

Title: Impact Assessment for the Product Safety and Metrology etc. (Amendment) Regulations 2024 IA No: DBT-003(IA-F)-23-TPIN RPC Reference No: RPC-DBT-5327(1) Lead department or agency: Department for Business and Trade Other departments or agencies: Department for Environment, Food and Rural Affairs Department for Energy Security and Net Zero Health and Safety Executive	Impact Assessment (IA)			
	Date: 15/04/2024			
	Stage: Final			
	Source of intervention: Domestic			
	Type of measure: Secondary legislation			
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Summary: Intervention and Options	RPC Opinion: GREEN
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Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status Qualifying provision
£558.2m	£558.2m	-£64.8m	

What is the problem under consideration? Why is government action or intervention necessary?

Since 1 January 2021, the UK has continued to recognise the CE (Conformité Européenne) regime alongside the UKCA (UK Conformity Assessed) regime for goods placed on the UK market. This approach has enabled businesses to use either when placing goods on the GB market. However, CE recognition is due to end on 31 December 2024. From 1 January 2025, businesses can only use the UKCA requirements or will not legally be able to place their products on the GB market. Through consultation, businesses have indicated that ending CE recognition could increase their costs or that they may choose not to supply the market, leading to higher prices and less choice for GB consumers.

What are the policy objectives of the action or intervention, and the intended effects?

The policy objective is to reduce duplicative costs and burdens faced by businesses when placing goods on the GB market. The measures will also maintain product supply and choice for consumers. Manufacturers exporting to the EU and other countries which recognise the EU mark will also benefit by not having to comply with two regulatory regimes. This will support economic growth by reducing duplicative requirements to sell goods on the GB market and continue to facilitate imports and exports of goods.

Bringing through the legislation will provide continued CE recognition for the 21 product regulations under the responsibility of the Department of Business and Trade; the Department for Environment, Food and Rural Affairs; the Health and Safety Executive (which sits under the Department for Work and Pensions), and the Department for Energy Security and Net Zero. See Annex 1 for a full list of legislation to be amended.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0: Do nothing: CE recognition will end on 31 December 2024 for the product regulations included within this legislation. The UK’s product regulatory regime including the UKCA mark, currently in full operation, will become mandatory for all relevant products placed on the GB market.

Option 1 (Preferred option): Extend CE marking recognition indefinitely: To indefinitely extend recognition of the current CE legislation and CE marking in GB, and provide additional flexibility to use the UKCA mark to demonstrate products meet EU regulations in areas where they are still recognised, and comply with GB requirements in areas where EU rules are not recognised.

Will the policy be reviewed? It will not be reviewed.					
Is this measure likely to impact on international trade and investment?			Yes		
Are any of these organisations in scope?		Micro Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/A	Non-traded: N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Kevin Hollinrake Date: 10/04/2024

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 150.3	High: 1461.8	Best Estimate: 558.2

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	2.7	Optional	2.7
High	13.2	Optional	13.2
Best Estimate	7.1		7.1

Description and scale of key monetised costs by 'main affected group'

Our best estimate is that 18,500 UK manufacturers, 88,900 retailers and wholesalers, 218 local authorities, and 145 UK registered conformity assessment bodies will incur familiarisation costs by the implementation of the accompanying SI. Under Option 1, we estimate there will be a one-off familiarisation cost of £7.1m for UK businesses incurred in the year when this legislation is introduced. There are no other monetised costs incurred by the affected groups under the preferred option.

Other key non-monetised costs by 'main affected groups'

We expect that UK Approved Bodies may see costs from lower demand for their conformity assessment services from manufacturers in Option 1, relative to Option 0. Most UK Approved Bodies are private sector businesses. In addition, the familiarisation costs incurred by UK and non-UK businesses could be passed onto UK consumers through higher prices for products. We expect any costs passed onto consumers to be minimal.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	19.2	163.6
High	Optional	172.9	1464.5
Best Estimate		66.7	565.3

Description and scale of key monetised benefits by 'main affected groups'

Under Option 1, we estimate there will be benefits to around 9,600 UK manufacturers through cost savings of £27m from avoiding making permanent conformity marking/labelling changes to products; and benefits to around 2,000 UK manufacturers of £538.2m via cost and labour time savings from avoiding duplicative conformity assessments, relative to Option 0.

Other key non-monetised benefits by 'main affected groups'

UK and non-UK manufacturers that save costs from conformity markings and conformity assessment (Option 1) could pass these savings on to the UK consumers and businesses through lower prices. UK consumers and businesses could also benefit from greater product availability in Option 1 relative to Option 0.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
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We have limited data with which to estimate certain impacts to business. We have consulted a wide range of manufacturers and industry bodies via extensive roundtable engagement, and we conducted a survey of businesses to improve our evidence base. To account for uncertainty around the representativeness of the data for this heterogeneous industry, we have consulted policy experts, external public databases, past and recent engagements with businesses. We assume impacts first occur in 2024, when the legislation takes effect. We estimate impacts over a 10-year period.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: -315.1
Costs: 0.8	Benefits: 65.7	Net benefit of: 64.8	

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Background

1. The UK Conformity Assessed (UKCA) regime was introduced in GB, following EU Exit, to replace the EU's CE marking to demonstrate products meet the UK's product regulatory requirements. The European Union (Withdrawal) Act 2018 enabled EU laws to be transposed into UK legislation as 'Retained EU Law' (REUL). As part of this, existing EU product regulations were preserved as UK product regulations as they applied on 31 December 2020.
2. The UK Government is responsible for introducing and implementing the UKCA product regulatory regime, with responsibility for individual regulations spread across several Departments¹. The Department for Business and Trade is laying legislation in collaboration with the Department for Environment, Food and Rural Affairs for Hazardous substances ("RoHS"), the Health and Safety Executive for Civil Explosives, and the Department for Energy Security and Net Zero for products under the Eco-Design regulations.
3. The regulations covered under this legislation are listed in Annex 1. The goods under these regulations are wide-ranging from consumer goods, such as mobile phones and toys, to industrial machinery used in critical national infrastructure such as nuclear power stations and wind turbines. Product regulations covered under this legislation ensure that products meet the specified safety, performance or environmental requirements (as applicable) by placing obligations on businesses - manufacturers, importers and distributors, which apply equally to all businesses.
4. The current regime, as directed by product safety and metrology legislation, places requirements on any business involved in the import, manufacture, and supply of goods. These requirements set out processes that economic operators must follow, including checks to ensure products conform with the requirements and mandatory labelling.
5. In advance of placing goods on the market, an assessment is undertaken to demonstrate a product is compliant with all relevant legislation. For certain products, manufacturers will self-certify that the products meet all appropriate requirements. If a product presents a more significant risk, the manufacturer may be required under the legislation to submit the product to a Conformity Assessment Body² (CAB) (Third Party) who will undertake a conformity

¹ Department for Business and Trade product sectors in scope of this SI: Toys, Pyrotechnics, recreational craft and personal watercraft, simple pressure vessels, electromagnetic compatibility, non-automatic weighing instruments, measuring instruments, measuring container bottles, Lifts, equipment for potentially explosive atmospheres (UKEX), radio equipment, pressure equipment, personal protective equipment (PPE), gas appliances, Machinery, equipment for use outdoors, aerosol dispensers, low voltage electrical equipment.

The following sectors fall under the scope of other Governmental Departments who are also included within this SI: Department for Environment, Food and Rural Affairs for Hazardous substances in electrical equipment ("RoHS"), Health and Safety Executive for Civil Explosives, and Department for Energy Security and Net Zero for Eco-Design.

² A conformity assessment body is officially appointed to undertake conformity assessment activities to demonstrate that specified goods meet the essential health and safety requirements to be placed on the GB market. UKAS (2021).

assessment of the product or processes, to determine if they meet the necessary requirements of the legislation.

6. Products are required to be labelled with the address of the manufacturer and, where relevant, the importer responsible for first placing the product on the UK market.
7. In 2022 the Government passed Secondary Legislation which allowed the period of CE recognition to be extended, which will end on 31 December 2024. The extension provided businesses an extra 24 months to prepare for UKCA and HMG published guidance on transitional measures for businesses. Making UKCA mandatory would lead to duplicative costs and burdens while UK and EU rules remain similar. In addition to CE recognition, we implemented a range of measures to help with the transition to UKCA (outlined below in 'Option 0'). These are due to end in 2027. The Department for Business and Trade, in collaboration with other Government Departments, has sought industry feedback on how to revise these in line with the indefinite CE extension.
8. The Department for Business and Trade has run over 21 roundtables, hearing views from businesses, trade associations and other industry stakeholders on our approach to UKCA. Over 170 stakeholders have participated in these engagements. Businesses indicated that ending CE recognition could increase costs, leading to higher prices and less choice for GB consumers. Some overseas suppliers stated their intention to limit product supply to GB if CE was no longer recognised. Engagement through industry roundtables indicates the importance of this longer-term product regulatory approach to encourage manufacturers to continue supplying the GB market.
9. This feedback has been used to develop the solutions outlined in 'Option 1'.

Evidence Base

Problems under consideration and rationale for intervention

10. Since 1 January 2021, the UK has continued to recognise the CE (Conformité Européenne) regime alongside the UKCA (UK Conformity Assessed) regime for the regulations included within the scope of this SI, allowing business transition time for placing goods on the GB market. This is due to end on 31 December 2024 for these regulations. From 1 January 2025, businesses who do not comply with UKCA requirements will not legally be able to place their products on the GB market. Businesses indicated that ending CE recognition could increase costs, leading to higher prices and less choice for GB consumers. Some overseas suppliers stated their intention to limit product supply to GB if CE was no longer recognised.

11. Feedback also highlighted the importance of simplicity, clarity and certainty on our product regulatory approach to encourage manufacturers to continue supplying to the GB market.
12. In response the Government (Department for Business and Trade) has announced that it is now revoking the sunset clause of existing CE recognition (currently lasting until 31 December 2024) to make the extension indefinite under this legislation. Government will also implement additional measures to support the CE extension, including a measure designed to reduce some of the business costs if UK and EU requirements diverge in the future.

Policy Objectives

13. The policy objective is to reduce duplicative costs and burdens faced by businesses when placing goods on the GB market. The measures will also maintain product supply and choice for consumers. Manufacturers exporting to the EU and other countries which recognise the relevant EU rules will also benefit by not having to comply with two regulatory regimes. This will support economic growth by reducing duplicative requirements to sell goods on the GB market and continue to facilitate imports and exports of goods.
14. This legislation will ensure that risks of any supply chain and market disruption are limited for the regulations in scope since businesses, including non-UK businesses, can continue to supply the GB market with CE marked goods.

Rationale and evidence to justify the level of analysis used in the IA

15. The Department for Business and Trade has developed robust, appropriate analysis for this SI, whilst recognising the limitations of our data and evidence. Our evidence base relies on business and industry engagement dating back to pre-2020. We have updated and combined this with more recent industry roundtables in 2023, a business survey (Summer 2023), and ONS Business Insights and Impact on the UK Economy survey (BICS) data. Recent business engagements and ONS data have allowed us to confirm or update some of our existing assumptions by factoring impacts from the Covid-19 pandemic and recent inflationary pressures.
16. In the analysis presented in this Impact Assessment, we assume impacts first occur in 2024, when the legislation is introduced into Parliament, and are considered over a 10-year period. The analysis presented in the main body of this Impact Assessment are in 2023 prices, unless otherwise stated, given that a sizeable share of the underlying evidence was collected in 2023. The impacts presented in the summary at the start of this Impact Assessment are in 2019 prices as per the Impact Assessment template. To account for

limitations in our data and to factor in the diversity of manufacturers impacted by the implementation of this SI, we have undertaken analysis for low to high scenarios, with a central estimate providing our headline impacts.

17. The SI covers a large part of the UK manufacturing sector from consumer products like toys, and electronics, to industrial products, such as lifts and machinery. Our best estimate is that around 18,500 UK manufacturers are involved in these industries and will be affected by this SI (14%³ of UK manufacturers). Our best estimate is that there are 88,900 retailers and wholesalers in the UK which sell these products. Retailers and wholesalers have relatively less responsibility than manufacturers in ensuring the compliance of their products with the regulatory requirements. These businesses will also be affected by the SI either indirectly or to a lesser extent than manufacturers.
18. Some of the impacts in the IA relate principally to impacts on GB businesses. For simplicity and data availability, most data used in the calculations are UK data. We expect this to have a small impact on results given NI manufacturing businesses and NI goods trade represent small shares of UK manufacturing businesses and UK goods trade respectively⁴. In the descriptions of impacts, we specify whether the impacts relate to GB businesses or UK businesses and how NI businesses are impacted by this legislation. In the calculations, we specify each of the data sources. For further details on the implications for Northern Ireland, see the Wider Impacts section of this IA. The introduction of this SI is also not expected to have any disproportionate impacts on different regions of the UK. Hence this Impact Assessment does not present regional analysis of the impacts resulting from this legislation.
19. The products in scope of the SI represent a large proportion of UK goods trade flows. The average annual value of all manufactured goods imported into the UK subject to UKCA or CE requirements is £110bn⁵, with around half of these imports from the EU. Imported products, which are subject to UKCA or CE requirements, represent up to 23% of all UK imported goods in 2019⁶. Thus, this SI will introduce flexibility for businesses supplying the UK market by extending the option to use the UK or the EU's regulatory regime to place goods on the GB market.

³ Based on number of enterprises (138,650 in 2021) within the manufacturing sector.

Source: Annual Business Survey. Available here:

<https://www.ons.gov.uk/businessindustryandtrade/business/businessservices/datasets/uknonfinancialbusinesseconomyannualbusinesssurveysectionsas>

⁴ For example, Northern Ireland businesses account for approx. 3% of total UK manufacturers. See UK Business Counts - enterprises by industry and employment size band (<https://www.nomisweb.co.uk/>)

⁵ Estimates are 2017-19 averages. See the *UK import values of UKCA applicable products* publication, available here: <https://www.gov.uk/government/publications/uk-import-values-of-ukca-applicable-products>

⁶ Based on UK imports of goods value (2019). <https://www.gov.uk/government/statistics/uk-trade-in-numbers/uk-trade-in-numbers-web-version>. 2019 data is used to compare against the data in the *UK import values of UKCA applicable products* publication.

20. The evidence for calculations in this Impact Assessment builds on the evidence from industry engagement with manufacturers and CABs conducted between 2017 and 2020 and used in the 2020 Impact Assessment for the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020.⁷ Since 2020, we have been developing our evidence base further through additional engagement with businesses. This includes a survey we conducted in Summer 2023 which received approximately 110 responses from UK businesses. The response rates vary by question. The sample is not representative of all UK businesses impacted by this SI, but the findings, in conjunction with wider evidence, have allowed us to check previous assumptions on conformity assessment, marking and labelling, and familiarisation costs.⁸
21. Due to the heterogeneity of businesses and sectors affected by the SI, we were not able to collect sufficiently detailed data at the sector level to use sector-specific assumptions in the cost calculations. Rather, we estimate broad averages from the data collected across all sectors, and develop low, central, and high costs estimates to take account of uncertainty in our assumptions. Where there has not been sufficient data to quantify impacts on businesses, we have provided a qualitative assessment of impacts based on information from businesses. One of our main sources for qualitative evidence is a series of industry roundtables conducted in Spring and Summer 2023 with more than 170 organisations.
22. The evidence for the assumptions used in our assessment of impacts are described in more detail in the relevant sections below and in Table 2.

Description of options considered

Option 0: Do Nothing

23. UKCA becomes mandatory on 1 January 2025 for the regulations covered under this legislation; and CE marking is no longer recognised.
24. The transitional easements legislated for in November 2022 would continue as set out below.
- Reduced re-testing costs: Any conformity assessment activities undertaken by EU bodies before the end of 2024 will be considered as the basis of certification for UKCA marking. These certificates will be valid until 2027 or when the certificate expires, whichever is sooner.
 - Removed need to re-test existing imported stock: This allows CE marked products that are manufactured and imported into the UK by the end of 2024 to be sold, without the need to meet UKCA requirements. This will

⁷ Available here: <https://www.legislation.gov.uk/ukdsi/2020/9780348213393/impacts>

⁸ Previous industry engagement was also not based on representative samples.

remove the current need for retesting and recertification for products that are imported whilst the UK recognises CE requirements.

- Continued labelling measures: To make it cheaper and logistically easier for businesses by allowing the UKCA marking to be placed on a label affixed to the product or on a document accompanying the product. This easement lasts until 11pm on 31 December 2027. After 1 January 2028, in most cases, businesses must affix the UKCA marking to the product itself or to the packaging to continue to supply goods to Great Britain.

Option 1: Extend CE marking recognition indefinitely (Preferred Option)

25. There is continued acceptance of products assessed under the EU regulations and CE marked products may continue to be placed on the GB market indefinitely for the sectors covered under this legislation.

Extend CE Recognition

26. The extension of CE recognition will revoke the sunset clause, currently lasting until 31 December 2024, making the recognition of CE indefinite.

Additional Measures

27. We also intend to include two additional measures, Measure A and Measure B, to give businesses additional flexibility and to maximise the benefits of CE extension. These are set out below.

Measure A: *Ensure that the reference to the relevant EU legislation is a reference to the latest version, whilst maintaining as much flexibility as possible to further update using REUL Act powers at a later date.*

28. Currently, CE marked goods accepted on the GB market must meet EU requirements as they stood on Implementation Period completion date (31 December 2020).
29. There have been some minor changes to some EU law since 31 December 2020. We have assessed the changes as largely minor. Therefore we plan to recognise the latest EU requirements to enable businesses to take full advantage of continued CE recognition and reduce confusion. If we do not update the recognition date, it will become more difficult for some businesses to use CE for the GB market, particularly where EU regulations have changed. Manufacturers of these products may therefore face confusion over requirements or be disincentivised from placing products on the GB market.

