EXPLANATORY MEMORANDUM TO

THE BIOCIDAL PRODUCTS (HEALTH AND SAFETY) (AMENDMENT) REGULATIONS 2022

2022 No. 1291

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Work and Pensions and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument addresses deficiencies in retained European Union (EU) law relating to biocidal products arising from the withdrawal of the United Kingdom from the European Union (EU Exit). It will extend the legal deadlines in place for processing biocidal product authorisation applications by the Health and Safety Executive (HSE) acting as competent authority. This instrument will ensure there is sufficient time to process applications and that biocidal products can remain legally on the market in Great Britain as intended by the legislative framework.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is formally prospective but will have some retrospective effect i.e. this temporary future change will have some effect on past arrangements. Stakeholders with an interest in the biocidal authorisation application process, particularly applicants, would not have reasonably expected the legal deadlines to be extended after applications had been submitted. Instruments made under section 8 of the European Union (Withdrawal) Act 2018[1] (EUWA) can have retrospective effect, but cannot be formally retrospective i.e. they cannot directly change past requirements (section 8(7)(b) of EUWA).

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is Great Britain.

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

5. European Convention on Human Rights

5.1 The Minister for Disabled People, Claire Coutinho MP has made the following statement regarding Human Rights:

"In my view the provisions of the Biocidal Products (Health and Safety) (Amendments) Regulations 2022 are compatible with the Convention rights."

[1] https://www.legislation.gov.uk/ukpga/2018/16/contents/enacted

6. Legislative Context

6.1 Regulation (EU) No 528/2012[2] of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products governs the authorisation of biocidal products. Biocidal products are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substance(s) contained in the biocidal product. Examples include wood preservatives and detergents.

6.2 Following European Union (EU) Exit, the Regulation (EU) No 528/2012 forms part of retained EU law under European Union (Withdrawal) Act 2018 (Great Britain Biocidal Products Regulation, abbreviated to GB BPR). After Implementation Period (IP) completion day (31 December 2020), it was amended so that references to EU decision making bodies were replaced by a Great Britain (GB) wide decision-making framework. Many processes which relied upon the EU system such as mutual recognition were also removed. By virtue of the Northern Ireland Protocol, Regulation (EU) No 528/2012 continues to apply in Northern Ireland.

6.3 Different types of authorisations can be obtained for biocidal products. Under the GB BPR, a national authorisation allows a biocidal product on the GB market, and a simplified authorisation allows a lower risk biocidal product on the GB market via a simplified procedure. Commission Regulation (EU) No 414/2013[3] sets out a procedure for authorising a biocidal product that is identical to another product that is already authorised or currently under assessment. Where changes are required to existing authorisations such as a change in formulation, Commission Implementing Regulation (EU) No 354/2013[4] sets out the process for allowing these changes in accordance with GB BPR.

7. Policy background

What is being done and why?

7.1 There are various stages to the process of considering applications such as informing the applicant of fees (invoicing), validating the application (following initial checks) and evaluating the application in order to decide whether to grant an authorisation. There are legal deadlines in place for each part of this process which the Health and Safety Executive (HSE) or the applicant as appropriate must meet.

7.2 Prior to the GB BPR, biocidal products were able to be placed on the market under pre-existing national law. Article 89 of GB BPR permits biocidal products, which are currently allowed to be made available on the market under that pre-existing national law to transition to authorisation under GB BPR. A period of three years is currently permitted for pre-existing national law to apply from the date of approval of the last active substance in that product. This timeframe would ordinarily allow sufficient time to process an application for authorisation of a biocidal product under GB BPR.

7.3 This instrument puts in place a temporary extension for a period of five years to the legal deadlines by which affected biocidal product authorisation applications are required to be processed by HSE. Where biocidal products were previously authorised under pre-existing national law, the instrument ensures they can continue

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0414
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0354

to be placed on the market and used until they are authorised under Great Britain Biocidal Products Regulation (GB BPR) rather than being required to be removed from the market once three years has elapsed from when the last active substance in that biocidal product was approved.

Explanations

What did any law do before the changes to be made by this instrument?

7.4 Under the GB BPR, the Health and Safety Executive (HSE) acts as the competent authority for Great Britain (GB) on behalf of the Secretary of State for Work and Pensions, the Scottish Ministers and Welsh Ministers under Agency Agreements.

7.5 Where applicants made an application under Regulation (EU) No 528/2012 on or before Implementation Period (IP) completion day and had not received a decision for the United Kingdom market, applicants were required to resubmit their applications to HSE by the relevant transitional deadlines if they wanted to access the market in GB.

Why is it being changed?

7.6 Two issues arising from European Union (EU) Exit have caused temporary delays to processing biocidal product authorisation applications.

