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

MINUTES

88th 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

14-15 May 2020

1. Adoption of the agenda	For adoption *CA-May20-Doc.1*	

The following points were included in the AOB section of the agenda: an issue related to the evaluation of an active substance (closed session), the renewal of rodenticides and an update on the use of a trivial name.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-May20-Doc.2*	

The minutes of the previous meeting were adopted after addressing one written comment.

3. Draft delegated acts		
3.1 Amendment of Annexes II and III to the BPR	For discussion *CA-May20-Doc.3.1*	

The Commission services introduced the agenda point by explaining the actions undertaken since the last meeting of February 2020. Two consultations were performed based on a draft legal text presented in February. The consultation of the members of the World Trade Organisation on possible technical barriers to trade led to no comments. However, the feedback consultation in the context of Better Regulation run by the Commission drew the attention of several stakeholders. A summary of the 11 received responses of this consultation is available in the explanatory memorandum of the proposal. All the comments received were analysed in detail by the Commission and addressed. Where necessary, ECHA was asked for scientific advices.

One Member State asked whether for ADS point for genotoxicity could be clarified by specifying the tests that could be performed. ECHA explained that several in vivo tests could be useful and that this will be reflected in revised guidance. Another Member State welcomed the proposal as it would enable competent authorities to conclude on the ED properties of a substance.

A NGO reiterated its views that details from the test guidelines (TGs) should not be replicated in the legal text of the regulation because the guidelines are subject to regular updates and the protocol details may change as new knowledge becomes available. This is for example the case for the Extended One Generation Reproductive study under point 8.10.2. In order to achieve consistency and to ensure that the TGs and the regulation do not diverge in the future, the NGO proposed that all the details from the TGs be removed from the Annexes. The Commission services replied that the text of this endpoint was discussed in details (in particular the reproductive endpoint) in many meetings and that such details were found necessary by the experts.

The NGO suggested also that the term ‘equivalent’ be clarified and replaced with “providing appropriate relevant information to conduct risk assessment”, because it is ambiguous what ‘equivalent’ means exactly e.g. data from *in vitro* studies may provide relevant information that is not exactly equivalent to the data that would be generated using *in vivo* test guidelines. The Commission services clarified that the word equivalent was introduced on the request of

a NGO to provide flexibility and should be understood as described by the NGO. ECHA could develop further guidance, if considered necessary.

One Member State asked about the application of this updated data requirements for plant protection products. The Commission services explained that, when the regulation has been adopted and passed scrutiny by Council and Parliament, it will align the Communication for plant protection products with the adopted delegated regulation. For the ECHA-EFSA guidance it will be checked with ECHA and EFSA whether there is a need to update the guidance.

Finally, the Commission services updated the CA about the following regulatory steps before the act can be published in the European Journal. The legal text could be published in the fall of this year. The Chair concluded that the CA agreed on the draft text proposed.

4. Biocidal products

4.1. Article 55(1) derogations for increasing the availability of disinfectants	For information	

The Commission services indicated that the notifications received from Member States are made public on CIRCABC. The Commission services expect that in the coming months the demand of disinfectants may increase and therefore the permits granted may need to be extended by the Commission or new permits need to be granted by Member States. It was stressed that new actors start regularising the situation by submitting 'normal' authorisations and respect the Article 95 provision. A Member State asked whether in the case a Member State needs to grant a permit to the same holder and the same product for a second time because of an increasing demand of disinfectants the 180 days period in Article 55 would start from the beginning and whether a Member State renews a derogation but changes the scope of the permit (for example, adding an additional product or other holder), the Member State has to notify again to the Commission. The Commission services indicated that Member States should address in a pragmatic way this crisis situation and grant a new permit with a time lag in between, if possible. It was stressed that Member States cannot extend the existing permit, but need to grant a new permit.

