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

MINUTES

100th 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

29-30 June 2023

1. Adoption of the agenda	For adoption *CA-June23-Doc.1*	

One point was added to the agenda on suggestion from one Member State, concerning the timing of distribution of documents prior to the meeting. The agenda was then adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-June23-Doc.2.a* *CA-June23-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 information on the main points discussed and/or agreed at the 56th and 57th meeting of the Coordination Group that took place on 25-27 April 2023 (CG-56) and 26-27 June 2023 (CG-57), respectively.

Main points from CG-56:

- Three formal referrals were discussed and agreement was reached for two of them;
- A new vice-chair was elected with a mandate starting on 24 May 2023;
- A revised document on post-authorisation conditions was agreed. The revision was needed to incorporate agreements at previous CG meetings (physical hazards and respective characteristics which affect product classification and labelling cannot be addressed by post-authorisation conditions and that post-authorisation conditions in exceptional cases are only possible for those physical, chemical and technical properties which would neither affect Article 19(1) conditions, nor the efficacy/risk assessment) and CG-53 meetings (shelf-life setting at product authorisation);
- Revised Rules of Procedure were agreed. The revision was needed to reflect the clarification of the interpretation of Article 35 of the BPR that for the resolution of referrals the agreement of the reference Member States and those Member States concerned in the mutual recognition procedure is needed (and not agreement of all Member States). That clarification triggered also the revision of the working procedure for resolving disagreements. The revised version was agreed by the CG;
- CG members were informed about the started maintenance by the CG Secretariat of the list of frequently used sentences in the SPC.

Main points from CG-57:

- Two formal referrals were discussed and agreement was reached for both of them;
- A document on grouping of changes was presented by the Secretariat, with the aim to collect feedback on the current practice in Member States with regard to grouping of changes;
- A discussion took place on rejection of applications in accordance with the BPR. It was acknowledged that having detailed validation requirements would be beneficial;
- The Commission presented a document aiming to clarify that a biocidal product family (BPF) cannot be considered as such if it comprises products/uses which fulfil the criteria in Article 19(1) of the BPR and product/uses which can be authorised under Article 19(5) of the BPR. The Commission also mentioned that a proposal for a new Q&A to be included in the CA document on the BPF concept will be presented at the CA meeting of June;
- The Commission presented a document aiming to agree on a harmonised approach with regard to risk mitigation measures (RMMs) required for rodenticides containing anticoagulant active substances and presented as wax blocks. The CG members did not agree to the proposal, as there are still divergent views on whether the RMMs should be applied to all these products or whether a case-by-case analysis is needed;
- Due to the early termination of the mandate of the vice-chair elected at the April meeting because of unforeseen circumstances, a new vice-chair was elected (the Austrian CG member), with a shorter mandate (from 1 July until the end of the year).

4.2. List of pending Article 36 requests	For information *CA-June23-Doc.4.2*	**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	

The Commission informed that internal discussion on this issue are ongoing and that comments receives from MSs and industry associations have been duly noted.

A Member State informed of the intention to vote against the proposal, in case the Commission insists that authorisations to which derogation from the mutual recognition procedure has been applies (Article 37 of the BPR) cannot be grouped for renewal. The Commission recalled that, as this is a delegated act, Member States will not vote in the Standing Committee on it.

4.4. Discussion on SBP Regulation (Regulation (EU) No 414/2013)	For discussion *CA-June23-Doc.4.4*	

The Commission explained that the purpose of the document is to provide Member States with proposals for possible amendment of Regulation (EU) No 414/2013, recalling that several issues on the interpretation and implementation of the Regulation have been discussed and invited Member States to provide their comments.

One Member State suggested to remove the validation step and the Commission agreed with its proposal.

Another Member State welcomed the notion of similarity between the same biocidal product (same BP) and the reference product, but suggested to revise the text of Article 7(b) in order to give more power to the reference authorisation holder.

Regarding Article 7(c), that Member State asked to clarify the meaning of the term "simultaneously" and what it will happen to products already authorised and placed on the market. They suggested also to have a transitional period.

The Commission replied that "simultaneously" means that the modifications need to be processed at the same time. If changes are not made simultaneously, the authorisation holder of a same BP can convert it in a national authorisation as this case it will not be the same BP.

Concerning the transitional period, the Commission confirmed that they will provide time for the system to adapt to the new rules.

One Stakeholder Observer commented that this proposal is very restrictive for the market. The Commission replied that the mutual recognition is a system which ensures sufficient flexibility and recalled that it has already been made possible to have a same BP authorised under a national authorisation on the basis of a reference product that was authorised by an Union authorisation. The principle is that a same BP needs to be a same BP. Too much flexibility makes the system too complex and not manageable.

ECHA suggested considering using another term instead of "simultaneously", which can be problematic. The Commission replied that this word has been used in order to avoid having different deadlines to assess same BPs. They remain open to suggestions, but it needs to be clear in which moments an application for a same BP should be submitted.

The Commission concluded that a newsgroup will be opened until 25 August and invited Member States to provide comments on the proposal and suggestions to improve the system.

4.5. Union authorisation: similar conditions of use	For discussion *CA-June23-Doc.4.5*	

The CA meeting started the discussion on the notion of "similar conditions of use across the Union" as pre-condition for Union authorisation several meetings ago. The Commission presented the document summarising the previous discussions / problems identified and providing some considerations for potential ways to improve the current situation. For the definition of "similar conditions of use", the Commission proposed a restrictive interpretation and that only differences in elements that are not covered by harmonisation and where EU legislation leaves room for national differences should be acceptable. With regard to the procedure to identify if there are similar conditions of use for an application, the Commission proposed to have more binding rules for the pre-submission procedure. The current agreement from 2013 would then have to be revised in accordance with the outcome of the discussions.

One Member State suggested to explore the possibility to refer an application for Union authorisation to national authorisation during the assessment if it is discovered that there would not be similar conditions of use. Another Member State indicated that they could not agree with the proposed approach for the definition of "similar conditions of use" as they would not be able to integrate some of their national provisions in Union authorisations, and they will provide further written comments on this.

The Commission invited the CA meeting to provide their view on the proposal and additional ideas through a newsgroup by 25 August 2023.

4.6. Union authorisation: acting as evaluating CA	For discussion and agreement *CA-June23-Doc.4.6*	**Closed session**

This item was discussed in closed session

4.7. Cancellation of Union authorisations for products containing iodine and/or PVP iodine	For information	**Closed session**

This item was discussed in closed session

4.8. Information from the Netherlands on phosphine plant protection and biocidal products	For information	

The Dutch Competent Authority for Plant Protection Products and Biocides informed that it is working on an amendment of the instructions for use of phosphine containing products based on article 44 PPPR and article 48 BPR because of two incidents where phosphine was accidentally released from loose pills in inland vessels in the Netherlands. These products are used for the protection of stored plants, plant products and goods

The Dutch authorities consider that the risks of phosphine release during transport via barge, train or truck can only be mitigated with a revision of the use instructions of the relevant authorized products. Other improvements could be proposed during the upcoming renewal of active substance approvals and subsequent renewals of product authorizations.

The following changes to the use instructions are proposed by the Dutch authorities:

- The use of loose pills and tablets during transport over inland waterways, road and rail will no longer be allowed;
- Areas (containers/silos/cargo holds/etc.) which are fumigated must be marked clearly and indelibly indicating the presence of phosphine gas, the danger to human health, the date and time when re-entry is authorised/allowed (exact date and time to be specified by the chief fumigation inspector) and when applicable, the number of packaging that has been applied. Re-entry into the fumigation area shall be allowed only after clearance by the chief fumigation inspector;
- All packaging must be removed before handling the stored goods. Residues must be stored and disposed of in accordance with hazardous waste legislation.

Once the Dutch authorities have notified Member States under Article 48(3) of the BPR, Member States have 120 days to update their national authorisations.

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

The Commission introduced the topic, recalling that a first discussion took place at the CA meeting of March 2023, where an agreement in principle was reached on the approach to be applied, that is not allowing potentially misleading terms as prefix or suffix in the trade names of any biocidal product.

The Commission mentioned that some elements related to the application of the approach still need to be agreed and that, based on the comments provided by Member States after the first discussion, a proposal is being put forward in the current document, comprising: application of the approach to ongoing applications for national and Union authorisation; amendment of authorisations granted to products having names affected by the approach at the moment of renewal; application of the approach to products made available on the market under the transitional rules; non-application of the approach to products made available on the market in accordance with Article 55(1) of the BPR; exemption from application in cases where the name of the company or a specific technology developed by a company contains a potentially misleading term, in which case that name may appear in the trade name. Upon suggestion from Member States, a draft non-exhaustive list of terms not allowed was provided and the Commission proposed that such list be reviewed (and updated if needed) twice per year at the CA meeting. The Commission also mentioned to have distributed to Member States prior to the meeting a letter from a company expressing concerns in relation to the proposed approach. The Commission informed then that a request for preliminary ruling C-296/23 on the interpretation of Article 72(3) on labelling was submitted to the European Court of Justice and that this case might have implications for the current discussion, given the link between the provisions of Article 69(2) and 72(3).

One Member State expressed agreement to the way forward outlined in the paper and, with regard to the proposed list of non-allowed terms, requested that it is made clear that the list is not exhaustive, meaning that if a term is not listed in there it does not mean it cannot be forbidden. Another Member State mentioned they would want to check the proposed list with their enforcement authority, to ensure coherence with their national approach. A third Member State asked, in relation to granted authorisations, whether it will be possible that the authorisation holder itself proposes a change of the affected trade name before the authorisation renewal and, in relation to products made available on the transitional measures, they stated to prefer the removal of the specific part in the document. The same Member State also brought to the attention of the Commission that the case in which two companies use the same trade name for two different products could be an instance of misleading. On the first point the Commission clarified that changes should be allowed before the authorisation renewal and the text will be modified to indicate that authorisations will be amended at the latest at the moment of renewal. On the point of different products bearing the same name, the Commission was of the view that it would be for the companies to solve the issue and that the specific case would not be covered by this paper. In relation to the point concerning products made available under the transitional measures, one Member State suggested to indicate in the paper that Member States may apply the approach to those products, thus not making it obligatory but also not preventing Member Sates who want to apply it to do so.

