number and details of the asset owner will now be populated and a sentence will also appear for the validity dates explaining how they should be calculated) for UA applications and the CG members agreed to the proposal that this function would be implemented for NA and SA procedures as well.
- The tentative dates for CG meetings in 2022 were communicated and it was agreed to organise the CG meetings as WebEx meetings, keeping at least one physical meeting in June held in one of the MSs (if there would be volunteers), or in Helsinki, if the evolution of the pandemic would allow.

Topics where further discussion will take place:

- The SECR presented a document concerning setting post-authorisation conditions for physical hazards; physical, chemical and technical properties, including full long-term storage stability test. The CG will provide feedback on the document and discussion will continue at the next CG meeting.
- A Member State presented an outcome of an e-consultation in relation to topic Storage stability and degradation of active chlorine. It was agreed that the iMS would provide a revised document and both MSs and ASOs would provide further feedback. Discussion will continue at the next CG meeting in the open session.
- A Member State presented an outcome of an e-consultation in relation to topic PT1 hand disinfectant packaging and labelling. The CG agreed that the Commission would bring this discussion to the CA level regarding 1) whether the dispenser should be interpreted legally as packaging of the product or a device, 2) what key information should be displayed on dispensers and on what legal basis the information could be required, 3) clarification concerning Article 69 of the BPR, whether it is the responsibility of the authorisation holder to include information on the dispenser.
- The Commission presented a proposal regarding the determination of the dermal absorption value in product authorisation for different scenarios. The Commission emphasised that new information (i.e. both data submitted by the applicant and new applicable guidance) should be taken into consideration for product authorisation. The Commission will revise the proposal and the CG will provide feedback on it. Discussion will continue at the next CG meeting.
- A Member State informed the CG about receiving questions and comments about errors spotted in the overview template for BPFs. It was agreed that the Member State previously in lead of the creation of the template would manage its revision and that both Member States and ASOs could provide feedback on their experiences with the template.

4.6. Mutual recognition of same biocidal product authorisations	For discussion and agreement <i>CA-Sept21-Doc.4.6</i>	
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The Commission presented the document (CA-Sept21-Doc.4.6) that is identical to the document discussed in the in the 92^{nd} CA meeting (CA-June21-Doc.4.12) 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. According to 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 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 agrees with the legal analysis but sees practical problems as the ones described in the document submitted in response to the proposed approach (CA-Sept21-Doc.4.6- DE comments). One of the main issues is which of the MSs should act as reference Member States in case of disagreement in a mutual recognition and also in case of amendments/cancelations of the authorisations made in accordance with Article 48 of the BPR on how these procedures could be regulated. Three other Member States supported this view, and one of them pointed out that this situation is unlikely to happen, as most of the time the applicant will not have the letter of access to the necessary studies in order to apply for a mutual recognition of the SBP. The Member States that raised the issue confirmed that they have been confronted already with applications for a mutual recognition of a SBP.

The Commission acknowledged that practicalities need to be addressed, either by a modification of the SBP Regulation or in the rules of procedure of the coordination group.

The Commission will analyse in detail the practical questions put forward and will try to provide a reply in the next CA meeting.

Member States agreed on the document.

E	For discussion and agreement <i>CA-Sept21-Doc.4.7</i>	Scheduled on 29 September
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The Commission presented the document *CA-Sept21-Doc.4.7* that intends to clarify if, in the context of mutual recognition, it is possible to raise a disagreement to the coordination group on a non-authorisation proposal of the reference Member State.

The question of whether a referral of objections to the Coordination Group in accordance with Article 35 (2) of Regulation No 528/2012 (the 'BPR') can be initiated if the assessment of the reference Member State results in a proposal for non-authorisation of a product was discussed in the Coordination Group in its meeting in February 2020 (CG-39). At the meeting, the Commission provided their interpretation (CG-39-2020 AP 16.2), concluding that this specific case is not specifically mentioned in Article 35(2) of the BPR and therefore cannot be subject to a referral. The same interpretation was provided to the competent authorities (CA-Feb20-Doc.4.5) in the CA meeting of February 2020 (87th CA meeting). However, further clarification is needed on the possibilities to discuss a non-authorisation proposal in the Coordination Group.

Article 35 (1) of the BPR establishes that a coordination group shall be set up to examine any question (emphasis added), other than matters referred to in Article 37, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 meets the conditions for granting an authorisation laid down in Article 19. Under Article 34(5), the MS concerned shall agree on the summary of biocidal product characteristics (the SPC) and also (even if not explicitly mentioned) on the assessment of the reference Member State (refMS) in order to have a basis for their national decision.

Therefore, bearing in mind Article 35(1) and recital 4 and the nature of the procedure of a mutual recognition in parallel, it appears that the coordination group can examine any question relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 34 meets the conditions for granting an authorisation laid down in Article 19, including the case of a non-authorisation proposal by the reference Member State, even if this specific case is not specified in Article 35(2) and a referral in accordance with Article 35(2) cannot be raised.

Some Member States signalled that the document was not clear. A Member State signalled that the different wording used in the text of the BPR and in the Changes Regulation makes the situation confusing. That Member State recalled some of the points discussed on the application of Article 35(2) of the BPR, where it was concluded that in case of a non-authorisation decision by the reference Member States the concerned Member States are not entitled to raise referrals, including the argument that this will not be possible in case of a mutual recognition in sequence and that Article 35 and Article 36 of the BPR apply also to mutual recognition in sequence. Another Member State supported the Commission views that it is possible to raise a referral on a non-authorisation decision. ECHA pointed out that a non-authorisation decision can also be taken if the fees are not paid, etc. The Commission clarified that the discussion is focused on non-authorisation decisions because of non-compliance of the biocidal product on Article 19 of the BPR. A Member State asked how can a non-authorisation decision be reflected in an SPC. The Commission replies that they will reflect on this also.

As this issue is interlinked with the question on the possibility to provide comments to the decision of a reference Member State that decided not to authorise an application changes (minor or major) (*CA-Sept21-Doc.4.8*), the Commission proposed to present an amended version of the document addressing the two issues for the 94th CA meeting.

4.8. Mutual recognition in relation to	For discussion and agreement
minor or major applications	CA-Sept21-Doc.4.8

The Commission presented the document CA-Sept21-Doc.4.8 which is identical to CA-June21-Doc 4.13.b that was discussed in the 92nd CA meeting.

The document 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.

Some MSs noted that the discussion is interlinked with the document CA-Sept21-Doc. 4.7., and it was decided to discuss both documents at the same time.

A revised version of the document will be prepared for the next CA meeting.

4.9. List of pending Article 36 requests	For information <i>CA-Sept21-Doc.4.9</i>	Closed session
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The item was discussed in closed session.

4.10. Designation of the biocidal product when free radicals are generated from a polymer	For discussion and agreement CA-Sept21-Doc.4.10 CA-Sept21-Doc.4.10.b	
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The Commission recalled that the objective of the document was to identify the biocidal product when free radicals are generated in situ from catalysts embedded in a polymer matrix. Following the discussion in the last CA meeting and the information received from a dedicated newsgroup, the initiating Member State proposed to amend the document CA-July19-Doc.4.1 on the management of product authorisation in case of in situ to cover this specific case under the case type 4 described in this document.

The initiating MS recalled that the discussion started because of the presence on the market of objects incorporating catalysts and generating free radicals that could not be covered by case type 3. Following last discussions, this Member State proposed an amendment to case-type 4 to cover all systems generating free radicals (from device or objects not falling under case-type 3).

One Member State indicated preference to apply case type 3 to all free radicals applications. The master batch could be considered as the biocidal product in that case. A proposal will be sent to the Commission. The initiating Member State recalled that in most of the cases, the concentration of the catalyst in the master batch is not the concentration used in the final plastic object for which efficacy is demonstrated. In addition, the catalyst might be incorporated in other materials than polymers like ceramic toilet bowls. It might therefore not be possible to identify the master batch as the biocidal product in all cases. The amended case-type 4 would cover all possible cases of free radicals generated from air and water which may not be covered with case-type 3. Another Member suggested to include free radical applications under case type 4.

The initiating Member responded that removing case type 3 and keeping only case type 4 would mean that the concept of marketable precursor (the coating) could no longer apply which is an important change to the agreed policy approach. Another Member State draw the attention of the CA to the fact that products under case types 3 and 4 fall under two different indents of the biocidal product definition. It might be difficult to reconcile this aspect into one case type for all free radicals applications.

The Commission concluded that a newsgroup to provide comments by 27 October 2021 would be opened to allow those Member States wishing to cover all free radicals applications under one case type to provide their suggestions.

4.11. Clarification regarding the scope of Regulation No 492/2014	For discussion and agreement <i>CA-Sept21-Doc.4.11</i>	
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The Commission presented the document CA-Sept21-Doc.4.11, recalling that the initiating Member State raised questions on the scope of Regulation No 492/2014 (Renewal Regulation). The initiating Member State had asked, more specifically, whether two different scenarios would fall under the Renewal Regulation. In the first scenario, a major change is introduced (e.g., a claim is added) in the reference Member State and not in the concerned Member State. In the second scenario, a minor change (e.g. a change in shelf-life or pack size) is introduced in the concerned Member State and not in the reference Member State.

The document clarifies that Article 1(3)(a), providing that the Renewal Regulation applies in case of authorisations having different terms and conditions on aspects "concerning merely information which can be the subject of an administrative change in accordance with [the Changes Regulation]", cannot be interpreted as covering authorisations that, at the time of renewal, differ with respect to any information which could, in the future, be subject to an administrative change.

With regard to the specific questions put forward by the Member State, it should first be recalled that the Annex to the Changes Regulation classifies "removal of a particular claim, such as a specific target organism or a specific use" as an administrative change; a "change in the shelf-life" or "change in the pack size range" (under certain conditions) as a minor change. If, at the time of renewal, the authorisations differ as a result of a major change (e.g. additional target organism) or a minor change (e.g. change in shelf-life or pack size, under certain conditions) that was previously introduced, Regulation (EU) No 492/2014 does not apply.

The discussion focused on possible approaches with regard to renewal applications that have already been submitted. The Commission did not consider it possible to introduce a transitional period in the document, but considered that Member States may decide to allow

applicants having already submitted their application to make changes so that the authorisations concerned fall under the scope of Article 1(3)(a) in the interpretation clarified in the document.

The Member States agreed on the document.

4.12. Renewal of "Same biocidal products" authorisations	For discussion and agreement <i>CA-Sept21-Doc.4.12</i>	

The Commission presented the document CA-Sept21-Doc.4.12, recalling that it was drafted in response to questions raised by a Member State on whether same biocidal product (SBP) authorisations in accordance with Commission Implementing Regulation (EU) No 414/2013¹ ('the SBP Regulation') can be subjected to renewal and, if so, what procedure should be followed.

The document clarifies that renewal of SBP authorisations is possible. As far as the procedures are concerned, the renewal of a national SBP authorisation is governed by Article 31 of the BPR, and the renewal of a Union SBP authorisation is governed by Articles 45 and 46. Renewal of an SBP authorisation based on a reference product authorised through mutual recognition falls under the Regulation (EU) No 492/2014 on renewals of authorisations of BPs subject to mutual recognition ('the Renewal Regulation'), provided that the conditions of Article 1 thereof are satisfied.

With regard to the case where changes are introduced regarding the related reference product and/or the SBP, these aspects must be considered already at the time of introducing the changes (and prior to renewal). Article 7(2), third subparagraph, provides that "in the evaluation of a proposed change of a same product or of a related reference product, the receiving competent authority or, where relevant, the Agency shall consider the appropriateness of cancelling or amending the authorisation of other products to which the product is linked in the Register for Biocidal Products". In considering the appropriateness of cancelling or amending the linked authorisations, the competent authorities must have regard to Article 1 of the SBP Regulation, which provides that the procedural rules laid down therein apply to a product which is identical to another product "with regard to all the latest information submitted in relation to the authorisation or registration, except information which can be the subject of an administrative change" in accordance with the Changes Regulation.

The initiating Member State stated that its support for this document depended on the outcome of the discussion on document CA-Sept21-Doc.4.11 on the scope of Regulation No 492/2014. The initiating Member State asked for clarifications on the issue of changes addressed in paragraph 14 and raised the issue of the letter of access requirements for renewal of SBP authorisations, suggesting that this could be addressed when amending the SBP Regulation.

The Commission indicated that it would reflect on the issue of the letter of access. The Commission clarified that the CAs' obligation to "consider the appropriateness of cancelling or amending the authorisation" of linked products, established in Article 7(2) of the SBP Regulation, entails a case-by-case assessment by the national authorities. The Commission suggested that the reflection on the issues linked to the handling of changes, which must be considered when the changes are evaluated, should be carried out separately from the reflection on renewals. Finally, the Commission underlined that the introduction of

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0414

clarifications on these matters could be considered in the context of the possible amendment of the SBP Regulation.

The Member States agreed on the document.

4.13. Authorisation of an in-situ biocidal product: case-type 2 vs. case-type 4	For discussion and agreement <i>CA-Sept21-Doc.4.13 CA-Sept21-Doc.4.13.b</i>	
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The Commission introduced this topic by explaining that the initiating Member State would like to clarify in which circumstances an application for in situ generation could be classified under case type 2 or case type 4. The initiating Member State had the particular example of active chlorine generated from sodium chloride by electrolysis in mind. It proposed to classify most of the IGS under case type 2 (where the biocidal product would be the precursor i.e. sodium chloride in its example) as following its interpretation, this case type which derives from the first indent of the biocidal product definition has a priority over case type 4 as being an interpretation of the second indent of the biocidal product definition. The Commission clarified that to its best knowledge there is no such hierarchy between the two indents of the biocidal product Regulation. The Commission also informed the CA that this question had raised the attention of two stakeholders that provided recent comments which were uploaded in CIRCABC just before the meeting.

The initiating Member State informed that its legal interpretation of the biocidal product definition was shared over the summer with other Members and that it was not supported by the three replying Members. The initiating Member State therefore proposed to focus on two main questions on which an opinion of the Commission and the CA was sought.

The first question was on whether for the same use and the same type of application (e.g. for pool disinfection), the two indents of the biocidal product definition could be used. According to the initiating Member State, the BPR specifies that the biocidal product could fall either under the first indent **or** under the second indent and that there is no possibility to choose one of the two options.

The second remark is that the salts used for the disinfection of swimming pools are clearly marketed for biocidal purposes and this cannot be ignored by the Competent Authorities. In this particular case, the salt is the precursor and at the same time the biocidal product as defined under the first indent of the biocidal product definition. In this case, case type 4 cannot be applied.

One Member State supported the views of the initiating Member State that sodium chloride for pool disinfection would probably fall under case type 2, although it is difficult to understand why a salt would have biocidal properties.

The Commission clarified that the biocidal 'character' of an in situ generation system might be given by the equipment used to generate the active substance and not by the precursor itself. The Commission also recalled that the notion of *intention* is mentioned in the two indents of the biocidal product Regulation and not only in the first indent of the biocidal product definition.

Another Member State indicated that device manufacturers should be also able to submit authorisation dossier because they are better placed than salt producers to provide information on the generation system. Another Member State agreed with this statement.

The initiating Member State added that device manufacturers should have access to data of salt manufacturers to become authorisation holder under case-type 4. A stakeholder

supporting device manufactures commented that the authorisation dossier are ready to submit their applications for authorisation and that the commercial activities of device manufacturers and salt producers are different and therefore both should be able to apply if they so wish.

The Commission questioned how the evaluating Member State could justify the reclassification of an application for authorisation from case type 4 to case type 2 if it does not know how the product is marketed in other Member States.

Another Member State indicated that salt manufacturers should be not be obliged to become authorisation holder if they do not know which devices would be used with their products and vice versa device manufacturers would have difficulties to control the manufacturing process of the salts used in their devices.

The Commission commented that, irrespectively of who would apply, the submitter would need to get data from the salts and the devices. The quality of the precursor in the case mentioned above was described in the approval of the active substance.

Another Member State commented that the first indent of the biocidal product definition would cover normal products whereas the second indent is intended to cover in situ. The initiating Member State disagreed and indicated that the first indent is also used to cover in situ generation system. According to that Member State, the second indent is there to capture all the cases where there is no precursor placed on the market. A legal interpretation of the biocidal product definition would help to clarify the situation.

