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

MINUTES

98th 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

6-7 December 2022

1. Adoption of the agenda	For adoption *CA-Dec22-Doc.1*	

The Commission informed that one item will be added as AOB, upon request from one Member State, concerning the borderline between plants protection products and biocidal products. Another point was added in the AOB section following the request of one industry association, concerning the requirement for new Safety Data Sheets as of 1 January 2023, following the entry into application of Regulation (EU) 2020/878, amending Annex II to the REACH Regulation.

One Member State made a general remark concerning the timing of distribution of the documents for the meeting. In some cases the late distribution of documents does not allow an appropriate preparation of the discussion. The Commission explained this is due to the high workload and the need for internal consultations. It will strive to distribute the document for future meetings in due time.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Dec22-Doc.2.a* *CA-Dec22-Doc.2.b_Restricted*	

The minutes of the previous CA meeting were adopted.

3. Draft delegated acts
No item for information or discussion

4. Biocidal products

4.1. Report from the Coordination Group	For information	

The Commission provided a summary of CG-54 meeting, held in November 2022, in which six formal referrals were discussed and two were briefly introduced. Agreement was reached for three of the referrals.

In that meeting:

- The Chair of the Coordination Group gave a presentation regarding the requirements of physical hazards for products in the Simplified authorisation procedure to clarify that all biocidal products need to be classified in accordance with the CLP Regulation and that in order to establish whether the product is eligible for the simplified authorisation procedure physical hazards need to be assessed.
- The secretariat of the coordination group presented a document recording quality standards for the submitted referral supporting documents.
- The Commission presented an updated document in the open 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. In addition, position papers from the H2O2 BPR Task Force and Peroxygens SG were also shared with the coordination group members and several industry association representatives expressed their view during the meeting. It was noted that industry association should bring forth any data and experience they have regarding classification of products containing this active substance during the classification review of hydrogen peroxide that would take place soon. The document was agreed by the coordination group members by consensus.

- A Member State presented an outcome of an e-consultation in relation to the topic – Use of the term "as required" for the application frequency in the open session. The initiating Member State proposed the approach of stating the (maximum or typical) number of applications per day in the summary of biocidal products characteristics authorised use and that the term 'as required' (or similar terms, e.g., 'daily use') not being accepted by the Member States for the application frequency without further justification (based on e.g., showing safe use by a reverse reference scenario). Member States agreed on the document by consensus.
- A Member State presented an outcome of an e-consultation in relation to the topic – Additional active substance data for overall systemic limit value for the human population (AEL) and dermal absorption value refinement. The subject of the e-consultation was the additional active substance data submitted during a national authorisation. The document was agreed with two-thirds majority. It was noted by several Member States and the Commission that the possibility of further discussion on working group level should be explored.
- A Member State presented a document about questions concerning the cancellation of authorisations in the event of the expiry of the active substance approval. Practical and legal questions were raised. The Commission informed the Coordination Group that a document would be drafted for the CG-55 meeting in regards of Article 48 of the BPR and that this specific situation would be addressed in it as well. It was agreed that MSs would provide further comments in writing.
- The secretariat of the coordination group presented an updated revised document concerning management of new active substance data submitted at product authorisation based on the agreed approach at CA-94 and taking into consideration the comments provided by Member States and the Commission during the written commenting for the first revised version. It was communicated that the revised BPC document is being drafted and would be made available for written commenting in January 2022, it was agreed that the document would be slightly revised based on the discussion and Member States and industry associations would provide comments on it.
- A Member Stats presented an outcome of an e-consultation in relation to the topic – Revision of harmonised SPC sentences for rodenticides. The subject of the discussion concerned environment related changes. Industry associations will provide comments on the document and discussion will continue at the CG-55 meeting.
- A Member State presented an outcome of an e-consultation establishment of a risk mitigation measures for the situation when wood is treated outdoors (e.g., when the wood is jacked up on sawhorses and then treated with a wood preservative e.g., by brushing/rolling or spraying) and then it is installed in use class 1 and 2 situations after drying. Discussion about this particular risk mitigation measure took place in the Environmental Working Group (WGII2019_ENV) and at the BPC-34 meeting, after which the matter was referred to the coordination group in the form of this e-

consultation. The MS will provide a revised, public version of the document and discussion will continue at the CG-55 meeting in the open session.

- A Member State presented an outcome of an e-consultation in relation to the topic – Local risk assessment of wood preservatives in the human health "sawing/sanding" scenario in the open session. The subject of the e-c was whether a risk assessment in the human health exposure scenarios "Sanding/sawing" and/or "handling" for secondary professional and non-professional exposure to the dried wood preservative should be done for local effects when a wood preservative is classified for local effects. Additionally, the question was raised that in case not, whether this decision would be based on the fact that classification only refers to the product in its liquid state or other arguments. The Member State also asked the view of the Member States regarding the methodology for a local qualitative risk assessment being discussed and agreed upon in the human health working group. The coordination group agreed by consensus that the Member State initiating the e-consultation would bring this topic to the human health working group and further discussion would take place there.
- A Member State briefly introduced an e-consultation in relation to the topic – Concentrations and contact times for various groups of target organisms. Member States and industry associations were invited to provide further comments.

4.2. List of pending Article 36 requests	For information *CA-Dec22-Doc.4.2*	**Closed session**

The item was discussed in closed session.

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

The secretariat of this ad hoc group, managed by one Competent Authority, indicated that not much happened in the group since the last CA meeting. One accessing country submitted comments that are currently being discussed by the group Members. The secretariat invited other Member States to submit their questions directly to the responsible Member State or the Commission.

4.4. Modification of Regulation 492/2014 on renewal of authorisations under mutual recognition	For discussion and agreement *CA-Dec22-Doc.4.4*	

The Commission introduced the document *CA-Dec22-Doc.4.4.* that compiles several issues on the interpretation and implementation of Regulation (EU) No 492/2014 on renewals by mutual recognition ('the Regulation') raised by Member States and industry representatives and discussed in the 89th CA meeting (September 2020), the 90th CA meeting (December 2020), the 92nd CA meeting (June 2021), the 93rd CA meeting (September 2021) CG-49 meeting (November 2021), CG-50 meeting (February 2022) and the 97th CA meeting (October 2022). The document proposes a draft text for the amendment of the Regulation to further discuss with the Member States. A newsgroup will be opened after the meeting for Member States to provide their comments to the proposal.

An amendment of recital (2) is proposed, to indicate that the reference Member State for the renewal should be in principle the Member State that acted as reference Member State during the earlier authorisation procedure and/or the Member State where, comparatively to the others, more uses of the product are authorised, and where justified, the applicant may choose another Member State subject to the latter's agreement.

An amendment of Article 1, paragraph 1, is proposed, to make clear that the renewal of same biocidal product authorisations based on a reference product authorised through mutual recognition should be carried out in accordance with this Regulation. Some Member States signalled the difficulty to trace back the connection between the same biocidal products authorisations and the reference products in R4BP3 and the incertitude on how to handle same biocidal products authorisations and reference products if their authorisations can be amended or cancelled independently of each other. The Commission confirmed that the intention of this proposal is to clarify these issues, together with a proposal to amend the Regulation on same biocidal products.

An amendment of Article 1, paragraph 2, is proposed, to clarify that the Regulation shall also apply to authorisations having different terms and conditions at the time of the application for renewal across the Member States where the renewal is sought, but for which one or more applications for administrative and/or minor changes are submitted no later than at the moment of the application for renewal to establish the same terms and conditions in all those Member States. An amendment of Article 1, paragraph 2, was proposed to clarify that the Regulation shall also apply to authorisations having different terms and conditions at the time of the application for renewal across the Member States where the renewal is sought, if the differences merely concern information which can be the subject of an administrative or minor change in accordance with Commission Implementing Regulation (EU) No 354/2013.

Five Member States were of the view that authorisations to which derogations to the mutual recognition were applied in accordance with Article 37 of the BPR should also be included in the grouped renewal for mutual recognition. This is especially important for rodenticides, as a high number of authorisations have derogations to the mutual recognition applied. The Commission explained that those type of authorisations will still be eligible for a grouped renewal if the difference with the authorisation granted by the reference MS can be the subject of an administrative or minor change. The Commission considers that the proposed wording is coherent with other exemptions to authorisations having the same terms and conditions, and avoids referring to the procedures under which the authorisations were granted (e.g., Article 37 or Article 19(5) of the BPR). The Commission pointed out that authorisations to which Article 37 is applied or authorisations granted in accordance with Article 19(5) of the BPR may differ on something that can be the subject of a major change and that, for reasons of coherence, if these authorisations are included in the grouped renewal, there would be a need to accept also authorisations that differ on something that can be the subject of a major change. The Commission also requested MSs to limit the situations in which Article 37 is applied to the strictly necessary and to reconsider their position on this point.

