

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

**2. Purpose of the instrument**

- 2.1 The instrument corrects deficiencies in retained EU law relating to the registration, evaluation, authorisation and restriction of chemicals. The instrument ensures that the EU legislation will operate effectively in the domestic context after the UK leaves the EU. It also makes transitional provisions to minimise the disruption to existing supply chains following EU Exit.

*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”). Regulations made under the EU REACH Regulation provide for the fees to be charged, the test methods to be used and rules relating to appeals. Decisions made under the EU REACH Regulation authorise people to use controlled chemicals for particular purposes. The EU REACH Regulation creates a single market mechanism to promote the safe production and use of chemicals to manage potential impacts on human health and the environment. There is a “no data, no market” rule, with industry responsible for providing the European Chemicals Agency (“ECHA”) with data relating to the chemicals they use. Industry is also responsible for managing the risks from their use of chemicals.

Why is it being changed?

- 2.3 The changes made by the instrument are needed to ensure the EU REACH Regulation will work effectively in the domestic context so that the UK has an effective system of chemicals regulation after leaving the EU. It provides for functions carried out by EU institutions to be carried out by domestic bodies, or to be omitted where they are not needed in the domestic context. For example, the functions of ECHA will be carried out by the Health and Safety Executive (“HSE”) which already exercises some functions under the EU REACH Regulation as the UK competent authority. It provides for appeals to be heard by the First-tier Tribunal, rather than the ECHA Board of Appeal. The instrument also provides for amounts specified in Euros to be converted into Pound Sterling. The EU REACH Regulation operates by reference to the EU single market. The instrument amends these references so that the legislation operates by reference to the UK market instead.

What will it now do?

- 2.4 The amended EU REACH Regulation will create a UK regulatory system for chemicals, which will be similar to the current EU system. The functions currently exercised by the European Commission will transfer to the Secretary of State, to be exercised with the consent of the Devolved Administrations in areas of devolved competence. The instrument also makes a number of transitional provisions to reduce the disruption to industry of the move to the new system. It provides for UK companies to be able to continue to carry out the same activities in relation to chemicals as they currently can under the EU REACH Regulation. They will need to provide the HSE with some basic information in order to do so. This will give industry time to prepare to comply with the new system, without any immediate disruption to their supply chains. It utilises existing domestic frameworks and institutional relationships developed during the 10 years of working under the EU REACH system, to avoid duplication and also achieve value for money for the UK taxpayer.

**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 varies between provisions.
- 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 paragraph 1 of Schedule 11 which extends to England and Wales.
- 4.2 The territorial application of this instrument is the United Kingdom, except for paragraph 1 of Schedule 11 which applies to England and Wales.

**5. European Convention on Human Rights**

- 5.1 The Parliamentary Under Secretary of State for the Environment Dr Thérèse Coffey MP, has made the following statement regarding Human Rights:
- “In my view the provisions of the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights”.

**6. Legislative Context**

- 6.1 The instrument amends both EU and domestic legislation to remedy deficiencies arising from the withdrawal of the United Kingdom from the EU and ensure the continued effective regulation of chemicals.
- 6.2 The EU REACH Regulation cross-refers to a number of other pieces of EU legislation. The directly effective legislation (regulations) referred to will become part

of retained EU law, while other legislation (directives) referred to will not. The instrument amends many of these cross-references.

- 6.3 Where references were out of date, they have been updated. Where references were to directives the legislation has generally been amended to refer to the domestic transposing legislation. In some places, though, it has made sense to retain the reference to the directive where the reference was to historic events.
- 6.4 Some of the regulations cross-referred to are being materially amended by other legislation made under section 8 of the European Union (Withdrawal) Act 2018. Those cross-references are being amended through consequential amendments contained in that other legislation. This will avoid a situation where the EU REACH Regulation is amended to refer to something that is not yet provided for.
- 6.5 This includes the cross-references contained in Article 15 of the EU REACH Regulation. It also includes some cross-references to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Those are the references to Part 3 of Annex VI to that Regulation, and the references to the classification and labelling inventory established under that Regulation.
- 6.6 The instrument makes minor amendments to two other pieces of domestic legislation. It amends the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009. Those amendments ensure that the Rules provide for appeals against decisions made by the HSE under the instrument.
- 6.7 It also amends the definition of “used PCBs” in the Environmental Protection (Disposal of Polychlorinated Biphenyls and other Dangerous Substances) (England and Wales) Regulations 2000. That definition currently defines the term “waste” by reference to a European directive. The amendment ensures that the definition will continue to be operable after the UK leaves the EU.

## **7. Policy background**

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

- 7.1 The purpose of the EU REACH Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessing the hazards of substances, as well as the free circulation of substances while enhancing competitiveness and innovation. The instrument makes the changes to the EU REACH Regulation that are necessary for it to continue to work effectively within the UK.
- 7.2 The effect of the instrument is to give the UK an independent capability to control the manufacture and import of chemicals into the UK and to understand the hazards and manage the risks connected to their manufacture and use.

### Definitions of duty holders

- 7.3 The instrument amends the definitions of duty holders such as manufacturers, importers and downstream users. They are now defined as being established in the United Kingdom rather than established in the Community. This is necessary to make sure that they remain bound by the duties in the EU REACH Regulation, such as the duty to register and the duty to identify, recommend and apply appropriate risk management measures.

### Governance and a UK Agency

- 7.4 Under the EU REACH Regulation, ECHA has the central role of managing the consistent implementation of the EU REACH Regulation across the EU. ECHA has a range of technical, scientific and administrative functions to enable it to carry out this role, and it also works collaboratively with Member State competent authorities. ECHA has powers to make technical and administrative decisions; it also makes recommendations which are given legislative effect by the European Commission.
- 7.5 Under the EU REACH Regulation Defra leads on UK policy, with the HSE acting as the competent authority (main delivery agency) for the EU REACH Regulation on behalf of the Secretary of State and Devolved Administrations. The Environment Agency provides expertise in relation to environmental science. The instrument reflects the continuing priority given to the protection of human health and the environment.
- 7.6 The instrument carries forward the central role of a regulatory agency. It designates the HSE as the UK Agency to carry out the functions which are currently the responsibility of ECHA. The instrument also gives the Environment Agency and the devolved environmental regulators the role of providing advice on environmental matters.
- 7.7 The instrument does not continue the competent authority role that exists under the EU REACH Regulation but transfers some of those functions to the UK Agency, the Secretary of State and the Devolved Administrations.

### Working in partnership with the Devolved Administrations

- 7.8 The instrument provides for a single UK-wide Registration, Evaluation, Authorisation and Restriction of Chemicals (“REACH”) regulation. This will facilitate the effective operation of a UK REACH system based on consistent policies and practices across the UK. It will also enable the maintenance of a coherent UK market across all four nations of the UK. REACH includes some matters that are devolved and some matters that are reserved, for example environmental protection and public health are devolved but occupational health and safety is reserved in Great Britain.
- 7.9 The instrument makes provision for the interests and roles of the UK Government and all the Devolved Administrations. It sets out how the returning EU powers, including the decision-making powers currently exercised by the European Commission, will return to the UK after EU Exit. The UK Agency will deliver its opinions to the Secretary of State and the Devolved Administrations. The Secretary of State will make decisions with the consent of the Devolved Administrations where the decision relates to an area of devolved competence. Commission powers that will return to the Secretary of State, to be exercised with the consent of the Devolved Administrations as appropriate, include decisions on restrictions, adding substances to the authorisation list and granting authorisations.
- 7.10 The Devolved Administrations will be permitted to take urgent, temporary restriction action in regard to a substance of concern through a safeguard clause (where such an action is within devolved competence). The urgent action is then to be followed up through the restriction procedure to assess whether it is appropriate to apply a permanent UK-wide control.

- 7.11 The competent authorities under the EU REACH Regulation are the Devolved Administrations on devolved matters and the Secretary of State in regard to England and reserved matters. In practice, all have delegated their roles to the HSE. The instrument does not continue the competent authority role in the UK system but the Secretary of State and the Devolved Administrations will still have the ability to receive information from the UK Agency, for example regarding registrations.

Scientific advice

- 7.12 The instrument provides for the input of external scientific advice to the UK Agency, so policy decisions on chemicals are supported by robust evidence and analysis. The UK Agency must then publish its opinions. This will ensure that there is transparency in the UK Agency's opinion-making processes.
- 7.13 The SI places a duty on the UK Agency to commission external scientific advice when developing its opinions except in particular circumstances where there are justifiable reasons, for example where ECHA has already published a robust opinion on a substance. The justification must be published if such advice is not sought. In order to reinforce transparency and consistency the UK Agency must consult on and publish a statement on how it will exercise these duties. The UK Agency will be able to seek advice from any experts it considers appropriate.

Transitional arrangements - supporting business continuity and compliance with REACH data requirements

- 7.14 The instrument preserves the essential registration and data provision principles of the EU REACH Regulation in the UK REACH system. While the instrument makes transitional arrangements for access to the UK market, it is not possible for the UK to legislate to facilitate continued access to the EU market by UK companies.
- 7.15 The transitional provisions in Schedule 2 to the instrument are described in more detail in paragraphs 7.16 to 7.26 below. They have the aim of minimising disruption to supply chains, trade flows, business continuity and economic growth. This will provide confidence in the UK chemicals industry and minimise the barriers to accessing the UK market.

Transferring existing UK registrants into the UK REACH system

- 7.16 One of the most important features of the EU REACH Regulation is the principle of “no data, no market” which is the basis of the registration process. Registration and the “no data, no market” principle continue in the UK REACH system. The instrument provides for the automatic transfer of the existing EU REACH Regulation registrations held by UK based companies, including UK-based Only Representatives, which meet certain criteria into the UK REACH system with no break in their validity. This means that the qualifying registrants will not have to re-register their substances in the UK and no new fees are payable. The effect is that they will continue to have access to the UK market. The automatic transfer of UK registrations applies to qualifying registrations held by UK based companies in the period of two years prior to EU Exit. This is to ensure that UK based companies who have transferred their EU registrations to an EU affiliate in order to secure continued access to the EU market will have a valid UK registration.

- 7.17 The instrument does require, however, that all transferring UK registrants need to resubmit registration data to the UK Agency and provides for a two stage process. At the first stage basic data will need to be submitted to the UK Agency within 120 days of exit day, including company details, the chemical registered, quantities produced and evidence of their existing ECHA registration. At the second stage the full information appropriate to the registrant's tonnage band will need to be submitted to the UK Agency within two years.
- 7.18 A UK IT system will facilitate the operation of the UK REACH system, including for UK based companies to upload the data required.
- 7.19 The instrument also provides that ECHA decisions concerning UK registrations existing immediately prior to EU Exit continue to have force, including decisions on testing proposals and dossier and substance evaluations. The UK Agency will be able to amend any deadline in those decisions, if considered appropriate.

Notification by UK importers from the EEA

- 7.20 Under the EU REACH Regulation, downstream users of chemical substances within the EEA do not have to register the substances they use. This includes UK companies who are currently sourcing substances from suppliers in the rest of the EEA. However, these UK companies will become importers into the UK market after EU Exit, which means they will have the duty to register the substances.
- 7.21 The instrument provides transitional support to these companies through an interim notification system instead of requiring them to undertake a full registration immediately after EU Exit. The effect of the notification provisions is that qualifying UK companies will be able to continue buying substances from the EEA without any interruption after EU Exit. At the same time it reflects the need for companies to be responsible for managing the risks from chemicals.
- 7.22 Under the notification system, those importing chemicals from the EEA will need to submit basic data on the company, substances and information on safe use within 180 days. These importers should have access to the necessary information, for example from the safety data sheets that REACH registrants must produce and pass down the supply chain. The interim notification will need to be replaced with a full registration after two years.
- 7.23 The aim of the various transitional and other provisions is to minimise disruption for citizens and business to ensure a smooth transition after EU Exit. The timelines set for data submission to the UK Agency, including for transferred registrations and notification represent a balanced approach to managing the risks around data gaps and burdens on business. The spacing of the timeline will help to spread the burden on companies and the regulatory authorities. The two year period in particular will allow additional time for companies that have to renegotiate access to data from EU partners.

Existing authorisations and authorisation applications

- 7.24 Any authorisations held by UK companies will continue to have effect after EU Exit. Applications to request an extension of the authorisation at the review date set in the authorisation should then be made to the UK Agency.

- 7.25 The instrument provides that a UK company whose use of a substance is covered by a non-UK authorisation can continue to use that substance for the length of the EU authorisation. The UK company will need to supply the Agency with, and continue to comply with, the conditions that govern that authorisation.
- 7.26 There will be cases where, at the time of EU Exit, ECHA's committees will have given their opinions on a UK application for an authorisation but the European Commission has not made a decision whether to grant the authorisation. The instrument provides that in these cases the Secretary of State, with the consent of the Devolved Administrations, will decide the case once the applicant has submitted the information necessary to take the decision.

#### Appeals

- 7.27 The EU REACH Regulation set up a Board of Appeal within ECHA to hear appeals against the Agency's decisions. The instrument provides for the role of hearing appeals against the Agency's decisions to be taken by the First-tier Tribunal. The Tribunal has the power to dismiss an appeal, remit the decision back to the UK Agency for reconsideration, or substitute its own decision for that of the UK Agency.

#### Fees

- 7.28 The EU REACH Regulation sets out the fees and charges which are payable to ECHA, for example when a company submits a registration dossier or an application for authorisation. The instrument retains this system of fees and charges, making them payable to the UK Agency, with the exception of the fees for appeals because the First-tier Tribunal is replacing ECHA's Board of Appeal. The instrument retains the reduced fees for medium, small and micro companies. The fees and charges are converted into sterling but otherwise unchanged. The exchange rate used is the average for 2017. No payments are required in relation to the transitional provisions.

#### Enforcement regulations

- 7.29 The existing enforcing authorities throughout the UK will continue their roles after EU Exit. The instrument establishes new enforcement duties with regard to the data requirements in the transitional provisions; these are enforceable by the HSE and the Health and Safety Executive for Northern Ireland.

### **8. European Union (Withdrawal) Act 2018/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. The instrument is also made using the powers in section 14(1) of, and paragraph 1 of Schedule 4 to, that Act. 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 None.

## **10. Consultation outcome**

- 10.1 DEFRA organised informal discussions with 23 stakeholders from large and small companies, trade associations representing different stages in the supply chain, non-governmental organisations, professional bodies and scientists in eight meetings between 26 June and 20 July 2018. The Devolved Administrations were invited to participate in the informal discussions with stakeholders and subsequently engaged in contributing to the drafting of the statutory instrument.
- 10.2 The meetings discussed proposed plans for a UK regulatory system to replace that contained in the EU REACH Regulation, in the event of a no deal exit from the EU in March 2019.
- 10.3 The informal discussions highlighted general agreement from stakeholders to plans to bring over existing UK registrations and provide for an interim notification procedure for UK companies that source chemicals from elsewhere in the EEA.
- 10.4 Stakeholders raised issues about the potential additional costs to industry, disruption to supply chains and business and scientific advice and transparency.
- 10.5 The Department responded to these concerns by seeking to minimise disruption to supply chains and business continuity including through additional guidance. The Department has provided for the UK Agency to obtain advice from the environmental regulators and take relevant scientific knowledge and advice into account. The UK Agency must also publish a statement on how it will take such knowledge and advice into account.

## **11. Guidance**

- 11.1 Guidance on regulating chemicals (REACH) if there is no Brexit deal is in a Technical Notice on the website [GOV.UK](https://www.gov.uk) published on the 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](https://www.hse.gov.uk) published on the 4 December 2018.

## **12. Impact**

- 12.1 There will be large benefits associated with introducing the instrument as it makes the necessary legislative amendments to make the regulatory system operable in the UK after EU exit. It will provide continuity, stability and legal certainty for businesses and UK regulatory authorities. This will maintain the UK's ability to manage risks to health and the environment.
- 12.2 The main impact on business, charities or voluntary bodies is that businesses will need to submit the supporting data for existing registrations and authorisations to the UK Agency. Firms may incur significant costs depending on the particular circumstance of their data ownership/data sharing agreements.
- 12.3 The impact on the public sector is that the Government will incur the costs associated with the UK implementing its own regulatory regime for chemicals.
- 12.4 A full Impact Assessment is submitted with this memorandum and published alongside it on the [legislation.gov.uk](https://www.legislation.gov.uk) website.

## **13. Regulating small business**

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

- 13.2 To minimise the impact of the requirements on small businesses (employing up to 50 people), the approach taken in the instrument is to retain in the UK system the reduced fees for medium, small and micro businesses that exist in the EU REACH Regulation. In addition, in order to minimise burdens, no fees are attached to the data requirements in the transitional provisions.
- 13.3 The basis for the final decision on what action to take to assist small businesses followed informal discussions with stakeholders.

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

- 14.1 The approach to monitoring of this legislation is to monitor the operation of the transitional arrangements, in particular the two year time periods for submitting the full information appropriate to the registrant's tonnage band and for replacing the interim notification with a full registration.
- 14.2 As this instrument is made under the EU (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](mailto: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 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.<br><br>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<br>In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all European Union (Withdrawal) Act 2018 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         | 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), 9, and 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 sections 8(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 1972.                                  | 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 1972.                                  | Statement setting out:<br>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,<br>b) containing information about the relevant authority's response to—<br>(i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and<br>(ii) any other representations made to the relevant authority about the published draft instrument, and<br>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 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) Regulations 2019 does no more than is appropriate”.

- 1.2 This is the case because it only makes the amendments and transitional arrangements necessary to make the retained EU legislation and EU derived domestic legislation operate effectively after the UK’s withdrawal from the EU.

#### **2. Good reasons**

- 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 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: that there is a need to ensure that the use of chemicals in the UK does not endanger human health or the environment. The instrument ensures the proportionate regulation of chemicals in the UK to achieve this.

#### **3. Equalities**

- 3.1 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”.

- 3.2 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”.

#### **4. Explanations**

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

## **5. Criminal offences**

5.1 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 creation of criminal offences and for the penalties in respect of them in the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019”.

5.2 These are: new offences created in relation to the transitional provisions contained in the instrument. The offences are similar in nature to those that already exist in relation to the submission of information in the REACH Enforcement Regulations 2008. The penalties are the same as for those existing offences.

## **6. Sub-delegation**

6.1 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 it is appropriate to create relevant sub-delegated powers in the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019.”

6.2 This is appropriate because: the relevant power in Article 64(8) of the EU REACH Regulation provides for the Commission to grant authorisations. These authorisations are granted to specified companies to allow them to undertake specified activities in relation to specified substances. This does not have the character of legislation as it is not of general application; it is more akin to the granting of a licence or planning permission. Requiring each authorisation to be made by a statutory instrument would mean that the process would take a disproportionately long time, to the detriment of industry. Instead, the Secretary of State will be able to grant authorisations through administrative action, subject to the consent of the devolved administrations where it relates to devolved matters.

6.3 The relevant power in Article 69(5) provides for the Commission to decide whether a restriction on the use of a substance should be re-examined. The decision to be taken is not of a legislative character as it does not itself affect how substances can be used; the decision of whether or not amend the restriction will have to be implemented by statutory instrument following re-examination. Requiring two statutory instruments to re-examine and amend a restriction would restrict the ability of the Secretary of State to ensure the right controls are in place to protect human health and the environment. Instead, the Secretary of State will take this decision through administrative action, subject to the consent of the devolved administrations where it relates to devolved matters.