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

MINUTES

97th 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

4-5 October 2022

1. Adoption of the agenda	For adoption *CA-Oct22-Doc.1*	

The Commission introduced the draft agenda. One Member State asked for updates on MRLs from the Commission. Another Member State asked for updates on the CLP Regulation. It was agreed to discuss both items in the AOB section.

The agenda of the meeting was then adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Oct22-Doc.2.a* *CA-Oct22-Doc.2.b_Restricted*	

One Member State pointed some editorial remarks. In addition, it pointed that in page 9, point 4.15 the Netherlands needed more time to prepare their position on this item, and asked to add this in the minutes. Moreover, they asked to move the item 4.11 to the open session minutes.

The minutes of the previous Competent Authority (CA) meeting were then adopted.

3. Draft delegated acts
No item for information or discussion

4. Biocidal products

4.1. Report from the Coordination Group	For information	

The CG-52 meeting was a hybrid meeting held in Helsinki, and the following report was provided:

- Five formal referrals were discussed, and three were briefly introduced. An agreement was reached for four of the referrals.
- The Commission informed the coordination group about the CA-96 agreement that in case an authorisation granted in accordance with Article 19(5) of the BPR is amended, concerned Member States would be able to assess themselves whether their authorisations would need to be amended or cancelled the same way in accordance with Article 48(3) of the BPR.
- The Secretariat informed the coordination group that the collaboration for updating the list of issues identified in the context of Union Authorisation (UA) has been launched and from now on should be updated by the Member States(MS.
- The representative from the French competent authority was re-elected as the Vice-Chair of the coordination group and her mandate for the second term began on 1 August 2022.

- The Chair presented a revised proposal regarding taking into consideration the agreements reached during referrals for other product applications. The document was agreed with slight changes by consensus.
- A Member State presented an outcome of an e-consultation in relation to the topic – Additional active substance metabolite data for PNEC refinement in a national authorisation application (NA-APP). The coordination group agreed with the assessment of the reference Member State by consensus.
- A Member State presented an outcome of an e-consultation in relation to the topic – Revision of harmonised SPC sentences for rodenticides. The discussion of the risk mitigation measures for the environment will continue at the CG-54 meeting.
- A Member State presented an e-consultation in relation to the topic – Impact of version 4 PT19 efficacy guidance. The coordination group agreed that the data requested as post-authorisation data would need to be submitted by the deadlines indicated in the authorisations in the form of a change application, unless it was already included in the renewal application, if the latter has to be submitted earlier. After the CG-52 meeting the final document has been made available on public CIRCABC.
- The Commission presented a document in relation to the topic whether a mutual recognition (MR) of an authorisation based on authorisation granted by MR is possible. The document reflected the interpretation of the Commission that a MR based on a MR is possible, and opposes the previous CG-37 agreement (CG-37-2019-01 AP 16.6 A_MR_of_MR_summary). The coordination group agreed on the document by two-thirds majority and the after the CG-52 meeting the CG-37 agreement was replaced by the final document on public CIRCABC.

The following report was made of the CG-53 meeting:

- Three formal referrals were discussed. An agreement was reached for one of the referrals.
- The Secretariat informed the coordination group members about the feedback received from MSs concerning validation of biocidal product dossiers. A brief summary of dossier validation for REACH registration was also presented.
- The Commission clarified for the coordination group members that they need to comply with Article 36 decisions and that national regulations cannot overrule the BPR.
- The Secretariat presented a revised document concerning shelf-life setting at product authorisation. Several clarifications on the wording were suggested and agreed by the MS. The coordination group agreed on the procedure with the modifications by consensus. The new agreed procedure will be applied for the product and product family authorisation applications submitted after the publication of the updated relevant coordination group and BPC documents, as well as APCP TAB entry. Member States and Accredited Stakeholders Organisations (ASOs) will be notified when all these documents have been published.
- The secretariat presented the revised procedure for updating the list of Frequently used sentences in the SPC and translations. The update was necessary to take into consideration the experiences of the previous updates and to align the procedure with the changes in commenting platforms (i.e., the use of Interact Portal). The coordination group agreed on the document by consensus. The next update of the list will take place in 2023.
- The Commission presented a document in the closed session in relation to the harmonisation of the classification of hydrogen peroxide containing products in

relation to the oxidising liquids property, proposing a harmonised application of the UN RTDG Model. The approach proposed by the Commission was supported by the Member States, but it was agreed that the topic would be scheduled for agreement in the open session of the CG-54 meeting, so ASOs would have the opportunity to also share their views.

- The Secretariat informed the coordination group members about the progress of the revision of the coordination group document about post-authorisation conditions. It was highlighted that the document would cover the simplified authorisation procedure as well and, due to this, the question of how to apply Article 48 of the BPR in such a situation still has to be clarified. This will be addressed in the Simplified Authorisation Procedure Q&A CA document. The coordination group document is still under preparation and will be discussed at the CG-54 meeting.

4.2. List of pending Article 36 requests	For information *CA-Oct22-Doc.4.2*	Closed session

This agenda item was discussed in closed session.

4.3. Update on ad-hoc group on in situ BP authorisation	For information	

The Member State responsible for the organisation of the ad-hoc group explained that the working procedure of the group has been accepted over the summer by the participants. Two Members of the group submitted a set of questions that should be debated in the next months. Only exchanges by emails are foreseen so far. Meetings could be exceptionally organised. Industry representatives will be invited on request. The responsible Member State will keep records of the list of topics discussed and will present the outcomes of the discussions at regular CA meetings for adoption.

The Commission recalled that the objective of the ad-hoc group is to provide legal solutions to concrete problems appearing during the evaluation of applications for the authorisation of in situ biocidal products. One industry representative expressed again its interest in the discussion and asked the responsible Member State to check if it has been identified as relevant industry stakeholder.

4.4. Modification of Regulation 492/2014 on renewal of authorisations under mutual recognition	For discussion *CA-Oct22-Doc.4.4*	

The Commission introduced the document that compiles several issues identified by Member States and industry representatives on the interpretation and implementation of Regulation (EU) No 492/2014 on renewals by mutual recognition. The purpose of the document is to further discuss these issues with the Member States.

- The first identified issue is on the possibility to apply for changes while the renewal of the authorisation is ongoing.

Member States views are that applications for minor and major changes should be submitted prior to the application for renewal and finalised before the evaluation commences.

If an application for minor change is necessary during the renewal process it should be applied for in all concerned Member States so that the authorisation still falls into scope of Regulation. The Commission proposed to clarify this issue in the ECHA Guidance. One MS considered that is necessary to clarify this and agreed that it will be enough to do it in the ECHA Guidance. There is a need to have an harmonised approach between Member States. Another Member State pointed out that applications for changes while the renewal process is ongoing will cause delays. As the delays will not fall on cases that are beyond the control of the applicant, this can lead to situations in which the authorisation cannot be extended and will expire before the changes applications have been processed.

The Commission requested contributions from Member States on how to address this issue and whether applications for changes made together with the application for renewal, in order to make the authorisations under the same terms and conditions, should be accepted.

Other Member State was of the opinion that applications for changes while the renewal is ongoing should not be accepted. They consider that this should be addressed in the legal text to have a legal base for rejecting those applications. This should also be addressed in R4BP3 so that those applications are not possible in the system and also clarified in the ECHA guidance.

Biocides for Europe recalled that sometimes applications for changes can be considered as beyond the control of the applicant, for example if they are made to substitute a co-formulant that is a Substance of Concern. They believe that this should be addressed differently (depending of the applications for changes was made to fulfil legal; requirements) and that R4BP3 should also discriminate both situations.

Other Member State pointed out the need to agree on how to deal with applications for changes and renewals as regards timelines, and to avoid to have two commenting periods for the renewal of the same product (one for the changes application, and the other for the renewal as such).

- The second identified issue was on the need to clarify how the renewals of same biocidal product authorisation that have as reference product an authorisation granted under mutual recognition should be renewed. This was clarified in the document CA-Sept 21-Doc.4.11-Scope of Regulation (EU) No 492/2014 and the Commission proposes to reflect that conclusion in the amendment of the Regulation.

One Member State welcomed the proposition from the Commission. In their opinion, the renewals of same biocidal products together with the reference product should be also under the same terms and conditions of the authorisation, as sometimes changes applications are made to the SBP but not to the reference product.

Another Member State requested that the applications for renewal of the Same biocidal product (SBP) is made together with the application for renewal of the reference products.

Biocides for Europe, pointed out that SBP authorisations can be national authorisations having as a reference product a Union authorisation, and wonder how this situation should be addressed.

SME United reminded that there are any SMEs that have to undergo the BPR procedures and that they should be clear and simple. In their opinion rules are highly complex and it is not easy for SMEs to follow them.

