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

MINUTES

86th 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

21-22 November 2019

1. Adoption of the agenda	For adoption *CA-Nov19-Doc.1.rev1*	

The agenda was adopted and the timing foreseen for the various items on the agenda was indicated by the Chair.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Nov19-Doc.2*	

The minutes of the previous CA meeting were adopted.

3. Draft delegated acts
No item for information or discussion

4. Biocidal products

4.1. Use of trivial name of the active substance on the product label	For discussion	

The Commission services introduced the topic, indicating that there is a need to reflect on the mechanism for the possible inclusion of the trivial name on the label in certain circumstances. CEFIC expressed their support for the idea, mentioning that appropriate information is needed in specific cases, especially for products intended for non-professional users. AISE was of the opinion that only one name should appear on the label, that is the systematic name, and expressed concerns related to making the indication on the label of both names mandatory. One Member State suggested that the trivial name could be included in the approval (or renewal) regulation.

The Commission services noticed that the majority of Member States seem to see the advantage of using the trivial name in certain circumstances, but more reflection is needed on the issue. The Commission services will look into possibilities to address the issue and will prepare a note for a future CA meeting, probably for the February one.

4.2. Union authorisation		

(a) Monitoring report on Union authorisation procedures	For discussion *CA-Nov19-Doc.4.2.a*	

The Commission services introduced the topic by a presentation describing the current state of play on the respect of the deadlines for Union authorisation, underlying that the delays that occurred during the validation and evaluation phases may affect the legal deadline for granting the authorisations as referred in Article 89 “transitional measures” of the BPR.

The Commission services thanked ECHA for the data provided and emphasised that there are clear indications that the validation and evaluation stage of the applications is substantiated prolonged affecting the 3-years legal deadline, therefore the Member States competent authorities and the applicants should make their efforts in addressing this issue.

The Commission services indicated that the noticed delays underline the need to optimise the process. It was also highlighted that at this moment there appears not to be a balanced share of applications among the Member States.

Several MSs supported the views of Commission, indicating that the complexity of the applications (biocidal product families) and the risk assessment of applications (product families, in situ, disinfection-by-products), and the insufficient quality of the submitted dossiers (lack of efficacy data, unclear claims etc.) induced delays in the whole process. As regards the quality of the submitted data a Member State noted that, in most of the cases additional information or even a resubmission of an application is necessary. One MS pointed out that it has to be re-thinked what to do with the 3-years deadline. Another MS suggested to have a co-rapporteur scheme for UA applications so up to no not involved MSs can start capacity building.

Some other MSs, raised the point of the time required for capacity building at the competent authorities and the backlogs due to the need of speeding up the review programme and the workload associated with authorisations at national level. ECHA also referred to the survey on the capacity of MS-CAs it conducted for preparing the active substances workshop of February 2019. Based on the information provided the competent authorities have an overall capacity to address 25 Union authorisation applications per year. This implies that approximately six years would be needed to finalise the assessment of the ongoing Union authorisations applications. However, the slowdown of the review programme will probably result in less product authorisation applications for competent authorities to deal with, and this may temporarily prevent further delays. ECHA stressed that the long validation phase is linked to an insufficient quality or completeness of the dossiers and expressed the opinion that Member States should consider to reject incomplete applications. The Commission agreed that applications that are not in accordance with the required data requirements should be rejected at the validation phase or at the evaluation phase if any requested additional data would not be provided.

An industry representative stated that additional data have been required by authorities at the validation stage and it seems that during the validation phase a type of evaluation is taking place. A Member State noted that an incomplete data set, or unclear uses and claims identified during the evaluation phase, may require modifications of the application and further delay the procedure.

Finally, the Commission services indicated that constructive pre-submission meetings, increased capacity of the Member States' biocides sector, a better share of the workload among the competent authorities and the respect of the legal deadlines, "stop of the clock" included, could optimise the process.

4.3. Report from Coordination Group	For information	

The Commission services debriefed the meeting on the main points discussed at the Coordination Group meeting held the previous days. During the CG-37 meeting 3 referrals were tabled for discussion and 1 referral was briefly introduced. An agreement was reached for one product and this product can be authorised. Three formal referrals will be further discussed via a teleconference.
Four e-consultations were discussed:

- *ED assessment of co-formulants by MS*. In general MSs supported a proposal with some changes introduced during the meeting. The discussion will be continued during the CG-39 meeting (open session).
- *Article 20(1)(a)(i) and Article 61 of BPR*. This e-consultation is related to the Letter of Access for UA applications. Member States agreed on the outcome of the e-consultation.
- *Anti-allergen claim.* The outcome of the e-consultation was agreed. It was agreed that in principle an "anti-allergen" claim is not a biocidal claim. The only situation when an "anti-allergen" claim could be indirectly related to a biocidal action is the situation that the product kills/controls the organisms that generate the allergens.
- *Responsibility of submission of information in accordance with requirements of Article 89(3).* In general, Member States agreed that where several marketing companies are involved in the application of an authorisation and/or where one or more companies rely on another company consultant to act as an applicant, it is the BPR applicant's responsibility to collaborate and coordinate in order to ensure that all products are clearly identified in the authorisation application.

Information was also provided on the progress on the update of the PAR template . An updated PAR template will be provided for commenting to member States and Accredited Stakeholder Observers at the end of November.

The Coordination Group agreed on the updated procedure to maintain a list of frequently used sentences in the SPC. Updates were also provided on the validation of the BPF matrix, which will be updated considering comments received during the meeting.

4.4. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-Nov19-Doc.4.4*	

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

4.5. Monitoring report on mutual recognition procedures	For information	

The item was postponed to the next meeting.

4.6. BPF concept: Q&A annex	For discussion *CA-Nov19-Doc.4.6*	

The Commission services explained that following the September discussion, several Q&A items of the former BPF guidance have been identified as candidates for transfer to the Q&A annex of the guidance adopted in July 2019. This information was gathered in a draft CA document that was put forward for discussion. The Commission service explained that three topics still required further clarification at the CA meeting:

1. The first question (Item 1 of the annex I to the CA document) was about the possibility to cover a group of products not containing the same active substance even if those active substances where covered by the same Implementing Regulation approving these active substances. It was indicated that the situation of iodine and PVP iodine is a

specific situation. The Commission services proposed to delete this item as it would be in breach of the requirement of the BPF definition to only cover products containing the same substance in a BPF. This position was supported by one Member State but not by an industry representative arguing that the new BPF guidance did not specifically address this point and that this item was already applied to justify the authorisation of a UA BPF.

2. On the second question (item 2 of the annex I to the CA document), the CA agreed that the second paragraph of the answer needs to be reformulated to better reflect the structure of the SPCs and how information on manufacturers are disseminated.

3. A third question (item 7 of the annex I to the CA document) arose as to whether a letter of access to the active substance dossier needs to be provided for each individual product covered by the BPF. The proposed answer in the former BPF guidance underlined that the provision of Article 20(1)(a) (iii) specifies that the applicant for an authorisation shall submit a dossier or a letter of access for each active substance present in the biocidal products and not for each individual product. A Member State pointed out that it depends on the letter of access submitted as it may cover only a limited number of products in the application. Another Member State reacted by explaining that this approach would be in contradiction with Article 32 of the BPR which stipulates that all Member States receiving applications for mutual recognition of a BPF shall authorise the biocidal products under the same terms and conditions. An industry association recognised that the issue is more complex than previously thought and promised to come back in writing.

Feedback on the above mentioned questions was requested before 13 December 2019. The Commission services will then prepare a draft for agreement at the next CA meeting.

Another Member State enquired whether the approach that only one set of hazard and precautionary statements is allowed for all products covered by one meta SPC is still valid and if so whether this does not need to be clarified in the Q&A. The Commission promised to come back to this at the next CA meeting.

An industry representative indicated that in the September CA meeting another Q&A was included concerning PT14 products the possibility for applicants to demonstrate that different PT 14 products including different baits can be covered by a BPF. A formal request to re-include this item will be made in writing.

Finally, the Commission services explained that the revision of the Q&A annex will be also used to revisit Annex IV of the new BPF Guidance that provides information on a Excel matrix that may be used to assess the similarity of uses.

5. Active substances

5.1. Free radicals generated from hydrogen peroxide	For discussion and agreement *CA-Nov19-Doc.5.1*	

ECHA presented its document concerning free radicals generated from hydrogen peroxide and put forward the question whether those free radicals can be considered as already covered by the current approval of hydrogen peroxide. ECHA proposed that free radicals generated from hydrogen peroxide are covered and could be managed during the evaluation of application of product authorisations .

The company representative indicated that they support the proposal of ECHA considering that the mode of action of hydrogen peroxide is based on the equilibrium of degradation products in hydroxyl radicals, and that it would be difficult to define the active substance otherwise.

