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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards a further extension of the duration of the work programme for the systematic examination of all existing biocidal active substances

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

According to Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[1] ('the Biocidal Products Regulation'), the Commission must continue to carry out the work programme for the systematic examination of all existing active substances in accordance with Article 16(2) of Directive 98/8/EC. The Commission aims to complete the work programme by 31 December 2024. It is empowered to adopt delegated acts in accordance with Article 83 on carrying out the work programme and specifying the related rights and obligations of the competent authorities and the participants in the programme.

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.

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

Initially planned to be completed by 14 May 2010 under Directive 98/8/EC, the review programme had first been extended in 2009 until 14 May 2014[2]. This date was kept by the Council and the European Parliament when the Biocidal Products Regulation was adopted. In 2013, after discussion with experts of Member States competent authorities on biocidal products within the meetings of the Commission expert group 'Competent Authorities for Biocidal Products (Regulation (EU) No 528/2012)' – Register Code E03125 (the 'CA meetings'), the review programme was re-organised and its duration further extended. Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 extended the review programme until 31 December 2024[3]. Specifically, the review programme was re-arranged into 6 different priority lists with time limits for the submission of the assessment reports to the European Chemicals Agency (ECHA), and a number of principles on a more efficient management of the dossiers were agreed between the Commission and the Member States competent authorities. Regulation (EU) No 1062/2014 ('the Review Regulation') was adopted to reflect those agreements, setting in particular these time limits in Annex III.

Considering the number of applications still under examination in 2014, ECHA needed to adopt 50 opinions per year to complete the review programme by the deadline of 31 December 2024.

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1 OJ L 167, 27.6.2012, p. 1.

2 Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (OJ L 262, 6.10.2009, p. 40).

3 Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances (OJ L 204, 31.7.2013, p. 25).

Although the speed increased and the objective of adopting 50 decisions per year was almost reached in 2016, the speed of progress started to decline from that year. The vast majority of Member States have not met the time limits for submitting the assessment reports by their competent authorities to ECHA. The Commission presented a detailed assessment of this situation to the Council and the European Parliament in the implementation report of the Biocidal Products Regulation in June 2021[4]. The main reasons for the delays are: i) the lack of resources allocated in Member States competent authorities for completing their tasks under the Biocidal Products Regulation; ii) delays by applicants in submitting additional data; iii) complex technical questions on specific dossiers that need to be resolved first; iv) evolution of technical guidance; and v) the adoption of new scientific criteria for determining endocrine disrupting properties[5], which triggered the need for further data and assessments. Commissioner Kyridakides responsible for Health and Food Safety sent letters to the responsible Ministers in all Member States to express her concerns about the delays in implementating the Biocidal Products Regulation (active substances assessments, product authorisations), and called on Member States to take action, including allocating sufficient resources[6]. However, so far, no significant improvement has been noticed regarding the resources available in the Member States or the submission of the draft assessment reports to ECHA.

Since 2015, discussions regularly took place in the CA meetings, and agreements were reached on a number of actions[7]. Workshops were organised by ECHA, and an ECHA action plan on active substances has also been agreed[8]. Regular reports are presented at each CA meeting.

The Commission has also taken further action. In 2023, it 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'*. It provides for EUR 10 million in grants to Member States to the authorities responsible for biocides (and plant protection products) to help them achieving progress in the implementation of the Biocidal Products Regulation (and the Plant Protection Products Regualtion) subject to the condition that a full cost recovery system is established or maintained. Nine Member States have successfully applied for this grant for biocides.

Despite these actions, and although some progress can still be achieved before 31 December 2024, the review programme will clearly not be finalised by that date given that, on 1 October 2023, only 46% of the work programme was completed.

In accordance with Article 89(1), second subparagraph, of the Biocidal Products Regulation, depending upon the progress of the work programme, the Commission is

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4 The Commission 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

5 Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

6 Similar letters were also sent in 2015.

7 CA-March18-Doc.5.1a - Final - Actions for AS review programme.pdf

8 CA-Feb20-Doc.5.2 - Final - AS Action Plan.doc

empowered to adopt delegated acts in accordance with Article 83 on extending the duration of the work programme for a determined period.

Given that the review programme will not be finalised by 31 December 2024, the duration of the work programme needs to be extended. After discussion with experts of Member States' competent authorities on biocidal products, the Commission deems it appropriate to extend the duration of the work programme until 31 December 2030. At this stage, it is considered unreasonable to postpone the finalisation of the review programme to an even later date, given that most applications for approval were submitted in 2004-2008 and that all the products containing those active substances are still placed on the market under transitional provisions applicable in Member States pending a decision on approval. Furthermore, the Commission intends to conduct a REFIT evaluation of the Biocidal Products Regulation to be concluded in 2026. Any potential changes that may result from the evaluation should be in place by the end of 2030.

Article 89(1), first subparagraph, of the Biocidal Products Regulation needs to be amended accordingly. This is the purpose of this delegated act.

Other actions may be neeeded to achieve progress in the review programme, including revising certain provisions in the Review Regulation to amend the rules governing the programme in order to help complete it.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has consulted the expert group 'Competent Authorities for Biocidal Products (Regulation (EU) No 528/2012)' – Register Code E03125 – consisting of experts of Member States' competent authorities for biocidal products and of ECHA, as well as observers from industry and civil society, in meetings on XXXX. A draft of the delegated act was made public before meetings.

A four-week public consultation was held from XXXX to XXXX via the Better Regulation Portal.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends Article 89(1), first subparagraph, of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, and extends the duration of the work programme until 31 December 2030.

The legal basis of this act is Article 89(1), second subparagraph, of Regulation (EU) No 528/2012.

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amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards a further extension of the duration of the work programme for the systematic examination of all existing biocidal active substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[9], and in particular Article 89(1), second subparagraph, thereof,

Whereas:

(1) Regulation (EU) No 528/2012 provides for the continuation of the work programme for the systematic examination of all existing active substances used in biocidal products commenced in accordance with Article 16(2) of Directive 98/8/EC[10].

(2) In accordance with Article 89(1), first subparagraph, of Regulation (EU) No 528/2012, the work programme is to be achieved by 31 December 2024.

(3) There are substantial delays in the completion of the work programme. The Commission presented a detailed assessment of this situation to the Council and the European Parliament in the implementation report of Regulation (EU) No 528/2012 in June 2021[11]. The main reasons for them are the lack of resources allocated in Member States, delays by applicants in submitting additional data, complex technical questions on specific dossiers that need to be resolved, evolution of technical guidance and the new scientific criteria for the determination of endocrine disrupting properties introduced by Commission Delegated Regulation (EU) 2017/2100[12], which triggered the need for further data and further assessments.

(4) Since 2015, discussions have taken place regularly with experts of the Member States' competent authorities on biocidal products, and agreements have been reached on a number of actions. Workshops have been organised by the European Chemicals Agency (ECHA), and an ECHA Action Plan on Active Substances has also been

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9 OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

10 OJ L 123, 24.4.1998, p. 1, ELI: http://data.europa.eu/eli/dir/1998/8/oj.

11 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

12 Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1, ELI: http://data.europa.eu/eli/reg_del/2017/2100/oj).

agreed. Despite the actions taken so far and the progress that can still be achieved before 31 December 2024, it is clear that the work programme will not be finalised by that date.

(5) Considering that the work programme will not be finalised by 31 December 2024, it is necessary to extend its duration. After discussion with experts of the Member States' competent authorities on biocidal products, the Commission deems it appropriate to extend the duration of the work programme.

(6) Regulation (EU) No 528/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 89(1), first subparagraph, of Regulation (EU) No 528/2012, the first sentence is replaced by the following:

'The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC with the aim of achieving it by 31 December 2030.'.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN