EUROPEAN COMMISSION

Health and Food Safety Directorate General

Standing Committee on Biocidal Products

8 December 2021
10:00 – 13:00
Webex meeting

MINUTES

Section A Information and/or discussion

A.01 Adoption of the Agenda *(SCBP74-Doc.A.01)*

One Member State asked to add a point under AOB to obtain information on the implementation of the Chemicals Strategy for sustainability and possible consequences for biocidal products. The agenda was then adopted.

A.02 Adoption of the minutes of the 73rd SCBP meeting *(SCBP74-Doc.A.02)*

The Chair mentioned that one Member State had provided comments in writing, which had been accepted in the draft minutes made available. No other comments were provided during the meeting. The minutes of the 73rd SCBP Meeting were then 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 *(SCBP74-Doc.A.03)*

The Commission informed that internal discussions were ongoing on the possible renewal of approval of creosote for railway sleepers, transmission poles and the three other specific uses supported by only one Member State, as well as the duration of a possible renewal of approval, and that it planned to present a draft decision at a forthcoming meeting of this Committee.

The Commission invited Member States to confirm the correctness of the information in the document tabled for the meeting as regards the two uses of creosote for which many Member States consider that they would meet the conditions for derogation to exclusion under Article 5(2)(c) of Regulation (EU) 528/2012 in their territory. This information will be the basis to

establish the list of Member States where those uses will remain authorised. In line with the outcome of the discussions at the last meeting of the Standing Committee, the list will be made available and maintained by ECHA in the future once the approval would be renewed.

One Member State indicated that it cannot yet confirm its support for the use of creosote in railway sleepers. Another Member State confirmed its support for the use in railway sleepers and transmission poles and informed that the use for agricultural poles is being discussed.

A.04 Information on ethylene oxide

The Commission recalled that ethylene oxide was supported under the review programme of existing active substances for the disinfection of single-use medical devices before packaging in the manufacturing plant. The BPC adopted its opinion on the application for approval in December 2020. The substance meets several of the exclusion criteria of the BPR.

In late 2020, industry had contacted the Unit in DG Health and Food Safety responsible for the implementation of the Medical Devices Regulation (the MDR) and had argued that the substance should fall within the scope of the revised MDR adopted in 2017. Subject to confirmation by the Legal Service of the Commission, the Units for the implementation of the BPR and the MDR provisionally agreed with the analysis presented by industry that this use falls within the scope of the new MDR and therefore is out of the scope of the BPR. The Commission added that further discussion is needed on whether the MDR allows to take a formal decision on what is a Medical Device or not as is possible under Article 3(3) of the BPR for biocidal products.

The Commission informed that this use was the only use defended under the BPR and that, if the above-mentioned interpretation was confirmed, there would therefore be no other representative use in the application dossier that could be a basis for an approval under the BPR. Further reflections are therefore needed on how to close the decision-making procedure for the application for approval under the BPR.

One Member informed that a national authorisation during the transitional period established by Article 89(3) of the BPR had been granted for that use and asked what would be the consequences if it is regarded as falling within the scope of the MDR in the future. The Commission explained that once the decision that this use is in the scope of the MDR will be formalised, the Member State should contact the authorisation holder under the national law and informed him that an authorisation under the BPR is no longer required.

The evaluating Member State informed that another use, i.e. disinfection of museum objects had also been discussed prior to the submission of the application for approval, but had eventually not been included – so the disinfection of medical devices was indeed the sole use in the application dossier. The Commission informed that it had scheduled a meeting with the applicant and will seek further confirmation on this. The information received during the consultation on the derogations under Article 55(3) for in-situ nitrogen will also be checked to verify whether this use had been mentioned at that time.

The Commission invited the representatives of the Member States to discuss the matter with their counterparts responsible for the implementation of the MDR to see whether they share the view of the Commission and indicated that it will inform immediately the Committee when a definitive Commission position is known.

