EXPLANATORY MEMORANDUM TO

THE REACH ETC. (AMENDMENT ETC.) (EU EXIT) (NO. 3) REGULATIONS 2019

2019 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 Act.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments and the Sifting Committees.

2. Purpose of the instrument

2.1 This instrument amends the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (the "REACH SI"). It inserts a new transitional provision relating to applications for authorisations to use chemical substances of very high concern (the "new transitional provision"). It also makes some minor amendments relating to dates, cross-references and recent amendments to EU the REACH regulation.

Explanations

What did any relevant EU law do before exit day?

- 2.2 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").
- 2.3 The REACH SI makes amendments to the EU REACH Regulation to make it operable in the domestic context and create a domestic regime for chemicals. The REACH SI contains a number of transitional provisions that allow for uninterrupted production and supply of chemicals.

Why is it being changed?

- 2.4 Under the REACH authorisation procedure, Substances of Very High Concern ("SVHCs") are subject to sunset dates, after which companies must stop using them or placing them on the market unless they have applied for and been granted an authorisation. Each sunset date is preceded by a Latest Application Date ("LAD"). If a company applies for an authorisation by the LAD it can continue to use the chemical or place it on the market until a decision is made on the authorisation application, even if such a decision is made after the sunset date.
- 2.5 There are a number of substances for which the sunset date has passed, but use is still permitted because the EU authorisation decision has not yet been made. Where the LAD or sunset date for a substance passes before exit day use of the substance in the UK would have to cease from exit day until such time as a UK authorisation is granted following a fresh application under UK REACH. This would have a significant impact on businesses which rely on substances while awaiting authorisation decisions.
- 2.6 Where the LAD would be soon after exit day, UK companies may not have adequate time to prepare an application for an authorisation before it passes, especially where

- they were expecting their EU supplier to make the application. This would mean they would not be able to continue using the substance after the sunset date if their application had not been determined.
- 2.7 This instrument also makes some technical amendments to the REACH SI. It amends deadlines that operate by reference to a fixed date. This is because the extension to Article 50 has had the effect of significantly reducing the time available to comply with these deadlines. It also amends the criteria for the transitional provisions to apply to registrations that are no longer held by a UK entity on exit day. Currently, the registration must have been held by a UK entity in the two years before exit day. However, as exit day has been delayed there is now a risk that a UK entity may have transferred their registration, as part of their no-deal planning, more than 2 years before exit day.
- 2.8 It also makes some minor amendments to reflect changes being made by another exit SI. Those amendments are to the Medical Devices Regulations 2002, which are cross-referred to in the UK REACH legislation. Furthermore, the instrument makes some technical amendments to the REACH SI relating to recent amendments to the EU REACH Regulation in order to make them operable in the domestic context.

What will it now do?

- 2.9 The approach taken in this new instrument is to amend the REACH SI by setting new LAD and sunset dates for certain SVHCs as listed in Annex XIV of UK REACH. There are difference provisions depending on whether the LAD falls before or after exit day.
- 2.10 Where the LAD falls before exit day a number of criteria must be met for the LAD and sunset dates to be extended, and only certain people can benefit from the extensions. When the new transitional provision applies, the LAD and sunset dates are extended to fall 18 months after exit day.
- 2.11 The LAD must be between 29 March 2017 and exit day. An application for an authorisation in relation to that substance must have been made before exit day.
- 2.12 There are two categories of people that can benefit from the extension. The first is the applicant if they were a UK entity. The second is a UK downstream user that uses the substance on the basis of the application. If the application was made by a UK entity, the new transitional provision will not apply if Article 127G applies to the application, as that already allows for continued use until such time as the UK application is determined. If the application was made by anyone else, the new transitional provision will not apply if the application was determined before exit day.
- 2.13 Where the LAD for a substance falls within 18 months of exit day, it is extended to 18 months after exit day. Any UK entity can take advantage of this provision. The sunset date for the substance is not amended.
- 2.14 This means that UK companies will have 18 months to apply for authorisations to the UK Agency (HSE) and, as under EU REACH, would be able to continue to use the substances until their applications are determined. Only those companies who make an application by the new UK LAD will be able to continue to use the substances beyond 18 months after exit.
- 2.15 Where deadlines operate by reference to fixed dates, they have been amended so that they operates by reference to exit day. Where the transitional provisions apply to

registrations no longer held by a UK entity, the cut off day has been amended to 29 March 2017.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments for Parliament and the Sifting Committees

