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

MINUTES

102nd 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

7-8 December 2023

1. Adoption of the agenda	For adoption *CA-Dec23-Doc.1*	

An AOB point was added in the closed session, concerning a question on disinfections swabs used for pre-injection, at the request of one Member State. The agenda was endorsed.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Dec23-Doc.2.a* *CA-Dect23-Doc.2.b_Restricted*	

The minutes of the previous CA meeting were adopted.

3. Draft delegated acts		
3.1. Draft Commission Delegated Regulation (EU) amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include nitrogen generated from ambient air as an active substance in Annex I thereto	For discussion and agreement *CA-Dec23-Doc.3.1*	

The Commission introduced the item, mentioning the two latest text proposals by ECHA and the German competent authority respectively regarding the draft Annex to the Delegated Regulation. The latter Member State explained in more detail their proposal.

Three Member States and ECHA supported both proposals. One of them proposed to slightly revise the wording of ECHA's proposal. Another Member State would prefer Germany's proposal since it would reflect more clearly the stepwise approach.

The Commission concluded to follow the German proposal and noted the CA agreement on the draft Delegated act. It also explained the next steps of the procedure for the adoption of the Delegated Regulation.

3.2. Draft Commission Delegated Regulation amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances	For discussion and agreement *CA-Dec23-Doc.3.2*	

The Commission introduced the item and clarified that the Delegated act will follow the format of the previous extension of the Review Programme in 2013. The Commission also explained the process on the feedback mechanism, which ends on 21 December 2023, and on the TBT consultation which ends on 23 January 2024.

One Member State asked details about the revision of the BPR under the REFIT process, and in particular on its timelines. The Commission explained that they will start working on relevant studies in 2024-2025 involving contractors, and highlighted the implementation report to be received from Member States in June 2025. The latter will feed the REFIT work which is to be concluded by the end of 2026. These are the current plans which may evolve over time.

The Commission noted the CA agreement on the draft Delegated act.

4. Biocidal products

4.1. Report from the Coordination Group	For information	

The Commission provided an overview of key discussions and agreements from the 59th Coordination Group (CG) meeting held on 28-30 November 2023 (CG-59).

Main points from the CG meeting were:

• Four formal referrals were discussed and agreement was reached on two, while an additional meeting may take place for the remaining two.

• Regarding the Art 36 decision on products containing DEET adopted in 2018, discussions focused on the post-authorisation condition for applicants to submit specific data within two years of ECHA guidance publication on insect repellent efficacy data. No conclusion was reached on the type of change required for submission of those data, but it was agreed that the post-authorisation data should not be dealt with in the form of amendment in these specific cases.

• Member States discussed how to handle new information submitted for both active substance renewal and product authorisation renewal. The Commission emphasized that evaluating CAs should collaborate on the matter.

• The renewal of anticoagulant rodenticides was discussed and the Commission reiterated that the June 2021 agreement has to be followed, and that there was no intention to reopen the discussion.

• Discussion on embedded files in redacted product assessment reports (PARs): the CG secretariat proposed that disseminated PARs should not contain embedded files. For ongoing and future applications, the reference Member State will ensure no embedded files are included in redacted PARs, and granted authorisations where the PAR contains embedded files will be reviewed at renewal, at the latest.

• The CG secretariat proposed amendments to CG rules of procedures, clarifying the participation of Norway and Switzerland in reaching agreements. The two countries can participate in reaching agreement on referrals, but cannot vote on topics requiring formal voting.

• Outcomes from two e-consultations were presented and agreed: one on the use of “as required” for application frequency and the other on the authorisation of a product containing an AS deemed non-necessary for one of the uses claimed.

• The CG secretariat proposed criteria for grouping changes, with discussions to continue in the next CG meeting.

No questions were raised by Member States.

4.2. List of pending Article 36 requests	For information *CA-Dec23-Doc.4.2_Restricted*	**Closed session**

This item was discussed in closed session.

