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

MINUTES

78th 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

28-29 May 2018

Location: Centre Borschette, Brussels – room 2C

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MONDAY 28 MAY		

Afternoon session		**14:00 – 18:00**

1. Adoption of the agenda	For adoption *CA-May18-Doc.1*	

The agenda was adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-May18-Doc.2*	

The draft minutes of the 77th CA meeting were adopted with the amendment proposed by one MS.

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	

The Commission services presented the progress made with EU 27 Member States, Norway and Switzerland concerning the organisation of the review programme and the re-allocation of active substance as a consequence of the future withdrawal of the UK from the EU. An amendment of the Delegated Regulation 1062/2014 will be prepared along the lines presented in the document.

In reply to a question from a Member State, the Commission clarified that the draft act will only concern the modifications related to the future withdrawal of the UK from the EU.
An Industry representative noted that fees may be requested by the future new eCA, and called Member States to consider the principles set in Article 80(3) of the BPR aiming to ensure a fair level of fees as well as fee waiving.

The Commission noted this point, explained that the receiving Member States will need to cover the costs of processing these applications, and encouraged concerned applicants to contact both with the UK and the future appointed eCA to discuss their case.

The intention is to prepare a draft delegated act for the next CA meeting and to conclude the discussions in the September CA meeting. This time schedule would allow the Commission to adopt and publish the act before the withdrawal of the UK.

4. Biocidal products		

4.1. Renewal of PT 8 products	For discussion and agreement *CA-May18-Doc.4.1*	

The Commission services briefly introduced document CA-May-Doc.4.1, which addressed the comments raised by Member States (MSs) and stakeholders at the last CA meeting. The main elements raised during the discussion were the following:

- Paragraph 20 should be redrafted in a softer manner, as otherwise it seems that applicants have an obligation to contact MSs. It was agreed changing the wording in the last sentence by indicating that applicants "could ask" instead of "would have to explore".
- Paragraph 22 should also include that applicants are also encouraged to submit a consolidated IUCLID file. It was agreed in the meeting to include a footnote indicating that applicants are encouraged to submit a consolidated IUCLID file. However, applications for renewal will not be rejected where the consolidated IUCLID file is not submitted, as the BPR does not contain a legal obligation to submit a consolidated IUCLID file.
- The estimated timelines in section A of Annex 1 for T2 might be impacted by the assessment of the ED properties of the active substance. It was agreed to include a footnote in the relevant part of the Annex 1 indicating that the estimated timelines may be affected by the implementation of the ED criteria.

On a more general note, the Commission clarified that for the calculation of T2 there is no need to count the 30 day period for the eCA to get the fee payment, since the legal deadline to assess the application in 365 days counts as from the acceptance of the application by ECHA.

With the three changes mentioned above, the Chair noted that the CA meeting endorsed document CA-May-Doc.4.1.

4.2. Report from Coordination Group	For information	

Since the Coordination Group meeting had not been held yet, the Commission services referred the meeting to the list of conclusions and actions that will arise from the CG-29 meeting, which will be made available after the meeting on the dedicated CG CIRCABC interest group.

4.3. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-May18-Doc.4.3*	

The Chair invited the CA meeting to take note of document CA-May18-Doc.4.3.

4.4. Executive report on product authorisations	For information *CA-May18-Doc.4.4*	

The Chair invited the CA meeting to take note of document CA-May18-Doc.4.4.

4.5. Union authorisation		
(a) Executive report on applications for UA	For information *CA-May18-Doc.4.5.a.1* *CA-May18-Doc.4.5.a.2*	

The Chair invited the CA meeting to take note of document CA-May18-Doc.4.5.a.1&2.

(b) Check of the translations of the SPCs	For discussion and agreement *CA-May18-Doc.4.5.b*	

The Commission services briefly introduced the topic by reminding that, from the Commission's perspective, what is important is that every single Union authorisation (UA) has a SPC with correct translations in all official languages. It was underlined that the SPC will be in the end the basis for the authorisation holders to create the labels in each language and for the enforcement authorities to check compliance.

The Commission services pointed out that the quality of the SPC translations depends on two key elements: i) the quality of the translations as provided by the applicant and ii) the quality check carried out by MSs. From the experience gained with the first UA applications it follows that the quality of the translations from some applicants is significantly better than from others, as well as that some MSs did not check the translations proposed by the applicant. A number of actions can be taken in order to improve the quality of the SPC translation and the Commission services will present some proposals for discussion at the next CA meeting. Therefore, it was proposed to focus the discussion on the proposal put forward by ECHA concerning the check of translations for SBP applications (document CA-May18-Doc.4.5.b).

