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

MINUTES

99th 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

15-16 March 2023

1. Adoption of the agenda	For adoption *CA-March23-Doc.1*	

On request from one Member State, one point was added to the agenda, regarding information from the workshop on legal matters that took place in December 2022 in Austria.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-March23-Doc.2.a* *CA-March23-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 55th Coordination Group meeting of 20-23 February 2023:

- Four referrals were discussed and agreement was reached for one of them; additional meetings will be organised to discuss the open points of the other three disagreements;
- The Commission informed about the upcoming discussion at the CA meeting on the application of Article 48 of the BPR (discussion foreseen at CA meeting of June);
- The Commission presented a document on the interpretation of Article 35 of the BPR, according to which the agreement of only the reference Member State and the concerned Member States is considered necessary for the agreement on referrals, instead of the current procedural way of consensus agreement of all Member States. The procedural documents of the Coordination Group would need to be amended to also reflect this;
- The Commission presented a document on biocidal products containing iodine or PVP-iodine and the implication of these active substances now meeting the exclusion criterion set out in Article 5(1)(d) of the BPR and informed the CG members that the way forward would be discussed at the CA meeting of March 2023;
- A new chairperson for the CG was elected (the French CG representative), with a mandate starting on 24 May 2023;
- The outcome of three e-consultations was presented: (i) revision of harmonised SPC sentences for rodenticides with regard to environment related changes; (ii) risk mitigation measures for PT 8 outdoor treatment of wood which is used in use class 1 and 2 after drying; (iii) concentrations and contact times for various groups of target organisms;

- The Secretariat presented an updated revised document concerning management of new active substance data submitted at product authorisation based on the agreed approach at CA-94 and taking into consideration the comments provided by Member States and the Commission during the written commenting for the second revised version. It was communicated that the revised BPC document would be discussed at the BPC-46 meeting in March. Several suggestions were made to the document during the closed session discussion and agreed in the open session. Several parts of the document were preliminary agreed in the open session, only leaving the part concerning the assessment of new active substance data submitted for product authorisation unagreed due to its close connection to the counterpart BPC document that has not been discussed at that point.

4.2. List of pending Article 36 requests	For information *CA-March23-Doc.4.2*	**Closed session**

The point was discussed in closed session.

4.3. Modification of Regulation 492/2014 on renewal of authorisations under mutual recognition	For discussion and agreement *CA-March23-Doc.4.3*	

The Commission introduced an updated proposal for amending Regulation (EU) No 492/2014 on renewals by mutual recognition ('the Regulation') to address the issues raised by Member States and industry representatives and discussed in the 89th CA meeting (September 2020), the 90th CA meeting (December 2020), the 92nd CA meeting (June 2021), the 93rd CA meeting (September 2021) CG-49 meeting (November 2021), CG-50 meeting (February 2022), the 97th CA meeting (October 2022) and the 98th CA meeting (December 2022).

The main issues addressed are the renewal of same biocidal products' authorisations linked to the renewal of mutually recognised products' authorisations, changes to the derogations to authorisations under the same terms and conditions that can be accepted for a grouped renewal of the products, the application of the period of grace, the possibility to apply for major or minor changes to the authorisation of the biocidal product while the renewal is ongoing and some other adjustments to make the text coherent with the provisions of the BPR.

As regards the possibility to apply for major or minor changes to the authorisation of the biocidal product while the renewal is ongoing, the proposal is to restrict that possibility for a period before the application for renewal is submitted. Two Member States supported the proposals, while others expressed concerns by the length of the deadline set. Two Member States requested clarification on the wording as regards the scope for the grouped renewals and the possibility to apply for changes. The Commission will try to make the text clearer and requested Member States for concrete proposals on the possibility to apply for changes while the renewal is ongoing.

One Member State enquired about the possibility to consider authorisations under mutual recognition as being granted "under the same terms and conditions" when derogations in accordance with Article 37 were applied, arguing that the English SPC that is used for the basis of the mutual recognition agreements is the same. The Commission replied that this is not possible, as the conditions of authorisation are different in the Member States. One

Member State indicated that will not support the proposal if authorisations to which Article 37 has been applied cannot be renewed in group. The Commission reminded Member States that the amendment of the Regulation will be adopted as a Delegated act.

Another Member State and a stakeholder observer voiced its opposition to not allowing grouped renewals of authorisations to which a derogation in accordance with Article 37 has been applied, as they consider that a derogation under Article 37 can be something minor that does not affect the composition of the products, while by comparison a standard minor change can lead to even more differences on the terms and conditions for the product. The Commission recalled that the definition of "minor changes" as provided in the Changes Regulation covers something that is expected to be minor, while a derogation under Article 37 can lead even to a non-authorisation of the products. The Commission has also considered to list the minor changes for which it would be possible to apply and requested Member States to further reflect on this issue.

ECHA signalled that the details on the transition from one regulation to another need to be specified. The Commission agreed with the remark.

A newsgroup will be opened after the meeting till 14 April for Member States to provide their comments to the proposal, and specially to the new article 2(a).

4.4. Discussion on SBP Regulation (Regulation (EU) No 414/2013)	For discussion and agreement *CA-March23-Doc.4.4*	

The Commission introduced an updated proposal for amending Regulation (EU) No 414/2013 on the authorisation of same biocidal products ('SBP') ('the Regulation') to address the issues raised by Member States and industry representatives and discussed in the 98th CA meeting (December 2022).

The main issues addressed are the renewal of same biocidal products' authorisations, changes to reference biocidal products' authorisations and to SBP authorisations and some other adjustments to make the text coherent with the provisions of the BPR.

