EXPLANATORY MEMORANDUM TO

THE CHEMICALS (HEALTH AND SAFETY) AND GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by Department for Work and Pensions and is laid before Parliament by Act.

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

2. Purpose of the instrument

2.1 This instrument is made using powers in the European Union (Withdrawal) Act 2018[1] ("the Withdrawal Act") to address deficiencies in retained EU law in relation to chemicals and genetically modified organisms (GMOs) legislation arising from the withdrawal of the United Kingdom (UK) from the European Union (EU). This instrument ensures that UK chemicals and GMO regulations will continue to operate effectively at the point at which the UK leaves the EU ("Exit"). This instrument does not make any policy changes beyond the intent of ensuring continued operability of the relevant legislation.

Explanations

What did any relevant EU law do before Exit day?

2.2 **The Biocidal Products Regulation (Regulation (EU) No 528/2012)**[2] ("the BPR") governs the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. The BPR sets out a two-step process, whereby active substances are first approved at EU level, before biocidal products containing those substances are authorised in individual Member States. The BPR simplifies the regime set out in the earlier Biocidal Products Directive 98/8/EC by introducing new routes to authorising products. This includes simplified authorisation for products containing active substances considered to pose a lower level of risk; and a 'Union authorisation' procedure, enabling a single decision to be taken authorising certain biocidal products across the EU. The BPR also sets timelines for Member State evaluations, opinion-forming and decision-making. The BPR promotes the reduction of animal testing by establishing mandatory data sharing obligations and encouraging the use of alternative testing methods. In addition, there is a range of related tertiary legislation affecting Biocidal products (*Commission Implementing Regulation (EU) No 354/2013*[3], *Commission Implementing Regulation (EU) No 414/2013*[4], *Commission Implementing*

[1] http://www.legislation.gov.uk/ukpga/2018/16/contents/enacted
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0354
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0414

Regulation (EU) No 88/2014[5]*, Commission Implementing Regulation (EU) No 1062/2014*[6]).

2.3 **The Classification, Labelling and Packaging of substances and mixtures Regulation ((EC) No 1272/2008)**[7] ("the CLP Regulation") adopts the *UN Globally Harmonized System of the classification and labelling of chemicals (GHS)*[8] throughout the EU. The CLP Regulation is a single market measure and applies to the supply of chemicals. The CLP Regulation requires manufacturers, importers, distributors, and downstream users[9] to classify (identify intrinsic hazards – e.g. carcinogenic, toxic for reproduction, mutagenic etc.), label (communicate those hazards) and safely package the chemicals they place on the market. These requirements apply throughout the supply chain down to the point of use so that chemicals can be supplied, handled and used safely. Manufacturers and importers are also required to notify the details of the hazard classifications of chemicals they manufacture or import to the European Chemicals Agency (ECHA) for inclusion in the ECHA Classification and Labelling Inventory[10].

2.4 **The Export and Import of Hazardous Chemicals Regulation (Regulation (EU) No 649/2012)**[11] ("the PIC Regulation") implements the international *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* in the EU. The PIC Regulation goes further than the Convention in applying the provisions to chemicals considered to be banned or severely restricted under other EU law. The PIC Regulation requires exports of listed chemicals to be notified to the importing country and for some chemicals the consent of the importing country must be obtained before export can proceed.

2.5 The Genetically Modified Organisms (Contained Use) Regulations 2014[12] and The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015[13] ("the GMO (CU) Regulations") implement *The Contained Use of Genetically Modified Micro-Organisms Directive ((EC) No 2009/41)*[14]; which lays down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. Section 2(2) of the *European Communities Act 1972*[15] is used to implement the aspects of the Directive which relate to protection of the environment.

Why is it being changed?

2.6 This instrument addresses deficiencies arising from the UK's withdrawal from the EU to ensure that retained EU law relating to chemicals and GMOs, including both direct EU law and EU-derived domestic legislation, continues to operate effectively and coherently. The deficiencies include provisions conferring functions on and in relation

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0088
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R1062
[7] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272
[8] https://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html
[9] Downstream users re-formulate, re-brand or re-package substances or mixtures in the course of their industrial or professional activities.
[10] https://echa.europa.eu/information-on-chemicals/cl-inventory-database
[11] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:EN:PDF
[12] http://www.legislation.gov.uk/uksi/2014/1663/contents/made
[13] http://www.legislation.gov.uk/nisr/2015/339/contents/made
[14] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009L0041
[15] https://www.legislation.gov.uk/ukpga/1972/68

to EU entities such as the Commission and the European Chemicals Agency (ECHA). This will allow for current levels of protection for people and the environment to remain in place once the UK has left the EU.

2.7 If these changes were not made, several chemicals regimes in the scope of the instrument would not be fully operable when the UK leaves the EU. This would leave the UK without fully functioning chemicals legislative regimes that allow for the safe trading of chemicals following Exit as well as associated enforcement activity.

2.8 Without these amendments the scope of the GMO (CU) Regulations will be inadvertently greater than originally drafted as GMOs that were previously out of scope of the Regulations would come within scope. If left unchanged they could become a legal impediment for other UK GMO-related policy areas and potentially introduce unnecessary legal burdens on industry.

What will it now do?

2.9 This instrument amends the relevant legislation to ensure that existing protections and regulatory frameworks are maintained and continue to operate effectively at the point at which the UK leaves the EU. Provisions are also made to enable fees to be charged for work in relation to the BPR, the CLP Regulation, and the Placing of Plant Protection Products on the Market Regulation (Regulation (EC) No 1107/2009[16]) ("the Plant Protection Products Regulation") that is being repatriated to the UK. Details on specific changes are listed in Section 7.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The decision to include requirements for several regulatory regimes in one statutory instrument was taken to reduce pressure on Parliamentary time.

