

EUROPEAN COMMISSION

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

MINUTES

87th 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

5-7 February 2020

| 1. Adoption of the agenda | For adoption <i>CA-Feb20-Doc.1</i> | |
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The following points were added to the agenda: (i) updates on the new organic farming Regulation and (i) explanations of consequences on the BPR implementation of the Withdrawal Agreement and transitional period following the withdrawal of the UK from the European Union and. The agenda was then adopted.

| 2. Adoption of the draft minutes of the previous CA meeting | For adoption CA-Feb20-Doc.2 | |
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The draft minutes of the November CA meeting were adopted.

| 3. Draft delegated acts | | |
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| 3.1 Amendment of Annexes II and III to the BPR | For discussion <i>CA-Feb20-Doc.3.1.a and b</i> | Scheduled for Thursday morning 6 February |

The Commission services explained that the Commission interservice consultation was closed on 3 February 2020. It also informed about the main changes to the text introduced by the interservice consultation compared to the version presented at the September CA meeting. The draft legal text will be available for comments for one month under the feedback mechanism. A link to the online consultation will be provided to the participants of the CA-meeting. It is anticipated that the draft delegated act will be adopted by the Commission before the summer and, following scrutiny by the EP and Council, the act could be published in the third or fourth quarter of 2020. The Commission services indicated that the Council and the EU Parliament were invited to attend the meeting in accordance with the interinstitutional agreement on better law making.

An NGO requested to specify in the act the possibility to combine studies in order to reduce animal testing. According to this NGO, combination of studies under REACH is sometimes not requested as it is not a legal requirement. A concrete proposal will be submitted. Moreover, for the genotoxicity endpoint, the NGO proposed to collect germ cells from in vivo somatic cell tests and store them for possible subsequent tests. The commission services responded that ECHA was already consulted on this particular point. The ECHA answer is reproduced below for the sake of transparency.

'ECHA already recommends under REACH dossier evaluation that germ cells samples are stored to be analysed in case of positive somatic cell results. This issue can be further described in guidance'

An industry association argued that the extended one generation reproductive toxicity study (EOGRTS) with an extension to a second generation will not provide conclusive data on the determination of the endocrine disrupting properties of substances. Moreover, according to the association, the capacity and expertise of laboratories capable of performing such tests in the EU are limited. Finally, the tests to be performed for the neurotoxicity endpoint should be

clarified and references to OECD guidelines should preferably be included. A proposal will be made in writing. ECHA explained that a survey on laboratory capacity is on-going.

The Commission services answered that the wording of the EOGRTS has been extensively discussed between the Member States, the Commission services and the agencies. Industry representatives were associated in these discussions. The outcome was to require a second generation to determine the ED properties of a substance.

An NGO asked whether an analysis of the EOGRTS data submitted under REACH could be conducted prior to the revision of the BPR annexes. This could help to understand the benefits of having EOGRTS as data requirement in the BPR for the ED assessment. ECHA and the Commission services explained that limited data are currently available on the use of EOGRTS under REACH. At the moment the first EOGRTS studies are being submitted.

An industry association called for a coherent approach between REACH and the BPR. As amendments to the REACH data requirements are being discussed, it was suggested to postpone the amendment of the BPR Annexes until an agreement is reached under REACH. The Commission services pointed out that the ED criteria are already applicable for biocides and therefore there is a need to have fit for purpose data requirements.

The Commission concluded by mentioning that the intention is to present a final draft at the May CA meeting that would include the outcomes of the feedback consultation.

4. Biocidal products

| 4.1. Use of trivial name of the active substance on the product label For discussion and agreement | |
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The Commission services introduced the item by indicating that they analysed with colleagues responsible for CLP and REACH whether those legal frameworks could provide a methodology to set a trivial name or common name for substances. An industry association mentioned they created a labelling guidance for their members, where they indicate the ordering principle of using the names as established by the CLP, and that they would send this guidance to the Commission services. Another industry association pointed out that it could be confusing to the public to have two names on the label and suggested to include the relevant names at active substance approval. The Commission services indicated that they may present a paper for the next meeting.

| 4.2. Report from Coordination Group | For information | |
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During the CG-39 meeting four referrals were tabled for discussion and three referrals were briefly introduced to the participants; an agreement by consensus was reached for two products and those products can be authorised, an agreement was not reached for two referrals to the CG and those will be referred to the COM. Three formal referrals will be further discussed in a teleconference.

