#### EXPLANATORY MEMORANDUM TO

# THE PRODUCT SAFETY AND METROLOGY (AMENDMENT AND TRANSITIONAL PROVISIONS) REGULATIONS 2022

#### 2022 No. 1393

#### 1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department for Business, Energy and Industrial Strategy and is laid before Parliament by Command of His Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

#### 2. Purpose of the instrument

- 2.1 The main objective of this instrument is to provide businesses with additional time to transition to the post-exit independent UK conformity assessment marking (UKCA) regime requirements, in order to legally place products on the market in Great Britain (England and Wales and Scotland). It also corrects a minor deficiency in the Pressure Equipment (Safety) Regulations 2016.
- 2.2 To this end, this instrument in particular:
  - extends existing transitional provisions allowing certain products meeting EU requirements and markings to be placed on the market, or put into service, in Great Britain;
  - provides that where manufacturers, or other relevant persons, have taken action under EU conformity assessment procedures that action will be treated as having been taken under the UK conformity assessment procedures for a time-limited period, ensuring these persons do not have to undertake re-testing; and
  - extends existing transitional provisions regarding labelling with respect to the UKCA marking, importer information and responsible person's information.

## 3. Matters of special interest to Parliament

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

3.1 This instrument amends instruments that were made (at least in part) under section 2(2) of the European Communities Act 1972. The amendments rely on powers under the European Union (Withdrawal) Act 2018.

## 4. Extent and Territorial Application

- 4.1 The extent of this instrument (that is, the jurisdictions which the instrument forms part of the law of) is England and Wales, and Scotland.
- 4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the same as its extent.

## 5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State has made the following statement regarding Human Rights:

"In my view the provisions of the Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 are compatible with the Convention rights."

#### 6. Legislative Context

- 6.1 Prior to the UK's exit from the EU, product safety and metrology was largely fully harmonised at the EU level, with individual pieces of legislation for a wide range of different product areas. However, much of this legislation followed the same structure, where manufacturers or other listed persons had to ensure certain "essential requirements" were met, and then ensure that conformity assessment procedures were undertaken to verify that the products did meet the essential requirements. There was a system of mutual recognition in place whereby bodies established in the EU could undertake conformity assessment for products that could then be placed anywhere on the EU market. Once the products' conformity with the essential requirements had been assessed by the appropriate conformity assessment procedure the CE marking, or the reversed epsilon marking, would be affixed to the product and the product could be placed anywhere on the EU market. There were then obligations on businesses throughout the supply chain to check that the products continued to meet the legislative requirements when making the products available on the market. Furthermore, certain economic operators had an obligation to affix their name and contact details to a product, to ensure traceability of the product.
- 6.2 The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 SI (S.I 2019/696) ("the 2019 Regulations")¹ ended mutual recognition and brought in an independent UK system, where any third-party conformity assessment must be carried out by a UK Approved Body, and the CE marking and the reversed epsilon marking was replaced by the UKCA marking, signifying that the product is in conformity with the UK requirements. Other aspects of the regulation, including the essential requirements and the actual conformity assessment procedures, remained largely the same. The main difference between the conformity assessment procedures relates to which bodies can undertake them. With respect to importers, prior to exit an importer was defined as a person established in the EU, who commercially supplies a product on the EU market. The 2019 Regulations amended this to provide that an importer must be established in the UK and commercially supply a product on the GB market.
- 6.3 However, to support businesses in transitioning to the new regime and reduce potential disruption to the supply of certain goods on the market in Great Britain following the UK's withdrawal from the EU, the 2019 Regulations included a time limited transitional arrangement whereby goods meeting EU requirements could be placed on the GB market. Under existing provisions, this transitional arrangement would come to an end on 31st December 2022. Additionally, the 2019 Regulations provided further transitional arrangements whereby the UKCA marking could be

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<sup>&</sup>lt;sup>1</sup> SI 2019/696 was amended by the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 S.I. 2020/1460 and the Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273).

affixed using a label or accompanying document, rather than on the product itself, until 31 December 2023, allowing businesses additional transitional provisions to assist them in complying with the new UKCA requirements. Given that businesses that were supplied with products from the EU prior to exit would become importers post-exit where they placed those products on the GB market, a further transitional provision was made where these "new" importers could place their name and contact details on a label affixed to the product or a document accompanying the product, rather than the product itself, for a period which currently ends on 31 December 2022. Finally, a similar transitional labelling provision was made with respect to cosmetic products, allowing the contact details of an EU responsible person, rather than a UK responsible person, to be included on the product until 31 December 2022.