Measure B: *Where multiple regulations apply to a product, enable manufacturers to use UKCA marking to demonstrate compliance with UKCA regulations and recognised CE regulations.*

30. Many products are covered by multiple regulations. Current policy requires compliance with all GB regulations covered by UKCA. This means where products are covered by multiple regulations, manufacturers may have to re-certify products to UKCA requirements across all applicable regulations if UKCA became mandatory for any of the regulations. This would mean manufacturers would potentially have to duplicate conformity assessments.
31. To illustrate, consider an example whereby a product is covered by regulations 1, 2 and 3. For product regulation 1, it is decided to mandate UKCA for new regulations in the interests of British consumers. The CE marking will continue to be recognised for product regulations 2 and 3. If we do not take action, manufacturers may need to go through UKCA processes for all applicable regulations, even though CE would still be recognised for the majority.
32. Measure B intends to future proof our CE recognition policy to reduce future costs for businesses. If the UK decides to exercise its Brexit freedoms to end recognition of CE marking in one set of regulations, manufacturers can still rely on EU conformity assessment procedures for regulations where they continue to be recognised.
33. In cases where businesses may want to use a mix of UKCA and CE for commercial purposes, they will also be able to do so with this measure. This will allow manufacturers to use the UKCA mark to demonstrate products meet EU regulations in areas where they are still recognised and comply with GB requirements in areas where EU rules are not recognised.

Other Options Considered

34. Additional options have also been considered ahead of the decision to introduce this SI. These included: Provide another time-limited period of CE recognition whereby UKCA becomes mandatory for the regulations covered under this legislation; and CE marking is no longer recognised from a later date (beyond 1 January 2025).
35. However, this was rejected as industry feedback indicated that time limited extensions continue to create uncertainty which can limit some investment and therefore reduce growth.
36. We have also previously considered sector specific extensions to CE recognition. Given the interconnected nature of sector regulations where many regulations often cover a single product, our assessment concluded that this approach was likely to create confusion. It would also mean some

products would benefit from reduced compliance processes whilst others would not; this would be difficult to justify.

Costs and Benefits of each option

37. The quantification of impacts in this section first considers the additional conformity assessment costs and the additional marking and labelling costs in Option 0 that do not occur in Option 1, our preferred option. It then considers the additional familiarisation costs that occur in Option 1, the preferred option, that do not occur in Option 0. We assume impacts first occur in 2024, when the legislation takes effect.

38. We assume in Option 0 that all UK businesses that were not using UKCA at the time of the announcement to extend CE recognition will start using UKCA when they are required to in the legislation. We assume in Option 1 that the share of businesses that were using UKCA at the time of the announcement to extend CE recognition remains constant in the future. In the calculations, we also assume a flow of new product ranges⁹ each year and, for simplicity, we assume a constant population of businesses. Impacts are estimated over a 10-year period. We do not assume any further changes to UK or EU regulations over the horizon of the analysis. Should the UK stop recognising CE marking in the future by introducing additional legislation, potential cost savings could be lower than those quantified in the calculations. However, there may also be benefits from any such legislation, for example, safety or environmental benefits, that are also not quantified in the calculations of this Impact Assessment.

Summary of Impacts

39. Our estimates show a total net present value benefit of around £640.5m under Option 1, the preferred option, relative to Option 0: Do Nothing (see Table 1). Benefits to manufacturers from duplicative conformity assessment cost savings make the largest contribution to the total net benefit of Option 1 relative to Option 0: Do Nothing.

40. Table 1 summarises the quantified impacts that occur in Option 1: Extend CE marking recognition indefinitely (the preferred option), relative to Option 0: Do Nothing. The quantified benefits incurred in Option 1, the preferred option, are via avoiding costs that would have been incurred under Option 0: Do Nothing.

41. Further information on the impacts incurred under each option, and details on the data and assumptions underpinning the quantified impacts and the policy dynamics that result in these impacts are provided below within this section.

⁹ A product range refers to one type of product which requires third-party conformity assessment to be sold in GB or EU.

Table 1: Summary of quantified impacts in Option 1: Extend CE marking recognition indefinitely, relative to Option 0: Do Nothing

Description	Directly impacted party	Cost or benefit	Type	Low (2023 prices)	Best (2023 prices)	High (2023 prices)
Additional duplicative conformity assessment cost-savings	Businesses	Benefit	On-going	£160.9m	£584.0m	£1.5bn
Additional labour time costs-savings for obtaining conformity assessment	Businesses	Benefit	On-going	£8.4m	£33.6m	£84.0m
Additional marking/labelling cost-savings	Businesses	Benefit	One-off	£18.4m	£31.0m	£46.8m
Familiarisation costs	Businesses	Cost	One-off	£3.0m	£8.1m	15.2m
Total net impacts	Businesses	Net Benefit	-	£184.7m	£640.5m	£1.66bn

Note: Quantified impacts are estimated over a 10 year time period and discounted with 2024 as the present value base year. Note that the benefits that occur in Option 1, the preferred option, relative to Option 0 are costs that occur in Option 0 but not Option 1.

Option 0: Do Nothing

Additional Conformity Assessment Costs

42. From 1 January 2025, businesses would no longer be able to put manufactured goods on the GB market which have only been conformity assessed against the EU’s product regulations (i.e. those that are CE marked). This will apply to all Department for Business and Trade product sectors¹⁰ and some product regulations, which may overlap, under the Department for Environment, Food and Rural Affairs, the Health and Safety Executive, and the Department for Energy Security and Net Zero. Products

¹⁰ The Department for Business and Trade product sectors in scope of this SI: Toys, Pyrotechnics, recreational craft and personal watercraft, simple pressure vessels, electromagnetic compatibility, non-automatic weighing instruments, measuring instruments, measuring container bottles, Lifts, equipment for potentially explosive atmospheres (UKEX), radio equipment, pressure equipment, personal protective equipment (PPE), gas appliances, Machinery, equipment for use outdoors, aerosol dispensers, low voltage electrical equipment.

The following sectors fall under the scope of other Governmental Departments who are also included within this SI: Department for Environment, Food and Rural Affairs for Hazardous substances in electrical equipment (“RoHS”), Health and Safety Executive for Civil Explosives, and Department for Energy Security and Net Zero for Eco-Design.

requiring conformity assessment will need assessment with a UK Approved Body¹¹ and will require UK certificates to prove their compliance to UK regulations. UK conformity marking will have to be applied to all products which require it.

43. This would mean that for manufacturers, it will no longer be sufficient to place goods on the GB market which have been assessed against the EU product regulation scheme. Hence manufacturers that had only been using CE marking would incur additional duplicative conformity assessment costs (either certification or full conformity assessment) resulting from the requirement to meet two regulatory regimes (UKCA and CE) when placing products on both markets.
44. The Government, as part of the Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 SI, introduced a retesting easement to facilitate the transition from CE product marking to UKCA marking. The retesting easement permits conformity assessment activities undertaken by EU Notified Bodies for CE certification before 11pm on 31 December 2024 to be used by manufacturers to declare *existing* product types as compliant with UKCA requirements.
45. Therefore, if an EU Notified Body has completed the relevant conformity assessment activities applying to a product before 11pm on 31 December 2024, this would allow manufacturers to apply the UKCA mark without the need for any UK Approved Body involvement.¹² They could continue to place their goods on the market based on their existing CE certification for the lifetime of the certificate issued, or until 31 December 2027 (whichever is sooner). After this point, they would be required to undergo conformity assessment with a UK Approved Body; and bear the UKCA marking on their products.
46. Under the Option 0: Do Nothing scenario, from 2025, there will be an impact on manufacturers who are not compliant with the UK's products safety regime. These businesses will incur the costs associated with UK conformity assessment to place goods on the GB market.
47. There are 21 directives/regulations in scope of the SI that require all or some of the products covered by the regulations to have had third-party conformity assessment by a Notified Body before placing on the market. Currently UK manufacturers can use a Notified Body in the EU to access both the EU and GB markets. This provision will end in 2025 under Option 0. Manufacturers will be required to use a UK-recognised body (which will be known as an

¹¹ A UK Approved Body is a conformity assessment body that has been officially appointed to undertake conformity assessment activities to demonstrate that specified goods meet the essential health and safety requirements to be placed on the GB market. UKAS (2021).

¹² An EU Notified Body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the EU market. Definition taken from the European Commission.

Approved Body) to place goods on the GB market, and where applicable, an EU-recognised body to place goods on the EU market.

Number of businesses impacted

48. We do not consider the impacts of this SI on non-UK businesses in this IA, including non-UK manufacturers exporting goods to be placed on the GB market. The scope of manufacturers impacted by additional conformity assessment costs include those under the Department for Business and Trade product regulations¹³ and some product regulations under the Department for Environment, Food and Rural Affairs, the Health and Safety Executive, and the Department for Energy Security and Net Zero. We estimate the impacts of additional conformity assessment costs on the UK manufacturers who are not compliant with the UKCA regime (estimated to be 52% of manufacturers in scope of this SI¹⁴); and those who export to the EU (estimated to be 20%¹⁵).

