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

MINUTES

80th 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

27-28 September 2018

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1. Adoption of the agenda	For adoption *CA-Sept18-Doc.1*	

The chair informed the meeting that agenda item 4.8 had been removed since the discussion in the Coordination Group (CG) had not concluded yet. The agenda was adopted with the addition of two AOB items, regarding (i) the detection of DMS (dimethylsulfamid) in drinking water in Denmark and (ii) concerns related to an invalid study on one active substance.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Sept18-Doc.2*	

The draft minutes of the 79th CA meeting were adopted.

3. Draft delegated acts		
3.1. Amendment of the Review Programme Regulation in connection with in-situ redefinitions and food and feed notifications	For discussion *CA-Sept18-Doc.3.1.a* *CA-Sept18-Doc.3.1.b*	

The Commission services presented their revised draft proposal for an update of Annex II of the Regulation (EU) No 1062/2014, which lists the active substances in the review programme. The draft delegated regulation has been published for public consultation under the feedback mechanism in June, and the comment received was taken into account.

One Member States enquired about the situation of chlorine dioxide for which it is needed to clarify whether several specific entries listed in the draft Annex could in fact be covered by the generic entry "chlorine dioxide generated from sodium chlorite by acidification" also listed in the Annex. The Commission services noted that this topic is under discussion with ECHA. However, for now, the Annex can remain as proposed as the generation in situ using the concerned precursors is legally possible.

Following the suggestion of a Member State, it was agreed to remove acetamiprid, empenthrin and cypermethrin from the Annex, as decisions related to these substances were recently published.

Switzerland indicated that they have been contacted by the participant for Orange extract and that they could agree to be the evaluating CA for this substance. France, as the currently proposed evaluating CA, agreed and the Annex will be modified to reflect this change.

Two Member States regretted that some of the proposed entries for food and feed active substance were not more general. For instance, the entry for "concentrated apple juice" could have covered more generally "fruit juices". The Commission noted the comment but remarked that these were the substances notified and which were discussed by ECHA's BPC and included in its opinion. This is the base on which the Commission can rely to include substances in the review programme. The Commission services reminded that Member States

can prepare and submit application to requests for Annex I of the Biocidal Products Regulation inclusion for any active substance which they believe could be listed in Annex I, in particular for food or feed active substances or other substances traditionally used for biocidal purposes. These Member States were encouraged to do so. One Member State further noted that these food and feed active substances were listed for PT19, although proposals discussed under item 3.3 of the agenda concerning Annex I amendments are not restricted to any PT. The Commission services clarified that the substances have to be included in the review programme for PT19 as the notification process was made only for this PT. The absence of limitation for specific PTs for the Annex I inclusion of eligible substances is part of the proposals which will be discussed under item 3.3 and 5.3 of the agenda of this meeting.

The expert group agreed with the draft delegated regulation with the amendments agreed during the meeting. The adoption by the Commission of the delegated act may take place in October/November 2018, and the draft delegated regulation will be forwarded to Council and the EU Parliament for scrutiny (2 months + 2 months in case of request for extension). If no objection is made the draft regulation will be published in the Official Journal.

3.2. Amendment of the Review Programme Regulation in connection with UK withdrawal pursuant to Article 50 of TFEU	For discussion *CA-Sept18-Doc.3.2.a* *CA-Sept18-Doc.3.2.b*	

The Commission services presented their revised draft proposal for a delegated act in order to amend Regulation (EU) No 1062/2014.

Following the last discussion in the CA meeting, editorial modifications were made, and the views of the expert group was taken into account in order to i) keep a flexible timing for the payment of the fees by concerned participants where requested by eCAs, and ii) set up the deadline for the submission of assessment reports to ECHA. The draft delegated regulation has been published for public consultation under the feedback mechanism until 12 October. The Commission services indicated that they will ensure full consistency on the substances listed between the Annex of the update to the review regulation discussed under item 3.1 of the agenda, and the present amendment, as some editorial modifications still needed to be made.

The expert group agreed with the draft proposal. The Commission services therefore concluded that, except if substantial comments are submitted during the feedback mechanism, this version with the editorial modifications previously mentioned will be the version proposed for adoption by the Commission. The adoption will take place after the adoption of the delegated regulation discussed under item 3.1 on the agenda, in October/November 2018, and the draft delegated regulation will be forwarded to Council and the EU Parliament for scrutiny (2 months + 2 months in case of request for extension), so that the measures are applicable by the date of the withdrawal of the UK from the EU on 30 March 2019.

