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

MINUTES

81st 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

22-23 November 2018

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THURSDAY 22 NOVEMBER		
Afternoon session		**13:00 – 17:30**

1. Adoption of the agenda	For adoption *CA-Nov18-Doc.1.rev2*	

The following points were added to the agenda under AOB: Unique Formula Identifier as part of the obligations to submit information on hazardous substances to Poison Centres (CLP Regulation), a scope issue submitted by a competent authority, the application of Article 95 and state of play of Court cases. The agenda was adopted.

2. Adoption of the draft minutes of the previous CA meeting	For adoption *CA-Nov18-Doc.2*	

The draft minutes of the 80th meeting were adopted.

3. Draft delegated acts
No item for information or discussion

4. Biocidal products		
4.1. Report from Coordination Group	For information	

The Commission services reported on some issues discussed at the 32nd meeting of the Coordination Group (CG) that took place on the two previous days, together with the seventh meeting of the CG working party on the biocidal product family (BPF) concept.

The CG working party (WP) on the BPF concept has made good progress in order to address the similarity of uses, composition and levels of risk and efficacy. The WP will have its last meeting in January 2019 in order to agree on recommendations to the CG. The CG will then consider those recommendations in March 2019 and forward them to the Commission in order to update the current CA document on the implementation of the BPF concept. The Commission indicated that it will give priority to such update, which could be tabled for discussion in the CA meeting of September 2019. Noting that the proposal would probably need a discussion in at least two CA meetings, the final agreed, revised version would only be available by the end of next year. A key element to be discussed is the applicability of the new CA document, taking into account the pros and cons of the possible options.

The CG is currently discussing two e-consultations that could be of relevance for the CA-meeting. One concerns how to consider whether there are indications that a given coformulant may have ED properties. Another one concerns the assessment of disinfecting by-products.

This matter might also require a policy discussion in the CA meeting on account of its complexity and how it has to be addressed within the legal deadlines for the evaluation of the applications for product authorisation.

The UK CA also informed the CG meeting about the outcome of the comparison of the assessment of a number of PT 21 products under two different models. This outcome will also communicated to the CA meeting in an upcoming meeting.

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-Nov18-Doc.4.2*	

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

4.3. Executive report on product authorisations	For information *CA-Nov18-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-Nov18-Doc.4.4.a.1&2*	

An industry representative indicated that the three years deadline after approval of an active substance included in the Review Programme cannot be respected by applicants because of a delayed authorisation process and asked how this would interact with enforcement. The representative proposed that the evaluating authority inform other authorities about the delays or inspectors could be informed by R4BP3, that could signal that a product is still under evaluation. The Commission services indicated that it is closely monitoring the authorisation process, can predict the authorisations that may be late and will communicate the monitoring results with the relevant authorities. The Commission services indicated that the applicant should have a mean to show that the product is still under evaluation.

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

4.5. Management of product authorisations for *in situ* cases	For discussion and agreement *CA-Nov18-Doc.4.5.a* *CA-Nov18-Doc.4.5.b*	

The Commission briefly introduced a new draft distributed via CIRCABC before the meeting. ECHA clarified that its experts are currently discussing the content of the BPCs working

groups recommendations on in situ to identify which elements should be revised in light of the draft CA note currently under discussion. ECHA indicated that the current planning is that the BPC expert groups recommendations will be updated by the end of 2019 as it will require probably several discussions in the Working Groups. One Member State expressed disappointment about this deadline and recalled that several applications for in situ authorisations have to be submitted early January next year. According to this Member State, applicants and Member States need urgently clear guidelines to properly handle upcoming applications.

Another Member State argued that the text should better explain which part(s) of the in situ generation system will be authorised as biocidal product. This would determine the data that has to be provided by the applicant, as the data requirements should be linked to the biocidal product. Although this Member State recognises the benefits of having information on the whole in situ system, it has to be clarified which type of data can be requested based on the legal setting. According to that Member State, the basic principles should be clearly stated in the text in order to achieve a harmonised approach. Industry representatives added that the policy paper should mainly focus on the output of the devices as that this is key for assessing safety. The organisation of a meeting to inform authorities about the functioning of devices are working was proposed in order to clarify the issue. A Member State recalled that data requirements for catalysts should be addressed in the future ECHA technical guidance.