49. Manufacturers who have had certificates issued by EU Notified Bodies, before 1 January 2025, can benefit from the retesting easement in current legislation. This will mean that manufacturers are not required to have their goods which are covered by these certificates assessed against the UK's regulatory regime until the end of 2027, or when their certification expired, whichever is sooner. This easement does not apply to new products introduced and conformity assessed from 2025.¹⁶

¹³ The Department for Business and Trade product sectors in scope of this SI: Toys, Pyrotechnics, recreational craft and personal watercraft, simple pressure vessels, electromagnetic compatibility, non-automatic weighing instruments, measuring instruments, measuring container bottles, Lifts, equipment for potentially explosive atmospheres (UKEX), radio equipment, pressure equipment, personal protective equipment (PPE), gas appliances, Machinery, equipment for use outdoors, aerosol dispensers, low voltage electrical equipment.

The following sectors fall under the scope of other Governmental Departments who are also included within this SI: Department for Environment, Food and Rural Affairs for Hazardous substances in electrical equipment ("RoHS"), Health and Safety Executive for Civil Explosives, and Department for Energy Security and Net Zero for Eco-Design.

¹⁴ ONS Business Insights and Conditions Survey (BICS) data available here:

<https://www.ons.gov.uk/economy/economicoutputandproductivity/output/datasets/businessinsightsandimpactontheukeconomy> Survey data from wave 81 is utilised, which was published on 4 May 2023 covering the period 17 April – 30 April 2023. The relevant survey question asked: 'Is your business using, or intending to use, the UKCA marking by 1 January 2025?'. 47.9% of responses self-categorised by businesses as those 'manufacturing products that need a CE or UKCA marking' selected the response 'already using UKCA marking'. The survey data reflects percentage of businesses not permanently stopped trading and business which require the CE marking or new UKCA marking, weighted by count. We assume in the calculations that those who report to be using UKCA are using it for all their products while those who do not report using UKCA are not using UKCA for any of their products.

¹⁵ To calculate the share of UK manufacturers exporting to the EU, we combine data from the latest ONS Annual Business Survey (ABS); and HMRC UK trade in goods, for the year 2021. The ONS ABS finds that 23% of businesses are exporters in the manufacturing industry. The HMRC UK trade data reports that for selected industry groups, 87% of businesses that are exporters, export to the EU. Multiplying this figure with the 23% figure from the ONS ABS allows us to estimate that 20% of manufacturers export to the EU. We assume this applies for the manufacturing sectors in scope of this SI.

When considering the HMRC dataset, we focus on manufacturing industry groups. Our focused industry groups are 3-9 which are: Group 3 – Chemicals; Group 4 – Pharmaceuticals; Group 5 - Electronic & Electrical equipment; Group 6 - Machinery & equipment n.e.s.; Group 7 - Motor vehicles, transport equipment; Group 8 - Aerospace and related machinery; Group 9 - Other manufacturing. See:

<https://www.ons.gov.uk/businessindustryandtrade/business/businessservices/datasets/annualbusinesssurveyimportersandexportersindustrybreakdown>; <https://www.gov.uk/government/statistical-data-sets/uk-trade-in-goods-by-business-characteristics-2021-data-tables>

¹⁶ For the purposes of this Impact Assessment, a product range refers to a category of product or products which require a single conformity assessment to be sold in each market.

50. Only businesses that export to the EU will incur duplicative conformity assessment costs for the same product range. Businesses that do not export to the EU and that are currently using CE would need to get UK conformity assessment certificates in Option 0. However, in our cost calculations we assume that businesses that do not export to the EU would not incur any additional conformity assessment costs because they would still only be undertaking one set of conformity assessments for a given product range. We also assume that the cost of conformity assessment under CE is the same as the cost of conformity assessment under UKCA, resulting in no additional costs to these businesses.
51. We estimate that around 1,500 to 2,400 UK manufacturers may incur additional duplicative conformity assessment costs in Option 0 (central estimate 2,000). This estimate considers manufacturers under the Department for Business and Trade product regulations¹⁷ and some product regulations under the Department for Environment, Food and Rural Affairs, the Health and Safety Executive, and the Department for Energy Security and Net Zero, who are not UKCA ready, and require conformity assessment with a CAB and sell in both the GB and EU markets. We assume that these businesses would typically have their certification with EU bodies and would face duplicative conformity assessment costs to continue to supply goods on the GB market.

Cost to businesses – additional duplicative conformity assessment costs

52. Under Option 0, we estimate: the costs to manufacturers from paying for duplicative conformity assessments; and the additional labour time cost in getting products conformity assessed again. We consider these costs over a 10 year period.
53. We assume that each year manufacturers will have on average between 4 - 8 product ranges (central estimate of 6) which require conformity assessment from a third party. This includes new product ranges¹⁸ which are first placed on the market and product ranges which will require reassessment from a third party due to the previous product certifications reaching their expiry dates. These assumptions are supported by findings from stakeholder engagement and our summer 2023 business survey. In this survey the average number of new or updated product ranges that are subject to the

¹⁷ The Department for Business and Trade product sectors in scope of this SI: Toys, Pyrotechnics, recreational craft and personal watercraft, simple pressure vessels, electromagnetic compatibility, non-automatic weighing instruments, measuring instruments, measuring container bottles, Lifts, equipment for potentially explosive atmospheres (UKEX), radio equipment, pressure equipment, personal protective equipment (PPE), gas appliances, Machinery, equipment for use outdoors, aerosol dispensers, low voltage electrical equipment.

The following sectors fall under the scope of other Governmental Departments who are also included within this SI: Department for Environment, Food and Rural Affairs for Hazardous substances in electrical equipment ("RoHS"), Health and Safety Executive for Civil Explosives, and Department for Energy Security and Net Zero for Eco-Design.

¹⁸ A product range refers to one type of product which requires third-party conformity assessment to be sold in GB or EU.

UKCA or CE mark regulations each year was 11.¹⁹ Of each businesses' total number of product ranges that are subject to the UKCA or CE mark regulations, not all product ranges would require third party conformity assessment as some can be self-certified. We therefore judge that our assumption of between 4 and 8 product ranges (central estimate of 6) which require conformity assessment from a third party to be broadly consistent with this survey evidence.²⁰

54. Products subject to duplicative third-party conformity assessment will require either a full conformity assessment or less intensive recertification depending on whether the CAB will accept some or all of reports undertaken previously. UK CABs have the authority to not accept the results of EU Notified Bodies and to require manufacturers to have a full conformity assessment before a UK certificate is issued. For both new product ranges and those requiring reassessment from a third-party, we assume that 40% will require full conformity assessment, and 60% will require less intensive recertification only.²¹ Our engagement with manufacturers suggests that many CABs would not require manufacturers to have a full assessment. However, some CABs suggested that they may have to carry out full assessments if past assessment reports are not satisfactory or they were concerned that accepting the results of other bodies may impact their legal position or reputation.
55. Our analysis assumes that, on average, full conformity assessment costs per product range are between £7,500 and £20,000 (central estimate of £13,300). This estimate is based on evidence summarised in the 2020 Impact Assessment²² (updated to account for inflation) and additional evidence from a business survey we conducted in summer 2023.

¹⁹ The summer 2023 business survey asked businesses: 'On average, how many new product ranges do you introduce or update each year that are subject to the UKCA or CE mark regulations? This refers to new types of product ranges rather than individual units'. This question received 74 responses with a weighted mean of 10.7. The responses to the business survey were weighted by a business size measure representing the proportion of SMEs and non-SMEs producing manufactured goods.

²⁰ As an illustration, approximately 60% of the UKs imports of goods that require a UKCA or CE mark may require third party conformity assessment. See estimates in the *UK import values of UKCA applicable products* publication available here: <https://www.gov.uk/government/publications/uk-import-values-of-ukca-applicable-products>

²¹ These assumptions are based on evidence summarised in the 2020 Impact Assessment. The assumptions are also checked against new evidence from a business survey we conducted in summer 2023. The summer 2023 business survey asked businesses a related, but not directly comparable, question: 'If you have obtained UKCA certification for product ranges requiring third party assessment and the products already had CE certification, to what extent were you required to do a full conformity assessment (including new testing) or rely on testing undertaken for CE?'. Businesses were provided with the following response options (with the proportion of all responses for each response in brackets):

- Full conformity assessment and new testing required for all products (9%);
- Full conformity assessment and new testing required for most products while able to rely on testing for CE in a minority of cases (8%);
- Full conformity assessment and new testing required for a minority of products while able to rely on testing for CE in most cases (30%);
- We were able to rely on testing undertaken for CE for all products.(31%);
- We have not obtained UKCA certification for products that already had third party conformity assessment for CE certification (21%).

While it is not possible to precisely estimate the proportion of products requiring a full assessment with this evidence, the responses to this question are not inconsistent with evidence collected previously.