One e-consultation on risk assessment for non-professional users PT21 was briefly introduced. This e-consultation will be further discussed during the CG-41 meeting.

One e-consultation was discussed in open session: identification of co-formulants in relation to endocrine-disrupting properties by MS. Stakeholders can will provide comments by 2 March.

| 4.3. Executive report on referrals to the Coordination Group in accordance with Article 35 of the BPR |
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The participants were invited to take note of the report uploaded in CIRCABC.

| 4.4. Monitoring report on mutual recognition procedures For information | |
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The Commission services indicated that it is the intention to have the relevant data from ECHA soon and to present a document to the next CA meeting.

| 4.5. Application of Article 35(2) of the BPR in relation to proposal by reference Member State not to grant an authorisation | For information <i>CA-Feb20-Doc.4.5</i> | |
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The Commission services introduced the item. One Member State enquired if a referral can be raised in the case in which the reference Member State restricts the authorisation only to some of the uses. It was clarified that in this case a referral can be raised concerning the authorised uses, but not the non-authorised uses. The Commission services took note of the comments of some participants that they would have preferred to have the possibility to trigger a referral if there is a disagreement on not granting an authorisation.

| 4.6. BPF concept : Q&A annex | For discussion and agreement <i>CA-Feb20-Doc.4.6</i> | |
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The Commission services presented a revised draft for the Q&A Annex based on the outcomes of the last CA meeting and inputs received via CIRCABC.

An industry association put forward a proposal to allow applicants and data owner to agree on a letter of access that would cover only specific studies or specific products in the BPF. The industry association explained that this wording is particularly helpful for consortia where several companies formulate products based on the same active substance(s) coming from different suppliers. Three Member States expressed strong reservation about this proposal because products are not evaluated individually in the biocidal product family but the family is evaluated as a whole. Moreover, the management of different letters of access would be challenging for the competent authorities. In case of same biocidal product applications, a specific letter of access for a specific product could be required, but not in the case of a family. Based on the discussion, the Commission concluded that only the first paragraph of the answer to question 7 will be kept.

An industry association requested the addition of category (3)i to use #8 on top of use #2 as the pattern category described in recital 50 of the guidance covers both uses. The Commission services will clarify the point with experts in ECHA and will inform the industry association accordingly.

Lastly, an industry association came back with a request to allow applicants to include different PT14 bait formulations within a biocidal product family. A Q&A covering this point was included in the former guidance of 2014 but was then removed as it may be difficult for

the applicant to demonstrate that all bait formulations in the family would have the same backbone composition which in practice would mean that the criteria of similarity of composition is not met. However, one Member State recognised that it would up to the applicant to demonstrate that the criteria of similar composition of a family will be met by using different bait formulations. On a more general note, the Commission services confirmed that it has never been the intention in the revision of the BPF guidance and the BPF Q&A to exclude PT14 products from the BPF concept.

| 4.7. BPF | For discussion | Closed session |
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A discussion took place in closed session.

5. Active substances

| 5.1. Progression of the review programme on active substances | For information <i>CA-Feb20-Doc.5.1 CA-Feb20-Doc.5.1.a</i> (restricted) | |
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The Commission presented the status report concerning the work performed in 2019, as well as the overall progress of the review programme. In particular, the Commission noted that only 7 draft reports were submitted in 2019 by Member States, only 10 opinions were delivered by ECHA, and only 8 decisions adopted related to the review programme at EU level. This is largely insufficient to conclude the review programme by the end of 2024 and meet the objectives of the BPR.

The Commission further invited Member States to implement the action already agreed in 2018 to finalise the review programme, and the future actions of the ECHA Action Plan that will be agreed under item 5.2 of the agenda.

| 5.2. Action Plan on active substances Review Programme | For discussion and agreement <i>CA-Feb20-Doc.5.2.a</i> | Scheduled for Thursday morning 6 February |
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ECHA introduced shortly the update of its Action Plan following the comments received after the last CA meeting.

Two Member States indicated that they would support a postponement of the renewal of approval process of active substances, due to the workload already existing for the review programme and first approval processes. The Commission services noted the request, but noted also that there does not seem to be a direct basis in the BPR to postpone renewals of active substances, and expressed concerns of creating another "review programme" for renewals, that may end up in the same situation as the current review programme for the first approval process. The Commission services recalled that Member States have to ensure having proper resources to implement the BPR, and that Member States can set up fees at the appropriate level to finance their activities.

