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

MINUTES

94th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

6-7 December 2021

1. Adoption of the agenda	For adoption *CA-Dec21-Doc.1*	

One Member State enquired on the planning of the CA meetings in 2022. The Commission clarified that the provisional dates indicated on the last page of the draft agenda regard 2022. The indication of the year will be added. The Commission indicated that one AOB was suggested ahead of the meeting by a Member State, for discussion in closed session. The agenda was then adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Dec21-Doc.2.a* *CA-Dec21-Doc.2.b*	

One Member State requested the correction of a typo in section 4.2 of the draft minutes of the open session. The minutes (of the open and closed session) were then adopted.

3. Draft delegated acts
No item for information or discussion

The Commission clarified that following the last CA meeting and the discussion on a draft Delegated act amending the Review Regulation, the substance brandy has been taken over by one Member State. The Commission also informed that the draft Delegated act should be adopted mid-January 2022 after the consultation of the WTO under the TBT agreement is over.

4. Biocidal products

4.1. Risk mitigation measures for products and treated articles	For discussion *CA-Dec21-Doc.4.1*	

The Commission introduce the topic by inviting the Member State having provided the document for the meeting to present the document. The same Member State had made a proposal at the previous meeting on how to better regulate treated articles, including the creation of a positive list of allowed uses. At the last meeting there had been some support for the proposal, with the caveat that the creation of such a list and adoption of a new approach with regard to treated articles should not further delay the Review Programme.

According to the Member State having prepared the document for this meeting, the discussions on treated articles have various implications. Firstly, a new consolidated guidance document should be created, since many previous CA documents on treated articles (listed on pages 2-3 of the document) are outdated. Secondly, if the positive list is to be established at the renewal or approval, work has to start soon, as renewals are approaching. From the experience of this Member State, the data in most dossiers under the Review Programme covers also the use in treated articles, since this was a requirement also under the BPD (where reference was made to treated materials instead of treated articles). In its view, however, it seems that the dossiers submitted after the entry into application of the BPR contain less data

on the use of treated articles. Guidance documents should therefore contain updated advice on both data requirements for uses in treated articles and on the evaluation of these uses. Other guidance documents likely to need updating include: the manual on preparing BPC opinions for active substance approval and renewal, the template for BPC opinion for first approval and renewal of active substances.

The Commission noted that the approach outlined is very ambitious, especially with regard to the first approval, where there is not enough knowledge of all possible uses that could be listed in the approval. Concerning the need to update various guidance documents, the Commission recalled that a Member State to be in lead for this exercise will be needed and invited this Member State to consider whether they would volunteer to lead the work.

One Member State indicated they are still reflecting on the pros and cons of having a positive list of allowed uses in treated articles. The downside of a positive list would be especially the burden to provide studies and information by the applicant in the substance approval, in order to avoid that some uses in treated articles could be missed at that stage, which would then be de facto banned and would have to be added via an amendment of the approval. Also the approach does not provide solutions as to how to address the risk from the use of treated articles, as in general under the BPR the only option foreseen is labelling. This Member State suggested that restrictions under REACH could be one possible option to be explored.

The Commission recalled that during past discussions on possibilities of having positive lists or negative lists of uses, the negative list was the option preferred and also reminded that the approval and renewal of active substances are already affected by long delays. For the approval one representative product is required and assessed, which does not cover all possible uses in treated articles while at the renewal stage there could be more information on the treated articles in which a specific active substance is present, as Member States will have authorised various products used for the treatment of different treated articles, and more conditions or restrictions could be added. In reply to the remark that under the BPR there are no possibilities of setting restrictions on treated articles, the Commission reminded that the recent approval of carbendazim actually contains restrictions for the use in treated articles. The Member State clarified that their remark was due to the fact the BPR only addresses the placing on the market but not subsequent making available and use.

In relation to this last remark, the Member State having prepared the document was of the opinion that the use of the treated article is regulated by regulating the treated article itself, which is intended for certain uses. With reference to the fact that at the approval one representative product is assessed, it stated that in many product-types a representative product can be used to treat many articles. Therefore, in its view the representative product is not crucial as the use categories would be more or less the same. The provisions of the BPR prescribe that the use *in* treated articles and use *of* treated articles is taken into account in the exposure assessment and risk assessment. The Member State was also in favour of using restrictions under REACH, but only after all the options under the BPR have been applied.

The Commission noted that in an application for approval a dossier is complete even when the dossier contains information on a representative product with only one use, therefore the approval cannot cover all the possible uses in treated articles. The Member State mentioned that, especially for product-types 6 to 10, the use of the representative product can be a sole use (e.g. to treat wood), but it can end up in many treated articles with many exposure scenarios. The Commission pointed out that the use has to be considered in all its components (e.g. use to treat wood in class 1 or class 2 etc., in-can preservation of paints, in-can preservation of detergents, etc.).

Another Member State expressed reservations on the possibilities to legally require applicants to provide information on all possible uses at active substance approval, and also on the

practicalities of doing so. The Commission noted that, while the legal requirements are clear (one representative product), in the guidance it could recommended to applicants to include more representative uses in their dossier.

A further Member State agreed that having a positive list of allowed uses would be ideal but also understood the reservations expressed by other Member States. The same Member State was of the opinion that having a concrete example of such list (for one PT) would be beneficial.

Another Member State had questions in relation to treated articles that contain multiple active substances and substances of concern and also asked how - in case a positive list is set at substance approval stage - changes in this list would be introduced. The Commission replied that an amendment of the list could be made via a review of approval under Article 15 in case a use found unsafe would have to be removed, or following an application under Article 7 to add further uses.

The Member State having prepared the document reiterated that even if the representative product is one, the uses can be multiple, and expressed disappointment at the reservations of the Commission to apply the approach only at renewal of approval. The Commission clarified that it mentioned (now and in the past) that it is willing to do more to regulate treated articles in approvals (in particular by prohibiting those unsafe) and more broadly at the renewal of approval, but recalled again the limitations set by the legal requirements for approval and feasibility of doing so in practice. It also highlighted that, whenever a specific use is proven to be unsafe, the approval can be reviewed to ban that use.