The Commission services stated that the biocidal product definition specifies that either the precursor(s) or the active substance(s) are authorised as biocidal product in case of in situ generation (under the first and second indent, respectively). However, other information (e.g. on the use conditions, the generation process) is needed in order to have a complete understanding of how the active substance is generated.

An industry representative explained that prospective applicants looking for product authorisation are sometimes not able to comply with the level of requirements for active substance described in draft BPC opinions. The concrete example of active chlorine generated by electrolysis from sodium chloride was discussed. Prospective applicants looking for product authorisation will likely be unable to comply with the level of requirements set in the draft BPC opinion for sodium chloride. Therefore, many existing situ generation systems for the sanitisation of drinking water or disinfection of swimming pool water may not be supported by the relevant product authorisations. One Member State argued that if the conditions set out in the BPC opinion are not in line with in situ systems used in practice, it should be explored whether the opinion could be revised. ECHA explained that applicants are involved in the setting of specifications and approval conditions. Overall, it will be explored whether technical equivalence assessment at product authorisation stage in relation to the specifications set in the BPC opinion for the active substance may address the issue. A more flexible approach to demonstrate technical equivalence for in situ generation systems could be examined on a case-by-case basis.

Two Member States urged the Commission to make progress on the file despite the many comments received at the meeting. According to those Member States, it should be possible to conclude on the parts of the text where a consensus is achievable and to address BPF for in situ in a second step by another CA document.

The Commission services concluded that the text still needed improvement and therefore it was not possible to conclude at the meeting. The specific data requirements should be addressed in the update of the technical recommendations. However, it will be analysed whether the CA document can point out to the type of the data requirements needed. A new

deadline for the submission of comments to the draft posted on CIRCABC for the November meeting was fixed on 16 January 2019. A videoconference with key players might be organised before the March meeting in order to help solving any remaining outstanding issues.

4.6. Use of same trade name in products of different product-types	For discussion *CA-Nov18-Doc.4.6*	

The Commission services briefly introduced this agenda item by referring to document CA-Nov18-Doc.4.6 and thanked those Member States having contributed to the discussion at the last meeting or having contributed during the commenting period. On account of the complexity of the matter, the difficulty to find a robust mechanism to address the issue of different trade names, the need to devote resources to other priority files, the Commission services indicated that no further action will be taken on this matter in terms of developing a harmonised approach. Therefore specific situations or conflicts on trade names should be arranged by the companies and authorities on a case by case basis.

4.7. Article 48 application (ensuring a level playing field with regard to generation of efficacy data for insect repellents)	For discussion and agreement *CA-Nov18-Doc.4.7*	

The Commission services briefly introduced document CA-Nov18-Doc.4.7. A Member State specifically thanked the Commission for having developed the document. Another Member State suggested that developing a more general paper on when and how to apply Article 48 of the BPR would be welcome.

The Chair noted that the document was endorsed by the CA meeting. A Member State indicated an operational reservation as the proposed approach needs to be agreed by the decision body of this competent authority.

4.8. Updated Q&A on how to express the content of the active substance in the SPC	For discussion and agreement *CA-Nov18-Doc.4.8*	

The Commission services briefly introduced this agenda item by referring to document CA-Nov18-Doc.4.8.rev1 (also distributed as a room document), which took into account the outcome of the discussions during the CG-32 meeting. In addition to the formerly discussed Q&A pair, associated stakeholders requested in the CG meeting whether a new pair could be inserted in order to address how the new approach (in line with Commission decision (EU) 2018/1305) would be implemented to on-going applications and already authorised products. By having this information in the same CA document, it would reach applicants in a more efficient manner than through the minutes of the CG. Since CG members agreed with that approach, a new Q&A pair was introduced just quoting the content of the agreed minutes of CG-31.

A Member State suggested a minor editorial change in the title of the second question. With such amendment, the Chair noted that the CA meeting endorsed the two Q&A pairs and

indicated that the Commission services will proceed to adapt document CA-May15-Doc.4.4 – Final.rev3 accordingly and to make it available on CIRCABC.

