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

MINUTES

79th 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

5-6 July 2018

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 2 299 11 11
E-mail: SANTE-BIOCIDES@ec.europa.eu

1. Adoption of the agenda	For adoption *CA-July18-Doc.1*	

The agenda was adopted with AOB of one Member State on substitution of products in product-type 8 and AOBs in relation to update of Annexes, Court case on a biocidal active substance, veterinary diagnostics (closed session) and Union authorisation (closed session).

Several Member States indicated the uploading of the documents shortly before the meeting and underlined that for preparing the meeting the documents should be available on time.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-July18-Doc.2*	

The draft minutes of the 78th meeting were adopted with the correction of one typo noted by one Member State. With regards to the minutes one Member State emphasised that in the context of in situ products catalysts should not be considered precursors.

3. Draft delegated acts

3.1. Amendment of the Review Programme Regulation in connection with UK withdrawal pursuant to Article 50 of TFEU	For discussion *CA-July18-Doc.3*	

The Commission services presented their draft proposal for a delegated act in order to amend Regulation (EU) No 1062/2014 along the lines agreed at the previous CA meeting and in the technical seminars. They explained that the proposed modifications of the Review Regulation are limited to what is strictly necessary to manage the future withdrawal of the UK from the EU. In particular, they asked the views of Member States on whether flexibility should be foreseen on the timing of the payment of fees by applicants.

The Commission services informed the meeting that in accordance with the Interinstitutional Agreement EP and Council were informed about this draft delegated act and invited for the meeting.

One Member State informed that it has difficulties to accept the proposed reallocation and to take over the role of evaluating competent authority for some substances as agreed in the technical seminars. The Commission services took note of this comment and will further discuss this issue with this Member State. To a Member State asking how it could charge fees for applications already under validation/evaluation/peer review, pointing out that fees are usually requested and paid during the validation step, the Commission services explained that the draft act includes a provision that specifies that Member States can ask fees after the reallocation. Some Member States informed about their intention to be flexible on the amount of fees payable by the applicant. Conversely, other Member States explained that they have no flexibility in their national rules for fees. As regards the timing of the payment of the fees

by applications, having flexibility on the timing of the payments was supported by Member States. One Member State asked about the amendment of the Review Regulation in relation to substances contained in food and feed. The Commission services clarified that the amendment of the Review Regulation for food and feed is a separate exercise, the draft act is currently under TBT consultation and recently the time period of feedback mechanism expired. For the next CA meeting an amended Review Regulation for food and feed will be scheduled for discussion.

CEFIC asked to have an explicit reference in the text that sets out the provisions for a specific fee related to the re-allocation of the applications in the context of the withdrawal of the UK from the EU. The Commission services indicated to not support such a proposal, and would prefer to keep a reference to the relevant article in the BPR that sets out the principles for fees.. It is up to Member States to decide whether fees will be requested, and if so, to set the level in accordance with the principles for fees included in the BPR. The Commission further encouraged Member States to have proportionate fees to the services delivered, and advised that participants should contact the future eCA to discuss the matter bilaterally.

With regard to the provisions in Article 6a(3) setting the deadline to submit assessment reports to ECHA, a few Member States indicated that the proposed date of "30 March 2020" , in particular in case of late dossiers from the UK (i.e. reports from the 1st, 2nd and 3rd priority lists not submitted by 30 March 2019), was not taking into account possible requests for further information during the evaluation phase. The Commission noted that this situation will not happen according to information provided by the UK. The provision follows the same logic as the current Article 6(3), where 1 year was provided to MS to submit their assessment reports when the transition was made from Reg. 1451/2007 to Reg. 1062/2014 on some dossiers. The Commission noted the suggestion to provide additional time by extending the date of "30 March 2020" and will further reflect on this. However, it was underlined that this amendment of the Review Regulation should not modify the whole organisation of the review programme.