The Commission presented some diagrams to Member States in order to explain the different cases which can occur. The Commission explained that several of the amendments proposed are reflecting an improvement of the wording, or the structure, or are needed to ensure consistency with the BPR and to improve the functioning of the SBP procedures.

The Commission presented the proposed amendments to the Regulation, among which:

- Inclusion of an acceptance step consistently across procedures;
- Inclusion of an express legal basis for the rejection of the application at both the acceptance and the validation stage;
- Inclusion of an express legal basis for the rejection of the application when the application of the reference BP is rejected;
- Inclusion of an express legal basis for the request of additional information in the framework of the simplified authorisation procedure;
- Inclusion of clarifications, such as that, in case the cancellation or the amendment of an authorisation occurs, the competent authorities shall consider whether an amendment or a cancellation of an authorisation granted in their territory is required;
- Inclusion of an article addressing the cancellation of an SBP authorisation at the request of the authorisation holder;

- Inclusion of a specific requirement for the same change (major or minor) to be simultaneously applied with regards to the SBP and the reference product, in order to observe the principle that the SBP and reference product may differ only to the extent of administrative change(s). The practical consequences of this approach were illustrated.
- Inclusion of provisions concerning applications for renewal of an SBP authorised by national authorisation or Union authorisation. The Commission informed that they have taken into account the comments of Member States in order to streamline the renewal procedure, considering that this is an SBP and to rely on the renewal of the reference product. The Commission mentioned also that there will be the assessment of the same terms and conditions in the validation stage. Once the application for the renewal of the SBP is validated, it will be necessary to wait the renewal of the reference product. The Commission specified that once the authorisation of the reference product will be granted, the renewal of the SBP authorisation will be granted too. However, if the reference product is not renewed, the SBP will not be renewed as a consequence.
- Inclusion of provisions addressing the situation where the reference BP is authorised via mutual recognition.
- Inclusion of provisions addressing the situation where the related reference BP is authorised via UA, a related SBP is authorised via NA and there is an authorisation via mutual recognition that has taken that SBP NA as a reference BP authorisation.
- Inclusion of provisions addressing the situation where an application for renewal is rejected on the basis that a major or minor change has been granted with regard to either the reference BP authorisation or to the SBP authorisation. A timeline will be set out for the authorisation holder to submit an authorisation application in accordance with the BPR without losing access to the market.

The Commission further clarified that the presence of major or minor changes on a product, compared to the "reference" product, makes a product not in line with the SBP definition already in accordance with the legal text currently in force.

A Member State raised a question concerning the timeline of the application for the renewal of the reference product and the SBP.

The Commission recalled that the main idea of the proposed modifications is to have all the renewal applications submitted at the same time. Once the validation of the SBP is concluded, the evaluation for the renewal of the reference product will continue, while the one of the SBP will await the end of the assessment of the reference BP application.

Another Member State pointed out that it often happens that the applicant applies for minor changes of the SBP and these changes are not reflected in the reference BP authorisation. The Member State asked if the Regulation has any transitional arrangement for these types of situations. The Commission replied that SBP may only differ from the reference BP to the extent that the information may be subject to an administrative change. If these authorisations differ for anything more than that, they are not in line with the current text of the Regulation (there is no change in Article 1 of the current SBP Regulation). The Commission took note of the comment.

One Member State asked if, in case of changes and separate applications, the timelines should be aligned. The Commission replied that, if at validation stage it is found out that it is not an SBP (i.e. the difference concerns more than merely administrative changes), the application for that product should follow a separate process. The application for the authorisation of a

product that is not an SBP will not be aligned with that of the reference product, because the applicant has to submit a new application for authorisation.

ECHA thanked the Commission for the document and appreciated the rationalisation of the renewal procedure for SBPs. ECHA confirmed that, once the text will be agreed, they will be able to align R4BP. ECHA also pointed out that certain provisions may be further improved, affirming that right now there is a possibility for the submission of the application of the SBP while the reference product is still under discussion and this causes inefficiencies concerning the finalisation of the SBP opinion. The Commission thanked ECHA for the comment and agreed to reflect on further improvements to the draft.

One Stakeholder Observer asked if, in case of an application for an SBP authorisation made after the authorisation of the reference product, the expiry date will be aligned. The Commission confirmed that the expiry date of the SBP authorisation will be the same as that of the reference BP.

The same Stakeholder Observer pointed out that some wording should be clarified. The Commission agreed and took note of it.

The Commission concluded that it is aware of the complexity of the matter, but the aim of the text is to rationalise concepts and procedures in line with the BPR, and to ensure that the applications which MSs receive are manageable. The Commission invited Member States to provide their comments the newsgroup by the 14th of April.

4.5. Union authorisation: Article 44(5) derogations	For agreement *CA-March23-Doc.4.5*	

The document was tabled for agreement. The Commission explained that the document reflects the agreement from the previous meeting on the principles and procedures for request for derogations in accordance with Article 44 (5) of the BPR which was presented in *CA-Dec22-Doc.4.5 - UA_similar conditions and derogations_update (1)*. Since the analysis and discussion on the definition of similar conditions of use is still ongoing it was considered useful to produce a standalone document concerning the agreement on the principles and procedure for the Article 44 (5) request. For the timeline for the submission, it was highlighted that after the adoption of the BPC opinion and the implementation of the agreed changes, there is no notification on the availability of the SPC for Member States.

No further comments were made and it was agreed to continue to implement the approach.

