NOTE FOR DISCUSSION WITH MEMBER STATES' COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS

This document is drafted in the interest of consistency of the implementation of Regulation (EU) No 528/2012 and with the aim of finding an agreement between Member States' Competent Authorities for biocidal products on a harmonised approach. Please note, however, it does not represent the official position of the Commission and that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Extension of the Review Programme of existing active substances beyond 2024

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

(1) At the 99th CA meeting in March 2023, discussions took place on the need for an extension of the period allocated to complete the review programme, and further actions needed to improve the progress and reach the objectives of high protection of human health, animal health and the environment aimed by the BPR ([1]).

(2) The purpose is to continue the discussions and find agreements on those issues.

2. ANALYSIS AND DISCUSSION

(1) Following the last CA meeting, a news group was opened asking Member States their views on:

a. The period needed for the extension of the review programme

b. Actions needed to speed up the completion of the review programme referred to in the CA document, including on other potential actions

(2) 10 Member States provided their views on those issues. An overview is presented in Appendix I to this document.

a. *On the period for extension:* Member States proposed a range from 3 to 6 years of extension, with several Member States noting that a minimum of 5 years would be necessary. It was also remarked that, due to some recent taking over of active substances, some applications may still be submitted 2 years after acceptance of the notification, and would therefore need time to be processed. One Member State remarked that 45% of the work was done in around 20 years, and questioned whether even 10 years would be sufficient.

([1]) CA-March23-Doc.5.2 - Extension of RP beyond 2024.doc

b. On actions needed:

i. On the ED assessment :

1. the views were diverse, some Member States favoured a common deadline for all active substances, while some other Member States remarked that each application for approval has a history and the deadline of submission of the data should be adapted to each case. One Member State intends to make some further proposals.

2. All Member States favoured finding ways to streamline the work, in particular when active substances meet already other exclusion criteria, when it comes to assess the ED properties for the environment which is not an exclusion criteria. One Member State considered, however, that a cautious approach should be taken as the BPR would be the only framework in which data could be requested to assess the ED properties of biocidal active substances.

ii. *On the application of new guidance document* the views were split, some Member States favoured no application of new guidance to on-going dossiers, while other supported the application of new guidance to ensure a high level of safety to human health, animal health and the environment. Another Member States considered that a case-by-case approach would be needed to define which guidance should be applied (e.g. Technical Agreements for Biocides - TAB entries versus Emission Scenario Documents).

iii. *On awaiting the RAC opinion when the evaluating CA proposals concerns a CMR cat 1A and 1B, and mutagen category 2*: some Member States support not awaiting anymore, while one Member State still supports awaiting the outcome of the RAC opinion. One Member States considered that it was not necessary to wait the RAC opinion when other exclusion criteria are already met.

iv. *On the opportunity to provide new information to show a safe use*: one Member State considers that the opportunity should still be given to applicant to provide new information when the unacceptable risk identified results from the application of new guidance posterior to the submission of the previous information by the applicant.

v. Member States made some additional proposals some of which, however, cannot be implemented as they would not be compliant with the rules currently set in the BPR, like postponing systematically all expiry dates of approvals to delay the submission of applications for renewal of approval, or not assessing anymore a representative product in the renewals. Other could further be discussed, but do not necessarily need to be reflected in the Review Regulation.

(3) Based on the contributions received, the Commission would make the following proposals.

2.1. New period of extension

(4) The Commission would propose to extend the duration of the review programme until 31 December 2030. At this stage, it would be considered not reasonable to postpone the review programme to an even later date, given that most applications were submitted in 2004-2008. Furthermore, the Commission intends to conduct a REFIT evaluation of the current Regulation to be concluded in 2026 – any potential changes resulting from the evaluation should be in place by the end of 2030.

(5) As discussed in the last CA meeting, the extension must not be considered by applicants as an opportunity to generate new data at their own initiative, or make changes in their application (ex: change the use because unacceptable risks are identified, etc.). Similarly, the extension shall not be considered by Member States and ECHA as a signal to diminish the efforts and progress in the review programme, and to further increase delays.

2.2. Other actions to improve the progress in the review programme

(6) The extension of the period cannot, alone, ensure the completion of the review programme. Further actions are necessary, and some may need to be drastic to limit further delays and finally conclude the review programme.

2.2.1. Resources in Member States

(7) Member States must allocate sufficient resources to complete the work, and review the financing of their activities to reach a full-recovery system as necessary. The call "*Contributing to more sustainable and circular food production systems by boosting Member States' capacities to evaluate and remove from the market unsafe pesticides and biocides – SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA*" will help those Member States having applied and whose applications will be accepted. Where necessary, Member States must also explore ways to recover costs on applications submitted years ago.

2.2.2. Governance in the assessment of applications for approval

(8) Backlog active substance reports: Greece, Malta, the Netherlands, Poland and Sweden must conclude on their backlog reports (i.e. those submitted to ECHA before 1 September 2013) so that the BPC opinions can be available by the end of 2024 at the latest.

(9) Respect of rules and procedures: A better respect of the procedures and rules in the Review Regulation is required by applicants and Member States. The current Review Regulation contains already rules and provisions which are not strictly applied by Member States. For instance, when no data is submitted by a deadline set, the application must be considered withdrawn. The "quest for a safe use" must stop.

