EXPLANATORY MEMORANDUM TO

THE BIOCIDAL PRODUCTS (DATA PROTECTION PERIODS) (AMENDMENT) REGULATIONS 2025

2025 No. 1221

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Sir Stephen Timms, Minister of State for Social Security and Disability confirms that this Explanatory Memorandum meets the required standard.

2.2 Kate Haire, Deputy Director (SCS1) of the Engagement and Policy Division in HSE confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Andrew Low at the HSE can be contacted by telephone 07584 909296 or email andrew.low@hse.gov.uk with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 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[1], known commonly as the Great Britain Biocidal Products Regulation (GB BPR), was assimilated in UK law by the Retained EU Law (Revocation and Reform) Act 2023[2]. GB BPR is further described in section 5.

4.2 This instrument amends the date set out in Article 95(5)[3] of GB BPR on which regulatory data protection for active substances (those substances which produce the biocidal activity of a product) ends, from 31 December 2025 to 31 December 2030. It also makes minor consequential amendments to update the cross-references to the repealed Regulation (EC) No 1451/2007[4] in Article 95(3) and Article 95(5) of GB BPR to cross-refer to Regulation (EU) No 1062/2014[5].

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[1] 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: https://www.legislation.gov.uk/eur/2012/528/contents

[2] The Retained EU Law (Revocation and Reform) Act 2023: https://www.legislation.gov.uk/ukpga/2023/28/contents

[3] GB BPR Article 95: https://www.legislation.gov.uk/eur/2012/528/article/95

[4] (Repealed) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC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: https://www.legislation.gov.uk/eur/2007/1451/adopted

[5] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council: https://www.legislation.gov.uk/eur/2014/1062/contents

Where does the legislation extend to, and apply?

4.3 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales, and Scotland.

4.4 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England, Scotland and Wales.

4.5 Under the Windsor Framework[6], Northern Ireland follows 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[7], known as the EU Biocidal Products Regulation (EU BPR), and therefore this instrument does not extend or apply to Northern Ireland.

5. Policy Context

What is being done and why?

5.1 GB 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.

5.2 A key principle of GB BPR is that data submitted by a company to HSE 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 GB 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.

5.3 The GB Review Programme[8] is the ongoing programme to review each active substance used in biocidal products that was on the market on 14 May 2000 for its safety and efficacy. After a decision is taken by the Secretary of State on whether to approve substances in this programme, they would, from the point of that approval decision, normally receive data protection for 10 years under Article 60[9] of GB BPR.

5.4 However, by virtue of Article 95(5) of GB BPR, the data protection period for approximately 300 active substance/product type combinations included in the GB Review Programme of existing active substances, but on which an approval decision has not yet been reached, would have ended on 31 December 2025. This would mean that those active substances which are yet to be reviewed would receive no data protection.

5.5 As a result, active substance manufacturers or those supporting their approval would no longer be able to charge other companies to use their data after 31 December 2025, preventing them from recovering any of the costs of commissioning the data. Although the consequences of not amending Article 95(5) are difficult to predict, there is a significant risk it would have:

- led to many companies supporting active substances in the review programme withdrawing their active substances from the GB market because they are no longer financially viable. Many active substances are essential to sectors such as

[6] The Windsor Framework: https://www.gov.uk/government/publications/the-windsor-framework
[7] The Biocidal Products Regulation 2012: https://echa.europa.eu/regulations/biocidal-products-regulation/legislation
[8] GB Review Programme for existing biocidal active substances: https://www.hse.gov.uk/biocides/active-substances/review-regulation.htm
[9] GB BPR Article 60: https://www.legislation.gov.uk/eur/2012/528/article/60

pest control, transportation and water treatment and their withdrawal from the GB market could increase public health and safety risks,

- caused widespread disruption to key sectors and major costs for downstream users,
- reduced market competition and consumer choice in biocides, and
- negatively impacted economic growth in the biocides sector.

5.6 Article 60 of GB BPR provides that where data has been protected under GB BPR, once that protection has expired it cannot be protected again. To avoid data protection ending permanently for active substances in scope, the period in Article 95(5) of GB BPR has to be extended. This instrument provides for that period to be extended by 5 years, from 31 December 2025 to 31 December 2030. By doing this, it allows the government to consider the issue of data protection alongside broader chemicals reforms which are currently being considered.

5.7 This instrument also makes minor amendments to Article 95(3) and (5) of GB BPR to update an out-of-date cross-reference to other legislation.

What was the previous policy, how is this different?

5.8 If left unamended, Article 95(5) of GB BPR would have ended data protection for relevant active substances on 31 December 2025. This provision was inherited from EU BPR when it was assimilated into GB law.

5.9 It is believed that this date was intended to coincide with the end of the EU active substance review programme[10], originally planned for 31 December 2024. If the EU's review programme had been completed by this date, this would mean that data protection periods would then be determined under Article 60 of GB BPR, and Article 95(5) would cease to apply. However, due to the amount of technical evaluation work involved taking longer than predicted, both the EU and the GB review programmes will extend significantly beyond this date.

5.10 Without the amendments made by this instrument, data protection would end before the end of the GB review programme, while a large number (approximately 300) of active substance/product type combinations are still awaiting review.