4.3. Discussion on SBP Regulation (Regulation (EU) No 414/2013)	For discussion *CA-Dec23-Doc.4.3*	

The Commission informed that internal discussions are still ongoing on the draft regulation, and that they have opted to have first the formal consultations within the Commission services before presenting a draft text to Member States. The Commission mentioned that they have acknowledged all the comments received previously on the measures proposed, including those from the industry, even if all were not eventually taken on board. An update on the proposal will be presented at the next CA meeting.

4.4. Union authorisation: similar conditions of use	For discussion and agreement *CA-Dec23-Doc.4.4*	

The Commission introduced the document in which it proposed five measures to improve the handling of the condition of "*similar conditions of use across the Union*" and to conclude on the discussion initiated in October 2022. There was general agreement on the Commission's proposals. One Member State indicated that they could not agree as the document was not indicated to be for agreement in the initial draft agenda. The proposals were discussed as follows:

1. Overview of past Article 44 (5) request
   The Commission provided a draft overview to Member States only and asked them to check for correctness by 31 January 2024. The overview will be published.
2. List of cases for which a harmonised solution was found
   Member States agreed on the list of cases provided in the document. On the request of an Accredited stakeholder, the Commission clarified that there is no harmonised definition for professionals/trained professionals and that the solution acknowledges the differences in the national legislation.
3. Gain a better overview of national provisions/policies which may have an impact on the conditions of use of a biocidal product
   The Commission encouraged Member States to proactively analyse their national rules and to provide a list of potential areas of derogation as other Member States and the links to such information. Several Member States provided such an overview before the meeting. One Member State indicated that they also have a list which they will update for publication and share it once it is published. Another Member State indicated that Union authorisation is an important procedure for authorisation and that the possibility for Member States to request derogations should not be limited. The Commission reminded of the purpose of Union authorisation to provide access to the EU market with one authorisation under the same terms and conditions, and not to have an authorisation including adaptation for Member States. Union authorisations should only be applied for if there are similar conditions of use and derogations should be an exemption.
4. Provide guidance to the applicant on the confirmation
   Member States agreed that it would be useful to provide more guidance and a template to the applicant for the confirmation of similar conditions of use they need to provide with their

application. The Commission confirmed that the guidance would make use of and reference to the information gathered under measures 1, 2 and 3.

5. Potential adaptations to the pre-submission procedure
   There was agreement that there are still benefits from the pre-submission procedure and to maintain it for now, and to assess if and how it should be amended to make it more meaningful. ECHA agreed to make an assessment of the current procedure and potential improvements.

The CA document was endorsed.

4.5. Union authorisation: acting as evaluating CA	For information	

ECHA informed that the gathered information will be published on their website in the next days. The link to the information will be provided[1].

4.6. Addition of a new Q&A to the document on Implementing the concept of biocidal product family: Q&A Annex	For discussion and agreement *CA-Dec23-Doc.4.6*	

The Commission reminded key points from the previous CA meeting:

- With regard to handling of ongoing applications and authorisations granted for groups of products not meeting the Biocidal Product Family (BPF) definition, the agreement was to require the applicant to split such groups, in accordance with Section 3.3 of the guidance document.
- Regarding already granted authorisations, considering the discussion at the previous CA meeting, the Commission proposed that they should be amended at the moment of the renewal, that is the eCA to require the applicant to split the BPF (i.e., submission of at least one new application). That proposal was made instead of requesting a single application for change, as some Member States considered unfeasible to the workload implied, and due to the setup of R4BP (i.e., one case generates one asset).
- Another discussed point was the application for change to families authorised in the past that might no longer qualify as a family due to the change. It was proposed that such changes should not be accepted, requiring a separate application for authorisation.

The Commission expressed its intention to reach an agreement on the proposed approach.

One Member State opposed splitting existing BPFs, mentioning increased workload without added value.

A second Member State criticised the Commission's approach, questioning its utility in terms of risk management.

[1] The link was given after the meeting : https://echa.europa.eu/evaluating-competent-authorities-for-union-authorisation

A third Member State supported the previous concerns and did not support the interpretation that BPF containing at the same time products authorised in accordance with Article 19(1) and 19(5) of the BPR does not fulfil the definition of BPF provided in the BPR.

The Commission noted the concerns, but reinstated that that products or uses authorised under Article 19(5) of the BPR cannot be part of the same family as those authorised under Article 19(1) of the BPR, as the legal definition of a biocidal product family is no longer fulfilled, and an assessment at Member State level needs to be made to authorise products under Article 19(5) of the BPR.

One Member State asked if, for uses which can be only authorised via Article 19(5) of the BPR, an application in all Member States would become necessary and expressed concerns about the increased workload. The Commission confirmed this, re-emphasising that this provision is stated in the BPR itself. The Commission acknowledged the unusual nature of mutual recognition for such products but confirmed that this procedure is possible. The details on how to deal with authorisations granted under Article 19(5) of the BPR and subject to mutual recognition will be discussed further in the Seminar on National Authorisations which will take place in February 2024.

The CA document was agreed, noting the positions of the three Member States referred above.

4.7. Seminar on best practices on national authorisations	For information *CA-Dec23-Doc.4.7*	

The Commission provided information on the organisation of the seminar that will likely take place in Brussels on 15 February 2024. The seminar will be organised back to back with the 60th coordination group meeting. The details for reimbursements of participants, venue, etc will be provided soon. The Commission suggested a list of topics to be dealt in the seminar and requested feedback from Member States, and also suggestions on other topics and volunteers to present them in the seminar.

It was emphasised that the objective of the seminar is to share best practices between Member States on key aspects of the system for national authorisations of biocidal products, and called for an active participation to the seminar.

5. Active substances		
5.1. Progression of the review programme on active substances	For information *CA-Dec23-Doc.5.1*	

The Commission introduced the item. In particular, it was mentioned that the Review Programme has been completed only by 47% despite two prolongations of the programme. 37 backlog dossiers are still pending and these need to be prioritized by Member States.

5.2. Progression of the renewal process of approval of active substances	For information *CA-Dec23-Doc.5.2*	

The Commission introduced the item and invited the evaluating Member States to inform the Commission the latest 90 days after the submission of an application if they are willing to perform a

full or limited evaluation. The Commission also mentioned new submissions for applications for renewals and coming deadlines for renewal submissions, highlithing that the work on renewal evaluations is expected to be increased in the coming years.

Two Member States suggested corrections for the table of the agenda item document.

5.3. ECHA Active Substance Action Plan – progress update	For information *CA-Dec23-Doc.5.3*	

ECHA presented the agenda item mentioning that there was no new draft assessment report submitted to ECHA concerning Review Programme substances within the last 3 months. However, ECHA marked the progress made on the evaluation of 5 backlog dossiers.

ECHA mentioned that only about 15 BPC opinions are expected in 2024, some of them corresponding to renewals, which means that no significant progress on the Review Programme would be achieved this year. ECHA will keep monitoring closely the progress of the Review Programme substances together with the evaluating Member States.

ECHA presented the actions referred to the CA document: 1) prioritization of dossiers; 2) support to the eCAs; 3) streamlining the peer review; 4) reduction of complexity.

ECHA also presented the outcome of the ED survey on Member States undertaken in November-December 2023. The Commission reminded that for backlog dossiers evaluating Member States need to assess ED data, but in case these are non-conclusive they can continue their evaluation without requesting additional data from the applicants. The Commission urged Member States again to make progress on backlog dossiers.

5.4. Postponement of the review programme beyond 2024	For discussion and agreement *CA-Dec23-Doc.5.4*	

The Commission introduced the item focusing on the part concerning the ED properties which was not yet agreed in the past CA meetings. It clarified that paragraphs 12(c) and 12(d) of the CA document will still need to be discussed internally after the agreement of the CA meeting.

One Member State supported the Commission proposals on ED but asked to provide additional six months for the related deadlines on ED data. The Commission replied that this cannot be accepted, emphasising that ED requirements are known at least since the adoption of the ED criteria in 2017 and the ECHA-EFSA guidance in 2018, and that ED forms part of the core data set, and that providing more time would make it difficult to reach the target of completing the Review Programme in 2030.

Two Member States supported the Commission proposals on the ED part and asked for more details on the ED data on the environment (non-target organisms). The Commission explained that in case an active substance is confirmed not to meet the criteria for ED on human health, and that all uses of the biocidal product are safe, it is proposed that the evaluating authority could proceed with the approval of the substance and ask for the missing data on ED for the environment in the renewal of approval, through an approval condition. As previously explained, this approach will still need to be discussed internally within the Commission subject to the agreement of the CAs.

Two Member States agreed with the Commission proposals on ED, and one of them asked for a targeted workshop on the matter. Two Member States agreed with such a proposal. The Commission referred to the recent information sessions organized by ECHA, and invited the latter and Member States to organize such a workshop on this topic.

ECHA remarked on paragraph (9) of the CA document, inquiring whether the deadline on three months could be prolonged in case of solid, justified reasons, in particular when the dossier was submitted a long time ago. One Stakeholder Association also stated that trhee months might not be enough for all cases of active substances. The Commission emphasised that dossiers have already been under evaluation for years, and replied that no exceptions on the three months deadline should be provided and that the proposal will not be amended, following also the practice under the Plant Protection Products Regulation. The use of exceptions lead to the major delays in the Review Programme.

The Commission clarified that some of the proposed measures of the CA document will be included in the amendment of the Review Programme Regulation. Some of the ECHA documents related to the matter would also need revision. The Commission emphasised that the approaches proposed in the document (except on paragraphs 12(c) and 12(d)) must already be implemented by Member States wihtout awating for an amendment of the Review Programme Regulation as they are in line with the current Review Programme Regulation.

The CA group endorsed the document. The Commission will start working on the amendment of the Review Programme Regulation.

5.5. Streamlining the process for substances meeting the exclusion criteria	For discussion and agreement *CA-Dec23-Doc.5.5*	

The Commission presented the agenda item, highlighting the input received from the latest newsgroup.

One Member State informed of its concern that the proposed changes in the evaluation process of substances meeting the exclusion criteria could result in delays in the Review Programme. They supported following a first ‘open’ approval of substance meeting the exclusion criteria, and in the renewal phase a detailed evaluation of all possible uses should rather be performed. Two more Member States supported such an approach, while another Member State disagreed with the latter proposal considering that that approach would not be legally possible under the BPR. The Commission also mentioned possible legal barriers on following an ‘open’ first approval approach considering the provisions of the BPR. One Member State replied that they would not see any legal barrier with such an approach. The Commission invited that particular Member State to provide their legal position on the matter in writing.

Another Member State highlighted its proposal for the ‘substitution plan’ (paragraph 19), which could put pressure on the applicants to invest towards alternatives. One Member State replied that they would need to reflect on the Member State proposal. ECHA mentioned that the applicant might not provide a solid substitution plan since they would not have an interest in replacing their substance by alternatives.

One Member State supported the synchronization of the evaluation of several active substances, although they recognized that this might be challenging to apply in practice; still, they would support to adopt such an approach where feasible, e.g. in smaller subgroups of substances. The latter was also

supported by another Member State. ECHA remarked that the synchronization would be very difficult.

The Commission asked for further input on paragraph 16 of the document, underlining that agreeing on which exact uses need to be analysed by the eCA during the evaluation of the substance is a crucial point. One Member State replied that they would prefer to focus only on uses explicitly included and assessed in the application, but they are concerned that without an 'open' first approval some uses might be overlooked.

ECHA recognized the challenge on which uses should be assessed during the evaluation. They remarked that an applicant could always apply for a modification of the approval conditions (if the substance is approved with restrictions) under Article 7 of the BPR. ECHA enquired why the condition of Article 5(2)(a) of the BPR is not included in the revised scheme of the third party consultation in the document. The Commission replied that because the public would not be in capacity to comment on this, considering that the term 'negligible risk' mentioned in that condition has not been precisely defined in the BPR and that it is rather for authorities to judge this aspect. No meaningful input from the public is expected on this, based on the experience seen in previous third party consultations.

A Stakeholder Association expressed their concern that the new scheme for the third party consultation will not leave enough time for the industry, in particular down-stream users, to react and provide detailed-enough feedback on the consultation. They would prefer to have an additional consultation, following the current established practice. Regarding the issue of third party consultation, the Commission noted that this is a challenge for the industry and Member States, who strive to reach the relevant stakeholders. However, the Commission stated that it would no longer support duplication in third party consultation, as it leads to delays and additional work, and the previous process proves to be not so effective. Industry and Member States to better identify channels, users, and markets, and this would enable them to mobilise their networks to gather information when substances are up for discussion. The final decision on whether or not an active substance should be approved is not only based on input coming from the third party consultation, but based on all information gathered, and in particular information and positions from Member States authorities.

Two Member States noted that they were not in a position to endorse the proposal of the document. Another Member State a agreed with the Commission while ECHA accepted the document. ECHA agreed on Article 5(2) consultation process but raised feasibility questions on other elements in the document.

With the exception of the two Member States referred above the CA meeting endorsed paragraphs 14, 15, 17, 18, 20, 21 of the CA document, noting that the questions referred in paragraph 18 could be improved, and that synchronization of active substances (paragraph 20) could be done if specific cases. The approach referred in these paragraphs must be already implemented. In particular, following a question by ECHA, the Commission clarified that the new scheme for the third party consultation should be applicable immediately unless an Article 10(3) consultation has already started.

A newsgroup will be open for further comments on paragraphs 16 and 19, with a deadline on 31/1/2024, to continue the discussion on these aspects.

5.6. Question from Switzerland on an active substance	For discussion and agreement	**Closed session**

This item was discussed in closed session.

5.7. Disodium tetraborate: renewal of approval and biocidal products	For discussion *CA-Dec23-Doc.5.7*	

The Commission presented the agenda item.

One Member State mentioned that the reference specifications of the substance will be defined by the eCA in the renewal procedure. Until the reference specifications are defined under the renewal procedure, it considered that there is no need to take action on the current extensions. Another Member State also agreed with this position.

Another Member State mentioned that an application for major changes could be followed in order to align with only one form of the substance (the pentahydrate form).

The Commission clarified that in Article 95 of the BPR there is currently only the pentahydrate form of the substance, meaning that only this form can be used for product authorizations. The Commission announced to open a newsgroup on the matter to collect the CA members opinions on the way forward by 31 January 2024.

5.8. Discussion on declarations of interest to notify under Article 15(a) of Regulation (EU) No 1062/2014	For discussion and agreement *CA-Dec23-Doc.5.8_Restricted*	**Closed session**

This item was discussed in closed session.

5.9. Information from the Netherlands on a future application to modify the conditions of the Annex I inclusion of carbon dioxide	For information	

The Netherlands informed that they will be the evaluating Member State for a future application to modify the conditions of the Annex I inclusion of carbon dioxide.

No CA member raised any comment.

6 Treated articles
No item for information or discussion

7. Horizontal matters

7.1. Financial assistance to Member States 2023-2028	For information	

The Commission informed Member States about the progress of the grant project: five grants on biocides have already been signed. Signatures are still pending from three Member States, and the Commission invited them to make progress at the internal level.
A specific request was addressed to one Member State for which an administrative document was still missing from one of its ministries, urging them to make progress in the upcoming days to avoid the risk that the grant would not be provided to that country due to missing the deadline.
The Commission invited Member States to make the necessary recruitments to ensure that the work will be performed and progress is made on both active substances and product authorisations. One concerned Member State confirmed that they are still waiting for the declaration of honour from one of its ministries, and is trying to speed up the process at the internal level.