7.7 First, following EU Exit, GB no longer has access to the databases where historical EU reports are stored. These reports contain information concerning the evaluations that were carried out by EU Member States to inform decisions on the approval of biocidal active substances and the authorisation of biocidal products. Some of this information is published but some is confidential and not published elsewhere. Information contained in these reports, including confidential information, would normally be used to process applications to authorise biocidal products. HSE is currently considering a number of options to mitigate loss of access to this information. However, the loss of access to historical reports has caused temporary delays to processing applications while this issue is resolved.

7.8 Second, the transitional arrangements requiring resubmission of applications to HSE have resulted in a one-off influx of applications simultaneously around transitional deadlines. This has caused a temporary backlog of applications.

7.9 This means that HSE will not be able to meet the legal deadlines for processing authorisations set out in GB BPR, Commission Regulation (EU) No 414/2013 and Commission Implementing Regulation (EU) No 354/2013 for a temporary period.

What will it now do?

7.10 Where there are legal deadlines in GB BPR for informing applicants of fees and for completing evaluations within a defined timeframe, this instrument extends those deadlines for a period of five years from the coming into force date of the instrument.

7.11 This applies to the following classes of application:

(i) applications previously submitted to HSE prior to IP completion day and then resubmitted under transitional provisions in the GB BPR (inserted by the EU Exit statutory instruments) after IP completion day; and

(ii) applications submitted to HSE up to 4 years after IP completion day, where processing these applications relies on historical information to which HSE has lost access.

7.12 The instrument also amends Article 89 of the Great Britain Biocidal Products Regulation (GB BPR) to ensure that where biocidal products are allowed to remain on the market and be used under pre-existing national law while they await authorisation under GB BPR, they may remain on the market and be used until such time they have been authorised under GB BPR in accordance with the extended deadlines.

7.13 Once the 5-year deadline extensions lapse, the normal deadlines in GB BPR will apply and processing will return to the usual timeframes.

7.14 The instrument also inserts a new transitional arrangement into GB BPR, Article 95FA. Article 95FA makes transitional provision for applications made to the United Kingdom competent authority under Article 4a of Commission Implementing Regulation (EU) No 414/2013 before Implementation Period (IP) completion day and in respect of which a decision was not made before IP completion day. Such applications must be resubmitted to the competent authority by 31 January 2023, in order to be considered for authorisation under GB BPR. This transitional provision was inadvertently omitted from the changes made to Regulation (EU) No 528/2012 before IP completion day, so this is now being corrected.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained European Union (EU) law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the EU. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 There are no plans for consolidation.

10. Consultation outcome

10.1 A formal consultation was not undertaken. The instrument is being made solely to remedy deficiencies that arise from unavoidable delays to the processing of biocidal product authorisation applications for reasons owing to EU Exit and outside the Health and Safety Executive's (HSE) control. There would be no clear purpose to a consultation.

11. Guidance

11.1 A communications plan will be developed to inform affected parties about the instrument, alongside HSE's broader plans to deliver biocides authorisations within the amended timeframes.

12. Impact

12.1 There is no, or no significant, impact on businesses, charities or voluntary bodies.

12.2 There is no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because it only provides for a technical change affecting deadlines for considering applications and legal status of biocidal products. The instrument will provide legal certainty that biocidal products can continue to be placed lawfully on the market and be used while

applications are being processed. If the instrument was not made, some biocidal products would become non-compliant with the Great Britain Biocidal Products Regulation through no fault of the applicant and may need to be removed from the market.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 This instrument does not place any new obligations on business. It will not therefore have any disproportionate impact on small business.

14. Monitoring & review

14.1 No specific monitoring arrangements are needed.

14.2 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

15. Contact

15.1 Pierre Cruse or Zameer Bhunnoo at the Health and Safety Executive, Telephone: 020 3028 2942 or email: Pierre.Cruse@hse.gov.uk / Zameer.Bhunnoo@hse.gov.uk can be contacted with any queries regarding the instrument.

15.2 Kate Haire, Deputy Director for Regulation, International and Major Hazards Policy Branch at the Health and Safety Executive can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Minister for Disabled People, Claire Coutinho MP at the Department of Work and Pensions can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018 and the European Union (Future Relationship) Act 2020

Part 1A

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before IP completion day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising section 8 or part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before IP completion day, and explaining the instrument's effect on retained EU law.

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees

Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

1. Appropriateness statement

1.1 The Minister for Disabled People, Claire Coutinho MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Biocidal Products (Health and Safety) (Amendment) Regulations 2022 does no more than is appropriate".

1.2 This is the case because the deficiencies arising from European Union Exit as set out in paragraphs 7.4 -7.6 are solely addressed.

2. Good reasons

2.1 The Minister for Disabled People, Claire Coutinho MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These are to ensure that biocidal products which have significant societal benefits remain legally on the market and no other course of action would achieve this.

3. Equalities

3.1 The Minister for Disabled People, Claire Coutinho MP has made the following statement(s):

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

3.2 The Minister for Disabled People, Claire Coutinho MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Claire Coutinho MP have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.".

4. Explanations

4.1 The explanations statement has been made in section 7 of the main body of this explanatory memorandum.