5.11 Ending data protection while many active substances are still awaiting review lacks any clear rationale and may be an unintended consequence of the provision. Extending data protection by five years to 31 December 2030 will ensure that businesses that have invested in regulatory data for those active substances can continue to recover their costs.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument substitutes Article 95(5) of GB BPR in order to extend the date on which Article 95(5) of GB BPR ends data protection by five years, from 31 December 2025 to 31 December 2030.

6.2 The instrument amends cross-references to Regulation (EC) No 1451/2007 in Article 95(3) and Article 95(5) of GB BPR. These cross-references are being replaced with references to Regulation (EU) No 1062/2014, which superseded Regulation (EC) No 1451/2007. Regulation (EC) No 1451/2007 and Regulation (EU) No 1062/2014 set

[10] Existing active substance Review Programme: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance

out arrangements for the EU and GB review programmes of existing biocidal active substances[11]. Annex 2 of both Regulations[12 and 13] list the active substance/product type combinations which are included in the review programme.

Why was this approach taken to change the law?

6.3 Through Article 95(5), GB BPR contains a provision which will end data protection for active substances still within the GB review programme on 31 December 2025. The only way to prevent this from happening is to amend the legislation.

7. Consultation

Summary of consultation outcome and methodology

7.1 A targeted consultation took place in April and May 2025. 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.

7.2 Stakeholders identified three main concerns if data protection were to end on 31 December 2025:

- lapsing of data protection may lead to many active substance manufacturers or those supporting their approval withdrawing active substances from the GB market because those substances are no longer financially viable. Many active substances are essential to sectors such as pest control, transportation or water treatment and their withdrawal could increase public health and safety risks,
- not extending the end date would allow alternative suppliers of active substances to access the GB market without the financial hurdle of needing to generate or purchase access to a full data dossier. This could allow substandard active substances, manufactured at lower costs, to enter the supply chain and be used in biocidal products. This could lead to harm to the environment and to public health, and
- competitor companies will be able to enter onto the GB Article 95 List[14] (the GB list of active substance suppliers) with minimal expense by using the unprotected data, undercutting suppliers who have invested in regulatory data and compliance. Many businesses interviewed considered this to be unfair.

7.3 The consultation also indicated that the removal of data protection from active substance manufacturers would be unlikely to result in an increase in innovation by product formulators, even though they would be able to use the data without paying to access it.

7.4 Consent for this Statutory Instrument has been granted by Scottish Ministers and Welsh Ministers.

8. Applicable Guidance

8.1 Existing guidance on data protection on HSE's website[15] has been updated to reflect this change.

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[11] An 'existing active substance' is defined in Article 3(1)(d) of GB BPR as a substance which was on the market on 14 May 2000, in a country which was a Member State of the EU on that date, as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development.
[12] (Repealed) Regulation (EU) No 1451/2007Annex II: https://www.legislation.gov.uk/eur/2007/1451/annex/II/adopted
[13] Regulation (EU) No 1062/2014 Annex II: https://www.legislation.gov.uk/eur/2014/1062/annex/II
[14] The GB Article 95 List: https://www.hse.gov.uk/biocides/active-substances/uk-article-95-list.htm
[15] Biocidal products regulation (BPR) data protection: https://www.hse.gov.uk/biocides/applications/data-protection.htm

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the annual impact on business is below the de minimis threshold of +/- £10 million equivalent annual net direct cost to business[16].

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is that the equivalent annual net direct cost to business of the change is estimated to be £550,000. The costs arise from the businesses continuing to negotiate access to protected data for the period up to 31 December 2030.

9.3 It is anticipated that there will be some non-monetised wider indirect costs and benefits to businesses. For example, interviewees highlighted that not amending Article 95(5) of GB BPR risked companies withdrawing active substances from the GB market, could cause increased risks from substandard active substances, and the lapse of data protection could open the market to new international alternative suppliers of biocidal active substances that could be of lower quality and greater risk. Extending the data protection period would delay these impacts by five years.

9.4 The legislation impacts small or micro businesses.

9.5 Small and micro businesses are not exempt from the legislation. Data protection provides a fair and level playing field for any business that invests in regulatory data and so there is no exemption based on the size of a business. Small and medium sized businesses which own data will also benefit from data protection for a further five years in the same way as larger businesses.

9.6 There is no, or no significant impact on the public sector as the legislation applies to businesses that supply biocidal active substances and biocidal products.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is that HSE's Biocides policy and specialist operational teams regularly engage with biocides sector stakeholders. They will gather feedback via formal and informal meetings, interactions with applicants and engagement with trade bodies. HSE intends to consult on longer-term options for data protection and this will include engagement with stakeholders to monitor the impact of the legislative change.

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015[17], Sir Stephen Timms, Minister of State for Social Security and Disability has made the following statement:

"In my view, it is disproportionate to include a statutory provision to review the Biocidal Products (Data Protection Periods) (Amendment) Regulations 2025."

[16] Better regulation framework guidance 2023 paragraphs 6.9 to 6.11: https://assets.publishing.service.gov.uk/media/67587ba55a2e4d4b993bfa83/better-regulation-framework-guidance-2023.pdf
[17] Small Business, Enterprise and Employment Act 2015: https://www.legislation.gov.uk/ukpga/2015/26/contents

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").