One Member State indicated that it would be useful to have an overview of the treated articles on the market, and this could be done via a notification system to be set up under Article 58(7).

One stakeholder expressed concerns of their members in relation to applying the approach at renewal, as applicants start preparing their renewal dossiers a few years before the deadline. Also applicants for active substance approval/renewal might not be aware of all the uses of the products containing their substance.

Another stakeholder mentioned that they had provided a legal analysis on risk mitigation measures for active substances in treated articles and asked whether the Commission will take it into account. The Commission indicated that no specific reply will be provided, but the comments made will be taken into account. A further stakeholder made reference to PT8 products, where five use classes are possible in an application (in accordance to EN335), but within each class several uses are possible, and that it does not seem reasonable to ask applicants for the active substance approval to provide data regarding every possible use. The Member State having prepared the document stated that applicants could make the effort of collecting as much information as possible regarding the various uses, for instance by approaching their downstream users.

The Commission suggested that the most sensible way forward could be to focus on increasing the knowledge on the use in articles and taking explicit decisions on non-allowed uses at approval (if so warranted in the outcome of the risk assessment) and on allowed and non-allowed uses at renewal of approval, based on the information available then. The Commission proposed that the approach could be refined by considering a concrete case, for instance a PT 6 substance, and see how the list of uses would look like.

4.1. Risk mitigation measures for products and treated articles	For discussion *CA-Dec21-Doc.4.1_Restricted*	Closed session

This item was discussed in closed session.

4.2. Management of new data on an active substance in an application for a biocidal product	For discussion and agreement *CA-Dec21-Doc.4.2*	

The Commission introduced the topic by means of a presentation summarising the comments received after the last meeting.

In light of the previous discussion and of the comments received, the principles of the process proposed at the last meeting had been slightly amended, while preserving the principle that there is a need for coordination in the process.

This process should take place in parallel to the evaluation of the application for product authorisation and be concluded in time, so that the refMS/eCA can consider the conclusion in their evaluation. If an agreement is reached on the principles, the Commission will request ECHA to develop a procedure along these principles. Previous BPC and Coordination Group procedural documents will also have to be amended to reflect the new agreements.

One Member State considered that the agreement on the validity of data and new endpoint values should take place in the appropriate working group of the Biocidal Product Committee (BPC), hence there is no need to have a validation by the BPC itself. The Commission explained that it is up to the BPC to decide how to organise itself for the validation of the agreement, bearing in mind that the objective is to ensure there is an agreement recorded, to ensure transparency and avoid re-assessment.

The same Member State considered that no update of the List of Endpoints (LoE) should be made, even if data is relevant, and that the applicant should submit an application for modification of conditions of approval according to Article 7 of the BPR as a basis for such an update. The Commission explained that the LoE is not part of the conditions for approval, therefore the procedure under Article 7 (application for modification of the conditions of approval) is not suitable to address this process. The Commission also reminded that the LoE is not mentioned in the BPR and is mostly used for product authorisation, being the key source of information for Member States.

Another Member State suggested to use Article 30(2) of the BPR to suspend the evaluation and request the applicant to re-submit the data via a 'scientific data update' application in R4BP, to be evaluated by the Member State initially responsible for the evaluation of the application for approval of the active substance. The Commission explained that in its view there Article 30(2) is not applicable to these cases, as that Article is meant to address the situation where the eCA for a product authorisation application identifies missing data that are then requested from the applicant, and not situations where the applicant is requested to re-submit data which were submitted via a different R4BP process. Furthermore, the Member State who evaluated the application for active substance approval is not directly involved in the product authorisation process and no specific fee is foreseen for that Member State in Article 30.

One Member State pointed out that the approval of the active substance is based on an assessment report which will be changed, but after the change (for instance an addendum to the assessment report) the legal act itself will not change. The Commission confirmed that the

assessment report itself is not part of the legal act and that, the addendum to the assessment report is one option to record the agreement on the new LoE, while another option is to have a separate document. However, if the modified endpoint or new endpoint give rise to concerns, a review of the approval of the active substance could be initiated under Article 15 of the BPR.

ECHA thanked for the revised proposals, noting that their idea of having a sort of filtering of the cases that the working groups would discuss had been taken into account. ECHA had a question on whether it is sufficient to have a change in the LoE or whether the Commission needs to reflect it in an implementing act, for instance in a case in which a new endpoint would mean that the active substance would meet the substitution criteria, or in the opposite case (substitution criteria no longer met). The Commission indicated that internal discussions are still ongoing for the case in which a substance would become a candidate for substitution, while in the opposite case (substance no longer candidate for substitution), companies can apply for an amendment of the conditions of approval. ECHA also questioned whether it was necessary to make a proposed list of information considered non-relevant. While acknowledging the need to have a record of the agreements, ECHA questioned whether the form of a list is really needed. The Commission was ready to consider other alternatives to a list and would leave it to ECHA/BPC to define how to record agreements.

With regard to the need of a letter of access (LoA) by subsequent applicants for product authorisation in case of modification of an endpoint value, the Commission explained its view that as long as the applicants for product authorisation submit a complete data package on the active substance, they would not need to provide a LoA to the specific new active substance data (as the applicant fulfilled its duty to submit a complete active substance dossier). However, when the new data cover an endpoint which was not addressed at approval stage, a LoA would be needed for product authorisation applicants as the dossier would not be complete otherwise.

A Member State had a question regarding data ownership and wondered whether an addendum to the assessment report can actually be made in case of different data ownership. The Commission state that there is no link between data ownership and the addendum to the assessment report or the new document produced, as these documents will just report a conclusion regarding the endpoint. Another Member State asked whether, in the case of new data covering a new endpoint not addressed at approval stage, all applicants need a LoA to the new data, or only those who need a refinement that would lead to a safe use. The Commission indicated its view that, if a refinement based on the specific data is needed for the identification of a safe use, then the LoA would be needed. The Commission mentioned that it would be helpful to have an analysis on a concrete case, as some cases might not be straightforward. A further Member State informed the Commission that they would still want to discuss the topic internally and submit comments in writing. The Commission was hesitant in opening a further commenting period, as the questions raised are not part of the core of the proposed process, and the changes in the process compared to the previous version are minor.