The Commission indicated that this question needs to be analysed case by case as discussed in the past, based on technical information and the way the product is marketed. A legal interpretation of a case by case analysis would not help.

The initiating Member State commented that the current national case law interpret the notion of intention in a broad sense and that, if it is clear from the circumstances that the product that is placed on the market has biocidal effects, then it should be identified as the biocidal product. An observer indicated like the Commission that on opinion of the Legal Service would not help to solve the issue and rather recommended a pragmatic approach.

The initiating Member promised to further reflect on the matter and come back to the Commission in writing. The Commission proposed to open a newsgroup to collect further information, to which Member States are invited to contribute by 27 October 2021.

4.14. Handling "carriers" in the authorisation of biocidal products	For discussion and agreement CA-Sept21-Doc.4.14 CA-Nov16-Doc.4.3-Rev1	
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Following a discussion in the frame of a referral to the Coordination Group, an update of point (18)(a) of the document "CA-Nov16-Doc.4.3 on handling carriers" was made by the reference Member State (France) for the biocidal product concerned in the referral, to clarify that in case of a type A or B carrier based product where the final biocidal mixture is a liquid, testing for corrosion to metals is possible.

One Member State proposed a further amendment to the text but withdrew the request.

Another Member State proposed further amendment to the document to make it coherent with the amendment made on paragraph 18 by another Member State. As the document needs an additional revision to reflect discussions held on the context of a Union authorisation, the Commission proposed that the amendment proposed by the second Member State will be discussed in the CA meeting of December.

Member States agreed on the amended document.

4.15. CA-March16-Doc.4.6 Final.rev2 - note for guidance Q&A on simplified	For discussion and agreement <i>CA-Sept21-Doc.4.15</i>	
procedure.	CA-March16-Doc.4.6 Final-rev3	

The Commission presented a revised version of CA-March16-Doc.4.6, that includes a new Q&A (number 17), to clarify that for the active substances listed in category 1 of Annex I (lactic acid, sodium acetate, sodium benzoate, (+)-tartaric acid, acetic acid, propionic acid), the requirement that the concentration is limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008 refers to the concentration of the active substance.

Member States agreed on the revised document and the new Q&A, with the exemption of Sweden that has further questions on the document that will be sent to the Commission.

5.	Active substances		
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The Commission informed that the discussions on this item are now closed, and that ECHA is proposing a project on the clarification of the identities of active substance (item 5.5 on the agenda).

5.2. Progression of the review programme	For information	
on active substances	CA-Sept21-Doc.5.2	

The CA meeting took note of the status report.

5.3. Inclusion of brandy in the Review	For information and agreement	
Programme	CA-Sept21-Doc.5.3	

The Commission informed that that ECHA recently declared a notification on brandy compliant.

Consequently, brandy needs to be included in the review programme, and the Commission asked for a voluntary Member States to be appointed as evaluating Competent Authority (eCA) in the Review Regulation, otherwise the Commission will have to designated one Member State.

One Member State indicated to have given its agreement in 2017 to the notifier to act as eCA, and the notifier contacted them again. However, the substances was no longer in its planning and in the meantime it accepted being the eCA for another active substance, and would appreciate if another Member State would volunteer.

A newsgroup will be open to provide one month to other Member States to volunteer by 27 October 2021.

It was also discussed whether Member States would consider relevant to make an Article 75(1)(g) request to ECHA concerning its eligibility for Annex I inclusion, considering the nature of this substance and its properties. It was agreed that there was no need to make such a request to ECHA, and that the normal dossier for approval will have to be submitted within the review programme, similarly to other "food and feed" active substances which were not eligible for Annex I inclusion (e.g. orange extract, capsicum extract).

5.4. Progression of the renewal process of		
approval of active substances	CA-Sept21-Doc.5.4	

The CA meeting took note of the status report.

5.5. ECHA Active Substance Action Plan	For information	
progress update	CA-Sept21-Doc.5.5	

ECHA gave an update on the progress of the action plan, as presented in the document.

