

## **EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION/DOCUMENTS WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK**

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### **“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”**

Submitted by The Health and Safety Executive (HSE), 07 April 2026

#### **SUBJECT MATTER**

1. The proposal amends the following Regulation:
  - 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 (EU BPR)
2. EU BPR regulates the placing on the market and use of biocidal products, which are a diverse range of products that control harmful organisms, such as insecticides, rodenticides and disinfectants. Active substances are the substances in biocidal products that give products their biocidal effect.
3. A key principle of EU BPR is that data submitted by a company in support of an application for a biocide active substance approval or product authorisation is protected for defined periods of time following its submission. This provides an important incentive for businesses to invest in the dossiers of data required to support active substance approvals. Data protection allows companies that generate the data to comply with EU BPR, which can cost millions of pounds, to recover their costs from other businesses who wish to use the data in support of their own applications. Costs are shared through the data owner charging other companies who wish to use their data for a ‘letter of access’ to their data.
4. The proposal amends the date, set out in Article 95(5) of EU BPR, on which regulatory data protection for active substances ends, from 31 December 2025 to 31 December 2030, for active substances which were still in the EU’s Review Programme of existing active substances on 7 June 2018.
5. This corresponds to a maximum period of data protection of up to 11.5 years for data generated since 7 June 2018. The European Commission considers this an appropriate period of time of protection during which participants in the EU’s Review Programme of active substances can obtain compensation for the costs of the generation of data required by evaluating Member States.
6. The proposal also allows data owners to claim compensation, where their data has been used by another party to support their application, between 31 December 2025 and the

entry into force date of the proposed Regulation. However, no details have been provided as to how this will work in practice.

7. Since this Regulation is listed in Annex 2 of the Windsor Framework, the new EU provisions on data protection will apply in NI.
8. The proposal is part of the cross-cutting legislative simplification package announced in the European Commission's Vision for Agriculture and Food, which can be found [here](#). As the data protection provisions have already expired, this part of the proposal has been prioritised and pursued as a separate proposal.

## **SCRUTINY HISTORY**

9. This Explanatory Memorandum is submitted to the relevant Parliamentary Scrutiny Committees to note the proposal, its significant policy context, and, specifically, its direct application and impact under the terms of the Windsor Framework.
10. On EU Exit, EU BPR was assimilated into UK law as the Great Britain Biocidal Products Regulation (GB BPR). GB BPR can be found [here](#).
11. The Biocidal Products (Data Protection Periods) (Amendment) Regulations 2025 (S.I. 2025/1221), which made similar amendments to Article 95(5) of GB BPR, i.e. to extend the cut-off date for data protection from 31 December 2025 to 31 December 2030, came into force on 30 December 2025. The Explanatory Memorandum is [here](#).

## **MINISTERIAL RESPONSIBILITY**

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

## **INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)**

13. EU BPR is listed in Annex 2 to the Windsor Framework.
14. Regulation of chemicals in the UK engages a mix of reserved and devolved competence. Environmental protection and public health are devolved to Scotland, Wales and NI. Scottish, Welsh and NI Ministers therefore have an interest in elements of chemicals regulation that affect these areas. The Northern Ireland Executive, as well as Scottish and Welsh Governments were consulted and had no comments.
15. Regulation of chemicals in the UK, including BPR, falls under the Chemicals and Pesticides Provisional Common Framework, developed jointly by Defra, Devolved Governments, including the Northern Ireland Executive, HSE and the Environment Agency. This framework facilitates cooperation between these parties to support regulatory consistency across the UK and enable the functioning of the UK Internal Market while acknowledging policy divergence.

16. In NI, EU BPR applies under the terms of the Windsor Framework to enable its dual access to both the GB Internal Market and EU Single Market. Competency in NI for BPR lies with the Department for the Economy (DfE).

