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) As evidenced in the status report presented in document CA-March23-Doc.5.1, only 45% of the review programme of existing active substances has been completed to date.

(2) According to Article 89(1) of the BPR, the review programme shall be completed by 31 December 2024. In the light of the progress to date, it is clear that this objective will not be met.

(3) The purpose of the document is to discuss 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

2. ANALYSIS AND DISCUSSION

(1) The review programme of existing active substances under Directive 98/8/EC started in 2000 with the identification and notification of existing active substances placed on the EU market for biocidal purposes before 14 May 2000.

(2) Regulation (EU) No 2032/2003 set up the list of identified existing active substances, and among them, notified existing active substances by prospective applicants with the view to support their approval for one or more biocidal product-types (PTs). According to that Regulation, most applications had to be submitted between 2004 and 2008 depending on the PTs.

(3) Initially planned to be completed by 14 May 2010 under the BPD, the review programme had been extended first in 2009 until 14 May 2014. In 2013, after discussion with Member States Competent Authorities, the review programme was re-organised and its duration further extended until 31 December 2024. In particular, the review programme was re-organised in 6 different priority lists with deadlines for the submission of the draft evaluation reports to ECHA, and a number of principles on a more efficient management of the dossiers were agreed

by Member States Competent Authorities. Regulation No 1062/2014 (also referred to as the Review Regulation) was adopted to reflect those agreements.

(4) It was agreed in the CA meeting that 50 opinions per year needed to be adopted by ECHA to complete the review programme by the target date of 31 December 2024.

(5) Although the rhythm increased and the objective of adopting 50 decisions per year was almost reached around 2016, the rhythm of progress started to decline from that date. Member States have not respected the deadlines for the submission of the draft reports to ECHA. The Commission presented a detailed assessment of this situation to the Council and the European Parliament in the implementation report of the BPR in June2021 ([1]). The mains reasons for the delays are the lack of resources allocated in Member States, delays of applicants in submitting additional data, complex technical questions on specific dossiers that need to be resolved first, evolution of technical guidance, and the adoption of new scientific criteria for the determination of endocrine disrupting properties which triggered the need for further data and further assessments. The Commission sent letters to the responsible Ministers in all Member States to express its concerns on delays in the implementation of the BPR (active substances assessments, product authorisations), and calling on Member States to take action, including allocating sufficient resources ([2]).

(6) Since 2015, discussions took place regularly in the CA Meeting, and agreements were reached on a number of actions ([3]). Workshops were organised by ECHA, and an ECHA Action Plan on Active Substances has also been agreed ([4]). Regular reports are being made at each CA meeting.

(7) Despite these actions, and although some progress can still be achieved before 31 December 2024, it is clear that the review programme will not be finalised by that date.

(8) The renewal of approval of various active substances for various products-types now runs in parallel, while, due to the delays referred to above, not all active substances have been assessed under the review programme for the same product-types. This does not allow an holistic view on the properties of active substances for the same PT, and does not ensure a level-playing field for economic operators on the market.

(9) Considering the fact that the review programme will not be finalised by the deadline set in the Regulation, the Commission has no other choice than to use the powers delegated by the Council and the European Parliament in the BPR, and start preparing a draft Delegated Act amending the BPR as regards the duration of the work programme for examination of existing biocidal active substances. Other actions may be necessary, including revising certain provisions

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([1]) The Report is available at this link: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1623326515401&uri=CELEX%3A52021DC0287 and the Staff Working Document, which presents detailed evidence for the findings outlined in the report, is available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0128&qid=1623670527414

([2]) Similar letters were also sent in 2015.

([3]) CA-March18-Doc.5.1a - Final - Actions for AS review programme.pdf

([4]) CA-Feb20-Doc.5.2 - Final - AS Action Plan.doc

in the Review Regulation (EU) No 1062/2014 (the Review Regulation) to amend the rules governing the review programme, in order to help achieving the completion of the review programme.

2.1. New period of extension

(10) It is necessary to discuss and agree on the period needed for the completion of the review programme. While it is clear that an extension is needed and the period for extension needs to be realistic, the Commission would like to highlight that the review programme has now effectively run since almost 20 years (from the submission of the first applications in 2004), and considers that a too long extension period will go against the objectives of the BPR and the level of ambition pursued by the co-legislators.

(11) The Commission notes that, in term of data requirements and evaluation criteria, only the scientific criteria to assess endocrine disrupting properties (ED criteria) may be considered as "new" since 2004. However, the Commission remarks that these ED criteria have been adopted since 2017, and applicable since 2018. A guidance was published at the same time. Member States must have requested the necessary information to the applicants, who must have already generated the required data or already launched the generation of the required data. The responsibility to provide all required data to allow a conclusion on the application for approval lays on applicants.

(12) The extension must also 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 increase delays.

(13) The Commission would therefore like to ask the Member States to provide their views on the period required for the extension of the review programme, when considering genuine efforts by their authorities to deliver the outstanding assessment reports as quickly as possible.

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

(14) 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

(15) 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.

(16) The Commission has taken action and has launched 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*" , and provides for

10 Million euros grants to Member States to biocides (and plant protection products) competent authorities to help achieving progress the implementation of the BPR subject to the condition that a full-recovery system is established or maintained. Application must be submitted by Tuesday 25 April 2023 at 17.00 (CET) at the latest.

(17) The Commission would like to invite Member States to take action in that respect and submit applications for obtaining grants.

2.2.2. Governance in the assessment of applications for approval

(18) During the discussions in the CA meetings over the years, it became apparent that there was sometimes a "quest for a safe use" during the assessment of applications, e.g. that applicants were requested by Member States to provide new information during the evaluation when unacceptable risks are identified; or that applicants were requesting Member States to allow them to generate and/or submit new data at their own initiative. These practises must stop: they are not provided for in the BPR or the Review Regulation. In those situations, the applications must be assessed and conclusions reached based on data submitted in the dossiers ([5]).