Another Member State enquired about the practicalities to use external experts as mentioned in the Action Plan. ECHA clarified that it has its own limits in the help it can provide to Member States and therefore will prioritise its support. The support of ECHA should be seen as bridging the gap between hiring and training new experts by MSs. ECHA pointed out that for hiring external experts it has to follow rules of public procurement for hiring consultants. Those consultants can be from public or private entities and underlined that it will be careful to avoid potential conflict of interests in case external experts are involved. The Commission services informed that they are also exploring the possibilities for funding to help Member States to make progress in the evaluations both under the BPR and the Plant Protection Products Regulation.

One Member State proposed to share its experience in assessing the same substance under the BPR and the Plant Protection Product Regulation (PPPR), and underlined the need for coordination between frameworks and agencies (ECHA-EFSA). ECHA stated that both competent authorities for BPR and PPPR are involved. It is important to identify issues as soon as possible so timelines and responsibilities can be discussed between authorities, EFSA and ECHA. The Commission services stressed the importance of the concept of 'one substance, one assessment'.

An NGO expressed concerns about the delays in the review programme as the end-users are bearing the burden, and wondered why this situation and delays seem to be accepted and considered as a normal situation. The NGO expressed concerns that biocides are still placed on the EU market without their properties and risks being assessed during the transitional period in most Member States. The Commission services stressed not to find the situation acceptable. The Commission services pointed out that it expresses its concerns on the progress on the review programme at each CA and ECHA BPC meetings, and agreed with the NGO that the situation is not acceptable. If civil society can raise the level of alertness in Member States, the Commission services would support this.

One Member State underlined that it would like to have the peer review under the BPR and the CLP process on exclusion substances taking place in parallel, and that it should not be necessary to wait for the RAC opinion on the classification of the substance before the peer review starts under the BPR, as currently is the situation. This Member State stressed that the BPR assessment report has to be updated if the classification is much delayed because of new guidance becoming applicable. It further outlined that processes under the PPPR are better aligned with CLP compared to biocides. The Commission reminded that the previous CA agreement to have the RAC opinion on exclusion substances before peer review would start was established in order to ensure certainty during the BPC peer review, also noting that knowing if a substance is a CMR has an impact on how the peer review is performed (i.e. a public consultation is run at the beginning of the process on exclusion substances). It also avoids having conflicting conclusions between the RAC and the BPC, and the need to amend the BPC opinion in case the RAC does not follow the proposal of the evaluating CA. The Commission services indicated to be open for more flexibility on this point, noting however that the RAC opinion has to be available before the BPC concludes on a substance. The Commission services further highlighted that the previous situation was completely unsatisfactory under the PPPR, as no CLP dossiers were submitted by Member States at all. The current step under PPPR is one step to improve the process. The Commission agreed on the need to improve the coordination between BPR and CLP, and already asked ECHA improvement on the matter, in particular on the time required to deliver a CLP opinion.

Another Member State indicated it was not satisfied by the answers provided by ECHA to its comments, in particular on how to handle data gaps in applications submitted under the BPD, which contained other waiving possibilities and data requirements. The Commission services reminded that this issue was discussed in 2015, and that it was agreed at that time that

evaluating CAs have to request the missing data to companies, especially when these are related to the assessment the exclusion criteria which are Core Data Set in the BPR. Article 6(2) of the BPR also states that sufficient data must be submitted by the applicant in order to allow the assessment of the exclusion criteria. The concerned evaluating CAs should reject the application if applicants do not submit data requested, using the provisions set up in the review programme in particular (Article 11 of Regulation 1062/20104). The Commission services is ready to support Member States on the matter and to handle the fall out, as done in previous cases. ECHA indicated that it is happy to discuss with the Member State a strategy for this specific situation.

Another Member State underlined that most dossiers do not contain a full dataset to assess endocrine disrupting properties (ED) as required by the EFSA-ECHA guidance, and suggested to have a pragmatic approach and to decide on the available information, in order not to block the whole review programme. It also requested the support of ECHA in such cases during the discussions at Working Group (WG) and BPC levels. ECHA agreed to have a holistic and pragmatic approach; however would not favour to rush to conclusions in the assessment report as normally no additional data could be requested during the peer review phase, and therefore preferred to have early WG discussions on ED assessment before an evaluating CA submits its draft report. The Commission services pointed out that moving slowly can also trigger further problems and noted that the assessment of ED properties is a specific case, where it has been recognised in the 2018 CA guidance that further data on ED can be requested by evaluating CAs during the peer review phase.

Although not blocking the adoption of the Action Plan, an industry association asked ECHA to further analyse the rules agreed for the applicability of new guidance during the evaluation of active substance, which in their view can also contribute to delays and complications. ECHA indicated to have reservations on the matter, considering that most guidance on active substances was developed to solve issues and make progress on the assessments, but agreed to further analyse the request.

The Commission services asked Member States to start implementing the actions proposed by ECHA and update if necessary. ECHA pointed out that they will contact Member States each month to be informed about the problems the authority is facing and the support that is needed. Member States are asked to be prepared for this monthly dialogue.

The ECHA Action plan was supported by Member States and endorsed.

| 5.3. Renewal of active substances already meeting an exclusion criterion | For discussion <i>CA-Feb20-Doc.5.3</i> | |
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The Commission services presented the stage of discussions with Member States on how to streamline the renewal process of active substances already known to meet the exclusion criteria.

| 5.4. Progression of the renewal process of approval of active substances | For information <i>CA-Feb20-Doc.5.4</i> | |
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| approval of active substances | CA-1'e020-D0C.3.4 | |

The Commission services presented the status report on the applications for the renewal of approval. It reminded that the evaluating CAs must inform ECHA and the Commission, within 90 days of acceptance of the application by ECHA, whether it intends to perform a full or limited evaluation. In that respect, it asked the evaluating Member State for acrolein to inform the Commission quickly, as it seems very likely that the Commission will have to

prepare a decision to extend approval of this substance (expiry of approval is on 31 August 2020).

| 5.5. Free radicals generated from hydrogen peroxide | For discussion and agreement <i>CA-Feb20-Doc.5.5</i> | |
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ECHA presented its revised proposal to consider free radicals generated from hydrogen peroxide as a technology already covered by the approval of hydrogen peroxide.

One Member State indicated to have difficulties in following ECHA's reasoning, as in previous cases separate applications were requested for in situ and non-in situ forms of an active substance. Another Member State supported ECHA's position, as hydrogen peroxide is naturally degrading into free radicals. ECHA also noted that this case is specific.

The other Member States who intervened supported ECHA's position on the matter. One Member State further proposed that the different sources of free radicals produced could be managed via the submission of a technical equivalence dossier at the product authorisation stage. However, ECHA considered that this is not a matter of "technical equivalence" as defined in the BPR, as in the present case the active substance remains hydrogen peroxide.

The representative of the applicant indicated that it would be difficult to quantify the radical species, agreed with ECHA that the technology and the risks will have to be assessed at product authorisation, and indicated that the chemical equilibrium is shifted constantly as in other biocidal products.

A Member State enquired, how it can be ensured when adding energy to the system via electrolysis that no other radical species or substances would be formed (e.g. would ozone be formed?). The applicant answered that the energy provided by the electrolysis system (around 17kV) would not be sufficient to form ozone. ECHA answered that free radicals are formed during the use of hydrogen peroxide, and that the electrolysis system would only increase the degradation of hydrogen peroxide in radicals during the use. The Member State kept reservations on the proposed approach by ECHA and asked that a sentence in the document asking to manage similar cases in the same manner is removed from the document.

The Commission services noted that consistency will have to be kept in mind if similar cases appear in the future.

With the sentence referred above removed, the approach followed by ECHA was supported by the CA meeting. It was agreed that the hydrogen peroxide is the active substance in this technology.

| 5.6. Availability of in-can preservatives and way forward For discussion an CA-Feb20-Doc.5. | |
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ECHA indicated that following recent contacts with an industry association, they suggested to consult the CA meeting on several questions relating to the use of in-can preservatives in treated articles (e.g. water-borne paints). Given the sensitising effects of such preservatives, it is important to ensure that the exposure to such chemicals is minimised for the general public. Before taking any decision on possible risk mitigation measures or any scientific approach to assess the risks of sensitizers in paints for the population, the agency wanted to consult the CA for its opinion on some policy aspects.

A few Member States raised questions about the enforceability of wearing gloves. One Member State indicated that it could accept it.

The Commission services reminded that gloves were accepted as a risk mitigation measure for antifouling paints although the situation of antifouling paints is very specific and risks mitigation measures for antifouling should not be automatically translated into similar provisions for domestic paints.

One Member State proposed to look at the expected level of protection by the authorities, in particular whether the aim would be to protect people from being sensitised and/or protect people already sensitised. This Member State suggested first to characterise the risks of sensitizers in paints and secondly to discuss proper risk mitigation measures according to the objectives.

