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

# MINUTES

# 96th 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

## 22-23 June 2022

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| **1. Adoption of the agenda** | For adoption<br>*CA-June22-Doc.1* | |

One Member State made a general remark regarding the timing of document uploading, as some documents were distributed shortly before the CA meeting, while Member States need time to prepare adequately. The Commission apologised for the late distribution of these documents and explained it was due to the high workload and resource limitations.

One industry association enquired whether there would be a debrief of the discussions in the closed session. The Commission explained that debriefs from the closed session are always foreseen; since at the last meeting the discussion in closed session took place at the end of the meeting, the debrief will be given in this meeting.

The agenda of the meeting was then adopted.

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| **2. Adoption of the draft minutes of the previous CA meeting** | For adoption<br>*CA-June22-Doc.2.a*<br>*CA-June22-Doc.2.b_Restricted* | |

The minutes of the previous CA meeting were adopted.

| **3. Draft delegated acts** |
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| No item for information or discussion |

| **4. Biocidal products** |
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| 4.1. Risk mitigation measures for products and treated articles | For information | |

The Commission informed on the latest developments as regards the setting of risk mitigation measures for treated articles in biocidal products and recalled recent discussions on the topic, on the different possibilities that have been explores to set risk mitigation measures for treated articles in the authorisation of biocidal products. More specifically, the Commission presented the draft proposed text for the approval of L (+) lactic acid that was modified to take into account the comments submitted by the Member States and the draft proposal to resolve a disagreement on a product during mutual recognition on the possibility to set risk mitigation measures for treated articles (Article 36 implementing decision). The outcome for the disagreements on the product is that that the safe use of the biocidal product in treated articles cannot be ensured only by imposing conditions on the use of the biocidal products in the treated articles, as opposed to placing on the market of treated articles themselves, the product does not meet the condition laid down in Article 19(1), points (b)(iii) and (b)(iv), of Regulation (EU) No 528/2012. The two drafts (approval of L(+) lactic acid and Article 36 implementing decision) will be presented and discussed in the next Standing Committee meeting.

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| 4.2. Consequences for biocidal products authorisations procedures of relevant information becoming available | For discussion and agreement<br>*CA-June22-Doc.4.2* | Closed session |

This item was discussed in closed session.

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| 4.3. Report from the Coordination Group | For information | |

The Commission provided a brief summary of the CG-52 meeting, that took place in April 2022 and in which:

- Four formal referrals were discussed and one was briefly introduced. Agreement was reached for three of the discussed referrals. For the other discussed referral discussion would continue and a date for an additional CG meeting was established for this and the introduced referral.
- The CG secretariat presented an updated list of the issues identified in the context of UA and informed the CG that in the future a collaboration would be launched for this purpose, presented an updated list of active substances meeting the exclusion or substitution criteria, gave a short summary to Member States in regards of the use of Interact Portal collaborations, informed stakeholders that the creation of a user group for them is expected by the end of 2022 and that for e-consultations where stakeholders will be involved, S-CIRCABC will still be used to share the document until that time. The CG was updated about the integration of SPC editor into IUCLID.
- Industry representatives drew the Member States' attention to the fact that the agreement considering the use of the new PAR template for renewal applications on a voluntary basis should be respected.
- The CG agreed on the revised templates for referral submission, on the amendment of the Working Procedure for resolving disagreements on the amendment of the Standard operating Procedures for the mutual recognition process in parallel and in sequence, as well as of minor changes applications to reflect that a referral can be raised in case of a non-authorisation assessment conclusion when the national application is subject to mutual recognition in parallel and the inclusion of references that in such situations SPC agreement is not part of the mutual recognition phase; clarification on which Member State needs to refer the referral to the CG in case of changes or renewal applications; references changed from S-CIRCABC to Interact Portal and amendments due to the amended rules of procedure (additional meeting instead of teleconference).
- A Member State presented an e-consultation in relation to the topic – Anticoagulant rodenticides renewal and waiving justifications for physical hazards. A Member State presented questions regarding the consideration of waiving justifications for physical hazards in case of the renewal of AVK PT14 products in light of the APCP WG training in 2021. The CG agreed that the available guidance as discussed at the WG should be followed.
- A Member State presented an e-consultation in relation to the topic – Updating first aid instructions. The updated document was agreed by the CG by consensus.
- A Member State presented an updated document for inclusion of P-statements in section 5 of the SPC. The update was initiated due to changes of the wording of P103 in the CLP regulation ("Read label before use." was amended as "Read carefully and

follow all instructions.") that entered into force in 2020. The CG agreed on the document by consensus.

- A Member State presented an outcome of an e-consultation in relation to the topic – Additional active substance data for PNEC refinement in applications for national authorisation (NA-APP). The subject of the e-c was the additional AS data submitted in the course of a NA being considered not reliable by the reference Member State. The CG agreed with the assessment of the reference Member State by consensus.
- The Chair presented a document in regards of taking into consideration the agreements reached during referrals for other product applications, including the establishment of a criteria for the similarity of cases. Discussion will continue at the next regular CG meeting.
- The Commission presented a document in relation to the topic whether mutual recognition (mutual recognition based on mutual recognition is possible, which was raised anew by a Member State at the CG-50 meeting for a particular case. The document reflected that mutual recognition based on mutual recognition. The Member States and industry representatives will provide feedback in writing. Discussion will continue at the next regular CG meeting.
- A Member State presented an e-consultation in relation to the topic – Impact of version 4 PT19 efficacy guidance.
- The CG secretariat informed the CG that development of new processes based on the agreed approach at CA-94 for assessment of new active substance data submitted at product authorisation is in progress and until its establishment the BPC and CG documents on the topic should be followed. Discussion of the topic was scheduled for the CG-52 meeting.
- The CG secretariat updated the CG about the discussion concerning post-authorisation conditions in regards of full long-term storage stability test and shelf-life that took place at the last APCP WG and informed the CG that discussion at the CG would continue at the CG-52 meeting.

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| 4.4. List of pending Article 36 requests | For information<br>*CA-June22-Doc.4.4* | Closed session |

This item was discussed in closed session.

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| 4.5. Handling "carriers" in the authorisation of biocidal products | For discussion and agreement<br>*CA-June22-Doc.4.5*<br>*CA-Nov16-Doc.4.3 rev2* | |

The Commission presented the amended document after having carefully considered all the contributions submitted by Member States in the newsgroup. After having discussed the document in several meetings, there is still no agreement from Member States on whether the carrier component needs to be taken into account for the calculation of the concentration of the active substance and substances of concern in the biocidal product. Therefore, the document has been amended to indicate that this should be decided on a case by case until discussion and agreement is reached by Member States in the working groups. The contributions submitted by some Member States in which the analysed thoroughly some examples of products with carrier competent could serve as a basis for the discussions in the working group.

One Member State acknowledge the need to further discuss the handling of carriers in the working group, and supports the amendments made to the document, even though in their opinion the document needs to be further developed to provide clear guidance. Another Member State acknowledged the difficulty to agree on the document at this stage and the need that further discussions take place on technical level and to build more knowledge based on concrete examples. That Member State agrees with the proposal to address the calculation of the concentration of the active substance(s) and substances of concerns on a case by case basis but foresees possible disagreements between Member States on authorisation of products that will emerge late in the procedures.

Two other Member States supported the amendment to the document and stressed that further development it may be needed in the future, once the discussions in the working group are concluded. One Member State made three editorial comments that were taken on board.

The document was endorsed by the Member States with the proposed changes.

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| 4.6. Wording of P-statements in SPC | For discussion and agreement<br>*CA-June22-Doc.4.6* | |

The Commission explained the approach proposed in the document which takes into account the discussion at the last CA Meeting and the received written comments in the aftermath. It was proposed to agree that the applicant is responsible to submit with the draft SPC all P statements according to the rules of the CLP the authorities' responsibility to verify that the proposal is in line with the legal requirements and the outcome of the risk assessment. This applies to combined P statements and the omission of non-relevant P statements due to the risk assessment. For the possibility to align the P statement section and the risk mitigation part of the SPC it is proposed that they could not be fully aligned due to their different nature, but should as far a possible be checked to not contradict each other. One observer voiced concerns on whether the approach would be in line with the principles of the CLP Regulation.

After clarification that the SPC will list all relevant P statements but the choice of the label of the product needs to be done by the applicant according to the rules of the CLP Regulation, and that P statements take the physical hazards but not potential accidents and misuse of the product into account, the document was endorsed by the Member States.

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| 4.7. Article 19(4) and in situ | For discussion and agreement<br>*CA-June22-Doc.4.7*<br>*CA-June22-Doc.4.7.a* | |

After the discussion and comments received after the last CA meeting, the Commission presented the view that Article 19(4) of the BPR - which excludes the authorisation of products with certain hazard properties to be authorised for the making available on the market for the use of the general public - should also apply for the different types of in-situ generating systems.
One Member State requested to clarify that the provision of Article 19(4) refers to the classification of the biocidal products and not to the active substance and that in the example of the in situ generation of ozone the concentration is not 100%. The Commission clarified that the case of ozone , as was presented in the BPC opinion available, was only chosen as an example but that there should be agreement on the general principle. It was also recalled that for the active substance approval of in situ ozone the representative product chosen was

100%. It was agreed to introduce a change to the document to clarify the reference to the classification of the product and not the active substance.

Two observers voiced their disagreement with the proposed interpretation of the provision as going beyond the wording.

The document was endorsed by the Member States with the proposed changes.

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| 4.8. Identification as SoC of ED non-active substance | For discussion and agreement<br>*CA-June22-Doc.4.8* | |

The Commission presented the document that proposes for that the concentration limit of 0,1% should also be applied for the determination of whether a substance identified as ED and contained in a biocidal product is a SoC. This proposal is coherent with the requirements set under Article 56(6) of REACH regarding the rules applicable to mixtures containing a substance having ED properties included in its Annex XIV, the approach agreed in the CA-Nov14-Doc.5.11 regarding when a substance should be considered as a substance of concern, and the approach agreed in CA-June21-Doc.4.3_final with regard to determining whether a substance identified as having PBT and/or vPvB properties and contained in a biocidal product should be considered as substance of concern. This implies that a substance identified as endocrine disruptor, and contained in a biocidal product, should be present in a concentration higher than or equal to 0.1% w/w for triggering its identification as SoC for the assessment of this biocidal product. However, where a biocidal product contains several substances in individual concentrations lower than 0.1% (w/w) which are identified as ED, but the sum of their concentrations is higher than or equal to 0.1% (w/w), they should be considered as SoC.

In all cases, the authorization holder should justify the need to use the substance identified as ED and contained in a biocidal product and the impossibility of immediate substitution, regardless of whether the concentration is above or below 0.1% (w/w). The authorisation holder shall prove its effort in doing so during the authorization process. In addition, the authorisation holder should try to substitute the substance as soon as possible.

The Commission also clarified that the document may need to be amended to take into consideration the final outcome of discussions on the proposal for the potential inclusion of hazard classes for endocrine disruptors in the CLP Regulation and that also the text of the BPR may need to be amended also, depending on the final outcome of the proposal.

One Member State indicated that they can support the document for pragmatic reasons but has concerns on the possible impact for authorisation under simplified procedure, as products containing an ED co-formulant below the threshold could be eligible for the simplified procedure.

Another Member State signalled that a risk assessment should be carried out when the ED co-formulant is in concentrations lower that the 0,1%, as there may be risk for human health even at very low concentrations. The Commission replied that this will be solved in the context of the revision of the CLP Regulation, as lower concentration limits can be applies, if it is known that an adverse effect takes place. The new CLP proposal may impact current guidance document on Eds that may need to be revised in the future.

ECHA expressed its agreement with the proposed document, as it is a pragmatic solution and is aligned with what is done in other frameworks (classification of mixtures).

Another Member States indicated that they could support the document also for pragmatism and asked that this is specifically mention in the document. The document was modified accordingly. One Member State requested that it is indicated in the document that the applicant should justify the need to use the substance identified as ED and contained in a biocidal product and the impossibility of immediate substitution, regardless of whether the concentration is above or below 0.1% (w/w), that the authorisation holder shall prove its effort in doing so during the authorization process and should try to substitute the substance as soon as possible. The document was amended accordingly.

France has concerns also on the impact of the agreed approach for products authorised in accordance with the simplified procedure.

Another Member State considered that all the references to CLP should be deleted till the proposal is adopted. The Commission clarified that the document was drafted in cooperation with the Commission services dealing with the new CLP proposal.

The document was endorsed by the MS Member States with the proposed changes.

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| 4.9. Substance identification for active chlorine released from sodium hypochlorite in case of a change of the pH value | For information<br>*CA-March22-Doc.4.12* | |

The Commission informed stakeholders on the agreed document CA-March22-Doc.4.12 that was discussed and agreed in the closed session of the 95th CA meeting. Member States concluded that a pH-change to a pH-value of <8 of the biocidal product due to a pH-regulator formulated to sodium hypochlorite would not be regarded to induce a change of the identity of the active substance. Thus, the active substance should remain sodium hypochlorite releasing active chlorine. The document has been uploaded in the public CIRCABC folder.

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| 4.10. Question from Norway on the application of Article 89(2)(b) | For discussion<br>*CA-June22-Doc.4.9* | Closed session |

This item was discussed in closed session.

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| 4.11. Amendment of authorisations of rodenticides by the Netherlands | For discussion and agreement<br>*CA-June22-Doc.4.11* | |

The purpose of the document was to agree on a way forward on authorisations of biocidal products granted in accordance with Article 19(5) of the BPR for which an application for a mutual recognition was submitted and for which an amendment in accordance with Article 48(1) of the BPR is made, to avoid that referrals are raised when Member States will amend those authorisations, as the Netherlands intends to do with the authorisations of rodenticides to adapt them to integrated pest management (IPM). The document reflects the current practice on the handling of these authorisations by the Member States.

It was agreed by Member States that in a mutual recognition procedure, when the reference Member State concludes that the biocidal product does not fully meet the conditions of Article 19(1)(b), points (iii) and (iv), an authorisation in accordance with Article 19(5) may be

granted only in those Member States in which not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation. Therefore, the concerned Member States need to assess whether not authorising the product would result in disproportionate negative impacts for society. As the assessment of whether the product may be authorised in accordance with Article 19(5) needs to be conducted by each Member State individually and as the proportionality assessment on the impacts on society may lead to the different scope of authorisation thus granted in a particular Member State (e.g. authorised use restricted to professionals or not), the necessary risk mitigation measures to ensure that exposure of humans and the environment is minimised can also differ depending on that different scope of authorisation granted.

Therefore, when amendments in accordance with Article 48(1)(a) are applied to authorisations already granted in accordance with Article 19(5) in the context of a mutual recognition, some Member States, when granting authorisations in accordance with Article 19(5), may amend their authorisations in a way that leads to certain different terms and conditions to the extent this is justified by the peculiarity of the Article 19(5) assessment.

One Member State requested that the title of the document is amended, to better reflect the content. It was agreed that the title will be modified to CA-June 22-Doc.4.11.-Amendments of authorisations granted in accordance with Article 19(5) and mutual recognition.

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| 4.12. CA-March16-Doc.4.6 Final.rev4 - note for guidance Q&A on simplified procedure | For discussion and agreement<br>*CA-June22-Doc.4.12*<br>*CA-March16-Doc.4.6 Final-rev4* | |

The question on whether authorisations granted in accordance with Article 25 of Regulation No (EU) 528/2012 (simplified authorisation procedure) was recently raised by a Member State.

*CA-Nov18-Doc.5.3-Final-Management of Annex I to the BPR*, paragraph 10, states that "the authorisation of biocidal products containing active substances included in Annex I have an expiry date. The authorisation shall be renewed for products authorised via the normal authorisation procedure. For products previously authorised or eligible for authorisation under the simplified authorisation procedure, a new application for authorisation must be submitted under such procedure".

A new Q&A number 37 has been introduced in the "*CA-March16-Doc.4.6 Final - note for guidance Q&A on simplified procedure*" to mention the procedure to be followed for the renewal of authorisations granted by simplified authorisation procedure.

In addition, a Member States asked recently for confirmation that biocidal products containing active substances included in Annex I to the BPR can be authorised for any product-type (PT). It was already clarified in document *CA-Nov18-Doc.5.3 - Final - Management of Annex I to BPR.doc* and *CA-Feb13-Doc.5.1.l - Final.rev1 - Substances in Annex I of the BPR.doc* that products containing active substances included in Annex I to the BPR can be authorised for any PT.

A new Q&A number 3 has been introduced in the *"CA-March16-Doc.4.6 Final - note for guidance Q&A on simplified procedure"* to mention that, if Annex I does not set an explicit restriction on the product-type, a product can be authorised for any product-type.

One Member State noted that the document presented does not contain some of the latest modifications made. The Commission will provide a consolidated version of the document, containing all the modifications made after the meeting.

Member States agreed on the addition of these Q&As.

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| 4.13. Derogations by Member States under Article 55(1) of the BPR | For discussion<br>*CA-June22-Doc.4.13* | |

The Commission introduced the document, which summarised the current situation with regard to the use of the Article 55(1) provisions by Member States. Most temporary permits have been granted for disinfection products during the COVID-19 pandemic, especially in the first year after its onset. Concerning the permits granted outside the pandemic context, it was noted that approximately one third of them have been granted by one Member State for the same product for use in apiaries against the American foulbrood. As to the other products temporarily authorised, most of them were products already authorised in the Member States granting the permit, for which a derogation was needed in order to allow different terms and conditions from those mentioned in the product authorisation.

With respect to the repeated permits for use in apiaries, the Commission enquired whether the Member State having granted them has investigated the possibility to use alternative products for the same use and asked other Member State what is their practice to control American foulbrood. The Member State having granted the permits mentioned they will contact the ministry which has the responsibility for granting such permits to gather more information and also informed that their national law obliges them to use sodium hydroxide for the treatment of the American foulbrood. The Commission opined that this Member State should have adapted their national law to allow other products, considering that sodium hydroxide is not an approved biocidal active substance, and wondered whether industry associations could indicate whether companies would be interested in filing an application for active substance approval. The Commission also invited the central authority of this Member State to monitor the situation and have a dialogue with the local authorities. The other Member States were invited to investigate what products are in use in their countries against the American foulbrood and provide this information by 15 July. Industry associations were also invited to send any information available on alternative products for this use.

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| 4.14. Update on ad-hoc group on in situ BP authorisation | For information | |

The Member State in charge of the organisation of this ad-hoc working group explained that a first list of regulatory questions will be sent out over the summer to the members of this group. Other Member States representatives are still welcome to attend. One representative of the industry enquired whether industry could be represented. The responsible competent authority answered that industry would be contacted when necessary to resolve a technical problem but that the intention is to restrict the group to Member States only.

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| 4.15. CA Dec 20-Doc.1.4. Warning sentence and RMM for bees_finalrev1 | For discussion and agreement<br>*CA-June22-Doc.4.15*<br>*CA Dec 20-Doc.1.4. Warning sentence and RMM for* | |

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| | *bees_finalrev1* | |

In the context of a referral in the additional meeting of the coordination group of 3 June 2022, the question on whether the inclusion of the warning sentence for bees that was agreed by CA-Dec20-Doc.4.1. Warning sentence and RMM for bees final for PT-18 products containing certain hazardous substances for bees shall be applied also to products that were authorised in the past and for which a mutual recognition in sequence is ongoing.

Member States considered that this issue should be discussed and agreed at the Competent Authorities' meeting, as a decision on this particular product will have an impact on other already authorised products. Two Member States indicated that they did not have sufficient time to prepare for the discussion.

As the purpose of the agreement on the inclusion of the warning sentence for bees was to find an interim solution before the ECHA guidance for assessing the risks to arthropod pollinators (including bees) is developed, the agreement should have been applied immediately and not 2 years after the agreement as done for regular guidance document. Furthermore, this situation cannot be considered either as new information on the active substance that becomes available, as the hazardous properties of the active substances were already known before the decision on the inclusion of the sentence was made.

Therefore, in order to avoid the amendment of all the authorisations of products for which the warning sentence is to be applied that were granted in the past, it is proposed that the warning sentence is included in the authorisations granted or renewed from 1 January 2021. The *CA-Dec20-Doc.4.1. Warning sentence and RMM for bees_final* has been amended accordingly.

Member States agreed on the proposed approach.

## 5. Active substances

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| 5.1. Progression of the review programme on active substances | For information<br>*CA-June22-Doc.5.1* | |

The Commission indicated that since the last progress report, no draft assessment reports have been submitted to ECHA. The Commission urged the Competent authorities to make progress on the completion of the work programme in accordance with the priority lists and to conclude as quickly as possible the review of their 40 backlog reports submitted before 1st September 2013. The Commission invited the Competent Authorities to liaise with ECHA when they experience difficulties in the assessment of the applications in particular as regard the assessment of the endocrine disrupting properties.

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| 5.2. Progression of the renewal process of approval of active substances | For information<br>*CA-June22-Doc.5.2* | |

The Commission mentioned that no dossier was submitted for the renewal of fipronil before the expiry date for the submission of application for renewal. The deadline for the approval is 30 September 2023. The Commission also indicated that the evaluation of renewal dossiers takes on average 5 years which is considered not in line with the intention of the Regulation.

The Commission called on the evaluating authorities to be stricter as to the submission of information.

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| 5.3. ECHA Active Substance Action Plan – progress update | For information<br>*CA-June22-Doc.5.3* | |

ECHA provided the regular update on the progress of actions in the context of the Active Substance Action Plan. In terms of the number of BPC opinions on active substances expected in 2022, it was mentioned that the estimate had to be lowered from 30 to 20, due to the submission of a low number of draft CARs in the last quarter of 2021 and first quarter of 2022. The update continued with the highlights concerning each of the four actions of the plan. ECHA concluded the topic with a few reminders to Member States (e.g. related to raising issues early during the evaluation phase, checking early if additional data is needed especially related to the ED properties assessment and modalities of submission of requests for further information) and mentioned that it has initiated bilateral discussions at managerial level with some Member States competent authorities, with a view to increasing mutual understanding on the state of play, challenges and opportunities.

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| 5.4. Guidance on analysis of alternatives | For discussion and agreement<br>*CA-June22-Doc.5.4.a*<br>*CA-June22-Doc.5.4.b* | |

ECHA presented this agenda item. The Agency initiated in spring 2021 the development of a framework guidance on analysis for alternatives to active substances candidate for substitution to the attention of applicants and Member States Competent Authorities (MSCAs). The framework guidance would provide recommendations on the steps to follow for identifying potential alternatives and recommendations on the set of information to include and assess, to determine their suitability. It aims to support applicants and MSCAs in using a more harmonised approach in analysing alternatives, which should lead to higher quality assessments.

The Agency presented a first draft of the framework guidance at the BPC-42 meeting in March 2022. It is inspired from the guidance and practice used under REACH applications for authorisation, other guidance from the OECD and the US, and recent cases of active substances renewal under the BPR such as boric acid and disodium tetraborate pentahydrate, propiconazole and creosote. Some BPC Members expressed concerns about the complexity of the information to be collected and the burden it would entail for public authorities. The Agency proposed therefore a new approach for the CA meeting and called Member States authorities for feedback.

One Member State called for more support from the Agency in particular regarding the analysis of the socio-economic impacts. The Agency replied that socio-economic analysis is an area where Member States lack experience and recalled that the Agency published a lot of material on how to conduct such study. It added that such analysis might not always be relevant to address the requirements of Article 5(2). Another Member State indicated that they would send written comments after the meeting.

An industry association claimed that the essential use concept, that can be found in Articles 5(2) and 55(1), should be looked at before performing an analysis of alternatives. The Agency responded that the question of essentiality is not covered by the draft guidance and that if alternatives exist, the question of essentiality is not relevant. The Commission added that

setting a guidance on the essentiality criteria might be very challenging as it might pretty much depend on the uses. The Agency indicated the existence of on-going work under REACH to include the essential use concept into that legislation.

The Agency invited the working group to send comments on the revised draft guidance and its annex by the end of July directly to the Agency.

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| 5.5. Approval of skin sensitizer in can-preservatives PT6 | For discussion<br>*CA-June22-Doc.5.5* | |

The Commission services briefly introduced the document, which summarizes past discussions in the CA meetings and highlights the current problems in the evaluation of skin sensitizers in in-can preservatives of PT6. The aim of this document is to pave the way forward regarding the pending approval/non-approval of the PT6 skin sensitizers, in particular for isothiazolinones.

A Member State highlighted the principle 63 of Annex VI of the BPR, that a biocidal product would normally not be authorized if, for non-professional users, the wearing of personal protective equipment would be the only possible method for reducing exposure to an acceptable level.

The Commission clarified that the issue with skin sensitizers of PT6 concerns mainly treated articles, such as paints and detergents, and not biocidal products. Therefore, the principle 63 of Annex VI of the BPR would not be applicable to this case.

ECHA mentioned that the analysis of alternatives of isothiazolinones depicted in Table 4 of the Document CA-June2022-Doc.5.5 is still preliminary, but constitutes a basis for such analysis. AISE and CEPE pointed the technical limitations that several alternatives to isothiazolinones might have. The Commission invited the Industry to provide clarifications on the matter.

A Member State noted that there can be non-chemical alternatives for paints, and there is a need to look broader options for alternatives, including paints that are not using biocides at all. CEPE mentioned that the existing alternatives cannot cover all the uses of domestic paints.

AISE mentioned that Table 3 of the Document CA-June2022-Doc.5.5 needs more explanations.

CEPE mentioned that there is no need for specific provisions on skin sensitizers used in paints under the BPR since they do not constitute a serious concern. Relevant risks have been identified before on skin sensitizers, but these concerned products in the area of cosmetics (eg. the case of MIT) and not in paints. CEPE questioned why ECHA is not delivering a Quantitative Risk Assessment (QRA) on skin sensitization, and invited this to be included in the upcoming mandate of Commission to ECHA mentioned in the Document CA-June2022-Doc.5.5.

The Commission replied that Member States have not been convinced so far by the argumentation provided by the Industry that skin sensitizers are not a concern under the BPR for treated articles, highlighting the recent provisions proposed by the BPC for BIT PT6. In addition, a QRA has been already addressed by the ECHA Human Health Working Group, which found that "*there is for the time being no agreed methodology to quantitatively assess the risk of sensitisation, and it is considered that the current scientific understanding does not*

*enable a sufficiently protective assessment*". ECHA complemented that they will take into consideration the OECD guidelines once adopted.

The Commission announced its intention to open a newsgroup to gather the views of the CA meeting members on the questions highlighted in the Document CA-June2022-Doc.5.5 (paragraphs 32-34), with a deadline set on 15 August 2022.

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| 5.6. Renewal of antifouling active substances PT21 | For discussion<br>*CA-June22-Doc.5.6*<br>*CA-June22-Doc.5.6.a* | |

The Commission services briefly introduced the document, which highlights the main current issues on active substances used in PT21 antifouling products, making also a brief sum-up of their history so far addressed during the CA and Coordination Group (CG) meetings. The document also aims to pave the way forward regarding the renewal of the PT21 active substances.

A Member State mentioned that there is an ongoing progress with the authorization stage of PT21 antifouling products, which could provide input in the questions posed in the Document CA-June2022-Doc.5.6, but they would need more time to elaborate. Another Member State mentioned the same, and pointed that a market study at national level on antifouling products and possible alternatives just started. This study is expected to provide input by the end of October 2022. A third Member State shared the position of the previous two Member States, mentioning also a study for non-chemical antifouling products.

CEPE highlighted the need for a refinement of the environmental risk assessment inside the marinas for pleasure crafts, and the need to take into consideration parameters such as boats density, depth, and exchange of water of the marinas. CEPE invited the Working Group of BPC to work on these issues through an ECHA mandate. When it comes to alternatives, CEPE mentioned that the current market cannot solely rely on them, that there is not a clear solution on alternatives, and raised the need for an holistic approach on the matter.

The Commission announced its intention to open a newsgroup to gather the views of the CA meeting members on the questions highlighted in the Document CA-June2022-Doc.5.6 (paragraphs 29, 30), with a deadline set on 15 August 2022. Based on the input received from the newsgroup, the Commission will investigate the need for a possible mandate for refining the environmental risk assessment. Due to time needs to provide input by the side of the Member States, COM pointed that the next discussion on antifouling products will take place either in the CA meeting of October or December 2022.

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| 5.7. Question from Austria on CLP and in-situ generated biocidal active substances | For discussion and agreement<br>*CA-June22-Doc.5.7* | |

A Competent Authority introduced the paper by explaining that in the context of the revision of the 'Recommendations of the BPC Working Group concerning in situ generated active substances', questions arose with regard to the classification and labelling of in situ active substance. The objective was to seek the agreement of the CA on two specific questions.

The first question relates to the necessity to provide a CLH dossier for in situ active substance. The CA agreed that the CA-Nov15-Doc.5.5 Final-Rev 1 still applies and therefore

that a CLH dossier shall be prepared by the evaluating authorities assessing in situ active substances applications.

Then, the Competent Authority went on by explaining that the CLH dossier shall refer to the 'pure' (i.e. 100%) active substance as CLH dossier are usually prepared for pure active substance and that information on impurities are not needed expect if they contribute significantly to the classification of the substance. However, if an in situ active substance is bottled and sold, the biocidal product containing this active substance shall be labelled taking into account the presence of impurities. The Competent Authority enquired about the positions of the other Member States on this issue.

Two Member States referred to the case where the active substance cannot be isolated and cannot be tested at the level of 100% purity and asked for some guidance on how to handle this case. The CA agreed to introduce a footnote 1 in the document to cover that case. This footnote reads as follows : "substances that cannot be isolated are exempted and should be tested at the highest concentration of the substance". The CA endorsed the document with that inclusion.

The Commission recommended to keep the document as open as possible and reminded the CA of the possibility to discuss specific technical issues at BPC Working Groups levels and include their outcomes in the BPC recommendations.

| **6. Treated articles** |
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| No item for information or discussion. |

| **7. Horizontal matters** |
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| 7.1. Letters addressed to Member States in 2021 on resources | For information<br>*CA-June22-Doc.7.1* | |

The Commission introduced the topic, mentioning that it aimed at providing an overview of the replies received so far from Member States to the Commissioner's letter on resources sent to the ministries responsible for biocides soon after the publication of the Commission report on the implementation of the BPR, in June 2021. The document distributed for the meeting presented the main elements that, in the view of Member States, cause delays in the approval and authorisation procedures, as well as the actions already taken and actions planned in the various Member States.

One Member State indicated that it is wrongly identified in the document as not having sent a reply, and informed that their reply has been sent in October 2021, and that it will send a copy of it in the following days. Another Member State apologised for the delay in providing a reply and mentioned that their reply will be received soon by the Commission. Another Member State indicated that, due to the very volatile political situation in their country in the recent months, they will not be in a position to provide a reply.

One Member State pointed out that there are other elements that cause procedural delays which were not indicated in the document, but were included in their reply letter, for instance the fact that there are certain costs related to applications for which there is no option of

charging a fee from the applicant - one such case is the costs related to the work on Union authorisation for which a certain Member State is not the evaluating Member State; with the increase in the number of Union authorisation applications such costs become a significant financial burden.

The Commission invited Member States who have not yet provided a reply to remind their ministries responsible for biocides to reply to the letter and to review the situation in their country.

All Member States were invited to continue to take the appropriate actions to ensure that their competent authorities can execute properly their role under the BPR. The Commission also reminded that it intends to open the possibility for Member States to apply for grants, subject to the condition of having in place or committing to establish a system properly financed through fees.

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| 7.2. Financial assistance to Member States 2022-2027 | For information | |

The Commission provided an update on the project to open the possibility for Member States to apply for grants, subject to the condition of having in place or committing to establish a system properly financed through fees. A specific workshop took place on 3 June with Member States authorities on biocidal products, and plant protection product, on this topic.

Member States interested to receive a specific letter calling the attention of their hierarchy on this project, once the grant is open for application, must inform the Commission by the end of July, indicating to whom the letter should be addressed.

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| 7.3. ECHA communications | For information | |

ECHA gave a presentation covering: the integration of the SPC editor into IUCLID (with a planned go-live date of May 2023), the main new features of R4BP introduced in 2021-2022, an update on the requests to ECHA under Article 75(1)(g) and an update on the EFSA & ECHA joint project on guidance development regarding information requirements for applicants and assessment methods under the revised Drinking Water Directive.

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| 7.4. Update on MRL for the active substance chlorocresol | For information | |

The Commission provided a brief update of the situation. Internal discussions are still ongoing on the harmonisation of MRLs set in the frame of the veterinary medicines legislation and pesticides and on the possibilities to authorise products for which conflicting MRLs exists.

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| 7.5. Assessment of metabolites in groundwater and drinking water | For discussion and agreement<br>*CA-June22-Doc.7.5* | |

In relation with questions raised by ECHA, the Commission introduced the topic by proposing a general approach regarding the relevance and the risk assessment of metabolites

of active substance for the groundwater assessment. The draft document clarifies that the SANCO guidance on the assessment of the relevance of metabolites in groundwater of substances regulated under the Plant Protection Product Regulation should continue to be used to assess the relevance of groundwater metabolites under the BPR. Seven Member States responded that they could support the Commission proposal and two other indicated not having had sufficient time to form an opinion.

On the question whether it could be possible under the BPR to derogate from the applicable threshold values set out under point 68 of Annex VI of the BPR, the Commission reading of the BPR is that it is not possible to conduct a risk assessment to derogate from those limit values. Four Member States agreed with the Commission's opinion. One Member State stated that it should be possible to deviate from these values but that comments would be sent in writing to explain this view.

The Agency stated that in the specific case of carcinogenic category 2 parent substance, the SANCO guidance seems to indicate that a risk assessment is possible to determine whether its metabolite would be relevant or not. The Agency agreed that when a metabolite is found relevant, the values of point 68 of Annex VI shall apply.

The Commission concluded this item by opening a newsgroup by 15th July to collect some additional information from the Members.

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| 7.6. Update on substitution by the Netherlands | For discussion and agreement<br>*CA-June22-Doc.7.6* | |

The Commission recalled a Member's proposal to collect information on national initiatives regarding the substitution of hazardous biocidal active substances. So far, only one contribution has been received. A Member State indicated that it is also collecting this information and that it should be made available to the Commission in the next weeks.

Another Member State enquired whether this information could also be inserted in a specific folder on CIRCABC. The Commission will discuss with ECHA to identify the most appropriate location to share this information.

The Commission concluded the topic by mentioning that the document on substitution will be amended to include in an Annex the information already available for the next CA meeting.

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| 7.7. Discussion document from the Netherlands on phosphine plant protection and biocidal products | For discussion and agreement<br>*CA-June22-Doc.7.7* | |

A Member State explained that several incidents with phosphine have been recently reported. For example, several crew members of inland vessels were intoxicated during the transfer of goods treated with phosphine. Similar cases have been reported across the European Union according to that Member State. In order to minimize such incident, that Member State proposed :

- An immediate action i.e. to harmonise the labelling and safety instructions for similar products under the BPR and the Plant Protection products Regulation (PPPR);
- A longer term action i.e. to address the question of workers intoxication during the transfer of goods during the renewal of the active substance under the BPR and the PPPR.

A proposal to harmonise a list of use instructions was proposed and discussed. Some editorial comments were proposed and accepted. A more fundamental revision of point 3 was proposed concerning the re-entry of the fumigated area. Two Member States requested more time to consult their PPP colleagues and requested the possibility to comment in writing. The Member State evaluating the renewal application promised to take this opportunity to provide an update of the assessment of this dossier in the newsgroup.

A Member enquired whether such accidents should not be better covered by the workers protection directive as most of them are related to the transport of goods coming from outside the EU. It was also requested to clarify if a ban of the use of phosphine during transport would have consequences on the supply chain. Furthermore, the labelling of the fumigated area should clearly indicate the company responsible for the treatment and the person of contact in case of poisoning. It would be also helpful to remove the labelling when all the packages containing phosphine have been removed so that inspectors do not look for them.

Another Member State requested clarification on whether the proposed use instructions should apply to all products (i.e. also to rodenticides) or only to the specific use of phosphine for the transportation of goods. It was proposed to only address the issue of the treatment of goods during transportation.

The Commission concluded the discussion and opened a newsgroup by 15th July to give the opportunity to the Members to liaise with their counterparts in the PPP area and contribute to the discussion.

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| 7.8. New CLP Regulation proposal (DG GROW) | For information | |

A DG GROW representative gave a presentation on the ongoing revision of the CLP Regulation. The presentation has been made available in CIRCABC.

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| 7.9. EU Pollinators initiative (DG ENV) | For information | |

The Commission presented the latest developments of the EU Pollinator initiative.

