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

MINUTES

95th 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 2022

1. Adoption of the agenda	For adoption *CA-March22-Doc.1*	

Upon suggestion of one Member State, one point - concerning an update on the project related to azoles resistance - was included in the AOB section. The agenda was then adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-March22-Doc.2.a* *CA-March22-Doc.2.b_Restricted*	

The minutes of the previous CA meeting (open and closed session) were adopted.

3. Draft delegated acts
No item for information or discussion

4. Biocidal products

4.1. Risk mitigation measures for products and treated articles	For discussion *CA-March22-Doc.4.1*	Closed session

This point was discussed in closed session.

4.2. Consequences for biocidal products authorisations procedures of relevant information becoming available	For discussion and agreement *CA-March22-Doc.4.2* *CA-March22-Doc.4.2.a*	Closed session

This point was discussed in closed session.

4.3. Report from the Coordination Group	For information	

The Commission provided a brief summary of the CG-50 meeting, that took place in February 2022 and in which:

- Seven formal referrals were discussed and two were briefly introduced. Agreement was reached for two;
- The Commission presented an updated document in relation to the amendment of Regulation (EU) No 492/2014 summarising previous CA discussions and comments provided after the CG-49 meeting;
- A Member State raised the question which Member State should be considered the reference Member State in regards of a mutual recognition in sequence. Mutual

recognition based on mutual recognition is possible and a new document will be prepared for the next regular CG meeting to reflect this;

- In relation to which Member State would need to refer disagreements to the CG in case of the renewal or change of a product, and what disagreement points could be raised for these cases, it was agreed that in line with Regulation (EU) No 492/2014 and 354/2013: the reference Member State needs to refer disagreements concerning the renewal or change of a product to the CG, a referral could only be raised on matters related to the applied change in case of a change application, while it could be raised on any conditions of granting an authorisation in case of a renewal application. The Working Procedure for resolving of disagreements, and the Standard operating Procedures for the mutual recognition process in parallel and sequence, as well as minor change applications will be revised according to these agreed legal interpretations;
- A Member State 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 document was agreed by consensus and the revised version of the document has now replaced CG document CG-34-2019-02 in public CIRCABC.

The main CG agreements reached during the CG-50 meeting were:

- dermal absorption value in product authorisation for different scenarios;
- an e-consultation in relation to the topic - Thermally inactivated target organisms;
- raising a referral in case of a non-authorisation assessment conclusion when the national application is subject to mutual recognition in parallel to address the practical implications of the new interpretation of the Commission agreed on CA level (i.e., that a referral can be raised in such a case). It was suggested and agreed that the reference Member State would send the draft PAR to the concerned Member States for commenting following the same process and timelines, as for applications where the assessment conclusion is authorisation. It was noted that the Working Procedure for resolving of disagreements, and the Standard operating Procedures for the mutual recognition process in parallel and sequence, as well as minor change applications will be revised according to this agreed approach.

Topics where further discussion will take place:

- e-consultation– Impact of version 4 PT19 efficacy guidance;
- e-consultation– Anticoagulant rodenticides renewal and waiving justifications for physical hazards;
- outcome of an e-consultation in relation to the topic - Storage stability and degradation of active chlorine. The initiating Member State proposed and the CG agreed to continue the e-consultation at a later date in the hopes that the suggested 50% degradation threshold would be discussed in the course of Union and National Authorisation applications with this PT/active substance combination;
- The SECR informed the CG that discussion concerning post-authorisation conditions in regards of shelf-life will be continued at the next regular CG meeting.

4.4. Hand disinfectants (PT 1) to be used with dispensers and refilled containers (clarification on risk assessment, SPC and labelling/information on dispensers and refilled containers)	For discussion and agreement *CA-March22-Doc.4.4*	

A Member State presented a revised version of the document after the comments received in the dedicated newsgroup. The Commission supported the proposals from that Member State and considered that after having discussed this topic in several meetings, agreement can be reached on the approach proposed.

Another Member State requested that the CLP- triggered labelling be further specified in the document, to avoid disagreements and ensure harmonisation. The Member State that made the proposal considered that Article 69 applies to hand disinfectants and similar considerations that have been agreed for all products would apply for hand disinfectants also. Therefore, the Member State that made the proposal was not in favour of further specifying these requirements. The Member State that initially suggested that the CLP triggered labelling is further specified in the document accepted to keep the document as it is. Another Member State raised questions on enforcement related to whether the obligations to label and use the product in accordance with the SPC can be transferred down the distribution chain to the supermarket or shops that offer the hand disinfectant to the final users and wondered if it will be necessary to issue additional national rules in order to be able to enforce. The Commission suggested that the details on enforcement and the practicalities be discussed in the BPRS and considered that the BPR establishes that the necessary information for a safe use of the product needs to be conveyed to the final user and that the product needs to be used in accordance with the instructions of use in the SPC. Another Member State suggested to add the commercial name of the products in the list of information that needs to be provided on the label.