3.3. Draft proposals including certain food and feed active substances into Annex I to the BPR	For discussion *CA-Sept18-Doc.3.3a* *CA-Sept18-Doc.3.3b* *CA-Sept18-Doc.3.3c* *CA-Sept18-Doc.3.3d* *CA-Sept18-Doc.3.3e* *CA-Sept18-Doc.3.3f* *CA-Sept18-Doc.3.3g*	

The Commission services presented their proposals for delegated acts including certain food and feed active substances into Annex I to the BPR, following the positive opinions from ECHA and the previous discussions in the CA meeting. In particular, the Commission services noted that these proposals are preliminary and still subject to internal discussions and some modifications still need to be made, for instance to include a condition that the inclusion only covers the substances that can meet the definition of a food or a feed according to the general food law. This is for instance particularly relevant for honey, as not all types of honey can qualify as food and some of them can have hazardous properties. The Commission services also pointed the attention to the draft recital 7 and the Article 2, which make reference to Article 89(3) of the BPR and aim at ensuring that products currently on the market under national rules becomes subject to the BPR authorisation scheme with a deadline for the submission of the applications for product authorisation.

To answer to one Member State, the Commission clarified that recital 7 was a copy-paste from the Article 89(3) of the BPR, and emphasised that the reference to possible mutual recognition was correct as products containing these active substances can either be authorised via the normal authorisation procedures (national, mutual recognition, or Union authorisation) or the simplified authorisation procedure, depending whether the conditions are met.

The expert group was invited to send comments to the Commission services by 19 October 2018.

4. Biocidal products

4.1. Report from Coordination Group	For information	

The Commission services reported on some issues discussed at the 31st meeting of the Coordination Group (CG) that took place on the two previous days, together with the sixth meeting of the CG working party on the biocidal product family (BPF) concept.

In terms of MR disagreements, CG members were able to find a consensus agreement in those cases for which a decision had to be taken at the meeting. On a more general note, the Commission services thanked MSs for making every effort to find a solution to the referrals.

The CG working party (WP) on the BPF concept is making progress not only in terms of addressing the similarity of uses but also similarity of composition and similar of levels of risk and efficacy. The WP will have its last meeting in November in order to agree on some recommendations to the CG. The CG will then consider those recommendations and forward

them to the Commission in order to update the current CA document on the implementation of the BPF concept.
The CG agreed on a document on the applicability of entries in the Technical Agreements for Biocides (TABs). The Commission, as an observer in the CG, has the duty to ensure communication and consistency with the CA meeting. As a consequence, it proposed that such document is tabled for discussion in the November CA meeting since there could be some conflicting aspects with document CA-July12-Doc.6.2.d – Final (relevance of new guidance).

For further information, the Commission services referred the meeting to the list of conclusions and actions arising from the CG-31 meeting, which would be made available on the dedicated CG CIRCABC interest group.

4.2. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-Sept18-Doc.4.2*	

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

4.3. Executive report on product authorisations	For information *CA-Sept18-Doc.4.3*	

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

4.4. Union authorisation		

(a) Executive report on applications for UA	For information *CA-Sept18-Doc.4.4.a-1* *CA-Sept18-Doc.4.4.a-2*	

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

4.5. Use of same trade name in products of different product-types	For discussion *CA-Sept18-Doc.4.5.a* *CA-Sept18-Doc.4.5.b*	

The Commission services introduced this topic with the support of a presentation (*post-meeting note: the presentation has been uploaded on Circabc as document CA-Sept18-Doc.4.5 – slides*). The main elements raised by MSs and stakeholder observers during the discussion were the following:

- Most of the MSs having taken the floor indicated that they use to check duplications in trade names (under the transitional period, where relevant, and under the BPR procedures), inviting companies to change the names. A MS particularly referred to some difficult experiences with trade names and BPF applications.