A.05 Exchange of views on a request under Article 3(3) of Regulation (EU) No 528/2012 on a product containing 'Capsicum oleoresin expeller pressed' as active ingredient (*SCBP74-Doc.A.05*)

The Commission introduced the document prepared in connection with the Article 3(3) request submitted by one Member State in September 2021. The request concerns a product with biocidal claims (repellent against cats and dogs) which contains 'capsicum oleoresin expeller pressed' as active ingredient and is neither authorised under the BPR nor registered under the national transitional rules. The manufacturer claims that it is not a biocidal product as, in its view, 'capsicum oleoresin expeller pressed' is not in the scope of the BPR, as it is not to be considered a substance in line with the definition in the REACH Regulation and in the BPR, similarly to dried lavender blossoms, for which the Commission had adopted a decision under Article 3(3) of the BPR in 2016.

With regard to the three cumulative elements of the definition of a biocidal product (presence of an active substance, mode of action and biocidal claim), the Commission indicated that the mode of action and claim are those of a biocidal product (mode of action which is not physical or mechanical and biocidal claim). As to the presence of an active substance, the Commission considered that 'capsicum oleoresin expeller pressed' is to be considered a substance in line with the definition in the REACH Regulation and in the BPR. While it is true that, according to applicable guidance, whole living or unprocessed dead organisms or parts thereof are not considered as substances, in the case of 'capsicum oleoresin expeller pressed' the manufacturing process includes a processing element, namely the expeller pressing, meaning that is to be considered a substance. Moreover, capsicum oleoresin had been successfully notified as an active substance in product-type 19 and included in the Review Programme in 2019, but eventually no application for approval had been submitted within the set deadline. Consequently, a product containing 'capsicum oleoresin expeller pressed' as active ingredient and intended to be used as repellent against cats and dogs should be considered a biocidal product.

The Commission asked for the views of the Member States and whether it is at all necessary to prepare a decision under Article 3(3) of the BPR, since the case seemed to be rather clear.

The Member State having submitted the request agreed with the Commission analysis and preferred to have a formal decision under Article 3(3) of the BPR. Another Member State also expressed the wish to have a formal decision adopted on the matter.

On request of a Member State, the Commission clarified that the current case is different from the case of a similar product intended to be used against humans, which had been discussed in the past. The product under discussion is not meant to be used for defence purposes, but to keep cats and dogs away from gardens or other areas (but not intended to protect plants). Eight other Member States supported the adoption of a formal decision by the Commission on the matter.

The Commission concluded that it will prepare a draft decision that will be presented at the next meeting of the Standing Committee.

A.06 Exchange of views on requests under Article 36(1) of Regulation (EU) No 528/2012 on products containing alphachloralose (*SCBP74-Doc.A.06*)

The Commission presented the document made available to Member States which provided background information and intended to seek Member State's opinion on several Article 36(1) referrals related to amendments of authorisations of rodenticides for indoor control of mice

containing alphachloralose. The disagreements are on the modifications made by two Member States of the existing authorisations pursuant to Article 48 of the BPR. For such referrals, the reference Member States are the Member States that modified the authorisations and the objections had been raised by two other Member States against those modifications.

The modifications were triggered by notifications from poisoning centres and veterinary clinics referring to primary and secondary poisoning incidents involving cats and dogs from products containing alphachloralose (primary poisoning incidents reported were few; the main issue was secondary poisoning). In response to these incidents, one Member State modified the authorisations to include further labelling requirements while the second Member State restricted the use to trained professionals.

One other Member State then objected to the modification made by the first Member State as it considered that the products should be restricted to professional use. On the other hand, a Member State objected to the restriction of the use to trained professionals introduced by the second Member State. In the course of the referrals, several Member States and the authorisation holders provided comments. Three Member States supported the modification made by the second Member State (and the position of the Member State objecting to the modification made by the first Member State. The second Member State informed that following a legal challenge of the modification by the authorisation holder, a national Court had confirmed the measure. Another Member State informed that it was in the process of amending the authorisations also to restrict them to trained professionals. On the other hand, two Member States agreed with the first Member State who had only introduced additional labelling requirements.

The Commission informed that alphachloralose had been approved on 01/07/2011 and that the renewal process is ongoing. The approval has been extended until 31/12/2023. There are 110 biocidal products/biocidal product families containing alphachloralose currently authorised in 26 Member States, (AT, BE, DK, FR, DE, IRL, IT, LT, LV, LU, NL, PT, ES, HR, CY, CZ, HU, PL, SK, SI, SE, FI, EE, RO), Norway and Switzerland.

In the assessment report for alphachloralose at the time of the first approval, it is indicated that: *"Chloralose is to be used indoors and the opportunity for primary poisoning to non-targets is negligible. The biocidal product is presented in a tamper resistant bait box as a non-spill wax block formulation. It is therefore not attractive to granivorous passerine and corvid species. There is unlikely to be an issue of secondary poisoning since a limited exposure to the environment is expected. Chloralose is for indoor use only and immobilisation of mice occurs shortly after bait consumption. Mammal predators may catch a poisoned mouse but with LD50 values no less than 100 mg/kg for cats and dogs, a secondary poisoning risk is considered negligible".*

However, after the restrictions imposed on rodenticides containing anticoagulant active substances, the sales of products containing alphachloralose and the poisoning incidents have increased in some Member States. The first reported cases of poisoning incidents, in which the diagnosis was based on the symptoms, are from 2018. Recent data based on a survey in poisoning centres and veterinary clinics to gather more data and also analytical tests on the animals carried out in a Member State had confirmed the poisoning with alphachloralose in a significant number of cases.

After having carefully examined all the available information on the matter, the provisional conclusion reached by the Commission is that the evidence that had become available recently demonstrates that the conclusions in the assessment report underlying the approval of alphachloralose with regard to the likelihood of secondary poisoning may need to be revised –

and this should be considered in the context of the ongoing renewal. In the meantime, it seems that the conditions laid down in Article 19 point 1(b)(iii) are not fully met by products containing alphachloralose as data from poisoning incidents show that products containing alphachloralose seems to have unacceptable risks for animal health. Therefore, in accordance with Article 19(5) the products may 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.

In addition, pursuant to Article 19(5) of the BPR, the use of the biocidal product shall be subject to appropriate risk mitigation measures. The Commission considers that risk mitigation measures to address the risk of primary and secondary poisoning incidents from the use of products containing alphachloralose may depend on the particular circumstances and available evidence in the Member States, so that some Member States may consider it necessary to restrict use to trained professionals while others may consider that additional labelling requirements would suffice.

Therefore, the Commission indicated that the current referrals could be resolved through a decision that would enable Member States to adopt the restrictions that they consider necessary in their territories. The Commission invited Member States to indicated their views on the proposed approach.

One Member State agreed with the Commission proposal, even if ideally the risk mitigation measures (RMM) should be harmonised. In their opinion, it is necessary to gather more data on poisoning incidents in order to support the ongoing risk assessment and the decision-making on the renewal of approval of the active substance. They are gathering data from poisoning centres, veterinary clinics to assess if the RMM adopted have been effective, and the conclusions should be taken into account for the renewal of approval of the active substance.

The Commission replied that the non-harmonised situation would be temporary as the risks of poisoning incidents will indeed be assessed in the process for renewal of approval of the active substance and this may help to achieve full harmonisation on the RMM that Member States should adopt when subsequently renewing the authorisations of products containing alphachloralose.

Another Member State supported the approach proposed by the Commission.

A further Member State informed that it had applied Article 37 of the BPR to restrict the authorisation to products in pre-filled and tamper-resistant bait stations. They wonder if they would need to amend the authorisations in accordance with Article 48 once a decision on the Article 36 referrals will have been adopted by the Commission.

The Commission clarified that the objective of the decision is to resolve the disagreement on the amendments made by the first and second Member States to the authorisations but the decision will enable all Member States to adapt the RMM to the needs and specific circumstances in their territories. In principle, as the Member State having asked the question had already adapted the authorisations, no further amendments would seem necessary.