The Commission invited for the submission of comments by 20 July at the latest in order to continue the internal processes. Being a delegated act, a maximum period of 2+2 months for scrutiny is allowed to Council and the EU Parliament. Taking into account that the delegated act should enter into force before the withdrawal of the UK, this leaves limited time for discussions in CA meetings. Therefore it is the intention that the discussions will be concluded in the expert group in the CA meeting of September 2018. Following this the Commission may adopt the act and the following steps of the regulatory process can be initiated.

4. Biocidal products

4.1. Report from Coordination Group	For information	

The Commission services reported on the meeting of the Coordination Group (CG) that took place on the two previous days, together with the fifth meeting of the working party on the biocidal product (BP) family concept.

In particular one referral was noted, on which agreement could not be reached and where the problem originates from the post-approval conditions set at the active substance approval stage.

Another relevant topic discussed regarded the Technical Agreements for Biocides (TABs) - whether they should be considered new guidance or clarification of existing guidance, so, whether they may trigger requirement of new data or a change in the risk assessment. It is expected that the discussion can be concluded at the September CG-meeting.

The introduction of post authorisation conditions at product authorisation stage was also discussed by the CG and it was agreed that it should be an exception, to be decided on a case-by-case basis, and only when duly justified.

It was reported that the CG also discussed three documents that were agreed in a previous meeting of the working party on the BP family concept and when to start applying them. These documents regard best practices on interactions between applicants and reference member states, the grouping of some co-formulants within the family and how to proceed when it is identified that some uses within the family are not similar. Discussions on this latter document will be concluded at the September CG-meeting.

4.2. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-July18-Doc.4.2*	

No information was provided for this agenda item because of the short time frame with the former meeting.

4.3. Executive report on product authorisations	For information *CA-July18-Doc.4.3*	

The meeting participants were invited to take note of the report uploaded.

4.4. Union authorisation		

(a) Executive report on applications for UA	For information *CA-July18-Doc.4.4.a*	

No information was provided for this agenda item because of the short time frame with the former meeting.

(b) Translations of the SPCs	For discussion *CA-July18-Doc.4.4.b*	

The Commission services indicated that, following the discussions at the previous CA meeting, some points were identified that needed to be addressed in a more horizontal manner for translations of the SPCs for UAs. The first point identified regards the quality of the translations provided by applicants, which in some cases appeared rather poor. Applicants need to be aware that they must provide good quality translations; poor quality of the translation may delay the entire process of granting the authorisation. The second element regards the fact that some MSs did not check the translations, which may lead to problems at the Standing Committee stage. The Commission services highlighted that in the future they only want to accept translations that were checked by MSs. Another critical point (not addressed in the document) regards the post-BPC phase, when the evaluating CA has to ensure that all the agreements in the BPC are reflected in the master SPC (which is in English), before the translation procedure is triggered.

One MS, even though understanding the benefit of the exercise, pointed out that there is no legal requirement in the BPR regarding the translation check to be performed by MSs. The same MS mentioned that allowing two days for the check is not realistic and asked for "responsible member state" to be replaced by "relevant/nominated member state" since "responsible" would imply an obligation which is not substantiated in the BPR. ECHA reminded MSs that the products could be made available on the national markets and the quality of the SPCs in the Members States' language(s), even if the authorisation is granted by the Commission, are each MS's responsibility.

Another MS mentioned that it is risky to have only one contact point in each MS with such a short deadline to perform the check (since the indicated contact point might not be in the office in that interval) and pointed out the impact of public holidays. This MS suggested to have at least two contact points in each MS. ECHA was also requested to pre-warn MSs when translations are about to be sent. ECHA clarified that it is mentioned in the document that timelines can be extended in the case of public holidays.

One Industry representative wanted to know what happens in the case one or more MS do not check the translation. The Commission services ensured that the process will not be delayed indeterminately and that they will urge the respective MSs to perform the check. Industry representatives were invited to remind their members to pay attention at the quality of the translations and to invite them to anticipate part of the work before the BPC phase.

Following a question of the Chair the participants agreed to conclude the discussion on the document in this meeting. With the modification indicated above (change of "responsible member state" to "relevant/nominated member state") MSs agreed the document.