4.9. Applicability of Technical Agreements for Biocides (TAB) entries	For discussion and agreement *CA-Nov18-Doc.4.9*	

The Commission services introduced this agenda item by referring to document CA-Nov18-Doc.4.9, providing a document of the coordination group (CG-31-2018-20) as agreed by the CG. The Commission, as an observer in the CG, has the duty to ensure communication and consistency with the CA meeting. As a consequence, it should be discussed whether the approach proposed in this document of the CG under type (d) could conflict with the overall approach in document CA-July12-Doc.6.2.d – Final (relevance of new guidance). Type (d) TAB entries consider 'New guidance as new or updated scientific advice is given in order to have a harmonised approach on how the assessment should be done'. For this type of Technical Agreements of Biocides (TAB) entry the CG agreed that the TAB entry should be applied for product authorisation where the reference date of the TAB entry is at least 6 months before the submission of the application. This is not consistent with document CA-July12-Doc.6.2.d – Final that provides 2 years before the date of submission. This is of particular relevance since TAB entries are not subject to further check or revision by the BPC. Moreover, type (d) TAB entries would in most cases also require the generation of new data by the applicant in case the new models or guidance could result in an unacceptable risk or efficacy, since applicants would try to defend the application.

The Commission acknowledged the possibility to deviate from the proposed approach in document CA-July12-Doc.6.2.d – Final on a case by case basis, following consideration by the CG of each entry in the TAB. In order to ensure greater predictability for applicants, consistency with the overall approach in document CA-July12-Doc.6.2.d – Final and to optimise the workload of the CG, the Commission services suggested that for scenario (d) the two years period in document CA-July12-Doc.6.2.d – Final would apply, while keeping some flexibility for the CG to decide, where duly justified, an earlier application of the TAB entry as currently proposed in the agreed CG document. A Member State indicated that the chairs of the WGs and the secretariat of the CG could play a key screening role in order to identify those entries for which an earlier implementation could be suitable and then check with the CG members.

A Member State indicated that the proposed approach for TAB entries, with some flexibility in certain cases, is not fully in line with document CA-July12-Doc.6.2.d – Final either. The Commission services indicated that such document could be revised in order to introduce some flexibility in duly justified cases. It was also added that such revision will be needed in the context of the upcoming review of the CA document on the practical implementation of the BPF concept. From the discussions in the CG working party (WP) on the BPF concept there are indications that the CG may propose an implementation of the new document earlier than the 2-year cut-off would be suitable.

Following a discussion on this proposed approach, the Chair noted the support of the CA meeting to the Commission's proposal. ECHA will inform the CG about the outcome of the discussion in the CA-meeting and invite the CG to amend the document accordingly.

4.10. Guidance on same biocidal products (SBP)	For discussion *CA-Nov18-Doc.4.10.a* *CA-Nov18-Doc.4.10.b*	

The Commission services briefly introduced this agenda item by referring to Article 4b of the Same Biocidal Products Regulation (Guidance on handling applications for authorisation of same products). Since such technical guidance is under development, ECHA wanted to check the policy views of the CA meeting on the two documents tabled for discussion before moving forward.

ECHA introduced document CA-Nov18-Doc.4.10.a, which questions the approach agreed in document CA-May14-Doc.5.1-Final. The key questions is whether a prospective authorisation holders needs to have full knowledge of the composition of the product. Several Member States indicated that it would be better if the authorisation holder (AH) was allowed to know the full composition of the product. Another Member State considered the arguments put forward by ECHA in the document as not being robust enough to change the currently agreed approach. A Member State also added that the BPR confers clear responsibilities to the AH, which have to be fulfilled irrespectively of knowing the full composition or not.

Industry representatives indicated that changing the formerly agreed approach will have a direct effect on applications for SBPs, particularly for consortia, where the basis of the cooperation is that only the consultant knows the full composition of the biocidal product family. It was stressed that the information on the composition of the product is available to the competent authority. A Member State indicated that this change of approach would also impact on SMEs.