- A few MSs indicated that they would be in favour of allowing the same trade name for products being used by professional users, where the risk of confusion would be minimised. A MS pointed out that the risk of confusion is less if the products concerned are used in different branches.
- Some MSs and one Accredited Stakeholder Organisation (ASO) indicated that for generic names, adding a suffix with the name of the company could be a way forward.
- A MS indicated that the discussion under the BPR provisions are without prejudice of more specific legislation on proprietary trademarks.
- A MS indicated that in addition to the possible risk of confusion for users, the same trade name might create confusion to poison control centres and even lead to an inappropriate treatment.
- A MS indicated that Article 30 of the BPR does not provide a legal base to reject the application.
- A MS indicated that notwithstanding enforcement inspectors can rely on other pieces of information (i.e. authorisation number) to identify a product, we should make their life as easy as possible by avoiding the same trade names for different products.
- An ASO indicated that specificities of in situ biocidal products should be considered in this debate.
- A MS underlined that, contrary to the changes Regulation, the BPR does not include any explicit provision in Articles 29 or 30 allowing CAs to reject an application due to a possible conflict on the proposed trade names.

The Chair invited MSs and ASOs to submit written comments on this matter by 19 October 2018 via the dedicated CIRCABC newsgroup. When preparing those comments, the following aspects should be addressed:

- How do MSs assess at national level the possible risk of confusion between the trade names of two different biocidal products? (i.e. which criteria are used);
- Whether MSs do check any duplication of trade names or any this possible risk of confusion between trade names at national or at EU level.
- In case of duplication or risk of confusion, how do MSs decide which of the two trade names was first (i.e. only considering BPR procedures or also products placed on the market according to the national systems).
- For an ASO, to confirm if the number of products having the same trade names refers to BPR authorisations or to the transitional period regimes.

4.6. Article 48 application (ensuring a level playing field with regard to generation of efficacy data for insect repellents)	For discussion *CA- Sept18-Doc.4.6*	**Closed session** **Open session**

The Commission informed ASOs of the discussion that took place in the closed session. Following an Article 36 Commission decision on a mutual recognition disagreement concerning the assessment of insect repellents, it had been concluded that accepting a discrepancy between the dose used in the efficacy studies and the (lower) application rate used in the exposure assessment is no longer satisfying the conditions in Article 19(1)(b) of

the BPR. Pursuant to Article 48(1)(a) of the BPR, MSs would have to cancel or amend any authorisation granted where they consider that the conditions referred to in Article 19 are not satisfied for this reason.

The Commission services will prepare a document for discussion at the next CA meeting in order to agree on a harmonised approach for the practical implementation of Article 48 to the affected insect repellents, as it was done in the case of anticoagulant rodenticides that were not subject to a renewal procedure and so subject to Article 48 procedure.

4.7. Management of product authorisations for in situ cases	For discussion *CA- Sept18-Doc.4.7*	

The Commission services introduced the topic by explaining the significant revision of the note on in situ, particularly addressing the comments expressed by ECHA and several Member States on the previous versions. Therefore, the current version focus on the regulatory aspects while it is the intention that complementary technical guidance on data requirements for in situ generation systems (IGS) authorisation will be provided by ECHA.

It was generally recognised that the approach for product authorisation of IGS should be able to address as much as possible all existing and future systems. The work already done at the approval stage should be taken duly into account at the authorisation stage. In this regard, access to data provided for the approval stage should optimised. Applicants should also benefit from the BPF concept whereby similar IGSs could be grouped under a biocidal product family. This should contribute to the reduction in the burden compared to individual IGS authorisations.

Four Member States thanked the Commission for the readability of the new version. Most of them informed that they were still consulting their experts and would submit written comments.
One Member State asked to clarify the wording of paragraph 6(b) and the sentence in paragraph 7, where it is explained that an authorisation could be granted to a 'system'. That Member State also pointed out the difficulties to reach all possible end-users in case of orphan devices.
The Commission clarified that the note describes the authorisation of a biocidal product and for in situ generation it is proposed that IGS should be included in the authorisation . This will be further clarified in the next version of the document

Aqua Europe welcomed the new version but underlined that some points remain unclear, for example what is an in situ system and a biocidal product in relation to in situ generation. Written comments will be provided and industry would appreciate to have a face-to-face meeting . Industry/ ASOs stressed the importance of reaching an agreement as soon as possible as many applications for product authorisation of IGSs are in preparation.

The Chair noted the general support to the revised document focussing on policy and regulatory issues and underlined the need to progress on this agenda item. The meeting was invited to provide comments by 19th of October via the dedicated CIRCABC newsgroup.

4.8. Updated Q&A on how to express the content of the active substance in the SPC	For discussion and agreement *CA- Sept18-Doc.4.8*	

This agenda item was withdrawn since the discussions in the CG had not concluded yet.