(c) EC report on Union authorisation to the European Parliament and Council	For information *CA-July18-Doc4.4.c*	

This agenda item was not discussed.

4.5 Management of product authorisations for in situ cases	For information *CA- July18-Doc.4.5*	

The Commission services provided an update of the agenda item by presenting several items which require further analysis and discussion by Commission services' and ECHA. One Member State mentioned its support to the clarifications put forward by the Commission services and ECHA. Another Member State strongly encouraged the Commission services to finalise the CA-document as soon as possible and reiterated its proposal to elaborate the technical requirements in cooperation with ECHA. The Commission services underlined to greatly appreciate the technical input of the Member States in this complex issue. AquaEurope underlined the uncertainty in the market, in particular on the requirements that may apply to devices and precursors. AquaEurope also reiterated its willingness to support the development of the technical requirements.

The meeting was invited to provide comments before 3 September.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-July18-Doc.5.1*	

The Commission services presented an overview of the progress of the work on the review programme, and reminded the meeting about the actions agreed at the previous CA meeting. The Commission services informed that ECHA has started to analyse in more detail with Member States the progress of the dossiers, in particular late dossiers; they also informed that they are considering to send letters to Member States who have still not submitted their reports for the 1st and 2nd priority lists. ECHA indicated that currently the BPC will not adopt opinions on active substances in upcoming meetings because the assessment of ED properties is lacking in the reports.

One Member State pointed out that the delay on one substance occurs because it does not have received a RAC opinion on the CLH of this substance. It also noted that this status report could be misleading for the public as it does not mention the impact of the future withdrawal of the UK from the EU, as well the assessment to be made in accordance with the new ED criteria, on the progression of the review programme. The Commission agreed to add a reference to these factors in the next update for the CA meeting, but remarked that the historical delays cannot be attributed to these factors.

The status report was noted by the CA meeting.

5.2. Progression of the renewal process of approval of active substances	For information *CA-July18-Doc.5.2*	

The Commission services presented the update of the overview of on-going and future renewals, and highlighted that in June the expected application for renewal of indoxacarb PT18 has been submitted, but no application has been submitted for thiacloprid PT08 which is an substance subject to exclusion.

The status report was noted by the CA meeting.

7. Horizontal matters		

7.1. ECHA communications	For information	

ECHA presented a subset of the slides already presented in the previous CA meeting focussing on the preparation for dissemination. It reminded the meeting which documents are going to be disseminated (i.e. final SPC, PAR and authorisation issued by the competent authority; in addition the BPC opinion in the case of Union authorisations) and what actions are needed from Member States in view of dissemination (in order to avoid confidential information to be disseminated). Member States were urged to take action in R4BP3 by the end of September to ensure that the documents have the correct type and access level.

An Industry representative reminded that Member States will have to manually delete from the SPCs information that is confidential (e.g. information requested and indicated by applicants at the application regarding the complete composition of their products). ECHA clarified that the information on the full composition of the products should be provided in the IUCLID file and not in the draft SPC; the SPC should only contain information on the active substances and on any substances of concern.

7.2. ECHA guidance		
(a) State of play ECHA guidance (on-going consultation, finalised guidance)	For information *CA-July18-Doc.7.2.a*	

The meeting participants took note of the document uploaded.

7.3. Endocrine disruptors		

(a) State of play	For information *CA-July18-Doc7.3.a*	

The Commission services provided a state of play of the implementation of the ED criteria. One Member State referred to the public consultation launched on the roadmap for a framework of policies on endocrine disruptors (Communication from the Commission to the EP and Council with the title 'Towards a more comprehensive EU framework on endocrine disruptors'). The consultation period for this roadmap is until 19 July 2018.

(b) The implementation of scientific criteria for the determination of ED properties for approved biocidal active substances	For discussion *CA-July18-Doc7.3.b*	

The Commission services introduced the agenda item by a presentation that will be uploaded on Circabc. A new version of the CA document will be uploaded on Circabc with the correct reference in the heading to CA-July18.Doc.7.3.b. It was underlined that in this meeting the item is for discussion and it is the intention to conclude the discussions in the next CA-meeting. Following the presentation one Member State pointed out that the Commission in its press release of 4 July 2017 stated that it would not delay any action for pesticides and biocides and an early review should take place of all substances identified under the different options in the screening study performed during the impact assessment accompanying the Commission's proposals for the new ED criteria. This Member State could agree with the proposed date of the end of 2020 for determining whether an early review would take place. The Commission services clarified that only option 2 and option 3 category 1 in the screening exercise match with the established ED criteria in Commission Delegated Regulation (EU) 2017/2100. Option 1 (interim criteria), option 3 category II (suspected EDs), option 3 category III (endocrine active substances) and option 4 (WHO/IPCS definition with potency) do not match with the established criteria and therefore for the substances identified under these options no significant indications exist that the approval conditions for those substances are no longer met. The Commission services indicated that the proposed way forward does not delay any action on EDs. One Member State pointed out that the procedure at ECHA level is not specified in this document and is likely to involve an increase of workload for Member States. This Member State also pointed out that workload of Member State will not covered by a specific fee. The Commission services pointed out that a request for an opinion of ECHA will be based on Article 15(2) of the BPR. Up to now ECHA did not receive an Article 15(2) request for an opinion and, therefore, the BPC did not establish a specific procedure for such types of request. ECHA clarified that, according to the Rules of procedure of the BPC, where the Committee is required to provide an opinion it shall identify one of its members as a rapporteur. Therefore a Member State has to be nominated as a rapporteur for the Article 15(2) opinion and most probably the eCA of the active substance will be proposed to act as rapporteur. A Member State indicated not to agree that the results of the screening sturdy match with 'significant indications' and that for prioritising also the risks of the substance should be considered.

One Member State indicated that in paragraph 1 of the draft document the tense used should be changed. A Member State pointed out that in paragraph 3 it is mentioned that 'significant indications that the conditions laid down in Article 4(1) are no longer met' and paragraph 12 refers to 'significant concerns' and asked whether this could be further specified. The Commission services pointed out that this drafting is similar to that used in the BPR for the two procedures. According to the Commission substances identified under the relevant option in the screening exercise can be considered to have 'significant indications'. This Member State pointed out not to agree with the conclusion in paragraph 11. A Member State asked to change the drafting in paragraph 11 by changing 'sufficient indication' to 'possible indication'.

The Commission services pointed out that in paragraph 8, fifth line of the draft document, the phrasing 'not yet adopted' should be changed to 'not yet applicable'. In paragraph 11 it will be specified that some biocidal active substances under option 2(WHO/IPCS) were identified as possible endocrine disruptors in the screening study performed during the impact assessment accompanying the Commission's proposals for the new ED criteria and that option 2 is similar to the established ED criteria in Commission Delegated Regulation (EU) 2017/2100.

One Member State asked to further clarify in paragraph 17 the drafting 'the limited period of 270 days also implies that the applicant will have a limited opportunity to demonstrate with the generation of new data that the substance may have ED properties'. The Commission

services indicated that ECHA has in total 270 days to prepare its opinion. ECHA has to decide how much time they will provide to the applicant to submit comments or information in this time period of 270 days. However, it is clear that generating data in relation to EDs can require up to 1-2 years. Therefore, it is included in the draft documents that there is a limited opportunity to demonstrate with new data that the substance may have not ED properties.

One Member State asked to add to paragraph 10, point 4 that a Member State can ask fees for the workload associated with being rapporteur Member State for preparing the ECHA opinion. Another Member State asked to refer to the Rules of Procedure of the BPC in this sentence.
One Member State asked to add to paragraph 18, point b that the renewal period shall be amended in order to ensure that a dossier for renewal of approval will be submitted within 24 months.

