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

MINUTES

101st meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

28-29 September 2023

1. Adoption of the agenda	For adoption *CA-Sept23-Doc.1*	

An AOB point was added concerning the meeting of the OECD Working Party on Biocides held in September 2023, at the request of one Member State.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Sept23-Doc.2.a* *CA-Sept23-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-Sept23-Doc.3.1*	

The Commission introduced the document, highlighting the recent editorial revisions applied to the draft proposal and the written contribution received by one Member State concerning the wording in the restriction described in the draft Annex. That Member State provided more details about it.

Another Member State questioned the latest modification proposed to the draft Annex, proposing a more flexible wording (including the statement 'if necessary'). A discussion followed on this, and the Commission concluded to a provide revised wording of the restriction in the draft Annex, which would be shared via email with the CA members for their feedback. That email would be sent immediately after the CA meeting by the Commission and the CA members will be invited to respond by 15 October.

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 information	

The Commission mentioned that a draft proposal will be presented in the next CA meeting. It remarked that the draft proposal will follow the exact wording of the past Delegated Regulation that extended the duration of the Review Programme until 31/12/2024. The new proposal will extend the Review Programme until 31/12/2030.

No comments were received from the CA members.

4. Biocidal products		

4.1. Report from the Coordination Group	For information	

The Commission presented the key points discussed and agreed during the 58th Coordination Group (CG) meeting that took place on 19-21 September 2023 (CG-58), held in Odense at the Danish CA premises. The Commission expressed gratitude to the Danish CA for hosting the meeting.

Main points from the meeting:

- Two formal referrals were discussed, with agreement reached on one of them;
- Several documents were published on the ECHA website, focusing on post-authorisation conditions for biocidal product authorisations and procedures for the submission, evaluation, and dissemination of data generated after active substance approval. As a result of this publication, several CG documents became applicable;
- Agreement was reached on the update of templates, including templates for supporting documents for changes and applications for the same biocidal products;
- The CG secretariat reminded that, for document dissemination, the assessment report is generally published on the ECHA website as a PDF file. Sometimes the product Assessment Reports (PARs) in word format contain embedded files that are not visible once converted to PDF. It was proposed that documents would not be embedded in the PAR anymore to ensure that users have full visibility of the content of the PAR. Discussion on this topic will continue.

4.2. List of pending Article 36 requests	For information *CA-Sept23-Doc.4.2_Restricted*	**Closed session**

This item was discussed in closed session.

4.3. Modification of Regulation 492/2014 on renewal of authorisations under mutual recognition	For information	

4.4. Discussion on SBP Regulation (Regulation (EU) No 414/2013)	For information	

The Commission has informed that, regarding points 4.3 and 4.4, no document has been distributed, as the Commission is still in the process of analysing the comments received on these topics. Specifically, with regard to the SBP Regulation, the Commission has received numerous comments and needs additional time for internal reflection. While the Commission is committed to addressing all concerns raised by Member States and industry, it also emphasised the importance of maintaining a manageable system. It was communicated that the two updated documents on these points will be presented at the CA meeting in December.

4.5. Union authorisation: similar conditions of use	For discussion *CA-Sept23-Doc.4.5*	

The Commission expressed the intention to continue the discussion on the identification of "similar conditions of use across the Union" as a condition for Union authorisations which was initiated several meetings ago and presented the document summarising the comments received on the proposals to further refine the definition and the procedure to identify similar conditions of use at the previous meeting. The written feedback received was limited and there was no strong support for the proposals made. Member States agreed that the definition should not limit the possibility for Member State to submit requests for derogations and that the procedure should not cause additional work. There was no clear view on who should assess and decide on the fulfilment of the requirement. The Commission had requested Member States to provide an analysis of their national legislation and policies and to indicate case where they would see a need to make a request for a derogation. Only one Member State provided the information that they publish a list of cases where they would derogate in accordance with Article 37 of the BPR and that they would provide an English translation of that list. The Commission requested the other Member States to also make such an analysis and overview.