For an industry association the main question is to know whether a quantitative risk assessment of sensitizers, and in the present case preservatives in paints, could be performed. The main industry objective is to avoid strict restriction at the substance approval stage and be allowed to demonstrate safe use at the product authorisation. In addition, the association informed that some ingredients in the paint could reduce the skin sensitizer potency of preservatives. Finally, the industry association informed that paint imports are very limited, which means that paints, being in most cases treated articles, are mainly manufactured in the EU. Companies will apply for the authorisation of preservative biocidal products so that they can be used by the EU paints manufacturers. Adding restrictions in the approval of the active substance to ensure the safety of imported treated article is therefore not relevant in this particular case.

The agency informed that there is currently no agreed method for a quantitative risk assessment of sensitisers. It could take years before such methodology is in place across different chemical sectors. Therefore, the agency proposed to introduce a simpler approach to mitigate the risks i.e. the wearing of gloves.

A Member State argued that it is important to demonstrate if there is a risk or not before considering the need for risk mitigation measures and taking a policy decision. Methodologies exist and are applied in other legal frameworks. It would be interesting to know whether such approach is pertinent also for articles treated with biocides.

The Commission services also highlighted that there is no restriction under REACH banning or restricting the use of general chemicals products classified as sensitisers, or treated articles containing them. There are on-going discussions under REACH on the matter. Biocides CAs should keep this in mind when reflecting on how to deal with sensitizers under the BPR. An industry association pointed out that for cosmetics a quantitative risk assessments is being applied.

It was agreed that the agency would analyse the possibilities to develop a quantitative risk characterisation for sensitisation. Member States and industry are invited to proactively support the agency in this task. Information from other regulatory areas (e.g. REACH, Cosmetic) should be investigated. The agency should report to the CA on the state of play during the last meeting of the year.

The agency announced that opinions from colleagues working in other regulatory frameworks will be taken into account. Preliminary discussions shows that, for the time being, there is no agreed consensus on a methodology to perform such quantitative risk characterisation.

| 5.7. In-situ generated nitrogen: Article 55(3) derogation | For information | |
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The Commission services updated the participants on the status of the process related to the application for an Article 55(3) derogation from Austria for in-situ generated nitrogen.

A short summary of the input received during the public consultation held between 19 November 2019 and 18 January 2020 was presented. Almost 1,500 comments were received from individuals, cultural institutions (e.g. museums, public libraries, archives), academia and other organisations. Of the comments received, three were not in favour of a derogation, while the others expressed support for a derogation. Many contributors submitted the petition letter that had been made available by ICOM/ICOMOS on their websites. The Commission services informed that the same letter, calling for granting of a derogation, was also received by the Commission, outside the public consultation, from approximately 200 individuals and organisations. The non-confidential comments provided during the public consultation will be published in the coming weeks on the ECHA website¹.

The contributors supporting the derogation highlighted that the technique using in-situ generated nitrogen is the least harmful option for users, cultural heritage objects and the environment and pointed out to the disadvantages of alternative methods. The comments that were not in favour of a derogation were submitted by providers of alternative techniques and pointed to the existence of alternative techniques available for the treatment of cultural heritage and indicated that the method of anoxia or modified/controlled atmosphere is not suitable for certain types of pigments.

With regard to the next steps in relation to the application from Austria, the Commission services communicated the draft Commission Decision granting a derogation to Austria was tabled for discussion in the meeting of the Standing Committee scheduled on the following day. The Commission services reminded that, if granted, the Article 55(3) derogation is only a first step towards the compliant use of products consisting of in-situ nitrogen, since the authorisation of those products - based on an application for authorisation - in the Member State benefitting from the derogation should then follow. The Commission services also mentioned that draft decisions were under preparation for two other applications for a derogation, received from Spain and France.

6. Treated articles

No item for information or discussion

7. Horizontal matters

7.1. Non-chemical alternatives for rodent control

For discussion
CA-Feb20-Doc.7.1

Wednesday 5
February

The Commission briefly presented the outcome of a workshop on rodent traps that was coorganised by the Commission and the German Environment Agency (UBA) on 5 February 2020. The event gathered almost 70 participants from Member States, industry and NGOs representatives. The objective was to discuss possible criteria to evaluate the efficacy and humaneness of rodent traps. A draft guidance document was presented by UBA.

¹ https://echa.europa.eu/de/previous-consultations-on-derogations-for-the-protection-of-cultural-heritage

The meeting identified several parts of the guidance that needed improvement. UBA will revise the draft based on the inputs received at the meeting. The meeting participants will be consulted on this revised version with the aim to continue to improve the draft guidance so that the efficacy and humaneness of chemical rodenticides and rodent traps can be compared at the next renewal of anticoagulant rodenticides.

The Commission services explained that further internal discussion is needed to clarify whether an opinion of the BPC on the guidance will be requested to ensure its suitability in future comparative assessments.

| 7.2. ECHA guidance | | |
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| (a) Draft guidance on data requirements and assessment of applications for renewal of active substances | For discussion and agreement <i>CA-Feb20-Doc.7.2.a</i> | Scheduled for Thursday morning 6 February |

ECHA shortly introduced its revised draft guidance for the evaluation of renewal applications of active substances.

One Member State noted that the section 1.5 on 5-batch analysis and reference specifications is still unclear, and that the document should be amended to reflect the possible flexibility on submission of draft reports when the RAC opinion would not yet be available for substances potentially subject to exclusion. Another Member State pointed out that it has to be decided whether there is a need at renewal of Article 95 data, and if so, how the competent authority can obtain the relevant data. On section 2.3, data submitted during product authorisation, this should normally have already been addressed.

ECHA replied that only very limited new Article 95 data exist, which therefore limits the workload on this aspect. It also noted that reflections are on-going within ECHA on the management of new data submitted during product authorisation and the possible update of the Listing of Endpoint (LoE) of the active substance.

Another Member State could not support the finalisation of the document, considering that some modifications would be needed on section 1.5 on specifications, and section 2.4.1 on efficacy in relation to treated articles. On the latter point, the Commission services reminded that it should be kept in mind that the BPR requests only to demonstrate that one reference product could be authorised in order to get an approval or renewal of approval, and not all possible treated articles have to be looked at: this is a case-by-case approach depending the representative use presented in the application. That Member State considered that treated articles have to be addressed during the renewal of approval of active substances, and encouraged the Commission services to consider the general policy lines developed by the new Commission (Green deal etc.). Another Member State noted however that articles and treated articles can be regulated by REACH, as already done in a number of existing cases (ex: wood treated with creosote).

An industry association informed to have submitted comments after the deadline and asked whether they could be addressed.

It was concluded that the document could not yet be finalised. The CA-meeting was requested to provide comments by 14 February, ECHA will provide an updated version by 10 March and it will organise a Webex afterwards for participants of the CA meeting with the view to prepare a final discussion at the next CA meeting.

| (b) | Priority setting for developing |
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| | ECHA guidance |

For discussion and agreement *CA-Feb20-Doc.7.2.b.1 CA-Feb20-Doc.7.2.b.2*

ECHA presented the new version of the document mentioning that limited input was received after the last discussion, hence there were no major changes to the content of the document. ECHA stated that the topics considered as having high importance, as included in the document, are: (i) update of Working Group recommendations on in-situ generated substances, (ii) adaptation of the guidance on information requirements following the amendments of the BPR annexes, (iii) mandate received from the Commission on a methodology to assess the risk to bees and other non-target arthropod pollinators and (iv) request from the Commission of a joint ECHA-EFSA guidance document on the impact of water treatment process on residues of active substances and (v) work on topics concerning environmental exposure in relation with the development of the new IT tool that will replace Chesar and EUSES. ECHA proposed to postpone the extension of the guidance on disinfection by-products to other PTs until progress is made on the mandate of the Commission on developing guidance on the impact of water treatment process on residues of active substances.

The Commission services mentioned that one item that would need prioritisation is the guidance on efficacy of insect repellents and that other topics that will have to be addressed soon regard substances of concern, referring to the discussions in the CG, and the risk characterisation of active substances with ED properties. ECHA clarified that the documents indicates only the new guidance work to be initiated, while other guidance documents are currently being developed, as is the case for the guidance on insect repellents efficacy, which is likely to be finalised at the beginning of 2021. ECHA was of the opinion that, if a guidance on risk characterisation of active substances with ED properties were to be developed, it should be a joint ECHA-EFSA guidance rather than an ECHA guidance and that other pieces of legislation should also be considered when developing such guidance.