5. Active substances		
5.1. Progression of the review programme on active substances	For information *CA-Sept18-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. The Commission services noted that only one assessment report has been submitted to ECHA the past 12 months. Progress must also be made on backlog reports which were submitted by Member before 1st September 2013 and for which no opinion has been yet delivered by ECHA's BPC.

One Member State noted that there were discussions the previous week at the BPC Human Health Working Group on the ED assessment of 3 active substances (two eCAs), where it was concluded that the ED submitted assessments were not sufficient. The same Member State also noted that the ED expert group were due to discuss at their October meeting a paper on how to address Environmental ED assessments for biocides. This Member State expressed concerns on possible delays.

The status report was noted by the CA meeting.

5.2. Progression of the renewal process of approval of active substances	For information *CA-Sept18-Doc.5.2*	

The Commission services presented the update of the overview of on-going and future renewals, and highlighted that this summer the expected application for renewal of etofenprox PT18 has been submitted, but the no application has been submitted for clothianidin PT08. They also informed that ECHA has now published information on the renewal process, the deadlines for submission of applications, as well as the name of the evaluating CA for the substances.

The status report was noted by the CA meeting.

5.3. Management of Annex I	For discussion and agreement *CA-Sept18-Doc.5.3*	

The Commission services presented a proposal for an update of the current approach concerning the management of Annex I to the BPR. The document attempts to provide a proposal on various questions or issues which emerged in the recent years, with the view to encouraging the development of products containing active substances which do not give rise to concern and having better toxicological and ecotoxicological profiles than non-Annex I substances. A few Member States could support the proposals in the document, but most Member States needed to further reflect on the various issues and aspects linked to them, and

could only provide preliminary views. Each of the specific section were explained by the Commission services, and the discussions was arranged section by section.

As regards in situ generation, several Member States supported the proposal in consistency with the approach followed in the review programme and the approvals. One Member State proposed to consider that the entries would cover already all in situ generation methods and precursors without any specific indication, but with the conditions that the precursors themselves do not give rise to concerns in accordance with Article 28(2) of the BPR.
Two Member States noted a case of nitrogen being generated in situ, and not having authorisations today. One Member States indicated that it may send further comments in writing on nitrogen.

As regards the relation to product-types for active substance currently listed category 6 of Annex I, two Member States indicated to support the proposal. Two other Member States indicated their need to reflect.

As regards to the management of substances currently listed in category 6 of Annex I when their side approval expires, similarly, two Member States indicated to support the proposal and more specifically the option 1 where no specific condition would be indicated. Two other Member States indicated their need to reflect, in particular on whether it is appropriate to have these substances included with no conditions anymore, although some of their uses require proper training. Carbon dioxide for use for PT15 and PT18, and nitrogen for PT18 were for instance restricted for use by professionals in the current approvals. One Member State also questioned what could happen in case new information becomes available showing that the active substance gives rise to concern and should not be listed anymore : on the matter, the Commission clarified that it is empowered by the BPR to remove the entry in Annex I, and it would be consequently needed to consider whether to have a normal approval instead.

As regards to the substances for which the BPC has identified that the substances could be eligible for inclusion into Annex I in its opinions, three Member States indicated their support for option to including them in Annex I already now. One Member State supported inclusion in Annex I if the participant make the request. On this aspect, the Commission services clarified that the empowerment of given by the BPR allows an inclusion in Annex I even in absence of agreement of the original participant, as original participants are not "owners" of an inclusion in Annex I (or normal approvals). An inclusion into category 6 of Annex I also allows the level playing field of active substance suppliers, as the provision of Article 95 of Annex I apply to this category. Member States should therefore reflect on the policy objectives of the BPR which are to facilitate the access to market for these kind of substances and low concern biocidal products.

Lastly, one Member State brought another issue for substances currently listed in the other categories than category 6, for which companies would like to apply for normal product authorisation routes (national, mutual recognition or Union authorisation). For these substances, no data package was actually reviewed by authorities, which can complicate the product authorisation stage as the Annex II data package is needed according to Article 20 of the BPR. The Commission services mentioned that it was indeed a clear consequence of the modification made in 2014 by Council and EU Parliament to the BPR to allow substances listed in Annex I in products to be authorised via the normal authorisation routes. The BPR makes indeed clear that an Annex II data package has to be submitted for normal product authorisations, and the Commission services noted that companies should discuss with the future evaluating CA of for their future application the appropriate level of data needed using as much as possible the possibilities of adaptation of data requirements mentioned in Annex

IV to the BPR. A certain level of pragmatism and expert judgement would also be needed, for instance for future products that would contain the food and feed active substances discussed under item 3.3 of the agenda.