One Member State supported a pragmatic approach when it comes to issues not harmonised by EU law but regulated by national law, in particular the definitions of the user categories "professional" and "trained professional", as a request for derogation should be avoided in those cases. It was mentioned that currently the issue of potential national differences of definitions of user categories is tackled by a specific sentence that is included in section 6 of the SPC of Union authorisations if relevant. That Member State requested to agree that this sentence should be included in the SPC of Union authorisations systematically. Another Member State supported that the sentence would sufficiently address this point.

One Member State proposed to have a list of cases where solutions like for the differences in user categories were found (e.g. also for the national OELs). The same Member State indicated that they agree that cases of derogations should be identified as early as possible in the process but it would not always be possible to do it in the beginning due to a complex national opinion-forming process.

ECHA explained their view that, while the BPR requires the applicant to submit a confirmation that there are similar conditions of use across the Union, it only allows ECHA to reject the application in case of the failure to pay the requested fee or absence of eCA. They emphasised that there is the obligation for the applicant to submit the confirmation and that a starting point should be to provide guidance and criteria for the applicant to provide such a confirmation and how it could be substantiated. The Commission raised the question if there would be sufficient information available for applicants to be able to provide such a confirmation without the involvement of the Member State.

The Commission encouraged Member States to provide further written reflections in the newsgroup by 31 October 2023 and to especially provide an analysis of their national legislation and policies which would trigger requests for derogations.

4.6. Union authorisation: acting as evaluating CA	For information	

The Commission informed that the information received will now be published by ECHA as a source of information for applicants. ECHA explained that it is intended to publish the information soon in a clear and visible manner on the ECHA website and that the publication will be communicated in "ECHA weekly" to ensure that all stakeholders receive the information once it is published. Member States should contact ECHA in case any changes to the information would be necessary or if they would like to add their information to the list.

4.7. Presence of misleading terms in biocidal products trade names	For discussion and agreement *CA-Sept23-Doc.4.7* *CA-June23-Doc.4.9.rev1*	

The Commission informed that a cover note was distributed for the meeting summarising what has been done since the last CA meeting together with an updated annex of the list of non-allowed terms. The Commission recalled that at the last meeting an agreement was reached on the approach to be adopted for problematic trade names. The only point that was not agreed by Member States concerned the non-exhaustive list of terms that are not allowed in trade names. The Commission provided a summary of its proposal, taking into consideration the comments provided by Member States, and invited them to share their views.

One Member State agreed with the list and informed that in its territory, for products authorised according to their national law, they have forbidden the term "baby" in trade names. They asked if it is possible to add this term to the list.

The Commission recalled that the list is not exhaustive, meaning that each Member State can conduct its assessment on trade names and make the decisions they consider appropriate. They also reminded that another Member State had requested to include the term "kids" in the list, but in some cases, such as repellents developed for children's use, the term "kids" is appropriate.

Another Member State welcomed the proposal, but had some observations:

- On the term *"eco",* they suggested introducing an exception when the term means "economic."
- Regarding the terms *'med,' 'medi,' or 'medical',* they considered it inappropriate to ban them because certain biocidal products can be used for instance for disinfecting surfaces in hospitals and in those cases these terms do not mislead users.

One Member State agreed with the list but disagreed with discriminating between *"eco"* as "ecological" and *"eco"* as "economic" because they considered that even the term "economic" could be misleading for biocides. The Commission suggested that the term *"eco"* itself should not be allowed in any case, with the only exception being for specific company names containing the term, and it was agreed that if *"eco"* is part of the company name and that name appears in the trade name, it should be allowed.

One Member State disagreed with the proposal to include the terms '*med,' 'medi,' or 'medical*' in the list, arguing that disinfectants can be used in the medical area, and restricting these terms in trade names or on the label would lead to the closure of the market. The Commission clarified that the discussion is only about trade names.

A Stakeholder Observer also raised concerns about the inclusion of the terms '*med,' 'medi,' or 'medical*.' They explained that in a hospital setting, there are products used for the disinfection of surfaces that are biocidal products and should pass several test conditions to be used in medical areas, according to ECHA efficacy guidance. Using those terms in the trade names is a way for companies to indicate that those products have met strict testing requirements, thus ensuring clarity and enabling users to identify products that meet these specific needs. They believe that using these trade names for professional users should not be considered misleading and consider it disproportionate to include them in the list.

The Commission concluded that the terms '*med,' 'medi,' or 'medical'* will not be included in the list but reiterated that, as the list is not exhaustive, Member States can make the decisions they deem appropriate at their level, depending on the specific cases they examine.

4.8. Addition of a new Q&A to the document on Implementing the	For discussion and agreement *CA-Sept23-Doc.4.8*	

concept of biocidal product family: Q&A Annex	*CA-July19-Doc.4.2. Guidance note on BPF concept_rev3*	

The Commission presented the document, recalling that an amendment to the guidance was presented at the last CA meeting and invited Member States to provide their views.

One Member State informed that they have an ongoing case in which the applicant split the family. This Member State questioned the need for two changes to split the family.

The Commission explained that an application for a change results in one amended authorisation. Therefore, to have two amended authorisations, two changes would be needed, resulting in two authorisations. The Commission invited ECHA to provide more details considering their knowledge of the R4BP platform.

Another Member State confirmed that the majority of their cases are related to BPF families for PT 19. They believe that splitting the family to authorise the products with two separate decisions would add unnecessary work for applicants and Member States without providing any added value. Regarding point 9) of the document, they suggested postponing the splitting of the family at the renewal stage and accepting minor/major changes in the current authorisation. They also asked for more clarification on the process of splitting and confirmation that there would be two different decisions in the end. For ongoing applications that are almost finalised, they inquired if there would be only one product assessment report.

Another Member State agreed with the previous Member State, stating that the approach presented in the document would create a significant workload for applicants and eCAs, without adding value to risk management since the products would anyway be eventually authorised. They suggested managing this as pragmatically as possible and accepting a single PAR, as proposed by the other Member States, to avoid increasing the workload.

One Member State informed that they have one case that is already closed and invited ECHA to provide guidelines on how to split this asset in R4BP. ECHA suggested using the same approach as for ongoing cases: change the existing asset and have a new application submitted. They also considered the need to establish timelines for harmonising the procedure.

To facilitate splitting cases, one Member State suggested a technical solution in R4BP, namely the reverse to the merge of products into a family. The application could be duplicated, which would be the easiest way for the eCA.

ECHA replied that the splitting of families needs to be implemented soon, while adapting R4BP cannot occur in the short term due to the need to include the item in the backlog requests, analyse feasibility, consider development options, and address financial considerations. They confirmed that in the long term, this could be a solution, but in the immediate term, a different approach is needed.

One Member State raised the point that if families are split, the same trade names should not be used for both cases. Therefore, document CA-June23-Doc.4.9.rev1 should be updated.

Another Member State commented that different trade names should be used if one product is authorised under Article 19(5) and another one under Article 19(1).

The Commission concluded that, to apply the pragmatic approach suggested by Member States concerning the splitting of the family at the renewal stage, they would need to revise the document, removing the part on changes ("if the change is applied for before renewal…") and present it at the next meeting. They also confirmed that they will reflect on how to deal with trade names in those cases.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-Sept23-Doc.5.1*	

The Commission presented the document giving an overview of the progress of the review programme. It also informed that there are still 40 backlog reports submitted before 1st September 2013 for which finalisation is pending. Overall, 45% of the review programme has been achieved.

No comments were received from the CA members.

5.2. Progression of the renewal process of approval of active substances	For information *CA-Sept23-Doc.5.2*	

The Commission presented the status report concerning this part of the activity. It reminded the Member States that they need to inform the Commission within 90 days after the acceptance of the renewal application by ECHA whether they intend to perform a limited or full evaluation, to allow the Commission to start preparing the necessary extensions concerning the substances, if needed.