Biocides For Europe asked to have further information about the FAST project, the timelines and purposes. ECHA informed to be working with a small group of Member States and discussing with the Commission, and that they will prepare a specific document on the matter for a forthcoming CA meeting.

The Commission echoed the invitation made by ECHA to identify missing data in the dossiers, in particular on endocrine disrupting properties considering that the criteria are now applicable since 3 years and the assessment of these properties is one of the drivers for delays in the review programme.

of substance identification CA-Sept21-Doc.5.6

ECHA is proposing a campaign to verify the substance identity of active substances under assessment in the review programme, in order to avoid the need for further re-definition in the future. The Commission supports this exercise and strongly invites Member States to provide to ECHA the necessary information, to avoid having re-definition in the future as it contributes to delaying the completion of the review programme started almost 20 years ago. Redefinitions should no longer happen and be exceptional at this stage of implementation of the BPR.

One Member State asked ECHA to clarify the scope of the exercise, and confirm that it would not apply to active substances generated in situ. The Commission noted that the exercise could cover in situ, but noted that there should normally be no need for these active substances, considering that a dedicated exercise was already done in 2015 for in situ active substances. ECHA had reservations about covering in situ active substance in this exercise.

One Member State noted that it will have difficulty to check the identity also for active substances under 5th and 6th priority lists due to their priority of work, but they will do their utmost to avoid further late redefinition.

One Member State noted that it was not in position to support the document for procedural reasons.

The CA meeting supported the verification campaign proposed by ECHA. Member States are therefore invited to work along the project defined in the document and work with ECHA on the matter.

6. Treated articles

No item for information or discussion.

7. Horizontal matters

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ECHA introduced the document, announcing it has been published on the ECHA website, and pointed out that the guidelines reflect the experience so far, clarify the general principles and provide practical recommendations. ECHA invited competent authorities to consult the guidelines when performing confidentiality claims assessments and stakeholder associations to share the document with their members. ECHA also informed that an update of the document is scheduled for the first half of 2024, in light of the experience, and feedback will be collected in the second half of 2023. One Member State asked whether it was possible to send comments on the document. ECHA clarified that the guidelines do not provide any new interpretation of the obligations under the BPR and for this reason competent authorities and stakeholders were not consulted when developing the document. Comments from Member States and stakeholders will be requested later on, ahead of the revision scheduled for 2024.

7.2. ECHA communications	For information <i>CA-Sept21-Doc.7.2</i>	

ECHA gave a presentation focusing on two topics: (i) progress on the development of guidance on analysis of alternatives under the BPR and (ii) future public consultation on anticoagulant rodenticides. On the first topic ECHA mentioned that the objective of developing such guidance is to provide a set of elements considered important to evaluate the availability of suitable alternatives to products containing active substance subject to exclusion and a structure for reporting this analysis. The guidance would be used by applicants, competent authorities, the BPC and third parties. As to the timeline, the probable adoption will be mid- or second half of 2022.

The second topic was related to the ongoing work of ECHA on the comparative assessment for anticoagulant rodenticides, for which an opinion should be delivered by the end of 2022. In this context a 60-day public consultation asking information on non-chemical alternatives will be launched in October. ECHA also mentioned that, in gathering information for the performance of the comparative assessment, bilateral meetings with industries involved might be beneficial.

7.3. ECHA guidance on bees and other non-target arthropod pollinators For information
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The Commission updated the CA-meeting on the state of play and pointed out that in the Council meeting of 28 June 2021 agreement was reached on Specific Protection Goals for bees. The Commission indicated, underlining the differences between biocides and plant protection products, that these goals should be considered as far as possible in the development of ECHA guidance for pollinators. One Member State indicated to understand the wish of having coherence between plant protection products and biocides, however, pointed out that for biocides the methodology of PEC/PNEC values apply to assess environmental effects. This Member State considered that changing the approach for assessing the risks for the environment should be broadly discussed and was reflecting whether to submit its concerns in writing.