The Commission services indicated that the key question to be addressed in the ECHA guidance is how CA can confirm, when receiving an application, that there is evidence that the products are identical on the relevant aspects, including composition (as per Article 2 (b) of the SBP Regulation). In that respect, it is important to analyse who is the applicant for the SBP:

- Where the applicant is the AH of the reference product, there is no issue, since he knows the full composition.
- Where the applicant is a consultant, there is no issue either, since the consultant may know the full composition.
- Where the applicant is the prospective AH of the SBP and he is also the manufacturer of the SBP, there is no issue, since he knows the full composition for manufacturing purposes.
- Only where the applicant is the prospective AH of the SBP and he is not the manufacturer of the SBP, there could be an issue.

In the latest case, it has to be explored whether the above-mentioned evidence can be made available to the relevant CA in a way that, ensuring compliance with the SBP Regulation (i.e. identity is confirmed), companies may still have some flexibility depending on the bilateral agreement reached between the AH of the reference product and the prospective AH of the SBP.

ECHA briefly introduced CA-Nov18-Doc.4.10.b, which was very much related to the main discussion point on the previous document. The Commission services reiterated that "who" is the applicant for the second SBP is an important element. Knowing that a letter of access will always indicate who is the data owner, again the bilateral agreements between the AH of the reference product and the prospective AH of the SBP would play a key role (e.g. whether the AH of the reference product allows the AH of the first SBP to give access to the data supporting the first SBP to another applicant for the purpose of authorising the second SBP).

The Chair invited Member States and ASO representatives to submit written comments by 16 January 2019.

4.11. Reports from Member States on the authorisation of creosote containing products	For information	

The Commission services briefly introduced this agenda item by referring to the provisions in Commission Directive 2011/71/EU (approval of creosote as active substance), which require that "*Those Member States authorising such products in their territory shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted. The Commission will make these reports publicly available*".

According to the information available in the Register for Biocidal Products (R4BP), 18 Member States have already granted product authorisations, but only 10 reports have been sent to the Commission. At the same time, a number of applications are still on-going, which should be concluded as a matter of priority.

As required by Directive 2011/71/EU, the Commission will list those Member States having authorised products and make publicly available the received reports of Member States early in 2019. Therefore, the Chair encouraged those Member States that had not yet submitted the above-mentioned reports to do it as soon as possible.

FRIDAY 23 NOVEMBER

Morning session		**11:30 – 13:00**

5. Active substances		
5.1. Progression of the review programme on active substances	For information *CA-Nov18-Doc.5.1*	

The Commission services presented an overview of the progress of the work on the review programme, highlighting that the figures in the overview take into account the in-situ redefinition and food&feed inclusion in the review programme currently under adoption. The Commission services also reminded about the actions agreed at the previous CA meeting. As indicated previously, progress is required on backlog reports which were submitted by

Member States before 1st September 2013 and for which no opinion has been yet delivered by ECHA's BPC.

The status report was noted by the CA meeting.

5.2. Progression of the renewal process of approval of active substances	For information *CA-Nov18-Doc.5.2*	

The Commission services presented the update of the overview of on-going and future renewals, and highlighted that applications for propiconazole and tebuconazole were submitted since the last CA meeting. In addition, the evaluating CA for indoxacarb informed the Commission and ECHA and it will perform a full assessment: consequently, an extension of the current duration of approval will be necessary. To answer to a question of a Member State, it was reminded that Member States must take similar national decisions to extend the duration on the concerned authorisations once the extension of the duration of the approval is adopted, as the Commission decision only covers the approval of the active substance (not the authorisation of biocidal products).

The status report was noted by the CA meeting.

5.3. Management of Annex I	For discussion and agreement *CA-Nov18-Doc.5.3*	

As a follow-up from the last CA meeting, the Commission services thanked the Member States having sent comments, and presented a proposal for an update of the current approach concerning the management of Annex I to the BPR. The revised document clarifies the proposals for agreements by the CA meeting, and addresses the comments received from Member States.

As regards in situ generation (see paragraph 12 of document CA-Nov18-Doc.5.3), the CA-meeting agreed that the consistency with the approach followed in the review programme and approvals should be maintained. This implies that an entry in Annex I does not cover the in situ generation of an active substance unless explicitly mentioned in the Annex. Companies may request the Commission to amend Annex I in order to include specific in-situ generation cases.