One stakeholder asked clarifications on the meaning of ‘reliable data’, as on some occasion reference was made to ‘relevant data’. The Commission replied that the term “reliable” is meant to cover the case of data which is of good scientific quality. The stakeholder also expressed concerns about the fact that, in the case of non-reliable data, no discussion at BPC level takes place. The Commission clarified that several Member States were not willing to discuss data deemed non-reliable, due to the workload it would generate, and this is why the specific point had been modified and did not include a discussion at BPC or WG level.

The Commission concluded by noting that the principles set out in the presentation were agreed by the CA meeting and invited ECHA to develop the practical implementation of the proposed process.

4.3. Consequences for biocidal products authorisations procedures of relevant information becoming available	For discussion and agreement *CA-Dec21-Doc.4.3*	

The Commission introduced the topic reminding that discussions on the document had taken place in two previous meetings. After the last meeting two Member States had provided comments – one opposing the approach in the document and the other one commenting on the timing and modalities for performing the comparative assessment.

The Commission mentioned that an agreement on the document will not be possible in this meeting, as reflections are still taking place on the cases when an active substance meets exclusion or substitution criteria.

One Member State made reference to Article 48 of the BPR, which gives the possibility to amend the authorisation of a product when the conditions in Article 19 are no longer met, but had doubts as to the performance of the comparative assessment and the legal basis of this requirement. The Commission mentioned that, different from the approach described in the past, it tends to think that the change of status of an active substance becoming a candidate for substitution can only be made at renewal of approval. However this new interpretation can be confirmed only after discussions with the Commission Legal Service.

Following a question from another Member State, the Commission clarified that section 1.3 of the document is still under discussion internally. The same Member State supported the idea of having changes applied as soon as possible, but had concerns regarding the requirement to carry out an assessment under Article 5(2) when considering applications for product authorisation, due to the delays this might cause and that this assessment would be better performed in a harmonised way at active substance approval level. The Commission noted that such assessment would also take place at EU level in case a review of the approval is made, but also in this case it will take more time than available during the product authorisation process. The same Member State expressed doubts on the efficiency of having two different processes running in parallel (at national and EU level). The Commission explained that the process at national level is required by the provisions in Annex VI and cannot be avoided.

Another Member State had a question regarding point 2.3 of the document (active substance now meeting substitution criteria), on the duration of the amended authorisation, as in some cases the change from ten to five years could lead to the authorisation being no longer valid. The Commission explained that this is part of the ongoing internal discussion and will be clarified at the next meeting. It also clarified that, in addition to section 1.3, also sections 1.4, 2.3 and 3.4 are subject to internal discussion.

One Member State supported the approach that when new information on the hazard properties of a substance becomes available it should be incorporated in the decision making as soon as reasonably possible and also supported section 2 of the document, on authorisations already granted. However, it had strong reservations for cases in which the pending application is almost due for decision making. This Member State suggested for such (exceptional) cases that the comparative assessment should be performed post-authorisation or at the renewal of authorisations and indicated that Article 23(4) provides the legal basis to

grant an authorisation without performing the comparative assessment, for a duration of maximum four years. The same Member State indicated also supported section 1 of the document, if a certain stage in the authorisation (cut-off date) is identified where the change of classification would not lead to the requirement to perform the comparative assessment. The Commission clarified that discussions on possible cut-off dates when new information would be disregarded already took place and that setting such cut-off dates is not possible.

An observer asked why, in section 2.1 reference is made to both the RAC opinion on a classification of a substance and the ATP Regulation including the classification in Annex VI to the CLP Regulation, instead of only mentioning the ATP Regulation, which represents the legal basis for the classification. The Commission clarified that, for cases where no harmonised classification exists, the RAC opinion is the first element, then after a while the ATP Regulation under the CLP Regulation will be adopted and the classification will be included in Annex VI to the CLP Regulation.

The Commission announced that a newsgroup will be opened for meeting participants to provide comments until 7 January 2022.

4.4. Report from the Coordination Group	For information	

The Commission gave the following report from the Coordination group :

- Six referrals were discussed and agreement was reached for two of the products. For the other four referrals and additional CG meeting has been scheduled, as further discussion would be needed.
- The Commission presented a document in relation to the amendment of Regulation (EU) No 492/2014 in the closed session that summarised previous CA discussions regarding unclarity on the interpretation of Regulation (EU) No 492/2014 and concerns or issues raised due to its current wording. The Commission asked for the input of the Member States regarding the topic. The Member States will provide feedback in writing concerning the document and any additional remarks concerning the amendment of this regulation.
- The Commission introduced a topic in relation to raising concerns in case of a non-authorisation decision when the national application is subject to mutual recognition in parallel. The purpose was to provide feedback from the ongoing discussion at CA level. Several Member States voiced their doubts regarding the new interpretation that it would be possible and in line with the BPR to initiate a referral in case of a non-authorisation decision of a refMS/eCA. The CG agreed that discussion on the practical implementations of such a situation would be revisited by the CG once the discussion had finalised at the CA level.
- The SECR presented an updated document concerning post-authorisation conditions for physical hazards; physical, chemical and technical properties, including full long-term storage stability test. The CG agreed by consensus on the proposal that: 1) the physical hazards and respective characteristics which affect product classification and labelling cannot be addressed by post-authorisation conditions, 2) post-authorisation conditions in exceptional cases are only possible for those physical, chemical and technical properties (long-term storage stability will be discussed further) which would neither effect Article 19(1) conditions, nor efficacy/risk assessment. As no

agreement was reached concerning shelf-life, MSs and ASOs will provide feedback on that and discussion will continue at the next CG meeting.

