

The Product Safety and Metrology etc. (Amendment) Regulations 2024

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| Lead department | Department for Business and Trade |
| Summary of proposal | The proposal is to extend <i>Conformité Européenne</i> (CE) marking recognition indefinitely in Great Britain. This allows businesses to either use CE or the new UK Conformity Assessed (UKCA) markers when placing goods on the GB market. |
| Submission type | Impact assessment (IA) – 26 January 2024 |
| Legislation type | Secondary legislation |
| Implementation date | 1 January 2025 |
| Policy stage | Final |
| RPC reference | RPC-DBT-5327(1) |
| Opinion type | Formal |
| Date of issue | 19 March 2024 |

RPC opinion

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| Rating¹ | RPC opinion |
| Fit for purpose | Overall, the Department provides a reasonable level of assessment for the proposal. The Department argues against mitigation and exemption for small and micro businesses because the proposal will benefit all businesses regardless of size. There are areas for improvement within the IA including further justification for some underlying assumptions, justification for sensitivity analysis and a more detailed monitoring and evaluation plan. |

Business impact target assessment

| | Department assessment | RPC validated |
|---|---------------------------------------|--|
| Classification | Qualifying regulatory provision (OUT) | Qualifying regulatory provision (OUT) |
| Equivalent annual net direct cost to business (EANDCB) | -£64.8 million | -£64.8 million (2019 prices, 2020 pv) against the 'do nothing' counterfactual only |

¹ The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the [Better Regulation Framework](#). RPC ratings are fit for purpose or not fit for purpose.

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| Business impact target (BIT) score | -£315.1 million | -£315.1 million |
| Business net present value | £558.2 million | |
| Overall net present value | £558.2 million | |

RPC summary

| Category | Quality² | RPC comments |
|---|----------------------------|--|
| EANDCB | Green | The IA helpfully outlines the key modelling assumptions and methodology used to estimate the direct cost on business and the rationale underpinning these. However, it would benefit from further justification of some assumptions. The IA makes good use of published data and draws on industry engagement, surveys and previous IAs to estimate the impacts of the proposal on business. It is important to note that the EANDCB estimates business impacts against a 'do nothing' counterfactual rather than the status quo. The IA would benefit from further sensitivity analysis and more justification for the choice of upper and lower bounds. |
| Small and micro business assessment (SaMBA) | Green | The IA is transparent about having imperfect information on the number of small and micro businesses expected to be affected by this SI. The IA appropriately concludes that exemptions are not applicable for small and micro businesses as the SI itself reduces duplicative costs and burdens faced by businesses when placing goods on the GB market. The Department should expand its assessment to include medium-sized business considerations. The Department should also expand the scope of the SaMBA to include UK Conformity Assessment Bodies (CABs) given these bodies are likely to lose revenue from a reduction in UK conformity assessments. |
| Rationale and options | Satisfactory | The Department presents a sufficient rationale for intervention based on the potential consequences to businesses and consumers of not extending CE recognition. Whilst the IA considers only two options, 'do nothing' option (according to which CE recognition would lapse at the end of the year) and the preferred option (which maintains the status quo indefinitely), the IA explains reasonably that an alternative time-limited extension of the CE recognition would create only further uncertainty for industry. The rationale could be strengthened by drawing on relevant international comparisons. |
| Cost-benefit analysis | Weak | The Department is transparent about the limitations of the data and evidence that are |

² The RPC quality ratings are used to indicate the quality and robustness of the evidence used to support different analytical areas. Please find the definitions of the RPC quality ratings [here](#).

presented. The IA usefully breaks down the calculation of costs and benefits for each option, clearly distinguishing ongoing and one-off impacts. Whilst the IA models scenarios to account for uncertainty in the underpinning assumptions, these scenarios would benefit from further justification. The Department provides a reasonable level of monetisation, but the IA would benefit significantly from further consideration and monetisation of the cost to CABs in the form of lost revenue as this could potentially lead to some bodies leaving the market.

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| Wider impacts | Satisfactory | The IA appropriately considers a range of wider impacts including competition, innovation, trade, environmental, and public sector impacts. The IA would benefit from drawing on evidence, where possible, to strengthen the discussion. The IA recognises the distinctive situation of Northern Ireland under the Windsor Framework, however, it would benefit from further consideration of regional impacts. |
| Monitoring and evaluation plan | Satisfactory | The IA makes no commitment to a post-implementation review (PIR) under the Retained EU Law (Revocation and Reform) Act. Whilst a PIR is not planned, the IA briefly outlines various monitoring activities that the Department will use to review the legislation. The IA would benefit from providing further detail including timeframes and key research questions, as well as considering the circumstances that might trigger a formal review. |

Summary of proposal

Since 1 January 2021, the UK has continued to recognise the *Conformité Européenne* (CE) regime alongside the UK Conformity Assessed (UKCA) regime for goods placed on the UK market. Both are marks that demonstrate that products meet the EU/UK's product regulatory requirements. This approach has enabled businesses to use either mark when placing goods on the GB market. However, CE recognition is due to end on 31 December 2024. Under current arrangements, from 1 January 2025 only the UKCA mark will entitle products to be placed legally on the GB market.

