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

MINUTES

84th 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

4-5 July 2019

1. Adoption of the agenda	For adoption *CA-July19-Doc.1*	

Two items were added to the agenda under AOB: (i) information from France on recent developments in their national legislation and (ii) scope matters raised during drafting of efficacy guidance. The agenda was then adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-July19-Doc.2*	

The draft minutes of the 83rd CA meeting were adopted, incorporating the comments by ECHA in sections 7.2.(b) and 7.2.(c).

3. Draft delegated acts
No item for information or discussion

4. Biocidal products		
4.1. Management of product authorisations for *in situ* cases	For discussion and agreement *CA-July19-Doc.4.1*	

The Commission services explained that since the last CA meeting and at the request of two Member States, a technical meeting was organised to define under which conditions an authorisation for in situ biocidal products could be granted in the form of either a single biocidal product or a Biocidal Product Family (BPF). The Commission Legal Service (LS) was also involved in the discussion, in particular on case type 4 as included in document *CA-July19-Doc.4.1*, and took the view that in most of the in situ cases, a single biocidal product authorisation could be granted because the generated active substance concentration(s) is/are not intended and rather depend(s) on environmental conditions. When applying for single biocidal product authorisation, a concentration range of the active substance could be allowed in case of in situ generation and could be considered as different in use concentration.

This point was lengthily discussed and the meeting agreed with the text in Section 3.3 after some modifications.

The Commission services clarified that for the case-types under the first indent of the biocidal product definition (when the precursors are the biocidal products), a specific variation in the composition of the formulation containing the precursor(s) could establish a BPF. A Member State asked to clarify under which situation a BPF could be established for case-type 4. The Commission services and a Member State answered that they were not able to identify a practical case that would allow the applicant to establish a BPF in that case. However, the Commission proposed to keep the last sentence of paragraph 19 as it is legally correct. The CA agreed to the proposal.

A Member State asked to clarify that devices are not biocidal products and will never be authorised.

A Member State indicated that further reflections on the way to communicate the SPC to the user when the active substance is the biocidal product (case type 4) should be incorporated in the Q&A Annex. Also Member States should have a common understanding of what should be considered as specified and unspecified variations to avoid referrals in the future. These issues should be clarified in light of the experience gained with the assessment of future applications for authorisation of in situ biocidal products. The Chair noted that with the points agreed during the meeting (and shown on a modified version of the document on screen during the meeting), the document was endorsed by the CA meeting.

4.2. Implementation of the Biocidal Product Family concept	For discussion and agreement *CA-July19-Doc.4.2*	

The Commission services informed about the outcome of several consultations conducted to improve the readability of the text proposed by the Coordination Group (CG). The discussion in the CA meeting focused mainly on two paragraphs of the draft CA note posted on CIRCABC.

Paragraph 37 on the grouping of co-formulants: the Commission services suggested the deletion of the last two sentences of that paragraph as it seems to contradict the first sentence of paragraph 40. In particular the Commission services mentioned that the last sentence of paragraph 37 suggests that a product composition not in the range of the initial BPF could be notified which seems very odd. An expert of the CG consulted on this issue expressed similar concerns. After a long discussion between several MSs, ECHA, industry associations and the Commission service, it was finally decided to remove the last two sentences of paragraph 37.

Paragraph 93 on the applicability of the guidance: the issue was discussed already at the previous CA-meeting and although Member States supported an early application of the guidance, there was no consensus as to whether it should apply to already submitted dossiers or only to new applications submitted after a certain date.

One Member State recalled its difficulties to assess applications consisting of very extensive BPF families and expressed the view that the guidance should help them to reject such applications. The Commission services explained that a competent authority could use Article (3)(1)(s) of the BPR to reject such type of applications if they do not fit with the BPF definition of the BPR and that the guidance aims at clarifying the legal context of that article.

Another Member State stated that applying the guidance to on-going applications would be unworkable given the tight deadlines for product authorisation. According to this Member State industry would need sufficient time to rethink their applications if rejected. The Commission services clarified that in case the BPF needs to be split, the products no longer covered by the application could stay on the market in accordance with Article 89. However, several conditions would need to be met that will be further discussed under point 4.3 of the agenda. A participant to the meeting indicated that the Coordination Group endorsed the paper on BPF the beginning of this year and applicants are aware that some applications are causing problems. A Member State proposed that paragraph 93 includes a sentence indicating that the guidance can apply to existing applications if the applicant agrees to apply the guidance as soon as possible.

The CA finally agreed that applicants and competent authorities shall apply the guidance note to new applications submitted for BPF authorisation as of 01/10/2019. This guidance could be applied for applications submitted before that date if the applicants agree. However, one MS disagreed with that conclusions and stated that an option where the

guidance would apply to on-going applications, even if the applicant disagrees, would be preferable.

Lastly, an industry association expressed the view that several points of the current Q&A are still valid and should be maintained in Annex VIII of the draft guidance. The industry analysis is available on CIRCABC for comments until 23 August 2019. The Commission service will collect the information and may submit a draft of the Q&A Annex VIII to one of the next CA meeting if there is a support to carry over some of the elements of the existing Q&A.

4.3. Transformations of applications for product authorisations and the applicability of provisions in Article 89	For discussion and agreement *CA-July19-Doc.4.3*	

The Commission services indicated that in a previous CA meeting paper three cases were described for which it was requested to clarify whether the biocidal products available on the national market can benefit of the transitional rules set out in Article 89. Several Member States provided their views on the cases for which Article 89 could be applicable. The Commission services informed that this issue was further discussed internally after the discussions in the CA meeting. It was highlighted that Article 89(2) sets out the transitional regime that allows biocidal products containing existing active substances to benefit from the marketing and use under the national system or practice until a certain time after the approval of the active substance, while applying in parallel for the authorisation under the BPR. Article 89(2), (3) and (4) have to be read together. In the three cases the applicants submitted new applications ('first application') under the BPR under the conditions set out in the second subparagraph of Article 89(3) and can therefore benefit from the transitional deadlines established under Article 89(2). These applications were/will be 'changed' ('second application') after the date of the approval the active substance. The scope of the 'first application' should guide the determination whether a given biocidal product may benefit from the transitional period set in Article 89(2). However, several conditions would need to be met. There should be no time-gap between the withdrawal of the 'first application' and the submission of the 'second application'. Also the 'change' of application should be properly motivated. The Commission services underlined that Article 89(2) does not envisage any possibility to prolong the transitional deadline linked to the approval date of the active substance.

4.4. Union authorisation		
(a) Process for the linguistic review of SPCs	For discussion *CA-July19-Doc.4.4.a*	

ECHA presented the revised linguistic translation process. The aim of the revision is to reduce the workload for the Member States and to improve the quality of the SPC. One Member State asked if the check should be performed on the .xml version and ECHA confirmed this. The Commission services clarified that the Word version is essential for the internal procedures and the adoption and the publication of the decision in the Official Journal. The Commission services also underlined that the purpose of the revision of the process is that Member States need to check only once and only one version. However, an update of the SPC-editor is required in order to automatically generate an aligned Word document. Since the xml. format needs to be fully aligned with the Word format, the format

of the SPC to be checked (word or .xml) would be decided on a case by case basis. Another Member State noted the poor quality of the different linguistic versions of the SPC. ECHA pointed out that the use of some standard phrases and the availability of these phrases in former authorisations may lead to improved quality of the translations. ECHA is expanding its database with these standard phrases. ECHA underlined the more time that is given now to applicants to submit the SPCs. The Commission services suggested that applicants sharing experiences on the quality of the provided translation services by companies may also be a good practice.

(b) Executive report on applications for UA	For information *CA-July19-Doc.4.4.b.1 & 2*	

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

4.5. Report from Coordination Group	For information	

The ECHA representative briefed the participant on the relevant topics discussed at the Coordination Group meeting held the previous days and also mentioned that five referrals were discussed, of which two were closed. Among the topics discussed an important one was the possibility to have mutual recognition from a mutual recognition; this topic will be followed up in the Coordination Group meeting of September 2019. Another relevant topic was related to how to take into account, at the renewal stage of a national or Union authorisation, all the changes made during the life cycle of the authorisation. On this topic the CG reached an agreement on the approach to follow for the two cases (national and Union authorisation).

