

# Amendments to Biocidal Products Regulation as regards the extension of certain data protection periods (Omnibus X)

2025/0408(COD) - 16/12/2025 - Legislative proposal

**PURPOSE:** to amend Regulation (EU) No 528/2012 on biocidal products with the aim of extending certain data protection periods.

**PROPOSED ACT:** Regulation of the European Parliament and of the Council.

**ROLE OF THE EUROPEAN PARLIAMENT:** the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

**BACKGROUND:** Regulation (EU) No 528/2012 establishes the framework for approving biocidal active substances and authorising biocidal products. However, significant delays by Member State competent authorities in assessing applications - due to resource constraints, data quality issues, complex technical questions, evolving guidance, and new scientific criteria on endocrine disruptors - have slowed the completion of the review programme for existing active substances.

Under Article 95(5) of that Regulation, data protection for certain active substance/product-type combinations was set to **expire on 31 December 2025**, in order to balance fair compensation for data owners with market access for alternative suppliers. Given the ongoing delays in the review programme, this end date is no longer appropriate.

**CONTENT:** therefore, this proposal, which is part the Commission's simplification omnibus package, aims to modify Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, 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 that Regulation.

It is proposed that all data protection periods for active substance/product-type combinations for which a decision on the approval has not been adopted in accordance with Regulation (EU) No 528/2012 by 7 June 2018 at the latest, **end on 31 December 2030**. This extension until 31 December 2030 corresponds to a maximum period of **11.5 years for data generated since 7 June 2018**, which is considered an appropriate protection period during which participants in the review programme can obtain compensation for the costs related to the production of data required by the Member States responsible for the evaluation.

By extending data protection periods, the proposal seeks to better incentivise innovation and investment in biocidal products, particularly where data generation is costly and time-consuming. The amendment supports the effective functioning of the internal market and aligns the biocidal products framework with the broader EU simplification agenda.

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.

Lastly, a provision stipulates that data owners may claim compensation for access to their data for the period from 1 January 2026 until the date of entry into force of the regulation from a supplier of substances or products that benefited from the lack of protection and were included in the list referred to in Article 95 during that period.