The work on the notion of similar conditions of use is still ongoing and the Commission invited Member States to provide further comments on this. An agenda point is planned to be tabled for the next CA meeting.

4.6. Union authorisation: acting as evaluating CA	For discussion and agreement *CAMarch23-Doc.4.6*	**Closed session**

The point was discussed in closed session.

4.7. Cancellation of Union authorisations for products containing iodine and/or PVP iodine	For discussion and agreement *CA-March23-Doc.4.7*	**Closed session**

The point was discussed in closed session.

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

The Dutch authorities informed about the preparation of a draft proposal for an article 48 BPR and article 44 PPPR procedure for phosphine based products used for protection of stored products.

In December 2022 and January 2023, the Dutch authorities organised several consultations in the Netherland but also across the European Union. The results of these consultations are being analysed and will be taken into account by the Dutch authorities in their final restrictions for use of phosphine based products.

The Dutch authorities informed that these amendments will be implemented in April in the individual instructions for use of the products authorised in the Netherlands. Afterwards all Member States will be informed of the new restrictions according to article 48(3) BPR and article 44(4) PPPR.

4.9. Update of document CA-March18-Doc.4.6_final-rev9-note for guidance QA on simplified procedure	For discussion and agreement *CA-March23-Doc.4.9* ➔ *CA-March18-Doc.4.6_final-rev9 note for guidance QA on simplified procedure*	

The Commission presented an update of the document CA-March18-Doc.4.6 on the practical implementation of the simplified authorization procedure and reminded all Member States that CA document cannot be considered a "Note for guidance", but just as agreements reached by the Competent Authorities on biocides. It reminded that to produce formal Commission technical guidance notes, the Commission must follow a specific procedure for adoption. It has therefore modified the title of the document in "Note for agreement", in line with the current practise.

The Commission informed that two modifications have been made:

- Annex I - Section 1. - Data requirements – Q&A 1: The Commission informed that this was a question raised by a Member State. The Commission clarified that the legal identification of the Active Substance includes the name and an appropriate EC/CAS number and that other forms of the Active Substance corresponding to different EC/CAS numbers not included in the list are not covered by the entry on Annex I. The Commission explained that even if the question has been made on a specific substance, it decided not to include the specific case because the document is already long and dense.
- Section 6: Amendment/cancellation of authorisations – Q&A 39: The Commission recalled that this issue has been discussed in the last CA meeting, but a Member State raised a question whether a referral to the Coordination Group can be made when the evaluating Member State proposes not to authorise a product.

To be coherent to what has been decided for the mutual recognition procedure, it was agreed that a notified Member State has the right to disagree with the evaluating competent authority when it decides not to grant an authorisation under the simplified procedure.

In case of an amendment of an authorization granted under the simplified procedure, if the authorisation holder wishes to make the product available in another Member State, a new notification needs to be done in accordance with Art. 27(1) of the BPR and the revised SPC should be submitted together with the new application to each Member State in the territory of which the product is made available, in the language of that Member State.

If a notified Member State disagrees with the cancellation or the amendment of an authorization made by an evaluating CA, a referral to the Coordination Group can be done by following the procedure established in Art. 27(2) of the BPR. The Commission informed that ECHA and some Member States pointed out that this proposal is not currently reflected in R4BP. The Commission agreed that R4BP does not provide for all these possibilities and proposed to discuss with ECHA on how to incorporate these developments in the next updates of R4BP. The Commission informed that a Member State has submitted another question on the simplified procedure but decided to take more time to reflect on this and to discuss it in the next CA meeting, if needed.

The Commission concluded that the document was endorsed by the CA meeting.

4.10. Warning sentence and RMMs for cats	For discussion and agreement *CA-March23-Doc.4.10*	

The Commission introduced the document CA-March23-Doc.4.10, that proposes some actions to address the risk for cats from the use of biocidal products containing pyrethroids, considering the discussions that have taken place in the context of Union authorisations and mutual recognition procedures.

The Commission explained that cats are sensitive to pyrethroids and that the exposure to them can be lethal. As there is currently no specific guidance on how to assess the risk of pyrethroids for cats, in case of discussion or disagreement in the Coordination Group, the only solution found was to remove some of the uses and add some risk mitigation measures or warning sentences for cats for those that were considered safe when using the warning sentences. The discussions did not concern only PT 18 products, but there were also cases of a PT 8 product, in which it was decided by Member States in the Coordination Group to introduce the warning sentence of the sensitivity of cats to permethrin.

The Commission remarked that the wording “risk mitigation measures” is not completely correct because so far there is not a risk assessment methodology developed but suggested to focus on the importance of having this sentence in the label to make the users aware of the risks for cats.

For PT 18 products, the Commission recalled that the proposal reflects what is currently done in Union Authorizations. For PT 8 products, the Commission agreed to include the sentence indicated in paragraph 4 of the document in the section 5.2 of the SPC, but this point should be discussed further in the Human Health Working Group.

The Commission proposed that the use of the statement would have a retroactive effect on existing authorisations, as it is not possible to leave products on the market without the warning sentence due to the risk for cats, and these sentences have already been applied to products authorised as result of disagreements in mutual recognition in sequence procedures.

Therefore, the Commission proposed to include these statements in Union authorisations and national authorisations regardless the concentration of the active substance as an interim solution. The Commission informed that it would give a joint mandate for ECHA and EMA to clarify what is a risk of products containing pyrethroids for cats, as some veterinary medicinal products containing pyrethroids are authorized by national procedures in some Member States. The Commission encouraged Member States' experts to investigate this point with their colleagues of veterinary medicines and proposed, as an interim solution, to include the warning sentence in the summary of biocidal product characteristics for PT18 and for PT 8.

Therefore, the Commission proposed to agree with the proposal and invited a MS to volunteer to prepare a proposal to be discussed at the Human Health Working Group (HHWG).

Two Member States agreed with the introduction of the warning sentence for PT18 products but expressed its doubts about the usefulness of this sentence for PT8 products. Those Member States expressed full support to the issuing of a joint mandate for ECHA and EMA to clarify the risk to cats. It also supported the development of harmonised criteria for warning sentences in general. The Commission proposed to remove the request to use statements in the PT8 authorisations.

The Commission stated depending on the outcome of the discussion in the HHWG the document could be further updated and detailed.

One Member State pointed out that permethrin, deltamethrin and cypermethrin are very toxic for cats according to EMA and, for this reason, in veterinary medicinal products containing these substances it is strongly recommended that, in case of exposure, the veterinary advice shall be sought immediately. For this reason the Member State suggested to include in section 5.3 of the SPC the following sentence: "if pets have exposure, get veterinary advice attention".

The Commission confirmed the necessity of discussing this type of issue in the HHWG, where experts can agree on slightly different wording, additional sentences and update the document.

One Member State volunteered to prepare the proposal to be discussed in the HHWG.

Another Member State asked if an exposure scenario will be developed in the guidance or if the mandate will only cover the outline of the warning sentence. The Commission replied that the purpose of the joint mandate will be only to develop a methodology for a risk assessment and to clarify what are the risks of these active substances for cats. It also specified that this proposal is an ad interim solution because the work of ECHA-EMA will take some time.

ECHA added that from its point of view cats have probably a negligible exposure to PT 8 products, and risk is probably negligible. Whether it is negligible depends on the uncertainty around it. ECHA declared that experts can identify the uncertainty, but it is the responsibility of policy makers to decide whether they accept these uncertainties. As, so far, the sensitivity of cats to pyrethroids has not been compared to the available data, ECHA proposed to use the wording "warning sentence" because these sentences are not yet based on a quantitative assessment. The Commission suggested to avoid a debate on risk mitigation measures versus warning sentences and stated that it will keep the wording "statement".

One stakeholder observer pointed out that in the document there is no distinction between pyrethroids which can create sensitivity to cats and those that are harmless to them. It considered therefore the document to be very restrictive. It raised also concerns on the retroactivity of the measure, asking what the timeline for companies would be to change the labels to comply with this intermediate solution. The Commission recalled that, as the development of new guidance will take few years and these products can't be left on the

market without the warning sentence, this proposal is the only possible intermediate solution. The Commission confirmed that once the HHWG will agree on the list of substances, the document will be revised.

The Commission concluded that the document was agreed by the CA meeting and thanked the Member State which volunteered to take the lead in the discussion in the HHWG.

4.11. Renewal of biocidal products containing propiconazole	For discussion and agreement *CA-March23-Doc.4.11*	

The Commission introduced the document CA-March23-Doc.4.11, that proposes Member States to prolong the authorisations of PT-8 products containing propiconazole for which the renewal is ongoing, to allow the final decision on their renewal to take place after a decision has been adopted on the renewal of the approval (before 31 December 2023). This will facilitate the ongoing renewals of PT-8 biocidal products containing propiconazole.

The Commission informed that several product authorisation holders have raised questions and concerns regarding the renewal these products.

The Commission recalled that propiconazole fulfils the exclusion criteria as it is classified as toxic for reproduction category 1B since October 2018, and as having ED properties with respect to humans. Member States have already had to assess whether at least one of the conditions for derogation to exclusion of Article 5(2) of Regulation 528/2012 (the BPR) is met for their territories, and products containing propiconazole should already not be authorised for use by the general public when classified as reprotoxic 1B and considered as the biocidal product having endocrine disruption properties.

It is proposed that, following the entry into force of the Implementing Regulation on the renewal of the approval of propiconazole, authorisation holders will have six months to complement their original applications for renewal of the products.

On a general note, the Commission considered that application of the approach described in CA-May18-Doc.4.1- Final may not be possible in the future, due to the variety of combination of active substances in PT-8 biocidal products (an overview can be found in Annex 3 of the document).

Several Member States voiced their agreement with the proposal. One Member State asked whether the approach should also apply to the PT8 product authorisations without propiconazole which were also administratively prolonged according to the approach in CA-May18-Doc.4.1-Final, and where the active substance renewals have not been finished yet. . The Commission requested that MS for further information on this to be able to reflect.

The document was agreed by the CA meeting with a modification in paragraph 2 (deletion of the reference to Article 19(5)).

4.12. Disinfectants in veterinary practices and hospitals	For discussion and agreement *CA-March23-Doc.4.12* ➔ *CA-May15-Doc.8.3rev1*	

The Commission presented the revision of the document CA-May15-Doc.8.3 on disinfectants used in veterinary healthcare, and informed that the issue started with the disagreement of a Member State in the Coordination Group on the product-type allocation for disinfectants used in veterinary practices in hospital.

The Commission explained that a draft decision on the unresolved agreement will be presented in the SCBP on 17 March 2023. To close the case, the Commission decided to revise this document and welcomed the suggestion of a Member State to make it clear that these types of products can be reallocated to PT2 or PT3 under the BPR by amending the paragraph 5 of the document to the following wording: "It is agreed that products applied for general disinfection of surfaces in the medical area (medical practices, hospitals) as well as of surfaces in veterinary practices or hospitals can be assigned to PT 2…"

The Commission stressed that the legal definition of product types in the BPR allows allocating these products to either PT2 or PT3.