One Member State expressed doubts on whether the term ‘safe’ should be included in the list, as, if a product is authorised it has demonstrated at least a safe use. The Commission recalled that a case where the trade name in a Union authorisation contained that term and it was agreed not to allow it. The Commission was also of the view that ‘safe’ could be interpreted as similar to ‘harmless’ or ‘non-toxic’, which are explicitly mentioned in Article 69(2), hence it should not be allowed. One Member State suggested to include in the list of terms two more terms, namely ‘med’/’medical’ and ‘kids’. In response to a question from this Member State, the Commission clarified that it is not certain that the request for preliminary ruling related to Article 72(3) will have an impact on the topic under discussion, but, if it were to have an impact, the approach outlined in the paper will be amended accordingly. Another Member State stated that in the case of use of ‘medical’ the products might be dual-use products. The Commission indicated that if a product is a medicinal product, it is outside the scope of the BPR and the same applies for disinfectants for medical devices and that in principle the two markets (medical and biocidal) should be separated, but it will further reflect on this point.

Another Member State informed that their enforcement authorities have a long experience in applying the provision on misleading terms and that a list of non-allowed terms has been developed by these

authorities. One Member State informed that a court case concerning the use of those terms for low-risk products is ongoing at their national level.

One stakeholder observer representing manufacturers of devices used for in-situ generation was of the view that the approach should not apply to devices. The Commission indicated that further reflection is needed on this topic, as the work of the working group dealing with the content of the authorisation for in-situ generated products is still ongoing.

The Commission concluded that the core of the document was agreed by the CA meeting, and invited for comments from participants on the Annex (non-exhaustive list of forbidden terms) by 25 August in the specific newsgroup that will be opened after the meeting.

4.10. Active substances as CfS and product authorisation	For information *CA-June23-Doc.4.10*	

The Commission described the purpose of this document, made an analysis of the relevant provisions in the BPR and the proposed way forward. It also recalled that this topic has been already discussed in previous meetings.

One Member State pointed that in paragraph 6, second line it is written "….for which the evaluation was completed by 1 September 2013", but it should be "…for which the evaluation was not completed by 1 September 2013". The Commission thanked for the correction and confirmed that the modification will be implemented and the amended document will be uploaded in CIRCABC.

Another Member State asked to clarify the sentence "Therefore, for these applications, a comparative assessment in accordance with Article 23(1) of the BPR shall be performed if the risk assessment of the active substance indicates that one or more of the criteria listed under Article 10 is met".

The Commission recalled that paragraph is an exact quotation of the BPR and is no longer relevant, therefore there is no need to modify the sentence.

The document was agreed by the CA meeting.

4.11. Correction of document on implementation of scientific criteria for the determination of endocrine disrupting properties in the context of product authorisation	For information *CA-March23-Doc.4.13_rev1*	

The document CA-March23-Doc.4.13 agreed at the 99th CA meeting has been amended because of the doubts on the possibility to use Article 42 as a legal basis to cancel already granted authorisations containing active substances that become exclusion substances due to their ED properties. In consequence, the respective paragraph has been removed in the revised version:
"(17) Based on Article 42 (1) of the BPR, biocidal products containing active substances meeting the exclusion criteria are not eligible for Union authorisation. Therefore, existing Union authorisations containing active substances that become exclusion substances due to their ED properties need to be cancelled.".

Member States agreed on the modification.

4.12. 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-July19-Doc.4.2. Guidance note on BPF concept_rev3*	

The Commission informed Member States of the decision to add a new Q&A to the guidance document on biocidal product family (BPF) concept to address a question raised by Member States on whether it is possible to have biocidal product families that contain products that comply with Article 19(1) of the BPR and products that do not fully meet the condition of Article 19(1) (b), (iii) and (iv) and could therefore be authorised in accordance with Article 19(5).

The Commission explained that such a group of products cannot belong to the same family because they do not comply with the definition of the BPF, namely products having similar levels of efficacy and risks.

The Commission recalled that this clarification was already provided to the Coordination Group and that the objective is to try to address how to deal with these authorisations, considering also the difficulty to know whether the application that is submitted will have products that do not fully meet the conditions of Article 19(1) (b), (iii) and (iv).

The Commission would like to agree with Member States on how to deal with ongoing applications in which it becomes clear that the BPF cannot be authorised because it does not fulfil the definition of BPF. For these cases, it is proposed that section 3.3 of this document applies, meaning that a new application needs to be submitted by the applicant to split the family.

Regarding the cases of BPF that are already authorised with products that comply with the conditions of Article 19(1) and products that need to be authorised under the condition of Article19(5), the Commission proposed that a request for a change is made by the applicant to split the family.

The Commission asked Member States to express their views on classification of the change. In the Commission's opinion those changes could even be considered as administrative changes, which would imply that no assessment will be needed.

One Member State informed the Commission that PT21 products have to be normally authorised in accordance with Article 19(5) of the BPR and this raises multiple practical questions.

Another Member State informed that they were not in favour of requiring a specific application, affirming that they normally authorise products under Article 19(5) because they need them, and if they draft them out of the product family the risk is that those products are not authorised at all.

The Commission recalled that even if these uses will be grouped in another meta SPC, the applicant can apply for a split of the family and made a new application for those products and the only issue would be that the applicant will need to pay more fees , but this is up to MSs to decide of fees at their national level. This would not mean that these products could not be authorised. These products need to be split into another family that will fulfil the definition of a BPF.

The Commission recognised that handling authorisations under Article 19(5) is very complex, especially in a mutual recognition and that more clarification is needed, but encouraged MSs to apply the basic principle that a BPF needs to comply with the definition of a BPF in the BPR.

Another Member State expressed its doubt on the possibility of using the administrative change procedure in this case because Article 19(5) is very complex and informed that for the merely administrative changes they have a very light system with only few people involved. It suggested reconsidering whether the family should be split because this would generate a lot of extra work while the result will be almost the same.

The Commission clarified that this regards the request of a change to split families that have already been evaluated and it has been decided that some of the products comply with art. 19(1) and some other products need to be authorised under Article 19(5). In the Commission's view, this would only require an administrative work without a need to reassess the family. The Commission invited Member States to reflect about this qualification of change and to confirm if administrative people are able to make this check.

One Member State asked how the SPCs will look like in the register and how to reflect in the SPC that products are authorised under Article 19(5). The Commission clarified that the master SPC is not the real SPC. It is the SPC used regarding mutual recognition. The valid SPC is the one that the Member State will translate into its language and that they will attach to their national authorisation.

The Commission informed that, in consideration of the complexity of this matter, a workshop on best practices and national authorisations is planned to be organised, including in order to clarify and agree on all these issues and to harmonise the practices on how to run those authorisations.

One Member State informed that they prefer to have it as a minor change (MIC) because also the PAR needs a reorganisation.

ECHA, in relation to the last sentence of the last paragraph on the possibility for the applicant to request ECHA a classification for the change, suggested to clarify that this is a step that has to precede the application for a change, so that the applicants are not confused. The Commission replied that they were discussing about the possibility of removing this sentence as they would prefer to agree on an harmonised approach to all the BPFs instead having the applicant to apply each time for an ECHA opinion to classify the change. The Commission recalled that the objective was also to agree on the classification of these changes so that ECHA does not need to issue an opinion every time an applicant would ask.

One Member State asked what does the Commission means with "application to split these family" because for ongoing application it is not technically possible in R4BP3 to submit any application if the case is not closed. It was clarified that this means that the applicant should withdraw the application and submit a new application. The Commission recalled that this is what it was already agreed in the past on how to deal with splits of BPF in R4BP, but invited Member States to check the section 3 of the document because it is possible that this needs to be amended.

Another Member State pointed out that there was also a general agreement from the Coordination Group on a document of 2018 that provides some guidance on procedures to split families. Commission thanked that Member State and invited it to provide the reference of this document in order to allow them to have an overview on what it has been agreed.

The Commission announced to open a newsgroup until 25 August and invited Members States to provide their views both on the opportunity of splitting and on the nature of the change.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-June23-Doc.5.1*	

The Commission presented the document giving an overview of the progress of the review programme. It also informed that some backlog reports have been closed, but there are still 31 backlog reports submitted before 1st September 2013 that are in the process of peer review and invited the concerned Member States to make progress on this dossier because these delays can have a negative

impact on the system. It informed that the discussion will be continued in the next point of the Agenda (point 5.2).

5.2. Postponement of the review programme beyond 2024	For discussion and agreement *CA-June23-Doc.5.2*	

The Commission recalled that the discussion started at the last CA meeting and a newsgroup was created in order to collect Member States' reflections on two elements: the duration of the extension and the actions and modifications of legislation that could be envisaged. The Commission thanked the ten Member States who contributed to the newsgroup, presented their views, explained the proposals made in the document and invited Member States to agree on its proposals.

One Member State welcomed the launching of this process by the Commission. They understand that an extension should not be longer than necessary, but suggested to have first a clear picture of the status of individual applications for approval, as this would help prioritise proper measures. Once concluded on the measures to be taken, it will be easier to decide on the number of years needed for the extension.

ECHA replied that an overview of the status of evaluation of different dossier exists and can be shared, but it is limited to the information that Member States provide to ECHA. In order to have a more detailed overview, competent authorities need to have a better insight into each individual case, which will allow ECHA to collect all the information.

The Commission recalled that it is important that Members State finalise the evaluation and submit the reports, in order to have significant progress by the time of the REFIT evaluation of BPR in 2025.

One Member State expressed its agreement to the proposal to extend the duration of the review programme until end-December 2030, and supported the majority of the actions proposed to ensure the completion of the review programme. It agreed also on the deadline proposed for application of new guidance documents published after 1 January 2024 to on-going applications for approval of active substances and for the submission by applicants of the missing ED data, as a good compromise between the respect of procedures and the need to set time limits. Furthermore :

- As regards point 11. "Examination of the ED criteria", question "b", that Member State asked if this proposal of restriction will be consistent with the obligation linked to the revised CLP Regulation which now includes ED classification. From its point of view, even if the finalisation of dossiers for active substances meeting exclusion criteria should be considered a priority, it is important also to have as much information as possible to establish if these active substances can be considered ED or not, so that products containing them can be correctly labelled.
- On question "c" it supported the proposal to make progress on the evaluation of active substances confirmed as not meeting the ED criteria for human health and for which the ED data for the environment are still missing, only if all emissions to the environment can be prevented.
- On point 14. a) it agreed that Member States should not hesitate to make use of the provisions of the BPR allowing them to perform a limited evaluation, but recalled that they also have to consider new scientific data and guidance. In fact, often these elements are considered to have an impact on the conclusion of the risk assessment. That Member State concluded that if there is a need for a reassessment of the complete data package, it makes difficult for the eCA to reduce its workload.

On point 11, question "b", the Commission replied that there is no contradiction or issue because the CLP is based on available data.