With regard to the category 6 of Annex I, a Member State considered that the limitation to the product-type having generated the inclusion into Annex I should be maintained for the concerned substances, as this Member State considered that the precise use of the substance could constitute an "equivalent level of concern" to the hazard properties mentioned in Article 28(2)(a) to (c). However, the other Member States considered that the criteria of Article 28(2) are only linked to hazard properties of the active substance. The proposal in the draft document (see paragraphs 16-19 of document CA-Nov18-Doc.5.3) was supported by the CA meeting with the exception of one Member State.

The CA-meeting agreed that in principle at the expiry of the approval of active substances, it is preferable not to have the active substance both approved and listed in Annex I (see paragraph 21 of document CA-Nov18-Doc.5.3).

As regards the management of substances currently listed in category 6 of Annex I, it was agreed that only an Annex I amendment may be necessary to maintain their use when their parallel approval expires: on a case-by-case, companies may have to take action to request the amendment of the current Annex I to allow the other uses covered by the approval currently not covered by the conditions listed in Annex I.

For ZETDA, the proposal in the draft document was agreed.

Regarding the case of carbon dioxide and nitrogen, two options were presented. Although the draft document proposed to follow option 1 (no conditions in Annex I), the Commission services indicated to be open to discuss a compromise solution working along the option 2 by setting appropriate conditions. Several Member States supported option 1 considering that the safety of the specific use of the substance can be ensured at the product authorisation stage. One Member State considered that nitrogen should not be in the scope of the BPR. Several Member States considered that having the substance listed without conditions will encourage innovation. A Member State pointed out that it is not always easy to make a distinction between products eligible for the simplified authorisation procedure and products not being eligible and therefore having to be authorised via the normal authorisation procedures. The Commission services pointed out that an authority can consult the Coordination Group to get the views of the other Member States whether a product is eligible for simplified procedure. This Member State, supported by two other Member States, supported to apply option 2 noting that carbon dioxide and nitrogen were part of the few substances for which strict limitation was set in the approval decision for the product-types reviewed (i.e. use by trained professionals). These Member States underlined that professionals require intensive training in order to work safely with these substances. According to those Member States no Annex I inclusion should be made for substances when it is difficult to set suitable conditions for the simplified and normal authorisation procedures. With the exception of three Member States, the CA meeting supported option 1 and the draft proposal in the document was agreed.

With regard to the substances that the BPC identified to be eligible for inclusion into Annex in their opinions and which were approved but not included in Annex I ((see paragraphs 38-45 of document CA-Nov18-Doc.5.3), the Commission services clarified that the three substances in paragraph 39 are provided as examples and would like to discuss the general principle. Following a comment of a Member State it was agreed to delete the example of citric acid in paragraph 39. The CA meeting supported option 1 and concluded to take action to include these substances identified as eligible for Annex I without further delay. The Commission services noted the support for option 1 and remarked that actions to get the substances in Annex I may not be taken quickly, as this depends on the workload and priority setting for next year. It was also clarified that an Annex I inclusion will be proposed directly by the Commission for upcoming ECHA opinions on active substances which will be identified by the BPC to be listed in Annex I.

With the points as agreed during the meeting, the document was endorsed and will be uploaded in the "finalised documents" folder.

5.4. Post-approval data on active substances	For discussion	

Following some alerts given by ECHA, the Commission services expressed their concerns on the flexible approach followed since the beginning of the review programme, implying in practice to approve substances although some limited data (e.g. analytical methods) is missing and to include the condition in the approval that the lacking data have to submitted within a certain deadline. It seems that the flexible approach does not operate properly, as in many cases data is not submitted 6 months before the date of approval by former participants and/or the related issue is not solved before the product authorisation process starts. It appears that biocidal products have been authorised even in absence of the data.

In addition, despite the requests made by the Commission services on multiple occasions to authorities and participants since the beginning of the operation of the BPC in 2014, it still remains very frequently the situation that data are reported as missing in the section 2.5 of the BPC opinions for basic information. This situation is considered no longer viable. Consequently, actions must be taken to ensure that all data is present in the dossier on an active substance as set in the BPR. At the moment the Commission services are considering various options, including taking non-approval decisions based on the fact that not all data required in the BPR has been submitted in the application for approval.

This topic will be discussed in the workshop organised by ECHA on active substances approval process in the beginning of 2019.