As indicated in the Appendix of the document, the Commission informed that for the active substances tralopyril and chlorfenapyr the deadline to submit a renewal application is closing soon. A Member State informed that an application for the renewal of approval of tralopyril for PT21 was recently submitted to their evaluating competent authority.

Another Member State highlighted that acrolein for PT12 should be erased from the list of renewals since a non-renewal decision has been already taken, which was noted by the Commission.

5.3. ECHA Active Substance Action Plan – progress update	For information *CA-Sept23-Doc.5.3*	

ECHA gave a presentation of the progress of the Active Substance Action Plan. No questions were raised by Member States.

5.4. Postponement of the review programme beyond 2024	For discussion and agreement *CA-Sept23-Doc.5.4*	

The Commission introduced the item and recalled the past discussions on the topic. They noted that there is still no agreement on how to manage substances meeting the endocrine disrupting (ED) properties and presented several concrete proposals on the matter.

Four Member States generally supported the document; however, they raised some concerns and/or expressed disagreements on specific points.

One Member State would support the postponement of renewals of approval also for exclusion substances. They proposed that a workshop with evaluating competent authorities (eCAs) and ECHA could further support the progress with the review programme. They also proposed to share finalised assessment reports with other eCAs. The Commission welcomed the latter.

A second Member State did not support the non-suspension of the evaluation pending a RAC opinion. They also proposed that the deadline for eCAs to request ED data from the applicants should be extended to 31/12/2024, and that applicants have to submit requested ED data by 31/12/2027 (instead of 2026).

They also supported that ED evaluation for environment should be performed in full, regardless of whether the substance is not an ED for human health.

A third Member State inquired about the scenario that the applicant cannot find a laboratory to perform the requested ED studies and thus is unable to meet the deadline of 31/12/2026 proposed in the document. The Commission mentioned that this could be considered if justified. A fourth Member State supported option #3 of paragraph 14(c) of the document for active substances meeting already other exclusion criteria and option #1 of paragraph 14(d) for substances confirmed as not meeting the ED criteria for human health, and for which the ED data for the environment are still missing. They did not agree with the deadlines given for eCAs and the applicants regarding the ED data requests and submissions, respectively. They were in favour of a step-by-step approach, which would ensure minimum animal testing. The Commission argued that no step-by-step approach is followed in the Pesticides Regulation (PPPR) where the same provisions apply regarding animal testing.

ECHA supported the Commission proposals but mentioned that for some active substances there might be the need to await the RAC opinion. They supported the fixed time window for ED testing and mentioned that the ED guidance of ECHA follows a step-by-step approach but this can be adapted accordingly (like in PPPR) and ask data of higher level in order to speed up the process. In addition, ECHA will conduct a survey, as proposed by the Commission, in order to collect information on the state of play of ED evaluations of review programme substances. Regarding paragraph 15, point (f) of the document, ECHA remarked that that lacking consensus on BPC opinions may result in requests to ECHA to address minority opinions, thus delaying the process.

One stakeholder observer did not agree with paragraph (11), where it is mentioned that eCAs may give the applicant the opportunity to submit new specific data within a specified and limited timeframe which should not exceed three months, mentioning that three months might not be enough in all cases of active substances. On the take-over mechanism, they asked if it will be allowed to substitute the applicant maintaining the dossier under examination. The Commission replied positively.

The Commission informed that a newsgroup will be opened and invited CA members to submit comments by 31 October.

5.5. Streamlining the process for substances meeting the exclusion criteria	For discussion *CA-Sept23-Doc.5.5*	

The Commission introduced the item, highlighting the difficulties faced during the evaluation of substances meeting the exclusion criteria and made proposals for speeding up the process. The Commission marked that these proposals are only preliminary, and that a related newsgroup will be opened.

