EUROPEAN COMMISSION

Health and Food Safety Directorate General

Standing Committee on Biocidal Products

17 March 2022
10:00 – 17:00
Webex meeting

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP75-Doc.A.01)*

Upon request from one Member State one item - concerning an update on the status of the application for inclusion of in-situ generated nitrogen into Annex I to the BPR - was added to the agenda as AOB point.

A.02 Adoption of the minutes of the 74th SCBP meeting *(SCBP75-Doc.A.02)*

The minutes of the 74th SCBP meeting were adopted.

A.03 Exchange of views on the examination of the renewal of approval of creosote for use in biocidal products of product-type 8 *(SCBP75-Doc.A.03)*

The Commission informed about its intention to present and discuss a draft Regulation proposing to renew the approval of creosote – however, the legal text was not yet available.

The Commission presented an illustration of the draft lists that would be established to indicate the Member States where the placing on the market of treated wood would be allowed, in line with previous discussions in the Standing Committee: one for railway sleepers and another one for utility poles. An introduction would describe how the lists will operate and be maintained by ECHA. The placing on the market of railway sleepers and utility poles would no longer be allowed in the Member States not included in those lists as of 30 April 2023.

The Commission is still reflecting on how the list could interact with the Mutual Recognition Agreement between the EU and Switzerland and with the Northern Ireland Protocol between the EU and the United Kingdom with respect to Northern Ireland. As to the latter, bilateral contacts will be established with the UK to know which treated articles would be allowed in Northern Ireland.

One Member State requested to have all the Member States listed for the first version of the list that should indicate where the treated wood could be placed on the market. When a Member State decides that treated wood can no longer be placed on the market, then the date of that decision should also appear on the list next to the statement 'NO'. The Commission agreed to reflect on the proposal but indicated that the content of the list will have to mirror the provisions of the renewal regulation.

Another Member State asked whether the movement of utility poles would only be authorised between countries on the list. The Commission explained that the placing on the market of treated wood will only be possible in Member States that are identified as allowing the placing on their territories of railway sleepers or utility poles. The Commission recalled that the BPR only regulates the placing on the market (i.e. the first making available on the market) of treated articles and that further supply of treated articles is regulated under the REACH Regulation. A Member State is preparing an amendment to the current restriction in that Regulation for wood treated with creosote. That Member State confirmed that a draft restriction had been submitted to ECHA in February and that a first discussion with Member States is expected in April. This is meant to complement the proposal from the Commission for the renewal of approval under the BPR.

A Member State asked to be added in the list for railways sleepers. Because of the aggression of Russia against Ukraine, that Member State preferred to wait until the situation is back to normal before taking any important decision on the ban of such treated article in its territory. The Commission accepted the request but invited that Member State to submit its request in writing for the records.

As to the draft Regulation, the Commission informed about the main elements it would contain, namely:

- a reminder about the provisions of Article 5(2) and point 10 of Annex VI to the BPR;
- a packaging bigger than 200 litres will be required in accordance with the information from the PAR;
- the necessity to apply risk mitigation measures to protect the environment and professional users when the biocidal products are applied;
- a deadline of 6 months after the expiry date of the current approval to phase out the uses no longer authorised;
- a requirement to label treated wood in accordance with the discussion of September 2021;
- a provision clarifying that railway sleepers and utility pools can only be used for these purposes;
- an approval period of seven years.

The Commission also clarified that some additional uses of treated wood supported in previous meetings by only one Member State respectively will not be taken on board because of the availability of alternatives. A company producing an alternative product had argued recently that creosote is still dominating on the market whereas a law firm supporting the applicant for creosote called on the Commission to not modify the current approval.

One Member State expressed its dissatisfaction with the conclusion of the Commission on the availability of alternatives as regards to the use in agriculture fencing and equestrian centre fencing. In its views, several years are needed for the alternatives to reach the current level of production of products treated with creosote and adapt the existing production lines. Given the tight deadline to phase out the uses not included in the Commission's proposal, it considers that this alternative biocidal product will not be available in sufficient quantity to ensure a smooth transition it its territory. That Member State will consider sending a letter from its Minister of Agriculture to point to the problems caused by a decision to not authorise the use of creosote for fencing posts and recalled that in previous discussion, there was no serious objection from the other Member States to not allow that use.

The Commission replied that full consideration had been given to the arguments presented by that Member State but they were not found convincing, as all other Member States did not find this use essential anymore. Some Member States opposed the continued use of agricultural fencing treated with creosote in that Member State. The Minister of Agriculture is however free to send a letter to the Commissioner for Health and Food Safety to raise his concerns.

A Member State asked what would be the legal provisions to be used by the enforcement authority if utility pools are found on the market although the Member State is not listed for that use. The Commission answered that the provisions of Article 58(2) of the BPR and the first paragraph on treated articles of the draft Annex to the act renewing the approval of creosote would be applicable.

Another Member State asked for confirmation that agricultural poles already installed would not be affected by the future Commission proposal. The Commission confirmed that all treated wood in place would not be affected by the Commission proposal. However, the second-hand market of treated wood is already regulated by the existing restriction in the REACH Regulation and will thus be affected by the proposal for an amendment of the REACH restriction.

Another Member State recommended an approval period of five years. The Commission noted this position and underlined that a cancellation of authorisation of the use of biocidal products containing creosote in line with their national conditions would be the most efficient way to phase out progressively the substance/products. A Member State supported the Commission proposal for a seven-year approval, hoping that this decision will not change the intention of the national railway company to phase out the use of railway sleepers treated with creosote as early as next year. That Member State also expressed the view that this should be the last renewal of approval of the substance.