6. Treated articles
No item for information or discussion

7. Horizontal matters		
7.1. ECHA communications		
(a) Biocides dissemination: publishing more information on biocides	For information	

ECHA gave a presentation explaining the main features of the new dissemination website. Several Member States asked questions on the process and whether technical guidance will be developed to determine whether certain information should be considered confidential and in order to ensure a harmonised approach in the Union. ECHA indicated to propose in the course of next year a guidance document.

Afternoon session		

7. Horizontal matters (cont'd)		
7.2. ECHA guidance		
(a) State of play ECHA guidance (on-	For information *CA-Nov18-Doc.7.2.a*	

going consultation, finalised guidance)		

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

(b) Priority setting for developing ECHA guidance	For discussion *CA-Nov18-Doc.7.2.b*	

The item was not discussed. ECHA colleagues stated that a document for discussion will be submitted for the next meeting.

(c) Technical equivalence assessment and Good Laboratory Practice	For discussion and agreement	

The Commission services introduced this agenda item by referring to the comments provided by several Member States and uploaded on CIRCABC. Taking into account the relevant industry representative was not present, the discussion will take place in the next CA meeting.

7.3. Outstanding Helpex questions	For information	Closed session

The discussion took place in a closed session.

7.4. Research use only products	For information	Closed session

The discussion took place in a closed session.

7.5. Concerns related to invalid study on one active substance	For discussion	Closed session

The discussion took place in a closed session.

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

A representative of DG ENV provided an presentation on IPCHEM.

7.7. Update of Annexes to BPR	For discussion *CA-Nov18-Doc.7.7.a&b*	

The Commission services thanked the Member States for their comments and presented a revised version of the note bringing together all requests for changes to the annexes II and III of the BPR. It was highlighted that the intention is to present to the March 2019 meeting a

draft delegated act. The Commission services clarified that the changes suggested by ECHA concerning the use of historical human data will be not further followed up given the little support received from the Member States.

The transitional period for the applicability of the amended provisions is an important issue that must be carefully addressed. The Commission services considered that a distinction should be made between the provisions in relation to EDs and the others. The Commission considers that the provisions in relation to the implementation of the ED criteria should apply immediately taking into account the legal obligations of the BPR. Most of the other items proposed for amendment reflect the current state of science and therefore could become applicable rapidly. Member States and industry were invited to give their opinions. The Commission services acknowledged the high technical level of the amendments and therefore a discussion in the CA-meeting was not found opportune.

Two Member States called for in-depth discussions on ECHA positions regarding the points raised by several Member States (mainly considering ED provisions and toxicological endpoints). According to these Member States, it is very important that Member States should be given the possibility to explain their views. Following a discussion on the procedure how to discuss the comments with the involvement of all relevant experts, it was agreed to organise a Webex meeting involving all countries that submitted substantial comments. This meeting will take place mid-January 2019. In order to prepare this meeting and also focus the discussions on outstanding issues, the Commission services will prepare a fourth columns document gathering all the comments received from Member States and industry and the preliminary views of ECHA. Member States will be asked to select their main issues for the Webex.

One Member State requested the opportunity to provide some more comments and expressed concerns about possible delays in the review programme if additional data (particularly on EDs) have to be generated and assessed.

The Commission services pointed out that the internal procedure for adopting the draft delegated act should start before the end of January in order to be able to consult the CA in March on a Commission services document. Therefore the deadline for the submission of further comments was fixed on 30 November 2018.

7.8. 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 seventh technical expert seminar, i.e. the transfer of ongoing applications for mutual recognition in parallel from the UK to another CA, the communications sent by the Commission services and ECHA to the affected applicants via R4BP, as well as some IT arrangements linked to the UK withdrawal.

On a more general note, the Commission services informed the meeting that an updated Q&A document related to the UK's withdrawal from the EU with regard to the biocides sector was made publicly available on 23 October. It is now available in a centralised repository where all Commission notices and Q&A documents are available (see https://ec.europa.eu/info/files/qa-biocidal-products).

7.9. EU wide forecasting of applications	For discussion *CA-Nov18-Doc.7.9*	

The Commission services introduced this agenda item by pointing out that a reliable forecast would allow authorities to adapt their resources timely. The meeting participants were invited to provide their views, in particular on the 4 points included in the note, before 16 January 2019. Based on this feedback will be discussed whether the development of a EU-wide forecast system will be explored.