The expert group was invited to send comments to the Commission services by 19 October 2018.

6. Treated articles
No item for information or discussion

7. Horizontal matters

7.1. ECHA communications	For information	

ECHA gave a presentation focusing on (i) the necessary preparations for dissemination and (ii) the results of a survey to identify the reasons behind the review programme slow down. On the first topic ECHA reminded the need for CAs to assess correctly the confidentiality claims. One Member State asked whether there are guidelines on the assessment of confidentiality claims, for example some applicants consider pack size as confidential information. ECHA indicated that it aims at providing guidance and that the first step is indicating what should not be considered confidential. ECHA's view is that pack size is not confidential information. In response to a question on whether in the context of the Access to data regulation the Product Assessment Report should be considered a third party document as the Member State produces this document, ECHA confirmed that the PAR is indeed a third party document. The meeting was informed that during the Biocides Stakeholders' Day on 24 October a preview of the dissemination website will be presented. One ASO referred to the presentation in which it indicated that ECHA will take action. ECHA clarified that it will provide training to Member States and ad hoc support on ED assessment of substances.

7.2. ECHA guidance		

(a) State of play ECHA guidance (on-going consultation, finalised guidance)	For information	

A short update on the latest development concerning guidance was provided.

(b) Priority setting for developing ECHA guidance	For discussion	

ECHA explained the current process applied to priority setting and the intention to refine it with the consultant group. ECHA stressed that missing guidance appears not to be a key issue for the evaluation process of active substance dossiers.

One Member State reiterated its request to give priority to develop guidance on efficacy of insect repellent and stressed the urgency to develop this guidance. This participant suggested that it would be beneficial to have a joint meeting of the Working Groups on Efficacy and Human Health with a view to discussing the issue of this missing guidance.

The Chair concluded that following the outstanding points the agenda item will be rescheduled for the next meeting.

(c) Technical equivalence assessment and Good Laboratory Practice	For discussion *CA-Sept18-Doc.7.2.c*	

FECC introduced the document of this organisation, that was also uploaded on CIRCABC, on technical equivalence assessment and Good Laboratory Practice requirements. The stakeholder stressed that the requirement in guidance that technical equivalence tests has to be carried out under GLP is not in line with the BPR. One participant indicated that GLP testing is not necessary for technical equivalence assessment if it was performed by international standards. The expert group was invited to send comments to the Commission services by 19 October 2018.

7.3. Presentation on the Information Platform for Chemical Monitoring (IPCHEM)	For information	

This agenda item was not discussed as the relevant colleagues were not available.

7.4. Towards the substitution of hazardous active substances in biocidal products	For discussion and agreement *CA-Sept18-Doc.7.4*	

The Commission presented a version of a note on substitution that was discussed in earlier meetings. The note includes all recent inputs received from Member States and ASOs.

The Commission recalled the importance of the topic and invited all stakeholders to initiate or participate in upcoming workshops on alternatives to hazardous biocidal products. The Commission will make use of the outcomes of the note to establish its priorities for research and development on biocides. Stakeholders will be kept informed of any development in this regard and should be ready to respond to call for tenders on biocide topics under H2020 and the future Horizon Europe framework programme.

One Member State asked for more information on the upcoming workshops. The organising Member States replied that information is available on CIRCABC but promised to share the information again via email. All workshops are open to ASOs unless otherwise indicated.
AISE and CEPE reported being on track to organise a dedicated workshop on in-can preservatives. The Commission recalled the importance of a collaborative approach between industry, administration and NGOs in the area of substitution of biocides.

One Member State proposed the inclusion of PT 22 products as a priority for substitution. The Commission suggested to clarify the issue with PT 22 products and to revise the note in due time if needed.

One Member State stressed the importance of PT 18 products in the effective control of insects. This is a major public health issue in Southern European countries that should be tackled in future EU research programme as there is currently a lack of PT 18 products on the market. Another Member State referred to need for innovation for in can-preservatives.

Following the discussion the document was agreed by the CA meeting.