4.6. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR	For information *CA-July19-Doc.4.6*	

The meeting participants were informed that the report has not been distributed for this meeting.

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

The Commission services introduced the topic and gave the floor to the Member State having raised it. The topic originated from one case of the occurrence of anaphylactic shock related to the use of a PT 1 biocidal product on the label of which only the systematic chemical name of the active substance was indicated and not also the trivial/common name. According to this Member State persons who are allergic to certain chemical substances may fail to identify them if these are specified on the label only by their systematic name. For the case under discussion, other chemical legislations (e.g. cosmetics) require the specific substance name to be indicated also by the common name, precisely due to its sensitisation properties. The Member State having raised the issue queried whether it would be possible, for products containing specific active substances, to oblige the authorisation holder to also include the

trivial name on the label of the product, for health protection reasons. ECHA mentioned that a somehow related issue they face is the case of including names of active substances on labels that have very long systematic names.

One Member State was of the opinion that competent authorities have not only the right but also the duty to establish risk management measures and, if requesting to have the trivial name indicated is deemed a risk management measure, it should be put in place. Another Member State considered that, in addition to having the common name on the label, consumers should be able to find information by common name and therefore it necessary to have somewhere a clear link between the trivial and systematic name (e.g. on the ECHA dissemination website). One industry representative indicated that for mixtures (as the case in question is) there is the obligation to label them according to the CLP provisions, which include mentioning the skin sensitising properties for substances having these properties. The Commission services clarified that the issue being discussed is not the lack of information on the label but the difficulty to identify the substance if only the systematic name is indicated.

Member States were invited to provide their comments by 23 August with a view to discussing again the topic at the September meeting.

5. Active substances		
5.1. The in-situ generation of nitrogen for the preservation of museum objects	For discussion *CA-July19-Doc.5.1*	

The Commission services introduced the topic and made reference to the form developed for possible applications from Member States for derogations in accordance with Article 55(3) of the BPR. Participants were informed that some aspects related to the Article 55(3) derogations are currently being discussed with the Commission Legal Service and the form might change in light of the outcome of these discussions. The Commission services also informed the meeting that the first application from a Member State has been received in the previous days and the Commission services will start analysing it.

Some Member States expressed doubts on whether nitrogen should be considered to be in scope of the BPR as no chemical reaction takes place. The Commission services re-iterated that the co-legislator included this substance when drafting the Regulation and also reminded about the preliminary ruling delivered by the European Court of Justice in the Söll case, which addressed what could be considered to be a biocidal product. One Member State asked whether a derogation in accordance with Article 55(3) is required as nitrogen is already included in Annex I. Another Member State questioned whether the mode of generation of the active substance matters for the purpose of Article 55(3) derogations (which refers to 'non-approved active substance') since the definition of an active substance in Article 3 makes no reference to the way the substance is generated. The Commission services reminded that in the past it was agreed that an active substance generated in-situ is considered different from the active substance non generated in-situ.

One Member State noted that Member States might have difficulties in filling in section 2.4 of the form (summary of toxicological and ecotoxicological information) for some substances and suggested to replace it by an annex to the form. The Commission services highlighted that at least basic information on the impact of substance on humans and on the environment is needed and this is why a summary is requested, but Member States can of course provide additional information in an annex.

Another Member State was of the opinion that by means of the Article 55(3) derogation the Commission allows Member States to authorise products and that it is in the end the responsibility of Member States to determine the level of information on the products to be requested. A Member State highlighted that Article 55(3) provides a derogation from point (a) of Article 19(1) but the conditions in other paragraphs of Article 19 has to be fulfilled.