²² The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 available at: <https://www.legislation.gov.uk/ukdsi/2020/9780348213393/impacts>

56. Although our analysis assumes an average cost for conformity assessment, the precise cost for each manufacturer and product range is dependent on the product type, type of assessment required and the manufacturer's characteristics such as assessment history and level of in-house expertise. For example, a large manufacturer covering multiple product regulations reported that on average, full conformity assessment costs per product range are £15,000, whereas another medium sized manufacturer of products under a number of regulations affected by this SI reported average full conformity assessment costs as £10,000. Overall responses to our business survey in summer 2023 found that full conformity assessment costs per product range varied from £1,500 on average for the respondent reporting the lowest average costs to £200,000 on average for the respondent reporting the highest average costs.
57. In addition, we assume that on average, the cost of the less intensive recertification only is between £1,000 - £4,000 (central estimate of £2,000). This is also informed by the summer 2023 business survey as well as evidence from previous business engagement. For example, a small manufacturer of electronic products reported that on average the cost of recertification only is £2,000, and a medium sized manufacturer of gas appliance products said these costs are £1,500.
58. The costs incurred for each product range will depend on whether UK Approved Bodies will require manufacturers to have a full assessment to issue a certificate or will be able to review the reports from the EU Notified Bodies and issue the certificate at a lower cost.
59. The scale and cost of each assessment required will depend on each manufacturer, product type, and CAB. The scope of assessment could range from situations where CABs review test reports from other testing bodies and issue new certificates, to full assessments where multiple audits and product checks could be carried out. Due to a lack of data and the variety of products and businesses in scope we are not able to quantify the full extent of this heterogeneity.
60. To estimate the total additional duplicative conformity assessment costs, we combine the number of UK manufacturers impacted with the estimated average number of product ranges per business that would require conformity assessment each year. The total additional duplicative conformity assessment costs for UK manufacturers under Option 0: Do Nothing, using 2023 prices, discounted over a 10 year period, is therefore estimated to be between £160.9m (low scenario) and £1.5bn (high scenario), with a central estimate of £584m. See Figure 1 for an illustration of calculating the estimate.

Conformity Assessment – Additional labour time cost

61. Manufacturers who require duplicative conformity assessment for their product ranges will incur costs from dedicating additional labour time to have products conformity assessed, as well as paying for conformity assessments. This could include: searching for an appropriate CAB and comparing quotes; time to contact and liaise with a CAB; completing forms/documentation; arranging for products to be sent to a CAB for conformity assessment etc. In our quantification of the labour time dedicated to obtaining conformity assessment certification for a product, we do not consider the total length of time to conformity assess a product from the point of starting the process to the point of completing the process. We consider only the additional time dedicated to conformity assessing a product. During this period, manufacturers can assign labour time to other tasks.
62. Our labour time cost estimates apply to the same scope of manufacturers that will incur duplicative conformity assessment costs.
63. We assume that on average between 5-15 hours (central estimate of 10 hours) of labour time will be dedicated to additional conformity assessment processes per product range requiring conformity assessment. The Department for Business and Trade's engagement with manufacturers suggests that manufacturers spend a sizeable amount of their time on conformity assessment activities. In our summer 2023 survey, business reported that they spend approximately a weighted-average of 71 hours per month on all conformity assessment activities. The assumption of 5-15 hours dedicated to additional conformity assessment processes per product range (central estimate of 10 hours) is our judgement and in practice the additional time cost for some businesses may be greater than our assumption and for other businesses, it may be lower.
64. We assume the labour cost per hour is £38, comprised of £32 average hourly wage²³ and an 18%²⁴ uplift to factor non-wage labour costs.
65. Thus under Option 0, the total additional labour time costs, in 2023 prices, discounted over a 10 year period, for getting products conformity assessed is estimated to be between £8.4m (low scenario) and £84m (high scenario), with a central estimate of £33.6m in the central scenario.
66. Under Option 0, the total additional costs incurred for duplicative conformity assessment and labour time, in 2023 prices, discounted over a 10 year period

²³ Average hourly gross wage for corporate manager or director is used, data from ONS Annual Survey of Hours and Earnings (ASHE) for 2022, uplifted to 2023 prices.

²⁴ Non-wage labour cost uplift of 18% calculated using ONS data on Index of Labour Costs per Hour. The data we consider is for the non-wage labour costs as a share of wages for the UK economy. The data is based on latest available estimates covering the average of the period between Quarter 4 2019 – Quarter 3 2020.
<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/indexoflabourcostsperhour/quarterly/quarterlytoquarterly2020>

are estimated to be £617.7m in the central scenario (ranging between £169.3m and £1.6bn). See Figure 2 for further details.

Figure 1: Additional Duplicative Conformity Assessment Cost Calculation in Option 0

Step 1: Total number of UK manufacturers incurring additional duplicative conformity assessment costs

- A. Number of manufacturers in scope: 13,900 – 23,200 (central est. 18,500)
x
B. Share of UK manufacturers not currently using UKCA: 52%
x
C. Share of UK manufacturers exporting to the EU: 20%

$$\mathbf{A \times B \times C = 1,500 - 2,400}$$

Central Estimate: 2,000

Step 2: Additional duplicative conformity assessment costs for products requiring full assessment or recertification per business per year

- A. Product ranges per business that need full assessment or recertification per year: 4 – 8 (central est. 6)
x
B. Share of products which will require full assessment (including testing): 40% in all scenarios
x
C. Full conformity assessment cost: £7,500 - £20,000 (central est. £13,330)
+
D. Product ranges per business that need full assessment or recertification per year: 4 – 8 (central est. 6)
x
E. Share of products which will require recertification: 60% in all scenarios
x
F. Cost of recertification: £1,000 - £4,000 (central est. £2,000)

$$\mathbf{(A \times B \times C) + (D \times E \times F) = \pounds 14,400 - \pounds 83,200}$$

Central Estimate: £39,200
(2023 prices)

Step 3: Total additional conformity assessment costs for products requiring third party full conformity assessment or recertification per business per year

Step 1 (Total number of UK manufacturers incurring additional duplicative conformity assessment costs)

x

Step 2 (Additional duplicative conformity assessment costs for products requiring full assessment or recertification per business per year)

$$\mathbf{= \pounds 21.2m - \pounds 203.7m}$$

Central Estimate: £76.8m
(2023 prices)

Note: Calculations presented may not equal precisely due to rounding but the underlying calculations are based on unrounded inputs.

Figure 2: Additional labour time costs from getting products conformity assessed (requiring full assessment or recertification) in Option 0, per year

Additional Time costs on getting products conformity assessed, per business, per year

- A. Number of businesses in scope: 1,500 – 2,400 (central est. 2,000)
x
- B. Product ranges per businesses per year: 4 – 8 (central est. 6)
x
- C. Time to get products conformity assessed (hours): 5 – 15 hours (central est. 10 hours)
x
- D. Average hourly wage for a corporate manager or director: £31.88
x
- E. Non-wage labour cost uplift: (1 + 18%)

$$\mathbf{A \times B \times C \times D \times E = \pounds 1.1m - \pounds 11m}$$

Central estimate: £4.4m
(2023 prices)

Note: Calculations presented may not equal precisely due to rounding but the underlying calculations are based on unrounded inputs.

Marking and Labelling

67. In the Option 0: Do Nothing scenario, businesses who are not UKCA ready (that is, those who have not yet put a UK conformity mark or label on their products) will incur a cost associated with permanently marking their products ahead of the labelling easement ending on 31 December 2027. The labelling easement currently allows manufacturers to place the UKCA marking on a label affixed to the product or on a document accompanying the product.
68. We assume that businesses who are not yet using UKCA will permanently mark their products in 2027. Businesses can utilise the labelling easement until that point which would involve businesses incurring a lower cost from affixing a sticky label to a product or packaging relative to physically marking a product. We have not quantified the impact from affixing a sticky label to a product or packaging for a temporary period but we expect that the costs to businesses would be low. In practice, some businesses may choose to permanently mark their products earlier than 2027.
69. We estimate that between 7,200 and 12,000 (central est. 9,600) UK manufacturers are not UKCA ready and will incur the permanent marking and labelling cost. This estimate is based on the number of UK manufacturers which are subject to this SI and considers evidence from the ONS Business Insights and Impact on the UK Economy survey (BICS) that indicates that 48% of UK manufacturers are currently using the UKCA marking.
70. Engagement with manufacturers suggests that the cost of adding the UK conformity marking varies between businesses and across sectors, ranging from minimal costs to tens of £1000s. Two out of 40 manufacturers interviewed reported that the cost of adding the UKCA mark would be minimal.²⁵ One manufacturer suggested a new printer for labels would cost around £1,000. Other costs can come from changing labelling software, purchasing new marking tools, hiring engineers to redesign labels, or some businesses may need to develop new production lines for a new marking. However, costs depend heavily on the type of products and manufacturing processes. For example, an industry representative for electronic products estimates that changing a tool to incorporate new conformity marking can cost over £20,000 per product range.
71. Due to a lack of data at the sector level, we aggregated data across all sectors. To estimate the average cost of new marking across all businesses impacted by this SI, we assume 3 categories of business costs for marking per business: low costs of £1,150; central costs of £5,750; and high costs of £11,500. We assume that the proportion of manufacturers with low, central, or high costs is 60%, 30% and 10% respectively in a central scenario. We assume that each business incurs these costs once. The assumptions used

²⁵ This evidence is from engagement conducted with manufacturers in 2019 and 2020 for the 2020 SI.

here are broadly consistent with the assumptions used in the Impact Assessment for the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020. They have been uplifted by the cumulative GDP deflator change between 2019-2023 to account for inflationary pressures. The low scenario assumes a greater proportion of businesses have low costs (£1,150), and a lesser number have high costs (£11,500).²⁶ For the high scenario, the opposite applies.