The Commission concluded the discussion by mentioning that it aims to have the draft proposal ready for a vote at the meeting of the Standing Committee in June and in any case before the current approval expires. As soon as the internal consultation of the Commission services concerned is completed, the draft Regulation will be posted on CIRCABC.

A.04 Exchange of views on the examination of the renewal of approval of cyanamide for use in biocidal products of product-type 3 and 18 *(SCBP75-Doc.A.04)*

The Commission informed that a letter from a consultant about the substance had been posted on CIRCABC together with a Commission background note. It recalled the history of this case and that the conditions for derogations to exclusion do not need to be assessed because the decision on the approval of the substance must be taken under the rules of the earlier Biocidal Products Directive as the draft assessment report had been submitted before 1 September 2013.

Although the substance has been identified as an ED, the BPC could not conclude on whether the level of the risks could be considered acceptable or not due to the ED properties of cyanamide. No safe threshold of exposure had been identified.

The preliminary conclusion of the Commissions was that the applicant did not demonstrate that the representative biocidal product submitted in the application for approval meets the conditions of Article 19(1)(b) of the BPR, i.e. that it has no unacceptable effects on human health and the environment. The Commission would therefore recommend to not approve this active substance for use in biocidal products of PT3 and 18, as the acceptability of the risks had not been demonstrated.

In addition to the assessment of the criteria for approval, the Commission found it appropriate to consider whether there would be disproportionate negative impacts for society from not authorising the substance compared to the risks of using a product containing cyanamide (the provisions Article 19(5) in connection with Article 4(1)). The availability of alternatives is key in that respect and based on the information available other means of control of the target organisms exist for the intended uses. The Commission preliminarily concluded that not approving cyanamide would therefore not create a disproportionate negative impact on society compared to the risks of using the substance for human health and the environment, in particular in the light of the endocrine disrupting properties of the substance.

The Commission requested the views of the Member States on a possible proposal for a non-approval following the assessment of the criteria under Articles 4 and 19 and the availability of alternative active substances or technologies for the disinfection of pig stables in the Member States.

Five Member States supported the conclusions of the Commission that the substance should not be approved, that alternatives are present on the market for both PTs, that stables are regularly cleaned and disinfected by other means and that manure does not necessarily need to be treated. Three Member States confirmed that the substance is not present on their markets. One called for more time to check the situation on the availability of alternatives with its farmers' association.

The Agency explained that an analysis of authorised products for the same uses and for the same target organisms shows that alternatives exist and that authorised disinfectants can effectively control the target organism.

One Member State asked whether the applicant had had the opportunity to submit comments during the opinion making process of the BPC. The Commission explained that the BPC had been requested to review its opinions when the criteria to identify endocrine disrupting properties entered into application in 2018 and to further assess the risks derived from these properties. The applicant had been involved and contributed to two public consultations. Furthermore, the Commission asked recently the Agency to collect information from R4BP about existing products that would have similar uses against the same target organisms to complete its analysis position and justify its recommendation.

The Commission informed that a newsgroup will be opened, allowing Member States to provide their views until 8 April 2022.

A.05 Exchange of views on the examination of the renewal of approval of DBNPA for use in biocidal products of product-type 4 *(SCBP75-Doc.A.05)*

The Commission explained the background of this case and recalled that the substance meets the exclusion criteria, as it had been identified as having endocrine disrupting properties. In

previous discussions of the Standing Committee, it had been agreed to further analyse the information provided by the applicant during the consultation and to assess whether the condition (a) of Article 5(2) could be considered met.

In July 2020, the Commission had requested the Agency to clarify whether the risks associated with the exposure to DBNPA could be considered acceptable or not acceptable for human health and for the environment in relation to its endocrine disrupting properties. The BPC had concluded that the risks from these properties are considered acceptable for both humans and non-target organisms in the environment, as the exposure from DBNPA is within the range of the natural background concentration of bromide. The assessment of the negligibility of the risks was however left for discussion in the Standing Committee.

The Commission proposed that the risks associated with the use of DBNPA for the disinfection of food processing vessels could be considered negligible taking into account that:

- bromide is a naturally occurring and essential halogen for humans, naturally present in the environment, and the existence of a threshold of adversity can be assumed;
- the risks associated with the endocrine disrupting effects of bromide are considered acceptable for humans and for the non-target organisms in the environment because the levels of exposure of bromide from this use is minor compared to the background concentration to which human and the environment are already exposed (from various anthropogenic sources and the environment).

In case the Standing Committee agreed that the risks could be considered negligible, the Commission asked for the views of Member States on two options:

A. consider that the criteria for derogation to exclusion under Article 5(2)(a) would be considered as met for the use in food processing vessels, even if alternatives exist, as health and the environment would be considered protected;
B. consider that the criteria for derogation to exclusion under Article 5(2)(a) would not be met, as alternatives exist and the availability of alternatives is a "key consideration" to assess the derogation criteria. In addition, it could be considered that the overall objective pursued by the legislation is to ensure a high level of protection of human health, animal health and the environment and that normally active substances with endocrine disrupting properties for humans should not be approved.

Two Member States supported option A whereas five others indicated to prefer option B.

Among the latter, one Member State explained that none of the derogation criteria can be found met as they are overruled by the availability of alternatives. If such alternatives have a better hazard profile, it would be another argument to not approve the substance - therefore, information on such alternatives would be welcome. The Agency informed that alternatives in PT 4 for this type of application are available. The Commission invited the Member States to contact their food business operators to know which kind of substances they use to disinfect their installations.

Three other Member State stated that the risks for the environment and human health cannot be considered negligible.

One Member opined that the guidance for the application of the criteria for identifying endocrine disrupting properties had not been properly followed during the discussions at the BPC. The Commission responded that according to the Agency and the evaluating Competent Authority, the guidance had been correctly followed and invited that Member State to provide its reasoning in writing by 8 April 2022 for further examination before the next meeting of the Standing Committee.

One Member State tentatively agreed with the Commission that the risks are negligible even if methodology issues and uncertainties could not entirely be dismissed. If it is considered that the risks are negligible, then the availability of alternatives is less relevant, as the risks are addressed. Points b and c of Article 5(2) would be more prone to an assessment of alternatives.

The Agency pointed out that the discussion on negligible risks is similar to the reflections that already occurred in the BPC and its working group i.e. that it is not possible to conduct a risk assessment for substances having endocrine disrupting properties. From a scientific point of view, it seems difficult to define a quantifiable safe threshold that could be compared with exposure as there is no data and no methodology to set such a value. As there are more and more requests to look at risks for substances meeting the criteria to be identified as endocrine disruptors, the Agency proposed to discuss this issue either in the Standing Committee or in the expert group composed of the Competent Authorities .

The Commission answered that in the case of DBNPA, the question was more about the comparison of the exposure to that substance from its use in biocidal products with the natural background exposure to bromide. The Commission proposed to have this discussion at the next Standing Committee together with the arguments to be sent by one Member State regarding the allegedly wrong application of the guidance for the criteria to identify endocrine disruptors. The Agency confirmed that the BPC tried to set a threshold and quantify the risks but the BPC concluded that this is impossible with the current knowledge.

The Commission concluded that some Member States considered the risks of using DBNPA non-negligible while others found that the presence of alternatives is a key consideration. A newsgroup was opened until 8 April 2022 to collect the arguments of the Member States whether the risks should be considered negligible or not. This information would help the Commission and Member States to gain experience in the assessment of the derogation criteria under the BPR.

A.06 Exchange of views on the examination of the Union authorisation of the product ARCHE chlorine *(SCBP75-Doc.A.06)*

The Commission listed several issues to be clarified before proceeding with a decision of the Commission to grant an authorisation or not for the product.

Firstly, the Commission explained that one Member State had raised questions on the safety of 'ARCHE chlorine' due to the risk profile of chlorine gas used as precursor to generate active chlorine. Additional risk mitigation measures on top of the ones proposed by the BPC had been proposed by that Member State, to guarantee the safety of professional users and workers present when the product is applied. The BPC, however, did not endorse these measures. The Member State indicated that these additional measures are still needed but that the issue would be addressed by an amendment of its national law on the use of gaseous biocides and the handling of them by trained professionals. However, at least six months would be needed to enact the revised decree. The Commission confirmed that a decision would not be adopted within that period.

Secondly, the Commission explained that a Member State had requested a derogation under Article 44(5) to adjust certain conditions of the uses for the disinfection of drinking water for human consumption because the conditions specified in the SPC did not correspond to its national requirements for Drinking Water (i.e. application method and frequency). On 7 March 2022, the Member State had provided additional information on how certain parameters of the SPC need to be adapted to meet these requirements as well as further information on their

national policy. With the additional information, the Commission considered to have sufficient elements for an adaptation of the German SPC and preparation of a derogation.

Thirdly, the Commission explained that another Member State considered insufficient some of the risk mitigation measures proposed in the BPC opinion to protect surface water when the product is used in water treatment plants to treat wastewater before discharge. The amount of product applied is three orders of magnitude higher than for other uses, which leads to unacceptable risks for surface water that could not be mitigated by the current measures. For example, the amount of active carbon or reducing agent needed to reduce the concentration of active chlorine below the PNEC for surface water is not demonstrated. In addition, according to the PAR, national quality standard for the concentration of active chlorine in treated waste water could be up to 10 mg/L whereas the PNEC value for free available chlorine in surface water is as low as 0.042 µg/L. This means that this PNEC value would be exceeded when the product is applied in the way approved by the BPC. It is not understandable why such national quality standard is used as risk mitigation measure. In addition, the Member State explained that such a limit is not enforced at national level, as chlorination of treated wastewater is no longer used like in other Member States.. Therefore the Member State requested a derogation under Article 44(5) on the grounds of national policy (Best Available Technique) and the protection of the environment (Article 37(1)(a)) as the PEC/PNEC value would be largely above 1. As an alternative, the Member State proposed additional risk mitigation measures to reduce the concentration of active chlorine in treated wastewater before discharge.

The Commission considered that the arguments are not specific to that Member State and asked whether the additional risk mitigation measures proposed were assessed for their efficacy to reduce the amount of chlorine released in the environment. The Agency clarified that the proposals for additional risk mitigation measures from that Member State had been discussed at Working Groups and BPC meetings but that some of the Members had no clear position, as this use is not common on their territory. There was no quantification of the effectiveness of the proposed additional risk mitigation measures, because no data was available. However, where this use is allowed, the authorities accept the risk mitigation measures set in the SPC, based on long-standing practices applied in waste water treatment plants. In addition, there is no explicit description on the way to monitor the application of the proposed risk mitigation measures, as the quality of surface water is under the responsibility of each Member State e.g. the permits of waste water treatment plant where this can be described.

The Commission expressed some concerns that the measures set in the SPC were accepted without an objective verification that they do actually work. In particular, the Member State had stated that based on a risk assessment, a retention time of 19 hours in a buffer zone before discharge would be necessary to reduce the concentration of active chlorine to a sufficiently low level. The Member State added that this estimate had been calculated based on data from the risk assessment. The Agency confirmed that monitoring data are not always available to confirm that the proposed risk mitigation measures are efficient to protect the environment and expert judgment is required, as applied in this particular case.

The evaluating Member State stated that the proposed risk mitigation measures are actually included in the approval of the active substance. They apply already for several other products and they are included in the agreed list of SPC sentences. Contacts with the sector have shown that the measures are well known, effective and applied. It is possible to derive a theoretical value for the retention of water but it was decided to not specify such a value in the BPC opinion as it would depend on parameters that are specific to the local conditions in the Member States. According to the evaluating Member State, it is expected that the waste water treatment plants

would use the necessary concentrations of reducing agents and would apply the necessary retention time to meet all the legal requirements of the Water Framework Directive.

The Commission noted that this approach gives some flexibility to the users and indicated that it will verify whether a limit concentration for active chlorine is included in implementing legislation adopted in the context of the Water Framework Directive.

Finally, the Commission explained that regarding the use for swimming pool disinfection, for which efficacy against viruses had not been demonstrated, the applicant decided to submit an application for a national authorisation covering that use in one Member State and that mutual recognition in sequence is envisaged. One Member State requested more clarification on the matter and asked if transitional arrangements would be needed to ensure that the current installations could continue to operate until the national authorisations are granted. The Member States to whom the application had been submitted answered that comments on the status of the dossier will be communicated in writing. The Commission also requested additional time to reflect on how the transition should best be ensured.

A.07 Exchange of views on the examination of the Union authorisation of the product Christiansen LD Bednet *(SCBP75-Doc.A.07)*

The Commission explained that the decision was related to ongoing discussions in the expert group of the competent authorities on consequences for biocidal product authorisation procedures of new information becoming available on active substances. Although those discussions on a general approach on how to address such new information on active substance during product authorisation were not yet concluded, the Commission explained that the BPC recommended authorising this particular product for indoor use only and to label the product with the instruction 'Do not wash', as risks were identified for the environment. Therefore, the currently proposed risk mitigation measures sufficiently cover the risks related to the newly identified persistence property of the active substance and no additional mitigation measures seemed necessary to address the risks for the environment. The Commission added that there is no need for a comparative assessment until the status of the substance as candidate for substitution is specified in the approval conditions.

Three Member States agreed with the conclusions of the Commission. One would have preferred that the BPC opinion included a reference to the new status of the substance. The Agency clarified that the new information that the substance is persistent was taken into account in the assessment and relevant risk mitigation measure were recommended.

Another Member State asked about the duration of the authorisation if the status of the substance as candidate for substitution is not yet formally referred to in the approval conditions, taking into account that the renewal of approval of permethrin is expected only for April 2026. An authorisation of five years would be in line with the provisions of Article 23(6) of the BPR in their views. The Commission argued that the renewal process of the substance will be most likely delayed because of the need to conduct a full assessment of endocrine disrupting properties. Therefore, if a short duration of the product authorisation is proposed, it is likely that it will need to be extended.

Another Member State commented that as the discussion in the expert group of the competent authorities on a general approach is not yet concluded, a comparative assessment and a maximum authorisation period of five years should be proposed as it is common practice for national authorisations. The Commission indicated that it will include more arguments in the note discussed in the expert group to explain why the identification of the new status of the substance and the obligation to carry out a comparative assessment could only apply after the

renewal of the approval, hoping that this information would lift the reservation of that Member State.

The Commission concluded by indicating that it will proceed with the preparation of the decision authorising the product Christiansen LD Bednet.

A.08 Exchange of views on the examination of the Union authorisation of the product Hokoex *(SCBP75-Doc.A.08)*

The Commission recalled the main issue related to the generation of melamine that could be formed during the degradation of the active substance cyromazine. Melamine was identified as relevant metabolite for the groundwater assessment as it is classified as carcinogen, category 2, STOT repeated exposure, category 2. From the provisions of point 68 of Annex VI, it could then be derived that the concentration of melamine in ground water cannot exceed the generic value of 0.1 µg/L stated in the Drinking Water Directive. Therefore, the BPC recommended authorising the product only for the uses leading to a concentration of melamine in ground water below 0.1µg/L.

One Member State expressed the same reservation expressed under agenda point A.07 with regard to the need for a comparative assessment as the active substance could potentially meet the P and T criteria. The Commission referred to the conclusions of the previous point. Taking into account that the approval will expire in 2027 and that one might expect delays in the assessment, the Commission will reflect on the most appropriate length of the authorisation to avoid multiple extension of the authorisation until the future assessment in the context of the renewal of approval of the substance is completed.

The same Member State and the Agency indicated that in the current guidance[1] that was used to decide whether melamine should be identified as a relevant metabolite for the groundwater assessment, the BPC followed the approach that melamine is relevant based on its hazard properties. Therefore, the BPC decided to apply the cut-off value of the Drinking Water Directive as explained above. However, this guidance does not seem to exclude the possibility to derive a threshold and conduct a risk assessment. Some inputs from the Commission would be appreciated to clarify this point as the BPC expects similar cases in the near future.

The Commission concluded that a draft decision for granting an authorisation would be tabled for the next meeting of the Standing Committee.

A.09 Exchange of views on derogations for the biocidal product BIOBOR JF *(SCBP75-Doc.A.09)*

The Commission introduced the document and summarised the current situation of the product Biobor JF on the EU market. This product is used to avoid microbiological contamination of aircraft fuel tanks and fuel systems and after the onset of the COVID-19 pandemic its use was needed, due to the immobility of aircraft (which aggravates microbiological contamination) and to the withdrawal from the market of the only alternative product available for this use. The Commission had received notifications of temporary permits granted for this product from 21 Member States and 16 of the permits have been extended following Commission Decisions allowing such extensions. The first extended permits will start expiring in May 2022.

Since the product is needed for the treatment of microbiological contamination also in operating aircraft and considering the absence of alternative products on the market, it is likely

[1] Sanco/221/2000 –rev.10- final (25 February 2003) – Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC

that its use will be needed also in the future. The Commission is therefore expecting that future temporary permits might be granted by Member States after the expiry of the current ones.

The approach presented by the Commission proposes to group the 16 extended permits in two groups (permits expiring in the first half of year and permits expiring in the second half of year) and, for future permits granted by the respective Member States, to apply a common expiry date for each group (31 October 2022 for the first group and 2 March 2023 for the second group). This would allow the Commission to treat potential future requests for extension in a single decision for each group and will also lead to a certain harmonisation of the length of the permits in various Member States.

One Member State appreciated the proposal from the Commission and invited to be critical concerning derogations in the longer term, since the conditions changed compared to the start of the COVID-19 pandemic. Another Member State stated that the product is needed also for in-service aircraft and that they chose to grant new permits without requesting extensions. The same Member State informed that they will be the evaluating competent authority for the evaluation of the application for approval of the active substance contained in the product and that they expect the submission of the application for approval by the end of 2022. Once the active substance will be approved, regular product authorisations can be granted. Upon request from a Member State, the Commission clarified that Member States cannot request from the Commission the extension of a permit already extended following a Commission decision, as the requests for extension have to relate to a permit (of maximum 180 days) granted by Member States.

Section B Draft(s) presented for an opinion

B.01 Exchange of views on the draft Commission Implementing Decision not approving N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine as an existing active substance for use in biocidal products of product-type 8 (*SCBP75-Doc.B.01*)

The Commission introduced the draft Decision intended to not approve diamine as active substance for use in biocidal products of product-type 8. The BPC opinion had identified unacceptable risks for human health and no suitable risk mitigation measures could be identified. In the extensive former discussions, the Standing Committee had concluded that the evaluation had been conducted according to realistic worst case conditions, and that limiting the number of cycles of treatment of wood to two per day per operator would not be a suitable risk mitigation measure to reduce the identified risks to human health to an acceptable level, due to difficulties of enforcement and control.

Therefore, the Committee had concluded that diamine may not be expected to meet the criteria laid down in Article 5(1), point (b) of Directive 98/8/EC which correspond to the criteria laid down in provisions Article 19(1), point (b), of Regulation (EU) No 528/2012.

The Commission informed that the vote in written procedure will be launched after the meeting of the Committee, once the commenting period following the notification of the draft Decision to the World Trade Organization under the Technical Barriers to Trade (TBT) Agreement will have expired.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision pursuant to Article 3(3) of Regulation (EU) No 528/2012 on a product containing '*Capsicum* oleoresin expeller pressed' *(SCBP75-Doc.B.02)*

The Commission introduced the draft Decision, which had been prepared after the discussion that took place at the previous meeting of the Committee. The argumentation in the draft Decision had been drafted along the lines of that discussion. The Commission recalled that the main element contested by the applicant is the qualification of the active ingredient as "substance" within the meaning of the BPR. The Commission explained that, based on the definitions in the BPR and on the applicable guidance, '*capsicum* oleoresin expeller pressed' is to be considered a substance, as explained in recitals (3) to (7) of the draft decision. Taking into account the mode of action of the product, the fact that it contains an active substance and its intended use, the draft Decision concludes that the product is a biocidal product of product-type 19. The Commission also mentioned that a position paper of the applicant had been distributed prior to the meeting to all Member States and had also been uploaded by the Commission on CIRCABC before the meeting.

The Member State having submitted the Article 3(3) request informed that they were approached by a law firm representing the product manufacturer who asked them to withdraw the request. However, the Member State decided not to withdraw the request and stated that it is important for them that the Commission takes a decision on the matter. Another Member State expressed support for the draft Decision and requested clarification concerning enforcement, since in this case the manufacturer had been misled by previous advice which generated the current situation of non-compliance. The Commission explained that one option could be the inclusion in the Decision of a deferred date of entry into effect, which could allow the manufacturer to submit an application for approval of the active substance. The Member State having submitted the request informed that the Review Programme had included certain *capsicum* substances, but applications for approval were never submitted, hence they have been removed from the Review Programme. The Commission indicated that it will investigate with ECHA whether it is possible to re-open the possibility for the manufacturer to declare an interest to notify the substance, in accordance with Article 15 of the Review Programme Regulation.

Another Member State made reference to the Commission Decision of 2015 on dried lavender blossoms which had decided that these were not a biocidal product and asked about the difference with the current case. The Commission explained that in that instance drying was not considered a processing step, while the mechanical pressing is considered processing. Another Member State pointed out that in the position paper of the manufacturer it is mentioned that an extraction takes place and in that case what is extracted is for sure a substance.

The Commission concluded the discussion recalling that the public consultation on the draft Decision will end on 5 April and reiterating that solutions in order to avoid an abrupt withdrawal of the product from the market will be sought.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Primer Stain TIP in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP75-Doc.B.03)*

The Commission presented the draft Decision on the unresolved disagreement for the authorisation of the product Primer Stain TIP, for which an objection had been raised by a

concerned Member State in the mutual recognition procedure, as it considered that in order to ensure the safe handling of the biocidal product, wearing of personal protective equipment is required. According to that Member State, the application of technical and organisational measures in accordance with Council Directive 98/24/EC, as set out in the authorisation granted by the reference Member State, as a possible replacement for wearing personal protective equipment does not ensure an adequate protection if those measures are not specified and evaluated in the assessment of the biocidal product.