Another Member State welcomed the proposal to extend the duration of the review programme until end-December 2030 and the proposal on application of new guidance documents to ongoing applications for approval of active substances. Furthermore, on the examination of ED criteria, point a), that Member State pointed out that this provision is difficult to apply because in most of the cases the applicant submits some data and the competent authority cannot conclude that the applicant has not replied at all to the demand of information, even if the reply does not fulfil completely what the eCA was expected to receive. Concerning the deadline that could be set for the applicant to submit ED data, the Member State was of the opinion that this provision can work if the eCA proposes a clear list of information that the applicant has to provide to complete the dossier. The Commission replied that even if the ED topic is very complex, it is necessary to make progress and encouraged Member States to provide their views.

Concerning the situation in which the applicant submits information that partially fulfil what has been requested, the Commission suggested to continue the evaluation based on the information provided and, if that does not allow the eCA to reach a conclusion, the outcome will be a non-approval proposal. On the type of data to be requested to companies, the Commission encouraged Competent Authorities to specify what kind of data they request.

One Member State welcomed the proposal and encouraged all Member States to focus on critical points that have an impact on the conclusion of the risk assessment because this will enable them to optimise the use of their resources for the review programme.

Another Member State highlighted the importance of the finalisation of the review programme, which might justify other drastic measures and suggested anticipating some elements like the REFIT to focus on the review programme. They considered it not realistic to complete the remaining 55% of the review programme in a couple of years. The Commission recalled that the purpose of the REFIT is to establish what works in the Regulation, what does not work, and what kind of measures can be conceived afterwards. If by 2026 there will be no significant progress, probably drastic measures will be needed, but it is not possible to advance the REFIT.

The Commission informed that a newsgroup will be opened for further comments, but an agreement on the date will be sought in this meeting. The workload is huge and for this reason Member States have to build up a system which is properly financed in order to have the resources to carry out the work.

One Member State agreed with the proposed prolongation, but they still have internal discussion on some actions to improve the progress and suggested to consider the possibility to evaluate just one use for one PT.

The Commission invited Member States to provide reflections on how to improve the system in the newsgroup.

One Member State suggested to clarify if, in the case where it might be necessary to continue without an ED conclusion, this ED conclusion will be requested at the renewal stage. On point 12, it asked what type of decision should be adopted if the BPC concludes that a substance fulfils exclusion criteria and if, in case of a non-approval decision, there is the possibility to have a court case if the substance is eventually not classified with an exclusion criteria classification. The Commission replied that a decision will be taken based on the best information and conclusion available at that point in time. If an applicant is still interested in supporting the substance, it always has the possibility to submit a new application for approval. In any case, progress has to be made and decisions adopted.

Another Member State supported many of the proposals, but asked the Commission to explore the possibility that the ED assessment be carried out on the basis of the available data and, if a conclusion cannot be reached, asked the Commission if the active substance could then be approved if there is no other reason against; if possible the missing data could then be listed in the BPC opinion as a requirement to be fulfilled in the renewal application. If the Commission concludes on this approach as

possible it could be a compromise which will allow Member States to progress. It also highlighted that several applicants have concerns due to the data protection period ending in 2025 and to the fact that they will not be compensated for the cost studies related to ED. On the latter, the Commission replied that the rule is clear in the BPR, and was decided by Council and the EU Parliament.

Regarding the proposal made by several Member States to postpone the renewal of active substances, they recalled that their proposal was not intended to leave the submission of applications. The applications have to be submitted by the deadline, but they proposed to put on hold the evaluation of all renewal applications for a certain period of time; in the meantime the approval of those AS for which renewal application has been received will be extended for that period. In their view, postponing the renewal process in the proposed way will allow Member States to focus on AS for which the first approval is still ongoing. To achieve this goal they believes that a common agreement among MSs will be sufficient. They concluded asking the Commission to investigate if this approach would be in line with the BPR.

The Commission confirmed the possibility to investigate on this last point and invited Member States to consider this possibility, but Member States must be consistent when discussions take place in the Standing Committee on proposals of extension of approval of active substances.

ECHA raised questions on several points:

- On ED they suggested that the deadline of two years to provide data should be put in a way that would avoid freezing the system. They also suggested to clarify if it is for Member States to request information or if there is a time window for applicants to provide them.

  Regarding the proposal of a Member State to consider to proceed on the basis of available information, ECHA suggested to make a differentiation between the cases where there is evidence of ED, for which ED would be requested for information, and cases in which there is no evidence of ED for which it can be concluded that there are no indication of ED, even though it is acknowledged that the information should be provided for the renewal to conclude on ED.
- On guidance, ECHA recalled that work on guidance is ongoing and also expected from the Agency.
- On harmonised classification, ECHA is of the opinion that it is not necessary to await the harmonised classification, but it should be considered if some exceptions need to be anticipated, eg. where the CMR/ED classification is uncertain and there is a risk of a conclusion on exclusion criteria that may be later not supported by RAC.

Concerning the proposed deadline of 2025, the Commission recalled that the Competent Authority is in charge of evaluation, and it has to go back to applicant when data are necessary.

One stakeholder observer asked if the general deadline for the ED data is set for applicants to provide the data of for Member States to request these data. If it is for applicants, they suggested to set also a deadline for Member States to request data, otherwise it will be difficult to give companies clear guidance. On the "taking-over" mechanism, they proposed to leave the possibility for taking over in exceptional situations. On the latter point, the Commission replied that exceptions are not possible.

The Commission concluded that they would start working on the delegated act with regard to the extension of the deadline to 30 December 2030, while for the other measures a newsgroup will be open for comments and proposals until 25 August.