One Member State welcomed the proposal, suggesting that in this specific case it would be preferable to keep the old test which uses the wording "shall be assigned" instead of "can be assigned", because it is referred to a very specific example. Another Member State reacted and supported the amendment proposed by the Commission, also in consideration of the feedback received from their efficacy experts that normally there are no specific claims in the proposal from the applicant, but it is possible to have specific claims in case of outbreaks. For this reason, the Member State suggested not to allocate a PT based on that, and considered the wording "shall be assigned" as a potential problem. A Member State suggested to replace the wording "specific" in page 2 point 5 of the document, with "only" and to delete the text in brackets, to be in line with the Commission implementing decision.

The Commission explained that in general "specific claims" should not be made. Claims against Coronavirus have been accepted because authorities and the companies received many requests from people who wanted to know whether the disinfectants were effective against the virus. To avoid future problems, the Commission proposed to keep this wording as open as possible and asked Member States to reflect and agree with the proposal.

One Member State suggested formulating the sentence of page 2 point 5 as follows: "whereas products for only veterinary hygiene purposes are considered to be in PT 3". The Commission rejected this proposal and decided to keep more flexibility in consideration of possible future problematic cases.

One Member State proposed to modify the wording as follows: "whereas products for only veterinary hygiene purposes are usually assigned to PT 3". The Commission welcomed this last suggestion as a compromise solution and modified the document. It also recalled that efficacy guidance refers to this document and reminded that if an adaptation is needed in technical guidance, it will be made by ECHA.

One stakeholder observer asked whether it would be possible to keep the reference to Annex V to the BPR after the wording "are usually assigned to PT 3" in page 2 point 5. The Commission accepted this proposal and modified the paragraph 5 as follow: "It is agreed that products applied for general disinfection of surfaces in the medical area (medical practices, hospitals) as well as of surfaces in veterinary practices or hospitals can be assigned to PT 2, whereas products for only veterinary hygiene purposes are usually assigned to PT 3, according to Annex V of the BPR".

The document was endorsed by the CA meeting.

4.13. Update of the CA document on Implementation of the scientific criteria for the determination of endocrine disrupting properties in the context of biocidal product	For discussion and agreement *CA-March23-Doc.4.13*	

authorisation		

The Commission presented a draft note that incorporates the conclusions reached in CA-Sept20-Doc.4.13.b. details of concentration of SoCs in the SPC, CA-March21-Doc.4.3_Final_Bridging Biocides with REACH, CA-March21-Doc.4.4.-Non-active substances with ED indications, CA-June22-Doc.4.2-New info available-consequences for BPR authorisations, CA-June22-Doc.4.8-Identification as SoC of ED non active substance, and replaces CA-March18-Doc7.3.b_final-EDs-biocidal products.

The note focusses on the assessment of the ED properties of the non-active substance(s) in the product, as the implementation of the scientific criteria for the determination of endocrine disrupting properties for active substances was agreed in CA-March18-Doc.7.3a-final- EDs-active substances under assessment and CA-Sept18.Doc.7.5.a-final EDs approved active substances.

One Member State raised several comments on the draft note: the section on the implementation of the scientific criteria to applications for product authorisation that were ongoing when the criteria were adopted, the REACH route for the identification of ED co-formulants and the coordination mechanisms should be kept in the note. That Member State also signalled that there is no guidance on how to perform the risk assessment for ED co-formulants and that is difficult to assess the efforts of applicants to remove those ED co-formulants from the product formulation and development of criteria to do so will be needed. That Member State considers that that the applicant should trigger the amendment or cancellation of an authorisation in accordance with Article 47 of the BPR when the biocidal product is considered as an ED, instead of competent authorities applying Article 48(1) of the BPR and asked if a period of grace can be granted to cancelled authorisations.

The Commission explained that the section on the impact of the adoption of the ED criteria for ongoing applications is no longer relevant, as the ED criteria were adopted 5 years ago. The provisions of the BPR as regards deadlines and procedures for product authorisation apply in any case. The REACH route and the coordination mechanisms (eg. the list with the information on the ED status of co-formulants used in biocidal products that ECHA provides for Member States) are reflected in CA-March21-Doc.4.3. On the efforts from the applicant to remove the ED co-formulants, the Commission agrees that is difficult to assess if the efforts are sufficient, and points out that, if MSs considered that criteria need to be developed, proposals from them will be welcomed. The Commission also reminded that the competent authorities are in the end responsible for the amendment of authorisations, independently from the actions taken by the applicants. The Commission confirmed that Article 52 applies also to the cancellation of products due to ED properties and that is up to the Member States to decide whether to grant it or not, depending on the risks posed by those products.

At request of another Member State, an addition to paragraph 7 was made to reflect the provision in Annex III of the BPR that the evaluating body may conclude that further data on the ED properties of co-formulants are required.

The CA meeting agreed on the note.

4.14. Compliance by MSs with Article 36 Decisions	For information	**Closed session**

This point was discussed in closed session.

4.15. Substitution of document CA-Nov16-Doc.4.1.b – Final - Harmonised sentences SPC AVKs	For information *CA-March23-Doc.4.15 Harmonised sentences SPC AVKs* ➔ ~~*CA-Nov16-Doc.4.1.b – Final - Harmonised sentences SPC AVKs.rev1*~~	

The Commission explained that this point has been added only "for information" because these revised sentences have been already discussed and agreed in the Coordination Group.