A company supplying an alternative technology for the protection of cultural heritage objects, namely the humidity controlled warm air treatment, attended the discussion and presented their position. The position paper of the company had been distributed before the meeting to the meeting participants. The technology used by the company allows the elimination of insects with heat using a climate controlled heating chamber which controls moisture content during heating and cooling. The company claimed that the impact of the BPR on the in-situ generation of nitrogen was not new for the museums and that the use of nitrogen is in the scope of the BPR had been discussed at several international conferences of museums between 2013 and 2017. The company went on informing that it brought legal proceedings in various German Courts against private companies using in-situ nitrogen and all these Courts were of the view that nitrogen generated in-situ falls within the scope of the BPR and that its use without a proper authorisation after September 2017 was illegal. As to the possible derogations under Article 55(3), the company considered that the only procedure contemplated according to the provisions is the national authorisation, while the simplified authorisation, Union authorisation and mutual recognition would all not be applicable in relation to Article 55(3).

According to the company the condition in Article 55(3) that no appropriate alternatives are available should be applied restrictively. The company considered that there is no current application of in-situ nitrogen for the protection of cultural heritage that cannot be replaced by available alternatives, among which the humidity controlled warm air treatment, which is currently used by world-renowned museums. Details on the various alternatives are included in the position paper. It considers that many museums use nitrogen as it is the cheapest method. The company also referred to other approved biocidal active substances that could be used as an alternative to in-situ generated nitrogen and indicated that nitrogen in ready-to-use canisters, which is included in Annex I, could be used for treatment of objects that fit into a 3-5 m^3 bubble. The company was of the opinion that, considering all the available alternatives, there would be no room for an Article 55(3) derogation for in-situ generated nitrogen and that if, however, such derogations are granted, they should be limited to museums or cultural organisations, should be limited in time and limited only to the treatment of those objects for which alternatives could not be identified. The company highlighted that many museums do not see a need for derogation.

The Commission services requested the company to provide reference of the national Court cases referred to in their presentation and also of the international museum conferences where the topic had been discussed.

One Member State stated that in their country none of the biocidal active substances that could be considered as alternative according to the company are authorised for the specific use of treatment of cultural heritage objects and, as to the biological treatment, it appears that no products are available currently. The same Member State stated that other literature and more recent than the one mentioned by the company in their paper, indicates that treatments as the one offered by the company are not suitable for leather and in general for organic materials.

Another Member State made reference to the standard for the cultural heritage preservation technologies in the context of integrated pest management and stated they considered it relevant when assessing the availability of alternative technologies. In the same standard the

side effects of the various techniques are mentioned (e.g. in the case of warm air treatment one side effect could be the release of previously applied biocidal products). One Member State mentioned that the aspects of proportionality, practicality and costs involved should also be taken into account when discussing this topic. Another Member State pointed out the museums in this Member State do no need a derogation.

The company then explained the practical application of the technology, which is suitable also for large objects, and stated that the switch from the nitrogen in-situ chambers to the warm air technology chambers is not complicated but it requires a certain financial investment. The company pointed out that the effect of a treatment on ageing of an object should be considered relatively as a few days additional ageing are not of high relevance.

One Member State enquired what would be the elements taken into account by the Commission when deciding whether to grant or not a derogation, in particular if the information on classification and labelling will be essential when taking the decision. The Commission services reiterated that information such as classification and labelling and summary of toxicological and ecotoxicological information is requested in order to know details on the substance, but will not be essential when deciding to grant or not the authorisation. Another Member State asked whether it will be possible to have mutual recognition of product that has been authorised in one Member State granted following a derogation and requested to address this question in the discussion at the next CA meeting.

5.2. Relevant renewal data under Article 95	For discussion *CA-July19-Doc.5.2*	

ECHA presented its revised version of the document.

Some Member States asked clarifications on the last paragraph of page 2 referring to what alternative suppliers should do after the renewal of approval of the active substance, and the provisions of Article 95(7). In particular, it was debated whether the only option for alternative suppliers was to submit a letter of access, or whether they had also the opportunity to submit their own relevant data. ECHA and the Commission services reminded that the provisions of Article 95 were historically built as a mechanism to deal with the "free-rider" issue, and to ensure that every supplier having an interest on an active substance contributes to the biocides system: as such alternative suppliers would normally be expected to join forces to contribute to the renewal of approval process, and not remain "alternative" suppliers. In this context it was indicated that a renewal application is not limited and there is no legal obligation to have a single application for renewal of an active substance. ECHA and Commission however agreed to further check the point and clarify this point in the note.

On section 4.1, some Member States asked clarification on what meant "which was actually used in the assessment report".