5.3. Progression of the renewal process of approval of active substances	For information *CA-June23-Doc.5.3*	

The Commission presented the status report concerning this part of the activity and informed that since the last CA meeting four applications have been submitted and invited concerned Member States to inform the Commission within 90 days after the acceptance of the application by ECHA to indicate whether they intend to perform a limited or full evaluation to allow the Commission to start preparing the necessary extensions concerning the substances.

As indicated in the Appendix of the document, the Commission informed that there are many deadlines at the end of July 2023, in particular for formaldehyde and carbendazim and invited the responsible Member State to inform whether the applicant has the intention to submit a renewal application. It recalled also that there are also many deadlines for the end of this year concerning many substances.

Some Member States took the floor to give updates on the status of their applications for renewal.

One Member State informed that on formaldehyde they will receive some applications from the applicant in PT2 and 3, while for carbendazim the applicant is not yet sure if he will apply for the renewal but they have asked him to keep them informed.

Concerning formaldehyde, the Commission pointed out that it is regrettable that companies do not succeed to work together and to find an agreement because this increase the complexity of the workflow. It stressed that collaboration is appreciated to limit the complexity for everybody.

Another Member State informed that on the renewal of Copper sulphate PT2 they have received the dossier for renewal in advance and they will need to extend the deadline for the approval because it will be a full assessment.

The Commission thanked the Member States which provided the information and invited them to send a written communication in order to use the information in its decision-making process.

5.4. ECHA Active Substance Action Plan – progress update	For information *CA-June23-Doc.5.4*	

ECHA presented the customary report on the Active Substance Action Plan. Concerning the planning for 2023 in terms of number of draft CARs to be submitted by Member States and opinions to be adopted by the BPC, the estimates were corrected downwards, to 22 and 13, respectively (from 118 and 28 estimated at the end of 2022). ECHA provided some updates related to the four actions of the plan (prioritisation of dossiers, support to eCAs, streamlining the peer review, reducing complexity) and reminded Member States of the general principles of the evaluation work.

5.5. Early review of iodine and PVP iodine for PT 1, 3, 4, 22	For information	**Closed session**

This item was discussed in closed session

5.6. Question from Germany on the ED assessment of an active substance	For discussion *CA-June23-Doc.5.7*	**Closed session**

This item was removed from the agenda.

5.7. One substance one assessment	For discussion *CA-June23-Doc.5.7*	

ECHA introduced the item, providing the background, the status quo, the development areas, concluding with concrete questions to the Member States on One Substance One Assessment (1S1A).

The Commission commented on the related case of the evaluation of the approval of sulfur dioxide and the challenges met during the different assessments performed by ECHA and EFSA.

A Member State mentioned that they run pilot projects on 1S1A. Also, they stressed the need for guidance and the alignment of different Union legislation. They proposed to establish a Board responsible to solve discrepancies in the different assessments. They also pointed out the need to implement the Data Regulation as soon as possible.

Another Member State asked about the legal status when aligning assessments from different regulatory frameworks. They mentioned problems with copyright and the handling of confidential information. In the absence of an EU copyright law they stressed the need for a practical guidance. They also proposed the organisation of a workshop on these issues. The experience with the assessment of sulfur dioxide was not entirely successful and they highlighted the need to establish practices for more efficient data sharing between ECHA and EFSA as well as the wish for an equal mutual involvement in both processes.

A third Member State agreed with the previous remarks, mentioning that the access to data is difficult and there is a need to coordinate the work among the evaluating Member States authorities for biocides and pesticides.

An additional Member State supported the ECHA document and mentioned they would also welcome alignment between different Union legislations.

Another Member State criticized the 1S1A document, mentioning the extra work needed, stating that the final results are not always helpful but create more work. ECHA agreed that extra work would be needed by the Member States, but this would pay-off in the long term.

One stakeholder observer asked whether the 1S1A would include also aligning the reference values and if this could be possible in the first place, considering the different levels of exposure between biocides and pesticides. They mentioned that a certain divergence should be acceptable at the end. The Commission pointed out that for the assessment of hazards there should be in principle no divergence in the conclusions.

The Commission clarified that DG ENV is leading on 1S1A, and referred to the existence of an expert group on 1S1A and invited Member States Competent Authorities on biocides to approach their colleagues at national level to be involved. The Commission concluded informing that a newsgroup will be opened and invited Member States to submit comments by 25 August on the ECHA document.

5.8. ECHA plan to structure active substances data in IUCLID format	For discussion and agreement *CA-June23-Doc.5.8*	

ECHA introduced the agenda item, proposing a roadmap for complying active substance data with IUCLID format.

Four Member States supported the ECHA's proposal, but expressed some concerns, including the implication to additional work needed due to the validation step of IUCLID data proposed by ECHA's roadmap. Most original applications of approvals took place before 2010 and the validation of these data under IUCLID would result in long delays.

One Member State questioned the legal basis for asking the applicants to submit the data again in form of a IUCLID dossier, as they submitted the data in the form accepted at that point of time, the so-called Doc I, II, III and IV documents. Moreover, those applications have to be evaluated based on the data requirements of the BPD. Therefore it is unclear, whether the validation tool will be applicable for this

task. The same Member State mentioned that they ask the applicants to submit old data in IUCLID at the occasion of the renewals of approval. However, not always the applicants are the same with those of the original approval and thus they do not have access to these data. They proposed for an IT solution to transfer old data (generated for the BPD) automatically to IUCLID format. Such a tool would allow to proceed without another validation step and without involvement of the applicants.

Another Member State did not support ECHA's proposal due to the required validation step, which would need too many resources, while prioritization should be given to the review programme.