An industry representative indicated they provided information on the market situation for disinfectants to the Commission. It is expected that the need will increase or shift, as we are entering in a new stage with moving out the lockdown situation. It was requested that Member States provide a forecast about the disinfectant needs, as it is difficult for industry to have a view what the future needs and demand will be on disinfectants, in particular because of the new players in the market. This will help to be as well prepared for this upcoming phase. It was acknowledged that having a quantitative overview on the demand of disinfectants is challenging, however, authorities have the overview of new suppliers based on the permits granted. The same industry representative also indicated that they encourage companies to be listed for Article 95. ECHA mentioned that they consider the aim of Article 55(1) derogations to be that of addressing a crisis situation and indicated to have received several Article 95 applications. The Commission services emphasised it is important that companies get on the Article 95 list and indicated that there is an alternative if companies prefer not to be on the Article 95 list: companies on the Article 95 list can make contractual arrangements with other suppliers and market the products. ECHA is providing assistance to

determine technical equivalence of similar products. Another industry representative informed they expect to have an increase of disinfectants because of the lifting of the Coronavirus restrictions in Member States. The Commission services mentioned that many Member States are not capable a quantitative forecast but some could do it. The Commission services agree that the broad spectrum of biocidal active substances, supplementing ethanol and isopropanol, should be used for disinfectants. It was agreed to establish a newsgroup in which Member States are asked to submit information on the expected demand on disinfectants in the near future.

4.2. Article 55(1) derogations for grounded aircrafts	For information	

The Commission services indicated that the Covid-19 crisis and the ensuing flight restrictions led to approximately 75% of aircraft being grounded. Up to a few months before one product was available for preservation of aircraft fuels against microbial contamination. The use of this product was discontinued because of safety issues. Several Member States granted a derogation for another product, which has been in use outside in the Union against microbial growth in aircraft fuels.

One Member State thanked ECHA for supporting Member States considering to grant Article 55 derogation with the risk assessment of the alternative product. Another Member State asked whether it is possible to grant a permit for the preservation of fuels in aircraft which are in use. The Commission services indicated that this is possible. An aircraft engine producer thanked the Commission and Member States' competent authorities for addressing this crisis and indicated the manufacturer of the alternative product hired a consultant for initiating the procedure to regularise the situation of the product. ECHA indicated that the use of the alternative product should be agreed by the Aviation Safety Agency. The Commission services confirmed that the Aviation Safety Agency agreed for the use of the alternative product.

4.3. Report from Coordination Group	For information	

The Commission services debriefed the meeting on the main points discussed at the Coordination Group meeting held on 31 March 2020. The principal aim of the CG-40 meeting was to discuss formal referrals on mutual recognition disagreements and technical and procedural issues raised by the Member States in relation to the UK withdrawal from EU. Since this meeting was dedicated mainly to a discussion of the formal referrals, only a closed session was organised.

Two formal referrals were discussed and four were briefly introduced. An agreement by consensus was reached for one product discussed and this referral is closed.

- A referral was discussed concerning a PT3 product containing lactic acid as an active substance (notification for placing on the market SN-NOT). The disagreement was related to the identification of possible substances of concern (SoCs). The initiating concerned MS (icMS) considered that due to the deficiencies of the study, it is not possible to rule out the classification of the product as corrosive to metals. If the co-formulants were considered as SoCs, the criteria for simplified authorisation according to Article 25 (b) of the BPR would not be met. The applicant provided an amended study report and the CG members agreed that

the biocidal product should not be classified as corrosive to metals. This referral was therefore closed.

- A referral was discussed concerning a PT18 product family containing permethrin as an active substance. This was the main discussion during the CG-40 meeting considering:

  a) This is a specific type of product - horse rugs impregnated with permethrin;
  b) There were 5 icMSs for this product;
  c) In total there were 25 points of disagreement referred to the CG;
  d) The points of disagreement were raised for all areas (efficacy (EFF), environment (ENV), human health (HH), including ED assessment, identity (APCP)).

A part of the points were discussed during the teleconference on 24 March. Remaining points were discussed during the CG-40 meeting. There were still four open points of disagreement where the CG agreed on the actions. Those points were further discussed during the teleconference on 14 April[1].

- A referral was briefly introduced concerning a PT8 product containing propiconazole, IPBC and permethrin as active substances. The icMSs indicated that (a) a risk characterization for combined exposure for the ENV to multiple active substances within a biocidal product should be performed for professional and non-professional users; (b) a risk mitigation measure (RMM) for human health (HH) in the SPC should be clarified and additional RMM for hand washing should be added to the SPC. This referral will be further discussed during the teleconference (22 April[2]).
- A referral was briefly introduced concerning a PT 2, 4 product containing iodine as an active substance. The icMS indicated that considering the new information provided by the applicant directly to the cMS during the MR process in sequence, the presented calculation of dietary residue levels would result in a significant exceedance of the acceptable iodine dietary intake for adults and toddlers. Thus, the icMS considers that the product should not be authorized. This referral will be further discussed during the teleconference (22 April[3]).
- Two referrals were briefly introduced concerning a PT 4 product containing hydrogen peroxide as an active substance. In both cases the point of disagreement is related to the letter of access (LoA) to the dossier of the active substance issued in support of the application. The asset owner is a consortium, however, the LoA is issued for individual companies of the consortium and not consortium itself. The icMS indicated that the consortium itself should be the beneficiary of the LoA on which the authorisation relies. Those referrals will be further discussed during the teleconference (22 April)[4].
- The Commission services informed the CG on practical consideration for referrals due to the UK exit from the EU.

4.4. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-May20-Doc.4.4*	

[1] Agreement by consensus could not be reached for some the disagreement points. The disagreements points will be referred to the Commission according to Article 36 of the BPR.
[2] Agreement by consensus could not be reached for one of the disagreement points. The disagreement point will be referred to the Commission according to Article 36 of the BPR.
[3] Agreement by consensus was reached for all disagreement points.
[4] Agreement by consensus was reached for all disagreement points.

The meeting was invited to take note of the document distributed in CIRCABC.

4.5. Monitoring report on mutual recognition procedures	For discussion *CA-May20-Doc.4.5*	

The item was postponed to the next meeting, as the data from R4BP3 were not provided by ECHA on time to be properly processed. The Commission services noted that there are many ongoing cases in R4BP3 that should have been closed and requested MS to check their cases in R4BP3 and close the finalised cases. An industry representative flagged that they receive more and more notifications from companies indicating that substantial delays take place and this is becoming a major concern because of the market distortion.

4.6. Article 52 of the BPR and Article 6 of Regulation (EU) No 492/2014: period of grace	For information *CA-May20-Doc.4.6*	

The Commission services presented a note explaining the interaction between Article 52 (Period of grace) of Regulation (EU) No 528/2012 and Article 6 (Period of grace) of Commission Delegated Regulation (EU) No 492/2014 on the renewal of authorisations. The interpretation of the interaction between those two articles is that Article 6 of Regulation 492/2014 extend the application of Article 52 of the BPR (grace periods) to other situations arising in the context of renewal of authorisations and where no regulatory decision is taken.

Therefore, even if no application for renewal was submitted, there is a need for a regulatory decision on whether a period of grace could apply (considering the possible exceptional case where continued making available or use of a product would constitute an unacceptable risk), and if so, the appropriate length of the period of grace. Such a decision would need to be taken before the expiration of the authorisation.

Several MSs expressed their disagreement with this interpretation. A newsgroup will be created in CIRCABC to provide their comments on this issue. The Commission services will collect and summarise them and will consult again the COM Legal Service on this issue.

4.7. Referrals covering scope issues	For discussion	

The Commission services informed the MSs that if there is a disagreement on a scope issue in the context of a mutual recognition procedure, it should be resolved in accordance with Article 35 of the BPR (through a referral to the Coordination Group).

The question whether a product is a biocidal product or not is a precondition for the application of the conditions of authorisations set out in Article 19 of the BPR. If a product is not a biocidal product, it cannot be authorised as a biocidal product, as it cannot meet those conditions under Article 19.

If the Member States fail to reach agreement within the 60-day period provided in Article 35, the unresolved objection will be referred to the Commission under Article 36 of the BPR. The Commission would be thus bound to decide, by way of implementing act in accordance with the examination procedure, whether the product is a biocidal product or not. ECHA pointed out that scope issues normally are noted in the beginning of a procedure, for example at the validation, and therefore should only occasionally appear in a referral procedure.

4.8. Non-active substances containing in biocidal products having indications for ED properties	For discussion	

The Commission services introduced the subject by referring to the agreement in SCBP to have a recital in an implementing regulation for granting a Union authorisation on a co-formulant contained in this biocidal product with indications to have ED properties. It is necessary to establish a priority list indicating the co-formulants for which the ED properties should be assessed as soon as possible. Therefore Member States are invited to provide information on the substances with indication of having ED properties. For this objective a newsgroup will be opened and Member States are asked to submit information before the 1st of July. The Commission will collect the information and based on this trigger a discussion with CA what should have priority. Also to discuss with REACH colleagues how they are setting priorities as Member States pointed out that for co-formulant they like to use the REACH procedure. One Member State welcomed this initiative and will contribute. An industry representative asked who is responsible to inform the applicant that a question is referred to ED Expert Group of ECHA to discuss their active substance or non-active substance. According to the representative it had received several notifications that the applicant, and/or relevant companies, were not informed about the discussion in the ED Expert Group. ECHA does not proactively inform an applicant for an active substance if a discussion will take place in EDEG as it expects that the Member State would inform the applicant. For co-formulants the situation is more complex and ECHA needs further reflection. Following a question of a Member State, one Member State indicated that it will provide information how the list was established on co-formulants with indications for ED properties.

5.	**Active substances**

5.1. Progression of the review programme on active substances	For information *CA-May20-Doc.5.1*	

The Commission services presented the progress report on the review programme. In particular, the Commission noted that several draft reports were submitted by Member States since the last meeting, both on the review programme and outside the review programme (ex: new active substances).

The Commission services further invited Member States to implement the action already agreed in 2018 to finalise the review programme, as well as the ECHA Action Plan agreed at the last CA meeting.

5.2. Progression of the renewal process of approval of active substances	For information *CA-May20-Doc.5.2*	

The Commission services presented the status report on the applications for the renewal of approval. It reminded that the evaluating CAs must inform ECHA and the Commission, within 90 days of acceptance of the application by ECHA, whether it intends to perform a full or limited evaluation. In that respect, it asked the evaluating Member State for metofluthrin

(Ireland) and alphachloralose (Poland) to inform the Commission quickly as the applications were submitted last year and the Commission has received no information so far.

5.3. Request of Denmark for early review of tolylfluanid	For information *CA-May20-Doc.5.3*	

Denmark submitted a request to the Commission for an early review of tolylfluanid for PT7. In the uploaded note on Circabc it is concluded that there are indications that the use raises significant concerns and the Commission intends to trigger the early review in accordance with Article 15.

6. Treated articles
No item for information or discussion

7. Horizontal matters

7.1. ECHA guidance		

(a) Draft guidance on data requirements and assessment of applications for renewal of active substances	For discussion and agreement *CA-May20-Doc.7.1.a1* *CA-May20-Doc.7.1.a2* *CA-May20-Doc.7.1.a3*	

The Commission services recalled that this item has been on the table for quite a while, and that the objective is to conclude at this meeting. The Commission services apologized for the late submission of a revised document due to intensive discussions with an industry association and one Member State.

ECHA shortly introduced the revised draft guidance. The Commission services proposed to go through the text section by section to address the remaining open points.

On section 1.2, industry and one Member State commented the sentence 'however, there might be situations where it is appropriate to replace the representative product considered in the previous approval …' and required the addition of '*or its uses*' after '*representative product*' for consistency reasons.

On section 1.4, concerning the information to be included in the renewal document, a Member State considered that a justification why no new information is considered necessary by the applicant should also be provided. This would allow the eCA to identify potential data gaps for which additional studies is needed. For ECHA, this situation is captured by the text of Appendix I to the ECHA guidance. The CA-meeting agreed to include the proposed changes in Appendix I.

On section 1.5, ECHA clarified that the objectives of requesting a 5 batch analysis is to verify whether the reference source is still within the established specifications. As long as the manufacturing process, synthesis pathway and starting materials are not changed, there is no reason to believe that the substance composition will change. Two Member States argued that

there might be situations where a change of the reference specifications is required for safety concerns. A sentence was added in Section 1.5 to reflect this situation.

Industry remarked that a new 5-batch analysis should only be required when there is a change in the manufacturing process. Industry added that with the new instrumental methods, impurities could be more easily detected but that those impurities might have been present in the original substance submitted to 5-batch analysis during approval. The Commission concluded by mentioning that the wording of the text as amended provides sufficient flexibility to address the need for a change of the reference specifications when duly motivated.

Finally, another Member State asked whether future guidance could provide more information in light with the experience gained during the renewals.

As to section 2, two Member States indicated a practical issue[5] for competent authorities to prepare and assess a CLH classification well in advance of the renewal risk assessment (RAR). ECHA answered that the submission of a proposal for CLH classification before the preparation of the RAR should remain the objective. The Commission services recalled that under the active substance action plan, ECHA is doing the utmost to streamline the CLH process with the BPR deadlines. The Commission suggested a slight modification of the text to reflect the discussion.

On section 2.1, a Member State asked if an evaluating Competent Authority should get a letter of access (LoA) to access data from the Article 95 list. ECHA indicated that it would be possible for the evaluating authority to use other sources of information than the applicants' data without a LoA if considered relevant for the evaluation. However, the use of such data may have consequences for the applicant. This is discussed in the document under point 7.2.

An industry association welcomed a new paragraph at the end of section 2.3 indicating that all data could be considered in the risk assessment.

Under section 2.4.1, at the request of two Member States, the text of the third paragraph was modified to clarify that the efficacy of all relevant products should be demonstrated. The use of the active substance in treated articles should only considered as an example.

On section 2.4.2, one Member State considered the sentence 'Furthermore, new guidance, e.g. entries in the TAB, must be considered for renewal' unclear and open for interpretation as regard the applicability of guidance. It could be useful if ECHA could develop more detailed information on the date of applicability of new guidance to identify more easily which parts of the initial evaluation is outdated. ECHA informed that the intention was to remind the applicants about the applicability of existing guidelines. The Commission pointed out that the wording of the last paragraph should be improved to indicate that in case such guidance becomes available, it would become applicable in accordance with the general rules of applicability of guidance. ECHA confirmed working on a revision of the TAB that would clarify which guidance are applicable as part of the active substance action plan.

One Member State proposed to add the reference to the CLP Regulation include under 2.4.2 also under points 2.4.3 and 2.4.4. ECHA explained that the reference to the CLP Regulation was included under 2.4.3 because of the introduction of new classes of hazard that may have an impact for physico-chemical properties.

In relation to Appendix I, one industry association requested the deletion of the request made to the applicant to submit an overview of the biocidal products authorised on the market and uses made of its active substances on the grounds that:

[5] Regarding the timelines of the BPR for the renewal

1) The renewal should focus on the active substance;
2) The ECHA dissemination website could help Member States to have an overview of the existing products on the market. The obligation should not lie with the applicant.

Two Member States supported the Commission and were in favour of maintaining this requirement. The Commission services informed that an applicant under REACH has the obligation to indicate the use made of their substance in the registration. The industry proposal was therefore not supported.

With the changes established during the meeting, the document was agreed. Taking into account it is not a CA-document it will not be published in the agreed CA documents. ECHA will ensure its publication.

