



2024/1398

22.5.2024

**COMMISSION DELEGATED REGULATION (EU) 2024/1398**

**of 14 March 2024**

**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 <sup>(1)</sup>, 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 of the European Parliament and of the Council <sup>(2)</sup>.
- (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 <sup>(3)</sup>. 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 <sup>(4)</sup>, 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 agreed. Despite the actions taken so far and the progress that can still be achieved by 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,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

<sup>(2)</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1, ELI: <http://data.europa.eu/eli/dir/1998/8/oj>).

<sup>(3)</sup> 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>

<sup>(4)</sup> 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](http://data.europa.eu/eli/reg_del/2017/2100/oj)).

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, 14 March 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN