

EXPLANATORY MEMORANDUM TO
THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT)
REGULATIONS 2024

2024 No. [XXXX]

1. Introduction

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

2. Declaration

- 2.1 Kevin Hollinrake, Minister for Enterprise, Markets and Small Business at the Department of Business and Trade confirms that this explanatory memorandum meets the required standard.
- 2.2 Gillian Econopouly, Deputy Director for UKCA Policy and Strategic Delivery, at the Department for Business and Trade confirms that this explanatory memorandum meets the required standard.

3. Contact

- 3.1 Connor O’Shea, Head of UKCA Policy and Engagement at the Department for Business and Trade, email: goods.regulation@businessandtrade.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

- 4.1 The Statutory Instrument (SI) has two main objectives:
 - To revoke the expiry date of the recognition of certain European Union (EU) requirements relating to goods, which is due to end on 31 December 2024 and to remove the associated transitional provisions which are no longer required. This will allow continued recognition of EU requirements for the product regulations within scope for goods placed on the market in Great Britain (GB); and
 - To replace the expiry provision and the associated transitional provisions, with a provision that recognises EU testing or conformity assessment procedures. This will mean that, where manufacturers have undertaken conformity assessment procedures with EU recognised bodies, the United Kingdom Conformity Assessed (UKCA) marking may be used, instead of the relevant EU conformity marking.
- 4.2 The removal of the expiry of recognition of EU product requirements will apply to the 21 product regulations covered within this SI, which are managed by the Department for Business and Trade [leading department], the Department for Environment, Food and Rural Affairs, the Department for Energy Security and Net Zero and the Department for Work and Pensions (Health and Safety Executive).

- 4.3 The provision recognising EU conformity assessment procedures applies to the 19 product regulations where there are requirements to undertake conformity assessment procedures.

Where does the legislation extend to, and apply?

- 4.4 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England, Wales and Scotland.
- 4.5 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England, Wales and Scotland.

5. Policy Context

What is being done and why?

- 5.1 Manufacturers are required to ensure that products placed on the market of GB, or put into service in GB, meet certain safety, accuracy or environmental protection requirements, set out as part of the United Kingdom's (UK) product regulations. Importers and distributors are then required to check the relevant requirements have been complied with.
- 5.2 The UKCA regime was introduced in GB, following the end of the transition period on 1 January 2021, to replace the EU's regime to demonstrate products meet the UK's product regulatory requirements. Under the EU regime, products are labelled with a 'CE' mark, which is an abbreviation of Conformité Européenne, to demonstrate they meet the EU's legal requirements (in 2 cases, the reversed epsilon marking is used instead of CE to this effect).
- 5.3 Since 1 January 2021, the UK has continued to recognise the EU regime alongside the UKCA regime for the regulations included within the scope of this SI. This is due to end on 31 December 2024 for these regulations. This SI will introduce continued recognition of the EU regime, beyond the current expiry date.
- 5.4 In 2023, the government held roundtables to hear views from businesses, trade associations and other industry stakeholders. Industry in the UK and those who supply the UK from abroad have asked for certainty and clarity. Continuing GB recognition of EU requirements (CE recognition) was highlighted by industry as important for reducing burdens to businesses, providing businesses with longer-term certainty, and reducing barriers to trade.
- 5.5 Considering the stakeholder feedback, ongoing supply chain issues, and broader inflationary economic conditions, the government took the decision to lay this SI to remove the deadline which would have ended recognition of EU requirements after 31 December 2024. The scope of this SI covers a wide range of products from personal protective equipment (PPE) to toys to machinery.
- 5.6 The main purpose of this SI is to continue to provide businesses with flexibility and choice on how they comply with regulations by giving them the option to follow either EU requirements (including use of the CE or reversed epsilon markings) or UKCA requirements (including the UKCA marking) for the product regulations included within the scope of this SI.
- 5.7 The government recognises that it may be in the interests of the UK in some product areas to stop recognising EU requirements in the future. Some products are subject to multiple regulations (e.g. where they are regulated for safety by one regulation, and for environmental impact by another regulation). It is therefore possible that at some

point in the future the UKCA regime will become mandatory for one set of regulations applying to a product but not another. This SI introduces a new recognition provision which will enable manufacturers to rely on EU conformity assessment procedures for the purposes of the UKCA regime. This will apply to UKCA and will enable the UKCA mark to be applied where any recognised conformity assessment procedure has been undertaken. Without this provision, if UKCA became mandatory for one regulation, it may mean that manufacturers would have to undertake costly and duplicative testing for all regulations that apply to the product even where the EU regime continues to be recognised for the purposes of some of those regulations.

What was the previous policy, how is this different?

- 5.8 From 1 January 2025, businesses who did not comply with UKCA requirements would not legally be able to place their products on the GB market, except “qualifying Northern Ireland goods” which remain unaffected by this SI. Businesses indicated that ending recognition of EU requirements including CE-marked products could increase costs, leading to higher prices and less choice for GB consumers. Some overseas suppliers also stated their intention to limit product supply to GB if CE-marked products were no longer recognised.
- 5.9 The previous policy established 31 December 2024 as the expiry date for EU recognition, and provided that UKCA would become mandatory from 1 January 2025. This meant that, up until 31 December 2024, where the EU’s product requirements had been met, including EU conformity assessment procedures and affixing a CE or reversed epsilon marking to the product, businesses could place the product on market in Great Britain. From 1 January 2025 businesses would no longer have this option and would have to comply with the UKCA regime.
- 5.10 This SI removes the time-limited expiry of EU recognition for the products covered by the 21 product regulations in scope.
- 5.11 The previous policy also provided transitional measures, introduced in June 2022, for some regulations. One of these measures meant that, where a manufacturer had undertaken any steps under relevant EU conformity assessment procedures in the period during which goods that met EU requirements were recognised (until 31 December 2024), but where those goods were not placed on the GB market, those steps will be taken or have been deemed under the equivalent UK conformity assessment procedures, and allowed UKCA marking to be applied. This only applied for as long as any certificate issued is valid, or until 31 December 2027, whichever is sooner. This instrument removes these transitional provisions and instead makes a provision that is more suited to an indefinite extension, which caters for the possibility of UKCA becoming mandatory for the purposes of different regulations at different points in time.

6. Legislative and Legal Context

How has the law changed?

- 6.1 The 21 pieces of legislation in scope of this SI regulate the safety or accuracy, or environmental protection of products before they can be either placed on the market or put into service in Great Britain.
- 6.2 Prior to the United Kingdom (UK)’s exit from the European Union (EU), the measures amended by this SI were either directly applicable EU law or domestic implementation of EU law. Under the European Union (Withdrawal) Act 2018 this

became retained EU law, with deficiencies (such as references to EU institutions) corrected using powers under that Act (many of these changes were implemented by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) 2019 SI (S.I. 2019/696). Under the Retained EU Law (Revocation and Reform) Act 2023 these measures became assimilated EU law. In the EU, there is a mutual recognition system in place for conformity assessment. This means that where EU legislation necessitates third party conformity assessment (3PCA) of a product, any EU recognised conformity assessment body located anywhere in the EU can provide that 3PCA so that the CE marking can be applied to the product, and it can be lawfully placed on the EU market. The 2019 Regulations, as applicable to Great Britain (GB), removed the mutual recognition of conformity assessment between the UK and the EU, and replaced it with an independent UK legislative regime (UKCA), to ensure the continuation of an effective functioning domestic regulatory framework for product safety and metrology¹.

- 6.3 The independent UK regime (UKCA) applies before a product can be placed, or put into service, on the GB market. It requires that a manufacturer must meet the UK(GB) essential requirements for the relevant product regulations, undertake the relevant conformity assessment procedure requirements as set out in that sector specific regulation, and then affix a UKCA marking to the product before placing the product on the GB market. The UKCA regime legally requires that any necessary 3PCA procedures must be undertaken by UK approved bodies (UK ABs), which are conformity assessment bodies based in the UK and which have been approved by the Secretary of State.
- 6.4 In order to give businesses time to adapt to the newly introduced UKCA regime, a time-limited acceptance of goods meeting EU requirements (including being conformity assessed by EU bodies) was introduced for the GB market. This EU recognition is implemented in GB legislation through a provision which provides that, where the corresponding EU requirements are met in full, the UK(GB) requirements are deemed to have been met. This provision therefore allows goods which have been affixed with the CE or reversed epsilon marking to be placed on the GB market. The time-limited aspect of this EU recognition was introduced through an “expiry provision”, which provided for the expiry of the provision which accepted EU requirements.
- 6.5 This expiry was first legislated for in 2020 and was subsequently extended on two further occasions due to evidence that there was a lack of sufficient readiness amongst businesses to transition to the UKCA regime. The most recently extended expiry date is 31 December 2024.
- 6.6 This SI revokes the expiry provision, thereby removing the legislative end date for EU recognition in GB for the products in scope. This will enable businesses to continue to place goods with a CE or reversed epsilon marking on the GB market.
- 6.7 This SI also introduces a new measure, which will create more flexibility on how manufacturers can use the UKCA marking to place products on the GB market. This measure is delivered through introducing a new provision in the legislation, where a manufacturer ensures that:

1.1 ¹ The Ecodesign for Energy-related Products and Energy Information (Amendment)(EU Exit) Regulations 2019, introduced similar requirements for Ecodesign. The Waste (Miscellaneous Amendments) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/188) introduced similar requirements for the Restriction on hazardous substances (RoHS) in electrical and electronic equipment.