3.1 On 8 April and 9 April the Sifting Committees agreed with the Government that the REACH No. 2 SI should follow the negative resolution procedure. This new instrument is being laid in similar circumstances so should be subject to the negative resolution procedure for the same reasons.

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 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is the United Kingdom.
- 4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for the Environment Dr Thérèse Coffey has made the following statement regarding Human Rights:

"In my view the provisions of the REACH etc. (Amendment etc.) (EU Exit) (No.3) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is being made using powers in the European Union (Withdrawal) Act 2018. It amends the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, which fixed inoperabilities in the EU REACH Regulation in order to avoid potential interruption in the supply of chemicals into the UK after exit day.

7. Policy background

What is being done and why?

- 7.1 This Statutory Instrument is needed to make adjustments to the REACH SI in order to resolve a developing issue concerning applications for authorisation under EU REACH, where an EU decision is still awaited. The need arises from the effects of the extension of Article 50 to the end of October, and a recent European Court of Justice judgement against the European Commission which overturned some existing authorisations.
- 7.2 There is an increasing backlog of undecided authorisation applications to use Substances of Very High Concern under the EU REACH regime. After the sunset dates for these substances, UK downstream users and applicants for authorisations will not be able to manufacture, place on the market or use the chemicals concerned. They will need to make an application under UK REACH and wait until the UK

- authorities have granted an authorisation before being able to do so. This process would be expected to take more than a year. The proposed resolution is to amend the REACH SI to give UK companies a window of opportunity to apply for authorisations after exit day to ensure the chemicals industry and supply chain is not disrupted.
- 7.3 The immediate cause for concern is a number of outstanding authorisation decisions on a range of chromate compounds, including chromium trioxide and sodium dichromate. These substances are used mostly for specialist engineering and aerospace uses such as chrome plating, various coating processes, and polyurethane castings. Given the size of the aerospace and automotive industries in the UK and the associated supply chains, it is likely that a substantial number of companies (100s) could be affected. Our assessment is that delays in the EU decision making process have increased the scale of the impact temporary loss of these substances to the supply chain.
- 7.4 A further issue has arisen due to the extension of Article 50 to 31 October, in that further SVHC LAD and sunset dates are passing during this period. As a result, UK applicants should have submitted applications to ECHA (rather than the UK authorities) to be able to continue to use those substances. After exit, they will need to redirect their applications to the UK authorities but they will not be covered by the provision that enables continued use after the sunset date where a decision is still pending. This is because they will not have been able to make their UK applications before the LAD.
- 7.5 This instrument addresses both of these issues by amending the REACH SI to set new LAD and sunset dates for those SVHCs which are listed in Annex XIV of UK REACH with current LAD or sunset dates between 29 March 2017 and exit day. The instrument moves the LAD and sunset dates to 18 months after exit day for UK applicants and downstream users.
- 7.6 Where the LAD is within 18 months of exit day, this may not provide sufficient time for an application to be made. This instrument addresses this by moving the LAD to 18 months after exit day.
- 7.7 The REACH SI applies some provisions by means of fixed dates or in other cases through "floating" timings tied to exit day. The extensions to Article 50 have implications for these dates or timings, which in some cases will affect the regulator's ability to carry out its duties or stop some businesses from benefitting from the transitional provisions. In these cases, the dates or timings are amended to preserve the original policy intent.
- 7.8 The REACH SI is also being amended to reflect recent amendments to the EU REACH Regulation and changes being made to some cross-referenced legislation through another exit SI.
- 7.9 This instrument will avoid the risk of disruption to chemical supply chains and provide industry with greater business certainty while at the same time providing a clear process and timescale to ensure that SVHCs remain effectively controlled.