3.2 To meet the Government's intention to repatriate powers to the UK, alternative arrangements to ensure routine updates to reflect scientific and technical progress need to be put in place. Currently, technical and scientific updates to the direct acting EU chemical regulations are proposed, considered and adopted through the EU's delegated decision-making arrangements. After Exit, the retained Regulations will provide that the same updates can be made via ministerial decision, following recommendations from the relevant competent authority or Agency. The alternative option considered was to make a new Statutory Instrument each time a technical or scientific update is required.

The decision to follow an administrative procedure was taken because under the current EU framework, these updates simply confirm the outcome of scientific assessment or evaluation against established criteria by regulatory scientists (for example, reflecting the latest scientific understanding of the intrinsic hazard of a given substance, or for biocides, a detailed assessment based on data submitted by the applicant of whether the risks from use of an active substance are acceptable). They do not represent policy changes, nor do they change the underpinning obligations, requirements or duties in the respective regimes. The updates are recommended by regulatory scientists in Member State competent authorities or other bodies, including those in the Health and Safety Executive and the Environment Agency. The

[16] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

Commission enacts the updates through Commission Regulations or Commission Delegated Regulations.

After Exit, the same UK regulatory scientists will recommend updates to ensure the continued protection of people, the environment, and the interests of UK business for the UK only, not as part of the EU system. Where ministers agree with the recommendation, they will issue a decision to this effect and the Health and Safety Executive (HSE) will then ensure that the updates are given effect from an agreed date, and alert duty-holders to changes. Enabling these updates in this way ensures that the updates are dealt with promptly and efficiently, which is necessary to provide legal certainty for UK business. The approach enables the UK to more easily follow the volume and pace of the scientific and technical changes involved and (in the case of the CLP Regulation) will allow for effective management of the downstream consequences. The approach also prevents undue pressure on Parliamentary time compared to the alternative option of making a Statutory Instrument for each update, as, for example, for the BPR regime there can be up to 50 active substance approval decisions a year.

This approach is being taken by a number of other government departments who are repatriating scientific and technical regulatory regimes. The Veterinary Medicines Directorate already operates an administrative approval system for the authorisation and approval for manufacturers of veterinary medicines and are aiming to have a similar regime in place to handle maximum residue levels for veterinary medicines. The Department for Environment, Food, and Rural Affairs are pursuing an administrative approach to decisions regarding Plant Protection Products active substance approvals and maximum residue levels. The Department for Transport is to amend the status of 'Technical Specifications for Interoperability' as part of its draft contingency legislation from Regulations to Ministerial 'Notices'.

3.3 It is a well-established policy of HSE to set fees to recover the full costs of its regulatory activities where it has determined that the costs of those services should be passed to the recipient of the service. Under most existing EU chemicals Regulations there is a system of variable fees and charges dependent on the size of organisation involved. However, the domestic fees and charges systems proposed in this instrument will be proportionate to the actual cost incurred of intervening. This follows approval from Her Majesty's Treasury.

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)

3.4 The territorial application of this instrument varies between provisions.

3.5 The powers under which this instrument is made cover the entire United Kingdom (see the European Union (Withdrawal) Act 2018 section 24) and the territorial application of this instrument is not limited either by the Withdrawal Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the UK only.

4.2 The territorial application of this instrument is the UK, except for amendments to The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013, The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015, The Biocidal Products (Fees and Charges)

Regulations (Northern Ireland) 2015, The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015 which apply to Northern Ireland only; and The Genetically Modified Organisms (Contained Use) Regulations 2014 which only applies to Great Britain. The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 apply to Great Britain, except for the elements relating to the PIC Regulations, which apply to the UK.

5. European Convention on Human Rights

5.1 The Minister of State for Disabled People, Health and Work has made the following statement regarding Human Rights:

"In my view the provisions of the *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019* are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is being made to correct deficiencies in chemical and other HSE related legislation as a result of Exit. The Withdrawal Act repeals the European Communities Act 1972, but section 2 continues to have effect in domestic law on or after Exit day. Exit day is defined by section 20 of the Withdrawal Act. The Withdrawal Act contains a power to make secondary legislation to prevent, remedy or mitigate deficiencies that will arise on Exit in retained EU law. This includes both domestic law and directly applicable EU law. The Withdrawal Act only allows corrections to be made to the retained EU Regulations that are appropriate to ensure the national regimes will work effectively after exit.

6.2 As directly applicable European Regulations, requiring no transposition into UK law, the BPR, CLP and PIC Regulations will be retained under the arrangements offered in Section 3(1) of the Withdrawal Act. The instrument makes corrections to these Regulations using the Withdrawal Act powers.

6.3 Due to amendments to the CLP Regulation made in this instrument, amendments are to be made to downstream legislation i.e. legislation that sits 'downstream' of the CLP Regulation, but which relies on hazard classification, in whole or in part, to define its intended scope and to act as a 'trigger' for additional risk control measures. This is to ensure that the downstream legislation continues to provide the appropriate and necessary references to the CLP Regulation and (where required) to the UK mandatory classification and labelling list that the amended CLP Regulation provides for. This instrument makes amendments to *The Control of Major Accident Hazards Regulations 2015*, *The Health and Safety (Enforcing Authority) Regulations 1998*, *The Control of Substances Hazardous to Health Regulations 2002*, *The Control of Lead at Work Regulations 2002*, *The Dangerous Substances and Explosive Atmospheres Regulations 2002*, as well to comparable Northern Ireland downstream regulations as referenced by *The Classification, Labelling and Packaging of Chemicals (Amendment) Regulations (Northern Ireland) 2015*[17]. In addition, similar necessary amendments are also to be made to the retained EU law *The Plant Protection Products Regulation* (*Regulation (EC) No 1107/2009)* and *The Registration,*

[17] http://www.legislation.gov.uk/nisr/2015/265/contents/made

Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (Regulation (EC) No 1907/2006)[18].

6.4 This instrument also amends The Plant Protection Products (Fees and Charges) Regulations 2011[19], The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013[20], The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013[21], The Genetically Modified Organisms (Contained Use) Regulations 2014[22], The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015[23], The Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015[24], The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015[25], and The Health and Safety and Nuclear (Fees) Regulations 2016[26], to address deficiencies arising from the UK's withdrawal from the EU to allow the Health and Safety Executive to enforce provisions and to recover costs for its work.

6.5 As part of the Exit process the Department for Environment, Food and Rural Affairs will also introduce other instruments to amend EU legislation in the area of chemical regulation. These instruments will amend *The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (Regulation (EC) No 1907/2006)*; *The Plant Protection Products Regulation* (*Regulation (EC) No 1107/2009); The Maximum Residue Levels (MRLs) Regulation (Regulation (EC) No 396/2005)*[27]*; The Sustainable Use Directive (Directive 2009/128/EC)*[28]*; The Persistent Organic Pollutants Regulation (Regulation (EC) No 850/2004)*29*; The Detergents Regulation (Regulation (EC) No 648/2004)*[30]; and *The Control of Mercury Regulation (Regulation (EU) 2017/852)*[31]. These instruments will also address deficiencies arising from the UK's withdrawal from the EU to ensure that retained EU law, including both direct EU law and EU-derived domestic legislation continue to operate effectively and coherently.

7. Policy background

What is being done and why?

7.1 This instrument corrects deficiencies arising from the UK's withdrawal from the EU to ensure working regulatory regimes after Exit as regards the BPR, CLP, and PIC Regulations. It makes corrections to the existing EU regimes as converted into national law through the powers of the Withdrawal Act; creating UK standalone

[18] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
[19] http://www.legislation.gov.uk/uksi/2011/2132/contents/made
[20] https://www.legislation.gov.uk/uksi/2013/1506/contents/made
[21] https://www.legislation.gov.uk/nisr/2013/206/contents
[22] http://www.legislation.gov.uk/uksi/2014/1663/contents/made
[23] http://www.legislation.gov.uk/nisr/2015/339/contents/made
[24] http://www.legislation.gov.uk/nisr/2015/254/contents/made
[25] https://www.legislation.gov.uk/nisr/2015/236/contents/made
[26] http://www.legislation.gov.uk/uksi/2016/253/made
[27] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R0396
[28] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:02009L0128-20091125
[29] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0850
[30] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32004R0648
[31] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0852

regimes with minimal modifications and no substantive policy changes. Without these changes, the legislation listed below would not be fully operable on Exit.

The Biocidal Products Regulation (BPR)

7.2 This instrument amends the BPR and related tertiary legislation to fix inoperabilities. Commission decision-making powers are transferred so that the Secretary of State will normally act as the decision-making body for the UK, with the consent of devolved administrations as appropriate (though in limited cases the devolved administrations may act alone, where they have competence to do so). Where the Commission is, in EU BPR, given the power to make implementing or delegated Regulations to enact decisions, this is normally replaced with a power for the Secretary of State to make regulations under the negative resolution procedure. However, in specific cases (approval or non-approval of an active substance, inclusion of a substance in the 'Simplified Active Substance List') provision is made for decisions to be taken administratively by the Secretary of State rather than by statutory instrument. This enables decisions to be taken in an efficient and timely way as explained in more detail in section 3.2.

7.3 Where the European Chemicals Agency (ECHA) previously undertook functions acting as the 'Agency' on behalf of the UK, where they are still relevant in a UK-only context, these functions are transferred to the competent authority as already defined in Great Britain and Northern Ireland enforcing regulations. Agency agreements will transfer the functions of the competent authority to the Health and Safety Executive (HSE) so that in practice, the latter work would effectively be undertaken by HSE. Relevant functions include undertaking technical equivalence assessments (assessing whether a new source of an active substance is sufficiently similar to one already assessed for the evaluation conclusions still to apply) and handling mandatory data sharing and requests to undertake new vertebrate tests.

7.4 Other ECHA functions are no longer considered relevant in a UK-only context and are deleted or replaced by suitable UK alternatives. For example, reference to the UK using ECHA IT systems is replaced with a provision to follow a UK system or for the competent authority to update its records. Reference to using ECHA's Biocidal Products Committee, a scientific committee whose membership consists of Member State experts, is omitted as it is no longer considered relevant in a UK only context.

7.5 Once the UK has left the EU, mutual recognition and Union authorisation options will not be applicable and HSE will instead evaluate applications for national authorisations and make decisions on behalf of the UK. Biocidal product authorisations and active substance approvals that were in place before exit day, including Union Authorisations and authorisations granted under mutual recognition procedures, will continue to be valid after exit until their normal expiry date (provided for product authorisations that the company is established within the UK within 12 months of exit day). Where applications were made to HSE before exit day for approval of an active substance or authorisation of a biocidal product, but no decision on authorisation or approval has been taken by exit day, provision is made for the data supporting the application to be resubmitted to HSE within defined deadlines This is necessary so that HSE can continue to process the applications and take a UK decision on authorisation or approval after access to the EU databases containing the data supporting applications is lost. Where such deadlines are not met, applications would be cancelled, and affected products would need to be removed from the market, subject to a period of grace for disposal of existing stocks.