Member States agreed on the document with the addition suggested. The agreed document will be uploaded in CIRCABC in the finalised document folder.

4.5. Proposal of Germany for ad-hoc group on the authorisation of in situ biocidal products	For discussion and agreement *CA-March22-Doc.4.5*	

Recent discussions in the context of Mutual recognition or Union authorisation highlighted the need to reach a common understanding on several regulatory issues regarding the authorisations of in situ biocidal products. In order to achieve this harmonised approach, a Member State proposed to set-up an ad hoc working group of the CA where legal aspects of the authorisation of in situ biocidal products could be discussed. It was proposed to start by collecting first the contact details of Member States authorities who would be willing to exchange their expertise and views on a set of preliminary questions. Industry would be allowed to participate on request. The outcomes of the discussion in this ad hoc WG will be reported to the CA meeting on a regular basis.

The Commission agreed with the stepwise approach proposed by the initiating Member State. Four other Competent Authorities supported the proposal as many issues are still unresolved regarding the authorisation of in situ biocidal products (in particular on how to present devices in the SPC). One Member State proposed to first select the questions at the CA level

in order to avoid excessive workload. The work of the WG should also be evaluated a year after its implementation. The Commission proposed to start with a list of questions raised by another Member State as part of the previous newsgroup, but considered that there is no need to have a preselection of questions to be agreed by the CA meeting first and that the work of the WG could be evaluated by the CA meeting after a year.

The Agency welcomed the initiative and highlighted the importance for the Competent Authorities to communicate and exchange on specific regulatory issues.

One stakeholder underlined the importance of keeping industry in the loop since the onset of the implementation of the ad hoc WG. Later involvement of industry in the context of the CA meeting might lead to delays in the final adoption of the conclusions of the group. It also highlighted the importance of the WG recommendations on data requirements in case of in situ generation. The Agency explained that the guidance on the active substance part is still under revision and that the WG recommendations will be finalised before the end of the year.

One Member State indicated its interest to participate in this discussion. One acceding country asked whether it could participate to the discussion. The Commission explained that the participation of acceding countries to general discussion is possible but on most sensitive topics where a specific company is involved, acceding countries might not be allowed to participate. The situation would be equivalent to what is happening in the Coordination Group meetings.

The Commission concluded by inviting the initiating Member State to draw a mailing list of possible participants. The list of questions proposed by another Competent Authority could be used to initiate a first round of exchanges by this ad hoc WG.

4.6. List of pending Article 36 requests	For information *CA-March22-Doc.4.6*	Closed session

This point was discussed in closed session.

4.7. Handling “carriers” in the authorisation of biocidal products	For discussion and agreement *CA-March22-Doc.4.7*	

The Commission introduced the topic recalling that it has been discussed in the two previous CA meeting and that the need to revise the document of 2016 arose during a referral. However, following the discussions at the BPC on a Union authorisation case, it appears that a more thorough revision of the document is needed. The Commission went on presenting some slides summarising the comments provided by Member States after the previous meeting and raising a few questions and mentioned that most comments concern the ‘practical implementation’ section of the document.

The first point of discussion regards the description of the product composition and whether the carrier component should be considered for the calculation of the concentration of active substance and substances of concern and, if yes, for which type of carriers. One Member State also pointed out that making a distinction between carrier types based on a secondary function is not comprehensible. How and if to consider solvents in the calculation of active substance and substances of concern concentration is another point of the discussion.

Other comments regarded the classification and labelling, specifically whether it should take into account the carrier component and the description of the carrier components (whether it

should be done only for type B carriers, or also for type A). With regard to physical-chemical properties, one Member State considered that the testing of these properties should be performed before the application to the carrier.

The three main question emerging from the comments provided by Member States regarded:

- relevance of the secondary function in classifying the types of carriers;
- elements on which the classification should be based (e.g. factors influencing the classification, risk assessment);
- whether there is a need at all to establish different categories, if it is considered that the carrier component does not have to be taken into account for risk assessment, classification and labelling and physical-chemical properties.

