

**EXPLANATORY MEMORANDUM TO**  
**THE REACH ETC. (AMENDMENT) REGULATIONS 2021**

**2021 No. 904**

**1. Introduction**

- 1.1 This Explanatory Memorandum has been prepared by the Department for Environment Food and Rural Affairs (“Defra”) and is laid by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

**2. Purpose of the instrument**

- 2.1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (“the EU REACH Regulation”) forms part of retained EU law by virtue of the European Union (Withdrawal) Act 2018. The retained version of the EU REACH Regulation is referred to as the UK REACH Regulation.
- 2.2 This instrument amends the UK REACH Regulation and related legislation that also forms part of retained EU law. It corrects deficiencies to ensure that the legislation operates effectively in the domestic context. It also makes some related minor amendments to ensure consistency in respect of references to medical devices.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory instruments*

- 3.1 On 20<sup>th</sup> July the Sifting Committees agreed with the Government that this instrument does not have to have a debate in parliament though one may still occur. The instrument will therefore remain subject to the negative resolution procedure.

*Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)*

- 3.2 None.

**4. Extent and Territorial Application**

- 4.1 The territorial extent of this instrument is England, Scotland, Wales and Northern Ireland.
- 4.2 The territorial application of this instrument is the England, Scotland, Wales and Northern Ireland.

**5. European Convention on Human Rights**

- 5.1 The Parliamentary Under Secretary of State for the Environment, Rebecca Pow MP has made the following statement regarding Human Rights:  
“In my view the provisions of the REACH etc. (Amendment) Regulations 2021 are compatible with the Convention rights.”

## **6. Legislative Context**

- 6.1 This instrument amends the UK REACH Regulation. It also amends Implementing Regulations and Decisions made under the EU REACH Regulation before the end of the transition period that form part of retained EU law. Under the Northern Ireland Protocol, the EU REACH Regulation continues to apply to Northern Ireland. The UK REACH Regulation therefore mainly applies to Great Britain, but some aspects of it also apply to Northern Ireland to facilitate the movement of chemicals between Great Britain and Northern Ireland.

## **7. Policy background**

### *What is being done and why?*

- 7.1 The changes made by this instrument are needed in order to address deficiencies in retained EU law, to ensure that it operates effectively in the domestic context. Those deficiencies relate to EU legislation that came into effect shortly before, or during, the transition period. The approach taken is the same as that already taken in relation to similar deficiencies in the UK REACH Regulation and related legislation.
- 7.2 This instrument amends several Commission Implementing Decisions which authorise the use of a number of substances in Great Britain as retained EU law. It will also amend two Commission Implementation Regulations made under the EU REACH Regulation relating to data sharing and registrants' duties to keep their registrations up to date.

### ***Explanations***

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

- 7.3 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("the EU REACH Regulation") sets out controls on the use of chemicals in the EU. It forms part of retained EU law by virtue of the European Union (Withdrawal) Act 2018.
- 7.4 The EU REACH Regulation places an authorisation requirement on the use of certain substances of very high concern. This means that the substance cannot generally be used unless the Commission has authorised its use. The Commission grants authorisations through making Implementing Decisions. Any such Implementing Decisions made before the end of the transition period form part of retained EU law to the extent that they grant authorisations to anyone established in GB.
- 7.5 Implementing Regulation (EU) 2019/1692 sets out more detail about how the registration and data-sharing provisions in the EU REACH Regulation apply. Implementing Regulation (EU) 2020/1435 sets out more detail about the application of the duty on registrants to keep their registrations up to date. Both of these Implementing Regulations form part of retained EU law.

#### *Why is it being changed?*

- 7.6 REACH legislation adopted in the EU before the end of the transition period became part of the UK's domestic legal framework, as retained EU law. Where those measures operate by reference to EU concepts, they need to be amended so that they operate effectively in the domestic context. The legislation also needs to be internally

consistent in the terminology it uses, and to use terminology consistently with other relevant domestic legislation

*What will it now do?*

- 7.7 This instrument ensures that retained EU law operates effectively in the domestic context. It will correct deficiencies such as references to the ‘competent authorities’ of Member States in a number of EU authorisation decisions. It will also correct deficiencies in the UK REACH Regulation and two implementing Regulations made under the EU REACH Regulation: Regulation (EU) 2019/1692 relating to data-sharing; and Regulation (EU) 2020/1435 relating to registrants’ duties to update their registrations. It will also make minor related amendments to ensure that medical devices are referred to consistently throughout the UK REACH Regulation, and with the Medicines and Medical Devices Act 2021.

**8. European Union Withdrawal and Future Relationship**

- 8.1 This instrument is being made in exercise of the powers conferred by the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a) to (d) and (g)) arising from the withdrawal of the United Kingdom from the European Union. 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 This instrument does not consolidate any legislation.

**10. Consultation outcome**

- 10.1 There has been no formal consultation on this instrument. The changes being made are operability amendments to existing retained EU law to ensure that the law is operable in a UK context.
- 10.2 Devolved administrations were consulted on the approach taken throughout the drafting of this instrument and the Scottish and Welsh Governments have given their consent to the instrument.

**11. Guidance**

- 11.1 Guidance on the UK REACH Regulation is available on the website [gov.uk/guidance/how-to-comply-with-reach-chemical-regulations](https://www.gov.uk/guidance/how-to-comply-with-reach-chemical-regulations).

**12. Impact**

- 12.1 An impact assessment has not been produced for this instrument as no significant, impact on the private, voluntary, or public sector is foreseen.

**13. Regulating small business**

- 13.1 This instrument applies to activities that are undertaken by small businesses.
- 13.2 The amendments in this instrument will benefit all businesses by removing deficiencies in and providing clarity on retained EU law.

#### **14. Monitoring & review**

- 14.1 The approach to monitoring of this legislation is covered by the requirement on the Secretary of State to publish a report every five years based on the experience acquired of operating REACH. The first report is due by 1 April 2023.

#### **15. Contact**

- 15.1 Rusty Odihiri, at the Department for Environment, Food and Rural Affairs, Telephone: 02080 258725 or email: rusty.odihiri@defra.gov.uk can be contacted with any queries regarding this instrument.
- 15.2 Gabrielle Edwards, Deputy Director for Chemicals, Pesticides and Hazardous Waste, at the Department for Environment, Food and Rural Affairs (DEFRA), can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 The Parliamentary Under Secretary of State for the Environment Rebecca Pow MP, at the Department for the Environment, Food and Rural Affairs (DEFRA), 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	Sub-paragraphs (3) and (7)	Ministers of the Crown	Set out the 'good reasons' for creating a

offences	of paragraph 28, Schedule 7	exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	criminal offence, and the penalty attached.
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. Sifting statement(s)

- 1.1 The Parliamentary Under Secretary of State for the Environment, Rebecca Pow MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018: “In my view the REACH etc. (Amendment) Regulations 2021 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)”.
- 1.2 This is the case because: the provisions in the instrument are limited to making minor and technical changes in relation to correcting deficiencies in retained EU law to ensure it operates effectively in the domestic context. The approach taken is the same as that already taken in relation to similar deficiencies in the UK REACH Regulation and related legislation.

#### 2. Appropriateness statement

- 2.1 The Parliamentary Under Secretary of State for the Environment Rebecca Pow MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:  
“In my view the REACH etc. (Amendment) Regulations 2021 do no more than is appropriate”.
- 2.2 This is the case because: the provisions in the instrument are limited to amending retained EU law to ensure that it is operable in the domestic context and internally consistent. There are no significant impacts on business, including small business, and the public sector.

#### 3. Good reasons

- 3.1 The Parliamentary Under Secretary of State for the Environment Rebecca Pow 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”.
- 3.2 These are: to ensure that the amendments to the EU REACH Regulation, and implementing legislation made under the EU REACH Regulation, that came into effect before the end of the transition period operate effectively in the domestic context as retained EU law.

#### 4. Equalities

- 4.1 The Parliamentary Under Secretary of State for the Environment Rebecca Pow 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”.

- 4.2 The Parliamentary Under Secretary of State for the Environment Rebecca Pow 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, Rebecca Pow 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”.

## **5. Explanations**

- 5.1 The explanations statement has been made in section 2 of the main body of this Explanatory Memorandum.