## 7. Policy background

#### What is being done and why?

- 7.1 The UK's departure from the EU has meant changes have been made to product regulations, including the introduction of the UKCA marking to replace the EU's CE marking and reversed epsilon marking. The UKCA regime has been operational since 1 January 2021, in tandem with continued recognition of products meeting EU requirements and markings, which under existing arrangements would cease to be recognised in Great Britain at 11pm on 31 December 2022 for most product sectors.
- 7.2 The purpose of this instrument is, without compromising on safety, or consumer and environmental protection, to correct a deficiency arising from EU exit by preventing immediate cost increases and burdens for businesses, which could otherwise be passed onto consumers and commercial supply chains. This instrument ensures that businesses continue to be provided with flexibility and choice on how they comply with product regulations. The provisions of this instrument will also prevent potential temporary and short-term market and supply chain disruption that may have occurred at the start of 2023 if the recognition of products meeting EU requirements and markings was to come to an end on 31 December 2022.
- 7.3 Firstly, this instrument extends time for existing transitional provisions allowing certain products meeting EU requirements and markings to be placed on the market, or put into service, in Great Britain. This will give businesses the option to choose to use the CE marking, or reversed epsilon marking, for a further two years, until 31 December 2024. This will prevent immediate cost increases and burdens for businesses in the context of current cost of living and global supply chain challenges.
- 7.4 Secondly, this instrument provides that where a manufacturer or other relevant persons has undertaken any steps under EU conformity assessment procedures in the period during which goods that meet EU requirements are recognised (until 31 December 2024), but where those goods have not been placed on the GB market, those steps will be taken to have been done under the equivalent UK conformity assessment procedures. This only applies for as long as any certificate issued is valid, or until 31 December 2027, whichever is sooner. This will reduce costs associated with third-party retesting and recertification without compromising safety or consumer or environmental protection.
- 7.5 Thirdly, this instrument extends time for existing labelling easements. This will allow businesses to affix the UKCA marking, and to include importer information for products imported from EEA countries and in some cases Switzerland, on a label

affixed to the product or an accompanying document, rather than on the product itself, and to include details of an EU responsible person, rather than a UK responsible person, on cosmetic products, until 31 December 2027. This will help ensure UKCA compliance is easier and less costly for businesses who use the marking, encouraging them to continue to supply goods to GB.

7.6 The instrument will also correct a minor deficiency in regulation 88A of the Pressure Equipment (Safety) Regulations 2016 to correct a drafting error in the definition of a "product".

#### **Explanations**

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

- 7.7 The UK's legislative framework for product safety operates via regulations covering specific product sectors (such as toys, electrical equipment or weighing and measuring instruments) or general product safety regulations which apply where there is no product-specific product regulation. These regulations are there to provide protection for UK consumers and other end users, and to ensure only safe or accurate products are placed on the market. They also make provisions to correct or remove unsafe or inaccurate products from the market so that consumers and other end users have reassurance about the safety and accuracy of products.
- 7.8 To prepare for leaving the EU and the end of the Implementation Period (IP), the Department introduced a package of legislation, with the aim of ensuring the continuation of an effective and functioning domestic regulatory framework for product safety and metrology. The 2019 Regulations were a significant element of this package of legislation, amending the UK's product safety regulations as they apply to Great Britain, in addition to other retained EU law, to achieve these objectives.
- 7.9 The 2019 Regulations set up an independent UK system but also included a time limited transitional provision which accepted goods that meet EU requirements on the GB market. This provision is currently due to end at the end of this year for most products.

#### Why is it being changed?

7.10 This instrument will further support industry in their transition to the UKCA regime by allowing additional time to adapt to UKCA requirements, preventing immediate burdens and cost increases for businesses, which could otherwise be passed onto consumers and commercial supply chains. It will reduce burdens for businesses at a time of cost of living and supply chain challenges.

#### What will it now do?

- 7.11 This instrument will reduce immediate costs and burdens for industry by continuing to allow them choice on how they comply with product regulations. It will provide businesses the option to continue to adhere to EU requirements and markings for a further two years.
- 7.12 The instrument will also allow any steps taken under EU conformity assessment procedures before 31 December 2024 to be considered as valid for manufacturers, or other relevant persons, to demonstrate compliance with UKCA, for the duration of the certificates issued, or until 31 December 2027, whichever is sooner. This will reduce

- costs associated with third-party retesting and make UKCA compliance easier and less costly for businesses, encouraging them to continue to supply goods to GB.
- 7.13 The instrument also further extends existing labelling easements, providing additional assistance to businesses using the UKCA marking by reducing burdens and preventing cost increases for businesses.

#### 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 law 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 power in paragraph 21 of Schedule 7 to that Act. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

#### 9. Consolidation

9.1 There are no plans to consolidate the legislation amended by this instrument.

#### 10. Consultation outcome

- 10.1 A formal consultation has not been completed for this instrument. The Department chose not to undertake a public consultation given that its provisions are limited to extending existing transitional arrangements for a time-limited period.
- 10.2 The Department does, however, continue to undertake regular engagement with a variety of stakeholders, including manufacturers and Trade Associations, across a range of sectors, which continues to inform policy development.