7.2. ECHA communications	For information *CA-Dec23-Doc.7.2.a* *CA-Dec23-Doc.7.2.b*	

ECHA gave a presentation covering updates on the IUCLID SPC solution, satisfaction surveys, Article 75(1)(g) mandates, and the Chesar Platform project.

One Member State asked if the new SPC tool should be used only for new applications or also for ongoing applications. ECHA confirmed that once the new tool is made available, the SPC Editor will be removed, and Member States must use the new tool to prepare the SPC. However, for ongoing cases and products already authorised, the SPCs will be automatically converted into the new format, so no action is required by Member States for these situations.

One stakeholder observer asked if, once the new tools start working, a transition period is foreseen, allowing their members to familiarise themselves with the tool and to facilitate the work of translation offices unfamiliar with IUCLID. ECHA replied that they will not maintain the two systems in parallel. However, if applicants have files in xml format, they can import them into IUCLID, and they will be automatically converted into the IUCLID dossier format. Regarding translations, ECHA invited stakeholder observers to provide in writing concrete examples of issues encountered by translation offices when dealing with the new SPC format. ECHA confirmed they would be willing to help in solving such issues and in providing further instructions, where needed. ECHA also emphasised the possibility for translation offices to train on the new tool already before the go-live date.

On the Chesar Platform project, the Commission reminded Member States wishing to be involved in the project to contact the email address provided by ECHA in the presentation.

7.3. Amendment CA-Dec20-Doc.4.1. Warning sentence and RMM for bees_rev2	For discussion and agreement *CA-Dec20-Doc.4.1. Warning sentence and RMM for bees_rev3*	

The Commission presented the revised document, reminding Member States that the topic had been discussed in several meetings, and invited them to agree on the amended document.

Compared to the previous version, it is proposed that the warning sentence is applied to biocidal products containing hazardous substances to bees regardless of the product-type and field of application (indoor/outdoor).

A Member State asked if the exceptions to this applicability should be extended to cases of major changes. The Commission confirmed they are not required to revise the authorisation unless it is directly related to the topic.

The document was then endorsed.

7.4. ECHA guidance on bees for biocides	For discussion and agreement *CA-Dec23-Doc.7.4-7.5*	

This item was discussed together with item 7.5

7.5. Applicability of ECHA Guidance on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted to produce drinking water	For discussion and agreement *CA-Dec23-Doc.7.4-7.5*	

The item was discussed together with item 7.4. The Commission summarised the current status of the guidance documents, the past discussions on their implementations and presented a proposal for a common approach for the implementation of both guidance documents.
It was proposed that the guidance documents shall apply to all (also on-going) procedures as from the date of publication, except for on-going and future approval procedures for active substances in the review programme in line with the agreements reached on item 5.4 on the agenda.

One Member State, supported by several others, disagreed with the proposal as they consider that the application of the guidance would lead to further delays in all processes due to the resources needed, which would be contrary to the priority of finalising the review programme. One Member State indicated that the guidance needs to be implemented at active substance level before it can be implemented in product authorisation containing the active substance. The Commission reminded that not all uses are assessed during active substance approval which may later be relevant in product authorisation, and explained that for the approach for PPP is simply to apply guidance available at the time of submission of applications (for active substance, and products).

ECHA explained that the water treatment guidance was developed due to a joint ECHA/EFSA mandate from the Commission in 2019 to address transformation products. One Member State proposed that the guidance documents should only be applied to new applications. Another Member State requested that the applicability should not be the same for both documents.

One Accredited Stakeholder Observer indicated that it welcomes the development of the guidance, but that it would not be manageable to implement it without leading to further delays of the processes.

The Commission invited Member States to further consider when to apply the guidance, and take into account the sensitivity of both topics (bees, and drinking water) to consider whether it is really

possible to await many years before applying these guidance, as several Member States requested during the discussion. Also, the Commission further requested Member States to discuss the matter with their hierarchy, considering the political relevance, especially of the bee guidance.