7.5. Endocrine disruptors		

(a) The implementation of scientific criteria for the determination of ED properties for approved biocidal active substances	For discussion and agreement *CA-Sept18-Doc7.5.a*	

The Commission services introduced the revised CA document by a presentation and pointed out that the results of the screening study, performed during the impact assessment accompanying the draft ED acts, provides a basis to initiate an early review of approved active substances. The Commission services also indicated that the BPR does not provide a clear legal basis for competent authorities to ask fees to cover the costs of their activities in the context of an early review. Two Member States stressed that an early review should take place of active substances identified as possible endocrine disruptors in other options (option 3 categories II and III) in the screening study performed during the impact assessment accompanying the draft ED acts. This could occur by a multi-annual working programme and prioritising certain substances. According to one of those two Member States the legal basis in the BPR for an early review does not prevent this. One Member State indicated that it is proposed to have an early review of iodine and PVP iodine and considered that these substances do not pose a real risk and it would be better to focus resources on other urgent issues. This Member State also pointed out some errors in the Annex of the documents. This view on iodine was echoed by another Member State , which questioned the added value of early reviewing iodine. This Member State pointed out that in paragraph 18 of the document it is proposed that a dossier should be submitted within 24 months of the Commission regulation. According to this participant 24 months may not be sufficient to generate the relevant data for determining ED properties. The Commission services pointed out that Article 15 of the BPR requires that significant indications exist for the active substance that the approval conditions in the BPR are no longer met. Only option 2 and option 3 category I in the screening study, according to the Commission services, match the established ED criteria and, therefore, only for the substances identified as possible endocrine disruptors under these options significant indications exist. The Commission services pointed out, as explained in the document, that Member States can ask the Commission to initiate an early review under certain conditions. In relation to iodine and PVP iodine it was indicated that the Delegated Regulation (EU) 2017/2100 specifies the criteria to identify ED properties and it does not include a provision to exclude substances like iodine. The meeting discussed whether the time period in paragraph 18 needs to be amended and agreed to amend the drafting to 'should normally be submitted within 24 months' as this would allow to have a longer period if it could be justified.

The document was agreed by the CA meeting with the amendments in paragraph 18 and addressing the errors in the Annex. The representative of the competent authority for the implementation of the BPR in France could not support the document.

7.6. Update of Annexes to BPR	For discussion *CA-Sept18-Doc.7.6_Annexes* *CA-Sept18-Doc.7.6_Annexes_HHD*	

The Commission briefly introduced the document prepared for the meeting. The main objective of the update of the Annexes is to address the entry into force of the endocrine disruptor criteria by including clear data requirements on EDs in the technical annexes. This opportunity can be used to address recent technical or scientific progress in other areas. ECHA suggested for example amendments leading to the reduction of animal testing or a better protection of human and animal health. A specific document on historical human data was developed so that the participants of the CA-meeting had an overview on how this issue is addressed in other legislation.

Two Member State said that comments on the tox/ecotox sections of the proposal will be sent in writing. One of the two Member States asked whether the Working Group of BPC has been consulted. The Commission will verify with the chairman of the BPC this specific question.

The same Member State asked why modifications to the endpoints on micro-organisms are proposed when there is no intention to modify similar provisions under the Plant Protection Products Regulation (PPPR). The Commission replied that the SANTE PPP team was consulted and confirmed that no major modification to the current endpoints for micro-organisms may be expected on the short term under the PPPR. However, the modifications proposed for the BPR annexes consist mainly in clarifying the existing endpoints and make them more relevant for micro-organisms. There is no intention to modify fundamentally the information requirements for micro-organisms.

Three Member States expressed reluctance to open the topic on historical human data indicating that the BPR provisions were copied from the PPPR. One Member State recalled basic policy principles:

- deliberate human exposure is prohibited for the purposes of the BPR,
- the use of all available data (in particular human data listed in point 1.1.3 of Annex IV) lawfully generated can be considered
- but the use of human data cannot override the results of animal studies to reduce the safety margins

Therefore it was suggested by this Member State that historical human data is used only to give positive evidence of hazard/harm not otherwise apparent, rather than to demonstrate absence of hazard/harm which is indicated from animal testing. Cefic (EBPF) will provide comments in writing but would be in favour of using human data when ethically conducted and underlined that the use of human data should not be regarded as the means to reduce the safety margins, but rather to refine the exposure assessment.