- The third identified issue is on the scope of the Regulation in Article 1(3). An interpretation of Article 1(3)(a) was requested by a Member State and it is reflected in the document CA-Sept 21-Doc.4.11-Scope of Regulation (EU) No 492/2014: the Commission proposes to amend the text of Article 1(3)(a), to align it to what was agreed

in the CA document and to avoid issues with its interpretation. Also, it is necessary to decide which exemptions to authorisations being under the same terms and conditions can be accepted for a grouped renewal of the authorisations. The Commission proposed to limit this possibility to authorisations differing on something that can be the subject of an administrative change.

Seven MSs expressed concerns on the proposal outlined in the document, as there are many authorisations granted by mutual recognition (specially for PT-14 products) to which Article 37 is applied. To not allow the grouped renewal of these authorisations will significantly increase the workload in the Member States. Also, some Member States considered that applications for changes are decisions made by the applicant, while application of Article 37 of the BPR is a situation that goes beyond the control of the applicant. The Commission pointed out that, according to the information provided by industry representatives, adaptations of authorisations in accordance with Article 37 are also addressed with minor changes applications, for example, the adaptation of packaging sized. Therefore, Member States should consider also the acceptance of authorisations that differ on an application of a minor change.

The Commission explained that Article 37 of the BPR allows a derogation from a mutual recognition, so, conceptually, the authorisations to which an Article 37 derogation was applied cannot be considered as being under the same terms and conditions at the moment of the renewal. Therefore, to include authorisations to which Article 37 was applied in the exemptions that can be accepted for a grouped renewal is doubtful, and opens the question on whether authorisations that differ due to a major change or minor change should also be accepted for a grouped renewal. Therefore, the Commission proposed that the discussion is focused on which type of differences are acceptable for a grouped renewal (differences that could fall under an administrative, minor or major change), regardless of the exact procedure or provision under which those changes were made or would be made (changes application, authorisation granted by Member States after the application of Article 37 or Article 19(5) of the BPR).

Biocides for Europe insisted on the need to find a pragmatic solution. In their opinion to limit the exemptions to authorisations differing only because of an administrative change is too limited.

- The fourth issue identified is to request that the applicant provides an IUCLID dossier with both the data on which the initial authorization is based and the data newly obtained was included at the request of a Member State. The Commission proposed to address this issue in the ECHA Guidance.

Another Member State signalled that, despite they agree with the proposal, the Product Assessment Report (PAR) is the responsibility of the reference Member States and it cannot be set as an obligation for applicants. Other Member State recalled that this issue was discussed in the coordination group (CG-36 Doc 16.4.) and it was agreed that at the time of renewal the initial PAR needs to be updated with the outcome of the renewal examination. Another Member State agreed with the proposal an thought it will be helpful to make this mandatory. Biocides for Europe recalled also extensive discussions on this topic in the past.

- The fifth identified issue is that, according to Article 3 (6) subparagraph 2 of Regulation (EU) No 492/2014, where the authorisation does not fall within the scope of this Regulation, the competent authority in the Member State concerned shall process the application as an application submitted in accordance with Article 31(1) of Regulation (EU) No 528/2012 and it shall inform the applicant and the competent authorities in other Member States accordingly.

According to one Member State, if an application is not within the scope of Regulation (EU) No 492/2014 it should be rejected and not automatically be dealt with as an application for renewal of a national authorisation in accordance with Article 31 of the BPR, as for this type of application different fees and data requirements apply. The Commission concurs with the view of that Member State and proposes to amend the text in the Regulation to reflect this.

- The sixth identified issue is a slight amendment of the wording in Article 4(1) to align it to the terminology of the BPR.
- The seventh identified issue is the application of the period of grace when no application for renewal was made. Member States agreed that this should not be possible and therefore, the Commission proposes to modify the text and just refer to Article 52 of the BPR.
- The eight identified issue was an inconsistency in the text of Article 7(2). The Commission proposes to amend the text of the Regulation, in line with the BPR, so that the reference Member State will be the one that refers to disagreement to the coordination group.

The Commission also recalled that clarifications on how to handle the procedures are already reflected in "CA-Sept14-Doc.5.7. Harmonised approach to expiry dates" (duration of the authorisations- mutual recognition in sequence, SBP, changes, and that maybe some of the elements in those documents should be incorporated in the ECHA Guidance.

The CA Meeting was invited to provide written comments through a newsgroup until 31 October 2022.