One Member State generally supported the document but noted they need more time to thoroughly assess it.

Similarly, two other Member States mentioned that they need more time to reflect on the document and that they will send their comments in writing. One of them mentioned a proposal for a substitution plan requirement for the applicant, which was briefly mentioned in the last CA meeting.

ECHA pointed out that several elements in the evaluation process of substances meeting the exclusion criteria need to be clarified. The Agency supports a single consultation early in the process. ECHA raised concerns about the proposal to consider alternate exclusion/substitution substances in the analysis of alternatives. This practise had shown to not be effective to their view. In addition, ECHA raised some concerns on the proposal that the BPC provides an opinion on the derogation conditions of Article 5(2), due to expertise and resources issues.

A stakeholder observer highlighted the need to ensure that downstream users participate in the public consultations concerning the substances meeting the exclusion criteria. Another stakeholder pointed out that the proposed merging of the two consultations, performed early in the process, should be considered with caution, since it might not always be possible to mobilise downstream users that fast. So to give them the possibility to be involved, input at a later stage should still be made possible in one form or another.

The Commission informed that a newsgroup will be opened and invited CA members to submit comments by 31 October.

5.6. One substance one assessment	For discussion *CA-Sept23-Doc.5.6*	

ECHA introduced the item, providing an update on the actions concerning the One Substance One Assessment (1S1A).

No comments were received from CA Members.

The Commission informed that a newsgroup will be opened and invited Member States to submit comments by 31 October on the ECHA document.

5.7. ECHA plan to structure active substances data in IUCLID format	For discussion and agreement *CA-Sept23-Doc.5.7a* *CA-Sept23-Doc.5.7b* *CA-Sept23-Doc.5.7c*	

ECHA introduced the agenda item, proposing a roadmap for transferring active substance data into the IUCLID format (IUCLID project).

One Member State supported ECHA's document but proposed to exclude one active substance initially included in the IUCLID pilot study. ECHA mentioned that they will seek alternative active substances to be included in the pilot study.

A second Member State inquired about the impact of the pilot study on the timeline of the IUCLID project. They also inquired about the case of renewals of approval where no data are submitted by the applicant but instead a letter of access. ECHA remarked that the pilot study is expected to speed up the process and the timeline proposed in the document can be revised based on the progress of the IUCLID project. Concerning the issue with the letter of access, ECHA acknowledged the difficulty of such case and pointed out the need to consider the issue together with the ongoing discussion under the topic of the letter of access in the frame of the CA meeting.

A third Member State welcomed ECHA's proposal but they still pointed out their concerns on the workload brought by the validation step. ECHA replied that the validation step should require minimum work from the side of the Member States.

Another Member State mentioned that they will not support the roadmap unless it is clarified in it that the IUCLID project will not affect the work on review programme substances. ECHA and the Commission clarified that the proposed IUCLID roadmap will not affect review programme substances, but it is applicable only to the renewals of approval of active substances.

Finally, a stakeholder asked that it should be ensured that future versions of IUCLID will preserve the information included during this exercise in the current version of IUCLID and ECHA replied positively.

The Commission announced that based on the CA members comments, the document is endorsed by the CA group.

5.8. Question from Switzerland on an active substance	For discussion *CA-Sept23-Doc.5.8*	**Closed session**

This item was discussed in closed session.

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 recalled that during the June CA meeting, Member States were informed that ten applications for biocides were received and evaluated. Following exchanges with Member States, nine of them were accepted, while one was withdrawn. The acceptance letters were circulated to Member States concerned during the summer.

They have also received the information that the grant agreements will be signed in November.

7.2. ECHA communications	For information	

ECHA gave a presentation covering updates on the IUCLID SPC solution, satisfaction surveys and a staff update. The Commission noted that the significant interest in attending the IUCLID SPC training is very positive and thanked ECHA for sharing information about the satisfaction survey. With regard to the IUCLID SPC training, one Member State enquired about the possibility of hybrid training. ECHA clarified that only physical attendance is foreseen, as they believe that in-person participation offers more benefits.

