EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL

Directorate E – Food and feed safety, innovation
E4 - Pesticides and Biocides

STANDING COMMITTEE ON BIOCIDAL PRODUCTS

MINUTES

58TH MEETING ON WEDNESDAY 30 MAY 2018, FROM 11:00 TO 16:30

Bulgaria was represented by Belgium, Croatia was represented by Slovenia, Cyprus was represented by Greece and Malta was represented by Italy. All other Member States were present.

1. Adoption of the Agenda

One Member State proposed an AOB item on the state of play of the decision-making process on formaldehyde for PT2 and 3, which was added. With this change the agenda was adopted.

The Chair informed that the draft acts had not been made available in all official languages because of the priority given at the translation services to the proposals concerning the multi-annual financial framework. Therefore the opinion of the Committee will be asked on the English version. Member States will have the opportunity to provide their comments on the other language versions as soon as the translations will be available.

2. Adoption of the Minutes of the 57th SCBP meeting

The minutes of the 57th SCBP meeting, on which no comments were brought forward by Member States, were adopted.

Section A – Draft(s) presented for an opinion

Section A.1 - Active substance approvals

3. Approval of Penflufen as an active substance for use in biocidal products of product-type 8

The Commission presented the proposal. After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

4. **Approval of Cypermethrin as an active substance for use in biocidal products of product-type 18**

The Commission presented the proposal. In particular, the Commission highlighted that the substance has been identified as a potential ED in the screening study conducted for the impact assessment accompanying the proposal for criteria to identify EDs, which had been performed in 2015-2016. The Commission noted that an assessment of endocrine disrupting properties of this substance is ongoing under the Plant Protection Products Regulation. Depending on the outcome, the Commission may decide to trigger an early review of this substance pursuant to Article 15 of the BPR. The eCA confirmed this situation, indicating their intention to submit it to ECHA's ED Expert Group in light of the preparation for the PT8 renewal process.

One Member State opposed the approval due to concerns on this substance as it had been identified as potential ED under the impact assessment, and noting that this substance is a Priority Substance under the Water Framework Directive (WFD) with a low Environmental Quality Standard. The Commission noted that only for Priority Hazardous Substance under the WFD emissions must be eliminated, which does not necessarily require a ban of the substances – no such obligation exists for Priority Substances. Member States can take appropriate actions at product authorisation. The evaluation performed for the screening in the context of the ED impact assessment was made following slightly different criteria than the final scientific ED criteria adopted for the BPR by Regulation (EU) 2017/2100. To date, there are therefore no sufficient grounds not to approve the substance for PT18, taking also into account that it is already approved for PT 8.

After a final examination of the proposal, the Committee gave a favourable opinion by qualified majority.

5. **Approval of Acetamiprid as an active substance for use in biocidal products of product-type 18**

The Commission presented the proposal.

One Member State explained that it has a horizontal approach to ban all neonicotinoids, and in consistency with its position in the PPP area, it cannot support the approval of this substance for PT18 in the biocides area. The Commission noted that the intended use in the biocides area does not lead to the same type of exposures as in the PPP area, as the use presented was for crack and crevices indoor or in perimeters of buildings. The safety of bees was considered by ECHA's BPC, which concluded that there are no unacceptable risks. Furthermore, in the PPP area, the approval had just been renewed for 15 years.

Another Member State noted that the development of guidance for the risk assessment to bees should be considered as a priority. The Commission noted that this could be included in the priority setting of ECHA for the development of technical guidance. The Commission further noted that an updated guidance on the risk assessment for bees had been developed by EFSA in the PPP area, but that guidance was blocked by several Member States who considered that it contained too high requirements.

After a final examination of the proposal, the Committee gave a favourable opinion by qualified majority.

6. **Approval of Cyphenothrin as an active substance for use in biocidal products of product-type 18**

The Commission presented the proposal. ECHA informed that the BPC opinion was not yet published on the ECHA website, as the participant had requested confidentiality for certain parts. Similar requests made in the past on another substance had been rejected. ECHA is currently studying this request.

After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

7. **Non-approval of Empenthrin as an active substance for use in biocidal products of product-type 18**

The Commission presented the proposal. After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

8. **Postponement of the expiry date of approval of sulfuryl fluoride for use in biocidal products of product-type 8**

The Commission presented the proposal, prepared along the agreement reached at the previous Standing Committee meeting.

One Member State expressed concerns about the contribution to global warming of this substance and mentioned that, inr consistency with its position in the PPP area, it will not support this proposal.

The Commission noted that it has the legal obligation extend the approval according to the BPR. Furthermore, as presented during the 62nd CA meeting of November 2015, following the reception of the ECHA opinion on the monitoring data provided, the contribution to global warming was small, around 0.03%, when compared to other anthropogenic emissions. It had been concluded then that the prospective applicant for renewal of approval would have to provide information on the risk mitigation measures to reduce emissions to the atmosphere. The extension of approval is made because the eCA is performing a full evaluation of the application for renewal.

After a final examination of the proposal, the Committee gave a favourable opinion by qualified majority.

Section A.2 - Article 36 decisions

9. **Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product containing deltamethrin referred by Sweden in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

The Commission briefly introduced the proposal and informed that, following the discussions at the meeting of the Committee in January and the identification of discrepancies between what different Member States understood by "technical" and "pure" active substance, the proposal now focused on the legal aspects raised by one

Member State regarding the interpretation of the definition of an active substance under the BPR and of a substance under the REACH Regulation. However, in order to further clarify this matter and ensure a common understanding of Member States at product authorisation, the Commission will propose a revised version of Q&A pair number 10 in document CA-May15-Doc.4.4 – Final.rev3 (Q&A on SPC content). The revised Q&A pair will take into account the previous contributions from some Member States and will be tabled for discussion in the meeting of the Coordination group (CG) in July for discussion and agreement, with a view to further update the CA document as soon as possible.

Member States agreed with such an approach and one Member States suggested that the CG could also consider whether the SPC editor should be amended in order to also allow the indication of the content in terms of "pure" active substance in the summary of the product characteristics (SPC).

The Commission also referred to some comments submitted by the applicant concerning the information on the content of the active substance to be indicated on the label of the products. However, since this aspect falls outside the scope of the proposal (i.e. how to indicate this in the SPC), the CG can discuss to what extent the comments can be addressed in the CA document.

After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

10. **Commission Implementing Decision on the terms and conditions of the authorisation of a biocidal product containing ethyl butylacetylaminopropionate (IR3535) referred by Belgium in accordance with Article 36 of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

The Commission briefly introduced the proposal by referring to the discussions at the meeting of the Committee in January. The Commission thanked those Member States having sent comments before the meeting. Some of those comments had been addressed in an updated version of the proposal that had been made available on CIRCABC before the meeting. The changes were also presented in the meeting and no Member States had any objections.

Some Member States suggested some drafting improvements in Recital 13 of the proposal, in order to further clarify to which guidance the proposal was referring to, as well as to indicate that the development of such guidance has already started. These were accepted.

Member States also raised some more general comments:

- While the scope of the proposal is limited to the 2 IR3535 products subject to the Article 36 procedure, the provisions therein should also apply to other already authorised insect repellents, in particular DEET containing products, for which the assessment carried out by the reference MS (refMS) had also been based on a discrepancy between the dose used in the efficacy studies and the (lower) application rate used in the exposure assessment. The Commission replied that since the BPC opinion clearly says that accepting 'the discrepancy' is not satisfying the conditions in

Article 19(1)(b) of the BPR, pursuant to Article 48(1)(a) of the BPR Member States shall cancel or amend any authorisation granted where they consider that the conditions referred to in Article 19 are not satisfied because of that reason. When amending the affected authorisations, the provisions in the proposal should be applied. The refMS indicated that there is no certainty about when other Member States would trigger Article 48 procedures. The Commission indicated that the CG could further monitor that element or even agree on a harmonised approach, as done in the past for anticoagulant rodenticides.

- There would be no need to apply for a major change as part of the post-authorisation condition and if so, this should also apply to other products (already authorised or on-going applications). The Commission indicated that an application for a major change according to Article 8 of Commission Implementing Regulation 354/2013 (i.e. submitted to the refMS and all the concerned MSs (cMSs) at the same time) is the best way to ensure that cMSs will agree with the conclusion of the assessment of the change made by the refMS (and if they would not agree, then the matter could be referred to the CG). In addition, the application for a change would allow Member States to charge a fee for the extra-work to be done. Regarding other authorised products, the same condition should be attached to the authorisations for all insect repellents through the Article 48 procedure, thus ensuring a level playing field for all companies. The same should happen with on-going applications that would lead to an authorisation, once the Commission Decision is adopted.