4.5. Alignment of authorisations of products containing alphachloralose	For discussion *CA-Oct22-Doc.4.5*	

The Commission presented the document that intends to clarify whether products containing alphachloralose comply with the conditions of Article 19 of the BPR and under which legal basis should they be authorised to ensure an equal treatment of applicants.

The Commission recalled the recently adopted implementing decisions to resolve disagreements between Member States on amendments made to authorisations of biocidal products belonging to PT14 (rodenticides) containing alphachloralose, that concluded that products containing alphachloralose do not fully meet the conditions laid down in Article 19(1), point (b)(iii) of the BPR and may only be authorised in accordance with Article 19(5). The Commission also concluded that the risk of secondary poisoning of animals due to the use of biocidal products containing alphachloralose, and the necessary risk mitigation measures to be applied in order to reduce that risk to an acceptable level, should be assessed in the context of the evaluation of the application for renewal of the approval of alphachloralose (evaluating CA Poland) and should subsequently be duly taken into account for the authorisation of biocidal products.

Consequently, Member States that have granted authorisations of biocidal products containing alphachloralose (either national authorisations or authorisations granted in mutual recognition procedures) under of Article 19(1) of the BPR, need to cancel or amend the authorisations in accordance with Article 48 of the BPR.

The assessment of whether the product may be authorised in accordance with Article 19(5) needs to be conducted by each Member State individually and the proportionality assessment

on the impacts on society may lead to a different outcome depending on the Member State (e.g. cancellation of the authorisation, authorised use restricted to professionals or not, etc).

The risk mitigation measures necessary to ensure that exposure of humans and the environment is minimised can also differ in Member States depending on the different scope of authorisation granted. Some Member States might, for example, consider it necessary to restrict the use of biocidal products containing alphachloralose to trained professionals while others might consider that additional labelling requirements suffice. These differences, however, should be kept to the minimum necessary and adopted only to the extent as strictly required by the specificities of Article 19(5) proportionality assessment.

One Member State requested and amendment of the document to use the adequate term that is "no unacceptable risks". The document was amended accordingly.

Other Member State expressed agreement with the document and informed that they have already proceeded with the amendment of the authorisations, that have been contested by the authorisation holders.

The Netherlands explained that they have already taken measures for amending these authorisations, and that instead of using Article 48 of the BPR, they have opted for an amendment at request of the applicant in accordance with Article 50. The Commission reminded on previous discussions on the application of Article 48 and Article 50 of the BPR, and considers that approach taken by the Netherlands as acceptable. The Netherlands requested to reflect their position in the minutes.

Another Member States asked if the amendments in accordance with Article 48 can be done at the renewal of the product. The Commission replied that the amendments have to be done as soon as possible, and that we cannot wait for this to be done at the renewal.

Member States agreed on the document, with the exemption of France that was not ready to endorse it, as in the agenda it was only indicated for discussion.

4.6. Union authorisation: similar conditions of use across the Union and Article 44(5) derogations	For discussion and agreement *CA-Oct22-Doc.4.6*	

Based on experiences made during the process of Union authorisation, the Commission presented this document with the aim to clarify and streamline the procedure with regards to two aspects:

1. Precondition of "similar conditions of use across the Union"

The Commission requests active involvement of all Member States in the pre-submission phase to ensure that only those applications enter the process that really fulfil this requirement. Later submissions of requests for national derogations that question the similar conditions of use should be avoided.

Some Member States and ECHA reminded that although the applicant needs to submit a confirmation of the similar conditions of use, the use of the pre-submission procedure is not mandatory for them. It is considered unclear where there is actually a decision taken and by whom if there are similar conditions for a product before the process starts. One Member State indicated a case where an application for Union Authorisation had been submitted despite their information that there would not be similar conditions of use. Some Member States are concerned that the information received during the pre-submission phase may evolve and the final application will be different. So it could not be out ruled that there will be

a need for a request for derogation at a later stage. An open discussion took place on the definition of "similar" in this context and which deviations would be considered to be similar. One Member State preferred to have a tacit agreement in the pre-submission stage and no requirement to actively react.

2. Requests for derogations in accordance with Article 44 (5)

The Commission highlighted several issues identified with recent requests. It was stressed that such requests should be only exceptional as Union authorisations are meant allow for placing on the market and use of the product under same terms and conditions in all Member States. Requests for derogations need to be well reasoned, justified and make a clear reference to one of the grounds of Article 37 (1). A simple reference to (national) legislation or to a policy that is applicable to all MS is not sufficient.