ECHA argued that the objective of the current provision is not explicitly stated pointed out that from a scientific point of view human studies showing toxicological effects are more

relevant than animal studies. ECHA stressed that the link with the PPPR is not fully clear in this regard as PPPs are clearly not intended to be applied on humans.
The deadline for commenting through the dedicated CIRCABC newsgroup was fixed to 19 October 2018.

7.7. 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 sixth technical seminar, i.e. the transfer of UK to other CA for ongoing applications for Union authorisation and mutual recognition in parallel. The Commission services and ECHA will inform the affected applicants via R4BP of any further developments.

On a more general note, the Commission services reminded ASOs that authorisation holders (AHs) have to be established in the EU. According to ECHA more than 600 assets in R4BP still belong to AHs established in the UK. Therefore, the involved companies should handle the relevant administrative changes (which require prior notification) in due time, so that the proposed changes are accepted by the relevant CAs before the withdrawal date.

7.8. MRLs – setting of reference values for intra EU trade for DEET and icaridin	For information	

The Commission services informed that reference values have been set for DEET and icaridin for various commodities in order to facilitate trade.

7.9. Research use only products	For information	**Closed session**

A discussion took place in closed session.

7.10. Outstanding Helpex questions	For discussion *CA-Sept18-Doc.7.10*	**Closed session**

A discussion took place in closed session.

8. Requests for opinions
No item for information or discussion

9. Enforcement issues

9.1 Conference on REACH, CLP and Biocides Enforcement - 13 November 2018	For information *CA-Sept18-Doc.9.1*	

The Commission services informed the meeting about the forthcoming enforcement conference of chemical legislations, that will take place back to back with the 6th meeting of the BPR subgroup of the Forum.

9.2 Fact finding missions	For information	

The Commission services informed the meeting that the first reports of the fact finding missions have been published. These reports are available on DG SANTE's website at:

- Spain: http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4001
- Germany: http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3976
- Hungary: http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4006
- Belgium: http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4030
- Netherlands: http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4047

The Commission services also indicated that Directorate F is working on an overview report summarising the main findings from a wider perspective.

10. International Matters

10.1 Process for inclusion of cybutryne into the AFS convention at IMO level	For information	

The Commission services that the process for inclusion of cybutryne into the AFS convention at IMO level is making progress. Since the last presentation on the matter in the CA meeting, work has been done by Commission, ECHA and EMSA in order to prepare the relevant documents for the IMO. The Commission services invited Member States Biocides Competent Authorities to liaise with their colleagues following IMO matters, as these documents will soon by under discussion in a Council Shipping Working Party.

11. AOB

(a) List of Competent Authorities and other Contact Points	For information *CA-Sept18-Doc.11.a*	

(b) Detection of DMS (dimethylsulfamid) in drinking water in Denmark		

Denmark informed the meeting that the compound DMS (dimethylsulfamid) has recently been detected in some drinking water supplies in Denmark. If ozonated, this metabolite may turn into N-nitrosodimethylamine (NDMA) which is genotoxic, mutagenic and carcinogenic. DMS may originate from the active substances tolylfluanid and dichlofluanid. Both active substances are approved in PT8 and PT21, and tolylfluanid is also approved in PT7 and both substances have also been used in plant protection products. According to investigations performed by a Danish water company, a significant source of contamination seems to be the

wooden houses painted with biocide-containing paint. The final data still have to be transmitted to and analysed by the Danish authorities. In order to get an overview of how widespread DMS contamination of the groundwater is, a screening has been initiated and the results are expected within the first six months of 2019. Denmark will present updates on this matter at a later stage.

(c) Concerns related to invalid study on one active substance		

A discussion took place in closed session.

Next meetings:

2018

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	27-28 September	-	-	IV: 4-14/09
-	-	12 November	15-19 October	-
19-21 November	22-23 November	-	-	V:?
-	-	-	10-14 December	-

2019 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
-	-	-	25 Feb-1 March	
12-13 March	13-15 March	21-22 March	-	
-	-	-	8-12 April	
14-15 May	15-17 May	-	-	
-	-	20-21 June	24-28 June	
3 July	4-5 July	-	-	
-	-	-	-	
17-18 September	18-20 September	-	-	
-	-	-	7-11 Oct	
19-20 November	20-22 November	7-8 November	-	
-	-	-	9-13 Dec	