One Member State informed to have uploaded to Circabc detailed comments the day before the meeting and mentioned the main points made in the comments: they recommend not to consider the carrier as part of the biocidal product (therefore for the calculation of the active substance and substances of concern concentration); the main reason for this is that the CLP Regulation only classifies substances and mixtures, and not articles. With regard to the categorisation, the distinction in types A, B and C is, in this Member State's view, not meaningful for classification purposes; the user comes into contact with the biocidal active substance irrespectively of the type of carrier, since the carrier does not dilute the product, but only carries it. Another Member State expressed an opposite view, and considered that the carrier component should be considered for impregnated products of type B, and enquired whether an extensive revision of the document will be carried out. The Commission replied that, before proceeding with an update, an agreement is needed on the main elements outlined in the questions on the slides. A third Member State stated that, contrary to their position in the comments provided, they now consider that the carrier component should not be considered in any of the types. This Member State also suggested to delete the entire sentence that was included in the first revision in point 15 of the document. Another Member State was of the view that what needs to be taken into account is the contact with the biocidal product therefore for type A the carrier component should not be considered in the calculations, while for types B and C the carrier should be considered. Another Member State expressed agreement with this view.

One Member State supported the view of the first Member State having taken the floor, which considered that the carrier component should not be taken into account due to provisions in the CLP Regulation. This Member State considered that in all cases the composition of the mixture should be indicated, and in addition also the absolute amount in the article, for the purposes of risk assessment.
ECHA provided some background information on the discussion that took part in the APCP working group regarding an insecticide net impregnated with an active substance, where it was discussed whether the impregnated solution or the biocidal product on the net would be considered for the determination of the physical-chemical properties. In the BPC working group there was a unanimous view that it makes no sense to test the liquid which is not present afterwards on the net. ECHA also mentioned not to agree with considering in all cases the carrier as an article and that case-by-case considerations have to be made. The first Member State to have taken the floor stated that type B carriers (e.g. impregnated T-shirt) are articles. The same Member State mentioned that in the case of an article treated with a product where the solvent is no longer present after treatment, the product without the solvent should be taken in consideration for testing.

Member States were invited to provide their comments in a dedicated newsgroup until 8 April, providing their view on each of the three questions on the last slide of the presentation.

4.8. Dermal absorption value in product authorisations	For information *CG 50-2022-AP.16.2*	

The Commission informed on the document agreed in the CG-50. The document intends to provide guidance to Member States on how to handle the dermal absorption value in the authorisation of biocidal products, to avoid disagreements and lack of harmonisation among Member States.

4.9. Wording of P-statements in SPC	For discussion *CA-March22-Doc.4.9*	

The Commission explained that the objective of the document is to resolve some disagreements raised on the wording of P-statements in meetings of the ECHA HH WG.

Firstly, the Commission proposed that in case of an open P-statement (e.g. P221 and P280), the applicant proposes a final version of the P-statement following the evaluation and that this information is assessed by the eCA, peer-reviewed by the relevant WG and endorsed by the BPC in case of UAs. The final choice of the protective equipment would remain under the responsibility of the authorisation holder.

Three Member States stated that the CLP put clear responsibility on the manufacturer to classify and label mixtures and select the correct P-statement before products are placed on the market (see articles 4, 22 and 28 of the CLP). The manufacturer is also responsible for specifying the type of equipment needed for the safe use of the product. According to those Member States, a guidance document cannot contradict the provisions of a legal act (e.g. the CLP Regulation).

The Agency agreed that the applicant has the responsibility to provide the final wording of the P-statements but argued that the eCA should have a look at the proposed classification in particular for the open P-statements. It recalled that under the BPR, public authorities are responsible for the authorisation and should take ownership of its content. One Member State supported the views of the Agency and explained that by knowing the exposure routes, the authorities can assess whether the proposal for the P-statement as provided by the applicant is relevant or not.

Secondly, the Commission also proposed an alignment of the wording of the P-statements between the sections 3, 4 and 5 of the SPC in order to provide coherent information to end-users. The Agency explained that in a recent example, the wearing of coverall was required under section 5 but not in section 3 of an SPC.

Four Member States did not support the Commission proposal and argued that the wording of the P-statements in the section 3 derives from the wording established under the CLP Regulation and are the consequences of hazard identification (Annex IV parts I and II) whereas the wording in the sections 4 and 5 of the SPC derive from the outcomes of the risk assessment and are intended to address the identified risks. According to those Member States, P-statements are defined by the CLP Regulation and cannot be modified. The Agency recalled that the intention is to provide reliable information for the safe use of biocidal products and that users are not necessarily aware of the legal background supporting the choice of the P-statements.

Two Member States supported the Commission proposal.

The Commission asked the Member States to provide their written comments and their full legal reasoning before 8 April on the two items described in the sections 3.1 and 3.2 of the working document. At the next CA meeting, it would be important to discuss a concrete example with P280 or P221 to show exactly what precisely should be corrected.

4.10. Article 19(4) and in situ	For discussion *CA-March22-Doc.4.10*	

The Commission explained that questions relating to the proper use of active substance generated in situ by the general public have emerged in the context of the discussions on the approval of the active substance ozone. Article 19(4) of the BPR provides that a biocidal product shall not be authorised on the market for use by the general public where it meets certain hazards criteria described in this Article. This is to prevent that the general public is in contact with biocidal products that may present certain risks as it is expected that they will not use appropriate protective equipment.