One Member State agreed with the Commission that derogation requests should be only exceptional. It suggested that a list of instances where derogations where justified could be helpful for applicants and Member States.

Several Member States criticised the proposal that the requests for derogations should be submitted within two weeks after the adoption of the BPC opinion, and within three weeks the official request through the permanent representations, and requested more time.

The CA Meeting was invited to provide written comments through a newsgroup until 31 October 2022.

4.7. Union authorisation: issues with SPC translations	For discussion *CA-Oct22-Doc.4.7*	

The Commission presented several recommendations to improve the overall quality of the English version of the Summary of the Products Characteristics (EN SPC) used in the Commission regulatory procedure. Some editorial rules need to be respected and the applicant should ensure that the instructions laid down in the SPC are clear and understandable for end-users. The Commission also requested ECHA and the evaluating Member State to check the quality of the EN SPC before its final submission to the Commission. It is for example important to verify whether the outcomes of the BPC have been correctly implemented in the final EN SPC.

The Commission also expressed concerns about the quality of the other linguistic versions which must be cleared from any text in English. The Commission added that applicants cannot introduce additional changes to the EN SPC during the linguistic review. The EN SPC as voted on by the Member States authorities is legally binding and final. Any modification of the EN SPC at that stage will only lead to additional delays in the publication of the authorisation as the modifications have to be removed.

An industry association welcomed the information but asked whether the presentation could be improved to make it more user-friendly for the applicants. This association also claimed that more time should also be given to the applicants to apply the changes agreed by the Standing Committee. The Commission will consult ECHA regarding the period given by applicants to adapt the SPCs. The Commission agreed to revise the document (*a new version has been made available on Circabc in the folder of the CA meeting, here*).

Another industry association requested clarifications on which part of the SPC are discussed with the Commission Legal service. The Commission explained that the Legal Service were

informed that some parts of the SPC can be hardly modified by the applicants as data is automatically downloaded from other IT applications into the SPC.

ECHA requested the possibility to discuss the matter bilaterally with the Commission and proposed to add a reference to the ECHA guidance on preparing SPCs in the slides of the presentation.

4.8. Union authorisation: acting as evaluating CA	For discussion *CA-Oct22-Doc.4.8*	Closed session

This item was discussed in closed session.

4.9. Warning sentence for bees	For information *CA-Dec20-Doc.4.1.Warning sentence and RMM for bees_rev2*	

The Commission presented the amended document for information, as revision 2, for the sake of transparency, as, after having agreed on the modification of the document in the CA-95, the conclusions of the ECHA BPC Environmental Working Group were incorporated to the document at the request of one Member States. Later on, the Commission realised that the version of the conclusion that were incorporated was outdated, and the correct version has been introduced to this document.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-Oct22-Doc.5.1*	

The Commission urged the Competent Authorities to make progress on the completion of the work programme in accordance with the priority lists, and to conclude as quickly as possible the review of their backlog reports submitted before 1st September 2013, which are evaluated based on Directive 98/8/EC. The Commission received letters from stakeholders inquiring the reasons for delays in the review programme. The Commission invited the Competent Authorities to liaise with ECHA when they experience difficulties in the assessment of the applications in particular as regards to the assessment of the endocrine disrupting (ED) properties. Moreover, several dossiers planned for discussion in the BPC were withdrawn this year, asked Member States to better respects the announced planning and invited them to reflect on the reasons behind it. Finally, the Commission reminded that the review programme normally expires in 2024. It is clear that it will not be finalised by 2024 and another extension will be needed. A key question would be for how long, and invited Member States to already reflect on this, as the review programme cannot be extended without an end.

ECHA provided details on the difficulties and the reasons behind the delays on the ED assessments. In several cases, eCAs have not requested data on EDs from the applicants. The Commission urged the concerned Member States to request the needed data, as the scientific ED criteria and technical guidance are now applicable since 4 years.

5.2. Progression of the renewal process	For information	

of approval of active substances	*CA-Oct22-Doc.5.2*	

The Commission informed that four applications for renewals of approval of active substances have been submitted over the summer. The eCAs should inform the Commission whether they plan a full evaluation or not of the renewal dossiers, so that the Commission can prepare the extensions of approvals accordingly. The application to renew the approval of Acrolein is no longer supported by the applicant. Finally, the number of extensions of approvals for each substance was pointe: 2 or even 3 extensions were made for several active substances, linked often to the need for ED properties assessment. The Commission invited Member States to reflect on the matter.