ECHA noted the comments and will consider them in a next version of the document. Member States were invited to send their comments again until 23 August.

5.3. Progression of the review programme on active substances	For information *CA-July-Doc.5.4*	

The Commission services presented an overview of the progress of the work on the review programme, noting that no progress was done since the last CA meeting. The Commission services encouraged again Member States to work along the priority lists, and make progress

on the backlog reports submitted before 1st September 2013. The status report was noted by the CA meeting.

5.4. Progression of the renewal process of approval of active substances	For information *CA-July19-Doc.5.5*	

The Commission services presented of the overview of on-going and future renewals. The status report was noted by the CA meeting.

6. Treated articles
No item for information or discussion

7. Horizontal matters		
7.1. Amendment of Annexes II and III to the BPR	For discussion and agreement *CA-July19-Doc.7.1.a* *CA-July19-Doc.7.1.b*	

The Commission services presented the outcomes of a WebEx meeting organised mid-June in order to find a way forward for the wording of the reproductive testing (fertility, developmental neurotoxicity and immunotoxicity) for active substances. The Commission services explained that there was agreement to consider information on developmental neurotoxicity as Core Data Set but national scientific experts were unable to find a consensus on the type of tests required to generate data on developmental neurotoxicity. Therefore, two options were presented in a note to the CA-meeting which was invited to take position in favour of one of them. The results of the consultation in the CA meeting was as follows:

Option 1 : OECD TG 426 (specific study for developmental neurotoxicity) with the possibility to replace this study with similar information including Developmental Neurotoxicity cohorts of the OECD TG 443 (Extended One-Generation Reproductive toxicity Study) provided that cognitive functions are studied and results are not equivocal. Two Member States, 1 non-Member State and ECHA supported this proposal.

Option 2 : A more flexible approach where the information on developmental neurotoxicity could be generated via different methods provided that a sufficient level of information is reached. 18 Member States, two industry associations and an animal welfare association[1] supported that option.

One Member State disagreed with both options as it will have a substantial impact on the number of animals required for testing and not sufficient scientific evidence exists for having developmental neurotoxicity testing as a Core Data Set. This Member State favoured a triggering system instead. Two Member States and a non-Member State abstained. Five Member States did not participate to the vote. 18 Member States voted in favour of option 2.

An involved Commission service asked whether the most suitable test methods under option 2 have been clearly identified by the WebEx. ECHA responded that, following an update of the Annexes, the ED guidance would have to be revisited and adapted.

[1] The animal welfare association took the view that DNT should be an Additional Data Set rather than a Core Data Set

Another Commission service asked information about the number of animal tested under each scenario and requested information on the difference between the two options. The responsible Commission service referred to the document setting out the number of animals required for the different tests and indicated that the difference lies in the fact that under option 1, OECD TG 426 is obligatory and in option 2 this test method is only an option among others.

A non-Member State country recalled that OECD TG 426 will have a higher statistical power, would provide more EDs endpoints and will assess the cognitive functions.

The animal welfare association clarified that test guidance on in vitro alternatives to in vivo methods for developmental neurotoxicity assessment is currently under development by the relevant OECD working group. An involved Commission service responded that these methods are not applicable until the relevant OECD test guidance is available. Therefore, data should be gathered based on available OECD test methods from the revised ECHA guidance.

Regarding developmental immunotoxicity (DIT) testing, one MS regretted that this end point is not included into the Extended One-Generation Reproductive toxicity Study (EOGRTS) as a mandatory cohort. Considering the increases of immune-related diseases and the additional information provided for ED assessment, it is a missed opportunity to guarantee a safer use of biocidal products. That MS also informed that several EOGRT studies with a DIT cohort have been requested under REACH. Two Member States supported this view. The Commission service indicated that, in the current proposal DIT testing is included as Additional Data Set and, therefore, Member States have the possibility to request DIT data if evidence exists that the substance may have immunotoxicity properties. A Member State suggested to include mechanistic information as a trigger to conduct DIT studies.

