

EXPLANATORY MEMORANDUM TO
THE REACH ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department for Environment Food and Rural Affairs (“DEFRA”) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument will help to ensure the UK meets its obligations under the Protocol on Ireland / Northern Ireland (“the Protocol”) in respect of the Registration, Evaluation, Authorisation and Restriction of Chemicals (“REACH”), by amending the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758) (the “REACH SI”) and the REACH Enforcement Regulations 2008 (S.I. 2008/2852) by making changes to the UK’s REACH regime, ensuring that it only applies to chemicals in Great Britain (“GB”).

2.2 In addition to enabling the EU REACH regime to continue operating in Northern Ireland as per the Protocol, this instrument also provides for the continued access of Northern Ireland goods into GB. This instrument amends the transitional provisions in the REACH SI to mitigate potential disruption to industry from the move to the new system and makes some minor amendments to ensure the cross-references in the UK’s REACH legislation are up to date.

Explanations

What did any relevant EU law do before exit day?

2.3 Controls on the use of chemicals are set out in 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 and establishing a European Chemicals Agency (“the EU REACH Regulation”).

Why is it being changed?

2.4 Under the Protocol, the EU REACH Regulation will continue to apply in Northern Ireland. Under the European Union (Withdrawal) Act 2018, the retained EU law version of the EU REACH Regulation will apply in Great Britain (“the GB REACH Regulation”). The REACH SI is drafted on the basis that the GB REACH Regulation would also apply to Northern Ireland. It must be amended to reflect that the EU REACH Regulation will continue to apply to Northern Ireland, and to update some cross-references.

2.5 In order to ensure that the GB REACH regime operates as it should, references in the REACH SI will need to be altered from UK to GB to correctly define the application of the new domestic chemicals regime. Further amendments are also needed to ensure that domestic regulation relating to the EU REACH Regulation continues to apply in Northern Ireland. After the end of the transition period, Northern Ireland and GB will

be subject to different REACH regimes. This instrument helps address the resultant barriers to trade between Northern Ireland and GB.

- 2.6 This instrument is also needed in response to a commitment made during the passage of the REACH SI to keep under review the REACH data submission deadlines which the transitional provisions place on manufacturers and importers of chemicals in GB. This commitment was made during debates in both Houses. Informal consultations have been held with both representatives from the chemicals industry and other stakeholders.

What will it now do?

- 2.7 This instrument will ensure that necessary amendments are made to the REACH SI, and domestic implementing legislation, to ensure that EU REACH continues to operate effectively in Northern Ireland as provided for by the Protocol. This instrument also makes special provision for the access of Northern Ireland chemicals to the GB market. Following the informal stakeholder consultations on the transitional REACH data submission deadlines, the instrument also introduces a new phased approach to REACH data submission.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

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 The territorial application of this instrument is the United Kingdom, except for Part 4 which only applies to Northern Ireland.
- 3.3 The powers under which this instrument is made cover the entire United Kingdom (see section 24 of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is set out in paragraph 4.2

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is the United Kingdom, except for Part 4 which only extends to Northern Ireland.
- 4.2 The territorial application of this instrument is the United Kingdom, except for Part 4 which only applies to 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:
- 5.2 “In my view the provisions of the REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 are compatible with the Convention rights.”

6. Legislative Context

- 6.1 This instrument amends domestic legislation (including domestic legislation that amends EU legislation) to remedy deficiencies arising from the withdrawal of the