#### **LEGAL AND PROCEDURAL ISSUES**

17. The legal basis of this instrument is Article 114 of the Treaty on the Functioning of the European Union (TFEU). The proposal is a legislative proposal as the relevant Regulation to be amended was adopted by co-decision / ordinary legislative procedure.

18. Under Article 60(1) of EU BPR, data for which the protection period under that Article has expired cannot be protected again. This proposal therefore amends Article 60(1) to create a derogation from that rule so that data protection will again apply to data for which protection has lapsed, once the amendment to Article 95(5) takes effect. Until the proposal is adopted, there will be a period during which the relevant data will no longer be protected, i.e. from 1 January 2026 until the data is protected again in application of the new provisions in Article 95(5). However, as new suppliers listed under Article 95 during the unprotected period may benefit from data owned by Review Programme participants, the proposal is to amend Article 95(5) to include a provision enabling data owners to claim compensation from these suppliers if they choose. No details have been provided on the mechanism for compensation.

#### **POLICY AND LEGAL IMPLICATIONS**

19. The proposed amendments are intended to maintain the data protection provisions in Article 95(5) of EU BPR that were in force up to 31 December 2025 for a further five years.

20. 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.

21. 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.

22. 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 (ECA). 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.

23. As it currently stands, under Article 95(5) 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.

24. This proposal 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 EU BPR and would negatively impact innovation and competition (see paragraph 34 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).
25. This proposal 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.
26. The data protection period under Article 95(5) of GB BPR, as it was in force up to 29 December 2025, was also due to expire 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 on 30 December 2025, extending data protection for active substances in the GB Review Programme until 31 December 2030 (see paragraph 12 above).
27. The EU's proposed Regulation is similar to the GB statutory instrument and addresses the same issue. 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.
28. 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.
29. A further difference between GB and NI is the 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.
30. In principle, this period where data is unprotected 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 create any negative impacts. Moreover, under the proposals any data owners disadvantaged by the period where data is unprotected may claim compensation, which would counteract any market imbalance it may cause.

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

## **CONSULTATION**

32. The EU carried out a call for evidence. The EU's Explanatory Memorandum outlines that stakeholders and some Member States advocated for extending protection—particularly for data on endocrine-disrupting properties—arguing that the hard stop creates free-rider risks, discourages investment, and undermines competition. Proposed extensions ranged from the end of the Review Programme to 10–15 years after substance approval. Conversely, some stakeholders oppose changes, citing concerns over prolonged exclusivity, higher costs, and reduced competition. The Commission's proposal aims to balance data owners' interests with fair access, while respecting the original intent of the 2025 deadline.
33. The Government has not consulted on this EU document. However, a targeted consultation took place in April and May 2025 on the equivalent provision in GB BPR. This consisted of 21 one-to-one interviews with a range of representatives from active substance manufacturers and biocidal product suppliers of all sizes, based in GB and internationally. The GB consultation demonstrated broad support for extending the expiry date of data protection in Article 95(5) in GB. A number of GB businesses interviewed in the informal engagement process indicated that they were worried about the Article 95(5) data protection issue in both GB and the EU.

## **FINANCIAL IMPLICATIONS**

34. The proposed measures are technical and do not change core policy objectives or add major new obligations. Therefore, the Commission has not carried out a full impact assessment; instead, an analytical staff working document accompanies the proposal, explaining the measures, evidence, analysis, stakeholder views, and estimated cost savings.
35. No direct cost savings are expected for industry because the instrument does not affect the requirement to generate data, including for assessing endocrine-disrupting properties. However, data owners gain legal certainty and the ability to seek compensation from other companies via letters of access. Access to protected data may be granted to alternative suppliers or companies seeking product authorisations, with terms ranging from financial compensation to free access.
36. Previous EU impact assessments estimated application preparation costs at €3–5 million, and studies on endocrine-disrupting properties are particularly expensive due to vertebrate testing. Costs for other studies vary widely. By extending data protection periods, the measures aim to secure fair returns on investment and maintain incentives for generating robust scientific data.



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