- the EU essential requirements, as recognised in GB, have been met, and
 - the relevant EU conformity assessment procedures have been carried out and required technical documentation has been drawn up;
 - then, the corresponding UKCA requirements (i.e. essential requirements and conformity assessment procedures and technical documentation) are deemed to have been met.
- 6.8 The UKCA requirements which are not, however, treated as being satisfied by the above steps are the manufacturer's obligations to:
- Draw up a UK Declaration of Conformity (DoC), and
 - Apply UKCA product marking.
- 6.9 Therefore, if the manufacturer relies on this new provision to place their product on the GB market without either drawing up a UK DoC or applying a UKCA marking, then they will be in breach of their legal obligations.
- 6.10 The SI also amends the existing references to most of the EU instruments that are recognised. Currently the existing recognition provision refers to the relevant EU instrument "as it has effect immediately before IP completion day". In most instances, the relevant EU instrument has not changed since IP completion day and the inclusion of this wording causes confusion. This SI therefore removes this wording, where appropriate. Where the EU legislation recognised has changed, the reference to the EU legislation has been updated so that it will capture the most up to date version of the EU instrument, applicable to all regulations except Gas Appliances. In respect of Restriction of Hazardous Substances (RoHS), provision has been made to ensure that exemptions to EU legislation are recognised where there is an applicable exemption in GB law.
- 6.11 This SI's legislative measures are being delivered by powers under section 14 of the Retained EU Law (Revocation and Reform) Act 2023 (see section 6.18 below for more detail).
- 6.12 The SI will amend the following legislation:
- Measuring Container Bottles (EEC Requirements) Regulations 1977/932
 - Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001/1701
 - Supply of Machinery (Safety) Regulations 2008/1597
 - Aerosol Dispensers Regulations 2009/ 2824
 - Ecodesign for Energy-Related Products Regulations 2010/2617
 - Toys (Safety) Regulations 2011/1881
 - Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 ('The RoHS Regulations')
 - Explosives Regulations 2014/1638
 - Pyrotechnic Articles (Safety) Regulations 2015/1553
 - Personal Protective Equipment (EU Regulation) 2016/425
 - Gas Appliances (EU Regulation) 2016/426
 - Electrical Equipment (Safety) Regulations 2016/1101
 - Pressure Equipment (Safety) Regulations 2016/1105
 - Equipment for use in potentially explosive atmospheres Regulations 2016/1107
 - Measuring Instruments Regulations 2016/1153

- Non-automatic weighing instruments Regulations 2016/1152
- Electromagnetic compatibility Regulations 2016/1091
- Simple Pressure Vessels (Safety) Regulations 2016/1092
- Lifts Regulations 2016/1093
- Radio Equipment Regulations 2017/1206
- Recreational Craft Regulations 2017/737

Why was this approach taken to change the law?

- 6.13 This SI is made using powers contained in section 14(1), (2) and (3) of the Retained EU Law (Revocation and Reform) Act 2023. Section 14 provides various powers for a relevant national authority to make regulations. The Secretary of State is a “relevant national authority” for these purposes. Section 14(1) can be used to revoke any secondary assimilated law without replacing it; section 14(2) can be used to revoke any secondary assimilated law and replace it with provision that the Secretary of State considers appropriate and to achieve the same objectives; and section 14(3) provides powers to revoke secondary assimilated law and replace it with such alternative provision as the Secretary of State considers appropriate.
- 6.14 All of the pieces of legislation amended by this instrument are secondary assimilated law within the meaning of section 14 (see section 12(21)). In some instances, provisions of secondary assimilated law are being revoked without being replaced, for example the removal of the expiry provision for Measuring Container Bottles (EEC Requirements) Regulations 1977, removal of certain words in the definitions of certain EU legislation and removal of redundant transitional provisions - and therefore fall within section 14(1).
- 6.15 In some instances, provisions are being replaced to better reflect the policy position, for example in the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 the current provision recognising EU requirements refers to “essential requirements”; whereas the correct terminology is “essential health and safety requirements”. This SI replaces the incorrect terminology with the correct terminology but achieves the same objectives.
- 6.16 Finally, this instrument revokes the expiry of the main EU recognition provision and replaces it in 19 instances with a provision that essentially recognises EU conformity assessment procedures. Section 14(3) provides that the Secretary of State can revoke any secondary assimilated law and replace it with provision that the Secretary of State considers appropriate. The provision can implement different policy objectives, as long as the Secretary of State considers it appropriate to do so.
- 6.17 The Secretary of State considers this approach appropriate because this is a cost-reducing measure for businesses supplying to the market of Great Britain, ensuring they do not have to undertake costly re-testing without any reduction to safety or accuracy. It will help to ensure the continued flow of safe and accurate and environmentally friendly goods to the market of Great Britain. Furthermore, this measure caters for the possibility that in future it will be in the interests of UK consumers and businesses to take a different approach in one set of regulations whilst continuing to recognise EU requirements in a different set of regulations, where a product is subject to multiple regulations. The new provision will facilitate this.
- 6.18 The powers in section 14 are subject to certain restrictions, including that the overall effect of the changes does not increase the regulatory burden. These changes offer choice to businesses, reducing costs, and therefore do not increase regulatory burden.