- The SECR presented a document concerning setting a criteria for a non-active substance having significant indication of ED properties and proposing that a non-active substance would only be considered to have significant indication of ED properties if there is an intention to prepare a proposal to include the substance in the Substances of Very High Concern list under REACH due to ED concern (according to Articles 57(f) and 59(1) of the REACH regulation). It was agreed to be included in the document that the criteria would be reviewed in the future based on more experience. The CG members agreed on the document by consensus.
- A MS presented a revised document of CG document CG-34-2019-02 on the instructions for applicants on the ED assessment of co-formulants. The aim of the revision is to provide practical information to the applicants on how to perform the ED assessment in complement to what is described in the CA-March21-Doc.4.3_Final document without duplicating the information in the CA document. The Member States and ASOs will provide feedback in writing. The Member State will provide a revised version of the document based on the discussion and the comments. Discussion will continue at the next CG meeting.
- The CG agreed by consensus on the revised overview template for BPF and its instruction manual with slight editorial changes.
- A Member State presented an outcome of an e-consultation in relation to the topic – RMMs for PT18 products. The CG was informed that there was no consensus concerning the raised questions, except for including a disclaimer for the list of Frequently used sentences in the SPC that the sentences are suggestions and their application as RMMs should be supported by further information showing their appropriateness for the intended use. One Member State noted that despite not reaching agreement for most of the questions, the document would be a good starting point for case-by-case discussions of particular cases in the future. The CG agreed on the document by consensus.
- A Member State presented an outcome of an e-consultation in relation to the topic – Storage stability and degradation of active chlorine. One Member State suggested and the CG agreed to change the proposal to have the 50% degradation limit as a recommendation. It was agreed that the iMS would provide a revised document and both Member States and ASOs would provide further feedback. Discussion will continue at the next CG meeting.
- The Commission presented a revised proposal regarding the determination of the dermal absorption value in product authorisation for different scenarios. Some of the MSs suggested some changes to clarify the text. The Member States and ASOs will provide feedback on the exact proposed modification of the current text of the document and discussion will continue at the next CG meeting.

4.5. Hand disinfection, PT 1: packaging and labelling/information on dispensers and refilled containers	For discussion *CA-Dec21-Doc.4.5*	

A Member State presented the document that summarises several issues encountered in the authorisation of hand disinfectants and that was discussed in several CG meetings (CG-46, CG-47 and CG-48). This Member State initiated the discussion with a hope to reach a harmonised agreement concerning those issues.

The first question posed was on whether Member States would be in favour of a common understanding of an appropriate maximum pack size for hand disinfectant products not to be used with a dispensing pump or in system. Based on the comments received, this Member State proposes to reach a common agreement that the product evaluation not only must include a thorough assessment of the intended use, but also include a detailed description on the suitable packaging and/or dispensing pump or system to be used with the product. Furthermore, when authorising the biocidal product, one must ensure that the SPC provides a use instruction and a thorough specification of the packaging and the dispensing pump or system to be used, all in accordance with the assessment. This will facilitate correct use in line with the product authorisation. If detailed information is provided in the SPC it is also easier for the authorisation holder (and distributers) to provide this crucial information to the downstream user chain. Clear SPC information is also important for enforcement in order to check whether the product is placed on the market in accordance with the authorised use.

Difficulties to set a maximum packaging size were highlighted by several Member States as they do not see a legal /scientific basis, This decision shall be taken on a case by case and agreement with the applicant. However, all Member States intervening agreed that too large packaging sizes would not fulfil the requirements. Two Member States were in favour of setting a maximum packaging volume to be sold out without a dispenser, and one of these Member States highlighted that the legal base to establish such a restriction is the risk assessment performed on the products.
One industry association agrees that a large packaging volumes without a dispensing pump should not be marketed, but has doubts on how to set a maximum packaging volume in general.

The Commission clarified that in the discussions in the CG it was concluded that there is a legal base to set a maximum packaging size following the risk assessment, but there is no such legal base for doing it in general for all disinfectants.

The Member State having raised the topic clarified that in the CG it was agreed that this should be done on a case-by-case and based on the risk assessment.

The second question regards what kind of information would be useful to include on the dispenser to ensure safe and efficient use of hand disinfectant products. Also related to the information to be provided to the user of the products, it is asked if it would be useful to include a sentence in the SPC that reminds the authorisation holder of their responsibility to also include information on the dispenser.

According to one Member State, there is a legal base in Article 17(5) of the BPR users shall use the product as authorised and the necessary information to be able to do it needs to be conveyed to them. The practice in this Member State is to make a picture of the label of the product and put it in the dispenser that shall be readable and include the relevant instructions of use. This is also necessary to comply with CLP requirements. Disinfectants have consequences for human health and it is important that hazard statements and instructions of use are available to the user.

Another Member State thanked for raising the issue and suggested that refilling should be assessed as a use of the biocidal products in the authorisation and therefore the use will be reflected in the SPC. It can be also reflected in the SPC that refilling is not allowed. The user

should label the dispenser in accordance with Article 69 of the BPR. One Member State agreed with this suggestion.

For one Member State the restrictions of packaging sizes is critical. They supported the views expressed other three MSs. Information for the final user should be available as stated in Article 69. Another Member State points out that most of the active substances used in disinfectants are still in the review programme and therefore most disinfectants are still under transitional rules.

One MSs expressed agreement with the proposal that this will be applied in future authorisations, and recommend the approach taken for products that are already authorised. In the opinion of AISE these obligations are already clear from the application of Article 69 of the BPR and the CLP Regulation. In their opinion, this is more an enforcement issue, as the legal obligations are already in place. Other MS agrees also with the proposal, and acknowledges that there are already legal obligations to label the products but that the obligations are not always fulfilled and there are also divergent interpretations on how to fulfil the labelling requirements and whether refilling is possible or not and on what exact information should be supplied to the final user of the products.

One industry association asks for the purpose of the discussions and wonders if the objective is that people that are visiting shopping malls, super markets etc. have information on the biocidal product when they apply hand disinfectants.
The Commission confirmed that the purpose of the discussion is to guarantee that the final user of the hand disinfectants have the necessary available information to guarantee a safe use of the product.

One Member State provided information on a survey made in their territory where the highs viral load in surfaces contaminated were hand dispensers. Therefore, for the control of the disease the best option would be to have non-contact dispensers for hand-disinfectants.

A newsgroup will be opened until 7 January so that MSs can reflect and contribute to the discussion.

4.6. Designation of the biocidal product when free radicals are generated from a polymer	For discussion and agreement *CA-Dec21-Doc.4.6*	

The Commission started the discussion by reminding the CA about the previous discussion on the matter. From the newsgroup opened after the last CA meeting, a consensus emerged on the possibility to amend the wording of case-type 4 as referred to in CA-Jul19-Doc.4.1 to address the issue of the designation of the biocidal product when free radicals are generated from a polymer without the intervention of a device and when air or water are the precursors

The initiating Member explained the content of the proposal. Three amendments were requested and accepted by the CA:

- To remove any reference to masterbatch in the final document but to keep the word mixture to make the link to case-type 3 where relevant;
- To remove references on how the object should be described in the SPC as this could be part of the discussion of a dedicated working group (see point below);
- To remove any reference to the pure (100%) composition of the free radicals as that should be evaluated on a case-by-case basis.

The document was agreed with these modifications.

4.7. Authorisation of an in-situ biocidal product: case-type 2 vs. case-type 4	For information	

The Commission recalled the discussion triggered by one Member State at the last CA meeting. A newsgroup was opened, as no conclusion could be reached at that meeting. From the contributions received, it appears that all responding Members States favour a flexible approach i.e. to leave the possibility to applicants to decide whether they want to apply for product authorisation under case type 2 or 4 as referred to in CA-Jul19-Doc.4.1.

The initiating Member State agreed with the conclusions reached at the newsgroup but called for a harmonised approach regarding the content of the SPC under case-type 4. A dedicated working group of the CA could be set up to discuss this issue. The agenda should be further elaborated by this initiating Member State but the discussion could go around the content of the SPC and in particular on the manner to convey information on the device to the user via the SPC. Further concerns could also be discussed. The Commission welcomed this initiative.

Four Member States indicated their interest for this idea but could not take any firm decision before consulting their relevant colleagues. One Member State asked whether the initiating Member State could prepare a scoping document for further reflection. Several stakeholders indicated their interest to attend such meetings and suggested to extend the discussion for the other case-types where a device is required (i.e. case-types 2 and 4).

The Commission concluded the discussion by indicating that a newsgroup will be opened until 7 January 2022. The CA meeting was invited to indicate for which case-type and for which specific issue a discussion is needed to provide this information to the initiating Member State.

4.8. List of pending Article 36 requests	For information *CA-Dec21-Doc.4.8*	Closed session

The item was discussed in closed session.

4.9. Handling "carriers" in the authorisation of biocidal products	For discussion and agreement *CA-Dec21-Doc.4.9* *CA-Nov16-Doc.4.3-Rev2*	

Following a discussion in the frame of a referral to the Coordination Group, an update of point (18)(a) of the document *CA-Nov16-Doc.4.3 on handling carriers* was made by the reference Member State (France) for the biocidal product concerned in the referral and agreed in the 93rd CA meeting. A further amendment was proposed by one Member State in order to guarantee coherence throughout the document.

In order to address the Member State's proposal and to address issues identified in the discussion for a Union authorisation in the Biocidal Products Committee, amendments to paragraphs 14, 15, 16, 19, 29 of the document are proposed. ECHA had taken care of the revision of the document and several amendments were proposed and explained by ECHA.

One Member State thanked ECHA for the modifications agreed with the amendments made. However, they proposed that in recital 14 the last sentence addressing case b is split and has its own recital to make the reading easier and proposed the wording to further clarify that for "case-type B" the carrier component is considered for the calculation of the concentration of

the active substance (AS) and SoCs (Substances of Concern). The wording proposed, supported by other MS is inserted in the document as new recital 14.

Another Member State questioned that wipes are included as an example for "case type A" in paragraph 8 of the document. In their opinion, a wipe can be also used for scrubbing and therefore has also a secondary effect- it can also be type B and therefore the example is not very fortunate and it will be better to delete it. They think it will be more adequate to put it as example of "case type B" and explained that because of the amendment made to the document now this has consequences for the calculation of the concentration of the AS and SoCs. The Commission clarified that this point was not proposed to be amended and was not the object of the discussion for this meeting. It also reminded that the discussion on how to address carriers started with the disinfection wipes and it was decided that they are case-A after long discussions, even if they have also a cleaning function. In addition, this paragraph was not proposed to be amended.

Another Member State expressed strong reservations to the amendments made to paragraph 14. They recall long discussions on whether the carriers should be part of the identity of the products and should be used for the calculation of the AS and SoC. In those discussions, it was concluded that a carrier should be considered as an article in the meaning of the REACH and should not be considered as part of the identity of the biocidal products. In the amended version of the document, a different approach is proposed and they do not understand the scientific reasons behind it. For them this makes no sense to make a distinction between "case type A" and "case type B" for the calculation of the concentration of the AS and SoCs, as the secondary function of the carrier has no impact on the risks from AS and Soc. They consider that the carrier component should not be considered for the calculation neither for "case-type A" nor for "case-type B".

ECHA clarified that this modification was triggered by a discussion that took place in the BPC on a Union authorisation and it was agreed in the BPC that the carrier should be considered for the calculation.

Other Member State confirmed that this approach was agreed in the BPC when discussing a UA and agrees with the modifications proposed.

Other Member State informed that they are still discussion internally in the proposed amendment and that they still have not a position on it.

A newsgroup will be opened for MSs to provide comments on the proposed amendments to the documents until 7 January 2022. ECHA requested input form MSs considering all the different cases they are confronted with, as the handling of carriers is a complex topic and experience would help to address all cases in the most adequate way.