The Commission thanked a Member State for the work done and informed that the changes can be easily spotted because they are highlighted in green or yellow. This will allow everybody to update the SPCs more easily.

ECHA pointed out that the text in paragraph 8 refers to SPC editor and they suggested to replace this wording with "proper IT tool" and to add the sentence "in practice, as long as the SPC editor is used to generate the SPC, applicants will have to copy and paste the relevant sentences, depending on the intended uses in the application, from the agreed documents to the draft SPC in xml format". On paragraph 11, ECHA pointed out that the reference to the CG-43 of September 2020 was not correct and should be replaced by the reference to the CG-51 of April 2022.

The Commission agreed with these suggestions and modified the document.

4.16. Presence of misleading terms in biocidal products trade names	For discussion and agreement *CA-March23-Doc.4.16*	

The Commission introduced the document and recalled the issue has been discussed shortly at the meeting of the Standing Committee of December 2022. Two options were presented to Member States, namely (i) not allowing terms that may be misleading in the trade names of any biocidal product or (ii) case-by-case/product-by-product analysis. Member States were requested to indicate which approach they would favour and also how to address specific elements mentioned in the document (when to amend authorisations granted under the BPR for biocidal products with such trade names, how to treat the temporary authorisations under Article 55(1) for products having such names, how to treat products with such names made available on the market under the transitional rules).

One Member State indicated to be in favour of the first option, and, concerning already granted authorisations, in favour of amending them at the moment of renewal. Another Member State was also in favour of the first option, but was of the view that an exhaustive list of terms that are not allowed should be developed. The same Member State indicated that 'eco' should not be included on that list, as it may be a contraction of both 'ecologic' and 'economic', that existing authorisations should be amended at the moment of renewal and that, if the problematic names derive from the name of the company being 'transferred' to products, they should be allowed.

A third Member State also indicated to support the first option, that should be applied with regard to granted authorisations at the moment of their renewal, to allow authorisations holders to adapt, with the exception of cases which are clearly misleading and lead to dangerous situations. The same Member State pointed out that such terms should also not be allowed to appear anywhere on the label, and not only as prefix or suffix of the trade name and that also, ideally, the trade names of biocidal products should be unique (in writing and

pronunciation). Another Member State expressed its support for the first option and was in favour of having of list of prohibited terms. A fifth Member State was also in favour of the first option, but thought that awaiting the renewal to amend authorisations already granted might not be appropriate and lead to unequal treatment of applicants, as products with problematic names might stay on the market for many years still in case of recently granted authorisations. The Commission acknowledged that the equal treatment is always prominent, however, also in light of the discussions concerning the progress with the Review Programme and general delays in applications for products' authorisations, authorities have to decide what to prioritise and where to assign resources.

Several other Member States indicated to be in favour of the first option and some of them mentioned the need to develop a list of terms which are not allowed. One Member State informed that a survey is ongoing at national level on how the choice of general public is influenced by specific terms and that the results of the survey will be shared with the CA meeting. Upon the remark of one Member State that such terms should be permitted in the names of products authorised by simplified authorisation, the Commission clarified that it is not possible to make this distinction, as the BPR itself does not distinguish - with regard to labelling requirements - between products authorised by regular or simplified authorisation.

One industry association explained that not in all case 'eco' or 'bio' are synonyms of organic and that it is in favour of a case-by-case approach and that in some cases these terms derive from name brands which are long established on the market. With regard to the applicability to products made available under the transitional rules, the same industry association noted that Article 69(2) of the BPR makes reference to 'authorisation holder', which is a term not applicable for products made available under the transitional rules.

The Commission closed the discussion concluding that Member States were in favour of the first option. Comments from Member States on the various elements indicated in the document under this option were invited until 14 April 2023, with a view to discuss and agree on them at the next CA meeting.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-March23-Doc.5.1* *CA-March23-Doc.5.1.a_Restricted*	

The Commission presented the general overview of the work performed in 2022, and general progress in the review programme. Overall, little progress was done in 2022. It further urged the Competent Authorities to make progress on the completion of the work programme, and to conclude as quickly as possible the review of their backlog reports submitted before 1 September 2013, which are still evaluated based on Directive 98/8/EC, and which remains too numerous.

5.2. Postponement of the review programme beyond 2024	For discussion *CA-March23-Doc.5.2*	

The Commission introduced the document, aiming at discussing the need for extension of the review programme beyond 2024 and improvements that should also be made to reach its

finalisation, and the BPR objectives to ensure a high level of protection of human health, animal health, and the environment. It enquired the views of Member States on the matter.

On the time needed for an extension, two Member States indicated that a minimum of 5 years may be necessary. Two other Member States estimated an extension needed for a period between 3 to 5 years, and remarked that radical measures may be needed, including lowering the level of work needed for the assessment of the applications as perfection cannot be reached, like on the endocrine disrupting criteria when another exclusion criteria is already met, and there is a need to be realistic. Another Member State considered that 5-year extension may be too short, considering also the increasing work in other areas of implementation of BPR (product authorisation, union authorisation etc.). The Commission also mentioned that some progress can still be achieved before the end of 2024, too.

One Member State pointed out that the grant project initiated by the Commission will last until 2028, so the review programme has to be extended at least until that date. The Commission clarified that the grant is not only for the review programme, but also to improve deliveries on product authorisation and systemic changes in Member States as regards to the financing of their biocides activities.

Another Member State mentioned that concluding the work in 3 to 5 years may not be realistic as some applications will still be submitted in the coming years. The Commission highlighted that Member States are not obliged to be as lenient as they were at the beginning on the Directive 98/8/EC, as the legislation is no lo longer new and companies have the duty to submit complete dossiers at their submission.