7.4. Article 65 reporting – Template for future reporting For discussion and agreement <i>CA-Sept21-Doc.7.4</i>	
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The Commission presented the template for future reporting as agreed at the previous meeting and mentioned that a few changes were introduced, following the discussions with the Member State that could not agree to the template in the previous meeting. Those changes are indicated in track changes in the document distributed for the meeting and regard: clarification of 'unacceptable effects' in the section regarding products authorised on the basis of Article 19(5); a modification in the section on Article 55(1) derogations, where only the number of permits granted is now requested; clarification that the controls on end-users should be reported as number of end-users controlled and non-compliances identified; reporting of controls as number of controls performed instead of number of products checked and clarification that the information on nanomaterials in biocidal products regards both product authorised under the BPR and products made available under the transitional measures.

One Member State had a suggestions to clarify the text in one table, which was accepted. The same Member State asked whether the wording 'adverse environmental effect' could be specified in more detail. Another Member State had the same request. The Commission stated that the wording used in the same wording used in Article 65(3) point (c) and that it is difficult to be more specific. Any available information on such adverse effects is useful, as it is specifically required to be included in the reports of Member States.

The amended template for reporting was then agreed by Member States.

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

The Commission indicated that internal discussions are on-going on the 16th amendment of the Plastics Regulation.

7.6. Guidance priorities	For discussion and agreement <i>CA-Sept21-Doc.7.6</i>	
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ECHA indicated that the document provides the status update of the current priorities and also includes a proposal for future additional guidance priorities. Some minor adaptations of the document were made in order to clarify some elements. One Member State had a question in relation to the ECHA-EFSA guidance related to water treatment, more specifically on who is responsible for the development of the toxicology section of the guidance. ECHA indicated that the specific section will be developed by the contractor. It was also clarified that ECHA remains responsible for the guidance document.

newsgroup and possible actions

The Commission introduced the topic by explaining the outcomes of a newsgroup that was opened following a first discussion at the last CA. There is support (8 Members responded positively) for the organisation of such trainings as Competent Authorities lacks resources. The training would help to close knowledge gaps and ensure a better harmonised interpretation of current guidance documents. Regarding the scope, the training should clarify how to build a Biocidal Product Family and how to assess such family. In addition, it could also include a training on in situ biocidal products and comparative assessments.

The Commission explained that a framework contract to organise such event is available in DG SANTE. This contract can employ suggested trainers from authorities or private consultants to give the training. A majority of Members still preferred to have it organised for and by authorities. Two Member States proposed to send trainers but this should be confirmed at a later stage when the content and the timing of the trainings would be known.

7.8. Update of MSs forecast on submission of active substance and Union authorisation assessments to ECHA in 2021-2024	For discussion <i>CA-Sept21-Doc.7.8</i>	
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ECHA introduced the document providing an updated forecast of the submission by Member States of active substance approval and Union authorisation assessments until 2024. With regard to active substances, according to the information provided by Member States, around 51% of the active substance/PT combinations will be submitted around Q3 2023, meaning that these combinations would meet the deadline of the Review Programme. By the end of 2024 around 87% of the assessment reports are likely to be submitted to ECHA. For 33 active substance/product-type combinations the evaluating CAs were not able to indicate the approximate timing of submission to ECHA.

For Union authorisation, the expected draft assessment reports are distributed evenly in 2022 and up to 49 applications are expected to enter the opinion forming phase. Member States were requested to update the table as soon as they have new information, as this would allow all parties involved to better plan their resources. The Commission noted an error in one of the figures in the document, that will be corrected. One Member State pointed out that the document shows an increasing workload for the decision-making bodies (BPC, Commission) with peaks in some periods, and wondered whether it would be possible for the future to spread the workload instead of having these peaks. With regard to the soundness of the forecast, ECHA indicated that for last year, 1/3 of the expected submissions of assessment reports for active substances and 3/4 for Union authorisation materialised, so it might be expected that the peaks might be less acute than expected.

A representative of DJ JUST made a presentation to Member States on the proposal for a Regulation that will replace the General Product Safety Directive (GPSD).

On the question of the applicability of the proposal to treated articles DJ JUST replied that this will depend also on the type of treated articles and on whether other harmonised Union legislation is applicable to them (e.g. Toy Safety Directive), and whether the risks are covered by that legislation or not. If the risks are not addressed in the EU specific/sectorial legislation then the GPSD applies.