4.10. CA-March16-Doc.4.6 Final.rev2 - note for guidance Q&A on simplified procedure	For discussion and agreement *CA-Dec21-Doc.4.10* *CA-March16-Doc.4.6 Final-rev4*	

The Commission presented a revised version of the *CA-March16-Doc.4.6 Final.rev2 - note for guidance Q&A on simplified procedure* that intend to address a proposal from a Member State to further clarify the Q&A 16 that was agreed in the previous CA meeting and the footnote 11 that was modified by the Commission. One Member State submitted remarks on the proposal ahead of the CA meeting. The Commission agreed with the proposal made by that Member State and will use it as a basis for the discussion in the meeting.

Germany does not agree with the modification made to the Q&A 16 as, in their opinion, this could encourage animal testing and testing of vertebrates.

The Commission pointed out that this is just a mention of the CLP rules and there is nothing in the Q&A that encourages animal testing and ,if studies are submitted in an application for a simplified authorisation they need to be checked by authorities, as this is a principle in the CLP regulation, in order to know if the product meets the requirement for a simplified authorisation.

The Member States that initiated the discussion confirms that they want this clarification to be added to the Q&A and aggress with the revised document.

The document was agreed by the CA meeting. Germany kept its position to oppose to the Q&A 16 and ask this to be reflected in the minutes of the meeting.

4.11. Dermal absorption value in product authorisations	For information	

The Commission provided information on the document, that will be further discussed in the next meeting of the Coordination Group.

The purpose of the document is to agree on a way forward to address dermal adsorption value in the authorisation of biocidal products and addresses different situations that can arise at product authorisation stage. The ultimate objective is to prevent disagreements in mutual recognition procedure, to have a harmonise approach between MSs when considering the dermal adsorption value in the authorisation of biocidal products and ensure equal treatment if applicants.

4.12. Non-authorisation decision in national authorisation, or major/minor changes applications that are subject to mutual recognition in parallel	For discussion and agreement *CA-Dec21-Doc.4.12*	

The Commission presented a document (*CA-Dec21-Doc.4.12*) that intends to clarify whether a referral of objections to the Coordination Group (CG) in accordance with Article 35(2) of the BPR can be initiated if the assessment of the reference Member State (rMS) results in a proposal for non-authorisation of a product.

In the CG-39 meeting it was discussed whether a referral of objections to the CG in accordance with Article 35(2) of the BPR can be initiated if the assessment results in a proposal for non-authorisation of a product. At the meeting, the Commission provided their interpretation (CG-39-2020-01), concluding that this case is not specifically mentioned in Article 35(2) of the BPR, and therefore cannot be subject to a referral. The same interpretation was also provided (CA-Feb20-Doc.4.5) in the CA-87 meeting in February 2020. The issue was further discussed in the CA-93 meeting (CA-Sept21-Doc.4.8).

Also, the question of whether the decision by the rMSs not to authorise a change in the context of applications for minor (MIC) or major (MAC) changes needs to be sent to the concerned Member States (cMSs) for commenting was raised by a Member State. The Commission provided their interpretation in the CA-92 (CA-June21-Doc.4.13.b) and CA-93 (CA-Sept21-Doc.4.8.) meetings.

It was clarified that the current document is not relevant for Mutual Recognition (MR) in sequence procedures as, if the rMS decided not to authorise the biocidal product, there would

be no authorisation that could be mutually recognised, and therefore an application in accordance with Article 33 of the BPR could not be submitted.

The interpretation of the Commission is that, bearing in mind Article 35(1) of the BPR and the nature of the procedure of a MR in parallel, in which an agreement on the conclusions on the PAR needs to take place in order to agree on the SPC, it appears that the CG can examine any question relating to whether a biocidal product for which an application for MR has been made in accordance with Article 34 of the BPR meets the conditions for granting an authorisation laid down in Article 19 of the BPR, including the case of a non-authorisation proposal from the rMS. This would imply also that cMSs are entitled to raise disagreements to the CG on a non-authorisation proposal from the rMS, and in case no agreement is reached, the rMS can refer the disagreement to the COM in accordance with Article 36(1) of the BPR.

Regulation No (EU) 354/2013 (Changes Regulation) establishes a procedure for resolving disagreements on the assessment of the rMS on changes applications, in Article 7 (4), Article 7 (6), Article 8 (4), Article 8(6) and Article 10. In accordance with Article 10 of the Changes Regulation, and for matters other than those included in Article 37 of the BPR, where the cMSs do not reach an agreement on the conclusions of the PAR or, where relevant, on the revised SPC, the rMS shall refer the matter to the CG referred to in Article 35 of the BPR. In accordance with Article 10 of the Changes Regulation, Articles 35 and 36 of the BPR apply to matters of disagreement on applications for MIC or MAC. Therefore, even in case of non-authorisation of the changes, the cMSs have the right to comment on the conclusions of the PAR or, where relevant, on the revised SPC.

One Member State does not agree with the proposed interpretation as in their opinion Article 35(2) of the BPR is quite clear, and even if in accordance with Article 35(1) a disagreement on non- authorisation proposal made by the reference MS is possible, in their opinion is not possible to raise a formal referral in accordance with Article 35 (2) of the BPR.

Another Member State agrees with the proposed interpretation. One Member State agrees with the interpretation as well and in their opinion is clear from Article 35(1) than any matter as regards compliance of the product with Article 19 of the BPR.

The document was agreed by the CAs.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-Dec21-Doc.5.1*	

The Commission reported on the progress of the review programme and informed that 5 draft assessment reports were recently submitted for formic acid for use in biocidal products of different PTs. Overall 42% of the review programme has been completed. The main concern remains with the 40 backlog reports for which an application was submitted before 1 September 2013. The Commission urged the evaluating Member States to finalise their assessments, in particular for the substances meeting the exclusion and substitution criteria.