One Member Stated proposed to delete the requirement in point 8.13.3 to have a systematic review of the literature on endocrine disruption of the active substance and include it in ECHA-guidance. One Member State expressed concerns about the time needed to assess the literature review provided by the applicant to assess the ED properties of a substance. The Commission services indicated that in Annex II the principle of a systematic review is established and the modalities are provided in guidance. The guidance should help applicants and evaluating Member States to identify existing evidence and avoid additional testing. Another Member State explained that additional guidance is needed to clarify under what criteria old studies should be replaced and superseded by more recent studies.

The Commission services explained the proposed amendments in Annex III in relation to biocidal products and the relevant reasoning for these amendments, in particular that further data will be required for non-active substances contained in biocidal products identified as substances of concern. The CA-meeting did not raise any question on the proposed amendments concerning Annex III.

The Commission services informed the CA-meeting that based on the discussions in this meeting a draft delegated act will be drafted to update the Annexes II and III. Following the conclusion of the internal procedures this draft delegated can be submitted for discussion to the next CA-meetings.

7.2. ECHA guidance		
(a) Draft guidance on data requirements and assessment of applications for renewal of active substances	For discussion *CA-July19-Doc.7.2.a*	

ECHA presented its revised version of the guidance on renewals. In particular, it was reported that it was difficult to find a balance between the requirements and the work to be performed by applicants and authorities. There are shared concerns that the renewal process could end up into a new review programme. The Commission services emphasized that there should not be all the time full re-evaluations, noting that the new ED criteria have to be considered, the process depends on the information available and the outcome of the former assessment and that the renewal process on a substance should not take several years as occurred for the first approval.

One Member State asked that the topic and document be discussed within the BPC and pointed out that multiple applicants may submit a renewal for the same active substances. ECHA is willing to discuss this issue in the BPC but would like to have clarifications on the policy context and guidance the work in the committee. Another Member State asked for a strategy to be defined.

ECHA enquired the views of Member States on priorities, on properties that may deserve more attention than others during the renewal and on whether certain substances or some part of the renewal work should be given priority. Member States and stakeholders were invited to send comments by 23 August.

(b) State of play ECHA guidance (on-going consultation, finalised guidance)	For information *CA-July19-Doc.7.2.b*	

This point was not discussed.

7.3. ECHA communications	For information *CA-July19-Doc.7.3*	

ECHA gave explanations concerning the IT systems unavailability for one and a half days in May 2019 and informed the meeting that the problems experienced in the past days with the dissemination website are now solved. Participants were encouraged to report to ECHA any issues they might encounter with the IT systems.

7.4. Update on Court cases T337/18, T347/18, T734/18(R)	For information	

The Commission indicated that the applicant for Court Case T-337/18 and T-347/18 on PHMB (1415; 4.7) asked the Court for a hearing. The Commission also informed to have sent its rejoinder to the Court on Case T-734/18 on empenthrin.

7.5. Overview of national fees for BPR procedures	For information *CA-July19-Doc.7.5*	

The Commission services thanked Member States for the input provided on the level of fees for the various BPR procedures and informed the meeting that an overview document has been prepared and distributed for the meeting. Those Member States that had not yet provided their input were invited to do so, with a view to finalising the overview document, that will be then posted in the library of the public CIRCABC interest group. Following a comment of a stakeholders it was agreed to update the document regularly.

7.6. Update on the detection of DMS in Danish drinking water	For information *CA-July19-Doc.7.6*	

Denmark gave an update on its monitoring of dimethylsulfamid (DMS) in Danish waters, and asked the other Member States to communicate them any information they have about their own national surveillance and the presence of this substance in their waters, as well as about the presence of paints treated with dichlofluanid or tolylfluanid on their markets.

7.7. CA meeting documents commenting: sharing MSs comments with stakeholders	For discussion	

The Commission services informed the meeting that they consider granting access to the accredited stakeholders to the newsgroups section of the CIRCABC restricted interest group, so that they can see Member States' comments on the CA meeting topics and also provide the own comments in the same space. It was reminded that, if this is agreed by Member States, they will have to be mindful of confidential information or personal data when uploading documents. It was also clarified that this will be applied for future newsgroups, meaning that stakeholders will not have access to the archived items.

Comments from Member States were invited until the 23 August 2019.

7.8. AISE event dedicated to the healthcare sector - 18 September 2019	For information	

The AISE representative briefly informed on the healthcare sector event scheduled on 18 September and that will be structured as conference in the morning and visit of an hospital site in the afternoon. The participants were also informed that the invitation to the event will be circulated in the following days.

8. Scope matters		
8.1 Disinfection of garden tools	For discussion and agreement *CA-July19-Doc.8.1*	

The Commission services introduced the topic and made reference to an ongoing Union authorisation procedure of a biocidal product for which one of the intended uses is the disinfection of gardening equipment. The Commission services wanted to consult Members States in order to decide whether the disinfection of gardening tools is to be considered as a biocidal use or a plant protection use. The meeting was informed that the matter will also be discussed in the upcoming Standing Committee on Plants Animals and Food.

The Commission services informed that the evaluating competent authority in the Union authorisation procedure considers the specific use to be a biocidal use, since the disinfection of gardening equipment would avoid possible infections of users that could be caused by injuries while using the equipment. Another competent authority is of the opinion that such use is a plant protection use because the aim would be preventing the spread of plant diseases by disinfecting the gardening equipment.

One Member State stated they had difficulties to understand the specific claimed use. A discussion then followed on the timing of disinfecting the equipment and getting injuries from the use of the equipment. Another Member State pointed out that once the equipment starts being used it is no longer disinfected. Another Member State asked what were the pathogens against which the product was supposed to protect and whether the efficacy of the product was proven. The Chair of the Biocidal Committee pointed out that the matter was discussed at the BPC meeting, where the applicant was asked to indicate specific pathogens but the applicant was not able to do so. One Member State pointed out that the SPC of the product makes reference generally to bacteria and yeasts. Another Member State was of the opinion that more clarity could be brought by also seeing the label of the product.

One Member State indicated that there were actually two points under discussion, namely (i) whether the use in question falls under the BPR or PPPR and (ii) whether such use should be kept in the Union authorisation and in the label or not. As to the efficacy, this Member State pointed out that it had been assessed and demonstrated under the Union authorisation application.

The Chair of the BPC pointed out that the product was intended for both professional and non-professional use and that it was advised to include on the label “disinfection of gardening equipment for human hygiene purposes only”.

Member States were invited to provide comments by 23 August 2019.

9. Enforcement issues		
9.1 Workshop on 19-21 June on fact finding missions	For information	

The Commission services informed briefly the participants about the workshop held on 19-21 June in Grange, based on the draft overview report of the five fact-finding missions. The workshop was held in a confidential setting and a report/summary is currently under preparation.

10. International Matters		
EU involvement in OECD work	For discussion	

The Commission services informed about an upcoming meeting of the OECD Biocides Task Force in September in Korea, where an ECHA representative will be present.

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-July19-Doc.11.a*	

(b) Information from France on recent developments in their national legislation	For information	

France informed about some decrees prepared in France to regulate the way some biocidal products are made available on their market. The Commission services clarified to the attendees that this information to the CA meeting does not substitute the obligations of Member States in relation to Directive 2015/1535, and informed that it had not been assessed whether these decrees should be notified.

(c) Scope issues raised during drafting of efficacy guidance	For information	

One industry association informed the participants that the Efficacy Working Group is drafting several chapters of product-type specific efficacy guidance, among which PT 11 and 12. During the early drafting some scope issues were identified, in that it was not clear whether some uses fall under PT 11, under PT 12 or even under other PTs. The Working Group requested the feedback from the industry association, which is currently preparing a document, that it would want to bring for discussion also in the CA meeting.

Next meetings:

2019 (provisional)

CG	CA and SCBP	BPR Subgroup Forum	BPC	BPC's WG
-	-	-	26 Feb-1 March	
12-13 March	13-15 March	21-22 March	-	
-	-	-	-	
13-14 May	16-17 May	-	-	
-	-	20-21 June	24-28 June	
3 July	4-5 July	-	-	
-	-	-	-	
16-17 September	19-20 September	-	-	
-	-	-	7-11 Oct	
19-20 November	20-22 November	7-8 November	-	
-	-	-	9-13 Dec	