72. Under the Option 0: Do Nothing scenario, the total additional costs of marking/labelling, are estimated to be £31m in the central scenario (estimated range £18.4m - £46.9m), in 2023 prices and discounted. We assume the costs will be incurred in 2027 when the labelling easement expires. See figure 3 for more details.

²⁶ Our scenario analysis considers the following adjustments to data variables in order to calculate a weighted average for permanent marking/labelling cost per business:

In the low scenario, 70% of manufacturers in scope will face a low cost of new marking per business (£1,150); 25% will face a medium cost of new marking per business (£5,750); and 5% will face a high cost of new marking per business (£11,500). In the central scenario, 60% of manufacturers in scope will face a low cost of new marking per business (£1,150); 30% will face a medium cost of new marking per business (£5,750); and 10% will face a high cost of new marking per business (£11,500). In the high scenario, 50% of manufacturers in scope will face a low cost of new marking per business (£1,150); 35% will face a medium cost of new marking per business (£5,750); and 15% will face a high cost of new marking per business (£11,500).

Figure 3: Additional Marking and Labelling Cost Calculation in Option 0

Step 1: Total number of UK manufacturers incurring additional marking and labelling costs

- A. Number of manufacturers in scope: 13,900 – 23,200 (central est. 18,500)
x
B. Share of UK manufacturers not currently using UKCA: 52%
=
C. Number of UK manufacturers not UKCA ready: 7,200 – 12,000 (central est. 9,600)

Step 2: Total additional marking and labelling costs

- A. Number of UK manufacturers not UKCA ready: 7,200 – 12,000 (central est. 9,600)
x
B. Average cost of adding new marking per business: £2,815 - £4,309 (central est. £3,560)
Cost of new marking per business: £1,150 - £11,491 (central est. £5,745)
x % of manufacturers with low/medium/high costs (60%/30%/10% in central scenario)

= £20.4m - £52.0m

Central estimate: £34.4m
(2023 prices)

Note: Calculations presented may not equal precisely due to rounding but the underlying calculations are based on unrounded inputs.

Option 1: Extend CE marking recognition indefinitely (preferred option)

Familiarisation Costs

73. Under Option 1, the preferred option, manufacturers, Approved Bodies, the United Kingdom Accreditation Service (UKAS)²⁷, distributors, retailers, and enforcement bodies will have to familiarise themselves with the new legislation. The SI accompanying this Impact Assessment will enable the continued recognition of the EU's product regulation regime alongside the UK's regime for placing manufactured goods on the GB market. Hence those businesses subject to the legislation will have to dedicate time familiarising themselves with the change in legislation and decide if they want to change how they operate.
74. Our central estimate shows 107,800 businesses are in scope of this SI. It is comprised of 88,900 UK retailers and wholesalers; 18,500 manufacturers; and 360 conformity assessment approved bodies and local authorities. See Figure 4 for further details.
75. Businesses will need to read and understand the changes in product regulation policy, end date of the deeming provision, minor amendments to specific regulations, and consider whether the regulatory changes apply to their business as only 21 product sectors are covered by this SI. We assume that it will take on average between 1 and 3 hours (2 hours in our central scenario) for a corporate manager or director to familiarise themselves with the new legislation in each organisation and communicate the changes to staff.²⁸
76. We assume the labour cost per hour is £38, comprised of £32 average hourly wage²⁹ and a 18% uplift to factor non-wage labour costs. Further, we expect all manufacturers providing goods subject to product regulations to already be familiar with the relevant product regulations, conformity assessment processes and other general processes for gaining approval for products to be supplied onto the GB market.
77. The range accounts for variability between businesses in the time needed to read and comprehend the changes. Some businesses may take longer than 3 hours, for example if businesses need to communicate the changes to overseas suppliers. Other businesses may take less time 1 hour.
78. Under Option 1, the preferred option, there will be familiarisation costs for manufacturers, approved bodies, UKAS, importers, retailers, wholesalers, and local authorities. This results in an aggregate cost estimate of £8.1 million in

²⁷ The United Kingdom Accreditation Service is the sole national accreditation body recognised by the British government to assess the competence of organisations that provide certification, testing, inspection and calibration services.

²⁸ This is also consistent with the range used in the Impact Assessment for the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020.

²⁹ Average hourly gross wage for corporate manager or director is used, data from ONS Annual Survey of Hours and Earnings (ASHE) for 2022, uplifted to 2023 prices.

our central scenario (2023 prices). See Figure 4 for details. The familiarisation costs are assumed to be one-off and will be incurred in the base year when the new legislation is introduced, 2024.

79. We assume in the calculations that familiarisation costs are one-off costs. It is possible that extending CE marking recognition will lead to some businesses choosing to monitor both the requirements for UKCA marking and CE marking over time when under Option 0, they may only monitor the requirements for UKCA marking. This is not quantified in the calculations as there is limited evidence to suggest that businesses would incur such additional costs in Option 1 and we do not assume any further changes to UK or EU regulations over the horizon of the analysis. Some businesses will monitor both the requirements for UKCA marking and CE marking in either Option 0 or Option 1. There is also no obligation for businesses to monitor the requirements for both UKCA marking and CE marking over time in Option 1.

Figure 4: Option 1 Familiarisation Cost Calculation

1) Familiarisation costs to businesses in scope occurring in year 1

- A. Number of businesses in scope: 81,000 – 134,700 (central est. 107,800)
- x
- B. Average time taken to read and understand legislation: 1 – 3 hours (central est. 2 hours)
- x
- C. Average hourly wage for a corporate manager or director: £31.88
- x
- D. Non-wage labour cost uplift: (1 + 18%)

A x B x C x D = £3m - £15.2m

Central estimate: £8.1m

(2023 prices)

Note: Calculations presented may not equal precisely due to rounding but the underlying calculations are based on unrounded inputs.

Small and micro business assessment

80. As this SI reduces duplicative costs and burdens faced by businesses when placing goods on the GB market, no exemption for small and micro businesses would be needed to limit any possible adverse effects of the legislation on small and micro businesses.
81. We expect that many small and micro businesses will be impacted by this SI. In 2022, 97% of all manufacturing businesses in the UK were classed as small (0-49 employees).³⁰ We have imperfect information on the number of small and micro businesses impacted by the implementation of this SI and the extent to which they will be disproportionately impacted relative to large businesses. Some impact channels could disproportionately impact large businesses while other impact channels could disproportionately impact small and micro businesses.
82. This SI will particularly benefit manufacturers who export goods and larger businesses are more likely to export than smaller businesses. ONS evidence finds that 23% of manufacturers in Great Britain were exporters in 2021.³¹ In addition, while not specific to the manufacturing sectors in scope of this SI, further evidence from the ONS finds that: 5% of businesses in Great Britain with 1 to 49 employees export goods; 21% of businesses in Great Britain with 50 to 249 employees export goods; and 25% of businesses in Great Britain with at least 250 employees export goods.³² Familiarisation costs may also be incurred by all businesses in scope of the legislation and such costs may represent a larger cost relative to total costs for smaller businesses.
83. At the same time, where small and micro businesses experience cost savings as a result of this SI, they may see a greater benefit than corresponding larger businesses as a proportion of their total costs. The costs to business of conformity marking and conformity assessment are often per business or per product range, meaning they can represent a greater share of total costs for smaller businesses than larger businesses. As such, smaller businesses could particularly benefit from reductions in duplicative conformity assessment costs for products that are placed on both the GB and EU markets. Cost savings for each business will depend on the type and design of products that it produces rather than the quantity produced.

³⁰ Business population estimates (BPE) for the UK; 2022. Note: not all manufacturing businesses would be in scope of this SI.

³¹ ONS (2023), *Exporters and importers by industry breakdown (Annual Business Survey)*

³² ONS (June 2023), *Annual Business Survey exporters and importers: 2021*.