Another Member State reported that there had also been notifications of poisoning incidents with products containing alphachloralose and the authorisations had been amended making use of Article 37 of the BPR to require that products for non-professionals may be only marketed in pre-filled bait stations. After the amendment of the authorisations, the number of notifications of poisoning cases has decreased steeply in that Member State, and therefore, they think the measures taken nationally had been effective. That Member State also wondered if

they would need to amend the authorisations in accordance with Article 48 one a decision on the Article 36 referrals will have been adopted by the Commission.

The Commission confirmed that following the adoption of the decision, all authorisations for products containing alphachloralose would need to be based on Article 19(5) of the BPR. However, the restrictions/RMM already set by Member States can be maintained and only a formal amendment of the authorisations will be needed to refer to a different legal base. A Member State highlighted that this could be problematic as national legislation sets out that products cannot be authorised under Article 19(5) of the BPR in their territory. The Commission replied that this would need to be solved at national level.

Another Member State provided information on the situation in their territory. The first products containing alphachloralose were authorised in this Member State in 2015. The products were for indoor use in bait boxes (but not prefilled bait boxes). In 2018, they received the first notifications oft poisoning incidents that then increased over time. The authorisations were amended in 2019-2020 to allow products only in prefilled bait stations for consumers and additional labelling warning about the risks of poisoning and an obligation to inform pet owners when alphachloralose was being used in their neighbourhood. The authorisation holder considered the restrictions acceptable. However, these measures did not reduce the number of notifications of poisoning cases. Therefore, and in view of the increased poisoning incidents they will restrict the use to professional users. That Member State pointed out that in their territory there are thousands of users that are considered as trained professionals (for example, those with qualification to apply plant protection products The authorisation holder contested the need for this restriction, as in their view secondary poisoning is not possible with their products when used correctly but in that Member State's opinion the biggest risks for poisoning of cats is secondary poisoning from alphachloralose. They believe that misuse of products is not the reason in their territory, as they have not faced a similar issue with rodenticides containing anticoagulants. They agreed with the need to assess the risks of poisoning incidents in the process for the renewal of approval of the active substance and supported the approach proposed by the Commission. The same Member State highlighted that the LD_{50} of alphachloralose for cats is lower than for mice and for some birds is even lower than for cats.

Another Member State reported on notifications of intentional poisoning of pets with rodenticides in the past, mainly involving stray cats and dogs. According to their data, in most poisoning cases, other household chemicals that are freely available and more effective are used.

A further Member State informed that products containing alphachloralose are restricted since May 2020 to trained professionals due to the increasing number of poisoning incidents that have been confirmed by analytical data. They have observed a decrease in the number of poisonings since the restriction applied.

In another Member State, hundreds of primary and confirmed secondary poisoning incidents of cats and dogs with products containing alphachloralose had occured, and therefore, a restriction to trained professionals had been found justified and confirmed by national courts. They supported the proposal from the Commission to base the authorisations of products containing alphachloralose on Article 19 (5) of the BPR.

Other Member States also agreed with the approach proposed by the Commission.

In light of the support of the Member States to the proposed approach, the Commission indicated that it will proceed to draft a formal decision that will be presented to the Standing Committee at a forthcoming meeting.

Section B Draft(s) presented for an opinion

B.01 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 Alkyl (C12-16) dimethylbenzyl ammonium chloride and marketed as a cleaning product *(SCBP74-Doc.B.01)*

The Commission recalled that the draft Implementing Decision under discussion originates from a request by a Member State, who asked the Commission to decide whether a certain product containing ADBAC/BKC (C12-16) is to be considered a biocidal product.

The Commission recalled that, in the meeting of the Standing Committee in September, a draft Implementing Decision had been presented for discussion. The draft had subsequently been revised and made available on CIRCABC.

Following the discussions at the Standing Committee, two Member States had sent comments in writing. The draft had also been made public to give stakeholders the possibility to provide their feedback.

The Commission informed the Committee about the outcome of the feedback received,: one comment by an EU citizen, one from the German Environment Agency, one by a business association and one by a company[1]. The Commission had also received by email, shortly after the feedback mechanism was closed, a comment by COPA-COGECA (Committee of Professional Agricultural Organisations and General Confederation of Agricultural Cooperatives). All the comments were supportive of the Commission's draft Implementing Decision. The comments generally focused on the presence of the active substance, its properties and its concentration level.