6.19 There are no other powers available to enable all these changes within the time frame required.

7. Consultation

Summary of consultation outcome and methodology

- 7.1 The Department for Business and Trade in collaboration with other government departments, have undertaken a total of 46 roundtables with industry across the UK and internationally, to hear views on our approach to product markings.
- 7.2 Industry in the UK and those who supply the UK from abroad have largely welcomed continued recognition of EU requirements. This was seen to reduce burdens for businesses and reduce barriers to trade.
- 7.3 As part of the roundtables with industry, the Department for Business and Trade held two bespoke sessions with conformity assessment bodies, attended by over 80 representatives of the sector. Many have raised concerns that demand for their conformity assessment services for the UKCA mark will fall. The government will monitor the conformity assessment market and will work with the sector to support a domestic route to market for relevant UKCA marked products.

8. Applicable Guidance

- 8.1 The government has published an outline of its policy on GOV.UK for the 21 regulations in scope of the SI². The government has also published an Industry Explainer³. The government is undertaking a full guidance update and will continue to work with industry to develop this.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

- 9.1 A full Impact Assessment is submitted with this memorandum and published alongside the explanatory memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

- 9.2 The central estimated quantified impact on businesses from this SI is a total net present value benefit of £558m⁴. More details are provided in the full Impact Assessment.
- 9.3 There is no, or no significant, impact on charities, voluntary bodies because the main affected groups are manufacturers, retailers and wholesalers, local authorities, conformity assessment bodies, and consumers.
- 9.4 The legislation does impact small or micro businesses. The impact on business is set out in the impact assessment.
- 9.5 The legal requirements on the industry do not differentiate between businesses in terms of their size. They are dependent on the type and nature of product being produced and placed on the market. As this SI reduces duplicative costs and burdens faced by businesses when placing goods on the GB market, no exemption for small

² <https://www.gov.uk/guidance/using-the-ukca-marking>

³ <https://assets.publishing.service.gov.uk/media/65b7b5058c576200126478da/industry-explainer-placing-products-on-the-market-in-great-britain-using-uk-or-eu-product-markings.pdf>

⁴ Estimated over a 10-year period and reported using 2019 prices.

and micro businesses would be needed to limit any possible adverse effects of the legislation on small and micro businesses.

- 9.6 There is no, or no significant, impact on the public sector because current costs to Government, will remain post SI implementation. These costs to Government include ensuring businesses and conformity assessment bodies are complying with the product safety regulations (the CE or UKCA marking), to ensure the safety of products on the GB market.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

- 10.1 The approach to monitoring this legislation is not required.
- 10.2 As this Statutory Instrument is made under the 2023 Act, no review clause is required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

- 11.1 Since this instrument is made, in part, under section 14(3) of the 2023 Act, it automatically triggers the affirmative procedure (see paragraph 5(1) and (2) of Schedule 5 to the 2023 Act).

12. European Convention on Human Rights

- 12.1 This instrument is not made under the European Union (Withdrawal) Act 2018. The Minister for Enterprise, Markets and Small Business, Kevin Hollinrake has made the following statement regarding Human Rights:

“In my view the provisions of the Product Safety and Metrology Etc (Amendment) Regulations are compatible with the Convention rights.”

13. The Relevant European Union Acts

- 13.1 This SI does not relate to withdrawal from the European Union nor trigger the statements required under the EU (Withdrawal Act) 2018. (NP) This SI does however relate to the reform of assimilated law under section 14 of the 2023 because the SI amends various provisions of secondary assimilated law.