Wider impacts

Impact on Conformity Assessment Bodies (CABs)

84. The demand for UK conformity assessment services is likely to be lower in Option 1 than Option 0. This is because some manufacturers, particularly those selling products in both the GB and the EU, will choose to use the CE marking on their products as this will allow them to reduce duplicative conformity assessment costs. Consequently, UK-based CABs could be impacted negatively due to loss of revenue from UK conformity assessment services. Note that the impact on CABs' overall profits in Option 1, relative to Option 0, is affected by changes to both revenue and costs. If CABs are providing less conformity assessment services in Option 1, some of CABs' operating costs (e.g. some labour costs, product testing costs) will reduce alongside the reductions in revenue. Therefore, the total reduction in CABs' profit in Option 1 will be smaller than the total reduction in CABs' revenue. The total reduction in CABs' profit will also be smaller than the conformity assessment cost savings to the manufacturers paying for the associated conformity assessments. The impacts on CABs from this SI are considered as the resources used to comply with regulation. Hence, we have not quantified this impact.
85. Following the announcement to extend CE recognition, engagement with UK CABs suggests there is a risk that some UK CABs could drop out of the market. We currently have insufficient data to estimate how many CABs are at risk. Engagement with manufacturers and CABs indicated that some manufacturers will still get the UK conformity assessment marking, so some demand for UK conformity assessment services is likely to continue. At industry roundtables, manufacturers and CABs explained that demand for UKCA may persist among some UK manufacturers because they have started the UK conformity assessment process, the UK is their primary market, or their clients have specifically requested the UK conformity assessment mark.
86. Evidence from interviews and surveys conducted with CABs indicated that the revenue makeup of CABs can vary significantly so impacts will also vary for each CAB. For some smaller CABs, UK conformity assessment services may be their sole source of income, whilst others are much larger multi-national businesses that have multiple revenue streams including education and training. There is also a diverse range of organisation types within the conformity assessment sector, including regulators, local authorities, further education institutions and private sector organisations.
87. As of September 2023, there were 145 UK approved bodies who can provide UK conformity testing and certification services.³³ Some sectors are more at risk from a loss in demand and a loss of CAB capacity than others, depending

³³ See the UKMCAB database.

on how many manufacturers there are in the sector and the coverage of testing modules accreditations within the sector. As of September 2023, the number of accredited CABs per sector, including those based outside the UK, ranges from 0 (cableways) to 36 (pressure equipment).

88. If UK CABs exit the market, this would lead to a reduction of conformity assessment services available to businesses that only use UKCA. At the same time, by continuing to recognise CE recognition, Option 1 would allow additional routes to market for UK businesses via EU CABs providing CE assessments.

89. CABs also use their technical expertise to support the development of standards via standards committees and support the UK government in designing regulations. If a significant number of CABs exit the market, this technical expertise could be reduced in the UK and it may be difficult and time-consuming to regain if needed in the future.

Costs for Government

90. There are no material additional costs for Government expected under Option 1 relative to Option 0: Do Nothing. Current costs to Government, will remain post SI implementation. These costs to Government include ensuring businesses and CABs are complying with the product safety regulations (the CE or UKCA marking), to ensure the safety of products on the GB market. There are also Government costs to enforcing the product safety regulations.

Non-Compliant Products & Market Surveillance

91. *REUL* powers only allow the continued recognition of CE regulations as they were on 31 December 2024. Any amendments that are made to EU regulations following that date cannot be recognised in the UK without its own additional legislation.

92. Where EU regulations diverge from the UK regulations post-2024, for example a new machinery regulation is due to become applicable from 2027, products that are CE marked under that Regulation may no longer be compliant with UK regulations. Therefore, there is a risk that manufacturers will continue to sell CE marked goods in GB which are not compliant with UK regulations. It may also place an additional burden on market surveillance authorities since it may be harder for them to identify when something is non-compliant. There is currently no data available on the effect of this legislation on the rate of non-compliance and the cost of this to the UK government.

Impact on consumers

93. UK consumers would benefit from this SI due to greater product choice in Option 1 than Option 0. Our engagement with UK importing businesses found that some product ranges risked not being supplied to the GB market without

the policy to extend CE recognition. UK consumers could also benefit indirectly from lower prices in Option 1 than in Option 0 insofar as business cost savings (including from both UK businesses and non-UK businesses) are passed on to UK consumers. Data on consumer impacts is limited and impacts have not been quantified.

94. The introduction of this SI is not expected to lead to visible changes for the majority of UK consumers. This is because product regulation marks (UKCA / CE marking) are primarily designed for product regulation enforcement and market surveillance, rather than being a consumer-related mark. Further the continued recognition of CE marking on products subject to this SI is expected to provide certainty for consumers that rely on product conformity marking. Survey evidence undertaken by OPSS³⁴ (January 2023) found that across 5 product types, the share of responses who looked for the CE mark ranged from 24% - 40%. Product regulation marking is not a major consideration for consumers when purchasing products.

Impact on non-UK businesses, supply chains and market disruption

95. Non-UK manufacturers exporting products that are in scope of this SI to the UK will also be impacted. Non-UK manufacturers supply a sizeable amount of products requiring conformity assessment in the UK. Imports of products requiring UKCA or CE were valued at £110bn annually.³⁵ Note that this SI covers a subset of products requiring UKCA or CE, specifically those covered by the Department for Business and Trade, the Department for Environment, Food and Rural Affairs (Hazardous substances “RoHS”), the Health and Safety Executive (Civil Explosives), and the Department for Energy Security and Net Zero (Eco-Design). Like UK manufacturers, non-UK manufacturers supplying the UK market will incur one-off familiarisation costs in Option 1. Some non-UK manufacturers will also incur cost savings from: not undertaking duplicative conformity assessments; and not undertaking additional marking and labelling.
96. For the purposes of this Impact Assessment, we have not quantified the potential impacts of Option 1 on non-UK manufacturers supplying the GB market but we expect the net impacts to be positive. Savings gained by non-UK manufacturers could, to an extent, be passed on to UK consumers and GB importing businesses purchasing the products via prices being lower than what they would be in Option 0.
97. This legislation will ensure that risks of any supply chain and market disruption are limited for the regulations in scope since businesses, including

³⁴ OPSS product safety and consumers: Wave 2, From: Office for Product Safety and Standards; Published 30 January 2023

Available here: <https://www.gov.uk/government/publications/opss-product-safety-and-consumers-wave-2>

³⁵ Average annual UK import value of UKCA manufactured goods from key UK trading partners, 2017 to 2019. See: <https://www.gov.uk/government/publications/uk-import-values-of-ukca-applicable-products>

non-UK businesses, can continue to supply the GB market with CE marked goods. We have limited evidence on UKCA usage among non-UK businesses. However, in industry roundtables some UK manufacturers explained that their overseas suppliers are reluctant to adopt UKCA. Some businesses explained that if UKCA became mandatory, non-UK suppliers may decide to stop supplying the GB market due to the costs from duplicative conformity assessment costs for CE and UKCA, and the inconvenience and time costs to arrange for additional testing. Therefore, if the UK were to end recognition of CE, as in Option 0, it is possible that there would be a shortage of certain products on the GB market and, in certain instances, impacts could amplify through supply chains. This risk is reduced in Option 1. Industries that have greater reliance on non-UK inputs for production and have just-in-time production models could have faced higher risk of disruption leading to loss in economic activity in Option 0.

Impact on trade, competition and innovation

98. The cost savings in Option 1, the preferred option, would facilitate international trade relative to Option 0. The savings gained by non-UK manufacturers could facilitate GB imports while providing a greater range of products to the GB market. UK manufacturers would also have the option of continuing to use CE which may reduce the barriers to supplying both the GB and EU markets relative to Option 0, potentially facilitating UK exports from some businesses.
99. Insofar as Option 1 reduces costs to businesses supplying the GB market, it would increase import competition and could raise business innovation relative to Option 0. By providing manufacturers with another route to supplying the UK market, it may reduce the barriers to entry in the GB market and reduce the barriers to trading, each of which should increase competition and innovation in Option 1 relative to Option 0.

Northern Ireland and the Windsor Framework

100. For simplicity and data availability, most data used in the calculations are UK data. We expect this to have a small impact on results given NI manufacturing businesses and NI goods trade represent small shares of UK manufacturing businesses and UK goods trade respectively³⁶.
101. Under the terms of the Windsor Framework, many manufactured goods need to follow EU product legislation to be placed on the NI market, and must demonstrate conformity through applying the 'CE' mark, or 'CE' and 'UKNI' markings. Goods marked with 'UKCA' only cannot currently be placed on the Northern Ireland market. Northern Ireland manufacturers also have

³⁶ For example, Northern Ireland businesses account for approx. 3% of total UK manufacturers. See UK Business Counts - enterprises by industry and employment size band (<https://www.nomisweb.co.uk/>)

guaranteed unfettered access to sell to the GB market. As such, they could use either the 'UKCA' or 'CE' mark to demonstrate conformity when placing goods on the GB market.

102. The recognition of 'CE' marked goods in Great Britain could complement the Windsor Framework's efforts to smooth the flow of trade within the UK internal market, by simplifying processes for Northern Ireland supply chains that rely on supplies from Great Britain.