- United Kingdom from the EU. It also makes amendments to implement and deal with matters arising out of, or related to, the Protocol.
- 6.2 It makes special provision in respect of qualifying Northern Ireland goods, enabling them to enter the GB market with minimal regulatory disruption whilst still ensuring high standards of protection for the environment and human health.
 - 6.3 This instrument also makes changes to the deadlines for the submission of registration data by existing registrants and downstream users. It extends the deadlines and provides for a new transitional phased approach to the submission of this data.
 - 6.4 Part 2 of this instrument inserts provisions into the REACH SI that operate by reference to qualifying Northern Ireland goods. That term is defined by reference to regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018. Those regulations will be made before this instrument is.
 - 6.5 Regulation 6 of this instrument inserts new Schedule 2A into the REACH SI. That Schedule inserts new Article 139C into the UK REACH Regulation, which states that Title 7 (authorisations) applies to imports from Northern Ireland. This provision is needed so that the exclusion from the mutual recognition principle for authorisations in the United Kingdom Internal Market Bill operates as intended.
 - 6.6 Part 3 of this instrument amends the commencement provisions of the REACH etc. (Amendment etc.) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/858) (the “Exit No. 2 Regulations”) and the REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019 (S.I. 2019/1144) (the “Exit No. 3 Regulations”). This is to ensure that they come into force before Part 2 of this instrument. Part 3 will come into force before the Exit No. 2 Regulations and the Exit No. 3 Regulations.
 - 6.7 Part 3 of this instrument also amends the Exit No. 3 Regulations to reflect a change to the way that medical devices are regulated in the EU that came into effect after the UK left the EU, but during the transition period. This means that a number of amendments made by the Exit No. 3 Regulations no longer need to be made.
 - 6.8 These Regulations create two versions of the REACH Enforcement Regulations 2008. One will apply to Great Britain, including to offshore installations other than those in the UK territorial sea adjacent to Northern Ireland. The other will apply to Northern Ireland, including to offshore installations in the UK territorial sea adjacent to Northern Ireland. These Regulations also provide for Northern Irish entities to be able to exercise certain functions under the GB REACH Regulation. Related GB REACH offences will be applied to Northern Ireland by the Northern Irish version of the REACH Enforcement Regulations.
 - 6.9 This instrument provides for the REACH (Appointment of Competent Authorities) Regulations 2007 (S.I. 2007/1742) to continue to apply in Northern Ireland as amended.
 - 6.10 The REACH SI is also being amended by the Environment (Miscellaneous Amendments) (EU Exit) Regulations 2020 (S.I. 2020/603). That instrument will amend references to “exit day” in the REACH SI so that they operate by reference to “IP completion day” instead. We mention this for completeness, but there are no interdependencies between the two instruments.

7. Policy background

What is being done and why?

The Protocol

- 7.1 The Protocol is a solution agreed between the UK and the EU, intended to preserve the unique relationship between the United Kingdom and Ireland and to prevent a hard border or splitting the UK customs territory.
- 7.2 Article 5(4) of the Protocol provides for certain provisions of Union law to apply in Northern Ireland. This includes the EU REACH Regulation.
- 7.3 As a consequence of Northern Ireland's continued obligations under EU REACH, a designated Competent Authority (the Department of Agriculture, Environment and Rural Affairs & the Department for the Economy acting alone or jointly) will be retained to cooperate with the EU. The version of the REACH Enforcement Regulations 2008 that will apply in Northern Ireland will ensure that Northern Irish enforcement authorities continue to have the necessary powers to enforce EU REACH. The duty to co-operate with EU enforcement authorities will also continue to apply in Northern Ireland.
- 7.4 References in the REACH SI will be altered from UK to GB, to reflect that the EU REACH Regulation will continue to apply in Northern Ireland. It also removes Northern Irish authorities from the decision-making and other regulatory processes that pertain to the operation of the GB REACH Regulation. The REACH Enforcement Regulations 2008, as they apply in Northern Ireland, will be amended so that they do not refer to Northern Ireland as a member State.

The Protocol – access to the GB Market

- 7.5 Further provisions will ensure that Northern Irish goods have easier access to the GB market and set conditions where appropriate. Whilst frictionless trade between Northern Ireland and GB is a stated aim of all parties to the Protocol, there is a recognition that the risks relating to certain categories of highly regulated goods such as chemicals mean special arrangements are necessary. In the case of chemicals this is to ensure effective regulation within GB to protect human health and the environment.
- 7.6 In order that the regulatory authorities know which chemical substances are entering and being used in GB, the person placing the substance on the GB market will need to notify the GB Agency. The notification will provide basic information about the substance. Usually, only GB-based entities can take steps under GB REACH. However, as an exception to this Northern Ireland suppliers will be able to notify the Agency directly. If they choose to do so, the duties relating to the notification would apply to the Northern Ireland supplier rather than the GB importer.
- 7.7 Where Northern Irish chemicals are already being traded into the GB market the notification must be made to the Agency within 300 days of the end of the transition period. Where the trade is made for the first time after the end of the transition period the notification must be made before the substance is placed on the GB market. The notification requirement replaces the duty to fully register the substance in GB.
- 7.8 This instrument also provides that a Northern Irish entity can apply directly to the Agency for an authorisation where they want to place a substance of very high concern on the GB market, instead of relying on their GB customer to make the

application. These provisions will all apply in respect of qualifying Northern Ireland goods, as defined in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018.