(19) A better respect of the procedures and rules in the Review Regulation should be ensured by applicants and Member States.

(20) Other actions may be investigated :

a. Backlog active substance reports: progress must be made on the 34 backlog reports submitted before 1 September 2013 and for which BPC opinions are still not available. The Commission has serious difficulties to see a justification for the lack of progress on these dossiers after so much time.

b. Guidance documents: stakeholders associations have regularly indicated in the CA meeting that guidance documents were frequently evolving, leading to the need to submit additional data. It should be reconsidered whether there are valid reasons to apply new technical guidance developed by ECHA to already submitted applications, or whether new guidance should no longer be applied to review programme applications still under the evaluation phase in the Member States.

c. Examination of the ED criteria:

    i. the Commission services are currently exploring possible ways to make faster progress in certain cases (ex: when the substance already meets other exclusion criteria, when data may be lacking to assess ED properties for the environment);

    ii. it should also be explored whether a common deadline should be set for all dossiers for which data may still be missing; and conclude the assessments based on the data available at that date.

([5]) It is however noted that, during the BPC peer review, the possibility may given to the applicant to submit available data within 10 days after the BPC working group in certain situations, which should not delay the peer review process:

d. 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:

   i. In the past, there was an agreement reached in the CA meeting ([6]) that, where it is suspected that the active substance might fulfil the exclusion/substitution criteria (for the moment on CMR 1A or 1B, P/B/T), it was strongly recommended that the evaluating Member State submits its draft assessment report to ECHA only when the RAC has given its opinion on the CMR 1A/1B status, or PBT subgroup has given its opinion when found necessary ([7]), in order to take into account these opinions before submitting the draft assessment report to ECHA for peer review.

   ii. Similarly, there was an agreement reached in the BPC meeting that the peer review would be put on hold if it would appear that the substance may meet those criteria, or also Mutagen category 2 ([8]).

   The purpose of these agreements was to ensure legal certainty on the properties of the substance before a BPC opinion is adopted, and eventually a decision adopted on the approval of the substance, in the light of the consequences implied for a substance meeting the exclusion criteria (for Mutagen category 2, on the risk assessment).

   These practices are actually not foreseen in the Review Regulation ([9]).

   It is established that the BPR and CLP Regulations are two independent regulations which establish independent processes, where under the BPR the purpose of the draft assessment report submitted to ECHA by the Member State is to decide whether or not the substance may be approved; while under the CLP Regulation the purpose of the CLH submission by the Member State is to establish or review the harmonised classification of the substance. Under the BPR, ECHA's BPC is eventually responsible to deliver an opinion on the approval of an active substance, including whether or not the substance meets the exclusion criteria.

   The agreements referred to above have been a source of delays, and in some cases the responsible Member State has taken a lot of time to submit the CLH dossier, or has still not submitted the CLH dossier to date. Furthermore, different competent authorities may be responsible for the BPR and CLP Regulations in the Member States, and coordination between both competent authorities has not always been optimal.

([6]) CA-Sept13-Doc.8.3 - Final – Review Programme.doc

([7]) For PBT, the consultation of the PBT expert group is not systematic, and was not considered needed on clear cases.

([8]) EHCA BPC Working procedure for active substance approval, https://echa.europa.eu/documents/10162/763823/bpc_working_procedure_active_substance_en.pdf/3a35e75d-7c08-4c87-b501-8c24f0081dde?t=1618316704855

([9]) Only the submission of the CLH dossier is required at the latest at the same time the draft assessment report is submitted to ECHA, when its concerns CMR 1A, 1B properties, as set out in Article 6(7) of the Review Regulation; the need to await the RAC opinion to make progress is not set out in the Review Regulation.

While recognising the advantages of awaiting a RAC opinion on the harmonised classification in particular for those hazard classes triggering exclusion before the decision-making process is made under the BPR, also in the context of the "One substance one assessment" objective in the Chemical Strategy for Sustainability ([10]), it should be considered whether this approach should be maintained considering the delays in the review programme for the concerned substances, in a context where the ED and PBT criteria are about to be added as classification criteria under the CLP Regulation ([11]). Delays under the BPR for those substances go against the high level of protection of human health, animal health and the environment aimed for by the BPR and by the Chemical Strategy for Sustainability.

Furthermore, it might be helpful to get an overview of the number of concerned substances, for which a classification potentially leading to exclusion would be at stake, which could be limited compared to the majority of actives substances still in the review programme. Such an estimation could be made by ECHA on the basis of information to be provided by Member States.

(21) ECHA will also make a presentation at the meeting about the actions are also on-going within the ECHA Active substance Action Plan.

2.2.3. Rules in the Review Regulation (EU) No 1062/2014

(22) Rules of the Review Regulation could be amended to remove drivers for delays.

(23) As already referred in previous discussions in the CA meeting ([12]), the Commission will propose to remove the possibility to take-over the role of participants in the review programme following a first withdrawal: interested economic operators had large amount of time to manifest their support or joining the current applicant to support an active substance. Such possibilities have been unique to the biocides area. No new application should be accepted in the review programme 20 years after its start.

(24) The Commission would like to hear the view of Member States, on other rules of the review programme that may need to be modified, or new rules that may need to be added in the Review Regulation with the view to complete the examination of the applications.

3. ACTIONS

(25) Member States are invited to reflect on these topics, and formulate their views as regards to :

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

b. Actions needed to reach the completion of the review programme, including on other potential actions

([10]) https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

([11]) https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7775

([12]) 90th CA meeting of December 2020, 93rd CA meeting of September 2021, during the discussions on re-definition, and identification of active substances.