Environmental Impacts

103. The Department for Business and Trade has considered the Government's net zero target and potential environmental impacts resulting from the introduction of this SI. This SI will have minimal environmental impacts.
104. This SI does cover regulations responsible for performance which could be important for the measurement of environmental applications or contaminants. It also covers and environmental regulations such as eco-design of energy-consuming products. However, we are not altering the essential requirements of these regulations.
105. There may be small environmental benefits in Option 1 relative to Option 0. By reducing duplicative testing for some products, any environmental impacts from such duplicative testing will be mitigated.
106. There may be environmental costs in Option 1 relative to Option 0 insofar as it facilitates economic activity and international trade, which would have an environmental impact. However, by reducing the regulatory burden and providing longer term certainty, businesses will be able to invest and grow, potentially creating greater long-term efficiencies and environmental improvements.

Risks and uncertainty

107. The Department for Business and Trade has identified the following risks and inherent uncertainties with assessing the impacts from introducing this legislation:
- a. There could be divergence between the UK and EU's product regulatory regimes. Currently it is not possible to determine whether in the future there could be divergence between the UKCA and CE marks for any or all of the product regulations subject to this SI, to what extent any level of divergence may be, and how businesses would respond. However the UK will retain sovereignty over its product regulation

regime and decide whether to follow any changes to the CE marking regime, or introduce its own changes to the UKCA marking regime. For the purposes of the analysis presented in this Impact Assessment, we do not assume any further changes to UK or EU regulations over the horizon of the analysis.

- b. Businesses' behaviour in response to this legislation – in particular manufacturers' choice of using UKCA marking and/or CE marking – is uncertain. We assume in Option 1 that the share of businesses that were using UKCA at the time of the announcement to extend CE recognition remains constant in the future.

Monitoring and Evaluation

108. The Department for Business and Trade will continue to maintain a robust evidence base for monitoring the conformity assessment market and the businesses in scope of this legislation. This includes continuing to engage UK manufacturers and CABs. Engagement will consider evidence from businesses including: the extent to which UKCA and CE marking are being used for products in the UK; the extent to which businesses encounter any additional burdens from monitoring the requirements for UKCA and CE marking over time; and the extent to which businesses consider the policy of CE recognition to reduce their costs and burdens relative to alternatives.
109. The Department for Business and Trade will also continue to monitor and utilise data from external surveys where available as well as data on international trade and CAB numbers. Recent data for each of these metrics are described in this Impact Assessment. External surveys to date have provided evidence on the proportion of businesses that are using UKCA among those that are subject to UKCA or CE requirements. This includes the evidence from the ONS BICS Survey summarised in Table 2. The Department for Business and Trade will continue to monitor ONS and HMRC goods trade data over time, including with countries where CE marking is used or recognised. The Department for Business and Trade will also monitor the number of CABs that can provide UKCA services using the UKMCAB database.
110. The engagement and metrics described in this section will contribute to judging the success of the policy.

Post Implementation Review

111. No post implementation review is required for Regulations made under the Retained EU Law (Revocation and Reform) Act 2023 – see s. 20(5). This does not remove the general need to review and improve legislation in due course, including in relation to regulatory divergence between the EU and GB markets. However, it removes the review requirements relating to this SI.

Table 2: Evidence for assumptions

Estimate	Source(s)	Assumption (s)	Description
Number of UK businesses impacted	<p>DBT analysis based on ONS Annual Business Survey (2021) and HMRC (2018); Gov.uk page on local government structure and elections.</p>	<p>Between around 13,900 and 23,200 manufacturers (best estimate of 18,500). Between around 66,700 and 111,150 retailers and wholesalers (best estimate of 88,900. Up to 145 approved bodies and 218 local authorities in GB enforcing product safety and metrology.</p>	<p><u>Manufacturers:</u> It is not possible to measure the precise number of manufacturers affected, since publicly available data does not record business activity according to which regulation applies to products that individual firms manufacture. To produce an estimate of the affected manufacturer population, we firstly estimate the coverage of regulations across product codes. We then map those product codes to the relevant SIC4 industry level data. In each of the SIC4 industries identified, there will be some manufacturers who would need to comply with the regulations in scope of this SI and some manufacturers who would not need to comply with the regulations in scope of this SI. We therefore apply a scaling factor to each SIC4 industry identified using HMRC trade data to estimate the affected manufacturer population for our best estimate. To account for the uncertainty surrounding our estimate for the number of manufacturers, we adopt an assumed range. The low end of the assumed range scales down the best estimate by 25%, and the high end of the range scales up the best estimate by 25%.</p> <p><u>Retailers/wholesalers:</u> Whether a seller is affected depends on whether they sell products in scope of these regulations; this is not available from publicly available data. To estimate it, we start with ONS (ABS) data on business activity by sector (SIC4) and assume that around two-thirds may stock products in scope based on the descriptions of each sector. To account for the uncertainty, we scale down the best estimate by 25% for the low end of the assumed range, and up scale the best estimate by 25% for the high end of the assumed range.</p> <p><u>Approved bodies:</u> According to the UKMCAB database, there are 145 UK approved bodies.</p> <p><u>Local authorities:</u> According to the OPSS, there are c. 218 local authorities enforcing product safety/metrology. The number of local</p>

			<p>authorities that enforce product safety/metrology comprises of 153 local authorities in England (less district councils who don't cover product safety) and 32 Scottish authorities, 22 Welsh and 11 Northern Irish authorities.</p> <p>Source: https://www.gov.uk/guidance/local-government-structure-and-elections#:~:text=In%20total%20there%20are%20317,district%20councils</p>
Share of UK manufacturers not UKCA ready	ONS BICS data (2023)	The ONS BICS data indicates that 48% of UK manufacturers are using the UKCA marking as of April 2023 and 52% are not using the UKCA marking.	<p>The ONS Business Insights and Impact on the UK Economy survey (BICS) indicates that 48% of UK manufacturers are currently using the UKCA marking.</p> <p>Survey data from wave 81 is utilised, which was published on 4 May 2023 covering the period 17 April – 30 April 2023. The relevant survey question stated: 'Is your business using, or intending to use, the UKCA marking by 1 January 2025?'. 47.9% of responses self-categorised by businesses as those 'manufacturing products that need a CE or UKCA marking' selected the response 'already using UKCA marking'. The survey data reflects percentage of businesses not permanently stopped trading and their business requires the CE marking or new UKCA marking, weighted by count. We assume that those who report to be using UKCA are using it for all their products while those who do not report using UKCA are not using UKCA for any of their products.</p>
Conformity assessment costs	Business engagement (2017-2023); and Department for Business and Trade's survey with businesses (Summer 2023)	<p>The average full Conformity Assessment cost is assumed to be £7,500 (low) - £20,000 (high), with a best estimate of £13,332.</p> <p>The average cost of re-certification is assumed to be £1,000 (low) - £4,000 (high), with a best estimate of £2,000.</p>	<p>We have collected data on the costs of conformity assessment and issuing certificates from UK businesses and approved bodies. Costs vary depending on the type of product and regulatory requirements being assessed: the precise cost of each manufacturer and product range is dependent on the product type, type of assessment required, and the manufacturer's characteristics such as size, assessment history and in-house expertise.</p>

<p>Marking and labelling costs</p>	<p>Business engagement; literature review.</p>	<p>Average cost of new marking/labelling changes are assumed to be £2,815 (low) - 4,309 (high), with a best estimate of £3,562.</p>	<p>We have collected data on the costs of adding new marks/labels to products from UK businesses and from external literature. Evidence suggests that there is a wide range of potential costs to adding conformity marking, as little as a few hundred pounds to £10,000s if there is a high volume of products and/or if new hardware/machinery is required. Therefore, the true cost for individual manufacturers may fall outside of the assumed range.</p>
<p>Familiarisation costs</p>	<p>ONS (2022)</p>	<p>We assume that it will take between 1 and 3 hours (best estimate of 2 hours) for a manager/director to read the guidance and pass on information to colleagues and clients.</p>	<p>We use ONS ASHE data (2022) on the average gross hourly wage of corporate managers and directors (£31.88) and apply an uplift to take account of non-wage labour costs (+18%).</p>

Annex 1: List of Regulations amended by this SI

1. Equipment for use in potentially explosive atmospheres Regulations 2016/1107
2. Electromagnetic compatibility Regulations 2016/1091
3. Lifts Regulations 2016/1093
4. Electrical Equipment (Safety) Regulations 2016/1101
5. Pressure Equipment (Safety) Regulations 2016/1105
6. Pyrotechnic Articles (Safety) Regulations 2015/1553
7. Recreational Craft Regulations 2017/737
8. Radio Equipment Regulations 2017/1206
9. Simple Pressure Vessels (Safety) Regulations 2016/1092
10. Toys (Safety) Regulations 2011/1881
11. Aerosol Dispensers Regulations 2009/ 2824
12. Gas Appliances (EU Regulation) 2016/426
13. Supply of Machinery (Safety) Regulations 2008/1597
14. Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001/1701
15. Personal Protective Equipment (EU Regulation) 2016/425
16. Measuring Instruments Regulations 2016/1153
17. Non-automatic weighing instruments Regulations 2016/1152
18. Measuring Container Bottles (EEC Requirements) Regulations 1977
19. Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012/3032 (RoHS)
20. Explosives Regulations 2014/1638
21. The Ecodesign for Energy-Related Products Regulations 2010