Deadlines for submitting information to the Agency

- 7.9 The initial notification stage for existing downstream users that will become importers of chemicals from the EU/EEA or Northern Ireland after the end of the transition period is being changed from 180 to 300 days from the day after the end of the transition period. This will give downstream users time to see what existing GB registrants do after the end of the transition period before deciding how to proceed. This opportunity to see what registrations are being transferred to GB REACH could help reduce the numbers of downstream users needing to notify.
- 7.10 The deadline for providing the remaining registration information in the case of existing GB registrants or completing a full registration for those importing from the EU/EEA or Northern Ireland, will be extended to run subsequently in a phased manner by 2, 4 and 6 years. This would mean a total of 2, 4 and 6 years + 300 days to supply the full information. The phasing will operate by reference to tonnage bands and hazard profile, with the highest tonnages and most significant hazards coming first. This will allow companies sufficient time to negotiate access to information where necessary and to form joint registrations. It is expected to reduce the burden on industry and ensure the completeness and quality of the information on substances in the GB REACH system.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument is being made using the power in section 8 of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies 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. This instrument is also being made under the power in section 8C of that Act to implement the Protocol, and deal with matters arising out of, or related to, the Protocol.

9. Consolidation

- 9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

- 10.1 The amendments relating to the deadlines for submitting registrations and notifications to the Agency are being made in response to issues raised by industry representatives concerning potential impacts on businesses after the REACH SI was laid. Informal discussions were held with industry and other stakeholders regarding the changes to data submission deadlines.
- 10.2 Devolved administrations have been consulted on the approach taken throughout the drafting of this instrument and given the opportunity to propose amendments to the text.

11. Guidance

- 11.1 Guidance on the specific steps required to register under GB REACH is available on the website gov.uk/guidance/how-to-comply-with-reach-chemical-regulations published on the 01/09/20. Further guidance with details of the other elements of UK REACH, including changes made by this instrument will be made available on the website hse.gov.uk

12. Impact

- 12.1 There will be positive impacts on business, charities or voluntary bodies. This instrument will mitigate potential disruption to chemical supply chains for GB companies. There will be simple and easy access to the GB market for Northern Ireland entities, whilst still ensuring high standards of protection for the environment and human health. The phasing of data reporting requirements will also reduce burdens on industry as their obligations to report will have more appropriate timescales, dependent on the tonnages used or levels of risk involved.
- 12.2 The positive impact on the public sector is that an extended timescale for data submission is likely to ensure complete and quality registration dossiers, as borne out via discussion with industry stakeholders.
- 12.3 An impact assessment has not been produced for this instrument as no, or 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 bring benefit to all businesses, but the phasing of data requirements will be of particular relevance to Small and Medium sized Enterprises (“SMEs”) due to the approach taken. SMEs are more likely to work with smaller tonnages, giving them up to 2027 to comply.

14. Monitoring & review

- 14.1 The approach to monitoring of this legislation is covered by the overall 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.
- 14.2 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required

15. Contact

- 15.1 Keith Bailey, at the Department for Environment, Food and Rural Affairs, Telephone: 020 8026 3477 or email: Keith.Bailey@defra.gov.uk can be contacted with any queries regarding this instrument.
- 15.2 Gabrielle Edwards, Deputy Director for EU Exit, 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

Part 1

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), 9 and 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), 9 and 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), 9 and 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), 9 and 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), 9 and 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 exit 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), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and 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 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit 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 exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 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.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

- 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:
- 1.2 “In my view the REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 do no more than is appropriate”.
- 1.3 This is the case because the amendments to the transitional provisions reduce the burden on industry, whilst ensuring the timely submission of data on the substances of greatest concern. The changes regarding Northern Ireland will ensure that the Protocol is implemented and that trade between GB and Northern Ireland is appropriately regulated. The other technical amendments are due to the extension of Article 50 and changes to some legislation that is cross-referred to by the EU REACH legislation.

2. Good reasons

- 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:
- 2.2 “In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action”.
- 2.3 These are: to reflect that the domestic REACH regime will apply to GB, and provide for the continued application of EU REACH in Northern Ireland; to ensure that industry has sufficient time to be able to provide the necessary data for notification or registration, given the resources required to produce a dossier or gain access to previous REACH datasets; and to update cross-references in the legislation.

3. Equalities

- 3.1 The Parliamentary Under Secretary of State for the Environment Rebecca Pow MP, has made the following statement(s):
- 3.2 “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”.
- 3.3 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:
- 3.4 “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”.

4. Explanations

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