

# PROPOSED REPLACEMENT EU ACT

## INITIAL ASSESSMENT OF IMPACT

Date: 16<sup>th</sup> February 2026

DSC REF: DSC/03a/2026

Department: Department for the Economy

### Proposed Replacement EU Act

[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](#)

This Regulation will replace [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](#)

(Protocol Annex 2, Heading 24. Pesticides, biocides)

### Summary of the Act

The proposal is a short amending regulation. COM (2025)1020 would amend the EU Biocidal Products Regulation No 528/2012 (BPR) to extend certain Article 95 data-protection periods that would otherwise expire on 31 Dec 2025. The EU's review programme for existing biocidal active substances is heavily delayed. The intent is to avoid a window where competitors can rely on others' data without compensation, while keeping the system workable until the review programme ends.

In practical terms, the proposal:

- extends protection for the relevant datasets to align with the extended review programme end-date (31 Dec 2030)
- amends the rules so data can become protected again
- adds a compensation element to address any gap between 1 Jan 2026 and the date the amending regulation applies

The Biocidal Products Regulation sets the rules for approving and selling biocidal products (like disinfectants, insecticides and preservatives), to protect human and animal health and the environment while allowing products to move freely across the EU market.

### **Department(s) Responsible**

The Secretary of State in the Department for Work and Pensions advised by the Health and Safety Executive (HSE), is responsible for policy questions that relate to data protection provisions or biocidal products and active substances.

The Department for the Economy holds competency in NI.

### **Initial Assessment of Impact**

The proposed measures are technical and do not change core policy objectives or add major new obligations. The Commission did not carry out a full impact assessment; instead, an analytical staff working document accompanied the proposal, explaining the measures, evidence, analysis, stakeholder views, and estimated cost savings.

No direct cost savings are expected for industry because the instrument does not affect the requirement to generate data. However, data owners gain legal certainty and the ability to seek compensation from other companies. Access to protected data may be granted to alternative suppliers or companies seeking product authorisations, with terms ranging from financial compensation to free access.

Previous EU impact assessments estimated application preparation costs at €3–5 million. By extending data protection periods, the measures aim to secure fair returns on investment and maintain incentives for generating robust scientific data.

### **UK Government Explanatory Memorandum**

Not yet available.

## **Analysis by the European Commission on its 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). 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.

## **Departmental Engagement**

DfE and HSE(GB) have regular engagement on BPR and DfE were engaged during preparation on the Explanatory Memorandum.

HSE(GB) provide technical and scientific support and deliver functions under an Agency Agreement.