The Commission invited comments and alternative proposals by 31 January 2024.

7.6. Update on Court cases	For information	

The Commission provided an update on Court cases.

7.7. Q&A from Austria on Data / Letter of Access (LoA)	For discussion *CA-Dec23-Doc.7.7*	

The Commission informed that a revised version of the document, incorporating comments from Member States in the newsgroup, has been uploaded. Austria presented the revised document. The Commission expressed gratitude for the presentation, with the objective to conclude the discussions during the meeting.

On requests made by a Member State, Austria responded:

- On question 2 (data protection): it agreed to modify the sentence as follows "*it is recommended that a clear reference to the source of data is given."*
- On question 3: it explained the need for clarity and retained the repeated reference.
- On question 6: it agreed with the proposed reformulation.

Another Member State inquired about the publication of the document and requested a link on the ECHA website for easier access. The Commission confirmed that a revised version with modifications in track changes would be uploaded on CIRCABC.

ECHA expressed concerns and raised points:

- Suggested deleting Annex I.
- Questioned a sentence in section 1) about the right to use data and expressed concerns on how to integrate the document in the practical guide already published on their website.
- Sought clarification on date references in the document.
- Proposed removing a sentence in question 5 about parallel evaluation.
- Questioned references in question 6 to CAR reports for substances of concern.
- Asked for clarification on the responsibility of the applicant for data used in other regulatory frameworks.

Austria answered to several points raised by ECHA:

- Agreed to delete Annex I.
- On question 1: Clarified the meaning of "*having access*" and suggested ECHA to provide advice concerning the wording
- On question 6, point c: Explained the reference to CAR reports for assessment.
- On question 6, point b: Confirmed it as a recommendation, not a requirement.
- On question 5: Agreed to delete the paragraph if deemed problematic.

• On responsibility for data use: Acknowledged unclear phrasing and provided a revised statement.

The Commission concluded that the CA group endorsed the document. Its publication will be however delayed until the end of January so that ECHA can further check whether some modifications would still be needed. If further issues are identified, they would be discussed at the next CA meeting, while otherwise, the final version as agreed during this CA meeting will be published.

7.8. ECHA guidance priorities	For discussion and agreement *CA-Dec23-Doc.7.8.a* *CA-Dec23-Doc.7.8.b_Restricted*	

ECHA introduced the revised document and expressed the wish to reach an agreement on it.

The Commission raised concerns about section three, specifically regarding table 3 for the entries 'Revision of existing and new emission scenario,' 'Revision of Biocides Human Health Exposure Methodology,' and 'Guidance for dietary risk assessment.' The Commission questioned the need for revising the existing guidance, considering the priorities in the implementation of the BPR and asked Member States to share their views.

Concerning 'Guidance for dietary risk assessment,' the Commission emphasised the need for harmonisation in the context of One Substance One Assessment and questioned the necessity of developing a specific methodology for biocides. The Commission suggested utilising existing guidance if applicable and asked ECHA to clarify if these could be used.

ECHA provided additional background on the entries in the table:

- On 'Revision of existing and new emission scenario,' ECHA explained the challenges arising during evaluation, triggering the need for revision.
- Regarding 'Revision of Biocides Human Health Exposure Methodology,' ECHA highlighted emerging issues and misalignments with current guidance.
- On 'Guidance for dietary risk assessment,' ECHA justified its inclusion due to the interim approach needing revision. On the latter, the Commission referred to the need first to progress on discussions on MRLs management, before discussing on further work.

Member States expressed support for updating existing guidance but suggested prioritising certain projects, such as the Chesar platform. They proposed sending written comments to specify which documents should continue receiving attention.

A Member State emphasised prioritising Table 1 and Section 2, noting that revisions often take precedence over creating new guidance. The Member State proceeded to indicate that priority should be given to those guidance revisions addressing issues that hinder the assessments.