7.3. Amendment CA-Dec20-Doc.4.1. Warning sentence and RMM for bees_rev2	For information	

The item was provided for information since more time is needed for the finalisation of the criteria for the applicability of the warning sentence, as harmonisation with plant protections products sector is sought. To this aim, the Commission will discuss internally for the preparation of the proposal for biocides. The item is planned for the next CA meeting in December 2023.

7.4. Applicability of ECHA Guidance on the impact of water treatment	For discussion and agreement *CA-Sept23-Doc.7.4*	

processes on residues of active substances or their metabolites in water abstracted to produce drinking water		

ECHA explained that the final version of joint EFSA/ECHA guidance has now been published on the EFSA website and that there is a link on the ECHA website to this publication with the information that the time of applicability of the guidance for biocidal products is still under discussion. In the meantime ECHA also provided response to the comments received from Member States during the commenting phase. ECHA introduced a revised document to continue the discussion on the applicability of the guidance which was initiated at the last meeting. In accordance with the course of discussion of the last meeting it was proposed that the guidance document should not apply to active substances of the review programme to avoid further delays but to new active substances and in renewal procedures or on a case-by-case basis, if there are indications that water treatment may have a critical impact on residues or metabolites.

Some Member States explained that they consider the approach of the guidance document too complex and that it would be a further burden for the evaluation. One Member State proposed that the BPC Working Group should play a role on the decision if an assessment would be necessary. Another Member State proposed to not apply the guidance to any procedure until the finalisation of the review programme. It was agreed that Member State could provide their proposals to ECHA and that a new document will be presented at the next CA meeting to finalise the discussion on the applicability.

7.5. Technical equivalence and *in situ* generated active substances	For discussion *CA-Sept23-Doc.7.5*	

ECHA presented the document, clarifying that the point was intended for discussion and not for agreement.

The Commission thanked ECHA for the presentation and inquired about a potential timeline for the consultation regarding the in situ ad hoc working group of the CA meeting

ECHA responded that they aim to consult the *in situ* ad hoc working group before the next CA meeting but acknowledged the complexity of the discussions, making it difficult to provide an exact timeline.

One Member State welcomed the proposal and emphasised the importance of ECHA taking steps to harmonise, even though they were aware that this would increase ECHA's workload.

Another Member State expressed their concerns about the issue and welcomed ECHA's action. It favoured retaining the step at the active substance approval to establish the reference specification for the in-situ active substance. The Member State also appreciated option 4.2 outlined in the document, as minor changes in the composition of precursors could affect the in-situ active substance composition, presenting a tangible issue for further discussion.

ECHA noted that the terminology for in situ is complex, highlighting that what is generated as in situ active substances depends on the specific product and conditions, making it challenging to anticipate all variations. Consequently, the definition of what has been approved would remain open.

One Member State inquired about the possibility of not having a technical equivalence assessment for *in situ* active substances. ECHA explained that there were two main possibilities:

- If technical equivalence was not considered for in situ generated active substances, the verification would occur at the product authorisation stage. However, this might result in additional work for

the eCAs to be performed during product authorisation, making more difficult to comply with the timelines for product authorisation.

- The second approach would involve developing different ad hoc solutions for the establishment of technical equivalence of in situ active substance

One Member State raised concerns about the shift of technical evaluation to the product authorisation stage and the situation where the content of the in situ active substance in the product would be outside the range set as reference specifications established at the approval stage.

ECHA concluded that, due to the multitude of divergent views and the complexity of the matter, discussions will continue with Member States Competent authorities and accredited stakeholders. In addition, the in situ ad hoc working group will be consulted on legal matters. The Commission invited ECHA to work on concrete cases to facilitate the discussion with non-experts.

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-Sept23-Doc.7.9*	

Austria recalled that they presented a document containing questions and proposed answers during the last CA meeting and received comments in the newsgroup. They attached these comments to the document without altering the answers, as they intend to have further discussions with Member States before finalising the document.

On points 1, 2, and 5, no Member State raised objections.

On Point 3, one Member State expressed concerns about how to justify the proposed approach to the applicant. Austria thanked them for the comment and suggested redrafting the question as follows: "If the applicant intends to purchase a complete AS dossier, what data should the letter of access cover?"

On Point 4, Austria proposed reformulating the question for this point as well: "If the applicant intends to gain access to a complete product dossier, what data should the letter of access cover?"
On Point 6, Austria informed that they will amend the text in line with the comments received. ECHA commented that data on active substances from other regulatory frameworks also relates to the area of One Substance One Assessment, and highlighted numerous open questions. They emphasised the importance of aligning with a practical guide from 2015 to avoid conflicting documentation.
The Commission informed that they would continue internal reflections and consult the legal service. The newsgroup will remain open for further input from Member States.

On point 7:
Austria commented that this point concerns more Competent Authorities and ECHA. It proposed to remove the question, suggesting it should be forwarded to ECHA since it is more of a procedural question and less regulatory in nature. ECHA agreed with this proposal.

The Commission thanked Austria for the document and mentioned they would await the updated document to upload it in the newsgroup, and will invite Member States to provide their comments by 31 October 2023.

7.8. Presentation of Belgium on a survey concerning the use of biocidal products PT1, 2 and 4 by the general public	For information	

Belgium presented a survey concerning the use of disinfectants by the general public, and the Commission appreciated the presentation, particularly highlighting the importance of educating the public on reading labels and instructions.

One Member State sought clarification on the figures related to reading difficulties mentioned in the presentation. Belgium explained that some people find labels unclear, especially in PT 1, due to small text size or scientific language. They noted that label clarity can vary among producers. Some individuals may not see the need to read labels, and using pictograms is seen as a potential solution to address language issues.

7.9. Presentation of European Biosafety Association on the availability of products for biosafety	For information	

The Commission introduced two representatives of the European Biosafety Association (EBSA), who wished to raise concerns regarding the availability of products for use in the biosafety sector. The Commission recalled that EBSA had sent a letter in 2022 outlining their concerns, and the Commission had responded to it. The letter and the response were shared with Member States at that time.

The Commission questioned the actual connection of their concerns with the BPR and the alleged negative impact of the BPR on the availability of disinfectants, as currently most disinfectants are made available on the market under transitional rules. The Commission also recalled that the choice of uses and field of use is at the discretion of the applicant.

They added that Article 55(1) of the BPR allows the use of non-authorised products if it can be demonstrated that these products are necessary to address a specific danger. In such cases, it is possible to apply to the Competent Authority, which may decide to grant a temporary permit for the use of that product.

The Commission invited Member States to provide their views.

One Member State supported the Commission's opinion, affirming that it is indeed the responsibility of the applicant to propose claims. Since most products are still under a transitional period, making an appropriate request to the CA is necessary if they are needed.

The Commission encouraged EBSA to reach out to industry associations, which are closer to the applicants, for issues related to claims and uses and to competent authorities in relation to potential derogations, as most disinfectants are currently made available on the market under transitional rules, which can vary from one Member State to another.

7.10. ECHA Guidance priorities	For discussion *CA-Sept23-Doc.7.10*	

ECHA presented a document intended for discussion and invited Member States to provide feedback.

One Member State raised three points:

1. They connected Belgium's presentation about people not always reading labels to ESD for PT18, emphasising the need to check for enforceable mitigation measures when exposure is anticipated.
2. They noted that the environmental part is included in disinfection products in the new version, but the human part is missing. They requested its reintroduction.
3. Regarding Union Authorisations and the recent issues related to maximum residual limits, they stressed the importance of eventually replacing current interim measures with a formal BPR approach.

ECHA thanked for the comments and committed to considering them, with a follow-up for Member States.

