PROPOSED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

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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.

This is a highly technical area and HSE is still analysing what, if any, implications this may have for NI businesses. However, because data protection rules do not directly affect which products may or may not be supplied in NI and GB, the differences in position are not anticipated to cause any issues for GB/NI trade.

HSE are monitoring a difference between GB and NI in the short period before the EU instrument enters force, where data may be unprotected. In GB, Article 95(5) was amended before 31 December 2025 so there is no similar gap.

UK Government Explanatory Memorandum

The proposed amendments are intended to maintain the existing data protection provisions in Article 95(5) of the Biocidal Products Regulation (BPR) for a further five years.

The EU's review programme is an ongoing programme to review each active substance that was on the market in biocidal products on 14 May 2000 for its safety and efficacy. Persons who submitted data to support the approval of the active

substances normally receive data protection for 10 years under Article 60 of BPR after a decision is taken on approval.

However, by virtue of Article 95(5) of BPR, the data protection period for approximately 305 active substance/product type combinations included in the Review Programme of existing active substances ended on 31 December 2025. This means that those active substances which are yet to be reviewed no longer have data protection.

Article 95 of EU BPR introduced provisions which ensure that for any biocidal product made available on the EU market, either the active substance supplier or the biocidal product supplier must be on a list maintained and published by the European Chemicals Agency. Companies are listed where they are either participants in the EU's review programme or where they supplied either a full active substance data dossier, a letter of access to such a dossier, or a reference to a dossier for which data protection has expired to ECHA.

As it currently stands, Article 95(5) entails that alternative suppliers of active substances who do not support the active substance in the review programme, will be able to freely use data without having to negotiate compensation for access rights with the owners of the data. Specifically, they will be able to request listing on Article 95 without demonstrating they have a letter of access or their own data dossier.

This instrument responds to widespread industry concerns which were raised during engagement undertaken by the European Commission that the end of data protection was unfair to those who have invested in regulatory data for BPR and would negatively impact innovation and competition (see paragraph 30 below). Particular concerns were raised about loss of protection for data required since 7 June 2018 on potential endocrine disrupting properties of biocidal active substances (i.e. the capacity to cause adverse effects via the hormonal system).

This instrument will re-instate data protection from the point of entry into force for any active substance which was still in the EU's review programme on 7 June 2018. This date corresponds to the date on which endocrine disruption data was required, though also applies to all data submitted in any application to approve the affected active substances, including data that has already benefitted from a longer period of protection.

Article 95(5) of GB BPR also expired on 31 December 2025 which meant that the GB biocides market would have been affected in the same way as the EU market. The UK Government addressed this through a statutory instrument that came into force in December 2025, also extending data protection for active substances in the GB review programme until 31 December 2030.

The EU's proposed Regulation is similar to the GB statutory instrument and addresses the same issue. However, there are some technical differences in how the EU and GB Regulations have been drafted which may lead to some differences in how data protection applies in NI compared to GB.

This is a highly technical area and HSE is still analysing what, if any, implications this may have for NI businesses. HSE may seek clarification from the EU on any issues arising. However, because data protection rules do not directly affect which products may or may not be supplied in NI and GB, the differences in the GB and NI position are not anticipated to cause any issues for NI-to-GB trade or GB-to-NI trade.

A further difference between GB and NI is the short period before the EU instrument enters force, where data remains unprotected. In GB, Article 95(5) was amended before 31 December 2025 so there is no similar gap.

In principle, this could affect NI businesses who are data owners, as they will lose data protection during this short period. It could also affect businesses who may request access to data without negotiating with the data owner to pay a share of the costs. However, the NI biocides market is small and at the time of writing this EM HSE has received no such requests for access therefore this is not expected to be a significant issue. Moreover, any data owners disadvantaged by this short delay may claim compensation, which would counteract any market imbalance it may cause.

The position will be kept under review to identify any potential unintended consequences or indirect impacts.

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.