The Commission reiterated also its request to the evaluating Member States to continue their efforts to complete the review programme by 2024 in particular for the substances in the first priority list which enter the renewal phase whereas the first approval is not yet finalised for others.

The Commission informed that half of the Competent authorities on biocides responded to the letters sent to their Ministers to collect data about the resources allocated in the Member States on the assessment of biocides applications. In some cases, the resources had been or will be increased. The Commission will present an overview of all the contributions as soon as they are all available.

Lastly, the Commission invited the evaluating Member States to make use of the support provided by ECHA concerning the review of the substances to finalize their evaluations.

5.2. Progression of the renewal process of approval of active substances	For information *CA-Dec21-Doc.5.2*	

The Commission explained that compared to the last meeting, there was no new deadline for the submission of renewal application for active substance. The Commission repeated its request to be informed sufficiently in advance of the expiry date of the approval of the intention of the evaluating Member State to conduct a full or limited evaluation. Lastly the Commission highlighted that at the end of December, the deadline for the submission of applications for renewal of DCOIT, abamectin and imidacloprid will be reached.

5.3. ECHA Active Substance Action Plan – progress update	For information *CA-Dec21-Doc.5.3*	

ECHA presented the regular report to the CA meeting on the progress of the Active Substance Action Plan, covering developments of October and November 2021. It was mentioned that the number of BPC opinions expected to be delivered by the end of this year is slightly higher than the figures achieved in 2020.

As to the specific actions, under action 1 (prioritisation of dossiers), the ECHA contact points continued discussing with the Member States the priorities for the submission of dossiers included in the plans for finalising the active substance dossiers by 2024. Based on indications of an increase in the number of dossiers, ECHA has updated its work programme for the next years and reorganised internally to allow a smoother peer-review. Under action 2 (support to the eCAs), ECHA continued to provide direct support in the assessment of active substances (e.g. monochlorines generated in situ, active chlorine), has started support activities in the physico-chemical assessment of active substances, has started to work on guidance for applicants and Member States to support the analysis of alternatives and is planning a workshop on environment ED assessment together with EFSA and a training on classification of mixtures. Under action 3 (streamlining the peer-review), at BPC-40 the outcome of discussions about alternative ways for working was presented. The proposal for co-rapporteurship was discussed but not supported by the BPC members while the proposal to limit adhoc follow-up to exceptional situations was agreed by the BPC meeting. At BPC-41 a new RCOM table template was presented, aiming at facilitating the commenting period during the pre-working group phase. Under action 4 (reduction of complexity), ECHA and representatives of six Member States have been working on best practices for a focused assessment of safety and efficacy, including the reduction of uses to be assessed. Some preliminary criteria for the application of a focused assessment, along with elements that would prevent its application have been identified. Further analysis is expected to take place to evaluate the impact of the proposal on the product authorisation.
ECHA invited Member States to flag issues and seek support from ECHA already during the evaluation phase and also to check as early as possible in the evaluation whether further information is needed in order to perform the evaluation. With regard to the Substance

Identity campaign, Member State were invited to contact ECHA by 31 March 2022, in order to discuss the need of support in the verification of the identity of active substances.

5.4. Early review of the substance tolylfluanid	For information	

The Commission announced its intention to review the approval of the substance tolylfluanid for use in biocidal products of product type 7 based on information provided by a Member State Competent Authority during the CA meetings of September 2018, March and July 2019 and May 2020.

According to the data collected, one of the metabolites of tolylfluanid has been found in some drinking water supplies. If drinking water is ozonated in water treatment plants, this metabolite can turn into N-nitrosodimethyl amine (NDMA) which is classified as category 1B carcinogen.

The applicant was informed of the intention to carry out a review and indicated that the renewal of approval of the substance will not be supported. He confirmed that there is no manufacturing capacity for this substance in the EU anymore.

In accordance with Article 15(1) of the BPR, the Commission had made publically available the information that a review of the substance is being performed. As the applicant is no longer interested in the substance, the Commission intends to proceed with the cancellation of the approval of tolylfluanid for PT 7 in early 2022 without asking an ECHA opinion. The applicant will be informed accordingly.

The Member State initiating the request welcomed the approach proposed by the Commission.

6. Treated articles
No item for information or discussion.

7. Horizontal matters

7.1. ECHA communications	For information	

No specific communications were presented in this meeting.

7.2. Incidents with phosphine releasing products	For information *CA-Dec21-Doc.7.2* *CA-Dec21-Doc.7.2a*	

The Commission explained that at the last meeting, a Member State reported several incidents when food and feed treated with phosphide pellets releasing phosphine are transferred from sea ship to inland vessels. A newsgroup was open to collect further information. Three Member States reported similar incidents and informed that actions had been envisaged at

national and EU level to limit the risks of exposure to the substance. This might result from the use as plant protection product and/or as biocidal product.

The initiating Member State welcomed those initiatives and explained that some adjustments to the conditions for product authorisation at the renewal of the active substances (Aluminium phosphide releasing phosphine and magnesium phosphide releasing phosphine) should be required.

One Member State informed that the topic was on the agenda of the last meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF). The Commission explained that no feedback had been received so far from the colleagues involved in the implementation of the Plant Protection Products Regulation.

The discussion will continue during the assessment of the application for renewals of the approval of aluminium phosphide and magnesium phosphide releasing phosphine where the initiating Member States intend to suggest additional restrictions to be discussed during the peer-review of the substances.

7.3. Questions regarding the MRL for the active substance chlorocresol	For discussion *CA-Dec21-Doc.7.3*	

The Commission invited the Member State having proposed this topic to introduce the document and mentioned that discussions with the Commission colleagues in charge of veterinary medicines took place leading to the conclusion that there was no need to establish an MRL for this active substance. The Commission asked the initiating Member State to clarify why an MRL would be needed as it appears that no unacceptable risk was identified. The initiating Member State explained that several applications for authorisation of PT3 products used for cleaning animal stables are ongoing. After disinfection livestock could come in contact with residues of the product, therefore a dietary risk assessment has to be performed and it has to be checked whether there is an existing MRL to be respected. Under the VMP legislation it was decided that there was no need to establish an MRL for chlorocresol; however this decision was taken more than 20 years ago and biocidal use has not been taken into account. Chlorocresol was also used previously as a plant protection product and a default MRL of 0.01 mg/kg might be applicable. There are therefore two contradicting statements - no MRL vs. default MRL. In the view of the initiating Member State the more restrictive value should apply. However, the interim approach for MRL makes reference to use of scientific data in order to establish the limits, while under the PPPR the default value is not based on specific scientific data.