The reference Member State considered that Directive 98/24/EC establishes the order of preference of different risk mitigation measures for protection of workers and prioritises the application of technical and organisational measures over wearing personal protection equipment for the use of the biocidal product. According to the reference Member State, pursuant to that Directive the employer is to decide which technical and organisational measures are to be applied, and as there is a broad range of such measures, it is not feasible to describe and evaluate the measures in the authorisation of the biocidal product.

In order to resolve the disagreement, the following elements were taken into account by the Commission:

- Article 2(3), points (b) and (c), of Regulation (EU) No 528/2012.
- Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.
- Point 9 of Annex VI to Regulation (EU) No 528/2012.
- Point 18(d) of Annex VI to Regulation (EU) No 528/2012.
- Point 56(2) of Annex VI to Regulation (EU) No 528/2012.
- Point 62 of Annex VI to Regulation (EU) No 528/2012.
- Article 4 of Directive 98/24/EC.
- Article 6 of Directive 98/24/EC.
- No suitable technical or organisational measures had been identified in the application for authorisation of the biocidal product, nor during the evaluation of that application.

Taking all these elements into account, the Commission considers that the biocidal product meets the criterion laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: "*The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing and rolling and automated dipping, wearing of chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by manual dipping and deluge, and wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work."* However, where the applicant for authorisation identifies technical or organisational measures that achieve a level of exposure reduction equivalent to or higher than the reduction achieved by wearing the protective equipment referred to, those measures shall be used instead of that personal protective equipment and shall be specified in the authorisation and on the label of the biocidal product. In that case, the obligation to include the condition regarding the use of the biocidal product laid down in the first paragraph shall not apply.

One Member State expressed its intention to vote against the decision in the current drafting unless the last sentence referring to Council Directive 98/24/EC is deleted. The member state provided detailed justification of this position to the Commission following the discussion in the last Standing Committee. It is based on the redundancy of the aforementioned sentence, its absence of effect on the resolution of the objection – the wearing of PPE remains compulsory, and the fact that it provides overall no benefit from a legal or worker protection standpoints.. The Commission asked that Member State to reconsider its position as the justification that the sentence is redundant – albeit correct - is not really an argument to vote against the draft Decision.

Another Member State raised comments on the drafting of the last paragraph of the Article, as it considers that if technical and organisational measures that provide a similar or higher reduction of the exposure are identified and included in the authorisation of the products, this shall be done with the agreement of the authority. The Commission agreed with the views of that Member State and to amend the draft Decision accordingly. A revised version will be circulated to Member States ahead of the vote in written procedure.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Primer PIP in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP75-Doc.B.04)*

The Commission presented the draft Decision on the unresolved disagreement for the authorisation of the product Primer PIP. The objection raised is very similar to the objection raised for the product Primer Stain TIP and the same elements have been considered by the Commission to resolve the disagreement.

The Commission considers that the biocidal product meets the criterion laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: "*The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing and rolling and automated dipping, wearing of chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by manual dipping and deluge, and wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.*" However, where the applicant for authorisation identifies technical or organisational measures that achieve a level of exposure reduction equivalent to or higher than the reduction achieved by wearing the protective equipment referred to, those measures shall be used instead of that personal protective equipment and shall be specified in the authorisation and on the label of the biocidal product. In that case, the obligation to include the condition regarding the use of the biocidal product laid down in the first paragraph shall not apply.

In line with the outcome of the discussion on point B.03, a revised version of the draft Decision will be circulated to Member States ahead of the vote in written procedure.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding on the terms and conditions of the authorisation of a biocidal product containing N-(trichloromethylthio)phthalimide (Folpet) referred by the Netherlands in accordance with Article 36(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP75-Doc.B.05)*

The Commission presented the draft Decision, for which an objection had been raised by a concerned Member State in the mutual recognition procedure, as it considered that the biocidal product does not meet the conditions laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012, as there are no conclusions on the classification of the biocidal product with regard to certain physical hazards and safety characteristics, which belong to the core data set pursuant to point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012 and therefore, those data requirements cannot be waived, unless adaptation is possible in accordance with Annex IV to that Regulation.

The reference Member State indicated that the biocidal product is identical to the active substance N-(trichloromethylthio)phthalimide (Folpet). Folpet has currently no harmonised classification with respect to physical hazards established in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

In order to resolve the disagreement, the Commission had considered the following elements:

- Article 19(1), point (d), of Regulation (EU) No 528/2012.
- Article 20(1), point (a)(i), of Regulation (EU) No 528/2012.
- Article 21 of Regulation (EU) No 528/2012.
- Point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012.
- Point 18(a) of Annex VI to Regulation (EU) No 528/2012.
- Article 4(1) of Regulation (EC) No 1272/2008.
- Article 8(2) of that Regulation (EC) No 1272/2008.

Despite the obligation under Article 20(1), point (a), of Regulation (EU) No 528/2012 in conjunction with point 4 of Title 1 of Annex III to that Regulation and the obligation under Article 8(2) of Regulation (EC) No 1272/2008, the applicant had not provided information on the classification of the biocidal product with regard to physical hazards and safety characteristics.

On 19 May 2021, the Commission had provided the applicant with the opportunity to submit written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. In its comments, submitted on 18 June 2021, the applicant had provided justifications for waiving the data requirements established in point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012 for some of the physical hazards (self-reactive substances and mixtures, pyrophoric solids, self-heating substances and mixtures, oxidising solids, organic peroxides, corrosive to

metals) by making reference to known experience, while for others (explosives, flammable solids, substances and mixtures which in contact with water emit flammable gases and relative self-ignition temperature for solids) the applicant made reference to the assessment report of the active substance established prior to its approval.

After having carefully examined the comments provided by the applicant and after having consulted the Agency, the Commission considered that with the exception of corrosive to metals, for which the waiving justification provided by the applicant can be accepted, all the other information provided by the applicant does not allow to conclude on the classification of the product for physical hazards and safety characteristics belonging to the core data set referred to in point 4 of Title 1 of Annex III to Regulation (EU) No 528/2012 and no adequate justification for adaptation of data requirements in accordance with Annex IV to Regulation (EU) No 528/2012 was provided. Therefore, the Commission considered that it is not possible to establish if the biocidal product meets the conditions laid down in Article 19(1), point (d), of Regulation (EU) No 528/2012.

The reference Member State clarified that, as the product was composed of 100% of the active substance, the conclusions on classification for physical hazards and technical properties that were derived for the active substance approval were used in the authorisation of the biocidal product, but afterwards they realised that the active substance was approved under Directive 98/8/EC and that those conclusions cannot be used directly for product authorisation today as the data made available under the Directive are not in compliance with Annex III of the BPR. That Member State, therefore, agreed with the draft Decision and considered that the data gaps need to be filled in any case at the renewal of the active substance.

The Member State that had initiated the disagreement also agreed with the draft Decision. The Commission announced that it will finalise the draft Decision on this basis.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product family Alphachloralose Grain in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP75-Doc.B.06)*

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product family Alphachloralose Pasta in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP75-Doc.B.07)*

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Pat'Appât Souricide Canadien Foudroyant in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*SCBP75-Doc.B.08)*

The three draft Decisions were discussed together. The Commission presented the draft Decisions that conclude that the biocidal product families Alphachloralose Grain and Alphachloralose Pasta and the biocidal products Pat'Appât Souricide Canadien Foudroyant do not fully meet the conditions laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 and may only be authorised in Member States who consider that not authorising them would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product

under the conditions laid down in the authorisation. The use of the biocidal product shall be subject to appropriate risk mitigation measures, as referred to in Article 19(5) of Regulation (EU) No 528/2012, which in each Member State shall be adopted based on the particular circumstances and available evidence of the occurrence of secondary poisoning incidents in that Member State.

The risk of secondary poisoning of animals due to the use of biocidal products containing alphachloralose and the necessary risk mitigation measures to be applied in order to reduce that risk to an acceptable level are currently being assessed in the context of the evaluation of the application for renewal of the approval of alphachloralose, and, when finalised, need to be duly taken into account by Member States in the authorisation of biocidal products.

The Commission informed Member States that the authorisation holders had submitted comments to the draft Decisions on the biocidal product families Alphachloralose Grain and Alphachloralose Pasta, and for the biocidal product Pat'Appât Souricide Canadien Foudroyant. In their comments, the authorisation holders disagreed with the proposals, claimed that their right to be heard had not been respected, that the Decisions are not based on scientific data and criticised that the Commission is not resolving the disagreement between Member States in a harmonised way. Therefore, the Commission intended to organise a meeting with the authorisation holders to discuss the draft Decisions and the vote on the three Decisions will be postponed.

One Member State indicated that they need to have a closer look at the recitals that refer to the renewal of approval of the active substance and that they will probably submit written comments.

Another Member State supported the proposals from the Commission and informed that they are requesting more data from poisoning centres, but the preliminary results seem to indicate that there has been a decrease in the number of poisoning incidents after the amendment of the authorisations made to include additional labelling requirements. The Commission requested that Member State to share this information with the evaluating competent authority for the renewal of approval of the active substance, so that this data can be taken into account when assessing the risks of occurrence of poisoning incidents from the use of products containing alphachloralose.

Another Member State raised concerns on the potential market disturbances that this decision may entail, as only some of the products containing alphachloralose are addressed in the Commission decisions and questioned if this should not be taken into account at the active substance level. The Commission clarified that it can only take decisions for the products for which disagreements have been submitted to the Commission, but that Member States should align all the authorisations of products containing alphachloralose, depending on their national conditions, using Article 48 of the BPR.

Another Member State raised the concerns on market disturbances and wondered if the poisoning incidents come from the use of alphachloralose products as rodenticides, or rather from its use in avicides. They also questioned if this should not be addressed by an early review of the active substance. The Commission recalled that the procedure for the renewal of the approval of the active substance is already ongoing and that in this context it does not make sense to trigger and early review. If Member States suspect that poisoning incidents are caused by illegal use of alphachloralose products as avicides they should investigate and prosecute such illegal use.

Another Member State supported the Commission proposals, as they believe that the poisoning incidents were caused by use of authorised rodenticides and before that active substance

entered their market there were no poisoning incidents. The source of alphachloralose in most of the poisoning incidents is uncertain, but in some of them the specific products had been identified as the source.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "INTEROX Biocidal Product Family 1" *(SCBP75-Doc.B.09)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing hydrogen peroxide. The products of product-types 2, 3 and 4 and containing hydrogen peroxide in concentrations between 13% and 49.9%, are intended for professional use.

The BPC had adopted its opinion in October 2021. The BPC did no propose any post-authorisation requirement and no Member State required a derogation under Article 44(5) of the BPR. The conclusion of the BPC was that this family can be authorised for the uses described in the SPC .
The Commission informed that the evaluating Member State has submitted comments prior to the meeting, correcting some typographical errors in the SPC, and that these corrections will be incorporated in the SPC. No other Member State had comments on the draft Regulation.

The Commission informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product "Bioquell HPV-AQ" *(SCBP75-Doc.B.10)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product containing hydrogen peroxide. The product in product-types 2, 3 and 4, is a 35% aqueous hydrogen peroxide solution to be used with a specific device and intended for the cleaning of small and large sealed enclosures. The product is intended for professional use.