7.10. Rules of procedure of the expert group	For discussion	

The Commission services indicated that currently no rules of procedure exist for this expert group. Following a discussion on advantages and disadvantages of establishing rules of procedure the CA meeting concluded not develop rules of procedure.

7.11. Update on EC policy on EDs	For information	

The Commission services updated the meeting participants on the state of play on endocrine disruptors referring to Communication adopted by the Commission 'Towards a comprehensive European Union framework on endocrine disruptors' and the upcoming training organised for authorities on evaluating ED properties in the context of Better Training for Safer Food.

7.12. Presentation from JRC on EDs and animal testing	For information	

A representative of JRC presented their activities on endocrine disruptors and animal testing.

8. Requests for opinions
No item for information or discussion

9. Enforcement issues		
9.1 Conference on REACH, CLP and BPR enforcement	For information	

The Commission services updated the meeting participants on the outcome of the conference on BPR enforcement that took place on 13 November and indicated that the report and recordings are available on the conference webpage: https://ec.europa.eu/growth/content/2nd-conference-reach-clp-and-biocides-enforcement_en.
It was also mentioned that the sixth meeting of the BPR Subgroup (BPRS) of the Forum took place in Brussels on the day before the conference and, as main highlight, it was reported that

the BPRS decided to join the Forum REF-8 project targeting online sales by preparing a dedicated module.

9.2 Fact finding missions: update	For information	

The Commission services updated the meeting participants on the state of play of fact finding missions. It was pointed out that the reports of the fact-finding missions are publicly available on http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm and that currently the overview report is being drafted with a view to having it published at the beginning of next year. The meeting was also informed that next year (tentatively in June) a workshop will be organised in Grange, for which the competent authorities will be invited.

10. International Matters
No item for information or discussion

11. AOB		
(a) List of Competent Authorities and other Contact Points	For information *CA-Nov18-Doc.11.a*	

(b) Interactions between BPR and Annex XVII of REACH on creosote	For discussion	

A Member State put forward a question whether railway sleepers could be placed on the market that fulfil the requirements of REACH but not the conditions in Article 58 of the BPR concerning treated articles. The CA meeting indicated that the railway sleepers have to respect Article 58 of the BPR.

(c) Announcement of a workshop on preservatives by AISE and CEPE	For information *CA-Nov18-Doc.11.c*	

AISE announced the initiative to organise a workshop on preservatives in 2019. It was proposed to plan the workshop on 15 May between the CG and CA meetings. The CA meeting agreed to have the CA meeting scheduled on 16-17 May.

(d) The application of Unique Formula Identifier for biocidal products		

In relation to Unique Formula Identifier for Poisson centres a Member State asked how to address this requirement in relation to biocidal products. Another participant asked how it in particular should be addressed in relation to Biocidal Product Families. Another question

concerned the position of the Same Biocidal Product. The Commission services will further investigate the impact of the Unique Formula Identifier for biocidal products and will report back to the CA meeting.

(e) Scope question on technology that control organisms on surfaces of materials	For information	Closed session

The discussion took place in a closed session.

(f) The application of Article 95 to redefined active substance		

Following the redefinition of an active substance, a Member State enquired how to apply the provisions of Article 95 of the BPR and what were the requirements so that they can grant its national authorisation during the transitional period.

The Commission services indicated that they thought that the matter had been already clarified in the past by ECHA in a presentation, and that the provisions of Article 95 would not apply for the re-defined entries until the applications for approval for these entries would be submitted and validated. However, they agreed to further check and confirm it for the next CA meeting.

(g) Court cases		

The Commission services provided an update concerning Court Case T-337/18 and Court Case T-347/18 where the participant for PHMB (1415; 4.7) lodged a request for suspension and for annulment of the decisions adopted on its active substance. The Commission informed that the Court dismissed the requests for suspension of the decisions, and informed that the main proceeding concerning the requests for annulment of the decisions were still on-going.

The Commission also informed to have received a request from comments on a preliminary ruling requested by a Dutch Administrative Court for Trade and Industry concerning a bacterial product and the scope of the BPR (case C-592/18).

Next meetings:

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 May	16-17 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	