EXPLANATORY MEMORANDUM TO

THE BIOCIDAL PRODUCTS (HEALTH AND SAFETY) (AMENDMENT AND TRANSITIONAL PROVISION ETC.) REGULATIONS 2024

2024 No. 352

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 (DWP) and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Viscount Younger of Leckie, Parliamentary Under Secretary of State for DWP 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 in the Biocides Policy team in HSE (andrew.low@hse.gov.uk) 0203 0283949 can be contacted 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 The Great Britain Biocidal Products Regulation[1] (GB BPR) were assimilated in GB law by the Retained EU Law (Revocation and Reform) Act 2023[2]. This instrument updates some of the data requirements in Annexes II and III of GB BPR to reflect scientific and technical progress since the regulation came into force in 2012.

4.2 These Annexes specify the data which must be provided when applying for the approval of active substances or the authorisation of biocidal products. The update will enable a transition to more modern test methods which do not require testing on live animals. The instrument also introduces a requirement to test for specific toxicological effects for which no reliable tests previously existed, alongside other technical updates.

[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), as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (https://www.legislation.gov.uk/uksi/2019/720/contents), The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (https://www.legislation.gov.uk/uksi/2020/1567/contents/made) and The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (https://www.legislation.gov.uk/uksi/2022/1291/contents/made)

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

4.4 The territorial application of this instrument (that is, where the instrument produces a practical effect) is Great Britain.

4.5 Under the Windsor Framework[3], Northern Ireland follows the EU Biocidal Products Regulation[4] (EU BPR) and therefore this instrument does not apply to Northern Ireland.

5. Policy Context

What is being done and why?

5.1 Biocidal products are products and substances which are intended to kill or otherwise control harmful organisms. They are used to protect people and animals, preserve goods, stop pests such as insects or rodents and control viruses, bacteria and fungi. Common examples are disinfectants, wood preservatives and rodenticides.

5.2 In Great Britain, biocides are controlled under the assimilated Great Britain Biocidal Products Regulation (GB BPR). Under GB BPR, both biocidal active substances (the substances which produce the biocidal effect) and the products which contain them are subject to rigorous scientific assessment for their potential risks to humans, animals and the environment, and of their effectiveness, before they can be placed on the GB market. This function is carried out by HSE on behalf of Ministers in England, Scotland and Wales.

5.3 Applicants, who are normally chemical companies working in the biocides industry, submit dossiers of scientific data, containing studies meeting the requirements set out in Annexes II and III of GB BPR to HSE to allow assessments to be carried out prior to an approval being granted to an active substance or an authorisation to a biocidal product.

5.4 This instrument amends GB BPR by updating some of the data requirements contained in these Annexes in line with scientific and technical progress. This will enable:

- a reduction in animal testing for specific outcomes
- alignment with current guidance specifying the use of newer Organisation for Economic Co-operation and Development[5] (OECD) validated test methods
- GB BPR to keep pace with other relevant scientific developments since the legislation came into force in 2012

5.5 Scientific and technological advances in testing methods now allow for the use of alternative testing approaches to determine some properties which previously required testing using live animals. New test methods are also now available to reliably determine effects which could previously not be tested for (such as animal tests capable of detecting effects on developing nervous systems in foetuses). This instrument updates GB BPR to reflect these changes alongside other scientific developments.

[3] The Windsor Framework https://www.gov.uk/government/publications/the-windsor-framework
[4] The Biocidal Products Regulation 2012 https://echa.europa.eu/regulations/biocidal-products-regulation/legislation
[5] Organisation for Economic Co-operation and Development (OECD) https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm

5.6 The new data requirements will fully replace the existing requirements 18 months after the legislation comes into force, becoming a legal requirement for new applications made after that point. Any applications received by HSE during this transitional period that have used the new data requirements, will be accepted.

What was the previous policy, how is this different?

5.7 Previously under GB BPR, older test methods were included in the information requirements, some of which required the use of live animals where new, validated non-animal methods are now available. Other tests, such as those looking for effects on developing nervous systems, were also not available in 2012 and therefore not reflected in GB BPR.

5.8 The policy objective has not changed; this instrument simply updates requirements in Annexes II and III of GB BPR to bring into scope modern test methods which reflect scientific and technical progress since 2012.

6. Legislative and Legal Context

How has the law changed?

6.1 These changes do not alter the fundamental operation of the regulatory processes under GB BPR, in that assessments of the risks and effectiveness of active substances and biocidal products will continue to be carried out.

6.2 Previously, technical Annexes II and III contained data requirements based on the scientific knowledge available in 2012. These Annexes now contain newer test methods in line with scientific and technical developments.

Why was this approach taken to change the law?

6.3 GB BPR contains a specific power (Article 85[6]) to allow the Secretary of State to amend Annexes II and III to take account of current scientific and technical knowledge.