One Member State asked for clarifications on the degradation products generated via the device, and considered that it is an in situ generated active substance as the radicals generated by the device would be different that the mere degradation of hydrogen peroxide in solution. To answer its question, the Commission services clarified that such free radicals generated from hydrogen peroxide could not be considered covered by the dossiers under evaluation pursuant to Article 93 for the free radicals generated from ambient air or water, as these on-going dossiers cover situations which were not considered covered by the scope of the directive 98/8/EC, which is not the case here. ECHA pointed out that the active substance hydrogen peroxide acts through the formation of free radicals. The only difference of the situation of the application for free radicals generated from hydrogen peroxide could be the concentration of free radicals that may result from a catalytic effect of the device.

One Member State suggested that the situation could be considered as a "releaser" substance, as opposed to in-situ generation. ECHA disagreed as in the present case there is a chemical reaction happening.

Another Member State considered that this technology modifies the profile of the active substance (hydrogen peroxide) and that it could be managed via a technical equivalence dossier. In any case, it considered that managing the situation only during the assessment of an application of product authorisation would be difficult.

To answer questions from the Commission services, the company representative clarified that their technology aims primarily at dispersing the hydroxyl radicals and to some extent at increasing their generation, and stated that the same radicals are formed intentionally by this technology compared to the natural behaviour of hydrogen peroxide.

One Member State indicated that it has difficulty to follow the argument that it would not be an in situ generation system that needs an approval on its own. Another Member State indicated that it could support the ECHA proposal, but at the same time would prefer to assess the case in a context of an approval as it would require a lot of work at product authorisation.
The former evaluating Competent Authority for the approval of hydrogen peroxide clarified that the radicals formed by the degradation of hydrogen peroxide were not particularly assessed and specified during the evaluation and the approval of hydrogen peroxide, and therefore there is no point of departure to make a comparison with the radicals produced by the present technology.

The Commission services reminded the importance to be consistent in the way to manage similar cases in the BPR. The Commission services invited Member States authorities to provide comments via the dedicated newsgroup until 13 December 2019 on what they consider as the active substance in the present technology: hydrogen peroxide, or the hydrogen peroxide radicals generated from hydrogen peroxide by a device, and referred to the questions formulated by ECHA in its document.

5.2. Action Plan on active substances Review Programme	For discussion *CA-Nov19-Doc.5.2*	

ECHA introduced its proposed action plan to increase the pace of the review programme of active substances. The lack of progress in recent years is a serious concern for ECHA and the Commission, as it prevents achieving a high level of protection of health and environment. ECHA indicated that earlier this year it intensified contacts with evaluating Member States and

asked where they have problems and how ECHA could help. This helped to establish what are the needs and to identify the areas where support would be most useful. ECHA underlined that the action plan also asks for a change of mind set and to focus on the most important topics. ECHA asked for the commitment of Member States for the various actions proposed in the document.

The Commission services highlighted that the implementation of legislation is a priority of the new Commission, and this applies also to the BPR. Ensuring the completion of the review programme and thus increasing the safety of biocides contribute to the achievement of the objectives of the European Green Deal, the Zero Pollution Ambition and the Farm to Fork strategy. The Commission services asked Member States to identify their needs and actively seek ECHA's help to conclude their assessments in the context of the review programme.

Several Member States indicated that they will send detailed comments in writing. One Member State asked to reduce unnecessary burdens. For instance, the early working group discussions sometimes lead to request to modify the assessment by the evaluating CA while they should not become equivalent to an anticipated peer review, as it is the very purpose of the peer review to have discussions and agree on the assessment performed by the evaluating CA. In addition, it was suggested to ECHA to discuss with the eCAs the issues identified in the accordance check before concluding; ECHA agreed. The same Member State suggested improving the effectiveness of working groups and asked for the possibility for specific experts to attend the BPC Working Group Meetings via Webex, as it is impossible to send all experts involved in an evaluation to meetings in Helsinki. On the latter, ECHA expressed reservations for logistical reasons and on the other hand indicated that the request will be further discussed internally. ECHA reminded that at peer review it is not possible to ask for further information if a gap is identified and that this is one of the benefit of the early WG discussions. Early working group discussions also help to ensure the alignment of the MSCAs especially when non-standard or novel approaches are considered by the eCA, thus overall saving time and resources. The Commission services considered that the Member State's requests for the remote participation of experts to working group meetings seemed pertinent, and that ECHA should accommodate requests made by Member States aiming at making progress in an efficient manner. The Commission services also pointed out that the peer review should not be a 'rubber stamping' exercise and repeated that there are limits to providing additional information. The objective is to have an appropriate BPC opinion and not to have the perfect data package and perfect scientific opinion.

Another Member State asked that active substances in PT8 and 18 and PTs with not many substances left be also prioritised, on which ECHA agreed as presented in the document.