WECF referred to its written comments and indicated that in the screening exercise 98 biocidal active substances have been screened and currently 141 active substances are approved. This stakeholder was of the opinion that an early review of suspected EDs in the screening exercise should take place and for many substances data gaps may exist that need to be addressed for which the relevant data should be generated the coming years. The Commission services pointed to Annex 4 of the Impact Assessment in which the chemicals selected for the screening exercise are described. Some approved active substances were excluded (for example micro-organisms). Moreover, the screening exercise was based on active substances approved in May 2015. In the following years active substances have been approved, however, the Commission services have no indications that these may have ED properties. The Commission services indicated that Member States may ask the Commission to trigger an early review if they have information that substances may have ED properties. This procedure is described in the draft CA document.

The Commission services pointed out that in paragraph 20 it should be included 'for the renewal applications has to be submitted before the end of 2020' in relation to renewal process under BPR or PPP-legislation.

The meeting was invited to provide comments before 24 August.

7.4. The notification of the United Kingdom pursuant to Article 50 of the Treaty	For information	

The Commission services briefly informed the meeting about the main topics discussed at the fifth technical seminar, i.e. the transfer of ongoing applications for Union authorisation and mutual recognition in parallel.

7.5. MRLs – Update on DEET and icardine	For information	

The Commission services informed that in the working group of Contaminants legislation the issue of setting limits for DEET and icardine was discussed. It is the intention to propose action levels to Standing Committee on Plants, Animals, Food and Feed for harmonising enforcement of residues of these substances.

8. Requests for opinions
No item for information or discussion

9. Enforcement issues

9.1 Subgroup BPR Forum	For information	

The Commission services reported the relevant topics discussed at the fifth meeting of the BPR Subgroup of the Forum on 21st June. The first enforcement project for biocides (BEF-1) on treated articles will enter its operational phase in 2019 and a dedicated event "Training for trainers" with a focus on treated articles will take place in ECHA on 4-5 October 2018. It was also mentioned that the second enforcement project, on active substances in biocidal products, is included in the Forum work programme 2019-2013 and will most likely have its operational phase in 2021. The meeting was informed that the BPRS has decided to adopt the Information and Communication System for Market Surveillance (ICSMS) as system for coordination and information exchange between national enforcement authorities. One MS expressed doubts on the suitability of this system and on its user-friendliness.

10. International Matters
No item for information or discussion

11. AOB

- France informed of its intention to start a project to identify PT08 active substances and biocidal products placed on the French and EU markets, with the view to identifying alternatives to PT08 active substances subject to exclusion and substitution, and to identifying specific areas where there could be issues. France asked MS whether they had similar projects ongoing, and which MS would be interested to collaborate. MS were invited to provide their feedback to France and Commission services on the matter.
- The Commission services informed that a participant in the review programme has lodged a request for annulment of the decisions adopted on its active substance: Commission Implementing Decision (EU) 2018/619 of 20 April 2018 not approving PHMB (1415; 4.7) for PT 1, 5 and 6 (Court Case T-337/18); and the Commission Implementing Regulation (EU) 2018/613 of 20 April 2018 approving the substance PHMB (1415; 4.7) for PT 2 and 4 (Court Case T-347/18).
- The Commission services referred to the intention to update Annexes to BPR (II, III and IV) as discussed in the former CA meeting. The CA meeting was invited to send to the Commission services (to the functional email address) any requests for amendments of the Annexes and their motivation.

- A discussion took place in closed session on veterinary diagnostics and Union authorisations.

11.1 List of Competent Authorities and other Contact Points	For information *CA-July18-Doc.11.1*	

The meeting participants were invited to take note of the document uploaded.

Next meetings:

2018 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
9-10 January	10-12 January	-	-	I: 16-26/01
-	-	-	-	-
12-14 March	14-16 March	16 March	5-9 March	II: 19-29/03
-	-	-	23-27 April	-
31 May – 1st June	28-30 May	-	-	III: 21-31/05
-	-	21 June	24-29 June	-
4 July	5-6 July	-	-	-
25-26 September	26-28 September	-	-	IV: 4-14/09
-	-	12 November	15-19 October	-
19-21 November	21-23 November	-	-	V:?
-	-	-	10-14 December	-