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 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.

9. Consolidation

9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 The amendments are being made in response to issues raised by industry representatives concerning potential impacts on businesses after the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 were laid.

The Devolved Administrations have been consulted and have consented to this instrument.

11. Guidance

11.1 Guidance is available on line and will be updated in the light of these amendments. The guidance on regulating chemicals (REACH) if there is no Brexit deal is in a Technical Notice on the website GOV.UK published on 24 September 2018. UK REACH Additional Guidance if there is no Brexit deal and a Table on steps to take is on the website hse.gov.uk published on 4 December 2018. The Technical Notice and Additional Guidance have been combined and expanded upon to create the "UK REACH guidance if there is no Brexit deal" document, published on the HSE website on 25 March 2019. Further guidance will be made available when this SI is made.

12. Impact

- 12.1 There will be positive impacts on business, charities or voluntary bodies. This instrument will avoid potential disruption to chemical supply chains for UK companies who are currently relying on an authorisation application to use a substance. They will be given the opportunity to apply for a UK authorisation and to continue using the substance until that application is determined.
- 12.2 The positive impact on the public sector is that there will be a clear process and timescale for transitioning the authorisation procedure into UK REACH. It will also mean that future use of these substances to clear conditions of use. This will contribute to the effective management of chemicals in the UK.
- 12.3 An Impact Assessment has not been prepared for this instrument because the SI relates to amendments of existing regulatory standards.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 The amendments in this instrument will benefit all businesses. We understand that there are a considerable number of downstream users who are reliant on pending EU authorisation decisions. They will benefit from these amendments as the instrument allows them or their upstream suppliers to apply for the authorisation to use these substances in the UK.

14. Monitoring & review

- 14.1 The approach to monitoring of this legislation is to monitor the operation of the new transitional provision, which allows businesses to continue using SVHCs by putting in an application within 18 months of exit date. When an authorisation is granted it is time limited and contains a requirement for review within a set timescale.
- 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 (DEFRA), Telephone: 020 8026 3477 or email: Keith.Bailey@defra.gov.uk can be contacted with any queries regarding the 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 Dr Thérèse Coffey 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 <u>may</u> 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	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising	Explain the good reasons for making the instrument and that what is being done is a

	paragraph 28, Schedule 7	powers in Schedule 2	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	State why it is appropriate to create such a sub-delegated power.

		of the Crown or a Devolved Authority by Statutory Instrument.	
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. Sifting statement(s)

- 1.1 The Parliamentary Under Secretary of State for the Environment, Dr Thérèse Coffey 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 etc.) (EU Exit) (No. 3) Regulations 2019 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 in scope. It amends the scope and operation of one element of the transitional provisions in the REACH SI in response to industry representations. It also provides for some minor technical amendments and the correction of a small number of deficiencies. The amendments remain within the scope of the policy intention of the transitional provisions to minimise disruption to supply chains, trade flows, business continuity and economic growth. The approach taken in relation to the deficiencies is the same as that already taken in relation to similar deficiencies in the REACH SI. The impacts on business, including small business, and the public sector are all positive.

2. Appropriateness statement

- 2.1 The Parliamentary Under Secretary of State for the Environment Dr Thérèse Coffey 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 etc.) (EU Exit) (No. 3) Regulations 2019 do no more than is appropriate".
- 2.2 This is the case because the amendments to the transitional provisions are limited to addressing the representations made by industry and the other technical amendments are due to the extension of Article 50 and amendments to the EU REACH legislation.

3. Good reasons

- 3.1 The Parliamentary Under Secretary of State for the Environment Dr Thérèse Coffey 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 there are clear arrangements concerning the manufacture and use of substances of very high concern to provide a managed transition into the authorisation procedure in the UK REACH system and to avoid potential disruption to

supply chains; to make technical adjustments to the REACH SI in response to the extension of Article 50.

4. Equalities

- 4.1 The Parliamentary Under Secretary of State for the Environment Dr Thérèse Coffey 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 Dr Thérèse Coffey 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, Thérèse Coffey 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.