The Commission explained the concrete example of ozone but insisted to not limit the discussion to this particular case.

In the example of ozone, ozone meets some of the criteria of Article 19(4) of the BPR and should normally not be authorised for use by the general public. However, according to the definition of biocidal product under Article 3(1), ozone can be:

- either generated from oxygen in bottles. In this case the biocidal product is oxygen which is not classified or;
- generated from ambient air. In this case no precursor is placed on the market and the biocidal product is the active substance generated which in the case of ozone meets the criteria of Article 19(4).

This would mean that depending on the choice of the precursor by the manufacturer, the biocidal product could be authorised or not for use by the general public even if the same technology is used and the same active substance is generated.

One Member State argued that the provision of Article 19(4) of the BPR does not apply to the case of in situ generation as no biocidal product is placed on the market. A case by case approach would be preferable for in situ generation. The Commission rather favoured a reflection on how to implement the general provision of Article 19(4) for in situ generation as other cases will soon be discussed.

Another Member State explained that the problems of the application of Article 19(4) might be avoided if the concern is addressed from the exposure/ risk side. In this case, it might be possible to conclude that as exposure to the general public is possible, no safe use could be identified unless the in situ active substance is generated in closed systems.

The Commission invited the participants to share their comments via a newsgroup until 8 April.

4.11. Identification of ED co-formulant as SoC	For discussion *CA-March22-Doc.4.11*	

The question of whether is possible to set a threshold for an ED co-formulant contained in a biocidal products in very low concentrations (0,0045%) was discussed in the framework of a disagreement on a mutual recognition of the authorisation of a product. The specific disagreement was solved, as the applicant agreed to remove the ED co-formulant from the

formulation of the product. However, it was consider necessary to agree on a way forward for future cases, as, in addition inconsistencies between the BPR guidance on human health and environment regarding the possibility to set a threshold for ED co-formulants were noted by Member States.

In order to help the discussion, the Commission prepared a presentation summarising the main elements that are related to this topic and that were agreed in previous CA documents..

The Commission informed it is discussing this issue with other Commission and will come back in next meeting with a more elaborated position and pointed out that, depending on the outcome of the discussions, the BPR Guidance may need to be amended.

The following questions were addressed to Member States:

- whether a concentration limit should be agreed, below which a non-active substance that meets the criteria for being an endocrine disruptor is not considered as a Substance of Concern in the biocidal product, for reasons of harmonised implementation and coherence with other hazards. There is currently a different approach in guidance documents as regards such a concentration limit on ED for environment and ED for human health.
- Do Member States agree to apply the approach agreed in the CA-June21-Doc.4.3_final (Categorisation of a biocidal product containing a non-active substance meeting the criteria for being PBT or vPvB to EDs)?

The Member States that intervened had different views, three of them being in favour of setting a threshold and three of them being against.

ECHA pointed out that a discussion on how to address substances of concerns in the authorisation of biocidal products is still pending, and reminded that they made a compilation of issues that need to be discussed. ECHA agreed that a revision of the BPR guidance may be needed, depending on the outcome of the discussions. ECHA recalled that the agreement that was reached on setting a threshold for PBT and vPvB is an artificial threshold coming from the ECHA Guidance on PBTs, but considers possible to follow the same approach for ED co-formulants.

A newsgroup will be opened for Member States to provide their views until 7 April.

4.12. Substance identification for active chlorine released from sodium hypochlorite in case of a change of the pH value	For discussion and agreement *CA-March22-Doc.4.12*	Closed session

This point was discussed in closed session.

4.13. Question from Norway on the application of Article 89(2)(b)	For discussion *CA-March22-Doc.4.13*	Closed session

This point was discussed in closed session.

4.14. Question of France on Article 25 biocidal products (simplified authorisation)	For discussion and agreement *CA-March22-Doc.4.14*	

The initiating Member State explained that biocidal products following the simplified authorisation procedure accounts for only 5% of the market and argued that this could be explained by the low number of substances approved under Annex I and the resistance of the biocides industry to develop products containing them. In addition, the fact that the product cannot be promoted on the label for its reduced impact on health and the environment is also a deterrent to innovation. This Member State welcomed a discussion on how to help the emergence of such products by giving the possibility to consumers to make informed choice when they want to buy biocidal products.

The Commission recalled that during the negotiations of the BPR, Member States were reluctant to allow certain labelling statements to promote the use of biocidal products following the simplified procedure on the grounds that advertisement of biocidal products should not be encouraged to mislead on their risk. There are however various possibilities under the current legal framework to support the development of safer active substances or biocidal products like the waiving of fees, or accepting to act as evaluating Member State. On the latter, several companies informed the Commission of the refusal of Member States to act as evaluating Member State. The derogations proposed by the initiating Member State in its note to the CA cannot be implemented until the BPR is opened for revision.