- The use of Article 19(5) might lead to a non-harmonised situation among Member States. The Commission recalled that Article 19(5) is not intended to ensure harmonisation between Member States but to address some particular needs of Member States (e.g. keeping sufficient availability of insect repellents for all user categories). The harmonised approach for products not meeting any of the conditions in Article 19(1) of the BPR would be a non-authorisation decision. The refMS indicated that the existing CA document on Article 19(5) and mutual recognition procedures could be improved in order to ensure that Member States do apply the provisions in Article 19(5) in a similar manner. This would also avoid a possible misuse of Article 19(5) without sufficient consideration on "why" a particular product is needed – which would be against the spirit of the BPR – or even its use to favour national companies. The Commission indicated that they trust that Member States will not do so – otherwise companies could complain at national or EU level about discrimination – and suggested that this more general discussion is handed over to the CA meeting in order to consider any amendment of the above-mentioned CA document.

A Member State suggested extending the deadline for the condition referred to in Article 3 of the proposal from 2 to 3 years, since it is likely that all applicants will be looking for testing facilities at the same time. Since some Member States opposed this suggestion the Chair proposed keeping the 2-year deadline.

Another Member State requested postponing the vote on this proposal, so that Member States would have more time to consider the consequences of this proposal for already authorised products. The Chair agreed postponing the vote to the meeting of the Committee in July at the very latest, since the 3-year deadline for the authorisation of IR3535 products is approaching soon (i.e. October 2018) and postponing the Decision would only increase uncertainty for applicants.

In order to support Member States, the Commission agreed to prepare a short paper on the consequences of the proposal for Member States pursuant to Article 48 of the BPR.

Section A.4 - Article 37 decisions

11. **Commission Implementing Decision on a derogation from mutual recognition of the authorisation of a biocidal product family containing creosote by France in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council**

The Commission briefly introduced the proposal by referring to the substitution aim in the BPR and in particular to the provisions in the second subparagraph of Article 37(1) of that Regulation. Therefore, the proposal considers that the derogation from mutual recognition proposed by France is justified on the grounds referred to in points (a) and (c) of Article 37(1) of the BPR.

One Member State informed the meeting that a "safeguard clause" procedure under REACH has been launched in order to further restrict the making available on its market of some wood treated with creosote. The Commission confirmed to be fully aware of the initiative under REACH and that it would be handled as foreseen in that Regulation.

After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

Section A. 5 – Union authorisations

The Commission underlined the fact that the Committee is asked to give opinions on the very first decisions to grant Union Authorisation (UA) for biocidal products and thanked all involved parties for the work done. The Commission had tried to ensure a good preparation for the meeting and all the relevant documents had been sent to Member States well in advance of the meeting (on 2 May) with 3 main objectives: i) check the content of the draft Implementing Regulations (IRs), so that it can be used from now on as a kind of "template"; ii) check that the SPC in its English version is in line with the SPC agreed by the BPC and sent to the Commission with the BPC opinion and iii) check the translations of the SPC provided by the applicant, since a number of Member States had not checked the translations at all.

In the course of these first procedures, a number of weak points had been identified and will need to be addressed in order to improve the efficiency of the process. Once they will be solved, the intention is that the opinion of the Standing Committee will be sought by written procedure in order to avoid any delays for companies to access the market between physical meetings of the Committee. Among the identified points, the following are the most relevant:

- The exchanges on the draft SPC (at eCA and BPC levels) should be based on the same format (i.e. xml). Once the final translations are available in all the linguistic versions, the xml format of the SPC will be converted into word format for the purpose of publication in the Official Journal.
- After the final BPC meeting, ECHA will have to check that the eCA has correctly implemented in the final draft SPC any amendments agreed at the BPC and that

there is no mistake. It is essential that any possible mistake is solved before the final draft SPC in English is sent to the applicant for the translations. Otherwise, identifying mistakes at a very late stage (e.g. at SC meeting) would lead to double work to amend the draft SPC both in word and xml in all the linguistic versions.

- The quality of translations is dependent on two key factors: i) the quality of the translations provided by applicants and ii) the check performed by Member States. A way forward on modalities to improve these two aspects will be tabled for discussion at the CA meeting in July.

The Commission also informed that a Member State had identified a number of discrepancies between the final draft SPCs in English sent to the Commission in the BPC opinions and the draft SPCs in English tabled for the BPC meeting where they were agreed. Therefore, after having checked those discrepancies with ECHA, the Commission had uploaded an updated version of the SPCs on CIRCABC on Friday, 25 May. These changes do not affect the recommendation in the ECHA opinions to grant UA for the four families.