ECHA highlighted the benefits of transferring data to IUCLID format. With regard to validation, the process should be automatized once established; competent authorities should send back the dossier to the applicant if the data are not complied.

The Commission announced to open a newsgroup by 25 August and invited Member States to send comments on the ECHA's document.

5.9. Correction to the CA document "CA-Dec22-Doc.5.4.a – AoA guidance implementation"	For information *CA-June23-Doc.5.9*	

The Commission presented the document and introduced the corrections made on page 3 of the document.

No discussion was necessary on this point.

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 that they received the applications at the end of April. In total 16 applications were submitted initially (10 for Biocides and 6 for PPP); after evaluation and discussion with Member States all the applications were or are about to be accepted except one which was finally withdrawn. The acceptance letters will normally be sent to Member States during the first week of July and there will be a process for the formal signature of the granted agreement between the two parties. This process can take several months and the Commission would like to have this agreement signed by the end of the year.

The Commission welcomed the fact that many Member States have applied and expressed its support to them.

7.2. ECHA communications	For information	

ECHA gave a presentation covering the achievements since the previous CA meeting (IUCLID implemented improvements, IT developments for systems integration and adaptation, activities related to stakeholder engagement) and ongoing activities (IT developments, follow-up of testing sessions, revision of supporting material for users). ECHA also announced that the current BPC Chair will leave for retirement on 1 August 2023, and the new Chair has already been selected. The Head of Unit Biocidal Products will also leave for retirement on 1 September 2023, and the selection process for the replacement is on-going.

7.3. Proposal for an overview of the ECHA guiding documents for stakeholders and Member States	For information *CA-June23-Doc.7.3*	

ECHA presented the initiative of developing a database of existing guidance relevant for biocides, which is currently available in different locations. The database will include, in its initial version, formal guidance, practical guides, submission manuals, legislation, forms and templates, Emission Scenario Documents, Technical Agreements on Biocides, documents related to technical equivalence, Working Groups scientific documents and BPC/WGs procedures and will cover only documents available on the ECHA website. External documents (CA and CG documents) will be added in future updates of the database. The documents will be categorised based on processes (active substance approval, product authorisation, other) and sub-processes within them (for instance renewal of approval, Annex I inclusion, exclusion/substitution, etc. in relation to active substance approval and national authorisation, Union authorisation, same BP, renewal of authorisation, etc. in relation to product authorisation). The update of the database is foreseen to be performed twice a year and it is planned to launch the database by the end of 2024.

7.4. 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-June23-Doc.7.4*	

ECHA introduced the document which is now at its final stage. It was developed together with EFSA and is based on a common mandate from the Commission for PPP and biocides. A public consultation on an earlier draft took place in autumn 2022 and Member States were given a final opportunity to comment in May 2023. In this last round of comments the Agencies received technical but also procedural/policy comments. ECHA and EFSA are currently working to address the technical comments and EFSA plans to publish the guidance on its webpage in July/August 2023.

ECHA asked the Member States to discuss the applicability of the guidance for the biocide processes. It asked whether the rules established for the applicability of new guidance should be applied (availability of the guidance 6 months before submission for active substances and 2 years before application for products) or if a different agreement on the applicability would be more appropriate in view of the potential workload. A proposal was made to apply the guidance only to the renewal and new active substances.

The Commission stressed that the guidance document is needed for the PPP processes and that the biocides process should not cause any delays of the availability of the document for the PPP sector. It reminded the Member States that the technical part of the guidance should be the same for PPP and biocides as there is no reason to differences in the assessment. For the question of the applicability

there could be room for some flexibility. The Commission confirmed that, in the light of discussion on item 5.2 on the CA agenda (extension of the review programme beyond 2024), the guidance should not apply to active substances still assessed under the review programme.

One Member State raised concerns about the workload and potential delays even if the guidance document will only be applied in the renewal process and to new active substances. They requested to first see the final version and to discuss it before a decision on the applicability can be taken. This was supported by three other Member States.

ECHA confirmed that they will provide the final version of the guidance document and an RCOM table to explain how comments were taken into account at the CA meeting in September. In the version that will be published by EFSA in July/August 23 a note will be added indicating that the discussion on the applicability for the biocides is still ongoing.

The Commission asked Member States to provide their views in a newsgroup by 25 August 2023.

7.5. Information on CLP : Commission Delegated Regulation (EU) 2023/707 of 19 December 2022, and Proposal COM(2022) 748 final revising CLP	For information	

A representative of DG GROW gave a detailed presentation on the Commission proposal revising the CLP regulation and the delegated act introducing new hazard classes (Delegated Regulation (EU) 2023/707).

7.6. Information on the initiative on prohibiting production for export of chemicals banned in the European Union	For information	

A representative of DG ENV gave a presentation on this initiative, which is related to one of the engagements in the Chemical Strategy for Sustainability, namely to ensure that hazardous chemicals banned in the European Union are not produced for export, including by amending relevant legislation if and as needed. In 2023, the evaluation of Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals (PIC Regulation) was initiated, in parallel with an impact assessment of the initiative to ban production for export. Several options for the measures to be adopted are being examined by the Commission. A public consultation was launched, lasting from 8 May until 31 July 2023 and the impact assessment will be finalised by the end of the year.

7.7. Information from France on a study on potential substitution of active substances for wood preservation PT8	For information *CA-June23-Doc.7.7*	

France gave a presentation on a study on potential substitution of active substances for wood preservation PT8.