One Member State stated that not all discussions in the last CA meeting seem to have been incorporated in the current version and was of the opinion that the item related to EUSES should be removed. ECHA replied that the discussions at the last meeting were not agreed, therefore they were not all incorporated in the current version and mentioned that, while they could agree to lower the priority of the item related to EUSES, they cannot remove the item due to the ongoing development of the new IT tool. ECHA also indicated that they are not able to be in the lead for all items due to resource limitations and that for some items Member States should take the lead, while ECHA would offer some support during the work.

The Commission services stated that the guidance on disinfection by-products should be considered as having high priority and the related work should run in parallel with the mandate related to residues in drinking water. ECHA called upon the Commission and Member States to be realistic as to the output that can actually be delivered in the next few years.

After some discussion the document was agreed by setting priority for the items indicated in the document, including guidance on disinfection by-products. A follow-up point will be included in the September meeting, with a view to providing an update on the progress on the prioritised items.

| 7.3. Disinfectant by-products: relevant guidance development by ECHA | For discussion and agreement <i>CA-Feb20-Doc.7.3</i> | |
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ECHA introduced the document prepared, already presented in November and complemented in the current version by elements regarding the priorities for environment. The main conclusion drawn for environment, in consultation with Member States, was that the current guidance needs to be improved in order to be usable in practice, therefore the proposal to postpone the extension of the guidance to other PTs.

One Member State recalled that the agreement reached at CA level was that, if guidance was not available on a certain topic, the assessment would be concluded without performing that specific evaluation and sought the view of other Member States on the approach to be followed in the case when guidance is available but not applicable in practice, like in the case of this guidance. The Commission services were of the opinion that this discussion should be separated from the discussion on the document, even though they are linked.

One Member State indicated their support for the document and, on the point raised by the other Member State, expressed the view that resources should be invested in improving the guidance for environment, so that the specific assessment can be performed. ECHA indicated that the problem could also be addressed from a different perspective, by taking measures to avoid that disinfection by-products are formed. The Member State having raised the point was of the opinion that the clarification/revision of the incomplete guidance on environment should have the highest priority, so that it becomes applicable in practice. The document prepared by ECHA was then agreed integrating the point on the incomplete guidance on environment.

| 7.4. Article 65(3) reporting: template for future reporting | For discussion | |
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The Commission services introduced the point mentioning that no revised template was prepared and distributed for the meeting. In order to address the two points still under discussion (reporting of poisoning incidents and of adverse environmental effects) it was decided to liaise with other Commission services, in order to gather an understanding on whether there is a harmonised poisoning score used by poison centres across the EU and on possibilities to use data reported under other pieces of legislation (e.g. water framework Directive) for the purposes of this report.

The Commission services also mentioned that a couple of Member States were of the opinion that it would beneficial to take stock of the first reporting exercise and then agree the final template for future reporting.

In light of these considerations, the Commission services proposed to bring back the item for discussion at the CA meeting of September.

| 7.5. ECHA communications | For information <i>CA-Feb20-Doc.7.5</i> | |
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ECHA briefed the meeting on recent IT tools developments. Information related to the updates of the SPC converter was provided and it was communicated that two major releases related to IT tools are foreseen this year. At the same time work is ongoing on the practical implementation on the discussions regarding the need of a range in the case of active

substances generated in-situ. ECHA also informed the meeting that some changes were implemented on the 1st of February in relation to the withdrawal of the UK from the European Union.

| 7.6. Update on Court cases F | For information | |
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An update was provided on recent Court cases in the biocides area, in particular the preliminary ruling on Case C592/18 'College van Beroep voor het Bedrijfsleven (Netherlands) Darie B.V. v Staatssecretaris van Infrastructuur' of 19 December 2019.

One Member State asked whether the Commission could establish guidance on how to deal with this preliminary ruling and concerned borderline cases. The Commission services indicated that it is not possible, considering that only the Court can take provide interpretations of the BPR.

| 7.7. Update on implementation of ED criteria | For information | |
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The Commission services provided a short update and mentioned that the fitness check performed by the Commission is ongoing and is likely to be finalised by the end of the year. A discussion on the assessment of non-active substances in biocidal products took place in the Coordination Group and stakeholders had the opportunity to provide comments on the document. The Commission services also informed the meeting that the early review of three active substances will be launched very soon and that a second annual forum on EDs will take place on 20-21 October.

| 7.8. | Insecticides authorised against mosquitos and ticks | For information | | |
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The Commission services debriefed the meeting about a workshop that was organised by the European Centre for Disease Control and Prevention early December. Although the event was not focusing on biocidal products, the public health authorities took this opportunity to express strong concerns about the availability of effective insecticides and advocated for a greater consideration of public health threats around transmissible diseases during the authorisation process of biocidal products. The Commission services invited biocidal competent authorities to discuss with their counterparts in the public health area to see how their concerns could be addressed.

| 7.9. Call for expression of interest for observers to the competent authorities expert group |
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The Commission services reminded of its intention to launch a call addressed to representatives of the industry, NGOs, trade unions and similar entities attending on a regular basis this expert group meetings.