The Commission further indicated that the translations of the IRs will only be available by the end of June because of the priority given by DG Translation to the legal acts related to the multiannual financial framework (MFF). Once the translations will be available, Member States will be given one week to check them. Therefore, the publication of the IRs in the Official journal should take place in July (but it could be delayed because of the length of the annexes to the IRs). In this respect, ECHA indicated that the BPC opinions will be made publicly available when the IRs granting the UA will be published.

The Commission proposed to discuss for each proposal first the draft IR and then the draft SPC.

12. **Union authorisation of the biocidal product family "Ecolab Iodine PT3 Family"**

The Commission briefly introduced the draft IR and referred to Recital 2, which includes a statement on the possible review of the active substance approval and if needed, of the UA decision, given that the active substance meets the criteria to be identified as an endocrine disruptor. A Member State indicated that the authorisation should be subject to compliance with the SPC, but also with the full composition indicated in the confidential Annex of the product assessment report. The Commission explained that referring to the full composition is not essential since the IR granting the UA should be read in association with Article 50 of the BPR and Commission implementing Regulation 354/2013. In other words, the authorisation holder can only change the composition of the product following an application for a change.

There was no comment on the content of the updated version of the draft SPC.

After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

13. **Union authorisation of the biocidal product family "HYPRED's iodine based products"**

The Commission briefly introduced the draft IR and referred to Recital 2, in which the name of the active substance included in the family had been corrected.

There was no comment either on the draft IR or on the content of the updated version of the draft SPC.

After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

14. **Union authorisation of the same biocidal product family "PRODHYNET's iodine based products"**

The Commission briefly introduced the draft IR and referred to Recital 2, in which the name of the active substance included in the family had been corrected.

There was no comment either on the draft IR or on the content of the updated version of the draft SPC.

After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

15. **Union authorisation of the same biocidal product family "QUAT-CHEM's iodine based products"**

The Commission briefly introduced the draft IR and referred to Recital 2, in which the name of the active substance included in the family had been corrected.

There was no comment either on the draft IR or on the content of the updated version of the draft SPC.

After a final examination of the proposal, the Committee gave a favourable opinion by unanimity.

Section A. 6 – Article 3(3) decisions

16. **Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a product containing permethrin used as a topical insecticide on livestock**

The Commission briefly introduced the proposal and referred to previous communications informing both Member States and the applicant about its content. The Commission services emphasised the main reasons that led to the new version of the proposal, which included: i) the contributions submitted by the law firm representing the applicant and the distributor of the product in one Member State, namely about the status of the product in another Member State; ii) the need to address the possible repellent effects of the product; iii) the need to ensure consistency with previous Commission Decisions (e.g. the non-approval of diazinon in 2010 and the horse rug decision in 2016) and iv) the request from a number of Member States to draw a clear borderline for this kind of products which is fully predictable for industry and easy to implement and to enforce by Member States, ensuring equal treatment of business operators. The proposal had been subject to a new public consultation under the so-called "feedback mechanism". The five contributions received had already been made available to Member States.

The Commission thanked those Member States having sent comments before the meeting and addressed some of those comments by amending some Recitals of the proposal during the meeting. The Chair indicated that this revised version would be made available on CIRCABC after the meeting.

The Chair then gave the floor to the applicant, who presented his views and points of disagreement with the proposal. The applicant also responded to some questions raised by Member States and the Commission.

Some Member States indicated that while sharing the conclusion of the proposal, they would prefer using the argument that the product is not a biocide because it is a veterinary medicinal product (VMP). The Commission clarified that Directive 2001/82/EC does not contain an empowerment for the Commission to adopt such a decision – this will only be possible once the forthcoming new Regulation on VMPs will be applicable (i.e. 3 years after its publication). Consequently, only the Member States in which the product is currently placed on the market or in which an application for authorisation under the BPR has been submitted, may decide if the product meets the definition of a VMP and as a consequence, that it no longer falls under the scope of the BPR. The Commission underlined that several Member States had already done so and that in the coordination group for VMPs (CMDv) a clear majority of Member States had considered the product in question to be a VMP. One Member State asked the Commission to include in Recital 3, or to note in the minutes, that the product was not available in its territory, but that if so, it would be classified as a VMP. Several Member States indicated the same position.

A Member State indicated that there is a very similar product under preparation for the mutual recognition phase in the context of mutual recognition in parallel (MR-P), for which the proposal would also be relevant.

A few Member State did not support the proposal since the new reasoning could have some unintended side-effects for other products (e.g. what is not explicitly mentioned in the product-type description would fall out of the scope of the BPR) – in their view the descriptions in the product types were only indicative and not exhaustive. The Commission responded that the description of product types is indeed indicative, within the meaning that it cannot list any possible intended use in real products. However, when it comes to the use of biocidal products on the skin of humans or animals, the analysis of the product-type descriptions in Annex V provides clear indications about which product-types are explicitly allowed to be used on the skin. This interpretation would allow Member States to have a clear borderline which is not dependent on the claims and target organisms, and therefore ensures an equal treatment of applicants.