7.6 Appeals will be determined in accordance with the provisions specified within The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 and The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013.

7.7 The instrument amends the retained Commission Regulation 1062/2014[32] setting out the work programme for the systematic examination of existing active substances ("the Review Regulation"). The EU Review Regulation sets out arrangements whereby evaluations of active substances are distributed between all 28 Member States and sets deadlines for the completion of such evaluations. BPR sets the deadline of 31 December 2024 for completion of the review programme as a whole.

7.8 The amendments to the Review Regulation will remove the provisions allocating active substance reviews to European Union Member States. This would have the effect of making the UK competent authority responsible for evaluating the remaining active substances in the review programme; effectively, establishing a stand-alone UK review programme covering the 488 active substance/product type combinations that are still to be reviewed.

7.9 The current deadlines in the Review Regulation and BPR for completing the review programme are based on work-sharing between 28 Member States and are considered to be deficient in case of a no-deal exit. This instrument therefore amends the BPR to give the Secretary of State the power to make regulations, with the consent of devolved authorities, to extend the date for completion of the review programme and specify other matters in relation to carrying out a UK work programme. The instrument also removes interim deadlines for completion of reviews from the Review Regulation and instead gives the Secretary of State the power to set suitable deadlines.

7.10 It is anticipated that this power would be used to amend the Review Regulation to put in place an alternative programme for reviewing the remaining substances. The details of how such a programme would operate are currently being developed. However, any reviews would be done to the same standards in terms of protecting human and animal health and the environment.

The Classification, Labelling and Packaging Regulation (CLP)

7.11 Currently, most functions can only be exercised at EU level, by EU entities. This includes the harmonisation of classification and labelling requirements for substances, following scientific assessment by the Risk Assessment Committee of the European Chemicals Agency (ECHA), The instrument repatriates functions and powers from the EU to the UK, using powers under the Withdrawal Act, and in line with the government's approach to EU exit and devolution. The tasks and functions presently carried out by EU institutions and "Member States" will instead be carried out in the UK by the Secretary of State. In most cases the exercise of the Secretary of State's function is subject to the consent of the devolved administrations, (to the extent that the function in question is within devolved competence). The regulatory functions currently carried out by ECHA will be carried out by the Health and Safety Executive (HSE) for the UK.

7.12 Manufacturers and importers will continue to have to comply with the duty to notify details of the self-classifications for the substances they place on the market. Currently, these notifications are made to the ECHA. In future, these notifications will

[32] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R1062

be made to HSE as the Agency and new notification arrangements put in place. Manufacturers and importers will not have to notify if the substance has already been notified before exit day to ECHA. HSE will also make information on hazard classification and labelling of notified substances publicly available in due course.

7.13 One of the most significant functions to be conferred on the Secretary of State is that of setting and revising at a national level mandatory classification and labelling requirements for substances, which will bind UK based suppliers. The instrument replaces EU arrangements by establishing a new procedure (as explained in more detail in Section 3.2) to give effect to decisions in an efficient and timely way, involving a UK mandatory classification and labelling list. Transitional provision is made so that all the existing harmonised classification and labelling requirements already agreed by the EU and listed in Part 3 of Annex VI of the Regulation will be included in the UK mandatory classification and labelling list, and so will remain legally binding on UK-based suppliers after Exit.

7.14 One function currently performed by the European Chemicals Agency (ECHA) is managing requests by suppliers for the use of an alternative chemical name. Such requests are made where it can be demonstrated by suppliers that the disclosure on the label or in the accompanying safety data sheet of certain information about the component substances may put the confidential nature of their business and intellectual property rights at risk. This process will be adapted to accommodate the needs of the UK market as opposed to that of the EU. The Health and Safety Executive (HSE) does not currently intend to charge a fee for this work but this will be kept under review with amendments to secondary legislation on fees if required. The UK will continue to recognise alternative chemical names already agreed before Exit.

7.15 Article 45 of the CLP Regulation currently obliges Member States to appoint a body responsible for receiving information on mixtures from importers and downstream users and for developing preventative and curative measures in the event of emergency response. This will be a deficiency after exit. The instrument will confer this function (which is a public health function and therefore devolved) on the Secretary of State in relation to England and the devolved authorities in relation to their respective countries. In practice, this will make little difference to current arrangements, under which appointing bodies under this Article is the responsibility of the Secretary of State for the Department of Health and Social Care for England and the devolved authorities for their respective countries. The National Poisons Information Service is the UK national service that provides expert advice to front-line NHS healthcare professionals on all aspects of acute and chronic poisoning.

7.16 The instrument makes consequential amendments to legislation that sits ‘downstream’ of the CLP Regulation, but which relies on hazard classification, in whole or in part, to define its intended scope and to act as a ‘trigger’ for additional risk control measures. This legislation was amended in 2015 on the introduction of the CLP Regulation and now needs amending again to ensure they continue to provide the appropriate and necessary references to the CLP Regulation as it is amended by this instrument.

7.17 The instrument amends the CLP and the Health and Safety and Nuclear (Fees and Charges) Regulations to allow HSE to charge fees to recover the costs of work relating to a proposal from a manufacturer, importer or downstream user for mandatory classification and labelling for a hazard class or differentiation (with

specified exceptions). This work is currently carried out by ECHA but will be carried out by HSE after Exit.