(10) Application of new guidance documents to on-going applications for approval of active substances: it is proposed that no new guidance document or updated version of existing guidance document is applied as from 1st January 2024. The

only exception is when a necessary element of the assessment cannot be completed due to absence of guidance. Considering that approval decisions have been adopted already for all product-types except PT17 (for which only one substance is under assessment), this means that the situation where a specific representative use would not have yet been assessed in the past for another active substance under the same PT would be rare.

(11) Examination of the ED criteria: the Commission services are still reflecting on this topic. The Commission would welcome the views of all Member States on the following questions :

a. Would Member States support setting a common date of 31 December 2025 (when all missing data on ED must be submitted by applicants?

   31 December 2025 still leaves more than 2 years to provide data, which means a total of more than 7 years after the adoption of the ED criteria (in 2017).

   Such a date should be seen as a maximum period of time that Member States may give to applicant to provide the data, but Member States remain free to set lower timelines to applicants, or not use it, when they already requested in the past the relevant data from applicants and the applicants failed to comply with their duties.

   No step-by-step approach should be implemented anymore by Member States, who have to apply the ECHA-EFSA guidance document more directly, without iterative process, as it done in the PPP area which applies the same guidance document.

   After 31 December 2025, the evaluation of the concerned dossier would either have to continue based on the available data, or when requested data have not been submitted by applicants, the provisions of Article 11 of the Review Regulation ([2]) and of Article 9(1)(b) of the BPR ([3]) would be applied by Member States, ECHA and eventually the Commission.

b. Would Member States support making progress on the examination of active substance meeting already other exclusion criteria, in absence of data to assess the ED properties and the risks linked to those properties?

c. Would Member States support making progress on the examination of active substances confirmed as not meeting the ED criteria for human health, and for which the ED data for the environment are still missing? In which cases would they accept it? (ex: indoor use? Use in closed systems? Etc.)

(12) Suspension of the progress of dossiers pending a RAC opinion on the harmonised CLH of the substance when the harmonised classification concerns an exclusion criteria, mutagen category 2: it is proposed to no longer await the outcome of the RAC opinion on this matter. The ECHA BPC is entitled by the BPC to make

([2]) Absence of data is considered as a withdrawal of the applicant.

([3]) The BPR states that: **The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), either**: …. (b) in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied **or where the requisite information and data have not been submitted within the prescribed period**, **adopt an implementing decision that an active substance is not approved.**

evaluation of biocidal active substance and set up its conclusions as regards to CMR properties, and related exclusion criteria.

(13) Modifications of the Review Regulation :

a. Taking-over mechanism: the provisions for taking over the role of participant will be removed for the Review Regulation. The Commission will start preparing a modification of the Delegated Regulation in this respect.

(14) Other actions

a. Renewal of approval of active substances: Member States are encouraged to make use of the provisions of the BPR that allows them to make a limited evaluation, to limit the general workload.

3. ACTIONS

(15) Member States are invited to reflect on all proposals made in section 2.1 and 2.2 of this document, and formulate their views to continue the discussions, and possibly reach an agreement on some or all of the proposals.

Appendix I

Feedback from Member States in the newsgroup following the last CA meeting

	Years of extension needed	Set strict (common) deadline for ED?	Waiving ED for already exclusion substances?	Wait for RAC CLP opinion before submitting the CAR?	Apply new guidance documents of ECHA?	Remove the possibility to take-over the role of participants after a first withdrawal?	Other comments / proposals
Member State 1	6	YES	YES	?	NO		. More money needed . Priority to RP instead on renewals/reviews/ Union authorizations
Member State 2	5						
Member State 3	4	?	YES	YES, but NO if already meets another exclusion criterion	case by case	YES	
Member State 4	10?	Yes (provided certain conditions)	YES	NO	NO	YES	. Formalize the 'Accordance Check' when CARS are submitted to ECHA . Limit the work of renewals (Renewal without or only limited evaluation, No evaluation of a representative product during renewal)

Member State 5	>5		Only in very specific cases such as the renewal of AVK products.	NO			
Member State 6	>5	YES		NO	YES		. Rules in which situation it is possible to lower the level of ambition of evaluation . Clarify the procedure in the situation where applicant has not delivered the requested information . Put renewals on hold
Member State 7	5 (+2 for in-situ)	YES (proposal by SE soon)	YES	YES	YES		
Member State 8	3						· Data gaps / data of insufficient quality: we need a system that forces the eCA to close the dossier when data gaps are too important / data quality is too bad / stop of the clock is exceeded. Maybe ECHA needs more decision power. · Simplify the process between eCA and peer-review by all MS, for example by implementing an eCA and one single co-rapporteur. (Other MS must have confidence in the eCA and co-rapporteur after 20 years of work sharing). · ED assessment lead to further data requirements: ?? is there any solution?? If key studies for instance for reprotox are available and of sufficient reliability, but key ED endpoints are missing, then postpone additional data requirements to the renewal of the a.s.; Better coordination between ENV and HH experts . Postponing renewals of a.s. (for 5 more years?)

Member State 9	3-5 years	YES		NO	YES		
Member State 10	>5	YES	YES	NO	NO		Commission could directly supply technical support by trained personnel for the evaluation of substances and products.