5.3. ECHA Active Substance Action Plan – progress update	For information *CA-Oct22-Doc.5.3*	

ECHA provided the regular update on the progress of actions in the context of the Active Substance Action Plan. In terms of the number of BPC opinions on active substances expected in 2022, the estimate had to be lowered from 30 to 19, due to the submission of a low number of draft CARs. In 2022 so far, 15 BPC Opinions have been submitted, and 4 more are expected by the end of the year. The main reasons provided by the eCAs for postponing the submission of assessments were the lack of conclusions regarding the identification of ED properties and lack of information to set reference specifications of the active substance. Other reasons mentioned were the failure of the accordance check for CLH dossiers and limited resources at Member State level. In ED assessments, related data on the environment are frequently missing. ECHA pointed the delays due to the need for ED testing and due to the saturated availability of laboratories performing these tests. Moreover, the 'one substance – one assessment' was mentioned. About 30% of active substances are also approved under food related regulations. ECHA is aligning its efforts with EFSA and eCAs to draw a roadmap that will allow a more coherent evaluation. In addition, the 'withdraw' option of the dossier provided by the review programme in case data are not submitted in time was marked.

ECHA concluded with a few reminders to Member States (e.g. related to raising issues early during the evaluation phase, checking early if additional data is needed especially related to the ED properties assessment and modalities of submission of requests for further information) and mentioned that it has initiated bilateral discussions at managerial level with some Member States competent authorities, with a view to increasing mutual understanding on the state of play, challenges and opportunities.

Biocides for Europe raised concerns on the recent streamlining of the review process of BPC affecting the commenting rounds given to the applicants.

5.4. Approval of skin sensitizer in can-preservatives PT6	For discussion and agreement *CA-Oct22-Doc.5.4*	

The Commission introduced the document, which summarizes the feedback received from the related newsgroup opened in the 96th CA meeting of June 2022, and proposed the way forward on regulatory aspects on skin sensitizers for PT6, focusing in the use of isothiazolinones (ISZs) in paints and detergents.

As regards to the proposal to not allow the use of ISZs in detergents above the sensitization threshold (paragraph 19 of the CA-Oct22-Doc.5.4 document), five Member States expressed their agreement. AISE did not agree with use of the Specific Concentration Limit in the proposed provision since this could evolve, and noted that a risk assessment should be instead used based on exposure. Moreover, AISE mentioned that the Detergents Regulation and the CLP provide already labelling requirements on hazards, thus the general public can make informed choices. Biocides for Europe shared the opinion of AISE. The Commission clarified that the points raised by the Industry have been discussed extensively before and not supported by Member States, and reminded that a quantitative risk assessment is not possible at the moment in absence of technical consensus. The Commission concluded that the provision proposed in paragraph 19 of the CA-Oct22-Doc.5.4 document for the detergents is endorsed by the CA meeting members.

As regards to the proposal on the use of ISZs in paints (paragraph 20 of the CA-Oct22-Doc.5.4 document), three Member States mentioned that they agree with the proposal, but to be adopted as a temporary solution until innovation permits the replacement of ISZs in paints. Another Member State inquired whether Article 19(5) of the BPR would be applicable for the proposed provision on paints. The same country marked its reservations if gloves can be provided together with the paints, and that it would need more time to reflect on it, anticipating also experience coming from the PT21 antifouling paints authorization.

Six Member States support the providing of gloves together with the paints. Another Member State also agreed, although not having strong views regarding the use of gloves, but not opposing to such use. Two additional Member States expressed their support to supplying gloves, not necessarily together with the paint but making sure that the gloves are available and provided in the same store; however, another Member State questioned how the paints sold online could be handled in such a case. The CA members pointed the need for clear instructions on the labelling. Three Member States mentioned that the Industry and the authorization holders could clarify practicalities on how gloves can be provided together with the paints.

CEPE considered the proposal on paints as pragmatic, but highlighted practicalities issues, such as the size of gloves if to be sold together with the paints.

The Commission asked for a pragmatic solution to move forward regulating the use of paints, otherwise they will continue to be sold unregulated in the EU market. Commission services also clarified that there is no need to use Article 19(5) provision at the active substance approval stage.

The CA Meeting was invited to provide written comments through a newsgroup until 31 October 2022 on whether gloves should be provided together with the paints and to express their views on paragraph 20 of the CA-Oct22-Doc.5.4 document.