Five Member States welcomed the initiative and recognised that the current provisions are not sufficient to promote the penetration of such products on the market. It is however uncertain whether less conventional products would be authorised if the promotion of simplified products is facilitated. One Member State stated that a competitive advantage for such products would be in line with the BPR and would ready to explore such option. Another Member State considered that Article 18 of the BPR on the sustainable use of biocidal products could be used to promote best practice instead of facilitating the use of certain types of biocidal products. Another route to explore would be to state on the label that the product complies with the provision of Article 25 as a factual element.

The Commission asked industry which incentives are lacking today to promote the uses of safer products. One Association promised to get back with suggestions.

The initiating Member States thanked the CA meeting for its supportive comments. Some of the solutions proposed by the other Members like the reduction of fees have been already implemented but did not lead to satisfactory results. The suggestion to inform consumers that the product is put on the market under the simplified procedure is used by some companies but is considered not clear enough for users.

A newsgroup was created to collect the ideas and suggestions of the CA until 8 April 2022.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-March22-Doc.5.1*	

As usual at the beginning of each year, the Commission reported on the progress achieved the past year. Only 5 assessment reports were submitted which is far below the objective to make progress on the review program. Also only 17 BPC opinions were adopted last year which compromise the objective of finalising the review programme by 2024 as at least 120 opinions should be delivered annually to achieve this objective now due to the accumulated delays.
The Commission informed that the prolongation of the deadline of 2024 for the review programme is not yet under discussion, that progress can still be done in the 3 coming years.

The Commission will also provide the possibly for grants to support financially Member States in their evaluations.

The Commission invited again the Competent Authorities to make progress on the ED assessment, in particular for dossier submitted before 1st September 2013, noting that the ED criteria are adopted since 2017. The Commission welcomed the progress on backlog dossiers for which the provisions of the BPD still applies, but noted that there are still 40 backlog dossiers pending and invited Competent Authorities to make progress on those files. All in all, 42% of the review program is now completed.

The Commission invited the Competent Authorities to implement the active substance action plan and to make use of the support provided by ECHA, in particular for the assessment of ED properties.

5.2. Progression of the renewal process of approval of active substances	For information *CA-March22-Doc.5.2*	

The Commission indicated that the deadlines for the submission of applications for renewals of approvals had been reached for three dossiers in December. One of them was not submitted by the applicant which triggers a deadline to remove the biocidal products that contain that substance from the market.

The Commission also invited the Competent Authorities to inform the Commission when they intend to conduct a full evaluation of the active substance at the renewal stage in order to extend the expiry date of the approval in due time. Several extensions will probably proposed at the next Standing Committee meeting.

5.3. ECHA Active Substance Action Plan – progress update	For information *CA-March22-Doc.5.3*	

ECHA provided an update on the progress with the Active Substance Action Plan. In 2021 a higher number of assessment reports were submitted by member States compared to 2020. However, this number was lower than the expectations based on the Member States' planning. For 2022 a slightly higher number of assessment reports is foreseen, as well as a higher number of BPC opinions. Some highlights concerning the four main actions described in the action plan (prioritisation of dossiers, support to eCAs, streamlining of the peer review, reduction of complexity) were then provided.

With regard to the substance identity campaign, launched after the CA meeting of September 2021, Member States were invited to screen their active substances and indicate to ECHA by 31 March whether redefinitions are needed.

6. Treated articles
No item for information or discussion.

7. Horizontal matters

7.1. ECHA communications	For information	

ECHA gave a presentation covering these topics: developments concerning guidance, feedback on the use of the Interact Collaboration tool, plans for submitting CARs and PARs, ongoing call for Seconded National Expert at ECHA and the SPC integration into IUCLID. Regarding the latter topic, it was mentioned that the development phase is taking place and will end in November 2022 and the go-live is planned for February 2023, with next testing sessions scheduled in May/June and September/October 2022.

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

The Commission informed Member States on the state of play of this topic, for which internal discussions are ongoing. A newsgroup was opened after the previous CA meeting and several Member States provided their views. Due to time constrains it was not possible to prepare an compilation of the comments received, but the views of Member States that did not contributed to the newsgroup will be appreciated.

An Article 36 request on a product containing chlorocresol will be submitted to the Commission, as Member States were not able to agree in a mutual recognition process.

The Commission provided its preliminary views of the questions that have been raised by one Member State, but signalled that discussions with other Commission services have not taken place yet. The Commission shares the views of those Member States that consider that the default MRL for chlorocresol applies to animal commodities, that it is necessary to establish an MRL for chlorocresol to take into account the exposure from biocidal use, and that this task should be a joint task for EMA, EFSA and ECHA.

