#### EXPLANATORY MEMORANDUM TO

# THE CHEMICALS (HEALTH AND SAFETY) TRADE AND MISCELLANEOUS AMENDMENTS REGULATIONS 2022

#### 2022 No. 1037

#### 1. Introduction

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

## 2. Purpose of the instrument

- 2.1 This instrument provides an information sharing gateway to the Health and Safety Executive ("HSE") to disclose information necessary to facilitate provisions contained in the trade agreement between the United Kingdom ("UK") and Iceland, Liechtenstein and Norway ("EEA/EFTA countries").
- 2.2 The instrument also addresses deficiencies in retained EU legislation relating to chemicals that have arisen from the withdrawal of the UK from the European Union ("EU"). This instrument does not make any policy changes beyond providing for the UK to disclose information on the trade and safety of chemicals under a relevant trade agreement. The amendments to retained EU legislation are minor in nature and will ensure the continued operability of the relevant chemicals regimes.

## 3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments.

3.1 None.

# 4. Extent and Territorial Application

- 4.1 The extent of this instrument is the UK.
- 4.2 The territorial application of this instrument is the UK except for amendments to retained EU legislation which have the same application as the provisions being amended.

## 5. European Convention on Human Rights

5.1 Claire Coutinho, Minister for Disabled People, Health and Work has made the following statement regarding Human Rights:

"In my view the provisions of the Chemicals (Health and Safety) Trade and Miscellaneous Amendments Regulations 2022 are compatible with the Convention rights."

# 6. Legislative Context

6.1 This instrument is made in exercise of the power in section 2(1) of the Trade Act 2021("Trade Act)<sup>1</sup>. Section 2 enables an appropriate authority to make regulations to implement an international trade agreement between the UK and another party, or

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<sup>&</sup>lt;sup>1</sup> https://www.legislation.gov.uk/ukpga/2021/10/contents/enacted

parties, to that agreement where they were signatories to an international trade agreement with the EU immediately before exit day. The trade agreement between the UK and the EEA/EFTA countries<sup>2</sup> contains a Technical Barriers to Trade ("TBT") chapter. The TBT chapter includes a specific annex on cooperation between the parties on chemicals regulatory issues ("Chemicals Annex")<sup>3</sup>. This instrument creates an information sharing gateway to enable HSE to share information that it holds on the trade in or safety of chemicals, including confidential information, to assist the UK in meeting its obligations on regulatory co-operation contained in the TBT chapter and Chemicals Annex of this trade agreement.

6.2 This instrument is also being made using powers in the European Union (Withdrawal) Act 2018<sup>4</sup> ("Withdrawal Act") and the European Union (Withdrawal Agreement) Act 2020<sup>5</sup> ("Withdrawal Agreement Act") to correct deficiencies in retained EU legislation in relation to chemicals arising from the UK's withdrawal from the EU that have been identified since the end of the transition period.

# 7. Policy background

#### What is being done and why?

- 7.1 This instrument makes provision for an information sharing gateway for HSE to disclose information necessary to facilitate provisions contained in the trade agreement between the UK and the EEA/EFTA. HSE needs a power in order to share information such as individual substance evaluations and risk assessments that it holds on chemicals to assist the UK in meeting its obligations on regulatory co-operation contained in the Chemicals Annex of this trade agreement.
- 7.2 This instrument amends Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products "Biocides Regulation" 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 1907/2006 ("CLP Regulation"), Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 ("PIC Regulation"), and related retained legislation to ensure the regulations continue to operate effectively.

#### **Explanations**

#### **Biocides Regulation**

What did any law do before the changes to be made by this instrument?

7.3 The Biocides Regulation governs the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against

<sup>&</sup>lt;sup>2</sup> https://www.gov.uk/government/publications/free-trade-agreement-between-iceland-the-principality-of-liechtenstein-and-the-kingdom-of-norway-and-the-united-kingdom-of-great-britain-and-northern

<sup>&</sup>lt;sup>3</sup>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/1003350/Fre e\_trade\_agreement\_between\_UK-Northern\_Ireland\_and\_Liechtenstein\_\_Iceland\_and\_Norway\_volume\_2.pdf

<sup>&</sup>lt;sup>4</sup> https://www.legislation.gov.uk/ukpga/2018/16/contents/enacted

<sup>&</sup>lt;sup>5</sup> https://www.legislation.gov.uk/ukpga/2020/1/contents/enacted