Some Member States indicated that the borderline should be mainly based on the claims and be subject to enforcement. The Commission indicated that enforcement actions would only take place a posteriori. The Commission also recalled that the applicant had significantly modified the claims for the product, reducing in particular the indicated target organisms – this could be done by others as well with the intention to get a (lighter) authorisation as biocidal products, while in reality intending to have the product used as VMP by the users. Enforcement authorities would only realise that such a product is used (illegally) as a VMP once Member States have invested significant efforts and resources in the authorisation and enforcement procedures. This would not be best use of the scarce available resources.

A Member State suggested that the borderline issues should be handled through guidance documents. The Commission indicated that since these are not legally binding, they

would not prevent a non-harmonised situation among the Member States. Conversely, a legally binding decision would have a clearer harmonising effect, again ensuring equal treatment of applicants in all Member States. This would also mean that some Member States would have to change their current practice during the transitional period.

The Chair suggested postponing the vote to the meeting of the Committee in July and invited Member States to send any further comments in writing that could improve the proposal by 15 June.

Section B – Items presented for discussion and/or information

Section B.1 - Active substance approvals

17. **Applicability of the conditions of derogation to exclusion set in Article 5(2) for Cholecalciferol for use in biocidal products of product-type 14** (*SCBP57-Doc.17.1*)

The Commission presented its preliminary analysis of the conditions for derogation to exclusion for this substance and asked for the views of Member States.

All Member States supported this analysis, expect one. The latter considered that this substance is an endocrine disrupter, thus meeting the exclusion criteria, and that the conditions for derogations are not met because there are already alternatives on the market. The Commission noted that cholecalciferol corresponds to Vitamin D, which is made available on the market as food supplement, that the main alternatives currently on the market are anticoagulant rodenticides which also meet the exclusion criteria and present overall higher concerns for human health and the environment. The approvals of these anticoagulant rodenticides had recently been renewed, as the Standing Committee had supported that at least one of the conditions for derogation was met for these substances.

Based on this discussion, the Commission will prepare a draft proposal for discussion at a subsequent meeting of the Committee.

Section B.2 - Article 3(3) decisions

18. **Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on pepper containing sprays to be used in case of attacks by aggressive dogs** (*SCBP57-Doc.18.1*)

The Commission briefly updated on the state of play of the proposal. It was still subject to the so called "feedback-mechanism" and TBT notification mechanism (60 days commenting period starting on 29 May 2018). Therefore, the Committee could only be asked for an opinion at the meeting in September. As indicated in a previous meeting, the proposal would conclude that this kind of products would fall under the scope of the BPR.

Several Member States indicated again that these products are considered as falling under their national "personal defence rules". They would be very concerned about the new regulatory situation for these products and might vote against the proposal. Upon request

from Member States, the Commission services clarified that if the decision was adopted, products for repelling "aggressive" humans would also fall under the scope of the BPR.

The Chair invited the Member State having triggered the Article 3(3) request to consider whether the request could be withdrawn and inform the Commission well in advance of the meeting in September.

19. **Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on Wolbachia trans-infected mosquitos used for vector control purposes** (*SCBP57-Doc.19.1*)

The Commission briefly updated on the state of play of the proposal. It was still subject to the so called "feedback-mechanism" and TBT notification mechanism (60 days commenting period starting on 29 May 2018). Therefore, the Committee could only be asked for an opinion at the meeting in September.

The Commission informed that the Member State having triggered the Article 3(3) request had submitted very detailed comments using very technical and scientific concepts that are not essential for taking the decision. These comments would be made available to all Member States on Circabc after the meeting.

A Member State suggested amending in Article 1 the reference to "experimentally" infected mosquitoes to "intentionally" or "non-naturally" infected mosquitoes. The Chair agreed with the proposed amendment and invited Member States to send any written comments that could improve the proposal by 15 June.

20. **Any Other Business**

Upon request from one Member State, the Commission gave an update on the progress of the decision-making process on the approval of the active substance formaldehyde for use in product-types 2 and 3. The Commission pointed out that the new criteria for determining endocrine-disrupting properties had become applicable and therefore ECHA had been requested to update the BPC opinion in order to include an assessment of whether formaldehyde can be considered to have or not to have ED properties.