One Member State welcomed the proposal to fit as many products as possible in the renewal procedure but also signalled the risk that small groups of products could be left behind. The Commission recalled that the concept of mutual recognition is quite flexible and that the possibility to apply for a national authorisation remains anyway available. The key objective is to have a manageable system. Another Member State was open to reconsider their position as regards the inclusions of authorisations to which Article 37 has been applied under a grouped renewal and will analyse if the derogations applied in Member States to the mutual recognition of rodenticides (in accordance with Article 37), differ from the reference authorisation on something that can be the subject of a minor change.

A new Article 2a is proposed, to clarify the possibility for applying for minor and major changes in the context of the renewal procedure. Two Member States expressed concerns on the proposal of the Commission to set time limits in the allowance of applications for minor changes submitted during the renewal procedure. They signalled that they deal with different situations and scenarios, which makes it difficult to set deadlines for those applications. The Commission explained that the intention is not to close completely the possibility to minor changes during the renewal process, but it is necessary to establish a deadline to have a manageable system. Therefore, the Commission remains open to proposals from Member States. Another Member State requested that there are no limitations for applications for administrative changes during the procedure, as these may be needed to address modifications in the authorisations or labelling due to CLP changes.

A replacement of Article 3, paragraph 6 is proposed, to make clear that if the authorisation does not fall within the scope of this Regulation, the competent authority in the Member State concerned shall inform the applicant and the competent authorities in other Member States accordingly, and that applicants intending to submit subsequently an application in accordance with Article 31(1) of Regulation (EU) No 528/2012 shall do so within 15 days of receiving the communication from the Member State. One Member State and ECHA requested that it is also clarified that, in those cases, the application shall be rejected. The Commission will amend the text accordingly.

A replacement of Article 4, paragraph 1 is proposed, to clarify that the time set for the submission of additional information by the applicant shall not be counted as part of the 90-day time limit for the decision of the competent authority. One Member State questioned the need for such clarification. The Commission requested that Member State to develop their reasoning in the newsgroup that will be opened after the meeting.

A replacement of Article 6 is proposed, to exclude the possibility to grant a period of grace when no application for renewal is submitted. One Member State requested to exclude the possibility to grant a period of grace if an application is submitted, but the applicant fails to comply with their obligations (such as paying the fees). The Commission considers that it will be difficult to go further than what is already established in the BPR for the period of grace but requested that Member States to submit this in the newsgroup mentioning specific examples, to see if this could be addressed in the proposal.

A replacement of Article 7, paragraph 2, is proposed, to align the text with the BPR and clarify that the concerned Member State shall send to the Coordination group the disagreement on a mutual recognition. ECHA suggested to quote Article 35 of the BPR. The Commission agreed to this suggestion.

An addition to Article 7, paragraph 3 is proposed, to indicate that for the purpose of this Regulation, “immediately” mentioned in Article 36, paragraph 1, of Regulation (EU) No 528/2012 shall mean “at the latest within 15 days”. Some Member States believed 15 days is not sufficient time for them to refer the disagreement to the Commission. One Member State questioned what the consequences would be if they did not refer the matter within 15 days. Other Member State asked if the 15 days must be considered as “calendar days” or “working days”. The Commission, specifying that the timeline is expressed in “calendar days”, recalled that the Regulation uses the term “immediately”.

The CA Meeting was invited to provide written comments through a newsgroup until 15 January 2023.

4.5.	Union authorisation: similar conditions of use across the Union and Article 44(5) derogations	For discussion and agreement *CA-Dec22-Doc.4.5*	

The Commission presented the document updated in light of the comments received after the last CA meeting.

It was agreed that further discussion was needed on the notion of "similar conditions of use" and the pre-submission procedure. One Member State explained that they introduce in the language version of their SPC changes with regards to the user category based on their national legislation, as they consider this to be similar. ECHA explained that they rely on the pre-submission procedure for the estimation of future workload and fee income.

Member States and applicants were invited to provide comments on this part of the document by 15 January 2023.