5.5. Guidance on analysis of alternatives	For information	

ECHA updated the CA meeting about the development of a guidance document on the analysis of alternatives (AoA). The Agency prepared a table summarising the comments received after the last BPC meeting and how they have been answered. The draft guidance is targeted to applicants but Member States could use it as well to prepare their own evaluation. Although the analysis of alternatives is a challenging task, the draft guidance is meant to be flexible and adaptable to each case in particular if limited information on alternatives is available. The guidance aims also to facilitate the systematic search for alternatives in

particular for exclusion substances. The Agency will update the draft guidance taking into account the comments received for the next BPC meeting in December. The Agency also announced that a CA document on the implementation of the guidance will be presented at the next CA meeting for discussion and possible endorsement.

An industry stakeholder asked whether contributions can still be sent. Another stakeholder indicated that downstream users should play a key role to propose alternatives to hazardous substances because they are close to the market. This stakeholder noticed that a similar approach has been followed under REACH but the outcomes is sometimes uncertain. A robust and conclusive approach is required. The Commission explained that public consultation should bring a lot of valuable information in the evaluation of alternatives.

According to another industry representative, the nature of the supply chain in the biocide market is different from the chemicals regulated under REACH. For biocides, it is most likely that the applicant will not have the possibility to identify all the possible uses of its substance. Industry stakeholders however recognised the benefit of having an AoA guidance but propose to postpone its implementation until the review programme is finalised. Industry finally recalled the need to keep sufficient substances on the market. The Commission replied that the search for alternatives might be indeed very complex in some instances but more straightforward in other cases and that the chemical diversity of the active substances is also a criteria that need to be taken into account during the comparative assessment of products.

5.6. Renewal of antifouling active substances PT21	For discussion *CA-Oct22-Doc.5.6*	

The Commission briefly introduced the document, mentioning that a related newsgroup was opened after the 96th CA meeting of June, and that limited feedback was received.

Taking into account the extra time requested by several CA members to contribute, the CA Meeting was invited to provide further written comments through a newsgroup until 31 October 22 , with the view to have a discussion on the topic in the CA meeting of December 2022. CEPE asked Member States from Southern Europe to contribute.

5.7. Discussion document from France on Annex I inclusion to the BPR	For discussion *CA-Oct22-Doc.5.7*	

France introduced the topic and pointed the difficulties faced by the Member States currently assessing Annex I applications. In more detail, Regulation (EU) N°88/2014 provides for a clear procedure to modify Annex I of the BPR in the case where ECHA gives a positive opinion on the active substance under assessment, but does not provides any possible outcome in the case where ECHA gives a negative opinion. To their views there is a need to agree on a potential procedure to officially close an Annex I dossier in case ECHA gives an unfavourable opinion on the inclusion. The Commission clarified that in case of negative opinion by ECHA, the active substance will surely not be included in Annex I.

Member States infirmed that there are currently 5 related dossiers on Annex I in R4BP. Member States asked clarifications on data requirements during the assessment of the substance for Annex I inclusion (e.g. are ED data needed for instance). An additional Member State asked for guidance in Annex I assessments, particularly for category 6 applications.

The Commission will reflect with ECHA and come back to France on the matter. The CA Meeting was invited to provide further written comments through a newsgroup until 31 October on their views on the issues and their experience on Annex I applications.

6. Treated articles
No item for information or discussion.

7. Horizontal matters

7.1. Financial assistance to Member States 2022-2027	For information	

The Commission provided an update on the project to open the possibility for Member States to apply for grants, subject to the condition of having in place or committing to establish a system properly financed through fees. 23 Member States Competent Authorities intend to apply for the grant on biocides. HaDEA (Commission Executive Agency) will publish the call document by the end of the year. All designated entities will receive an invitation to apply to the call. HaDEA will also organize a workshop to present the call for the grants. Member States will have 3 months-time to apply to the call. The amount of money given through the grants to each applying Member State will be depend on the number of Member States that applies. The Commission will keep Member States updated on the matter.

One Member State inquired whether it would be possible to withdraw from their intention to apply for the grant. The Commission replied that there are not forced to apply for this grant, but strongly advised that Member State to use the possibility now granted by the Commission to get additional resources considering its own situation.

7.2. ECHA communications	For information	

ECHA gave a presentation covering: a) Member States supporting articles treated with creosote, b) visibility of MSCAs' plans for CARs submission, c) guidance on impact of water treatment processes on active substances residues, d) update on SPC Editor integration into IUCLID, and e) report on relevance and sensitivity of non-bee pollinators.