<sup>&</sup>lt;sup>6</sup> https://www.legislation.gov.uk/eur/2012/528/contents

<sup>&</sup>lt;sup>7</sup> https://www.legislation.gov.uk/eur/2008/1272/contents

<sup>&</sup>lt;sup>8</sup> https://www.legislation.gov.uk/eur/2012/649/contents

harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. The Biocides Regulation was amended by the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019<sup>9</sup> ("the 2019 Exit SI") and the Chemicals (Health and Safety) and the Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020<sup>10</sup> ("the 2020 Exit SI") to correct deficiencies arising from EU exit and reflect the provisions of the Northern Ireland Protocol. Before IP completion day the EU Biocides Regulation set out a two-step process, whereby active substances were first approved at EU level before biocidal products containing those substances were authorised at Member State level. Post IP completion day approval in GB is by the Secretary of State, with consent from Scottish and Welsh Ministers, and product authorisation by HSE as the competent authority. Under the terms of the Northern Ireland Protocol, Northern Ireland (NI) continues to follow the EU Biocides Regulation. In addition, there is a range of related tertiary legislation affecting biocidal products (Commission Implementing Regulation (EU) No 354/2013<sup>11</sup>, Commission Implementing Regulation (EU) No 414/2013<sup>12</sup>, Commission Implementing Regulation (EU) No 88/2014<sup>13</sup>, Commission Implementing Regulation (EU) No 1062/2014<sup>14</sup>). The Regulation is also supported by domestic provisions on enforcement and appointment of authorities and fees and charges in SI 2013/1506, the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013<sup>15</sup> and SI 2021/33, the Health and Safety and Nuclear (Fees) Regulations 2021<sup>16</sup>.

# Why is it being changed?

- 7.4 This instrument makes minor amendments to the Biocides Regulation, tertiary legislation and domestic implementing legislation to correct outstanding deficiencies relating to EU exit, for example to delete one mention of Union legislation, correct some cross references and refer to the GB mandatory classification and labelling list.
- 7.5 Some references are corrected to the GB "simplified active substance list". Biocidal products containing active substances on this list are eligible for a simplified authorisation procedure. Schedule 4 ("Provision relating to the Simplified Active Substance List") of the 2020 Exit SI added a transitional provision to the Biocides Regulation which changed the nomenclature for categories of active substances in the simplified list from categories "1"-"6" to categories "A", "B", and "C". However, some references to categories 1-6 were not amended. This instrument will make the necessary corrections. The 2019 Exit SI made some changes to the Health and Safety and Nuclear (Fees) Regulations 2016 to correct deficiencies arising from EU exit. However, when the 2016 Regulations were replaced with the Health and Safety and Nuclear (Fees) Regulations 2021, the changes made by the 2019 Exit SI were erroneously discarded. This instrument amends the 2021 Regulations to reinstate the changes made by the 2019 Exit SI. As this statutory instrument makes these minor corrections it will be issued free of charge.

<sup>&</sup>lt;sup>9</sup> https://www.legislation.gov.uk/ukdsi/2019/9780111181539/contents

<sup>10</sup> https://www.legislation.gov.uk/ukdsi/2020/9780348213409/contents

<sup>11</sup> https://www.legislation.gov.uk/eur/2013/354/contents

<sup>&</sup>lt;sup>12</sup> https://www.legislation.gov.uk/eur/2013/414/contents

<sup>&</sup>lt;sup>13</sup> https://www.legislation.gov.uk/eur/2014/88/contents

<sup>14</sup> https://www.legislation.gov.uk/eur/2014/1062/contents

<sup>&</sup>lt;sup>15</sup> https://www.legislation.gov.uk/uksi/2013/1506/contents/made

<sup>16</sup> https://www.legislation.gov.uk/uksi/2021/33/contents/made

If these changes were not made, there is a risk the retained Biocides Regulation (as amended) would not operate effectively.

# The Classification, Labelling and Packaging Regulation (CLP)

What did any law do before the changes to be made by this instrument?

- 7.6 The CLP Regulation adopts the UN Globally Harmonized System of the classification and labelling of chemicals ("GHS") 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 users 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 Inventory.
- 7.7 This instrument makes amendments to the CLP Regulation relating to the Withdrawal Agreement, to omit provisions which set out the European Commission's delegated powers to make amendments to specified articles and annexes. Under the 2019 Exit SI as amended by the 2020 Exit SI, the power to make amendments to specific annexes and articles was transferred to the Secretary of State through amendments to Article 53 of that Regulation. However, it has now been identified that due to the retention of Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019<sup>17</sup> those corrections to the CLP Regulation did not fully address the deficiency and the CLP Regulation continues to have reference to the Commission and the procedure of delegated acts to make amendments to the annexes and articles. This has no practical effect in GB and therefore this instrument transfers this power to the Secretary of State and omits the articles which outline the relevant EU legislative procedure.
- 7.8 The instrument also omits an obligation on the European Commission and Member States to promote the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances at the level of the UN. The European Commission discharged this obligation in 2009 and no longer has any practical effect in GB.

#### Why is it being changed?

7.9 If these changes were not made, there is a risk of confusion between the Articles inserted by the 2019 Exit SI (as amended by the 2020 Exit SI) and the Articles which are inoperable. If not removed, deficient provisions will remain on the statute book.

# The Prior Informed Consent Regulation (PIC)

What did any law do before the changes to be made by this instrument?

7.10 The PIC Regulation implements the international Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in

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<sup>17</sup> https://www.legislation.gov.uk/eur/2019/1243/

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 legislation. 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.

7.11 This instrument amends the definition of "export" in the PIC Regulation following changes made to the Taxation (Cross Border) Trade Act 2018<sup>18</sup> subsequent to the end of the Transition Period following the UK's withdrawal from the EU. The amendment ensures that "export" clearly captures removal of chemicals from Great Britain to Northern Ireland, as intended.