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| 7.10. Presentation from Greece on SIT technique to control mosquitoes as alternative to biocides | For information<br>*CA-June22-Doc.7.10.a*<br>*CA-June22-Doc.7.10.b* | |

A Member State presented an innovative means of control of invading mosquitoes species (in particular Aedes mosquitoes) that consist of a sterilisation method of male mosquitoes to prevent further mating with wild females. By releasing constantly sterilised males in a given area, this technique prevent the outbreak of vector-borne diseases. The technique also reduces the need for conventional biocides that are not targeted to a specific species. It was also noted that naturally breeding sites cannot be reached with a biocidal product application in particular in urban areas. The relative efficacy of sterilising methods is therefore much better. This technique is already routinely used in several regions of Europe. However, only two Member States have reached the level of being able to produce a critical mass of sterilised mosquitoes (up to a million mosquitoes per week can be released). The presentation is available on CIRCABC.

One Member State asked whether plans are foreseen to extend the technique to the sterilisation of Culex mosquitoes. The expert responded that Culex is only responsible for the West Nile virus disease and that there is currently no plan to control Culex mosquitoes with this method.

Another Member State enquired at what stage of the development of the mosquitoes population such techniques should be implemented. The expert responded that the first actions of the Competent Authorities should be to eliminate as far as possible the breeding sites to avoid the settling of mosquitoes. In case of mosquitoes establishment, an eradication plan is put in place in order to prevent further dissemination. This analysis is always case by case.

An industry association enquired what was meant by the statement that biocidal products are useless and requested clarification whether this was in situations where breeding sites cannot be easily identified. The speaker confirmed that this was indeed the case. The industry representative underlined that the biocides industry encourages also the use of integrated pest management and the appropriate use of biocides. The experts clarified that genetically modified mosquitoes have been developed in non-European countries to transfer biocidal active substances to breeding sites.

Another Member States asked how males and females mosquitoes can be separated in a safe manner. The female pupae is larger than males pupae and can be easily separated mechanically. It was also asked whether research is on-going on Wolbachia infected mosquitoes. The use of Wolbachia is allowed in some non-EU countries but the release of genetically modified organisms is a concern in the European Union although some trials were conducted in Roma.

The Commission thanked the expert for his very interesting presentation and invited the Member States to liaise directly with the expert referred in the presentation for further information on these techniques. Several trainings are organised every year by the FAO-IAEA Insect Pest Control Sub-Programme. The expert confirmed that they are in regular contact with the Centre for Disease and Control in Stockholm.

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| 7.11. Information on the proposal for a Regulation of the European Parliament and of the Council on statistics on agricultural input and output and repealing Regulations (EC) No 1165/2008, (EC) No 543/2009, (EC) No 1185/2009 and Council Directive 96/16/EC | For information | |

The Commission introduced the topic explaining that the background of this proposal is the major modernisation plan that the European agricultural statistics system has been undergoing since 2018. One step of this plan is the introduction of a framework regulation on statistics on agricultural input and output (SAIO), which brings together under a common legal framework the statistics on agricultural production, on agricultural prices, on Plant Protection Products (PPPs) and nutrients.

The Commission proposal was presented in February 2021 to the EU institutions and the inter-institutional negotiations started in February 2022. The European Parliament (EP) put forward several amendments, including the proposal to include the use of biocidal products in the scope of this regulation. DG SANTE explained to the Commission colleagues in the

Directorate-General that took part in the negotiations (Eurostat) why the EP proposal could not be implemented and suggested that the Commission should not accept the amendment related to biocides.

Contrary to the PPP Regulation, the BPR sets no obligation for users to keep records of the quantities of biocides that they use. The obligation set in Article 68 of the BPR on authorisation holders is only that they should to keep records of the products placed on the market. However, no systematic collection of such data by competent authorities has been taking place. DG SANTE also explained that there is no specification of the meaning of 'record' and that, considering that the review programme is not yet completed, only some of the products available on the market have an authorisation under the BPR. During the second trialogue of April 2022 the EP agreed to remove the suggested amendment concerning biocides. A recital would instead be included in the text of the future regulation, mentioning that the statistics will be extended to biocides evaluation of active substances for use in biocidal products is finalised.

| **8. Scope matters** |
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| No item for information or discussion |

| **9. Enforcement issues** |
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| No item for information or discussion |

| **10. International Matters** |
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| No item for information or discussion |

| **11. AOB** |
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| (a) | List of Competent Authorities and other Contact Points | For information<br>*CA-June22-Doc.11.a* | |

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| (b) | Organisation of future meetings | For information | |

The Commission informed that the following meeting (scheduled at the beginning of October) will have a hybrid set-up, unless the pandemic situation does not deteriorate dramatically. Participants who want to attend the meeting in-person in Brussels will be able to do so. A webex link will also be provided, allowing participants who will not travel to Brussels to attend remotely.

## Next meetings:

## (provisional 2022)

| CG | CA and SCBP | BPR Subgroup Forum | BPC | BPC's WGs |
|---|---|---|---|---|
| 15-17 February | | | | |
| | | | 1-3 & 8-9 March | |
| | 9-11 March | | | |
| | | 22-24 March | | |
| | | | | 28 March – 8 April |
| 26-28 April | | | | |
| | | | | 30 May – 10 June |
| | | | 8-9 & 14-16 June | |
| | 22-24 June | 21-23 June (or 17 June) | | |
| 28-30 June | | | | |
| | | | | 5-16 September |
| 20-22 September | | | | |
| | | | 26-30 September & 3-7 October (TBC) | |
| | 4-6 October | | | |
| | | 14-18 November | | |
| | | | | 14-25 November **Or** 5-16 December |
| 22-24 November | | | | |
| | | | 28 Nov-2 December | |
| | 6-8 December | | | |