

EXPLANATORY MEMORANDUM TO
THE CHEMICALS (HEALTH AND SAFETY) AND GENETICALLY MODIFIED
ORGANISMS (CONTAINED USE) (AMENDMENT ETC.) (EU EXIT)
REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

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

2. Purpose of the instrument

- 2.1 This instrument is made using powers in the European Union (Withdrawal) Act 2018¹ (“the Withdrawal Act”) to address deficiencies in retained EU law relating to chemicals and genetically modified organisms (“GMOs”) legislation arising from the withdrawal of the United Kingdom (“UK”) from the European Union (“EU”). This instrument amends The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (Statutory Instrument 2019 No.720)² (“the 2019 Regulations”) to ensure that UK chemicals and GMO legislation will continue to operate effectively in conjunction with the Withdrawal Agreement³ at the end of the transition period.

Explanations

What did any relevant EU law do before the end of the transition period?

- 2.2 Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, known as the “Biocidal Products Regulation”⁴ (“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

¹ <http://www.legislation.gov.uk/ukpga/2018/16/contents/enacted>

² <https://www.legislation.gov.uk/uksi/2019/720/contents/made>

³

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840655/Agreement_on_the_withdrawal_of_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_from_the_European_Union_and_the_European_Atomic_Energy_Community.pdf

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528>

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*⁵, *Commission Implementing Regulation (EU) No 414/2013*⁶, *Commission Implementing Regulation (EU) No 88/2014*⁷, *Commission Implementing Regulation (EU) No 1062/2014*⁸).

- 2.3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006⁹ (“the CLP Regulation”) adopts the *UN Globally Harmonized System of the classification and labelling of chemicals (GHS)*¹⁰ 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, downstream users¹¹ and producers of certain articles 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 Inventory¹².
- 2.4 Regulation (EU) No 649/2012 of the European Parliament and the Council of 4 July 2012 concerning the export and import of hazardous chemicals¹³ (“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 2014¹⁴ and The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015¹⁵ (together referred to as “the GMO (CU) Regulations”) implement *The Contained Use of Genetically Modified Micro-Organisms Directive ((EC) No 2009/41)*¹⁶; which lays down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. Section

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0354>

⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0414>

⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0088>

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R1062>

⁹ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272>

¹⁰ https://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

¹¹ Downstream users re-formulate, re-brand or re-package substances or mixtures in the course of their industrial or professional activities.

¹² <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>

¹³ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:EN:PDF>

¹⁴ <http://www.legislation.gov.uk/uksi/2014/1663/contents/made>

¹⁵ <http://www.legislation.gov.uk/nisr/2015/339/contents/made>

¹⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009L0041>

2(2) of the *European Communities Act 1972*¹⁷ was used to implement the aspects of the Directive which relate to protection of the environment.

Why is it being changed?

- 2.6 This instrument makes amendments to the 2019 Regulations relating to the Withdrawal Agreement, including the Protocol on Ireland/Northern Ireland (the “NI Protocol”), 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 from the end of the transition period.
- 2.7 If these changes were not made, several chemicals regimes in the scope of the instrument would not be consistent with the Withdrawal Agreement and the NI Protocol when the transition period ends.

What will it now do?

- 2.8 This instrument amends the 2019 Regulations to ensure that existing regulatory frameworks are maintained and continue to operate effectively at the end of the transition period, in particular so that they remain consistent with the provisions of the NI Protocol. 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 and the Secondary Legislation Scrutiny Committee

- 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 provisions containing the powers under which this instrument is made extend to the whole of the UK (see section 24 of the Withdrawal Act) 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.
- 4.2 The territorial application of this instrument is Great Britain, except for certain provisions. The provisions containing 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*, *The Classification, Labelling and Packaging of Chemicals (Amendment) Regulations (Northern Ireland) 2015* and *The Control of Major Accident Hazards Regulations (Northern Ireland) 2015* only apply to Northern Ireland. The provisions containing amendments to *The Genetically Modified Organisms (Contained Use) Regulations 2014* only apply to Great Britain.

¹⁷ <https://www.legislation.gov.uk/ukpga/1972/68>

The provisions containing amendments to *The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013* apply to Great Britain, except for the elements relating to the PIC Regulation, which apply to the UK. The provisions containing amendments to *The Plant Protection Product (Fees and Charges) Regulations 2011* apply to the whole of the UK.

- 4.3 The BPR, the CLP Regulation, and the PIC Regulation are incorporated into domestic law under section 3 of the Withdrawal Act save insofar as it applies to Northern Ireland for the purposes of the NI Protocol. In order to implement the NI Protocol, the instrument removes Northern Ireland from most of the substantive provisions in BPR, the CLP Regulation and the PIC Regulation. The retained BPR and CLP Regulation as amended by the instrument, will, however, continue to apply to Northern Ireland to a limited extent to implement provisions on ‘Unfettered Access’ (see paragraphs 7.6-7.11).

5. European Convention on Human Rights

- 5.1 The Minister for Employment, Mims Davies, has made the following statement regarding Human Rights:

“In my view the provisions of *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020* are compatible with the Convention rights.”

6. Legislative Context

- 6.1 The 2019 Regulations were made using powers in the Withdrawal Act to correct deficiencies in chemical and other Health and Safety Executive related legislation as a result of the withdrawal of the UK from the EU. *The European Union (Withdrawal Agreement) Act 2020*¹⁸ amended the Withdrawal Act so that EU law was not retained and domesticated on the UK statute book until the end of the transition period. It is therefore necessary to amend the 2019 Regulations to reflect this. Accordingly, provision is also made under powers in the European Union (Withdrawal Agreement) Act 2020, which enable consequential and transitional provision to be made; this covers changing references from “exit day” to “IP completion day” where required.
- 6.2 As part of the Withdrawal Agreement, the NI Protocol provides for arrangements that seek to ensure that the UK (including Northern Ireland) does not remain in a customs union with the EU. The NI Protocol also makes arrangement to ensure that there are no checks and controls conducted at or near the border between Northern Ireland and Ireland, as well as providing that the arrangements contained in the NI Protocol are to be subject to democratic consent in Northern Ireland. The UK is required to set up the framework necessary to give effect to the obligations contained in the NI Protocol. This requires amendments to the 2019 Regulations to further amend domestic legislation and retained direct EU legislation in the areas covered by the NI Protocol.

7. Policy background

What is being done and why?

- 7.1 This instrument amends the 2019 Regulations, which in turn amend retained EU Law relating to chemicals, in particular to ensure that legislation governing the BPR, CLP,

¹⁸ <https://www.legislation.gov.uk/ukpga/2020/1/contents/enacted>

and PIC regimes works effectively from the end of the transition period. Changes are being made by this instrument to correct deficiencies arising from the UK's departure from the EU that require correction beyond what was provided for in the 2019 Regulations; this includes changes which are required to give effect to the NI Protocol as regards Great Britain (Northern Ireland legislation is due to make such provision in relation to Northern Ireland). From the end of the transition period, the existing EU regimes at that point in time are being saved (or converted) into national law through provisions contained in the Withdrawal Act. Without the changes made to the 2019 Regulations by this instrument, the retained legislation which the 2019 Regulations amends (as referred to in more detail below) would not operate effectively.

References to 'Exit Day'

- 7.2 In consequence of the transition period, paragraph 1(1) of Schedule 5 to the European Union (Withdrawal Agreement) Act 2020 provides that any statutory instrument made to enter into force on "exit day" (which was 11pm on 31 January 2020), will instead enter into force at the moment the transition period ends, which is referred to in legislation as "IP completion day" (meaning 11pm on 31 December 2020). This instrument amends other references to "exit day" contained in the 2019 Regulations to refer to IP completion day where necessary.
- 7.3 Some references to "exit day" in the transitional provisions that were inserted into BPR by the 2019 Regulations (and are now being replaced by Schedule 4 to these Regulations) are instead being amended to "30 March 2019". This is because certain work on evaluating active substances was transferred from the UK competent authority to EU Member States from this date as a result of provisions in Commission Regulation (EU) 2019/227¹⁹. The date of transfer was 30 March 2019 as this was, at the time the Regulation was enacted, the date on which the UK was due to leave the EU and hence would no longer be undertaking work as part of the EU's review programme of active substances.

Nomenclature/Scope

- 7.4 As a consequence of the NI Protocol a number of areas of law in Northern Ireland are to remain aligned with the EU after the end of the transition period. This includes the BPR, CLP and PIC Regulations. As a result, the 2019 Regulations need to be amended to remove Northern Ireland from the arrangements due to take effect at the end of the transition period.
- 7.5 References to the 'United Kingdom' or 'UK' will be changed to 'Great Britain' or 'GB' respectively where the relevant legislation no longer applies to the entire UK. There will still however be aspects of the legislation that refer to the entire UK where it is appropriate.

Unfettered Access

- 7.6 The NI Protocol is clear that nothing in it prevents Northern Ireland business enjoying unfettered access to the rest of the UK internal market. As set out in 'New Decade,

¹⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0227&from=EN>

New Approach'²⁰, the Government will legislate to guarantee unfettered access for Northern Ireland's business to the whole of the UK internal market.

- 7.7 As set out in the Command Paper²¹, the default approach for unfettered access is that for those goods with qualifying status, the movement of those goods from Northern Ireland to Great Britain will not be subject to additional checks or controls. Furthermore, where a Northern Ireland business has secured approvals for a product to be placed on the Northern Ireland market (including where secured through EU processes), that product will be able to be placed on the Great Britain market without further approvals.
- 7.8 Changes to the standard policy approach for unfettered access are needed for highly regulated goods, including chemicals, with a focus on transparency requirements (i.e. providing the requisite information to UK regulators in parallel to that provided to EU regulators), with a strong presumption against additional market approvals for Northern Ireland goods being placed on the Great Britain market. This is on the basis of the risks these goods could pose to workers, consumer and animal health, and/or the environment, such that regulators would require information about them if they are to be placed on the market in Great Britain on the basis of an EU approval valid in Northern Ireland.
- 7.9 In the case of the CLP Regulation, Northern Ireland businesses can supply chemicals direct to Great Britain provided they meet Great Britain classification, packaging and labelling requirements, and (except where specified exemptions apply) notify the Health and Safety Executive (HSE) to confirm the hazard classification and labelling of the substance(s), either on their own or in a mixture that they intend to place on the Great Britain market. A business seeking to change the name of its chemicals to protect its intellectual property may submit a request to HSE to use an alternative chemical name. In this way, HSE will be aware of the chemicals on the Great Britain market where an alternative name is used.
- 7.10 For the BPR, where a Northern Ireland-based business has obtained an authorisation or other permit for a biocidal product and wants to market the product in Great Britain, it is proposed that HSE will treat the product as authorised in the whole of the UK as long as certain conditions are met. These include that the active substance is on the Great Britain approved list, and the Northern Ireland business notifies HSE by submitting the same information that was submitted in support of the original authorisation or permit.
- 7.11 Once this information has been submitted, the product may be made available on the market in Great Britain after 90 days, provided HSE does not raise any objections. If HSE identifies concerns over whether the product could pose unacceptable risks or is sufficiently effective, it may request additional information. In this case the 90 day period may be suspended for up to 90 days for the provision of such additional information and a further 90 days for the information to be considered by HSE. HSE also has access to a 'safety valve', whereby a product may be prohibited or the terms and conditions under which it can be marketed and used may be amended, where this can be justified on specific grounds including the protection of the environment, the protection of health and life of humans, particularly of vulnerable groups, or of

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/856998/2020-01-08_a_new_decade_a_new_approach.pdf

²¹ <https://www.gov.uk/government/publications/the-uks-approach-to-the-northern-ireland-protocol>

animals or plants and the protection of national treasures possessing artistic, historic or archaeological value.

Amendments to Northern Ireland Legislation

- 7.12 Due to the absence of a Northern Ireland Executive at the time that the 2019 Regulations were made, it was agreed that the UK Government would make necessary secondary legislation at Westminster for Northern Ireland in close consultation with the Northern Ireland departments, to ensure a functioning statute book across the UK after the UK's withdrawal from the EU. As a consequence of the NI Protocol, EU law in specified areas will continue to apply in Northern Ireland after the end of the transition period. Therefore, this instrument revokes the changes made by the 2019 Regulations to Northern Ireland legislation, so that the law applicable in Northern Ireland immediately before the end of the transition period is untouched. In many cases, that will result in the law in Northern Ireland continuing to operate in the way it needs to after the end of the transition period, and no further changes for Northern Ireland may be required. As the Northern Ireland Executive was restored in January 2020, any necessary amendments to Northern Ireland legislation are due to be made, by Northern Ireland Statutory Rule, through the Northern Ireland Assembly.

The Plant Protection Products (Fees and Charges) Regulations 2011

- 7.13 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.
- 7.14 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.
- 7.15 The Plant Protection Products (Fees and Charges) Regulations 2011 need to be amended to reflect those changes to the regulatory regime for PPPs that are necessary to implement the NI Protocol. Some fees will remain unchanged and will continue to apply to applications made to the competent authorities of both Great Britain and Northern Ireland, but some will now only apply to applications made to the competent authorities of Great Britain. Some fees removed by the 2019 Regulations will need to be reinstated only in relation to Northern Ireland because the regulatory regime for PPPs in Northern Ireland will remain aligned with the EU.

Amendment to Article 37 and Article 37A of the CLP Regulation

- 7.16 Article 37 of the CLP Regulation as amended by the 2019 Regulations sets out the process by which Ministers make decisions on new Mandatory Classification and Labelling (MCL) requirements for Great Britain (GB MCLs) for substances in relation to which the Committee for Risk Assessment of the European Chemicals Agency (RAC) publishes an opinion. According to this process, HSE would have a duty to consider EU opinions on harmonised classification and labelling requirements published by RAC and within 6 months publish its own opinion, then within 12 months of publishing its own opinion, make a recommendation to Ministers.