#### Why is it being changed?

7.12 If these changes were not made, there is a risk the retained PIC Regulation (as amended) would not operate effectively with respect to the movement of chemicals between GB and NI.

#### EU-derived domestic legislation

7.13 This instrument also corrects deficiencies that remain in EU- derived domestic legislation. The Plant Protection Product (Fees and Charges) Regulations 2011<sup>19</sup> and Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013<sup>20</sup> are amended to correct references to EU law which should reference the Protocol on Ireland/Northern Ireland, and update references of exit day to IP completion day. The Health and Safety and Nuclear (Fees) Regulations 2021<sup>21</sup> are amended to remove reference to member State and clarify the fee provisions for activities done under the Biocides Regulation, and tertiary legislation under that Regulation, undertaken by the competent authority.

# 8. European Union Withdrawal and Future Relationship

- 8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU legislation to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. The instrument is also made under the powers in section 8C of the Withdrawal Act in relation to the implementation of the Protocol on Ireland/Northern Ireland, and the power in paragraph 7 of Schedule 4 of that Act to amend fees. 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.
- 8.2 Alongside powers in the Withdrawal Act, the instrument is also being made using powers in section 41 of the Withdrawal Agreement Act to make consequential provision on the coming into force of that Act.

#### 9. Consolidation

9.1 There are no plans for consolidation.

<sup>18</sup> https://www.legislation.gov.uk/ukpga/2018/22/contents/enacted

<sup>&</sup>lt;sup>19</sup> https://www.legislation.gov.uk/uksi/2011/2132/contents/made

<sup>&</sup>lt;sup>20</sup> https://www.legislation.gov.uk/uksi/2013/1506/contents/made

<sup>&</sup>lt;sup>21</sup> https://www.legislation.gov.uk/uksi/2021/33/contents/made

#### 10. Consultation outcome

10.1 No consultation is considered necessary as the instrument does not make any policy changes but instead gives effect to certain provisions of an already agreed international trade agreement and corrects deficiencies in retained legislation to ensure their continued operability.

#### 11. Guidance

11.1 Guidance in relation to information sharing under international trade agreements is neither required nor appropriate. HSE provided guidance on its website when the chemicals regulations were retained under the Withdrawal Act. No additional guidance is needed as a result of the amendments in this instrument.

# 12. Impact

- 12.1 There is no impact on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 An Impact Assessment has not been prepared for this instrument because there is not expected to be any additional costs to business, charities or the voluntary sector.

# 13. Regulating small business

- 13.1 The legislation applies in part to activities that are undertaken by small businesses.
- 13.2 This instrument does not place any new obligations on business. It will not therefore have any disproportionate impact on small business.

## 14. Monitoring & review

- 14.1 No specific monitoring arrangements are needed.
- 14.2 As this instrument is made under the Trade Act, Withdrawal Act and Withdrawal Agreement Act, no review clause is required.

#### 15. Contact

- 15.1 Leo McDaid, Health and Safety Executive (Telephone: 020 3028 2909 or email: leo.mcdaid@hse.gov.uk) or Frances Rowswell, Health and Safety Executive (Telephone: 020 3028 2878 or email <a href="mailto:frances.rowswell@hse.gov.uk">frances.rowswell@hse.gov.uk</a>) can be contacted with any queries regarding the instrument.
- 15.2 Kate Haire, Deputy Director for Engagement and Policy Division, Health and Safety Executive can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Claire Coutinho, 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 and the European Union (Future Relationship) Act 2020

# Part 1A Table of Statements under the 2018 Act

This table sets out the statements that <u>may</u> be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1) or 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) or 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) or 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) or 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) or 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 IP completion 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) or 23(1) or jointly exercising powers in Schedule 2 to create	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		a criminal offence	
Sub- delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising section 8 or 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 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament 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.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion 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 IP completion day, and explaining the instrument's effect on retained EU law.

# Part 1B

# Table of Statements under the 2020 Act

This table sets out the statements that <u>may</u> be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 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

# Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

# 1. Sifting statement(s)

# 2. Appropriateness statement

- 2.1 The Minister for Disabled People, Health and Work 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) Trade and Miscellaneous Amendments Regulations 2022 does no more than is appropriate".
- 2.2 This is the case because this instrument does not make any policy changes beyond the intent of ensuring continued operability of the relevant legislation.

#### 3. Good reasons

- 3.1 The Minister for Disabled People, Health and Work has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
  - "In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".
- 3.2 These are given in the policy background section of this explanatory memorandum (paragraphs 7.1 to 7.13).

# 4. Equalities

- 4.1 The Minister for Disabled People, Health and Work has made the following statement(s):
  - "The [draft] instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts."
- 4.2 The Minister for Disabled People, Health and Work has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
  - "In relation to the [draft] instrument, I, Claire Coutinho have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

# 5. Explanations

5.1 The explanations statement has been made in section 7 of the main body of this explanatory memorandum.