The BPC had adopted its opinion in October 2021. The BPC did not propose any post-authorisation requirement and no Member State required a derogation under Article 44(5) of the BPR. The conclusion of the BPC was that this family can be authorised for the uses described in the SPC.

One Member State informed that they could not examine the proposal since the specific BPC opinion was not yet available on the Agency's website. No other Member States had comments.

The Commission reminded the first Member State that the BPC opinion was available to all Member State even if not yet published and informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Contec Hydrogen Peroxide Biocidal Product Family" *(SCBP75-Doc.B.11)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing hydrogen peroxide. The products of product-types 2 and containing hydrogen peroxide in concentration of 6.67% are ready-to-use products for professional use, intended for hard surfaces disinfection in isolators and Restricted Access Barrier Systems positioned in cleanrooms and for hard surface disinfection of cleanrooms.

The BPC had adopted its opinion in November 2021. The BPC did not propose any post-authorisation requirement and no Member State required a derogation under Article 44(5) of the BPR. The conclusion of the BPC was that this family can be authorised for the uses described in the SPC.

No Member State commented on the draft Regulation.

The Commission informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Hydrogen Peroxide Family 1" *(SCBP75-Doc.B.12)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing hydrogen peroxide. The products of product-types 1, 2, 3 and 4 containing hydrogen peroxide in concentrations between 1% and 36.75% are intended for professional use. The Commission reminded that the draft Regulation had already been presented for discussion at the meeting of the Committee in December 2020 and that the adoption had been put on hold due to exchanges with the applicant on the potential inclusion of the recital disclosing the names of the two co-formulants identified as potentially having endocrine disrupting properties.

The Commission also reminded that in parallel, in November 2021, Member States adopted at the Coordination Group meeting a document on criteria for deciding when a non-active substance should be considered to have significant indications of endocrine disrupting properties (in which case the name of the substance would be disclosed in the Commission legal act). The sole criterion included in that document was the intention to prepare a proposal for inclusion of that substance in the list of Substances of Very High Concern established under the REACH Regulation due to concerns about endocrine disrupting properties. The Commission considered that the approach agreed by Member States should apply to the case under discussion. Since for none of the two co-formulants there is such an intention, it can be considered that there are no significant indications of endocrine disrupting properties, and, consequently, the recital disclosing the names should not be included in the Regulation.

One Member State expressed its dissatisfaction concerning the document agreed at the Coordination Group, considering it a step back in transparency with regard to the presence of co-formulants identified as potentially having endocrine disrupting properties, but mentioned that they will nevertheless support the draft Regulation. No other Member State had comments on the draft Regulation.

The Commission informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Brenntag GmbH propan-2-ol Product Family" *(SCBP75-Doc.B.13)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing propan-2-ol for product-types 1, 2 and 4. No substance of concern was identified in the composition of the family. The BPC did not propose any post-authorisation requirement and no Member State required a derogation under Article 44(5) of the BPR. The conclusion of the BPC is that this family can be authorised for the uses described in the SPC.

No Member States had comments on the draft Regulation.

The Commission informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "L+R Propanol PT 1 Family" *(SCBP75-Doc.B.14)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing a mixture of propan-1-ol and propan-2-ol in product-type 1. The co-formulant tetradecanol was identified as a substance of concern in meta SPC 1. All products are restricted to professional or industrial users that are expected to apply the recommended risk mitigation measures.

The BPC did not propose any post-authorisation requirement and no Member State required a derogation under Article 44(5) of the BPR. The conclusion of the BPC is that this family can be authorised for the uses described in the SPC.

No Member State had comments on the draft Regulation.

The Commission informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Knieler & Team Propanol Family" *(SCBP75-Doc.B.15)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing a mixture of propan-1-ol and propan-2-ol in product-types

1, 2 and 4. No substance of concern was identified in the family. All products are restricted to industrial and professional users.

The BPC did not propose any post-authorisation requirement and no Member State required a derogation under Article 44(5) of the BPR. The conclusion of the BPC is that this family can be authorised for the uses described in the SPC.

No Member State had comments on the draft Regulation.

The Commission informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

B.16 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Active chlorine based products BPF – CID Lines NV" *(SCBP75-Doc.B.16)*

This item was postponed as the consultation of the Commission services concerned was not closed at the time of the meeting.

B.17 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the biocidal product family "Lactic acid based products – CID Lines NV" *(SCBP75-Doc.B.17)*

The Commission presented the draft Regulation intending to grant a Union authorisation for a biocidal product family containing L(+) lactic acid in product-types 1, 2, 3 and 4. Several substances of concern were identified in the family. Unacceptable risks were identified for several uses leading to the exclusion of five of the thirty-four uses proposed by the applicant.

No Member State required a derogation under Article 44(5) of the BPR. The conclusion of the BPC is that this family can be authorised for the uses described in the SPC subject to the conditions specified therein. In particular, the BPC did propose a post-authorisation requirement which is included as an approval condition in Annex I to the draft Regulation. The Commission also explained how recent comments from the Commission's Legal Service and one Competent Authority had been addressed in the SPC.

No Member State had comments on the draft Regulation proposal.

The Commission informed that the vote in written procedure will be launched without delay after the meeting of the Committee.

Outcome of the vote by written procedure that took place between 6 April 2022 and 29 April 2022: favourable opinion.

Section C AOB

C.01 Update on the application for inclusion of in-situ generated nitrogen into Annex I to the BPR

The Commission informed that an application for inclusion of in-situ generated nitrogen into Annex I had been submitted to the evaluating Member State in February 2022. However, the application had not yet been validated, as the evaluating competent authority requested the applicant to submit more detailed information on how the specific technique of in-situ generation of nitrogen is working.