(b) Draft guidance on relevant renewal data under Article 95	For discussion and agreement *CA-May20-Doc.7.1.b*	

ECHA indicated that several comments were taken on board since the last discussion on the document in particular a new section on data sharing mechanism has been developed.

Two Member States and an industry association reported concerns on some parts of the document and requested more time to provide written comments. The Commission services agreed to postpone the final discussion to the September meeting. A newsgroup will be open and Member States and stakeholders were invited to send comments by 8 June.

7.2. ECHA communications	For information *CA-May20-Doc.7.2*	

ECHA gave a presentation covering (i) the updated ECHA organisation in the biocides area, (ii) update on the Active Substance Action Plan, (iii) actions related to COVID-19 and (iv) update on IT tools. The new Head of Unit of unit Biocidal Active Substances introduced himself to the expert group and mentioned that the two units dealing with biocides (Biocidal Active Substances and Biocidal Products) will work in an integrated approach.

With regard to the Active Substance Action Plan, the actions in the four clusters (prioritisation of dossiers, support to competent authorities, streamlining the peer review, reduction of complexity) were mentioned, together with the positive results achieved so far.

On the support actions related to COVID-19, ECHA indicated the actions taken in support to both industry and Member States, which included: publication of a dedicated webpage, an accelerated technical equivalence procedure for propan-1-ol and propan-2-ol as well as an accelerated Article 95 procedure for disinfectants, publication of recommended requirements for several active substance and of a guidance for Member States on efficacy assessment in the context of Article 55(1) derogations.

Concerning the IT tools, ECHA mentioned that the interaction with IT users is crucial. A new release of R4BP and SPC editor is scheduled for June and testing sessions took place in advance of the release. A further release (with a prior training session) is scheduled for November. ECHA invited the participants to flag any issues or limitations they encounter when using the IT tools. The main elements of the forthcoming release of R4BP and SPC editor were then mentioned.

7.3. Update on Court cases	For information	

The Commission informed about recent cases in the biocides area :

- Case C-29/20, which is a request for a preliminary ruling on a dispute between two companies and the definition of "biocidal product" as regards to the action of the product by mere physical means. The contested product contains kieselguhr, which is an approved active substance;
- Cases T-122/20 and T-123/20, where the applicant contests the non-approval decisions adopted on silver zeolite and silver copper zeolite for PT 2 and 7.

7.4. Member States' report on the implementation of the BPR by 30 June 2020 and COVID-19 crisis	For information	

The Commission services referred to a question from one Member State, regarding the possibility for Member States to submit the reports in accordance with Article 65(3) after the deadline mentioned in the BPR, due to the shifting priorities in Member States because of the Covid-19 pandemic. The Commission services acknowledged that, in the current circumstances due to the Covid-19 pandemic, Member States had to give priority to other activities. At the same time it was explained that, since the deadline is explicitly indicated in the BPR, the Commission has no empowerment to change it. The Commission services therefore encouraged Member States to submit their reports by that deadline - to the extent to which they were able to compile the data by that time - indicating which parts are incomplete and when they would be in a position to provide the data related to those parts.

7.5. Guidance on pollinators: status update	For information	

ECHA informed on the status and planning regarding the development of the Guidance. The Commission services stressed that for plant protection products and biocides equivalent protection goals would apply. This implies that very close coordination and cooperation is necessary with EFSA. ECHA invited Member States to participate in the expert group to develop the guidance, in particular those Member States in the regions not well represented.

7.6. ECHA-EFSA guidance on residues of BP and PPP in drinking water: status update	For information	

ECHA informed on the state of play.

7.7. UK's withdrawal from the EU: mutual recognition procedures	For discussion	

The Commission services informed on how to deal to with procedures of mutual recognition in sequence, major changes, minor changes and renewals, for ongoing cases for which the UK was the reference Member State. For mutual recognition in parallel an agreement was already established between Member States. The Commission services also clarified that as, the UK

cannot act as reference Member State since its withdrawal from the EU, it is not possible - if no MS is taking over the role of reference Member State - to refer points of disagreement to the Coordination Group for procedures in which the UK was acting as reference Member State. For the ongoing cases of mutual recognition in sequence for which a new reference Member State is needed in order to be able proceed, a proposal was made. For cases having only one concerned Member State it was proposed that this Member State takes over the role of reference Member State. When there are several concerned Member States, a new reference Member State among those was proposed as new reference Member State. For minor changes, major changes and renewals the UK also cannot longer act as reference Member State. A table is provided for the on-going cases to establish a new reference Member State. For new cases the applicant has to find a new reference Member State. ECHA indicated that the document will be discussed in detail in the CG-meeting next week.

The Commission services noted that there are many ongoing cases in R4BP3 that should have been closed and requested Member States to check their cases in R4BP3 and close the finalised cases. It was underlined that applications for mutual recognition and changes submitted after the withdrawal of the UK, and having the UK as reference Member State, have to be rejected.

One Member State has a different interpretation of the provisions of the Withdrawal Agreement and in its opinion, mutual recognition in sequence from a UK authorisation is still possible. This Member State also referred to the possibility to have notifications in Member States for products authorised by the UK in accordance with Article 26.

7.8. UK's withdrawal from the EU: mutual recognition procedures	For discussion	Closed session

This item was discussed in closed session.

7.9. Personal data and CA-documents	For information	

This point was not discussed.

7.10. Information sources in relation to Covid-19	For information *CA-May20-Doc.7.10*	

This point was not discussed.

8. Scope matters	

8.1 Scope issues identified during the drafting of PT 11-12 efficacy guidance	For discussion *CA-May20-Doc.8.1.a* *CA-May20-Doc.8.1.b*	

The Commission services indicated that EBPF, an industry stakeholder, submitted a position paper on the classification of products in PT11 and PT12. An industry representative thanked Member States for their inputs on its position paper regarding the classification of certain

'borderline uses' in particular those related to PTs 11 or 12. The efficacy working group of the BPC is awaiting the CA views for endorsing the revised guidance on efficacy. It was recalled that further reflection is needed how to deal with products changing PT and it could also have implications on other PTs (i.e. PTs 1 to 5). The approach would avoid duplication of work to submit data for both PT 11 and PT 12 which would reduce applicants costs and also allow them to meet deadlines.

One Member State indicated its general support to the industry proposal pending some clarifications and redrafting certain paragraphs. Four other Member States provided comments in writing before the meeting.

The Commission services suggested going through the different sections of the proposal. One Member State requested the possibility to delay the final Member States agreement until September.

Biofilm prevention during preservation of liquid-cooling and processing systems

One Member State clarified that the text is acceptable but could be further improved to better match with the text of the BPR. The Commission concluded that this section is supported by the CA meeting pending some improvements of its wording.

Preservation of fluids in sterilizers, conveyor belts and pasteurizers

This section was supported.

Preservation of air washer systems and sump water in air conditioning systems

Two Member States expressed reservations about the classification of this use as PT 11 as the protection of human health is the most relevant objective compared to the preservation of the air conditioning system itself. This use should therefore belong to PT2. One Member State indicated that for Legionella there are performance standards for the protection of health. This is more consistent with PT 2.

For industry, two designations are needed to achieve different functions like for cooling towers. The PT 2 designation should be used for the periodic disinfection of the air conditioning system requiring dismantling works. Between the periodic disinfection, a treatment of the water circuit is needed for preservation to maintain the integrity of the system. This should be designated to PT11. According to the industry representative, each PT would also require different active substances. This also applies for cooling towers. At the request of the Commission services, industry clarified that disinfection should occur with proliferation of Legionella. A Legionella claim under PT 11 could occur in combination with other microorganisms for maintaining the integrity of the system to keep those a low concentration level in the water circuit.

Two Member States stressed that cooling towers and air conditioning systems are not comparable. Air conditioning systems work in an open circuit with air vapour and air droplets distributed constantly into the air of the treated area.