#### 11. Guidance

- 11.1 Alongside the Government's announcement of these provisions to further assist businesses in their transition to the UKCA regime, the Department has updated guidance on how to place products on the market in Great Britain on GOV.UK (https://www.gov.uk/government/collections/placing-manufactured-products-on-the-market).
- 11.2 There is further guidance on the UK's product safety framework, provided to support businesses, enforcement agencies and consumers, which can be found on the Office for Product Safety and Standards section of GOV.UK (https://www.gov.uk/government/organisations/office-for-product-safety-and-standards).

## 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 (IA) has not been prepared for this instrument because the quantifiable annual net costs are de-minimis (i.e. the impact is less than ±5m per annum).
- 12.4 There are three key components of this instrument that directly affects businesses: acquiring conformity assessment certificates from UK Conformity Assessment Bodies

- (CABs) if they are currently with EU bodies (i.e. approaching UK bodies for new certification); marking and labelling products; and costs associated with businesses familiarising themselves with the changes in legislation.
- 12.5 For conformity assessment certification, this will be a net benefit to businesses. This is because businesses who still hold conformity assessment certificates with EU-recognised CABs will have more time to transfer them to UK CABs carrying out conformity assessment, depending on the issue date of the certificate. Marking and labelling changes will be a net benefit to businesses, as they have more time to mark and label products, with more flexibility in using accompanying documents. Familiarisation costs are a net cost to businesses. Overall, the combination of the impacts of these three components results in quantified annual net impact that is deminimis.
- 12.6 In addition, there may also be indirect benefits of this measure associated with avoiding potential temporary and short-term market disruption that could arise if this measure was not introduced. Without this instrument, if there are products for which businesses are not able to get certification from a UK Approved Body or affix the UKCA marking before 31 December 2022, for example due to associated costs, they cannot legally be placed on the market in Great Britain after 31 December 2022. This could have wider impacts like reduced product availability and choice, and/or higher prices which could add to current cost of living and global supply chain challenges, and which this instrument seeks to mitigate. Despite significant previous engagement with businesses and other stakeholders, it has not been possible to quantify these impacts due to uncertainties over the scale of products affected and the extent to which sales would be forgone rather than delayed.
- 12.7 Lastly, earlier amendments made by the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 SI No. 1460 and the Product Safety and Metrology etc. (Amendment) Regulations 2021 SI No. 1273 were also assessed as de-minimis. This instrument will impact a subset of the original business population in scope of the 2021 and 2020 Regulations and the quantified net annual costs of this instrument are also de-minimis.

#### 13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise the regulatory burdens on small businesses.
- 13.3 The legal requirements on the industry do not differentiate between business in terms of their size and they are dependent on the type and nature of products being manufactured and placed on the market. Therefore, we are unable to take any mitigating actions to reduce burdens on small business. The Department however does not expect a disproportionate impact on small and/or micro businesses. The instrument seeks to reduce the legal requirements for all applicable businesses, regardless of their size.

#### 14. Monitoring & review

14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

14.2 Subject to the Retained EU Law (Revocation and Reform) Bill coming into force, the Department will however review this instrument under the requirements set out in that legislation.

#### 15. Contact

- 15.1 Katherine Seddon at the Department for Business, Energy and Industrial Strategy Telephone: 07917 495067 or email: katherine.seddon@beis.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Rosanna Wong, Deputy Director for Trade and Investment Negotiations (Goods), at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Kevin Hollinrake MP, Parliamentary Under Secretary of State at the Department for Business, Energy and Industrial Strategy 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	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 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. Appropriateness statement

- 1.1 The Parliamentary Under Secretary of State, Kevin Hollinrake has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
  - "In my view the Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 does no more than is appropriate".
- 1.2 This is the case because the instrument makes only the necessary changes to extend the time period for recognition of products meeting EU requirements and markings until 31 December 2024, to extend existing labelling easements until 31 December 2027, and extending the time period to allow any steps taken under EU conformity procedures before 31 December 2024 to be considered valid to demonstrate compliance with UKCA, for the duration of the certificates issued or until 31 December 2027, whichever is the sooner.

#### 2. Good reasons

- 2.1 The Parliamentary Under Secretary of State, Kevin Hollinrake has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
  - "In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".
- 2.2 These are that this instrument makes appropriate amendments to domestic legislation to address deficiencies arising from the withdrawal of the United Kingdom from the European Union. The amendments relying on section 8(1) of the European Union (Withdrawal) Act 2018 are limited to achieving that purpose. Details as to the purpose of this Instrument are explained in paragraphs 7.1 to 7.6 of this Explanatory Memorandum. The relevant background law is explained in paragraphs 6.1 to 6.3 of this Explanatory Memorandum. The effect on retained EU law is explained in paragraphs 7.7 to 7.13 of this Explanatory Memorandum.

#### 3. Equalities

- 3.1 The Parliamentary Under Secretary of State, Kevin Hollinrake has made the following statement:
  - "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 Parliamentary Under Secretary of State, Kevin Hollinrake has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
  - "In relation to the instrument, I, Parliamentary Under Secretary of State, Kevin Hollinrake have had due regard to the need to eliminate discrimination, harassment,

victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

# 4. Explanations

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