The impacts covered in the IA relate principally to impacts on GB businesses. Under the Windsor Framework many manufactured goods need to follow EU product legislation to be placed on the Northern Ireland (NI) market, and must demonstrate conformity through applying the CE mark, or CE and UKNI markings. Whereas NI manufactures could use either UKCA or CE to demonstrate conformity when placing goods on the GB market.

The IA considers the following options:

- **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 that products meet those EU regulations still recognised under UK legislation, and comply with GB requirements in areas where EU rules are not recognised.

Familiarisation costs are identified as a direct cost to businesses affected by the regulations. Direct benefits to business are identified as the avoided costs that would have occurred under the 'do nothing' option, namely the cost to manufacturers of duplicative conformity, the labour cost associated with obtaining conformity assessments or losing access to some markets, and the cost of updating/replacing marking and labelling on products.

The Department estimates the indicative EANDCB of the preferred option as -£64.8 million; the total benefit to business over the ten-year appraisal period is estimated to be £558.2 million. The overall net present social value is also estimated to be £558.2 million.

EANDCB

Counterfactual/baseline

The IA assesses the impact of the regulations against a 'do nothing' counterfactual in which CE recognition ends on 31 December 2024 and the UKCA regime becomes mandatory for all relevant products placed on the GB market. It is important to note

that the EANDCB reflects the position against a ‘do nothing’ counterfactual only, rather than against the status quo. Validating the EANDCB against the status quo would be approximately zero, as the preferred option reflects continuity of existing arrangements already in place. The impacts of the proposal against the ‘do nothing’ counterfactual derive largely from avoided costs.

Data and evidence

The IA makes use of published data and clearly communicates that where there is insufficient data to quantify impacts on businesses, the assessment is based on industry roundtables and surveys conducted with businesses in 2023. The IA would benefit from discussing how representative the respondents – and the responses - to the surveys are of the sector as a whole.

Some of the analysis could benefit from using more recent evidence. For example, paragraph 19 cites the average annual value of all manufactured goods imported into the UK subject to UKCA or CE requirements as being £110 billion; however, this is based on 2017-19 averages.

Assumptions

The IA helpfully outlines key assumptions used when estimating the direct cost to business and the evidence underpinning these assumptions in the Annex (see Table 2). The IA would benefit from further justification of some assumptions, including the assumption that the cost of conformity assessment is the same under CE and UKCA (paragraph 50).

Sensitivity analysis

The Department has conducted sensitivity analysis to test assumptions and provides ranges of some estimated impacts to appropriately demonstrate the implications of this uncertainty. In some instances, the IA would benefit from further sensitivity analysis as well as more justification for the choice of upper and lower bounds. For example, when assessing marking and labelling costs the Department assumes an upper bound of £11,500 (paragraph 71, however, during engagement with manufacturers an industry representative estimated the cost to be as high as £20,000 per product range (paragraph 70). The Department should consider adjusting its upper bound estimate to reflect this or explaining why this estimate would not apply to industry as a whole.

SaMBA

Scope

The IA is transparent about having imperfect information on the number of small and micro businesses on which the proposals are expected to have an impact. The IA outlines the proportion of exporting manufacturers in GB, which are likely to benefit from the proposals, based on 2021 ONS data.

If possible, the IA would benefit from disaggregating the survey responses by size of business to estimate the proportion of small and micro businesses who are compliant with UKCA. The IA could also benefit from disaggregating the survey responses by sectors, given that the burden of compliance is likely to differ by sector. The Department should also expand the scope of the SaMBA to include UK CABs, given that these bodies are likely to lose revenue from a reduction in UK conformity assessments compared to what might be expected under the 'do nothing' option (see 'Cost-benefit analysis').

Exemption

The IA appropriately concludes that exemptions are not appropriate for small and micro businesses as the proposals avoid potential duplicative costs and burdens faced by businesses when placing goods on the GB market, which would otherwise have either to obtain both CE and UKCA certification (if exporting to the EU) or to change from CE to UKCA certification if they currently rely on the former.

