EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EU) NO 528/2012 AS REGARDS THE EXTENSION OF CERTAIN DATA PROTECTION PERIODS

REGULATION (EU) 2026/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 May 2026

amending Regulation (EU) No 528/2012
as regards the extension of certain data protection periods

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

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1 OJ C, C/2026/1969, 28.4.2026, ELI: http://data.europa.eu/eli/C/2026/1969/oj.

2 Position of the European Parliament of 28 April 2026 (not yet published in the Official Journal) and decision of the Council of 11 May 2026.

Whereas:

(1) In its communication of 19 February 2025 entitled ‘A Vision for Agriculture and Food’, the Commission announced a cross-cutting simplification package aimed at reducing unnecessary regulatory burdens while maintaining high standards for food and feed safety, for human and animal health, and for environmental protection.

(2) Regulation (EU) No 528/2012 of the European Parliament and of the Council[3] sets out the procedures for approval of biocidal active substances and for authorisation and placing on the market of biocidal products. The vast majority of Member States' evaluating competent authorities have not met the time limits for sending to the European Chemicals Agency the assessment reports for applications for approval of existing active substances. This has delayed the finalisation of the work programme for the examination of existing biocidal active substances set out in Article 89 of that Regulation (the 'review programme'). As explained in the Commission report of 7 June 2021 on the implementation of Regulation (EU) No 528/2012, that was submitted to the European Parliament and to the Council, the main reasons for failing to meet the time limits are the lack of resources in Member States' competent authorities; the quality of the initial applications and delays caused by applicants when not submitting additional data on time; the need to resolve complex technical questions in relation to certain dossiers; the evolution of technical guidance; and the adoption of Commission Delegated Regulation (EU) 2017/2100[4], which specifies new scientific criteria for determining endocrine disrupting properties.

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[3] 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 (OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj).

[4] 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).

(3) By way of derogation from Article 60 of Regulation (EU) No 528/2012, Article 95(5) of that Regulation provides that all data protection periods for active substance/product-type combinations listed in Annex II to Commission Regulation (EC) No 1451/2007[5], but for which a decision on inclusion in Annex I to Directive 98/8/EC of the European Parliament and of the Council[6] was not taken before 1 September 2013, are to end on 31 December 2025. The objectives of that Article are to provide for the fair compensation of review programme participants which are data owners and to avoid the establishment of monopolies and a disproportionate protection period, by providing for the possibility for other economic operators to freely use the data from 1 January 2026 in order to access the market more easily and to reduce the costs for the producers of biocidal products that buy active substances from the suppliers and ultimately for the users of the biocidal products.

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5 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3, ELI: http://data.europa.eu/eli/reg/2007/1451/oj).

6 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).

(4) Due to the delays in the finalisation of the review programme, the end date of 31 December 2025 for the protection of data set out in Article 95(5) of Regulation (EU) No 528/2012 should be adapted to strike a balance between the interests of review programme participants on the one hand, and the interests of alternative suppliers of active substances and applicants for product authorisation, on the other hand. Such a balance between the various interests needs to be considered when deciding which active substances and data are concerned by the extension of protection, as well as on the extended duration of protection.

(5) The evaluation of active substance/product-type combinations which were still in the review programme on 7 June 2018 has been further delayed due to the need to generate new data to allow for the evaluation of the new scientific criteria for determining endocrine disrupting properties which became applicable on that date. Furthermore, since then, other new data also had to be generated at the request of the Member States' evaluating competent authorities due to the quality of the initial data submitted in certain applications being insufficient and to the evolution of technical guidance and data requirements. As a consequence, and given the end date for data protection periods currently specified in Article 95(5) of Regulation (EU) No 528/2012, the protection period for such newly generated data for active substance/product-type combinations for which a decision on the approval had not been adopted by 7 June 2018 in accordance with Article 89(1), third subparagraph, of that Regulation would be considerably shorter than for data generated earlier. Therefore, the protection period for such newly generated data should be extended. In order to ensure that the implementation of such an extension by all parties is administratively simple, the extension of protection should cover all data for the active substance/product-type combinations concerned.

(6) The duration of the review programme of existing biocidal active substances has been extended until 31 December 2030 by Commission Delegated Regulation (EU) 2024/1398[7]. The protection period for the data concerned should therefore be extended until 31 December 2030. This corresponds to a maximum period of 11 years and 6 months for data generated since 7 June 2018, which is considered to be an appropriate period during which review programme participants can obtain compensation for the costs of generating data required by Member States' evaluating competent authorities. While the protection period will be shorter for data generated only in recent years, the proposed extension of protection will cover all data in the application, including data submitted since the submission of the application, which have already benefitted from a longer period of protection. Furthermore, the Commission will conduct a full evaluation of Regulation (EU) No 528/2012 in the course of 2026/2027, including its rules on data protection, which will provide a basis for the consideration of potential changes in the future.

[7] 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 (OJ L, 2024/1398, 22.5.2024, ELI: http://data.europa.eu/eli/reg_del/2024/1398/oj).

(7) Following the expiry of the protection periods on 31 December 2025, the data concerned were unprotected in the period from 1 January 2026 to ... [date of entry into force of this amending Regulation]. Article 60(1), second subparagraph, of Regulation (EU) No 528/2012 lays down a rule according to which data for which the protection period has expired are not to be protected again. As the proposed extension of protection for the data concerned would result in that data being protected again, that provision should be amended to provide for a derogation from that rule for such data. During the period in which the data concerned were unprotected, alternative substance suppliers and product suppliers have been included in the list referred to in Article 95 of Regulation (EU) No 528/2012. Since those suppliers could have benefitted from the costs incurred by the review programme participants to generate such data, Article 95(5) should be amended to allow data owners to claim compensation from those substance suppliers and product suppliers, if they find it appropriate.

(8) Since the objective of this Regulation, namely to ensure an appropriate protection period for data for active substance/product-type combinations for which a decision on the approval had not been adopted by 7 June 2018, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

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

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 528/2012

Regulation (EU) No 528/2012 is amended as follows:

(1) in Article 60, paragraph 1, the second subparagraph is replaced by the following:

‘Without prejudice to Article 95(5), second subparagraph, protection periods under this Article which have expired shall not start to run again.’;

(2) in Article 95, paragraph 5, the following subparagraphs are added:

‘By way of derogation from the first subparagraph of this paragraph, all data protection periods for active substance/product-type combinations for which a decision on the approval has not been adopted in accordance with Article 89(1), third subparagraph, by 7June 2018, shall end on 31 December 2030.

Data owners may claim compensation for access to their data for the period from 1 January 2026 to ... [date of entry into force of this amending Regulation] from a substance supplier or product supplier having benefitted from the absence of protection and having been included in the list referred to in paragraph 1 of this Article during that period.’.

Article 2

Entry into force

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 Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*