Another Member State asked to have more detailed information on the progress of dossiers and an improved planning of the BPC. The Commission services noted that there is already a planning available for the discussions in the BPC and its Working Groups. The Commission services considered it key to have information on why certain dossiers are not progressing. It was also clarified that Member States can communicate their needs for training to ECHA and the Commission anytime.

A Member State noted its reservations on section 2.4.1 on the proposal to develop guidance on how to make a focused assessment, but it will follow this project with interest.

Another Member State asked how ECHA intends to accommodate the prioritisation of dossiers that Member States have defined for themselves. ECHA is rather searching for an alignment of priorities, noting however that some priorities were already set in the legislation.
CEFIC noted that the evolution of guidance during the evaluation generates delays, and called to examine the possibility to change the application timeline of new guidance in the approval process of active substances. CEFIC considers the 6-month period for applying new guidance

as practised by the BPC non-proportionate. The Commission services noted that in the Plant Protection Product Regulation it is clearly laid down that only guidance documents available at the time of submission of a dossier can be applied. On the other hand, it has to be acknowledged that no dossier has been pending for such a long time in the PPP area as some of the dossiers in the review programme under the BPR. The Commission services suggested to re-consider the date of applicability of new guidance documents if this could accelerate the review programme.

Another Member State noted some difficulties with the CLP process for biocidal active substances giving as example *in-situ* generated substances and also asked for further clarification on the need to assess ED properties and more in general how to assess data gaps for a substance submitted under the Directive when a substance is already known to meet another exclusion criterion. The Commission services noted these points and referred to on-going discussions with ECHA on the first issue and in the Standing Committee on the second issue.

The Commission services invited Member States authorities to provide any written comments via the dedicated newsgroup until 31 December 2019 on the actions proposed by ECHA, and invited them to formulate any other proposals to make progress on the review programme. A revised version of the action plan will be prepared by ECHA, with a view to concluding at the next CA meeting.

5.3. Availability of in-can preservatives and way forward	For discussion *CA-Nov19-Doc.5.3* *CA-Nov19-Doc.5.3.a (restricted)*	

CEPE presented a joint document prepared with AISE on the availability of in-can and film preservatives, PT6 and 7 respectively. It referred to the past CA discussions on the matter, and a workshop organised in May 2019 by industry where several Member States also participated. It re-expressed industry concerns regarding future decisions on isothiazolinones other than CMIT/MIT which included restrictions on treated articles. According to industry, such restrictions would lead in practise to a ban for consumer products, although the skin sensitizing potency of these substances might differ from CMIT/MIT potency. CEPE pointed out that currently 47 active substances are available but only a few can be used effectively in formulations. For the setting for conditions for treated articles it underlined that the CA agreed that it should only take place for a 'major concern'.

CEPE and AISE disagreed with the RAC classification but recognised that the RAC opinions should not be discussed under the BPR. CEPE and AISE asked for possibilities to approve these preservatives and propose two possible options presented in the joint document to move forward:

1. an approval of the substance with harmonised conditions (i.e. grouping approach), and/or
2. the possibility to discuss at technical level (i.e. BPC Human health Working Group) how skin sensitization and potency are taken into account in the risk assessment. According to CEPE it can be demonstrated that safe uses exist for products with concentrations above 15 ppm.

CEPE and AISE re-affirmed that they want to use safe substances and place on the market safe products.

One Member State commented that the risk of skin sensitization from mixtures containing such substance has to be addressed and that a mere labelling system is not enough to protect

consumers, arguing that numerous studies on CMIT/MIT show an increase of the sensitization of the population to this substance.

One Member State noted that many formulators (ex: producers of detergents, paints) using these preservatives are SMEs, and that a pragmatic way forward should be found. Six other Member States recognised that the availability of preservatives is an issue and called for innovation from industry. On the short term, a group approach could be explored, and they would support technical discussions at BPC or BPC Working Group level.

A Member State also noted the need for in-can preservatives and requested a socio-economic study from industry on the impact of potential restrictions. A longer time to prepare product authorisation could help.

A Member State emphasised that the decision on CMIT/MIT was appropriate, and that it even favoured its identification as a candidate for substitution which was not supported by other Member States at the time of the approval. The importance of this class of substances should be explored as well as the potential consequence of risk management options. It recognized the objective to avoid regrettable substitution, and considered that technical discussions at BPC or BPC WG level was needed as each substance should be assessed based on its own merits.

A Member State noted the limited provisions in the BPR to manage treated articles/mixtures, and stressed the importance to avoid discrimination between treated articles manufactured in EU or imported. Another Member State considered that each compound should be looked at the own merit and pointed out most consumers using paints are using personal protection any way.

An NGO would support a grouping approach as it may help to prevent 'regrettable substitution' but data may be missing for some substances. It noted that in-can preservatives are present in many products, and the general public is not specifically trained to understand complex labels. It argued that the possibility to demonstrate safe use at the product authorisation stage would be against the BPR objective to protect human health.

CEPE highlighted that around 3.5 Mio tonnes of paints are placed on the EU market each year and most of them contain in-can preservatives. Only a few active substances are used in reality for preservation. A group approach would allow to have an overview of all substances and their benefits and disadvantages. Technical discussions are needed at BPC level for its opinion about the risks of isothiazolinones in treated articles. CEPE repeated that substances have a difference in potency and a safe use can be demonstrated. It informed that at this moment only some indoor matt paints do not need preservatives but these do not represent the majority of the paints on the market. These paints also require dedicated manufacturing lines and an increase of pH.

One Member State considered that the two proposals made by industry in its document do not contradict each other. The use of personal protective equipment cannot be an acceptable risk mitigation measure for the general public and labelling measure should not be considered sufficient for high potent skin sensitizer.

As a conclusion, the availability of in-can preservatives was recognised as an important issue as well as the need for further technical discussion. The Commission services will reflect with ECHA whether further discussion will take place at the CA meeting or at BPC/BPC Working group level.

5.4. Progression of the review programme on active substances	For information *CA-Nov19-Doc.5.4* *CA-Nov19-Doc.5.4.a (restricted)*	

The Commission services presented an overview of the progress of the work on the review programme, noting that almost no progress occurred since the last CA meeting. One report was submitted on carbon dioxide PT19 and one report for a new active substance. The overall progress of the review programme passed from 33% to 34% due to the 7 inclusions of food and feed active substances published recently.

The status report was noted by the CA meeting.

5.5. Progression of the renewal process of approval of active substances	For information *CA-Nov19-Doc.5.5*	

The Commission services presented the overview of on-going and future renewals. One application was submitted in October, and the Commission reminded the evaluating Competent Authority to inform within 90 days of ECHA' acceptance whether it intends to perform a limited or full evaluation. It also reminded that Member States may use the provisions of Article 52 of the BPR when they decide to cancel the authorisation of products containing active substances for which no renewal is requested.

The status report was noted by the CA meeting.

5.6. In-situ generated nitrogen: Article 55(3) derogation	For information	

The Commission service informed the meeting that a public consultation concerning the derogation requested by Austria for in-situ generated nitrogen was launched on the ECHA website a few days earlier, with a deadline for providing comments of 18 January 2019. The aim of the public consultation is to allow interested third parties to submit comments in relation with the derogation requested for the specific substance and, in particular, to provide information on chemical or non-chemical alternatives available for the treatment of cultural heritage objects. The comments submitted during the public consultation will be taken into account by the Commission services when preparing the draft act. Regarding the possible timeline for the decision of the Commission, the meeting was informed that the intention is to present a draft act for discussion at the meeting of the Standing Committee of February 2020.

The Commission services also informed that a second application for derogation for in-situ generated nitrogen, from Spain, was received.

6. Treated articles
No item for information or discussion

7. Horizontal matters

7.1. ECHA guidance		

(a) Draft guidance on data requirements and assessment of applications for renewal of active substances	For discussion and agreement *CA-Nov19-Doc.7.1.a*	

ECHA presented its revised version of the draft guidance document on renewals, noting that certain comments were unfortunately not considered in this new version, but would be taken into account in the next revised draft.

On page 2, one Member State informed to have sent late comments in writing and asked for clarifications on answers provided by ECHA in the document. Two Member States noted the difficulty to retrieve old data submitted for the initial approval. Another Member State considered that the focus put on the update of the List of Endpoint (LoE) could be misleading. A Member State pointed out that the line in the third paragraph about 'If applying new guidance […]' could be read that the applicant could discuss with authority whether new data is necessary. ECHA indicated that the applicant should discuss with the Member State whether sufficient data is available or should be generated. CEFIC pointed out to consider the 6 month applicability period of new guidance in the context of this document. The Commission indicated that the word "preferably" should be deleted in third paragraph of section 1.1, as all needed data should be generated and available at the submission of the application, and also invited ECHA to include a specific paragraph on the applicant duty to provide sufficient data to assess endocrine disrupting properties at the submission of its dossier.

On page 3, two Member States asked clarifications on the need to provide a literature search, and insisted on the need to coordinate the assessment of ED properties of substances under both the Biocidal Product Regulation and the Plant Protection Product Regulation. It should be clarified under which legislation the assessment of EDs will take place and cooperation should be ensured. The Commission asked an editorial correction in section 1.3 as the applicant submits a dossier and not the draft assessment report on the substance.

On page 4, one Member State questioned the need to request new 5-batch analysis studies. Another Member State considered that there are various situations where specifications may have to be modified as foreseen in the SANCO guidance applied in the Plant Protection Products area. If a "full evaluation" is made, it can be questioned why the evaluation of specifications would be excluded *a priori*. AISE supported the need to check at the technical equivalence of alternative sources. The Commission services noted that it must be done in the context of the renewal of product authorisations containing the concerned sources, not at the renewal of approval process on the active substance. Companies having alternatives sources should submit the relevant requests to ECHA in case the reference specifications are changed.

On page 6, in section 2.1, one Member State asked ECHA to provide a list of "third party dossiers" submitted in the context of product authorisations. AISE supported the need to assess the Article 95 data at the occasion of the renewal of approval, as they would never be assessed otherwise and this would be questionable. The Commission services noted that the assessment of Article 95 data should not be "optional" for the evaluating Member State. In addition, these data are likely to have been submitted in the context of product authorisation, and would thus normally have been assessed. One Member State asked to specify how Article 5(2) assessment should take place.

On page 7, one Member State asked clarifications on section 2.3.1 on efficacy for treated articles. The Commission services also noted that the drafting was confusing on the matter and underlined that the efficacy is assessed of the biocidal product used in treated articles and not the efficacy of a treated article is being assessed. One Member State asked to include analysis

on the development of resistance. It will submit a text proposal. ECHA further indicated that it will harmonise the human health and environmental sections.

On Appendix I, the Commission proposed that the applicant should provide an overview of the uses made of its active substance in biocidal products to get more knowledge on the uses made of the substance. The renewal document should also contain a specific section for exclusion substances where the applicant should give justifications on the reasons why the conditions for derogation to exclusion would be met.

ECHA took note of the comments made during the meeting. The Commission services invited Member States authorities to provide comments via the dedicated newsgroup until 13 December 2019, so that ECHA prepares a revised draft for the next CA meeting.

(b) Priority setting for developing ECHA guidance	For discussion *CA-Nov19-Doc.7.1.b.1* *CA-Nov19-Doc.7.1.b.2*	

ECHA introduced the document prepared for the meeting, which is a follow-up of previous discussions on overall guidance needs and prioritisation of guidance developments. The document shows that guidance needs were identified in many different areas and that there are a few areas identified to which ECHA will have to dedicate resources, due to the amendment of Annexes II and III to the BPR and to forthcoming mandates from the Commission (e.g. water treatment processes). ECHA highlighted that in order to progress on some high priorities topics the active involvement of Member States and of stakeholders will be needed. The Volume X indicated in the document should be Volume I.

The Commission services reminded that several contributions had been provided by Member States following discussions in previous CA meetings. One Member State enquired whether a guidance for bees will also be included. The Commission services mentioned that a mandate to ECHA on this topic is under preparation. Another Member State asked clarification on one topic (extension of guidance for disinfectant by-products to other PTs) for which the document indicates that Member States are supposed to take over. ECHA indicated that this point was identified as having high priority but, since the expertise lies within Member States and due to the availability of resources in ECHA, it was considered that Member States should take this point over. The same Member State was of the opinion that, since it is a must-do guidance, coordination is needed at a different level. The Commission services also mentioned that the coordination should not occur at the Member States level, but ECHA should be coordinating. ECHA stated that one Member State should be in the lead, as it happened in the past for other topics. One Member State was of the opinion that ECHA should be in the lead, due to the relevance of the topic and considering that it was on hold for quite some time.

Another Member State appreciated that most of the topics they suggested were included in the document but noticed that a few other topics were not included. ECHA mentioned that the first document (general overview) includes all items flagged by Member States while the second document, which proposes the priorities, includes the proposal of ECHA of prioritised items. One Member State expressed some scepticism on the joint development of guidance for bees by ECHA and EFSA since the exposure scenarios under the two regulations (PPPR and BPR) are different.

Commission services indicated that they would prefer that the efficacy guidance for PT 19 products was included among the ‘must-do’ items. ECHA states that, even if not indicated as a ‘must-do’ item, there is progress on the topic and some Member States are already involved. It

was agreed that the item related to EUSES updates will be de-prioritised and the one on efficacy of PT 19 products will replace it.

As to the Member States that would lead and would be involved in the development of 'must-do' guidance, one Member State expressed their willingness to contribute to the topic on the in-situ. The Commission services reminded that, if guidance is to be developed, Member States have to dedicate resources to this. Member States were invited to reflect and indicate their willingness to be involved in specific topics by 13 December 2019.