The Commission recalled that, during the disagreement in the mutual recognition, experts could not agree on how to perform the dietary risk assessment of the products and encouraged Member States to sort this out in the BPC working group, as similar problems can be faced for other products and in order to know if the product can be authorised it is necessary to agree on how to perform the risk assessment and whether it is likely that the MRL will be exceeded due to the use of the product. The other aspect of the discussion was on whether is possible to authorise a biocidal product if its use will lead to an exceedance of the default MRL, as Article 19 of the BPR does not provide a clear answer. Those Member States that consider that the product can be authorised even if the exceedance of the MRL is expected were invited to submit their legal reasoning.

One Member State expressed concerns on the time needed to set the MRL and the consequences for ongoing applications and suggested that the products are authorised with a post authorisation condition to gather analytical data on the use of the products that would allow to set an MRL, similarly to what has been done for quaternary ammonium compounds. The Commission shared the concerns of that Member State and confirmed that this possibility will also be investigated and recalled that analytical studies were submitted and accepted during the approval of the active substance, that lead to the conclusion that there was no risks that the MRL will be exceeded.

The Commission will discuss this issue internally and will try to come with an position for the next meeting.

7.3. Technical support to Member States 2022-2027	For information	Closed session

This point was discussed in closed session.

7.4. Question from Lithuania on applicability of Article 69(2) of the BPR	For discussion *CA-March22-Doc.7.4*	Closed session

This point was discussed in closed session.

7.5. Industry feedback on the implementation of the BPR	For information	

Representative of two industry associations gave a presentation on the industry experience with the implementation of the BPR. The speaker highlighted that the replacement of the BPD by the BPR, with its novel concepts and its main aim of ensuring a high level of protection for human health and environment, was welcomed by the industry, as it was considered this would increase consumers' confidence in biocidal products, since they undergo a thorough assessment before being made available on the market. Two industry associations have run a comprehensive survey among their members (around hundred companies, covering the entire supply chain) in order to understand the impact of the BPR on their activities and their experience with the implementation of the regulation, also in light of the concerns raised lately by companies concerning for instance the increasing difficulty in finding an evaluating competent authority.

Key concerns revealed by the survey were: complexity, moving goalposts, delays, non-harmonisation, lack of predictability, lack of level playing field, reduced innovation. With regard to complexity, three aspects were highlighted: complexity of legal framework (further enhanced by the co-existence of the BPR rules and national rules until the Review Programme is completed), guidance and borderline and scope issues. The main recommendations on the topic related to complexity are: creation of a document capturing previous decisions related to borderline and scope issues and creation of an overview of all guidance documents needed in order to prepare an active substance and product dossier. For the second main topic - moving goalposts - industry recommendations are not to apply new guidance to ongoing applications and to check best practices from other relevant legal frameworks. With regard to harmonisation, it was highlighted that, whilst the BPR aims to harmonisation, there are also procedures allowing for deviations (e.g. disagreements/referrals during mutual recognition). The fact that 70% of the disagreements were raised by two Member States indicates a lack of balance among Member States on how the assessment of applications is carried out, on the level of expertise and resources available in Member States. The increase of expertise in Member States could allow them to rely on each other's work. Another aspect of non-harmonisation is caused by the substantial delays in the Review Programme, as a consequence of which the majority of the products on the market are still regulated by national rules, which differ greatly among Member States.

Concerns related to level playing field have also been raised by companies and are due to complexity, delays and the co-existence of BPR rules and transitional measures. The completion of the Review Programme should therefore be pursued as first priority by Member States, as this would reduce complexity and increase harmonisation.

With regard to delays, it was highlighted that the delays affect not only the Review Programme, but all the procedures in the BPR. The lack of resources and expertise and

complex questions to be addressed during evaluation as well as poor communication in some cases between applicants and competent authorities, are all factors that contribute to delays.

One of the main concerns identified in the survey is the lack of predictability. The various elements outlined above (complexity, non-harmonisation, delays) are causes of the lack of predictability. The uncertainty on the outcome of the evaluation process challenges the commercial viability of applications and could hinder innovation. It was mentioned that a longer-term forecast on the BPC work programme for active substance approval would be beneficial to companies.

In relation to innovation, it was highlighted that lack of innovation (especially innovation on new active substances) is a consequence of many issues, such as long time to market, complexity and unpredictability, late return on investments.

The industry associations representatives highlighted that the issues outlined and the recommendations for addressing them are all interlinked, therefore some of the recommendations could bring improvements in several problematic areas. A follow-up discussion at the next CA meeting was suggested by the industry association.

With regard to the difficulty of finding an evaluating competent authority, the Commission invited Member States to accept acting as evaluating competent authorities when they receive such requests. The Commission also mentioned the planned grants aimed to support Member States. As to the possibility of establishing a central document (similar to the Manual of Decisions of the past), the Commission indicated it is not favourable to make again such document and that the tool of the Article 3(3) Decisions is available to Member States for questions of whether a product is a biocidal product or not. On the moving goal post issue, the Commission reminded industry that the rules of the BPR are clear since 10 years, in particular on the objective to not approve active substance meeting exclusion and invited industry to not support anymore these substances and support alternatives. The Commission also indicated that it will reflect on how to better organise all relevant documents available on Circabc, so that they can more easily be retrieved. ECHA welcomed the report and indicated that they will have a more in-depth look into it. ECHA is currently analysing possible solutions for the storage and access of relevant documents.

The Commission will reflect on whether a follow-up discussion on the topic is needed in a future CA meeting.

7.6. REACH restriction of substances in tattoo inks	For information	

A representative of DG GROW provided updates on the restriction under REACH of substances in tattoo inks. The restriction has been published in December 2021 and is applicable since 5 January 2022, meaning that preservatives in tattoo inks must comply with the requirements in the REACH restriction, as well as with the requirements in the BPR. Some preservatives which are covered by the restriction might not be used any longer. It was mentioned that stakeholders have flagged that very few preservatives are available on the market for this use.

A webinar aimed mostly at companies producing tattoo inks will be organised by ECHA on 29 March, and the topic of availability of preservatives will also be covered. ECHA has sent an enquiry to Member States regarding the availability on their markets of preservatives for use in tattoo inks, both authorised under the BPR and made available under the transitional measures and Member States were invited to provide feedback to ECHA by 18 March.

7.7. Labelling of carry-over preservatives in detergents	For information	

A representative of DG GROW provided updated the CA meeting about the development of the revision of the Detergents Regulation to include provisions on the labelling of carry-over of preservatives in detergents. The current provision[1] needs clarification. The term "if added" might be interpreted as covering the preservative added intentionally by the detergent manufacturer ('in can') or also the carry-over preservatives already present in the constituents mixtures. The Competent Authorities on Detergents agreed that if the manufacturer of the detergent is aware of the presence of the preservatives in the constituent mixtures then this should be listed on detergents labels. However, no consensus was found as to *how* carry-over preservatives should be labelled in detergents. As an alternative to the Commission's draft proposal, some Competent Authorities on Detergents proposed the following wording :

Preservatives shall be listed, using where possible the system referred to in Article 33 of Regulation (EC) No 1223/2009, irrespective of their concentration, if they contribute to the qualification of the detergent or a constituent of the detergent as a treated article within the meaning of Article 3(1)(l) of Regulation (EU) No 528/2012

This should ensure that all preservatives present in the detergents are actually labelled. However, many stakeholders indicated that the labelling of detergents are not effective in conveying targeted information to end-users as they are often overloaded with information that is not understandable by consumers. This was also the finding of the Detergents Evaluation[2] and the Chemicals Fitness Check[3]. In that context a concerned stakeholder proposed to label carry-over preservatives based on the most conservative value among the following values:

- The threshold for EUH208 under CLP for skin sensitizers preservatives;
- A default value of 100 ppm for all non-sensitizing preservative;
- A value below which studies demonstrate that an ingredient has no longer preservation effect in a final formulation based on literature review and expert judgment from industry.

However, this proposal was not supported by the Member States Competent Authorities on detergents. Given the lack of consensus within the Detergents Working Group, the Commission decided to address this point in the ongoing revision of the Detergents Regulation. The Commission, therefore, asked the CA on biocides whether an extension of the labelling requirements to carry-over preservatives is appropriate from the perspective of the protection of human health and whether it is coherent with the current legal framework as it is the first time that such ingredients would need to be labelled.

The Agency commented that in the context of the restriction on tattoo inks, the unknown presence of carry-over preservatives is an issue as the tattoo inks manufactures do not know the exact amount of preservatives already present in the ingredients. However, no similar solution as the one proposed for detergents to tackle this issue was proposed in this restriction. The Commission highlighted that contrary to detergents, tattoo inks are meant to be injected under the skin and remain. Further reflection is needed to know exactly if the measure under

[1] If added, preservation agents shall be listed, irrespective of their concentration, using where possible the common nomenclature established under Article 8 of Council Directive 76/768/EEC of 27 July 1976 on the approximation of laws of the Member States relating to cosmetic products.

the Detergent regulation would be beneficial for the protection of human health or whether this would only add administrative burden and complexity to the label of detergents.

A newsgroup was opened until 8 April to allow time for the participants to reflect on the questions, and the feedback collected will be forwarded to DG Grow.

7.8. Belgian study on the development of (cross-)resistance to antimicrobials following the use of biocidal products	For information *CA-March22-Doc.7.8*	

One Competent Authority presented a study on the development of (cross-)resistance to antimicrobials following the use of biocidal products in the frame of the Belgian action plan to fight antimicrobial resistance (AMR). The study shows that the role of biocidal products in the emergence of AMR as demonstrated in many studies. The importance of this role depends on:

- The type of active substance contained in a biocidal product;
- The target organism (gram negative bacteria are more likely to develop resistance);
- The bad use practices (use of insufficient doses, failure to respect the required contact time).

Potential cross resistance to antibiotics following exposure to certain active substances has been reported. Therefore the study recommends:

- To develop good practice for the use of biocidal active substances;
- Raise awareness about resistance and cross-resistance of the use of biocidal products among the general public and health care workers
- Use more sensitive bio-indicators
- Target active substance at high risk of resistance development
- Monitor the emergence of resistance and cross-resistance in all areas of biocides uses

The initiating Member State noted the development of a guidance on AMR and suggested to use the study in this context. The initiating Member State also intend to support actions at EU level to address this issue across different sectors.

The Commission thanked that Member State and explained that the information might be useful also for ECHA during the peer review process where an assessment of resistance needs to be made.

One Member State welcome the report which confirms the outcomes of similar studies conducted in the past by two other Member States on the careful use of disinfectants. The idea of covering the role of biocides in AMR under the EU one health initiative was proposed.

7.9. Update on substitution by the Dutch Competent Authorities	For discussion	

The initiating Member State called for a revision of the CA document of September 2018 on substitution. This document identified areas where substitution of hazardous substances is urgently needed. It seems opportune to discuss the progress made so far by Member State to support innovation in such areas. Such information could then be collected and annexed to the current version. Future cooperation between Member States could be envisaged if needed.

The Commission welcomed the proposal and agreed to revise the existing documents based on contributions from the CA. A newsgroup was opened until 8 April to collect this information and any relevant material.

7.10. Use of active substance trivial name	For discussion and agreement *CA-March22-Doc.7.10*	

The discussion was a follow-up and to attempt to finalise the discussion that took place at the previous CA meeting. The Member State having proposed this item presented an overview of the comments received after the meeting and the emerging considerations. Setting trivial names should occur at the stage of active substance approval and should be indicated in the respective Implementing Regulation. It is clear that the procedure set out in Article 24 of the CLP Regulation for deciding on an alternative chemical name is not applicable, as this procedure is targeted to industry and should apply for confidentiality reasons. Another difficulty comes from the different nomenclature among legislations – for instance for *Chysanthemum* extracts under the PPP Regulation the name pyrethrins is used. In certain cases, setting a common name could not solve the problem for similar substances, however, reflecting the method of extraction allows to distinguish between extracts (e.g. supercritical carbon dioxide extraction vs. hydrocarbon/solvent extraction.

Other elements which Member States were invited to agree upon were:

- a clear link between the systematic name and common name should be publicly available and linked in;
- common name should be decided case-by-case, with the acceptance of industry and competent authorities.

The Commission mentioned being favourable to finding a pragmatic solution for the few cases where setting a common name would be beneficial. Two Member States indicated they agreed to the approach outlined in the document. One Member State was of the view that indicating both systematic name and common name on the label would be the best option; the presence of the common name is needed for instance for enforcement purposes. ECHA expressed hesitation to accept the proposal in the absence of clear rules on how common names should be derived. The Commission reiterated that the problematic is limited to very few cases, of which *Chysanthemum* extract is one and noted that in the Member State's proposal there is reference to a document developed in the United States on how to develop common names. The Member State having proposed the item mentioned that more detailed discussions could take place in the APCP working group when a concrete case is examined, and acknowledged it is very difficult to develop rules on how to derive a common name.

One industry representative advocated for coherence with the rules for naming under REACH and the applicable guidance. ECHA was in favour of discussing the topic more in detail at the APCP working group.

The discussion concluded noting the agreement on the document presented at this meeting. The document will be transferred to the APCP working group, for more detailed discussions.

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-March22-Doc.11.a*	

(b) Dutch request for an update on azole resistance		

The Commission explained that a joined mandate addressing five agencies and the support of one Directorate General of the Commission has been issued earlier this year. The mandate requests the recipients to prepare a scientific report on the impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp. A report addressing the terms of reference has to be delivered by 15 July 2024.

The Agency commented that EFSA had been appointed as coordinator of the project. A kick-off meeting took already place where the distribution of different working packages among agencies was discussed. Due to its One Health nature, this is a very challenging project that will require also to find synergies between agencies. The report might recommend some regulatory actions or follow up work.