- 7.17 This instrument amends the 2019 Regulations, which in turn amend the CLP Regulation, so that the process provided for in Article 37 works effectively from the end of the transition period. The amended process would mean that HSE would consider the Committee for Risk Assessment of the European Chemicals Agency (RAC) opinions and within 6 months produce a technical report, then within 12 months of the publication of the technical report, publish its own opinion, then as with the previous process there would be a maximum of 12 months before a recommendation is made to Ministers. The additional maximum 12 months is to provide sufficient time for HSE to develop an opinion, which can include identifying the supply and use profile of the affected sectors for each substance, working with economists to produce a proportionate impact estimate, developing any mitigating measures, and consulting with affected stakeholders.
- 7.18 In addition, the position under EU law is that once a recommendation is made to the decision maker there is no timescale for when a decision is required. The process legislated for by the 2019 Regulations retained the wording from the EU Regulation that a decision is made “without undue delay”. It is believed that the absence of timings is inappropriate as persons and businesses with duties under the CLP Regulation will expect to know when the action will be taken and how long that action will take. If timeframes are absent, there is no clarity or accountability about when the different actors in the process should take action, and the risk is that considerations can be delayed and there is no statutory requirement to come to a decision. Therefore, there are amendments that specify a decision is required within 3 months of a recommendation being made to Ministers, and within 1 month of that decision HSE must update the GB MCL list.
- 7.19 Similar amendments, imposing timeframes for decision making, are made to Article 37A of the CLP Regulation, which sets out the process by which Ministers make decisions on new MCL requirements for Great Britain in relation to substances for which RAC has not published an opinion.

Amendment to Article 45 of the CLP Regulation

- 7.20 In addition, amendments are required to provide powers for the Secretary of State to specify the information relating to emergency and preventative measures that must be provided for the purposes of Article 45 of the CLP Regulation to the appointed body, the National Poisons Information Service (“NPIS”), by importers and downstream users of hazardous substances and mixtures. Specifying the required information from industry will support NPIS in providing clinical advice in the case of poisonings and suspected poisonings. These powers can only be exercised by the Secretary of State following consultation with relevant stakeholders, including NPIS and the industry’s representative bodies, and are subject to the consent of the devolved administrations.

Transitional provision relating to the PIC Regulation

- 7.21 This instrument makes transitional provision to ensure that steps taken by exporters during the transition period in relation to export notifications and explicit consent for exports in the immediate period following the end of the transition period will not need to be repeated after the end of the transition period.

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. It is also made under the powers in section 8C of the Withdrawal Act in relation to implementation of the NI Protocol, and Schedule 4 and paragraph 21(b) of Schedule 7 of 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.
- 10.2 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 public health issues to consider. During the development of this instrument draft proposals were agreed with the DAs to ensure that any existing DA powers are maintained after IP completion day and that an appropriate framework for DA involvement has been agreed. It is intended that the existing Memorandum of Understanding between HSE and the DAs on GMOs will continue to operate along established lines.

11. Guidance

- 11.1 Where HSE considers it appropriate to do so, HSE will provide guidance on its website and through publication of Regulatory Updates, on the operation of the BPR, CLP and PIC Regulations as amended by the 2019 Regulations and these Regulations. The Department for Work and Pensions is not producing any specific guidance on the amendments provided for in the instrument.

12. Impact

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 A full Impact Assessment has not been prepared for this instrument because 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. There will be costs arising to duty holders that would be a cost of the UK's withdrawal from the EU, rather than of this instrument, which are not applicable to this assessment. In accordance with UK Government guidance, the baseline for EU Exit SIs assumes that the UK has left the EU and therefore that the NI Protocol is already in place. Given that NI Protocol SIs are in effect implementing these obligations by ensuring the statute book, is operational and 'fixed' to take account of the NI Protocol, there are no burdens on business over and above the baseline.

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 Laurence Hodgson, at the Health and Safety Executive (Telephone: 020 3028 2678 or email: laurence.hodgson@hse.gov.uk) or 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 Richard Daniels, Director of Chemicals, at the Health and Safety Executive can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Mims Davies, the Minister for Employment 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 for Employment, Mims Davies has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment Etc.) (EU Exit) Regulations 2020* 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 for Employment Mims Davies 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 7.20).

3. Equalities

- 3.1 The Minister for Employment, Mims Davies 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 for Employment, Mims Davies has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In relation to the instrument, I, Mims Davies 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 2020* 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.