As regards to actions needed to improve the system, one Member State supported stopping applying new guidance to on-going assessments, and supported to disconnect the BPR assessment from the CLH processes (e.g. not awaiting RAC opinions on certain classification criteria before progressing the evaluation of dossiers under the BPR). That Member State emphasised the importance of the accordance check at ECHA level, as some draft assessments were submitted by some Member States, although they were not of the required quality to ensure a smooth peer review. It was also noted that no representative product should be assessed in the renewals of approval procedure.

Another Member State supported measures reported in section 2.2.2 of the discussion document, including setting a common maximum deadline for the submission of missing data to assess the ED criteria. Contrary to the previous Member State, it considered beneficial to apply new guidance to on-going dossiers in some cases.

Another Member State reminded the CA meeting to be mindful, when reaching agreements in the context of CA meeting discussions, to not create more workload and complexity, and be careful to not move the goalposts. It also enquired whether there were some intentions to postpone a REFIT of the BPR. The Commission indicated that no REFIT on the BPR is foreseen for the moment, but some actions to improve the review programme can already be taken in the context of the current legislation. When a REFIT would take place, Member States will be associated and consulted.

One Member State further asked for pragmatism, but remarked when a Member State tried it receives many comments from other Member States during the peer review. The Commission noted the comment, and referred to the need to discuss more these aspects in the context of technical discussions in the BPC and the workshop planned by ECHA on active substances' process.

CEFIC (Biocides for Europe) enquired what will be the next steps in the process, expressed some concerns if there will no longer be the possibility to take over the role of participants in case of withdrawal, and consider that the possibility to submit new data when guidance

changes or risks are identified. The Commission clarified that a Delegated act will have to be adopted to modify the deadline for completion of the review programme. As regards to the possibility to take over the role of the participant, the Commission services remarked that it is the only framework, to their knowledge, that included that possibility, and the time when a decision has to be made to support a substance in the review programme was in 2003. Companies can always choose to support an active substance outside the review programme.

Member States were invited to express their comments on the various elements indicated in the document, as well as other measures to improve the review programme, until 14 April 2023, with a view to discuss and agree on them at the next CA meeting.

5.3. Progression of the renewal process of approval of active substances	For information *CA-March23-Doc.5.3*	

The Commission informed that three applications for renewals of approval of active substances have been recently submitted. It was remarked that many applications could be extended this year. The evaluating CAs (eCAs) were reminded that they have to inform the Commission whether they plan a full evaluation or not of the renewal dossiers, so that the Commission can prepare the extensions of approvals accordingly.

5.4. ECHA Active Substance Action Plan – progress update	For information *CA-March23-Doc.5.4*	

ECHA provided the regular update on the progress of actions in the context of the Active Substance Action Plan. It further encouraged Member States to contact ECHA in case of issues to make progress on their dossiers.

5.5. ECHA - Transparency on active substance planning	For discussion and agreement *CA-March23-Doc.5.5*	**Closed session**

The point was discussed in closed session.

5.6. Information from CEPE on the implementation of risk mitigation measures for skin sensitizers in can-preservatives PT6	For information *CA-March23-Doc.5.6*	

CEPE presented a document on how to arrange practicality issues when supplying gloves with paints classified as skin sensitizing. They argued that providing gloves through the point of sale is better than providing gloves inside the packaging. They also delivered relevant experience coming from PT21 antifouling paints.

Two Member States agreed with CEPE positions. One of them highlighted the need for flexibility when providing gloves with the paints. They also stressed the need to monitor the situation once this measure is implemented.

The Commission informed that the issue will be transferred to BPRS planned the next week. At the same time, the Commission will start drafting relevant approvals on the next isothiazolinones that will come to the pipeline for adoption.

5.7. Renewal of antifouling active substances PT21	For discussion and agreement *CA-March23-Doc.5.7*	

The Commission introduced the document and highlighted the past discussions on the possible need to: a) revise the efficacy assessment of antifouling products, b) to refine the environmental risk assessment for the regional marina approach for pleasure crafts, and c) to continue allowing the use of PPE (e.g. gloves) as risk mitigation measure for non-professional users during application of PT21 products. The Commission pointed out that there is no clear agreement by CA members whether these elements should be forwarded to the BPC relevant Working Groups (WG), and asked the opinion of the CA members that have not taken a position, yet.

One Member State supported forwarding all 3 elements to the BPC WGs.

Two Member States pointed out that there is no need to re-investigate all elements, but would prefer to be flexible, through a case-by-case approach.

CEPE recalled their document submitted in the 96th CA meeting of June 2022, raising a concern that the current environmental scenarios would not lead to any PT21 product authorization.

The Commission underlined that CEPE concerns were addressed in the past CA meetings and associated newsgroups, and in overall these were not shared by several CA members.

It was agreed that the use of PPE (e.g. gloves) will continue to remain an acceptable risk mitigation measure for non-professional users during application of PT21 products. When it comes to the need to revise the efficacy assessment and to refine the environmental risk assessment for the regional marina approach for pleasure crafts, it will be up to the Member States to bring forward specific technical questions/issues to the relevant BPC WG.

5.8. Second renewal of anticoagulant rodenticides	For discussion and agreement *CA-March23-Doc.5.8*	**Closed session**

The point was discussed in closed session.

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

The point was discussed in closed session.