Impacts

The IA briefly outlines how some impact channels could affect larger businesses disproportionately while others would affect small and micro businesses disproportionately. For example, evidence shows that larger manufacturers are more likely than smaller businesses to export to countries requiring CE marking and would, therefore, see more benefit from the extension of CE. The IA also recognises that the cost savings for each business will depend on the products that they produce; this is not necessarily linked to the size of the business.

Medium-sized business considerations

The IA should also provide an assessment of whether there are likely to be any disproportionate impacts on medium-sized businesses, usually identified as businesses with 50-499 employees, which may justify the consideration of measures to mitigate the burdens on these businesses.

Rationale and options

Rationale

The IA presents a reasonable rationale for intervention based on the ending of the CE regime on 31 December 2024 and the potential consequences for businesses and consumers. Furthermore, the IA outlines policy objectives of the proposed extension including a reduction in duplicative costs and burdens imposed on businesses when supplying goods to the GB market. The rationale could be strengthened by drawing on international comparisons where possible, such as the effectiveness of CE or similar regimes or examples of countries with their own product regulation system similar to UKCA, including those that also recognise CE.

Options

While the IA considers only two options, with one being ‘Do Nothing’, paragraphs 34 to 36 explain sufficiently that an alternative time-limited extension of the CE recognition would create only further uncertainty – a notion that is supported by industry. It is also implicit that non-regulatory measures would not address appropriately the problem under consideration. The IA could benefit from further consideration of alternative options, for example, a more-selective targeted recognition scheme.

Cost-benefit analysis

Data and evidence

The IA is transparent about the limitations of the data and evidence presented. There is a range of evidence underpinning the analysis, including pre-2020 business and industry engagement, 2023 industry roundtables, business surveys and ONS data.

Modelling

The IA usefully breaks down the calculation of costs and benefits for each option, clearly distinguishing ongoing and one-off impacts. The counterfactual is clearly explained and appears appropriate.

Unmonetised impacts

The IA treats the impact on UK CABs as a wider impact of the proposal (see below). The Department classifies appropriately the loss of revenue from UK conformity assessment services as *‘resources used to comply with regulation’* (paragraph 84). Whilst the IA correctly does not include this impact in the EANDCB figure, the RPC still expects this impact to be quantified, where proportionate, as a potentially significant distributional impact. The Department should consider further the scale of this impact as it could be significant for some bodies, potentially leading them to leave the market.

Uncertainty, risks and assumptions

Whilst the IA models three different scenarios (low, central and high) to account for uncertainty in the underpinning assumptions, the scenarios themselves appear arbitrary in places and would benefit from further justification.

Wider impacts

The IA appropriately considers a range of wider impacts on groups including CABs, government, consumers and non-UK businesses. The IA also includes a brief discussion of trade, competition, innovation and environmental impacts. The IA would benefit from drawing on evidence, where possible, to strengthen the discussions. For example, the Department could consider the impact of CE or similar regimes in other countries.

The Department considers the impact on international trade, arguing that the preferred option (extending CE) would facilitate international trade, relative to the ‘do nothing’ option, as UK manufacturers will be able to use CE to supply goods in EU markets. The IA could also consider the benefit of CE giving access to other countries’ markets outside of the EU, for example, Canada, Singapore and the US. The IA could benefit from considering further the potential impacts on international competition. While the Department argues that the proposal is likely to increase competition (paragraph 99), the IA would benefit from considering the UK’s ability to compete with other CE-recognised markets.

The IA could also benefit from considering distributional impacts. The IA states the proposal is not expected to have any disproportionate regional impacts in the UK (paragraph 19), however, the IA does not justify this assumption. The Department should consider whether the proposal could affect regions differently, since the impact will differ by industry, and industries are distributed unevenly across regions.

The IA recognises the uncertainties regarding present and future divergence between UK and EU product regulatory regimes. Similarly, the IA could benefit from considering the extent to which the proposal to extend CE may make it more difficult, or more costly, for the UK’s regime to diverge from the EU in the future.

Monitoring and evaluation plan

The IA does not commit to a PIR, citing that there is no requirement for a PIR under the Retained EU Law (Revocation and Reform) Act 2023. Even though not conducting a PIR has been justified for this reason, the IA states that the Department will continue various monitoring activities to review and improve the legislation. These range from continued engagement with businesses to continuing to collect and analyse data from external surveys. The IA would benefit from setting out timelines for these activities. Given the lack of statutory commitment to PIR, the Department should also consider the circumstances under which a formal review of the policy would be necessary or appropriate, for example if the EU made substantive changes to the CE regime or the product regulations to which it applies.

Whilst the IA briefly outlines potential data sources and metrics the Department will use to monitor the impacts of the proposal, any future evaluation would benefit from the IA outlining key research questions that the Department would use to measure the success and/or continued need for the proposal.

Regulatory Policy Committee

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