More information on the status of the biocidal group expert group can be found here.

A Member State asked whether rules of procedure will be required for this group as in the past, it was agreed that such rules are not necessary. The Commission services explained that

the text of the call leaves open the possibility to draft such rules. However, the responsible Commission service for the implementation of rules on Commission expert groups may ask the development of rules of procedure.

The Commission services invited the meeting to comment the section 4 of the call on selection criteria before 1st of March.

| 7.10. Farm to Fork Strategy | For information | |
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The Commission services informed the meeting about the state of play of the Farm to Fork Strategy.

8. Scope matters

| 8.1 Scope issue in relation to animal semen extenders | For discussion and agreement | |
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The Commission services reminded that the key point in the discussion on the product-type to which such products would possibly be allocated was the manufacturing aspect and indicated that some comments were submitted after the last meeting. In reply to a question from the Commission services, the Member State having raised the issue stated that they will consider in the coming weeks whether or not to submit an Article 3(3) request to the Commission on the matter.

| 8.2 Scope issues identified during the drafting of PT 11-12 efficacy guidance | For discussion CA-Feb20-Doc.8.2 | |
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The Commission services reminded that one Member State was invited to take the lead and launch the topic in Helpex and enquired on the state of play. That Member State informed that the Helpex consultation was not yet launched, but that they performed an internal consultation during which they received comments and those comments will be provided to Cefiethe relevant industry association. The item will be brought back for agreement at the May meeting. The Commission services invited participants to prepare for the discussion at the next meeting and highlighted that one point that will have to be agreed is the timing of applicability of the agreement.

9. Enforcement issues

The Commission services informed the meeting that the overview report of the fact finding missions was published on the DG SANTE website:

https://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=135

| 9.2 Findings from REACH-En-Force 6 project (Classification and labelling of mixtures) – biocides module | For information | |
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The Commission informed the meeting about the findings, with respect to biocidal products, of the 6th project of the Enforcement Forum (REF-6), that had a focus on classification and labelling of mixtures. The operational phase of the project took place in 2018, the reporting was done in 2019 and the final report² of the project was adopted in December 2019.

24 Member States participated in the biocides module of the project and 760 products were inspected. The elements checked during the inspections were:

- legality of products on the market: only approximately 8% of the products inspected were illegally placed on the market, while approximately 51% were placed on the market according to the BPR and 41% according to national legislation during the transitional period;
- consistency of the information on the label with the information in the SPC, with regard to hazard and precautionary measures: for approximately 91% of the products placed on the market under the BPR the information on the label corresponded to the information in the SPC;
- consistency of the information on the label with the provisions of Article 69(2): the compliance rate for products placed on the market in accordance with the BPR was 84%.

The Commission services also informed that the first enforcement project dedicated solely to biocides and focused on treated articles is currently in its reporting phase and that a project on online sales, which will contain a biocides module, will enter the operational phase in 2021.

| 10. Interna | 10. International Matters | | | |
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| No item for i | No item for information | | | |
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| 11. AOB | | | | |
| | Competent Authorities and ntact Points | For information <i>CA-Feb20-Doc.11.a</i> | | |
| | | | | |
| (b) Update | on organic farming | For information | | |

At the request of an industry organisation, the Commission indicated that it had no specific update to provide. Organic farming authorities are supposed to continue the work in updating their list of authorised biocides for use in organic farming, as the new organic farming regulation should enter into application in January 2021. The Commission further invited Member States to discuss at national level with their authorities in charge of organic farming.

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 $^{^{2} \}underline{\text{https://echa.europa.eu/documents/10162/13577/ref-6 project report en.pdf/bfa9fc69-fdfd-2f52-bf96-5174d7e29cf8}$

| (b) Update on implementation of the Withdrawal Agreement | For information | |
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The Commission services gave a presentation on the implications of the withdrawal of the UK from the European Union, mentioning the main elements of the foreseen transition period.

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 | |