A Member State asked about the applicability of the GPSD to biocidal products under transitional rules of Article 89 of the BPR. DG JUST replied that the GPSD applies for the cases where the risk is not covered by specific legislation.

7.11. Risk assessment of skin sensitizers	For information	
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The Commission explained that discussion had started with ECHA on a possible mandate under Article 75(1)(g) to clarify the causal link between the presence of isothiazolinones in paints and detergents and human health effects. The mandate may also cover an analysis of the elements to be considered in a quantitative risk assessment approach. The CA noted the information provided by the Commission.

8. Scope matters

8.1 Borderline between Regulation (EC) No 1107/2009 on plant protection products and 528/2012 on biocidal products	For discussion <i>CA-Sept21-Doc.8.1</i>	
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The Commission recalled that the point had been raised by one Member. This Member recalled the previous discussions in recent SCOPAFF for plant protection products and CA meetings, as well as the Commission proposal on a decision tree. The goal of the discussion was to reach further agreement on the borderlines between plant protection products and biocides. In order to achieve this, this Member State proposed different criteria that were detailed in the note tabled for discussion. A central point would be to agree on a list of intended uses and define whether these uses should fall under the scope of the PPPR or the BPR.

The Commission recalled that such decision should be taken case by case and that it would be difficult to propose general rules. However, in case a product is identified as a PPP, it should no longer be considered as a BP.

The Commission indicated that the decision tree mentioned above had been endorsed by the SCOPAFF and incorporated in a scoping document on borderlines cases that contains already more than 250 entries. It reported a discussion with enforcement authorities on the matter where it was mentioned that intended uses are not always matching with the claims. Such cases should be further investigated. The Commission clarified that the list presented by the

initiating Member State will be presented at the next SCOPAFF for discussion. If the authorities cannot take a decision on a borderline case by using the decision tree proposed by the Commission, the information available to the authorities should be forwarded to the Commission for further examination, decision and inclusion in the scoping document of the SCOPAFF.

The Member State initiating the question requested additional time to further reflect on the Commission proposal. On the decision tree, another Member State reminded its concerns about the possibility to decide on scope issues based on a human protection claim as suggested in the second row of this tool. In addition, the Commission was asked to clarify in which case a product used in urban areas should be considered a PPP. The Commission clarified that the reference to civil or urbans areas is meant to cover the case of herbicides used in airports, on railways. The Commission agreed with the Member that any product aiming at protecting humans against pests should be considered a biocide but that in some cases, the control of pests to ensure the protection of consumers could fall under the PPPR.

Finally, at the request of a Member State, the Commission clarified the scope of the PPPR that covers plants (any living plants or plant parts) and plant products (product of plant origin after pressing, milling or drying).

8.2 Toys with biocidal claims	For discussion <i>CA-Sept21-Doc.8.2</i>	Closed session
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The item was discussed in closed session.

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 <i>CA-Sept21-Doc.11.a</i>	
(b)	Point from NL on phosphine releasing products	For CA-Sept21-Doc.11.b	

The Netherlands introduced this AOB point on incidents with the use of phosphine producing plant protection products and biocides. A letter of the Netherlands on this issue has been uploaded on Circabc. A Newsgroup will be opened for participants to provide their views by 27 October 2021 on which measures could be introduced to increase the safe use of phosphine containing products.

(c) Products containing active chlorine	For discussion CA-Sept21-Doc.11.c	Closed session			
The item was discussed in closed session.					
(d) Union authorisations		Closed session			
The item was discussed in closed session.					
(e) Update on a Court case					

The Commission informed about the Judgement of the General Court of 15 September 2021 on the cases T-337/18 Laboratoire Pareva v European Commission and T-347/18 Laboratoire Pareva and Biotech3D Ltd & Co. KG v European Commission. In its judgment, the General Court dismissed an action challenging the Commission's decision non-approving the active substance PHMB (product-types 1, 5 and 6) and the conditional approval of that substance (product-types 2 and 4).

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	

2022 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WGs
	9-11 March	22-24 March	28 Feb-4 March	
	22-24 June	21-23 June (or 17 June)	13-17 June	
			26-30 September	
	4-6 October			
		14-18 November	28 Nov-2 December	
	6-8 December			