The Commission also announced the opening of a newsgroup until 31 October.

7.11. ECHA guidance on bees for biocides	For discussion *CA-Sept23-Doc.7.11.a* *CA-Sept23-Doc.7.11.b*	

ECHA summarised the progress of the ECHA Bee guidance and informed that no comments were received in the written consultation of competent authorities. The guidance expert group seeks feedback from Member States on the regulatory consequences of sublethal effects and on the applicability date of the ECHA Bee guidance.

A presentation was given by a member of the guidance expert group on the technical aspects of the sublethal assessment, as background information for the discussion point. Member States were invited to reflect internally on the possible regulatory consequences when an active substance is identified as having concerns for sublethal effects. Member States should also coordinate internally with the authorities for plant protection products since a similar discussion is taking place under the Plant Protection Product Regulation framework. A newsgroup will be opened to collect feedback from Member States. This discussion is taking place separately from the ECHA Bee guidance finalisation and will not have an impact on the publication timelines.

Member States were asked to provide feedback on the applicability date of the ECHA Bee guidance for active substance under review programme, new active substances, renewal process and for product authorisation. It was noted that the applicability date of the EFSA Bee guidance has not been fixed yet either. When deciding on the date, the time required for toxicity studies should be accounted for. Considering the general need to speed up the review programme, it was noted that the ECHA Bee guidance may need to start to be applied to substances in the Review Programme only at the renewal stage.

A newsgroup will be opened to collect feedback from Member States as conclusion by them on the applicability date(s) will be needed before the publication of the ECHA guidance.

8. Scope matters		
8.1. Monitoring products containing attractants to rodents	For discussion and agreement *CA-Sept23-Doc.8.1*	**Closed session**

This item was discussed in closed session

9. Enforcement issues		
9.1. Findings from the second BPR enforcement project (BEF-2)	For information	

The Commission presented the main findings of the second harmonised enforcement project and informed that the report will be published on the ECHA website in the coming weeks.

They recalled that the operational phase, that is the inspections phase of the project, took place last year. The topic was the inspection of biocidal products, including those authorised under the BPR and those made available on the market under the transitional measures. Additionally, some optional modules covered Article 19(5), labelling, advertising, chemical analysis, and a specific module regarded disinfectants made available on the market.

All Member States participated in the project, resulting in the inspection of 3,700 products. A quarter of these products were products authorised under the BPR, while three quarters were products made available under the transitional measures. The inspections were predominantly on-site inspections.

The main finding is that 18% of the products displayed at least one non-compliance issue, which is a notably high percentage. Other findings concern Article 19(5), where around 1,000 products were inspected, and the non-compliance rate is 4%. For labelling in national languages, the findings were positive as only 1% of products still lacked labels in the national languages. However, regarding the inclusion on the label of all mandatory points in Article 69(2), the non-compliance rate was higher, standing at 20%. Chemical analysis was also conducted, and for three quarters of the products inspected, primarily PT1 and PT2, the content of the active substance was correct, while in 6% of the cases the concentration of the active substance was higher than what indicated on the label and in 19% of cases it was lower.

The Commission concluded that at the next CA meeting a more detailed presentation and figures will be presented.

10. International Matters
No item for information or discussion

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-Sept23-Doc.11.a*	

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) Update from The Netherlands on the OECD Working Group on Biocides	For information	

The Netherlands provided feedback on the OECD Working Group on Biocides held in September and extended an invitation to Member States to attend the upcoming meeting scheduled for 2024.

Next meetings:

(provisional 2023)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WGs
21-23 February				
			1-2 March	
	15-17 March			13-24 March
		21-23 March		
25-27 April				
			5-16 June	
		12-16 June		
				19-30 June
26-27 June	28-30 June			
			4-15 September	
19-21 September				18-29 September
	27-29 September			
		13-17 November		
21-23 November			20 Nov-1 December	
	5-8 December			4-15 December