The proposals of the document for the principles, timelines and template be used for the requests for derogations in accordance with Article 44 (5) of the BPR were endorsed. One Member State could only agree to the use of the template since the internal opinion forming process on the timeline was still ongoing. On the request of another Member State, the Commission confirmed that the deadline is not a legal deadline, but is necessary to ensure timely management of the authorisation decisions and all Member States should therefore respect the proposed procedure. The Commission agreed to make available a list of request for derogations that were accepted as a source of information to Member States and potential applicants.

4.6.	Union authorisation: acting as evaluating CA	For discussion and agreement *CA-Dec22-Doc.4.6*	**Closed session**

The item was discussed in closed session.

4.7.	Discussion document from the Netherlands on phosphine plant protection and biocidal products	For discussion *CA-Dec22-Doc.4.7.a* *CA-Dec22-Doc.4.7.b-Restricted*	

Following the previous discussions in CA meetings, the Dutch authorities informed about their plans to further restrict the uses of phosphine-based plant protection and biocidal products. The Dutch authorities asked the other competent authorities to discuss these draft restrictions with their colleagues responsible for the implementation of the Plant Protection Products Regulation.

The Commission commented that the intention is to harmonise the conditions of use for the plant protection products and biocidal products and requested the authorities to pay particular attention to the practicability and feasibility of the proposed measures.

The Commission invited Member States to send comments directly to the Dutch Competent authorities by 15 January 2023 at the latest.

4.8.	Update of document CA-March18-Doc.4.6_final-rev8-note for guidance QA on simplified procedure	For discussion and agreement *CA-Dec22-Doc.4.8*	

	➔ *CA-March18-Doc.4.6_final-rev8 note for guidance QA on simplified procedure*	

The Commission presented the document that intends to address amendments and cancellation of authorisations of biocidal products granted under the simplified procedure. This is presented in the new Q&A number 39.

The new Q&A clarifies that the evaluating competent authority can cancel or amend an authorisation granted under the simplified procedure by using Article 48 of the BPR, when it considers that any of the situations referred in points (a) – (c) of Article 48(1) apply. The evaluating competent authority shall notify the amendment or cancellation to the authorisation holder and the competent authorities of other Member States without delay in accordance with Article 48(3). Upon this notification, each Member State on the territory of which the product is made available should cancel the notification. In case of the amendment of an authorisation granted under the simplified procedure, if the authorisation holder wishes to make the product available in another Member State, a new notification needs to be done in accordance with Article 27(1) of the BPR. The revised SPC should be submitted together with the new application to each Member State on the territory of which the product is made available in the official language(s) of that Member State. If a notified MS disagrees with an amendment of the authorisation made by the evaluating competent authority, as it considers that the product does not meet the conditions of Article 25, a referral to the coordination group can be triggered by following the procedure established in Article 27(2) of the BPR.

One Member State asked whether it would be possible for a notified Member State to comment on or disagree with a cancellation of the authorisation under simplified procedure or a non-authorisation proposal. The Commission requested that Member States to submit this question in writing and informed that a new version of the document will be circulated to try to address it.

The CA Meeting was invited to provide written comments through a newsgroup until 15 January 2023.

4.10. ECHA identified issues noted during the linguistic review of the SPC translations	For information *CA-Dec22-Doc.4.10*	**Closed session**

This point was presented in closed session.

4.11. Discussion on SBP Regulation (Regulation (EU) No 414/2013)	For discussion *CA-Dec22-Doc.4.11-Amendment SBP Regulation*	

The Commission presented its proposals to address several issues on the interpretation and implementation of Regulation (EU) No Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products ('the Regulation') that were discussed and agreed in the 93rd CA meeting (September 2021) and are reflected in document CA-Sept21-Doc.4.11.SBP renewals. The purpose is to provide Member States with proposals for amendment of the Regulation..

Four new articles are proposed to be introduced following Article 7 of that Regulation:

- new Article 7a. Cancellation or amendment of an authorisation pursuant to Article 48 of the BPR,
- new Article 7b. Cancellation of an authorisation of a same biocidal product at the request of the authorisation holder pursuant to Article 49 of Regulation (EU) No 528/2012,
- new Article 7c. Amendment of an authorisation of a same biocidal product at the request of the authorisation holder pursuant to Article 50 of Regulation (EU) No 528/2012 and
- new Article 7d. Renewal of same biocidal product authorisations. The new Article 7d addresses renewals of same biocidal products having as a reference product national authorisations, Union authorisations and authorisations granted by mutual recognition. It also addresses the renewal of SBP national authorisations that have as a reference product a product authorised at Union level and the renewal of authorisations granted by mutual recognition of a same biocidal product that is a national authorisation and has as a reference product a product authorised at Union level.