ECHA briefly introduced the proposal addressing the concerns expressed by MSs, in particular the workload associated with a check . ECHA stressed that only very limited sections of the SPC may differ from the SPC of the reference product. Therefore MSs would have only to check a very limited amount of information corresponding to what can be subject to administrative changes in the SBP application. ECHA would check whether the proposed SPC would go beyond the allowed changes for the SBP application.

Several MSs voiced that the translations were of low quality. Several MSs raised concerns related to the approach proposed by ECHA since the check of information related to administrative changes would not require any linguistic skills and therefore, according to those MSs, could be performed by ECHA. Moreover, this check, notwithstanding only a limited number of sections of the SPD are affected by the SBP compared to the reference product, will ask substantial resources in the case of large families. A MS also indicated that any possible mistake could still be addressed at the SC level. The Commission responded that looking at the annex to the Changes Regulation, what ECHA is proposing requires a very limited effort which might in some case be limited to check the change referred to in point 7 of section 2 ('More precise instructions for use, where only the wording but not content of instructions are changed'). When this check is done by a native speaker from a MSs, it would have an evident added value in terms of accuracy of information. The Commission services also indicated that introducing corrections at the SC level would imply the same workload for MSs and would generate unnecessary work as it would imply amending both the Word and the XML versions at a very late stage of the procedure.

A MS indicated that the applicant is responsible for the information on the labels. The Commission services agreed with this view, but argued that, if any incorrect information on the label is compliant with the information in the SPC in a given linguistic version, then the enforcement authorities could probably not take any action against the authorisation holder. That underlines the importance of having good quality translation in the SPC.

In the light of the above discussion, the Chair noted that the CA meeting agreed with the way forward proposed by ECHA in the document CA-May-Doc.4.5.b, with reservations from Germany and Sweden. It was agreed to note in the minutes that, if needed, the agreed approach could be revised in the future in the light of gained experience.

4.6 Management of product authorisations for in situ cases	For discussion *CA- May18-Doc.4.6*	

The Commission services informed the CA meeting about the results of two consultations on the first draft document presented in March. The objective of this document was to describe a possible way forward for the management of product authorisation in case of in situ generation.

Two Member States and an industry federation clarified that in their views, catalysts should not be regarded as precursors since they were not included in the review programme (e.g. TiO2). ECHA added that catalysts may have an impact on the kinetics of the chemical reaction and therefore their impacts should be addressed in the risk assessment. The participants taking the floor agreed that catalysts cannot be considered a precursor, however, these substances can be part of the risk assessment.

An industry association asked whether only internationally recognised standards should be considered when preparing an authorisation dossier or whether a reference to national standards could be also envisaged. The Commission services indicated that this is an open issue and asked the views of the participants of the CA meeting on this issue.

Final comments on the presentation of May 2018 and the draft document presented in March 2018 should be submitted before 15 June at the latest. It was clarified that after a CA-agreement is reached on the main principles for product authorisation in case of in situ, ECHA will start reflecting on the technical requirements needed for product authorisation in case of in situ.

5. Active substances

5.1. Progression of the review programme on active substances	For information *CA-May18-Doc.5.1*	

The Commission services presented an overview of the progress of the work on the review programme, and reminded that actions agreed at the previous CA meeting must be implemented.

One Member State noted the deadline to submit report for PT 2 and 4, and the BPC guidance to not submit the report if the ED assessment is not performed. The Commission services noted this point and the practical implementation discussed in the BPC. The Commission

services reminded that Member States must be diligent in assessing applications for approval, in particular on the ED criteria published since last November, and must be in close contact with ECHA concerning the progression of their assessment.

The report was noted by the CA meeting.

5.2. Progression of the renewal process of approval of active substances	For information *CA-May18-Doc.5.2*	

The Commission services presented an overview of the coming deadlines for the renewal of approval of active substances, and noted that the actions agreed on the review programme to better manage the review of dossiers are also relevant for the applications for renewals. The Commission services informed that the information currently available on the ECHA website will be improved. The Commission services also reminded the actions that Member States must perform in case no application for renewal is submitted.

The report was noted by the CA meeting.

5.3. Renewal of approval of active substances which are both approved and listed in Annex I to the BPR	For discussion and agreement *CA-May18-Doc.5.3*	

The Commission services informed the meeting that some progress was made internally on questions related to Annex I and that, if possible, a document will be prepared for the next CA meeting.

5.4. Opinion on a declaration of interest to notify under article 15(a) of Reg. 1062/2014	For discussion and agreement *CA-May18-Doc.5.4*	Closed session

The discussion took place in a closed session.

TUESDAY 29 MAY 2018

Morning session		**09:30 – 13:00**

6. Treated articles		
6.1 Scope issues related to the enforcement project		

(a) Labelling of treated articles	For discussion *CA-May18-Doc.6.1.a*	

The Commission services indicated to withdraw the uploaded document on the language of the label of a treated article as there is no further need for it. The Commission Notice – The 'Blue Guide' on the implementation of EU products rules 2016[1] provides a response to the question raised, as it indicates that the products should be accompanied by instructions in a language which can be easily understood by consumers and end-users.

(b) Selected examples for discussion	For discussion *CA-May18-Doc.6.1.b*	

The Commission services indicated that MSs had been asked to submit cases of articles that could be subject to diverging views whether it are biocidal products, treated articles or out of the scope of the BPR. For this meeting the Commission services have selected for discussion three cases with the most diverging views. The discussion of the three cases showed that it is key to have sufficient information to analyse whether the article can be considered a biocidal product or a treated article. According to the Commission the discussion showed that the CA-document on 'Frequently asked questions on treated articles ' and already established Article 3(3) decisions provide the required guidance to establish whether an article can be considered to have a primary biocidal function.

7. Horizontal matters		

7.1. ECHA communications	For information	

ECHA gave a presentation focusing on the new release of R4BP3 (R4BP 3.11) and SPC editor 2.2 and on the preparation for dissemination and actions requested from MSCAs in view of the launch of the new dissemination website.

7.2. ECHA guidance		

(a) Priority setting for developing ECHA guidance	For discussion *CA-May18-Doc.7.2.a*	

ECHA introduced this agenda item and underlined that it is necessary to set priorities, as it is not possible to address all requests for guidance. ECHA also indicated that the role of the BPC in relation to products will increase because of the Union authorisations. It was underlined that the document is not exhaustive for the intended items selected for guidance. Moreover, this document only discusses ECHA guidance, while other types of guidance are

[1] 2016/C272/01 of 26.7.2016.

not addressed (for example recommendations of WGs, CG guidance). Several MSs asked to have an exhaustive overview of all guidance and 'quasi' guidance being developed by ECHA and CG. One MS pointed out that for certain guidance cooperation of several WGs would be needed. ECHA agreed that for certain types of guidance several WGs need to be involved. Such overview is considered necessary because of the interaction between the different developments and the workload it will generate for CAs.

(b) State of play ECHA guidance (on-going consultation, finalised guidance)	For information *CA-May18-Doc.7.2.b*	

ECHA introduced the state of play of ECHA guidance and underlined that the ECHA-EFSA guidance is close to finalisation. This week ECHA and EFSA colleagues will collect the comments of risk managers and consider whether there is a need for amendments. A pre-final version will be published on the ECHA website and it the final version will be published in the EFSA journal[2] and the ECHA website will make a link to it.

7.3. Endocrine disruptors		

(a) State of play	For information *CA-May18.Doc7.3.a*	

The Commission services provided a state of play of the implementation of the ED criteria.

(b) The implementation of scientific criteria for the determination of ED properties for approved biocidal active substances	For discussion *CA-May18-Doc7.3.b*	

The Commission services introduced the topic and indicated that the intention is to submit a draft CA document for the next meeting while in the present meeting the intended approach will be presented.

One MS asked which option in the screening study will be used in order to determine whether indications exists that an approved active substances may have ED properties. Another MS asked when the EC may start the early review. The Commission services indicated that the option in the screening study that will be used that is the one mostly aligned with the established ED criteria. The EC will start the process of early review as soon as possible after the ED criteria become applicable. One MS asked to include in the minutes the three active substances indicated in the presentation and that, based on preliminary analysis, may have ED properties (iodine, PVP iodine and zineb). Several MS expressed concerns about the MS resources associated with an early review indicating that ECHA will ask a MS to assess ED criteria and no fee is provided for that. One MS enquired on the impact for biocidal products such a procedure and pointing out that Article 48 procedures do not include comparative assessment.

[2] https://www.efsa.europa.eu/en/efsajournal/pub/5311

Afternoon session		**14:00 – 18:00**

Horizontal matters (cont'd)

7.4. Update of Annexes to BPR	For discussion *CA-May18-Doc7.4*	

The Commission services explained its intention to revise the technical annexes of the BPR following becoming applicable the ED criteria and the establishment of ECHA-EFSA guidance. This provides the opportunity to adapt also the BPR annexes II to IV to technical and scientific progress .