6.4 As GB BPR applies to both reserved and devolved policy areas, Article 85 of GB BPR states that regulations made under this power are subject to consent from Ministers in Scotland and Wales. Consent was received from both Scottish and Welsh Ministers prior to laying this instrument.

7. Consultation

Summary of consultation outcome and methodology

7.1 HSE carried out an 8-week public consultation from 17 January 2023 to 14 March 2023 on proposals to amend Annexes II and III of GB BPR. 50,000 interested parties who subscribed to updates on the Biocides Regulatory Scheme were informed of the consultation and their contributions were requested. The consultation and HSE's consultation response are available on the HSE Consultation Hub[7].

7.2 Of the 21 respondents, 6 were in full agreement with the proposals, while 11 disagreed with one or more of the proposals. Comments received raised concerns about issues such as additional costs, divergence from the EU position, or expressed a

[6] The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (https://www.legislation.gov.uk/uksi/2019/720/contents), Schedule 2, Paragraph 126

[7] https://consultations.hse.gov.uk/crd-biocides/rev-gb-bpr-annexes-ii-and-iii/

desire to move further away from animal testing. However, many of these concerns were based on a misunderstanding of the impact of the changes, which will be very small (i.e. they will only apply to new applications), or raised broader questions of government policy beyond the scope of this technical update.

7.3 Comments were also received in relation to the length of the transitional period before the changes become mandatory. HSE originally proposed a 12-month transitional period; in response to comments received on the time required for testing to be completed according to the new requirements, this has been increased to an 18-month transitional period. HSE has also clarified that the requirements will not apply retrospectively to applications received before 6 October 2025. However, any applications received by HSE before 6 October 2025, which have used the new requirements, will be accepted.

8. Applicable Guidance

8.1 HSE's website[8] explains the data requirements for applications to approve biocidal active substances and to authorise biocidal products, and how to comply with them. There are no plans to issue further guidance for this instrument as detailed and comprehensive technical guidance is already available, and production of further guidance would be disproportionate.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 An Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is estimated to be around £400,000 in one-off familiarisation costs plus, very rarely, additional costs for testing new biocidal active substances. This applies to businesses and not to charities or voluntary bodies, because these types of organisations are not within scope of the legislation. It is anticipated that these costs will primarily be incurred by manufacturers of biocidal active substances and products. It is estimated that around 2,950 businesses will incur one-off familiarisation costs of around £400,000 (equating to around £136 per business). In addition, businesses undertaking additional required tests for new biocidal active substance dossiers will incur additional test costs only rarely.

9.3 It is estimated that less than one active substance application every 10 years would incur additional costs. These average total additional costs are estimated at between around £150,000 and £550,000 in present values.

9.4 The majority of businesses in scope would be expected to incur these costs already through compliance with similar requirements previously introduced in the EU, as they are expected to be trading in both markets.

[8] HSE webpage Biocides applications: information requirements, assessments and evaluation (www.hse.gov.uk/biocides/how-to-apply)

9.5 In addition, most of the updated data requirements are already being requested by HSE under existing guidance. Also, Article 62[9] of GB BPR already requires that animal testing may only be undertaken as a last resort. Therefore, HSE already requests data to be generated using appropriate non-animal test methods where these are available and so most of the updates will impose no additional costs on businesses.

9.6 The legislation does impact small or micro businesses as they are not exempt from the requirements in this instrument. This is because the hazards that GB BPR regulates arise from the properties of the substances that manufacturers produce and these do not differ depending on the size of the business. Therefore, it would not be appropriate to exempt such businesses.

9.7 Costs are not expected to be disproportionate for small and micro businesses. The costs of the tests are expected to be the same (on average) for each substance. Costs for a business will vary based on the number of biocidal active substances and products for which they apply for approval or authorisation; and the hazard that they present (e.g., whether they present a genotoxicity or developmental neurotoxicity hazard).

9.8 There is no, or no significant, impact on the public sector. HSE, as the regulatory authority, already processes applications for approval and product authorisation based on submitted data, and this instrument will only slightly modify the data package received.

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 are in regular contact with businesses in the biocides sector and will monitor the implementation of changes made by this instrument via formal and informal meetings, interactions with applicants and engagement with trade bodies. HSE will also monitor the experiences of its regulatory scientists in undertaking biocidal active substance and product evaluations using data submitted under the new requirements. Feedback via these various channels will allow HSE to assess the impact of the changes against the original objectives and whether there are any changes required in future. This approach will allow maximum flexibility and HSE considers that it is the most proportionate and cost-effective approach given the bespoke and technical nature of the proposed changes and the very low estimated costs to businesses of the changes.

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[10], Viscount Younger of Leckie, Parliamentary Under Secretary of State for Work and Pensions, has made the following statement.

"In my view, it is disproportionate to include a statutory provision to review the Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024."

[9] 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)

[10] Small Business, Enterprise and Employment Act 2015 (legislation.gov.uk) Section 28(2)(b)

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

13. The Relevant European Union Acts

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").