One Member State raised concerns on the complexity of the proposal and pointed out to the current difficulties to handle the renewal of authorisations linked by different procedures (SBP, mutual recognition, mutual recognition of SBP, etc). The Member State believed this issue should be tabled for discussion in the Coordination Group.

The Commission considered that the current text of the SBP Regulation needs to be amended, as it provides for the possibility to apply for a minor or major change to the SBP or the reference product independently, but there is no clarity in the legal text on the consequences and how these authorisations should be further process or renewed. It is necessary to clarify that, if a minor or major change is applied for, it needs to be applied for in all the related products to which the authorised product is linked, otherwise the SBP definition will not be fulfilled.

Another Member State thanked the Commission for the proposal and noted that currently there is no legal clarity on how to handle SBP authorisations for which a minor or major change has been applied for.

Member States and ECHA asked whether it would be possible to raise additional issues in the context of the amendment of the SBP Regulation. The Commission confirmed that Member States and ECHA are invited to raise any issues with the Regulation that they are aware of and pointed out that concrete proposals to address them are also welcomed, as well as comments on the wording of the proposed additional provisions.

The Commission concurred with ECHA that this issue is broader than mutual recognition procedures and, therefore, it will be discussed in the CA meetings. An information point on it will be scheduled for the next meeting of the Coordination Group.

The CA Meeting was invited to provide written comments through a newsgroup until 15 January 2023.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-Dec22-Doc.5.1*	

The Commission informed CA members on the progress of the review programme, which has been completed by 43%. It urged the Competent Authorities to make progress on the completion of the work programme, and to conclude as quickly as possible the review of their backlog reports submitted before 1 September 2013, which are evaluated based on Directive

98/8/EC. The Commission invited the Competent Authorities to liaise with ECHA when they experience difficulties in the assessment of the applications, in particular as regards the assessment of the endocrine disrupting (ED) properties, highlighting that ED assessments are one of the main reasons for the relevant delays in the review programme. 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.

5.2. Progression of the renewal process of approval of active substances	For information *CA-Dec22-Doc.5.2*	

The Commission informed that three applications for renewals of approval of active substances have been recently submitted. In 2023, the approval of 29 active substances will expire and the relevant renewal processes should be initiated. Several of these active substances meet the exclusion criteria. In the CA meeting of March 2023, the Commission intends to prepare a document aiming to improve the handling of active substances meeting the exclusion criteria; a Member State CA has already sent to the Commission a relevant email with concrete proposals. Finally, the evaluating CAs (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.

5.3. ECHA Active Substance Action Plan – progress update	For information *CA-Dec22-Doc.5.3*	

ECHA provided the regular update on the progress of actions in the context of the Active Substance Action Plan. Only 19 BPC Opinions were adopted on active substances in 2022. This low number is due to the submission of a low number of draft CARs (i.e. only 14 draft CARS were finally submitted to ECHA, which is the 1/3 of the original estimation for 2022). For 2023, the adoption of 26 BPC Opinions on active substances is estimated, but ECHA pointed out to the uncertainty on this number. ECHA is aligning its efforts with EFSA on the assessment of sulfur dioxide, and a joint note by ECHA and EFSA is expected to analyse any differences in the sulfur dioxide assessments by the two agencies. ECHA finally highlighted key points of the Active Substance Action Plan: 1) prioritisation of dossiers; 2) support to the eCAs; 3) streamline the peer review; 4) reduction of complexity.

5.4. Guidance on analysis of alternatives	For information *CA-Dec22-Doc.5.4.a* *CA-Dec22-Doc.5.4.b*	

ECHA introduced a CA document on the implementation of framework guidance on analysis of alternatives for biocidal active substances, and asked the CAs members' endorsement. The Commission thanked ECHA for the proposal, which is partly based on the experience gained during the renewals of borates and hexaflumuron. According to the Commission, this guidance document should help applicants and Member States in their assessment of alternatives to substances meeting the exclusion and substitution criteria.

The Commission recalled that several dossiers on substances meeting the exclusion criteria will be discussed in 2023 and that the eCAs for these dossiers are expected to assess whether there are alternatives for these substances.

The Commission proposed to apply the guidance for active substances meeting the substitution criteria starting from 2025 instead of 2026.

A Member State suggested to apply the guidance for active substances meeting the exclusion criteria starting from 2024, and until then to continue the related work through specific mandates to ECHA. The Commission replied that the timeline of a mandate would take at least 6-9 months, so it was suggested to start applying the guidance immediately for active substances meeting the exclusion criteria. Biocides for Europe mentioned that the applicants would need 6-12 months to be prepared for such an analysis on alternatives.

CA meeting members agreed to modify the document in terms of timelines. The document was endorsed with those changes.

5.5. Approval of skin sensitizer in can-preservatives PT6	For discussion and agreement *CA-Dec22-Doc.5.5*	

The Commission introduced the document, which summarises the feedback received from the related newsgroup opened in the 97th CA meeting of October 2022, and proposed the way forward on regulatory aspects on skin sensitizers for PT6, focusing in the use of isothiazolinones (ISZs) in paints.

Three Member States took the floor to support the Commission's proposal.

A Member State inquired about imported paints, proposed to forward the Commission's proposal to BPRS, asked how the practicality issues of applicability would be ensured, how innovation by industry can be pushed forward, what are the exact risks of ISZs from application in paints, and if lowering the dosage of ISZs in paints could be effective. The Commission clarified that imported paints would need also to comply with the proposed provisions. It also pointed out that the obligatory use of gloves for paints is a step forward to push industry towards innovation. ECHA added that the efficacy issue can be forwarded for discussion to the respective Working Group of BPC. ECHA also mentioned that a quantitative risk assessment of ISZs in paints is problematic; the epidemiological studies are unclear on the matter since they cannot define the source of the risk with certainty. ECHA also added that there is an associated call of evidence on-going under the REACH framework, and any relevant data will be shared.

A Member State indicated no support towards the Commission's proposal. According to them, gloves cannot be enough to eliminate the risk of ISZs, since other parts of the body can be exposed. They propose to use the provisions of Article 19(5)of the BPR to authorise products leading to the use of treated mixtures by non-professional users. Another Member State was reluctant to this proposal, since it would require to perform each time an assessment of Article 19(5) conditions when authorising biocidal products. An additional Member State was also rather negative towards the Article19(5) proposal, stating that it could be problematic for imported paints. Another Member State was also negative to the Article 19(5) application. The Commission questioned the added value of performing each time of a product authorisation an assessment of Article 19(5) conditions.

CEPE supported the Commission's proposal and intend to share experience coming from PT21 antifouling paints. CEPE also mentioned its efforts towards innovation but underlined the

challenges to bring forward efficient alternatives to ISZs. They also mentioned problems when lowering the ISZs dosage in paints in terms of preservation and coloration properties.

While noting several Member States' reservations and inquires, the CA document was endorsed. The Commission asked CEPE to provide input from the PT21 antifouling paints experience in the next CA meeting. It will also forward the matter to BPRS and wait for any ECHA updates on the efficacy from the relevant Working Group. At the same time, the Commission will work along the present agreement to start drafting approvals on the next ISZ that comes to the pipeline, and further reflect with the Member States on the relevant provisions of the relevant draft approval regulations.

5.6. Renewal of antifouling active substances PT21	For discussion and agreement *CA-Dec22-Doc.5.6*	

The Commission introduced the document, summarising the input received from the related newsgroup opened.

A Member State supported to forward Commission's proposal questions to the BPC Working groups.

Another Member State pointed out that it is premature to provide feedback if certain PT21 products can be replaced by alternatives. It also mentioned that the environmental scenarios widely vary based on the region and technical work is needed to make a representative choice for a product that can be used all over EU.

Another Member State supported that the marina scenarios do not need any refinement. Using Article 19(5) of BPR is an option if the risk is found unacceptable. It also pointed to the difficulty to distinguish freshwater *vs* marine scenarios since in their country ships sail frequently to both environments. An additional Member State also supported that the marina scenarios do not need additional work, and that any mandate to ECHA would only delay the ongoing processes.

A Member State stated that the leaching rate in the current scenario is not representative based on data coming from field trials. They invited CA members to further assess the issue.

CEPE did not agree with Member States that marinas should not be considered as technospheres. It highlighted the problem of aquatic invasive species. It also mentioned that an efficacy revision would not be fruitful.

ECHA mentioned that further refinement of the marina scenarios could be possible, but it need to reflect first on the added value. If a request for refinement was forwarded to the Working Groups, questions should be very specific, and the overall goal of the effort should be clear. ECHA would welcome more field trials data on the leaching rates. The Commission added that there is also the need for technical discussion concerning the dermal absorption values in the human health risk.

The Commission concluded indicating that a newsgroup will be opened and invited CA members to provide specific feedback on which questions should be forwarded to the Working Groups of BPC (environment, efficacy, human health). The deadline for the newsgroup was set to 15 January 2023.

5.7. Second renewal of anticoagulant rodenticides	For discussion and agreement *CA-Dec22-Doc.5.7*	**Closed session**

This item was discussed in closed session.

5.8. Early review of propiconazole for PT7 and 9	For discussion and agreement *CA-Dec22-Doc.5.8*	

The Commission introduced the document and invited CA members to indicate their preference on whether to continue with the early review process or wait for the expiration of the approval of propiconazole for PT7 and 9.

Three Member States took the floor to support to stop the early review. Two Member States stated that there are no authorised products of PT7 and 9 in their countries. One Member State highlighted that they are not in position yet to provide an opinion.

The Commission concluded that the CA meeting agreed to stop the early review of propiconazole for PT7 and 9, and let the approval of the substance expire: on 30 November 2026 for PT7 and on 31 May 2025 for PT9, considering that the initial applicant for approval does not intend to apply for the renewal of the approval of the active substance, and noting also that there are no biocidal products authorised under the BPR for these PTs. After the expiration of the approval, related treated articles will not be allowed to be placed on the EU market anymore.

5.9. Early review of iodine and PVP iodine for PT 1, 3, 4, 22	For discussion and agreement *CA-Dec22-Doc.5.9*	**Closed session**

This item was discussed in closed session.

5.10. Discussion document from France on Annex I inclusion to the BPR	For discussion and agreement *CA-Dec22-Doc.5.10*	

France summed-up the newsgroup input received on the topic that Regulation (EU) No 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 provide any possible outcome in the case where ECHA gives a negative opinion. The Commission mentioned that it could consider revising that Regulation and could propose a modification in 2023. It also suggested that for several technical questions, a Member State could take up the lead to bring technical discussions among the relevant BPC Working groups, for instance clarifications on data requirements during the assessment of the substance for Annex I inclusion,.

5.11. ECHA - Transparency on active substance planning	For discussion *CA-Dec22-Doc.5.11*	**Closed session**

The item was discussed in closed session.

5.12. ECHA – FAST project	For discussion *CA-Dec22-Doc.5.12*	

ECHA provided a background of the FAST project, highlighting objectives, legal considerations, participants, and proposals to speed up the process of active substances evaluations. ECHA put emphasis on the examined use(s) and mentioned that eCAs should analyse the representative use(s) submitted by the applicant and not struggle to find an acceptable use at all costs.

A Member State mentioned that they allow the applicants a period of 6 months to submit requested additional data. If the applicant cannot meet the deadline, a justification should be submitted (e.g. laboratory not available).

Biocides for Europe asked for further clarifications on the document.

6. Treated articles

6.1 Wood treated with creosote	For information	

The Commission explained that the provisions of Article 52 of the BPR are not applicable to treated articles, as there is no reference to treated articles in these provisions. As a result, relevant provisions for the phasing out of treated articles were added in the regulation renewing the approval of renewal for certain uses. The relevant timelines applicable are those mentioned in the Implementing Regulation on the renewal of creosote. The Commission asked Member states to comply with these timelines. ECHA will finalise the relevant list of Member States that will allow the placing on the market of railway sleepers and utility poles treated with creosote, and will publish it before 31 January 2023.

7. Horizontal matters

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

The Commission informed the CA meeting that the call for the grants will be published in mid-January 2023. An explanatory document will accompany the call, with detailed instructions on how to apply. Member States will have 3 months to apply. After the publication of the call, a relevant workshop will be organised. The Commission will keep the Member States informed on the matter.

7.2. ECHA communications	For information	

ECHA gave a presentation on the following issues: a) update of efficacy guidance on disinfectants (PTs 1-5); b) "Guidance on impact of water treatment processes on active substances residues" – progress update; c) Bilateral meetings with Member States; d) Update on SPC Editor integration into IUCLID.