With the support of ECHA, several points were identified for which an amendment to the BPR Annexes is desirable. Member States, industry and NGOs representatives were requested to provide their views on the note distributed via CIRCABC in advance of the meeting before the end of July and to motivate their requests to adapt the annexes.

Several Member States indicated that they support the initiative. One Member State expressed concerns about the wording proposed under point (12) of the note. In relation to the section 3.4 (micro-organisms) this MS proposed to look at the discussion on this issue for plant protection products.

7.5. Outstanding Helpex questions	For discussion and agreement *CA-May18-Doc7.5*	**Closed session**

A discussion took place in closed session and MS were asked to provide their written comments.

7.6. Towards the substitution of hazardous active substances in biocidal products	For information and discussion *CA-May18-Doc.7.6*	

The Commission services announced their plans to develop targeted actions on the substitution of substances of high concern in biocidal products. Recalling the main provisions of the Biocidal Products Regulation on substitution, it was indicated that the draft note points out that action is needed for six specific areas i.e. rodenticides, mosquitoes control, antifouling, in-can preservatives and wood preservatives for railways sleepers and poles. It was also indicated that information on possible alternatives to existing critical chemicals are available in various EU databases (e.g. CORDIS, LIFE and ECO-innovation program) and invited industry in particular to have a look at the content of those databases.

Member States were invited to share their expertise, inform the expert group about any initiative related to the development of alternatives to substances of high concern and share

results with other participants. Member States were also requested to provide their opinions on the draft note presented at the meeting before the end of July 2018.

One Member State called for more research and a holistic approach on mosquitos' control. Another Member State explained that similar priorities as those presented in the draft note were identified as part of the national safety chemical initiative agenda. The initiative will aim at promoting chemical innovation across the Member States. Feedback will be given as soon as the outcome is published.

One Member State indicated that a workshop on alternatives to chemical rodenticides is planned for 20 November in Brussels. Another Member State argued that research on wood preservatives should not be limited to insecticides but should be extended to fungicides.
Finally, one Member State requested more information on the nature of the preservatives used in in-vitro veterinary diagnostics. The Commission services indicated that this type of information would be useful and currently is not available.

The Commission services explained their intention to have more topics on substitution of biocide active substances in the future EU research program (FP9). It was recalled that most of the budget in the Union comes directly from Member States.

7.7. Data protection	For discussion	

This point was not discussed.

7.8. Update on fipronil	For information *CA-May18-Doc.7.8*	

The Commission services provided a state of play on fipronil referring to the analysis of EFSA of the obtaining results in the ad-hoc monitoring exercise[3] and the four fact-finding missions to four MSs.

7.9. Proposal for a Regulation on Enforcement and Compliance in the Single Market for goods (Goods package)	For information	

The Commission services provided a state of play on this proposal.

7.10. Research use only products and in vitro diagnostics for veterinary use	For information	**Closed session**

A discussion took place in closed session.

[3] https://www.efsa.europa.eu/en/efsajournal/pub/5164

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

The Commission services briefly informed the CA meeting about the main topics tabled for discussion at the 4th technical seminar. So far priority has been given to the reallocation of applications concerning i) active substances, both within and outside the review programme and ii) the renewal of PT 8 and PT 18 products for which the deadline for application for renewal falls in 2018. In that respect, it will be discussed at the meeting how to inform applicants about the shift to another eCA/refMS, action that should start as soon as possible after the meeting. The discussions on the transfer of on-going applications for UA or MR-P will follow in the upcoming meetings.

On a more general note, the Commission services thanked the UK for the feedback provided on the state of play of the evaluations for all the on-going applications. This information will be very helpful for the new eCAs/refMSs in terms of resource planning.

8. Requests for opinions
No item for information or discussion

9. Enforcement issues

9.1 Subgroup BPR Forum	For information	

ECHA informed the CA meeting about the items discussed in the March meeting.

9.2 Fact finding missions	For information	

This item was not discussed.

10. International Matters

OECD Working Group on Biocides	For information and discussion *CA-May18-Doc.10.1.a* *CA-May18-Doc.10.1.b*	

The Commission introduced the topic. No discussion took place.

11. AOB

A MS asked other CAs for any alternatives on their market for a specific anti-lice product.

11.1 List of Competent Authorities and other Contact Points	For information *CA-May18-Doc.11.1*	

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	-