The main question posed is whether the default value under the PPP is to be used or whether no MRL is applicable, as decided under the VMP legislation. While it is true that no unacceptable risk for dietary exposure was identified, however the default value set under the PPPR is exceeded. As to the consequences for product authorisation, according to the interim approach they could be authorised, with a post authorisation condition that an application for MRL evaluation has to be submitted. A question is raised also on who is supposed to submit such application (and pay the respective fees). The initiating Member State also suggested that the assessment or re-assessment of a MRL should be integrated in the approval or renewal of the active substance.

Concerning the MRL set under the PPP area, the Commission noted that the biocidal product is to be used for disinfection of animal stables and asked why the value set for PPPs would be particularly relevant. The initiating Member State acknowledged that the biocidal use is more similar to the one under the VMP legislation, but however the default value set under a

different legislation cannot be ignored. The Commission also noted that in the interim approach, when two values are set under different frameworks, the highest limit should be used, which in this case would mean the fact that no MRL is applicable. This is however a preliminary view.

One Member State mentioned that currently there are discussions in the PPP area with regard to MRLs for pesticides and veterinary medicines and that this point should be integrated in those discussions. Another Member State informed that in the assessment of ongoing applications they use the default value set under the PPPR and that they will provide comments on the document after the meeting. The Commission invited those Member State having authorised products containing chlorocresol to indicate how they considered the issue of MRLs in their assessments and their authorisations.

Another Member State noticed that under Regulation 396/2005 the MRLs are set considering PPP uses and expressed doubts as to the existence of an appropriate legal framework under which MRLs for biocidal use could be set. The Commission explained that historically it was decided not to develop a specific approach for establishing MRLs under the biocides regulation and that, if residues were found in a plant product then the approach under the PPPR would be used and if residues were found in animal meat, then the approach under the VMP legislation would apply; in case substances were not used in either of the two areas, the approach under the contaminant legislation would apply.

One Member State was of the view that the approach under the plant protection products area should be applied, as the approach was used previously for other active substances.

Concerning the question on post-authorisation requirement, the Commission mentioned that generally the Commission prefers not to have post-authorisation requirement, but this possibility was agreed and included in the interim approach. The Member State having indicated to use the default value in their assessment mentioned that a referral was raised in the Coordination Group on this matter.

On the question of possibility of setting MRLs at the stage of approval/renewal of the active substance, the Commission stated that for this case it was not possible to set MRLs at approval stage, due to the information in the dossier. One Member State mentioned a specific point in the interim approach mentioning product-types which are prone to lead to residues in food and feed. These should be assessed at approval stage but there is a question on how to do it in practice.

A newsgroup will be opened for Member States to provide comments until 7 January 2022.

8. Scope matters
No item for information or discussion

9. Enforcement issues
No item for information or discussion

10. International Matters
No item for information or discussion

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-Dec21-Doc.11.a*	

Member States were invited to consult the latest version of the document and indicate to the Commission if there are any changes in the details of their competent authorities.

(b) Compiled minutes of CA meetings 2005-2020	For information *CA-Dec21-Doc.11.b*	

The Commission informed that compiled minutes of the CA meetings from 2005 until 2020 have been prepared, with the aim of allowing to retrieve the history of the discussions held on specific topics.

(c) Use of active substance trivial name	For discussion *CA-Dec21-Doc.11.c*	

The Member triggering the discussion explained that in some instances (e.g. labelling of long name of active substance), it would convenient to agree on a trivial name mainly for information purposes to the consumers. In general, plant extracts and other active substances with complex names would benefit having a trivial name.

As the name of the active substance is determined following the criteria established by the CLP Regulation, the trivial name cannot substitute the CLP name, but could be used once a link is set between the chemical and the trivial name. The Member State triggering the discussion asked whether it is possible to establish a trivial name under the CLP and if so which process should be followed. The chemical and the trivial names could be reported in the SPC and the assessment report but only the trivial name should appear on the label.

A stakeholder replied that when an applicant does not want to disclose the name of a non-active substance in a biocidal product, the use of an alternative name is allowed under Article 24 of the CLP. However, it was also recalled that the unique formula identifier (UFI) is also the main gateway to information on a specific mixture. The UFI is a unique code assigned to one specific mixture composition that will be required both in the submission of information and on the label, or in some cases the packaging, of the biocidal product. The trivial name should therefore be recognised across legislations and accepted widely by stakeholders.

A Member State added that the link between the chemical and trivial names are also highly relevant for the poison centres notifications. This Member informed that internal consultation is necessary to see whether the labelling of a trivial name only is possible on the label. Another Member added that the trivial name should be reported in the approval Regulation as well.

The Commission asked whether the idea of having trivial name reported in the assessment report, the approval Regulation and the SPC could be at least accepted in principle by the meeting, as this approach would be anyway limited to specific cases. In a second step, the process to establish this trivial name could be discussed.

The discussion went on with an exchange of views on the possibility to label the trivial name only. One Member indicated its support to label both the chemical and trivial names as the

chemical name is necessary for enforcement purposes. The initiating Member argued that the link between the chemical and trivial names should be mentioned in the SPC. Therefore only the trivial name could be labelled (with possibly the chemical name in a footnote).

The Commission concluded the discussion by opening a newsgroup. Comments were welcome until 7 January 2022. More information from CLP colleagues in the Agency could be useful to better understand how this issue could be addressed.

(d) Item suggested by Norway		Closed session

The item was discussed in closed session.