7.2. Disinfectant by-products: relevant guidance development by ECHA	For discussion and agreement *CA-Nov19-Doc.7.2*	

ECHA introduced the topic related to the scope of the guidance for disinfectant by-products (DBPs). The identified areas with high priority are drinking water disinfection and treatment of drinking water of livestock. The priorities indicated were based on the needs identified for human health, while for environment the feedback from the working group was still to be received, so they are based mostly on human health-related considerations. Environmental related considerations will be taken into account later on.

One Member State mentioned the case of food contact material incorporating/treated with other biocides (e.g. crates treated with PT 8 antifungal products used for transportation of food on which PT 4 disinfectants are applied) and asked whether this case could be included with medium priority. The same Member State enquired whether ECHA will only work on areas identified as high priority, leaving aside the medium priority ones. The Commission services clarified that the scope of the exercise is related to disinfectant by-products (product types 1 - 5) and the focus should be on these product types. In terms of the general approach, ECHA indicated that the fist areas to be addressed are the ones identified as high priority. Another Member State recalled the discussion of whether the assessment of the DBPs should take place at the level of substance approval or product authorisation and pointed out that the agreement to have it performed at product authorisation stage is not reflected in the document. The same Member State invited ECHA to also consider PT 4 products and referred to the exercise ongoing at the Coordination Group of prioritisation of certain substances, therefore on a different level than the discussion on product-types. On the latter remark ECHA clarified that the approach of the two exercises is not conflicting and that guidance is not active substance specific.

One Member State pointed out that evaluators performing product evaluation, where DBPs have to be assessed, are in difficulty due to the lack of guidance. The same Member State expressed disappointment at the fact that ECHA is able to consider only PT 5 as high priority and at the fact that little progress will be made on a very complex and important area.

It was agreed to discuss the topic again at the meeting of February 2020, when the feedback from the working group on environment will have been considered. Member States were invited to provide written comments by 13 December 2019.

7.3. Article 65(3) reporting: template for future reporting	For discussion *CA-Nov19-Doc.7.3*	

The Commission services introduced the item and mentioned that, as agreed at the CA meeting in January 2018, the provisional template for the future rounds of reporting was brought for discussion in this meeting, with a view to getting an agreement at the following meeting, in February 2020. One Member State was of the opinion that the agreement should be sought at a later meeting. The Commission services mentioned that having an agreement sooner, that it as

the beginning of next year – which is the start of the new reporting period – would allow Member States to have clarity as to what data and information they have to report and to get organised for the collection of such data. Two Member States suggested that after the agreement in February 2020, the template could be discussed again after some time when the Member States gained experience with actually collecting the data. The Commission services accepted this idea.

The Commission services indicated that the template was shared with the BPR subgroup of the Forum, which commented mainly on the enforcement section, and the templates used for reporting under the BPD and under REACH were analysed. The main changes compared to the provisional template were then presented. These regard in particular: new questions on resources of the competent authorities and enforcement authorities; some changes for the reporting of official controls; in the section on poisoning incidents the use of the poison severity score published in Persson et al., 1998; new question on adverse environmental effects. On the latter point a short discussion followed. One Member State asked whether only the instances where the use of biocidal products was confirmed need to be reported. Another Member State pointed out that it is very difficult to ascertain whether a certain event was caused by the use of biocidal products or of other products. The Commission services appreciated the difficulty but they mentioned that in case of environmental adverse effects it is expected that the authorities would perform a detailed investigation that would clarify to the extent possible the causes of the incident. It was also mentioned that reporting by Member States of adverse environmental effects is explicitly mentioned in Article 65(3).

With regard to the first reporting exercise (due in June 2020), for which the web survey form was circulated in October, the Commission services informed the meeting that official letters to the national competent authorities will be sent in the coming weeks. It was also mentioned that, in the section on official controls optional tables allowing to indicate a more detailed reporting were also included in the web survey. Member States were encouraged to use these tables if detailed figures on controls are available.

Comments from Member States on the template for future reporting were invited until 31 December 2019.

7.4. ECHA communications	For information *CA-Nov19-Doc.7.4*	

ECHA informed the meeting about the IT user group meeting held at the beginning of the week and reminded Member States that feedback from Member States on the IT tools is welcome also outside that meeting.

One Member State enquired whether any training on IT tools is foreseen. ECHA mentioned that training sessions are generally organised when there is a major release of IT tools. For Member State-specific trainings, the participants were invited to contact ECHA bilaterally.

