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PROPOSAL

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date of receipt:	17 December 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2025) 1020 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) No 528/2012 as regards the extension of certain data protection periods

Delegations will find attached document COM(2025) 1020 final.

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2025/0408 (COD)

Simplification Omnibus Package

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The proposal is part of the cross-cutting legislative simplification package announced in the European Commission's Vision for Agriculture and Food[1]. The aim of the package is to reduce unnecessary regulatory burdens identified as particularly burdensome by industry and authorities while maintaining high standards for food and feed safety, and the protection of human and animal health, and the environment. The package responds to repeated requests from stakeholders and EU Member States for faster and clearer regulatory procedures. It aims to simplify certain provisions and procedures of the following acts: Regulation (EC) No 1107/2009, Regulation (EC) No 396/2005, Regulation (EU) No 528/2012, Regulation (EC) 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation 1099/2009, Regulation (EC) No 999/2001, Regulation (EU) 2017/625, Directive 98/58/EC and Directive 2009/128/EC.

More specifically, this initiative aims at modifying 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[2], in order to address specific concerns which have been expressed by Member States competent authorities on biocidal products and economic operators regarding the expiry of the protection of certain data by 31 December 2025 in accordance with Article 95(5) of that Regulation.

The completion of the review programme of existing biocidal active substances set out in Article 89 of Regulation (EU) No 528/2012 has suffered from major delays. Initiated on 14 May 2000 under Directive 98/8/EC[3], and planned to be completed by 14 May 2010, the review programme had to be extended a first time in 2009 until 14 May 2014[4], a second time in 2013 until 31 December 2024[5], and recently a third time until 31 December 2030[6].

The vast majority of the Member State competent authorities have not met the time limits for submitting the assessment reports for applications for approval of existing active substances. The main reasons for the delays, as identified in the Commission implementation report

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1 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0075

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

3 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, pp. 1–63, ELI: http://data.europa.eu/eli/dir/1998/8/oj)

4 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, ELI: http://data.europa.eu/eli/dir/2009/107/oj).

5 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, ELI: http://data.europa.eu/eli/reg_del/2013/736/oj).

6 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).

submitted to the Council and the European Parliament in June 2021[7], are: i) the lack of resources in Member State competent authorities; ii) quality of the initial applications and 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[8], which triggered the need for further data and assessments. That implementation report also announced that, instead of a second implementation report, an evaluation of the Regulation (EU) No 528/2012 will start in 2025 with the aim of analysing the fitness of the regulatory system set out in the Regulation. While any fundamental changes to Regulation (EU) No 528/2012 should await the outcome of that evaluation, a few targeted amendments should be enacted earlier to increase the efficiency of its implementation.

Article 95(5) of Regulation (EU) No 528/2012 foresees that on 31 December 2025 protection expires for all data submitted for existing active substance/product-type combinations in the review programme but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013 and which will still be under examination in the review programme after 31 December 2025. The protection period was set to expire 10 years after mandatory listing of active substance suppliers of existing active substances on a specific list maintained by the European Chemicals Agency (ECHA) that took effect on 1 September 2015 (the Article 95 list). The purpose was to guarantee a fair compensation period for review programme participants, considering also that, for most participants, their data had already been protected since 2004-2008 (the time of submission of most of the applications for approval in the review programme), while foreseeing the possibility for other economic operators to use freely the data as from the beginning of 2026 to access more easily the market and bring down costs for the producers of biocidal products who buy active substances from the suppliers – and hence ultimately for the users of the biocidal products.

However, a number of active substance suppliers and their representative organisations have repeatedly raised concerns that, in the light of the delays in the completion of the review programme, as described above, the expiry of all data protection needs to be reconsidered, among others, at an Implementation Dialogue on the Regulation (EU) No 528/2012 held on 15 July 2025 with stakeholders representing businesses (active substance manufacturers, product formulators and downstream users) and civil society[9], in recent discussions with experts of Member State competent authorities on biocidal products[10], as well as during the

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7 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

8 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).

9 The dialogue aimed to gather feedback from companies on the main challenges faced in bringing biocidal active substances and products to the market and their ideas on how to address them and, more in general, on how to simplify the regulatory framework for biocidal products and encourage innovation. It also aimed to obtain views of non-industry stakeholders on the implementation of the Biocidal Products Regulation and on its contribution to a high level of safety for humans, animals and the environment. This constituted a first step for the evaluation of the Biocidal Products Regulation (https://health.ec.europa.eu/events/implementation-dialogue-biocides-2025-07-15_en).

10 Commission expert group 'Competent Authorities for Biocidal Products (Regulation (EU) No 528/2012)' (the 'CA meetings'), Register Code E03125 (Register of Commission expert groups and

Call for Evidence on the Food and Feed Safety Simplification Omnibus[11]. In fact, the adoption of new scientific criteria for determining endocrine disrupting properties, which were adopted by Commission Delegated Regulation (EU) 2017/2100[12] and are applicable since 7 June 2018, required that specific data had to be generated since then – or are still in the process of being generated – for those active substances still under examination in the review programme after 31 December 2025. In addition, other data had also to be generated and submitted due to the lack of quality of initial data submitted in the concerned applications and/or due the need to submit new data following the evolution of technical guidance or requirements. These data would currently not benefit from appropriate periods of data protection (or no data protection at all). Therefore, the end date for the protection of the data for existing active substances that were still in the review programme on 7 June 2018 should be extended, striking a balance between the interests of review programme participants, on one side, and the interests of alternative suppliers of active substance and product authorisation applicants, on the other side. The scope of the data concerned by the extension of the protection, as well as the duration of the extended protection, should be considered for this balance. Until the proposal is eventually adopted by the Council and the European Parliament the potential risks for the competitiveness of review programme participants and incentives for innovation, referred to by stakeholders, will remain. In practical terms, this means that other companies, in particular the alternative suppliers of active substances who do not support the active substance in the review programme, will be able to re-use freely data without having to negotiate compensation for access rights with the owners of the data.

In this context, to ensure that the period during which the data will not be protected is limited to the minimum possible, a proposal separate from the rest of the other measures proposed in the Food and Feed Safety Simplification Omnibus, which is dedicated solely to the modification of the data protection under Article 95(5) of Regulation (EU) No 528/2012 and related modifications, is needed. This is the purpose of the present initiative.

- **Consistency with existing policy provisions in the policy area**

The proposal is part of a package of measures concerning simplification, aiming at reducing administrative burden and costs for industries.

- **Consistency with other Union policies**

This initiative contributes to simplification and reduction of regulatory burdens for the agrifood sector, as announced in the Vision on Agriculture and Food while maintaining the high standards of protection for the human, animal health and the environment.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

Article 114 of the Treaty on the Functioning of the European Union (TFEU).

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other similar entities) ; CA-June25-Doc.7.10 - Point from NL on data protection.pdf, CA-June23-Doc.11.b - CEFIC-BfE-Data Protection.pdf

11 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14824-Food-and-feed-safety-simplification-omnibus_en

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, pp. 1–5, ELI: http://data.europa.eu/eli/reg_del/2017/2100/oj).

- **Subsidiarity (for non-exclusive competence)**

The proposed amendment is adopted at EU level as the Regulation concerned was adopted at EU level before and only a modification of the provisions of Article 95(5) of Regulation (EU) No 528/2012 performed at EU level can address the issue on data protection. Accordingly, an amendment to this Regulation needs to be made at EU level.

- **Proportionality**

The initiative only proposes to modify a specific provision of Regulation (EU) No 528/2012 related to the expiry of data protection for data related to active substances still in the review programme of existing active substances on 7 June 2018, and does not go beyond what is necessary to achieve the objectives of ensuring an appropriate period protection of data generated by review programme participants.

- **Choice of the instrument**

This proposal for revision is a legislative proposal as the relevant Regulation to be amended was adopted by co-decision / ordinary legislative procedure.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

This proposal is accompanied by a Commission Staff Working Document that includes a detailed overview of the positive impacts of the proposed amendment of the relevant provisions of food and feed safety legislation, based on existing data and information gathered during the Call for evidence and the previous analyses, including on the specific data protection issue under Article 95(5) of Regulation (EU) No 528/2012.

- **Stakeholder consultations**

The limitation of data protection until 31 December 2025 for existing active substances in the review programme, as set out in Article 95(5) of Regulation (EU) No 528/2012, has triggered calls from parts of industry as well as some Member States' competent authorities on biocidal products for action to provide appropriate protection for data only recently generated (or still to be generated) for the purposes of the review programme for existing active substances, which is significantly delayed. Several industry stakeholders requested meetings with the responsible Commission services on this topic. CEFIC (Biocides for Europe) requested an extension of data protection for all data generated since 7 June 2018 (date of application of the scientific criteria for identifying endocrine disrupting properties). Member State competent authorities for biocidal products requested to extend data protection for substances in the Review Programme, at least those related to endocrine disrupting (ED) properties, until 31 December 2031. On the other hand, the Commission services have also been contacted by companies who reported difficulties in obtaining letters of access to protected data or in getting agreement from established review programme participants to join them in the support of the substance and may thus benefit from free access to data. For instance, SME United indicated the importance to strive for a balance between the interest of data owners in the review programme and other actors[13].

[13] CA-Sept25-Doc.7.11 - SMEunited feedback.pptx

During the Call for Evidence on the Food and Feed Safety Simplification Omnibus, a large number of companies and associations criticised the current hard stop of data protection for substances in the review programme, arguing that it is misaligned with the extended review programme and creates free-rider risks, distorts competition, and disincentives to invest in data packages, notably the costly studies that are necessary for the application of the scientific criteria to identify endocrine disrupting properties. Many explicitly supported extending or resetting protection for all data generated after 2018 and not solely those data submitted to determine endocrine disrupting properties as they argued that other updated data had to be generated due to the evolution of other technical documents or requirements, but had diverse views on what should be the extension period: until the end of the review programme; a 10-year extension from 2025 (i.e. until 2035); normal application of Article 60 of Regulation (EU) No 528/2012 which provides for data protection after the approval of a substance for a period of 10 years; up to 15 years after the decision on the approval of the active substance; until the end of the review programme or 10 years after the approval of the substance, whichever is the earliest. Manufacturers warned that companies that invested early in compliance would lose protection before competitors have to share costs, undermining innovation and supply security. On the other side, a stakeholder was against the extension of data protection beyond 2025 and worried about over-changing the rules which were clear since 2013, extending exclusivity and complicating data-sharing, potentially slowing authorisations if access negotiations stall, discouraging innovation by prolonged market protection for the benefit of a few companies. It indicated that steady delays in the review programme resulted already in considerably longer amortisation of costs periods, and that an extension of data protection decreases competition and keeps product costs at high level, maintaining oligopolistic-like situations. It described difficult experiences in data sharing negotiations. NGOs and citizens did not provide comments. This proposal takes into account the input received, with the objective to strive for a balance between the interests of data owners who are participants in the review programme of existing active substances and other actors, taking also into account the original intentions of the expiry date for data protection set in Article 95(5).

- **Collection and use of expertise**

Different suggestions for clarifying certain provisions of food and feed safety legislation and removing the excessive administrative burden stemming from these provisions have emerged through stakeholders' proposals concerning the provisions of Article 95(5) of Regulation (EU) No 528/2012, as described above. Furthermore, in response and the follow-up of the Call of evidence mentioned above, the Commission received detailed position papers from stakeholders.

- **Impact assessment**

The proposed simplification measures are highly technical in nature. There are no viable alternatives to achieve the objectives, and the proposed measures do not alter core policy objectives or introduce significant new obligations. For these reasons, a full impact assessment would not bring added value. Instead, the proposal is accompanied by an analytical staff working document. The document clearly explains the proposed measures and present the underlying evidence, analysis and stakeholders' views, as well as estimating the potential cost savings.

No direct cost savings are expected for industry, since the data in question must in any case be generated and submitted to complete the assessment of the active substance, and in particular for the assessment of endocrine-disrupting properties. However, data owners would benefit

from greater legal certainty and the possibility of obtaining compensation from other interested companies through letters of access. Access to protected data may be granted to alternative suppliers of the same active substance, or to companies seeking product authorisations once the substance is approved. The terms of access could vary, ranging from financial compensation to free access when data owners also act as substance suppliers.

In the Impact Assessment performed in 2009 for the proposal of Regulation (EU) No 528/2012 revising the former Directive 98/8/EC, the cost of preparation of an application for approval of an active was estimated between 3 to 5 million euros (based on a study performed in 2007)[14]. Although no specific figures are available on the average costs of generating data related to endocrine-disrupting properties, these studies are generally considered highly costly, particularly because they often involve vertebrate testing. The costs for the generation of new studies related to other elements of an application are highly variable, depending on the particular issue for which evaluating competent authorities have requested a new study. By ensuring an appropriate period of protection, the measure helps secure a fair return on these investments and maintains incentives for data generation, which is essential for the scientific robustness of the review programme.

- **Regulatory fitness and simplification**

This proposal is part of the commitment of the European Commission to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the EU. The proposal is part of a package of measures which are therefore aiming at simplifying provisions of food and feed safety legislation, reducing unnecessary burdens and costs for businesses and authorities, without undermining the protection of human and animal health and the environment.

- **Fundamental rights**

The proposal respects the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union and adheres to the principles recognised therein. The reduction of administrative burden on companies should lead to societal gains in terms of wealth creation, employment and innovation. At the same time, the proposal will not undermine the objective of ensuring a high level of protection of human health and of the environment.

4. BUDGETARY IMPLICATIONS

This initiative will not imply any additional costs for the Commission or any regulatory Agency.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will monitor the implementation and application of the new provisions and compliance with them. Furthermore, the Regulation to be amended by this proposal is subject to regular evaluation of its efficiency, effectiveness in reaching its objectives, relevance,

[14] See pages 13, 14, 85 and 86 of Commission Staff Working document Accompanying document to the Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products, Impact assessment, SEC(2009)774, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC0773

coherence and value added in accordance with better regulation principles. This proposal does not require an implementation plan.

- **Detailed explanation of the specific provisions of the proposal**

The cut-off date for the protection of data related to existing active substances, which were still under review in the review programme on 1 September 2013, should be reconsidered, striking a balance between the interests of review programme participants, on the one side, and the interests of alternative suppliers of active substance and applicants for product authorisation, on the other side, taking also into account the original intentions of the expiry of data protection set out in Article 95(5) of Regulation (EU) No 528/2012. The balance in the various interests should be reflected in the scope of the active substances and data concerned by the extension of protection, as well as in the duration of protection.

The evaluation of active substances/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[15] that became applicable on that day. Furthermore, since that date, other data had also to be generated and submitted to evaluating Member States who considered this necessary due to the lack of quality of initial data submitted in the concerned applications and/or following the evolution of technical guidance or updated data requirements. It is therefore proposed to extend the protection period for all data for active substance/product-type combinations for which a decision on the approval had not been adopted in accordance with Article 89(1), third subparagraph, of Regulation (EU) No 528/2012 by 7 June 2018. In order to ensure a simple application of the new provision by all parties, the extension of protection covers all data without any distinction.

The completion of the review programme of existing biocidal active substances has been extended until 31 December 2030[16]. It is therefore proposed to extend the protection of the concerned data until the same date. This corresponds to a period of maximum 11.5 years for data generated since 7 June 2018, which is considered an appropriate period of time of protection during which participants in the review programme can obtain compensation for the costs of the generation of data required by evaluating Member States. It should also be noted that under the rules of Regulation (EU) No 528/2012, the evaluation of an application of an active substance should last normally for one year during which the data is protected, followed by a 10-year period of protection after the finalisation of the evaluation and adoption of the decision on the approval, which overall would correspond to a period of 11-12 years of protection of the data[17]. While the period of protection will be shorter for data generated only in recent years, the proposed extension of protection will cover all data in the application,

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15 Commission Delegated Regulation (EU) 2017/2100 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, pp. 1–5, http://data.europa.eu/eli/reg_del/2017/2100/oj), entered into application on 7 June 2018.

16 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).

17 Duration of evaluation by the evaluating Member State of 12 months with possible suspension of 6 months, followed by a peer review by ECHA of 9 months, and the time for decision-making process at Commission level.

including data submitted since the submission of the applications which have already benefitted from a longer period of protection[18]. It remains necessary to maintain the initial objectives of Article 95(5). For these reasons, no clause of revision of this new period of protection is proposed. 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.

Article 95(5) is modified to achieve this extension of data protection.

Until the proposal is adopted, there will be a period during which the concerned data will no longer be protected, i.e. from 1st January 2026 until the data is protected again in application of the new provisions in Article 95(5). Article 60(1), second subparagraph, established that data for which the protection period has expired shall not be protected again. As a protection will be conferred again to the concerned data, Article 60(1), second subparagraph, is modified to establish a derogation to that rule for the concerned data. A provision is also established in Article 95(5) to allow data owners to claim compensation from a substance supplier or product supplier having benefitted from the absence of protection and having been included in the Article 95 list during that period, if they find it appropriate.

[18] Most of the applications were submitted since 2004-2008.

2025/0408 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) In its Communication A Vision for Agriculture and Food[1], 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 environmental protection.

(2) Regulation (EU) No 528/2012 of the European Parliament and of the Council[2] sets out the procedures for approval of biocidal active substances and authorisation and placing on the market of biocidal products. The vast majority of Member State competent authorities have not met the time limits for submitting the assessment reports for applications for approval of existing active substances, which has delayed the finalisation of the review programme of existing biocidal active substances set out in Article 89 of that Regulation. The main reasons for the delays, as identified in the Commission implementation report submitted to the Council and to the European Parliament in June 2021[3], are: i) the lack of resources in Member States competent authorities; ii) the quality of the initial applications and delays by applicants in submitting additional data; iii) complex technical questions arising on specific dossiers that need to be resolved; iv) evolution of technical guidance*;* and v) the adoption of

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[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0075

[2] 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, pp. 1–123, ELI: http://data.europa.eu/eli/reg/2012/528/oj)

[3] 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

new scientific criteria for determining endocrine disrupting properties by Commission Delegated Regulation (EU) 2017/2100[4].

(3) Article 95(5) of Regulation (EU) No 528/2012 provides, by way of derogation from Article 60, 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 objective was, on the one hand, to provide for a fair compensation of review programme participants which are data owners, and on the other hand, to avoid avoiding the establishment of monopolies and a disproportionate protection period, by foreseeing the possibility for other economic operators to use freely the data as from the beginning of 2026 in order to access more easily the market and to reduce the costs for the producers of biocidal products who buy active substances from the suppliers and ultimately for the users of the biocidal products.

(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 should concern the scope of the active substances and data concerned by the extension of protection, as well as in the extended duration of protection.

(5) In particular, 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 had also to be generated on request of the evaluating Member States due to the lack of quality of initial data submitted in the concerned applications and following the evolution of technical guidance or data requirements. As a consequence, due to 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 in accordance with Article 89(1), third subparagraph, of Regulation (EU) No 528/2012, by 7 June 2018, would be considerably shorter than for other data generated earlier. Therefore, the period of protection for such data should be extended. In order to ensure an administratively

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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, pp. 1–5, ELI: http://data.europa.eu/eli/reg_del/2017/2100/oj)

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, pp. 3–65, ELI: https://eur-lex.europa.eu/eli/reg/2007/1451/oj/eng)

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, pp. 1–63, ELI: http://data.europa.eu/eli/dir/1998/8/oj).

simple implementation of the new provision by all parties, the extension of protection should cover all data for the concerned active substance/product-type combinations.

(6) The completion of the review programme of existing biocidal active substances has been extended until 31 December 2030[7]. The period of protection of the concerned data should therefore be extended until 31 December 2030. This corresponds to a period of maximum 11.5 years for data generated since 7 June 2018, which is considered an appropriate period of time of protection during which participants in the review programme can obtain compensation for the costs of the generation of data required by evaluating Member States. While the period of protection 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 applications 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) Article 95(5) should be amended to extend the data protection period accordingly.

(8) From 1 January 2026 and until this Regulation enters into force, the data concerned will no longer be protected. Article 60(1), second subparagraph, of Regulation (EU) No 528/2012 provides that data for which the protection period has expired is not to be protected again. As protection will be conferred again to the data concerned, that second subparagraph should be amended to establish a derogation to that rule for such data. As alternative substance suppliers and product suppliers that will be included in the Article 95 list during the period of absence of protection could have benefitted from the investments done by the review programme participants for the generation of such data, a provision should also be established in Article 95(5) to allow data owners to claim compensation from these suppliers, if they find it appropriate,

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 subparagraph is added:

‘By way of derogation from the first subparagraph, 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 7 June 2018, shall end on 31 December 2030. Data owners may claim compensation for access to their data for the period starting from 1 January 2026 until [*OP, please insert the date: date of the entry into force of this Regulation*] from a substance

[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).

supplier or product supplier having benefitted from the absence of protection and having been included in the list referred to in paragraph 1 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*