7.18 The instrument amends Annex II of the European Economic Area agreement (which becomes retained EU law after exit by virtue of section 3(2)(b) of the Withdrawal Act) by revoking modifications to the CLP Regulation which would not be relevant to the UK after exit. The instrument does not, however, revoke modifications to the CLP Regulation where they would remain relevant to the UK after exit, and where incorporating them into the text of the CLP Regulation by textual amendment would be disproportionately onerous.

The Export and Import of Hazardous Chemicals Regulation (PIC)

7.19 This instrument amends the PIC Regulation, making those changes necessary for it to continue to operate in the UK after Exit. It also ensures that these arrangements fully implement the requirements of the Rotterdam Convention, with which the UK, as a Party, must comply. The PIC Regulation requires exporters of certain hazardous chemicals to notify the importing country and in some cases obtain their explicit consent before export can proceed. The chemicals within the scope of the PIC Regulation are those listed under the Rotterdam Convention and those that are not approved for use or have severe restrictions on their use under other chemicals legislation.

7.20 The main deficiencies that this instrument seeks to remedy in relation to PIC are:

7.20.1 to repatriate functions relating to participation in the Rotterdam Convention from the European Commission to the Secretary of State;

7.20.2 to repatriate functions placed on the European Chemicals Agency (ECHA) to the Designated National Authority (the Health and Safety Executive and the Health and Safety Executive for Northern Ireland);

7.20.3 to replace references to information being publicly available by means of 'the database' (ECHA's 'ePIC' IT system) with references to information being publicly available via the website of the Designated National Authority. This will ensure that such information remains publicly available;

7.20.4 to make minor corrections to the text to address any references which assume EU membership and remove any elements which are reliant on EU membership e.g. to amend 'Union' and 'Member State' to 'United Kingdom';

7.20.5 to establish a new national mechanism to give effect to national decisions in an efficient and timely way by the listing of various chemicals on an administrative list to be known as the UK PIC list (as explained in more detail in Section 3.2). The chemicals that were previously listed under Parts 1 to 3 of Annex I and Parts 1 and 2 of Annex V to the PIC Regulation will instead be incorporated into one of 5 corresponding Parts of the UK PIC list (see Articles 7 and 23 of the PIC Regulation). Transitional provision is made so that all existing chemicals listed in Annexes I and V to the PIC Regulation will be incorporated in the UK PIC list after Exit;

7.20.6 to create a consent requirement which applies to provisions where the Secretary of State is required to make a decision which may concern pesticides, given that pesticides is a devolved matter in Scotland, Wales and Northern Ireland. The consent requirement applies to a decision of the Secretary of State to adopt an import decision and a revised import decision (Article 13(1) of PIC), and the decision of the Secretary

of State to include a chemical in the UK PIC list (Article 23(3) of PIC), where such a decision concerns a pesticide.

The Plant Protection Products (Fees and Charges) Regulations

7.21 Plant Protection Products (PPPs) (also known as "pesticides") are treatments that protect valuable plants such as crops against pests and diseases or prevent the growth of unwanted plants such as weeds. An active substance is the key component in a PPP that brings about the desired effect.

7.22 It has been the policy of successive governments to recover certain costs to government arising from the operation of the PPP regulatory regime through fees and charges. This is achieved through two charging mechanisms as regards PPPs: the payment of fees for evaluating applications for product authorisation and dossiers for approval of active substances; and a charge on the annual turnover of authorisation holders.

7.23 *The Plant Protection Products (Fees and Charges) Regulations 2011* need to be amended to reflect those changes to the regulatory regime for Plant Protection Products that are necessary to ensure an operable national system. The regime changes include replacing the decision-making role of certain European institutions with a new national decision-making process and an independent expert advice function. Changes will also provide for the introduction of a small number of fees to recover the costs of work which was previously carried out by EU institutions, but which will be repatriated to the UK after Exit.

The Genetically Modified Organisms (Contained Use) Regulations (GMO (CU))

7.24 This instrument makes amendments to the GMO (CU) Regulations. It amends references within the GMO (CU) that currently refer to a European Directive and Regulation.

7.25 Regulation 3(2)(a)(iii) provides an exemption from these Regulations for GMOs deliberately released into the environment that have a written consent from a European Economic Area (EEA) state in accordance with *EU Directive 2001/18*[33] - on the deliberate release into the environment of genetically modified organisms. The exemption will be removed for post-Exit consents, but will contain a transitional provision to ensure GMOs deliberately released into the environment that have a written consent from an EEA state in accordance with EU Directive 2001/18 pre-Exit will remain exempt from the scope of the GMO(CU).

7.26 Regulation 3(2)(b)(i) references *Regulation (EC) No 726/2004*[34] to provide an exemption for GMOs in medicinal products for human or veterinary use marketed in accordance with that Regulation35. That Regulation is intended to be revoked and restated under amendments to *The Human Medicines Regulations 2012*[36] for human medicines and *The Veterinary Medicines Regulations 2013*[37] for veterinary medicines. This instrument makes 'fixes' in relation to veterinary medicines. The instrument

[33] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001L0018
[34] https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf
[35] https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf
[36] http://www.legislation.gov.uk/uksi/2012/1916/contents/made
[37] http://www.legislation.gov.uk/uksi/2013/2033/contents/made

amending *The Human Medicines Regulations 2012* will make the 'fix' in relation to human medicines. This instrument includes a transitional provision to ensure medicinal products for human or veterinary use, marketed in accordance with *Regulation (EC) No 726/2004* pre-Exit, remain exempt from the scope of the GMO(CU).