7.3. Update of DG ENV on the modification of the groundwater directive	For information	

DG ENV provided a presentation on recent updates of the Ground Water Directive (GWD) and its linkage with Water Framework Directive (WFD) and the Environmental Quality Standards Directive (EQSD). Changes to main pollutants and standards were highlighted. 25 new priority substances, but also deselections were mentioned for EQSD. Updates were given on GW pollutants of EU concern.
Member States CAs on biocides were invited to discuss at national level with their colleagues in charge of this area.

7.4. Dissemination of CA finalised documents on Circabc	For information *CA-Dec22-Doc.7.4*	

The Commission presented the document that provides an Index of applicable CA documents finalised in the CA meetings. The Index corresponds to the folder of finalised CA documents of CIRCABC that has been updated by the Commission. Those finalised CA documents which are considered obsolete have been moved to the folder of obsolete documents and the applicable CA documents have been saved in several subfolders. The Commission noted that there are several folders in CIRCABC that are no longer in use and committed to also revise those folders.

7.5. ECHA Guidance priorities	For discussion and agreement *CA-Dec22-Doc.7.5.a* *CA-Dec2Doc.7.5.b*	

ECHA presented the document on setting of list of future priorities. ECHA clarified that not all items in Table 3 of that document are expected to be addressed and asked for a prioritisation by the Commission and Member States.

Following a question by a Member State, ECHA also clarified that the guidance for human health was extended after discussion with the associated Working Group. Experts will investigate if this work should be put in the associated pipeline.

The task on developing guidance on MRLs was deleted at the request of the Commission. The Commission explained that there are different legal frameworks, which generate issues which cannot be addressed by an ECHA guidance. The Commission is monitoring the relevant discussions with the other services concerned.

Biocides for Europe asked for clarifications concerning the human health guidance. ECHA will cross-check internally and liaise with Biocides for Europe.

The CA meeting agreed on the priority list and invited ECHA to proceed accordingly.

7.6. Update on Court cases	For information	

The Commission provided information on recent judgements. The first one is the appeal judgement on case C-702/21 P concerning the non-approval of PHMB in PT 1, 5 and 6 and the approval of the same substance in PT 2 and 4, in which the Commission was supported by

France and ECHA. The Court of Justice, in the appeal stage, confirmed the earlier findings of the General Court that the Commission acted lawfully, in line with the EU law and the BPR in particular. The appellants had introduced two pleas in order to get the General Court judgement set aside, regarding (i) the failure of the General Court in the alleged duty to raise a plea *ex officio* that the reasoning of the Commission in the two acts was inadequate and (ii) that the General Court distorted the facts by holding that the substance in question is teratogenic. Both pleas were discarded by the Court of Justice.

The second judgement is the General Court judgement on joined cases T-122/20 and T-123/20 concerning the non-approval of silver zeolite and silver copper zeolite in PT 2 and 7. The court discarded all pleas introduced by the applicant and concluded that the Commission did not err in considering that the applicant has not demonstrated sufficiently the efficacy of the substances, in particular with regard to the request of tier 2 testing in addition to tier 1 tests.

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-Dec22-Doc.11.a*	

(b)	Borderline between plant protection products and biocidal products - update	For information *CA-Dec22-Doc.11.b*	

The Member State having proposed the item wanted to bring to the attention of all Member States that the discussions that have taken place at various CA and SCoPAFF meetings on borderline issues have been included in a staff working document on scope and borderline issues produced by DG SANTE in the plant protection product area (more specifically in chapter 4 of the document), and published in September 2022 and distributed for this CA meeting. The main points to be highlighted are that the competent authority shall verify the applicant's choice between the BP or PPP status in the early stage of assessment of an application for authorisation, based upon the submitted efficacy studies and the claimed functions and that attention has to be paid to the intended and not only to the claimed use. In

case the claimed use clearly differs from the actual intended use, the intended use should be leading.

(c) Requirement for new Safety Data Sheets as of 1 January 2023 under the CLP Regulation	For information	

One stakeholder observer asked whether there will be still some derogation to application of Commission Regulation (EU) 2020/878 and the requirements on new safety data sheets as of 1 January 2023. The Commission explained that the Commission Regulation (EU) 2020/878, implementing the corresponding changes in the Globally Harmonised System, has been applicable since 1 January 2021. However, there is a derogation in its Article 2 indicating that safety data sheets not complying with the amendment may continue to be provided until 31 December 2022. Therefore, the Commission pointed out that there has already been a grace period of two years, and no further transition period is foreseen.