The Commission then outlined the comments submitted by the Member States. In its written comments, one Member State had expressed the view that a decision which hinges on the intended use of the product as presented on the market would not be sufficiently operational. The Member State proposed that biocidal intent of the product is assumed by the presence the biocidal active substance and considers this to be in line with the case-law of the Court of Justice, including the recent case C-29/20 *Biofa*. Another Member State had sent written comments suggesting to take into account the *Biofa* judgment.

The Commission recalled that, on the other hand, during the meeting of the Standing Committee in September a number of Member States had stressed that the way the product is presented on the market forms part of the case-by-case assessment carried out by national authorities to establish whether a product is a biocidal product.

The Commission explained, in light of the above, the changes introduced to the draft. The name of the product was removed in order to facilitate enforcement by national authorities. Following the consultation of the Commission services concerned, it was considered necessary to add in Article 1 a reference to the information provided by the manufacturer or by distributors and to the intended use of the product. With respect to the comment by a Member State proposing that biocidal intent is assumed by the presence the biocidal active substance, the Commission recalled that the presence in the product concerned of an active substance does not, in itself, even if the active substance is present above a certain concentration, have the effect of

[1] These comments are public and can be found at the following address: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13060-Biocidal-products-classification-of-a-product-containing-the-active-substance-ADBAC-BKC-C12-16-_en

conferring on it the status of a 'biocidal product' within the meaning of the BPR (see C-29/20, *Biofa*, para. 28).
One Member State supported the draft although it considers that their inspectors might still have some difficulties in enforcement. Another Member State welcomed the removal of the name of the product making the Implementing Decision more general.

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

Outcome of the vote by written procedure that took place between 17 December 2021 and 7 January 2022: positive opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the United Kingdom Health and Safety Executive permitting the making available on the market and use of the biocidal product Mydis in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP74-Doc.B.02)*

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the extension of the action taken by the United Kingdom Health and Safety Executive permitting the making available on the market and use of the biocidal product Clinisept + Skin Disinfectant in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP74-Doc.B.03)*

Items B.02 and B.03 were discussed together. The Commission briefly introduced the two draft decisions, which intended to allow the extension of the temporary permits granted by the United Kingdom in respect of Northern Ireland for two hand disinfection products.

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

Outcome of the vote by written procedure that took place between 17 December 2021 and 7 January 2022: positive opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation granting a Union authorisation for the single biocidal product "ARIEL chlorine Professional System 5 Chlorine Bleach for white wash" *(SCBP74-Doc.B.04)*

The Commission explained the outcome of the BPC discussions on the way to express the concentration of the active substance in the biocidal product in section 2.1 of the SPC in case of active chlorine released *in-situ*. The Commission invited the Committee to endorse the BPC conclusions. No further comments were received on the draft proposal.

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

Outcome of the vote by written procedure that took place between 17 December 2021 and 7 January 2022: positive opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the unresolved objections regarding the terms and

conditions for granting an authorisation for the biocidal product Sojet in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council *(SCBP74-Doc.B.05)*

The Commission presented the draft decision on the unresolved objections during a mutual recognition in sequence of an insecticide to be used by professionals for indoor application in industrial or commercial premises, households or private areas, public areas and animal housings for the control of flies. The biocidal product is dispersed in water and applied on cardboard sheets by brushing and contains as active substances imidacloprid and cis-tricos-9-ene.

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, consisting of protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and single-use coverall of at least type-6 EN 13034, 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 considers 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.

The Commission explained that in order to resolve the disagreement, it had taken the following elements into account:

- 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.

The Commission therefore 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 (glove material to be specified by the authorisation holder within the product information) and single-use protective coverall of at least type-6 EN 13034 or equivalent is required for the handling of the product. 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, if the applicant for authorisation or the authorising authority identify effective technical or organisational measures leading to an equivalent or higher level of exposure reduction, those measures should replace the wearing of personal protective equipment and should be specified in the authorisation and on the label of the biocidal product.

The Commission explained the amendments introduced in the draft decision uploaded in CIRCABC to specify that the protective coverall must be single-use in order to avoid emissions to the sewer system from washing of contaminated clothes that is included in the authorisation granted by the reference Member State for the product and that results from the environmental risk assessment.

One Member State insisted on the views expressed in the written comments submitted prior to the meeting that the use of single-use coverall cannot be replaced by technical and organisational measures due to the risks for the environment from the washing of multiple use coveralls.

The Commission clarified that in the replacement of the use of the coverall by technical and organisational measures makes the requirement of single use coverall not relevant, as risks for the environment from washing the used coverall will be eliminated. The Commission invited that Member State to reflect on this point and to provide a position by 17 December 2021.

Another Member State agreed with the proposal made by the Commission to sort out the disagreement provided that the following sentence proposed would be eliminated: *"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".* The Member State argued that this is already stated in Article 2(3) and (c) of Regulation (EU) No 528/2012 and is therefore not necessary and also noted that labels of biocidal product already contain a lot of information so that unnecessary statements should be avoided.

The Commission explained that the conditions to be included in the authorisation and in the label of the products had been intensively discussed with the other Commission services concerned. The reason to include the sentence is to remind employers, who might not all be familiar with the text of the Biocidal Products Regulation that in application of Council Directive 98/24/EC they have the obligation to assess whether exposure can be reduced or eliminated by application of technical and organisational measures, even if the wearing of protective equipment is prescribed for the use of the product (as technical and organisational measures were not identified so far). The legislation is clear that the wearing of personal protective equipment shall only be required when it is not possible to prevent exposure to the hazardous substance by other means. That is also the reason why the decision provides that if the applicant for authorisation or the authorising authority identify effective technical or organisational measures leading to an equivalent or higher level of exposure reduction, those measures must replace the wearing of personal protective equipment and should be specified in the authorisation and on the label of the biocidal product. The Commission invited that Member State to submit their legal reasoning to sustain their position by 17 December 2021.

Section C AOB

1. Biocides in the context of the Chemical Strategy for Sustainability

The Commission provided information on the ongoing activities related to the Chemical Strategy for Sustainability (CSS). Several interservice groups led by the Directorates-General

responsible for the CSS work on the various actions announced in the strategy. Some topics are of direct relevance for biocidal products and/or plant protection products, in particular:

- Revision of the CLP Regulation to introduce criteria for endocrine disruptors (distinguished in categories) and PBT substances. For the time being, there seems to be acceptance of the criteria established under the BPR and PPPR for category 1 endocrine disruptors, while the discussions are more complex on the envisaged additional category for suspected endocrine disruptors.
- Additional hazard categories to become exclusion criteria such as immunotoxicity and neurotoxicity. So far, most substances classified for these properties have not passed the risk assessment under the BPR or PPPR.
- Discussions on the essential use concept. An external contractor will examine how to develop this concept in the context of REACH and will consider the experience gathered under the BPR.
- One substance one assessment. Data ownership and possibility to access data submitted in different legal frameworks need to be examined, as well as the implications on the IT systems in use in the various agencies and the timing of assessments. Discussions are also ongoing on the scope of the concept, i.e. whether to limit to one substance one hazard assessment, leaving out the exposure and risk or whether including all elements.
- Cumulative risk assessment. In the CSS it was announced that under REACH the introduction of a mixture assessment factor as an additional safety factor will be considered.
- Export bans for substances no longer allowed in the EU – particular consideration will need to be given to the interactions with the Rotterdam Convention (and the PIC Regulation), also bearing in mind that some substances might be banned in the EU under one legal framework but not under other ones.

The Member State having requested the inclusion of this AOB point thanked for the update from the Commission and asked about the possible removal from the ED criteria for biocides of the exemption for substances for which the mode of action is intended to control target organisms other than vertebrates via their endocrine systems, which is not contained in the criteria established under the PPP Regulation). The Commission indicated that it considers to remove the exemption during the review that is foreseen by 2025 in the regulation on the ED criteria and reminded that it appears that the specific clause does not have any practical implications under the BPR, as no active substance in the Review Programme falls under that clause.