7.27 Amendments to *The Human Medicines Regulations 2012* are scheduled to be laid in January 2019, so the amendments to refer to *The Human Medicines Regulations 2012* within the GMO(CU) will be delivered via consequential amendment, when the amendments to *The Human Medicines Regulations 2012* are presented to Parliament.

7.28 Schedule 3, Part 2(3)(d) requires the consideration of relevant EU legislation when conducting a risk assessment under the Regulations. This Schedule will be amended to remove references to EU legislation, as they will no longer be a relevant consideration for a risk assessment.

Amendments to Northern Ireland Legislation

7.29 This instrument applies to health and safety at work which is a transferred matter for Northern Ireland under section 4(1) of the *Northern Ireland Act 1998*. The UK Government remains committed to restoring devolution in Northern Ireland. This is particularly important in the context of EU Exit where we want devolved Ministers to take the necessary actions to prepare Northern Ireland for Exit. We have been considering how to ensure a functioning statute book across the UK including in Northern Ireland. In the continued absence of a Northern Ireland Executive, the window to prepare Northern Ireland's statute book for Exit is narrowing. UK Government Ministers have therefore decided that in the interest of legal certainty in Northern Ireland, the UK Government will take through the necessary secondary legislation at Westminster for Northern Ireland, in close consultation with the Northern Ireland departments. This is one such instrument.

Amendments to Fees and Charges Legislation

7.30 *The Health and Safety and Nuclear (Fees) Regulations 2016* provides for the Health and Safety Executive (HSE) to set fees to recover the full costs of its regulatory activities where it has determined that the costs of those services should be passed to the recipient of the service. This is being amended to enable HSE to charge for work that was previously carried out by the EU but will be repatriated to the UK after Exit. In line with requirements in the Withdrawal Act, HSE cost recovery regimes have been agreed with Her Majesty's Treasury.

7.31 *The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013* formally appoint national authorities and provide for enforcement, including penalties for offences, in respect of the BPR, PIC and CLP Regulations. Similar arrangements exist for Northern Ireland under *The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013* and *The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015.* These regulations are to receive minor amendments to ensure continued operability.

Devolution

7.32 Discussions on how to deal with repatriated powers between HSE and devolved administrations (DAs) have ensured that any existing DA powers are maintained during Exit and that an appropriate framework for DA involvement has been agreed.

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 Withdrawal Act to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the UK from the EU. The instrument is also made under the powers in schedule 4 and schedule 7 paragraph 21(b) in the Withdrawal 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 There are currently no plans to consolidate the relevant legislation.

10. Consultation outcome

10.1 As this instrument does not make any policy changes beyond the intent of ensuring continued operability of the relevant legislation, formal consultation on this instrument is not considered necessary. However, consultation was conducted on an informal basis in relation to chemicals, although until very recently this was constrained due to sensitivities arising from the ongoing UK withdrawal negotiations with the EU. Consultation on the minor technical amendments in relation to GMOs was not deemed necessary and not taken forward.

10.2 In February 2018 the Health and Safety Executive (HSE) held a round of one to one stakeholder meetings with trade associations. Trade associations involved included the Chemical Business Association (CBA), British Coatings Federation Limited (BCF), UK Cleaning Products Industry Association (UKCPI), and Chemical Hazards Communication Society (CHCS). These meetings enabled HSE to share an overview of the preparations being made for a contingency scenario and to hear from trade associations about the main issues that would affect their members as a result of the UK leaving the EU.

10.3 On 19 July 2018 HSE published information on developments in the EU withdrawal negotiations for businesses affected by chemicals regulatory processes[38]. Further technical notices were published on 12 October 2018, outlining the arrangements that would come into force to regulate chemicals in the event the UK leaves the EU with no agreement in place.

10.4 On 1 August 2018 an EU Exit Chemicals workshop was held providing an update on HSE's plans for a contingency 'no deal' scenario and gaining feedback from stakeholders to identify impacts proposed changes are expected to have. The wide range of 120 stakeholders included chemical manufacturers, suppliers, small and medium enterprises, other government departments, and non-governmental organisations. Polls published during the day indicated that stakeholder awareness in relation to the impact of Exit on the chemical regimes improved because of the event (54% had a moderate to reasonable amount of awareness at the beginning of the day

[38] http://www.hse.gov.uk/brexit/brexit-no-deal-guidance.htm

compared to 93% at the end of the day). Feedback following the event showed that stakeholders found the event valuable and informative (responses to a survey poll showed that 80% of responders had gained useful information from the event to help their organisation in a possible contingency scenario).

10.5 On 10 October 2018 a further stakeholder event was held jointly between HSE and the Department for Environment, Food and Rural Affairs (Defra) to provide further updates on plans for a contingency scenario and in light of technical notices due for release. Question and answer sessions during the day also provided HSE and Defra with the opportunity to listen to industry views and concerns. Survey responses showed that as a result of the event, 80% of responders had a better understanding of the impact a 'no deal' Exit from the EU would have on the chemicals regimes. In addition to this, 80% of responders felt that they had gained useful information from the event that would help them/their organisation to prepare for a contingency scenario.

10.6 Consultations with stakeholders emphasised that they would welcome an approach that allows technical and scientific updates to the regulations be made in a flexible and timely way that will offer businesses sufficient time to make adjustments and better manage the potential downstream effects of such updates where they result in additional control measures under other chemicals legislation.

10.7 The Scottish, Welsh and Northern Irish devolved administrations (DAs) have been consulted about the proposed amendments. Although health and safety is a reserved matter in Great Britain there are environmental and wider health issues to consider. During the development of this instrument draft proposals were agreed with the DAs to ensure any existing DA powers are maintained during Exit and that an appropriate framework for DA involvement has been agreed. It is intended that the existing Memorandum of Understanding between the Health and Safety Executive (HSE) and DAs on GMOs will continue to operate along established lines.

11. Guidance

11.1 HSE will provide further information on its website and in Regulatory Updates in the period up to 29 March 2019.

11.2 Where appropriate and relevant, HSE will, at least in the short term, continue to direct stakeholders to European Chemical Agency (ECHA) guidance on technical matters. In due course HSE will look to produce its own guidance.

12. Impact

12.1 The main businesses in scope of these Regulations will be the chemicals industry (manufacturers, importers and exporters, downstream users, distributors, and others using chemicals related to work activities).

12.2 The proposed amendments in this instrument relate to the maintenance of existing regulatory standards. Therefore, this instrument has been calculated to have a net direct impact on business or civil society organisations of less than £5 million annually, qualifying for the de minimis threshold so that a full regulatory impact assessment is not required. There will be costs arising to duty holders that would be accost of Exit, rather than of this instrument, which are not applicable to this assessment.

12.3 The main requirements for the regimes will remain the same, so it is unlikely familiarisation costs to duty holders will be great.

12.4 HSE intends to use existing technology to establish any required IT and other support arrangements to ensure operability, so costs should be minimal.

The Biocidal Products Regulation (BPR)

12.5 The BPR has requirements that split into those related to the approval of active substances, and those relating to products containing those active substances. Under the proposed amendments HSE will recreate the BPR regime for the UK as closely as possible.

12.6 Assessed against a static acquis baseline:

12.6.1 For active substance approvals, the Health and Safety Executive (HSE) will require the applicant to submit similar evidence as needed for the European Chemical Agency (ECHA), so the applicant should not incur any additional costs generating evidence.

12.6.2 HSE already undertakes authorisations for UK products, so there should be no change in costs.

12.6.3 If HSE does not have access to data held by ECHA following Exit, then suppliers will need to resend their data to HSE. This would present a one-off cost for suppliers of around five-sixths of the biocidal active substances on the UK market. However existing actives will be recognised, and it is a small task to supply HSE with direct access to information suppliers have already provided or have a letter of access to.

12.6.4 If the UK has recognised another Member State's product authorisation, the authorisation holders will need to submit information on their products. The cost to gather this information should be minimal.

12.6.5 If HSE no longer has access to the ECHA database and an authorisation depends in part on data already submitted as part of another approval, HSE might need to request the information on the other substance from the applicant for the new product.

12.7 Assessed against a 'do nothing' baseline:

12.7.1 The costs to business of fixing the inoperabilities would essentially be the costs of complying with the existing system of approvals and authorisations that otherwise cease to be legally operable. This would include the costs of supplying data, discussed above.

12.7.2 However, the benefit to business (and users) would be the ability to continue to bring current and new authorised products to the UK market and to use them. This would probably be legally impossible otherwise - without the proposed instrument fixes, the regulations would say that products needed to be authorised to be used or placed on the UK market, but that the authorisation holder must be a 'person established in the EU', which would essentially bar UK biocidal products from the UK market.

12.7.3 The inoperability of application processes would also mean that applications to renew or change existing products could not be operated in the UK, meaning such authorisations would lapse and could not be renewed. Key types of product such as rodenticides, wood preservatives and insecticides could cease to be available. Fixing the inoperabilities would prevent this.

12.7.4 Businesses would also be able to bring new active substances for approval, which would otherwise probably be legally impossible.

12.7.5 There could be health and safety benefits as biocidal products would continue to be assessed and regulated against the higher standards in the BPR. Were the legislation not fixed, many biocidal products would probably continue indefinitely to be regulated under legacy regimes that apply lower standards of protection to human health and the environment.

12.7.6 The impact on government would be uncertain – having no operable regime would mean that HSE would not be able to undertake the assessment work that it currently does, but those resources may need to be redeployed to develop and operate contingency arrangements so that alternative legal routes are available to market for vital biocidal products.

The Classification, Labelling and Packaging Regulation (CLP)

12.8 Assessed against a static acquis baseline:

12.8.1 There will be little difference in the main requirements for the classification, labelling and packaging of substances and mixtures. However, there would be changes to certain obligations and processes.

12.8.2 UK based manufacturers and importers will need to notify the classification and labelling of the hazardous substances that they place on the UK market to the Health and Safety Executive (HSE) rather than to the European Chemical Agency (ECHA). The type of information submitted is likely to remain the same and so there will be no change in cost.

12.8.3 Requests for the use of an alternative chemical name will be managed by HSE instead of ECHA. HSE does not currently intend to charge a fee for this work, which would save some applicants around EUR4,000 per application. There will be no requirement to re-submit alternative chemical names already agreed.

12.8.4 HSE will charge a fee to cover the cost of the work required to process any UK industry mandatory classification and labelling proposal where the substance in question fulfils the criteria as hazardous but not for carcinogenicity, mutagenicity, reproductive toxicity or respiratory sensitivity. However, it is anticipated that fees will generally be below the current ECHA standard fee of EUR12,000 so there will be no additional cost.

12.9 Assessed against a ‘do nothing’ baseline

12.9.1 The costs to business of fixing the inoperabilities would be the costs to duty holders to classify, label and package their substances appropriately, as they do currently. If the inoperabilities were not fixed, there would be no legal duty holders and no route to enforce the requirements – businesses could choose not to comply if they wanted to.