Following a related question by the Commission, they clarified that the BPC Opinions on borates' alternatives and propiconazole were not taken into account for their report, since the former opinions came later. However, the French report contributed to the BPC Opinions on borates and propiconazole.

One Member State commented that the exact uses of wood preservatives would need more clarification. Another Member State asked about the methodology followed and if persistency was

considered. France clarified that no further analysis on persistence was done. They also mentioned that stakeholders did not provide much feedback on the issues mentioned in the report.

7.8. Update on Court cases	For information	

The Commission provided an update on Court cases.

7.9. Q&A on Data / Letter of Access (LoA)	For discussion *CA-June23-Doc.7.9*	

Austria presented the document which summarises several questions raised by different Member States with possible answers and invited Member States to provide their views in order to reach a final conclusion for each question.

On the first question, one Member State supported the proposal of Austria, but asked if in this case it is still necessary to have a letter of access. They explained that as far as the data are presented in the dossier, the CA does not check if the applicant has access or not because they consider that when the data are submitted the applicant has access to them by default.
If the CA does not have to check the letter of access, its workload would be consistently reduced.
Another Member State supported this proposal and suggested to apply it also to ongoing applications.
The Commission stressed that there is a difference between data protection and confidentiality, and only very limited data are considered confidential. It recalled that in the PPP area all the data are published on the EFSA website.

One Member State suggested to look at the different existing concepts reminding that there is no data protection across different legal instruments. Concerning the letter of access, it highlighted that it only concerns data submitted under the BPR. About other means of immaterial rights, in particular copyright, the Member State clarified that copyright does not prevent from using data. It only prevents the publication and copying of information.
It also strengthened that when data protection will expire, there will be a lot of applications submitted by applicants who do not have yet access to the data, nor the right to get this information: at that moment, ECHA dissemination portal will become more important for those applicants who do not have the information. The Member State concluded that they would summarise their views in the newsgroup.

Another Member State expressed its support to the proposal and stressed that the letter of access allow CAs to use the data; but this not implies that companies know the data. Austria took the floor confirming that the letter of access will still be needed because it is allowed in Article 20.

ECHA thanked Austria for the document and informed that they will provide comments in writing.

One Stakeholder Observer recalled that it is important to make a distinction between the ownership and the right to refer to data. The applicant does not own the data; however, if the original data is needed, this can be submitted by the data owner.
If the data protection expires the applicant does not own the data and has no possibility, under the BPR, to force the data owner to give him the data.
They proposed to cooperate with Member States, providing the feedback they have from companies.

Another Stakeholder Observer commented that data sharing is a very important issue. They asked for more clarity and formal rules in the letter of access.

The Commission announced to open a newsgroup by 31 August and invited Member States to provide their comments.

8. Scope matters

8.1. Monitoring products containing attractants to rodents	For discussion and agreement *CA-June23-Doc.8.1*	**Closed session**

This item was discussed in closed session

8.2. Disinfectant for medical devices, for medicines production	For information	

The Commission services informed the CA members that following the case of the evaluation of ethylene oxide (EtO), they concluded that the disinfection of medical devices is considered covered by the Medical Devices Regulation (MDR) and not the BPR. The applicant of EtO expressed interest in supporting: a) sterilisation of medicinal products; b) sterilisation of packaging, intended for either medical devices or medicinal products, but without the product itself being present during sterilisation; and c) sterilisation of 'combi-products' which contain elements defined in both medical device and medicines regulations (e.g. a drug-coated catheter or stent). After analysing the cases, the Commission services concluded that none of these uses is covered by BPR, but under the Union legislation on medicinal products or the MDR accordingly. Member States are invited to take note of this in the context of the implementation of the BPR.

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-June23-Doc.11.a*	

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

(b) Point from CEFIC/Biocides for Europe concerning data protection	For information	

CEFIC made a presentation on the 2025 expiry of data protection set in Article 95 of the BPR, expressing its concerns, and , clarifying that the intention is not to extend the data protection for all the data but only to data newly submitted.
It considered that the expiry date of data protection will have a lot of consequences also on the main objectives of the BPR and they asked the Commission to recognize this as an issue and to work together to check if a solution exist.

The Commission thanked for the presentation, recalled that specific meetings with CEFIC have already took place on this topic, and explained that submitted eligible data are protected since the day of their submission, and the 2025 expiry of data protection was decided by Council and the EU Parliament in the BPR to not create monopolies and extensive data protection, since the transitional period started since 2004. If there would be an issue as regards to data protection, maybe the whole data protection system needs to be revised and for that the Commission does not have a delegation; this can only be done when there will be make an valuation of the BPR.
The Commission concluded inviting Member States to read the presentation which will be uploaded in CIRCABC and eventually share their concerns.

(c) Follow-up on on-line meeting (30 March) 'Exclusion criteria substances in PT8 – Public interest, alternatives and a synchronized decision making process'	For information	**Closed session**

This item was discussed in closed session

(d) Workshop on market data for biocides	For information *CA-June23-Doc.11.d*	**Closed session**

This item was discussed in closed session

(e) Point from one Member State on the distribution of documents	For information	

One Member State highlighted the importance to have the documents for agreement at least 14 days before the meeting to allow Member States them to have a position on them and invited the Commission to respect this delay.

The Commission took note of the point.

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
	26-29 September			
		13-17 November		
21-23 November			20 Nov-1 December	
	5-8 December			4-15 December