Section 1 and 2 of the document were agreed.

The Commission announced a newsgroup open until January 31 for comments from Member States concerning section 3 of the document, to ensure the scope of the prioritised projects is limited to what is really needed, and conclude the discussions at the next CA meeting.

7.9. Information from AISE on a 'COVID-19 lessons learnt' exercise	For information *CA-Dec23-Doc.7.9*	

AISE and CEFIC presented their lessons learnt exercise.

One Member State emphasised differences among Member States, highlighting that Article 55(1) derogations are used not only during pandemics but also to address various emergencies. They shared experiences from the past decade, noting challenges in implementing Art 55(1) of the BPR due to limited capacity of the eCA for supervising products with temporary permission.

Another Member State thanked AISE, emphasising the report's value in understanding how different Member States handle Article 55 derogations. They proposed a discussion among Member States to share their views and experiences.

The Commission suggested creating a newsgroup until 31 January 2024 for Member States to submit comments. Additionally, if Member States see a need to harmonise the practise, it encouraged Member States to consider whether this is a priority considering the other works in the implementation of the BPR, and to consider taking the lead for developing a document on good practices for emergency authorisations.

7.10. Information on future training on the evaluation of micro-organism (BTSF)	For information	

The Commission announced that a second session of the training on the risk assessment of micro-organisms will be organised from February 2024 until March 2025. Human health and environment experts are invited to contact their Better Training for Safer Food (BTSF) contact points directly for more information and registration[2].The training is not open to non-EU countries (e.g. UK) but Switzerland, EFTA, candidate and potential candidate countries can participate.
No remote participation is possible, only physical attendance. Compared to the first session, the new training will cover the new data requirements on micro-organisms adopted under the Plant Protection Products Regulation, some additional explanatory notes and cross-sectorial matters.

7.11. Information from DG GROW on a proposal of restriction of sensitisers in certain articles under REACH	For information	

DG GROW introduced the agenda item through a power-point presentation.

One Member State inquired about the different definition under REACH of '*placing a treated article in the market*' compared to BPR definition. DG GROW confirmed that the definition under REACH is broader and includes also what corresponds to the '*making available in the market*' under the BPR.

Another Member State indicated to have already had internal discussions on REACH restrictions, based on which they are having concerns if the restrictions set in the approval Regulations of active substances under the BPR are always enough to regulate properly the treated articles.

[2] Available at BTSF: BTSF National Contact Points List (europa.eu).

The Commission asked Member States to liaise with their national authorities working on REACH on the matter. They announced to open a newsgroup by 31 January 2024.

7.12. Information from the Netherlands on its Strategic framework for the use of biocides to prevent and control unwanted organisms	For information *CA-Dec23-Doc.7.12*	

The Netherlands presented the strategic framework as outlined in the document.

The Commission expressed gratitude for the presentation and announced the opening of a newsgroup until 31 January 2024 to invite Member States to share their comments or questions to the Netherlands.

8. Scope matters
No item for information or discussion

9. Enforcement issues

9.1. Summary of report of the second BPR enforcement project (BEF-2)	For information	

The Chair of the BPRS Working Group responsible for managing this project, delivered a detailed presentation on the findings of the second harmonised enforcement project, focused on control of products available on the market.

The Commission urged industry associations to disseminate information about the BPR so that operators are aware of their obligations under the Regulation, emphasised the importance of compliance with its provisions, and reminded Member States that the conclusion of the review programme largely relies on their cooperation.

10. International Matters
No item for information or discussion

11. AOB

(a) List of Competent Authorities and other Contact Points	For information	

The Commission invited Member States to inform them in case of changes to be made, so that the list can be updated before the next CA meeting.

(b)	Consequences on wood preservatives products containing propiconazole following the renewal of approval of the active substance	For information	**Closed session**

This item was discussed in closed session.

(c)	Information from Denmark on a question on disinfection swabs used for pre-injection	For information	**Closed session**

This item was discussed in closed session.