6. Treated articles
No item for information or discussion

7. Horizontal matters

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

The Commission reminded Member States of the deadline of 25 April for them to apply for the grants provided by the Commission. It further encouraged Member States in need to apply for it, with the view to make structural changes to improve the financing of their activities and comply with their duties under the BPR.

7.2. ECHA communications	For information	

ECHA provided an update on on-going matters.

7.3. Dissemination of CA finalised documents on Circabc	For information	

The CA meeting was reminded that finalised CA documents are included in the dedicated folder of Circabc.

7.4. ECHA Guidance Pollinators	For discussion and agreement *CA-March23-Doc.7.4*	

ECHA presented its plan for the finalisation of the ECHA bee guidance and the proposed approach to address the development of guidance for non-bee pollinators (NBP), which were agreed by the CA meeting. It was considered important to have the guidance for the risk assessment of bees ready as soon as possible and not to delay the overall development of ECHA guidance due to the identified lack of information on NBPs.

One Member State had questions on the interim measures (use of warning sentence in the authorisation of biocidal products), the scope of the ECHA bee guidance and asked further details on the planning for the NBP guidance development. The Commission clarified that the interim measures continues to apply according to current practice. Regarding the scope of the ECHA guidance, it was clarified that as a result of a thorough screening of exposure scenarios and expert judgement, the expert group concluded that selected PT18 uses are the only ones which warrant development of exposure scenarios. Although the focus of the first version of the guidance is on PT18, it doesn't exclude that in certain cases assessment may be required also for other PTs.

Regarding NBPs, it was clarified that development of the future guidance will have an impact on the BPR guidance Vol IV Part A (Information requirements) and Vol IV Part B+C (Risk assessment). Regarding the timelines for the development of the NBP guidance, a detailed action plan is not yet in place. However, it is expected that it will take at least three years and depends on the availability of information from current and future research projects.

7.5. ECHA Guidance on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted to	For information *CA-March23-Doc.7.5*	

produce drinking water		

ECHA introduced a document on the next steps for this joint EFSA and ECHA guidance with the aim to consolidate the different procedural steps before the publication of the final version. ECHA explained that there will be a final feedback collection on a consolidated draft (taking into account the comments received in the public consultation) expected to be launched in May/June 2023. After the collection and considering the feedback, the guidance will be published in the EFSA journal and a cross-link to the document and the information on its applicability will be made available on ECHA's webpages.

7.6. Update on Court cases	For information	

An update on the on-going Court cases was provided. One Member State had a question on the relevance for biocides of a Court case that no derogation for authorisation can be granted for plant protection products if a non-approval exists for the active substance contained. The Commission clarified that this case was very specific to plant protection products and not relevant for biocides.

7.7. Amendment to Annex III of CA-Sept18-Doc.7.4 on substitution	For discussion and agreement *CA-March23-Doc.7.7*	

The Commission informed that an amendment to the Annex III of the CA document on substitution has been introduced, to include two new references to national studies collecting information on potential alternatives to hazardous biocidal active substances used for wood protection.

One Member State remarked that the section 3.1.1 on rodent control needs to be amended as it still contain information on the first comparative assessment of anticoagulant rodenticides. The Commission will reflect on how to address this point.

8.	**Scope matters**

8.1 Products with mode of action at molecular level	For discussion *CA-March23-Doc.8.1*	

Switzerland, that proposed this point on the agenda, introduced the topic and explained that the conclusion they reached with regard to the products described is that such products fall in the scope of the BPR, as their mode of action cannot be considered as purely physical/mechanical. They also consider that, at molecular level, it is actually impossible to qualify a mode of action as purely physical; modes of action at molecular level are mostly biochemical. The Commission informed to agree with the draft analysis of Switzerland. One Member State expressed agreement with the analysis presented and was of the view that a distinction between purely physical and chemical mode of action is only possible at macromolecular level, while at molecular level it is not really possible to have this distinction. This Member State also noticed that in some instances heat and radiation (which in the document are included as examples of physical action) can be used in a system generating an in-situ active substance, and in that case the generating system falls in the scope of the BPR. Another Member State was also of the view that interactions at molecular level are of

biochemical nature. A third Member State expressed support for some of the conclusions in the document, but not for all of them, fearing that the interpretation in the document would broaden too much the scope of the BPR. The Commission reminded of some cases in the recent past where the debate physical vs. chemical mode of action took place, for instance the preliminary ruling concerning silicon dioxide, where the Court confirmed that its mode of action was not purely physical, as the company claimed. The recent jurisprudence seems to show that the Court has a narrow interpretation of what a purely physical mode of action is.

Another Member State informed to have received a question on a similar product and that they also consider such products to be biocidal products. Further comments from Member States were invited until 14 April 2023 to provide to Switzerland for their consideration.

9. Enforcement issues		
9.1 Products intended to kill vertebrates illegally made available on the market	For information	

The Commission informed that, in December 2022, following a question from a member of the European Parliament, it became aware of a US-based company operating worldwide sales which was advertising and selling on its website products intended to kill vertebrates (birds, foxes, rabbits, etc.) The Commission alerted immediately the BPR Subgroup of the Forum and also informed the US Environmental Protection Agency (EPA). A couple of Member States informed that they have contacted the company to make them aware that the sale of those products was illegal and the same did the US EPA. As a result, by mid-January those products were no longer advertised and sold on the website of that company.

10. International Matters
No item for information or discussion

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-March23-Doc.11.a*	
(b) Article 55(1) derogations for disinfectants	For discussion	**Closed session**

The point was discussed in closed session.

(c) Report from the legal workshop organised in Austria in December 2022	For information	**Closed session**

The point was discussed in closed session.

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