12.9.2 The benefits to both suppliers and users of substances and mixtures of a fully operable CLP Regulation are that they would be properly informed of the hazards of supplied substances and mixtures through CLP-mandated requirements to classify (identify hazardous properties present), communicate those hazards to all in the supply chain down to the end user, and to ensure such chemicals are safe and securely packaged. This would reduce the risk of injury and illness for professional, consumer and other users.

12.9.3 There would also be benefits to workers, members of the public and others exposed to risks managed through legislation that relies on chemical hazard classification, as well

as requirements that are 'downstream' of the CLP Regulation, which would otherwise be legally impeded from operating.

12.9.4 The benefits to Government are that the UK would continue to adopt the *UN Globally Harmonized System of the classification and labelling of chemicals* (GHS), which is a stated Government policy; and the government would not need to create an alternative regime to bring about GHS-compliance. Enforcing authorities could also enforce the provisions of the CLP Regulation and ensure compliance.

The Export and Import of Hazardous Chemicals Regulation (PIC)

12.10 Assessed against a static acquis baseline:

12.10.1 The logic and the requirements of the PIC Regulation will remain the same, but the application area will move from the EU to that of the UK. Requirements will be applied to all exports of specified substances, rather than just the exports of specified chemicals to countries outside of the EU.

12.10.2 The Health and Safety Executive (HSE) would continue to receive and process notifications, with the introduction of new UK procedures for notification.

12.11 Assessed against a 'do nothing' baseline:

12.11.1 The costs to business of fixing the inoperabilities relative to the 'do nothing' baseline are due to duty holders making PIC notifications for the export of specified substances. Without fixing the inoperabilities there would be no legal basis for the PIC Regulation to operate in the UK and no business would be legally required to make such notifications.

12.11.2 The health and safety benefits of fixing inoperabilities are that third countries, particularly developing countries, would receive information about the human and environmental hazards of the chemicals exported and would be able to make informed decisions about import. Also, the internationally agreed export bans on persistent organic pollutants and mercury enacted through the PIC Regulation would be maintained.

12.11.3 The benefit to Government would be that the UK would fulfil its Rotterdam Convention obligations, which are enacted through the PIC Regulation; and would not need to develop a wholly new regulatory regime to do so.

The Plant Protection Products (Fees and Charges) Regulations

12.12 Certain costs to government arising from the operation of the Plant Protection Products regime are recovered through fees and charges.

12.13 Assessed against a static acquis baseline:

12.13.1 Most of the fees and charges regime will remain unchanged as a result of Exit. The range of fees and the Annual Charge and the level at which they are set will be unchanged.

12.13.2 For the estimated 4 import tolerance applications currently arising from the UK each year, there will be an additional administrative charge of £2,101 to cover the coordination work HSE would need to carry out. This will include additional assessment work to be undertaken for substances reviewed by other Member States.

12.13.3 Assessed against a 'do nothing' baseline

12.13.4If the inoperabilities were not fixed, HSE assessments for import tolerances would be required by the changes to the Plant Protection Products Regulations, but HSE would have no means to recover the costs. So, fixing the inoperability generates a transfer of the cost from Government to business.

The Genetically Modified Organisms (Contained Use) Regulations (GMO (CU))

12.13.5The GMO (CU) Regulations only require minor amendments to ensure operability after Exit. Relative to a static acquis baseline, there will be no changes in requirements. Therefore, there should also be no costs as a result of the amendments if the inoperabilities are fixed.

12.13.6Assessed against a 'do nothing' baseline, fixing the inoperability will generate a very small saving to business by preventing the need for them to notify HSE.

Amendments to Northern Ireland Legislation

12.14 As the Northern Ireland Regulations being amended mirror the corresponding Great Britain Regulations the impact will be similar (on a proportionate basis).

13. Regulating small business

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

13.2 No specific action was required to minimise the impact of the requirements on small businesses (employing up to 50 people).

13.3 The basis for the final decision on what action to take to assist small businesses was that this instrument maintains existing regulatory standards.

14. Monitoring & review

14.1 No specific monitoring arrangements are needed.

14.2 As this instrument is made under the Withdrawal Act, no review clause is required.

15. Contact

15.1 Matthew Penrose, Head of Chemicals EU Exit Unit, at the Health and Safety Executive (Telephone: 020 3028 4909 or email: Matthew.Penrose@hse.gov.uk) can be contacted with any queries regarding the instrument.

15.2 Dave Bench, Director of Chemicals EU Exit Unit, at the Health and Safety Executive can confirm that this Explanatory Memorandum meets the required standard.

15.3 Sarah Newton, the Minister for Disabled People, Health and Work at the Department for Work and Pensions 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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising 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 Minister of State for Disabled People, Heath and Work, Sarah Newton has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment Etc.) (EU Exit) Regulations 2019* does no more than is appropriate".

1.2 This is the case because this instrument does not make any policy changes beyond the intent of ensuring continued operability of the relevant legislation

2. Good reasons

2.1 The Minister of State for Disabled People, Heath and Work, Sarah Newton 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 given in the policy background section of this explanatory memorandum (paragraphs 7.1 to 7.24).

3. Equalities

3.1 The Minister of State for Disabled People, Heath and Work, Sarah Newton has made the following statement(s):

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

3.2 The Minister of State for Disabled People, Heath and Work, Sarah Newton has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Sarah Newton 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. This Act does not extend to Northern Ireland, and as *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment Etc.) (EU Exit) Regulations 2019* extend to Northern Ireland, I have given equivalent due regard to the need to eliminate discrimination, harassment and victimisation in relation to Northern Ireland."

4. Explanations

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