Preservation of washing water in the rinse area of tunnel washers

This section was supported.

Claims against *Legionella*

An industry representative reiterated its point of view defined for air washer systems that the designation of a product to a PT should not be based on the equipment but on the intended function of the product being preservation or disinfection. A claim for Legionella could be contained for both PTs. Routine level dosing for preventive use should be designated to PT11.

The Commission services explained that active substances have been approved under PT 11 for preservation and curative uses. One Member State asked to submit comments.

Slimicide treatment in the pulp and paper manufacturing process

This section was supported.

Preservation of fluids used in paper production

The section was supported.

Preservation and in-use application

This section was supported.

Wood preservatives and in use application

This section was supported.

Preservation of polymers used in enhanced oil recovery

One Member State proposed to cover this case with PT12 and another Member State agreed.

The Commission services concluded the discussion by announcing the opening of a newsgroup for further comments and asked Member States to provide concrete proposals by 30 June. The Commission recognised the need for further guidance on this issue but internal reflections are needed to discuss how the conclusions on this industry initiative could be endorsed by the CA. Industry indicated that based on the consensus reached in the CA, the efficacy WG could produce a formal output in the format of a revised efficacy guidance that would reflect the agreement in the CA meeting. In that situation there is no need for the CA to adopt a CA document.

One Member State requested the preparation of an updated version of the paper based on the results of the today's discussion. The industry representative agreed to provide an updated document.

8.2 Scope question from Austria	For discussion *CA-May20-Doc.8.2*	Closed session

This item was discussed in closed session.

8.3 Scope question from Latvia	For discussion *CA-May20-Doc.8.3.a* *CA-May20-Doc.8.3.b* *CA-May20-Doc.8.3.c*	Closed session

This item was discussed in closed session.

9. Enforcement issues		

9.1 Illegal disinfectants	For information	

The Commission services informed that, following recent reports in the media indicating an increase in the number of non-compliant disinfectant products on the market of some Member States, the BPR Subgroup of the Forum decided to run a survey in the Member States, to understand the extent of the matter and if appropriate enforcement measures have been taken to address it. Based on the result of the survey it will be decided whether harmonised action at EU level is needed.

10. International Matters

10.1 OECD involvement in COVID-19	For information	

The Commission services informed about the OECD involvement.

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-May20-Doc.11.a*	

(b) The renewal of rodenticides		

An industry representative informed about a position paper on anticoagulant rodenticides. The second renewal of these products will start in 1-2 years and it is proposed to have a similar approach as in the past (comparative assessment at EU level and the renewal of products taking place after the renewal of the active substances). The idea is to have a discussion in the September CA meeting and to conclude in the November CA meeting. This would allow a smooth renewal procedure. The position paper of EBPF will be uploaded on CIRCABC and a newsgroup will be opened for comments.

(c) The use of a trivial name on the label		

One Member State asked the Commission services to provide an update on the use of trivial name on the label. The Commission services clarified that a paper was not presented to the CA-meeting because the Member State triggering this discussion considered it less important or not anymore necessary to have it. The Commission informed that it started analysing the issue with colleagues responsible for CLP and REACH and it appears that one of the challenges of having a trivial name on the label is how to ensure that the name would be unique. The Member State suggested the following points to be addressed in a paper: substances consisting of complex substances, for example plant extracts and the procedure for deciding on the trivial name. The Commission services proposed that a Member State would prepare a discussion paper on this issue for the next CA meeting.

(d) Issue related to the evaluation of an active substance		Closed session

This item was discussed in closed session.

Next meetings:

2020 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
-	3-7 Feb	-		
		26-27 March	2-6 March	
-	-	-	-	
	12-15 May	-	-	
-	-	25-26 June	15-18 June	
		-	-	
-	-	-	-	
	22-25 Sept	-	-	
-	-	29-30 Oct-	5-9 Oct	
			-	
-	8-11 Dec	-	30 Nov - 4 Dec	