7.3. Assessment of metabolites in groundwater and drinking water	For discussion and agreement *CA-Oct22-Doc.7.3*	

The Commission explained that following the outcomes of a newsgroup, a new question was added to the list of section 3 of the document to cover the case of a carcinogenic category 2 metabolite. It is concluded that under the current guidance, metabolites classified as carcinogenic category 2 shall be considered as relevant metabolites for the groundwater assessment in all cases and that there is no need to conduct a risk assessment to assess the relevance of such metabolites. Therefore the regulatory limits of point 68 of Annex VI should apply to such substance.

The CA meeting endorsed the revised CA document without any comment.

7.4. Update of DG ENV on modification of groundwater directive	For information	

The Commission informed that there will be a presentation on this topic at the next CA meeting in December.

7.5. Update on substitution by the Netherlands	For agreement *CA-Oct22-Doc.7.5_rev1*	

The Commission explained that the document CA-Sep18-Doc.7.4 on substitution has been amended to include contributions from two Member States on efforts undertaken to substitute hazardous biocidal active substances. The Commission also invited the other Member States to inform directly Member States and the CA meeting when similar information is available. The CIRCABC website of the CA meeting has been amended to include this information and is available here.

One Member State mentioned that its contribution as reported the annex III to CA-Sep18-Doc.7.4 seems to be incomplete. The Commission checked and agreed with that Member State.

The document was endorsed by the CA meeting .

7.6. Discussion document from the Netherlands on phosphine plant protection and biocidal products	For information	

At the last CA meeting, the Netherlands briefly informed that they intend to propose new restrictions regarding the fumigation of inland vessels with biocidal products containing phosphine. However, no concrete proposal was presented at the meeting as the conditions of the restrictions were still being discussed. A proposal could be discussed at the next CA meeting in December or even later at the beginning of 2023.

The Netherlands proposed to use the provision of Article 48(3) of the BPR to amend the existing authorisations. The eCA for the evaluation of the renewal of phosphine substances asked the Netherlands to share its recommendations as quickly as possible as these evaluations are nearly closed. Another Member State announced its support to amend the authorisations and informed that specific rules on fumigation are already in the place at national level. Another Member State expressed concerns about the safety of goods if fumigation with phosphine is further restricted.

The Commission concluded that this point will be followed up at the next meeting.

7.7. Dissemination of CA finalised documents on Circabc	For information	

The Commission informed Member States about the reorganisation of the folder of documents finalised in the CA meetings in CIRCABC. The Commission has made a revision of all the available documents and has moved to the folder of obsolete documents those that are no longer applicable. The rest of the documents have been grouped in different folders.

The objective is to provide to the CAs a list of applicable CA documents that will be regularly updated. To that end, the Commission requested Member States to check the folders in CIRCA, and in case they detect error in the filling of the document, to communicate it to the Commission.

7.8. ECHA Guidance priorities	For discussion and agreement *CA-Oct22-Doc.7.8*	

ECHA introduced the document, providing details on the updates of ongoing projects, and the setting of list of future priorities. Member States endorsed the ongoing work (Table 1 of the document).

Concerning the guidance priorities for 2023 (Table 2), a Member State asked to enrich the efficacy guidance with more elements. ECHA clarified that not all items in Table 2 are expected to be assessed and asked for a prioritization by the Commission and Member States. The CA Meeting was invited to provide further written comments through a newsgroup until 31 October 2022 on Table 2.

8. Scope matters
No item for information or discussion

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-Oct22-Doc.11.a*	

(b) Update on MRLs	For information	

The Commission informed that discussions are still ongoing internally and that it will try to come with updates in the meeting of December.

(c) Update on the revision of the CLP Regulation	For information	

The Commission informed that the internal procedures are ongoing and that the CA meeting will be kept updated on developments.

Next meetings:

(provisional 2022)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WGs
15-17 February				
			1-3 & 8-9 March	
	9-11 March			
		22-24 March		
				28 March – 8 April
26-28 April				
				30 May – 10 June
			8-9 & 14-16 June	
	22-24 June	21-23 June (or 17 June)		
28-30 June				
				5-16 September
20-22 September				
			26-30 September & 3-7 October (TBC)	
	4-6 October			
		14-18 November		
				14-25 November **Or** 5-16 December
22-24 November				
			28 Nov-2 December	
	6-8 December			