7.5. Amendment of Annexes II and III to the BPR	For information	

The Commission services explained that the interservice consultation on the revision of the BPR annexes was still running. The comments of the other Commission services will be collected and discussed. A final document including all agreed comments will be presented at the next CA meeting. The Commission services also indicated that an NGO provided additional recommendations regarding animal welfare. These comments will be taken into

consideration as well. In this context, the Commission services also reminded the CA-meeting of the possibility to provide comments via the feedback mechanism that is foreseen before the Commission adopts the Delegated Act. Finally, the Commission services recalled that the EU Parliament and the Council will be invited to attend the next CA meetings where a draft final legal act should be presented.

One Member State asked clarification on the status of the wording on the pre-natal developmental test (PNDT) following the intervention of another Member State in September 2019. The Commission services explained that the text of that point has finally not be modified for coherence with the Plant Protection Product Regulation.

7.6. Update on Court cases	For information	

The Commission services indicated that the case T734/18 on empenthrin was withdrawn by the applicant. As regards cases T337/18 and T347/18 on PHMB, the Court has still to decide whether to hold an hearing.

The Commission services also informed about the prejudicial question C592/18 and the Advocate general opinion given on 17 October 2019, which concerns matters related to the scope of the BPR.

7.7. Update on EDs	For information	

The Commission services informed about the first annual forum on endocrine disruptors that took place on 8 November and about the forthcoming BTSF training for Member States scheduled on 27-28 November. The Commission is also working on the launch of the early review for three active substances.

7.8. Information on insecticides authorised against mosquitos and ticks	For information	

The Commission services remembered the CA-meeting of the previous discussion on the topic. Twelve Member States Competent Authorities send their lists of national insecticides under transitional rules. ECHA also provided a list of about 80 insecticides that have been authorised under the BPR rules. This information will be provided to human health authorities at a meeting organised by the European Centre for Diseases Control and Prevention early December.

The Commission services invited the other Member States to contribute to this exercise by sending the list of national insecticides under the transitional rules as soon as possible.

7.9. Call for expression of interest for observers to the competent authorities expert group	For information	

The Commission services explained that they will launch a continuously open call for applications for the selection of observers of the biocidal expert group. This is in line with the general Commission transparency objective on the composition of expert groups. Moreover, it

is noted that that about 2/3 of the observers listed in the Commission Register of expert groups for the CA-meeting are not actually participating in our meetings. Reactions from the Member States are expected before 13 December 2019.

7.10. Availability of insecticides for vector control	For discussion	**Closed session**

A discussion took place on the availability of effective products for vector control concerning mosquitoes.

8. Scope matters

8.1 Scope issue in relation to animal semen extenders	For discussion *CA-Nov19-Doc.8.1*	

The Member State having proposed the item introduced the point, which was also discussed in Helpex but triggered only one response. The discussion concerns additives (so-called extenders) used for the transportation of animal semen and whether these should be considered in the scope of the BPR. Four questions are relevant for the discussion (i) if the extenders are to be considered in the scope of the BPR; (ii) if yes, what would be the relevant product-type; (iii) if animal semen preparations can be considered manufactured products; (iv) if antibiotics can be considered biocidal active substances.

One Member State was of the opinion that such product is to be considered a biocidal product in PT 6. Another Member State considered that the product could not be considered a manufactured product, and consequently there is no appropriate PT for it, it cannot actually be considered in the scope of the BPR. Comments by Member States were invited by 13 December.

8.2 Scope issues identified during the drafting of PT 11-12 efficacy guidance	For information	

The Member State that volunteered to introduce the item for discussion in Helpex informed that they will do so soon and that in the meantime they await an analysis/overview prepared by Cefic on what would be the impact of the new organisation of the PTs and uses within the PTs on the active substances.

9. Enforcement issues
No item for information or discussion

10. International Matters

10.1 OECD Working Group on Biocides meeting on 25-26 September 2019	For information	

A presentation of the OECD WG on Biocides was uploaded on CIRCABC and the Commission services invited the attendees to look at it and address any questions directly to ECHA after the meeting.

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-Nov19-Doc.11.a*	

(b) Notification of France of the decree concerning the ban of self-service sale to the general public	For information *CA-Nov19-Doc.11.b.1* *CA-Nov19-Doc.11.b.2* *CA-Nov19-Doc.11.b.3* *CA-Nov19-Doc.11.b.4 (restricted)*	

France informed about recent legislation adopted at national level with the view to limit the sell in free service for the general public of certain biocidal products. The Commission services highlighted to the attendees that the Commission does not take position on the legislation adopted by France by including this item on the agenda of the CA-meeting.

Next meetings:

2020 (provisional)

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