

## **Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020**

### **Department for Business, Energy and Industrial Strategy**

#### **RPC rating: fit for purpose**

The impact assessment (IA) is now fit for purpose following the Department's detailed response to the RPC's initial review. As first submitted, the IA was not fit for purpose. The Department's best estimate of the direct impact on business is below the better regulation framework threshold for independent scrutiny and, therefore, the RPC welcomes the Department's voluntary submission of the IA for scrutiny.

#### **Description of proposal**

Product safety and metrology legislation places requirements on any business involved in the import, manufacture, and supply of goods. In advance of placing goods on the market, an assessment needs to be undertaken to demonstrate that the product is compliant with the relevant legislation. For products presenting a greater risk, the manufacturer is required to submit the product to a notified body, which will undertake a conformity assessment to determine if the product or processes meet the necessary specifications. Currently, UK business can use any notified body in the UK or any EU member state. The conformity assessment process can cover checks on product design, construction, and performance. A notified body is a conformity assessment body (CAB), which has usually been accredited by the national accreditation body nominated by the country (EU member state or the UK) where they wish to register. From 1 January 2021, all UK notified bodies will be converted into approved bodies, which will allow them to assess conformity of products for the UK market.

In Autumn 2019, as contingency for a no-deal EU exit scenario, the UK Government legislated for a UK product safety and metrology regime to come into force on 1 January 2021. These regulations (SI 2019/696) legislated for a so-called 'deeming provision', under which businesses could continue to place products, which were assessed against EU rather than UK rules, on the UK market for an undefined time-limited period.

The proposal (Option 1) would end the deeming provision, where manufacturers can continue to place CE-marked goods on the UK market, which will end after a period of 12 months (or, in very exceptional circumstances, 24 months), dependent on the sector, giving businesses time to prepare. After this period, on 1 January 2022, all products sold in GB will have to comply with the UK regulations. Businesses would have to comply with the UK regime by the end of this period, which requires them to apply UK conformity marking or labelling to products and, where necessary, have UK conformity certificates issued by UK-recognised approved bodies.

## Impacts of proposal

The Department estimates that between 10,000 and 17,000 UK manufacturers, and up to 135,000 UK wholesalers and retailers, will be affected by the implementation of the regulations. The IA quantifies the costs to business resulting from conformity assessment, conformity marking and familiarisation costs relative to the counterfactual of Option 0 'do nothing' over a standard ten-year appraisal period. The total net present value for businesses is estimated to be a cost of £35.9 million. The monetised costs do not take into consideration the potential mitigating cost savings of the transitional measure related to removable labels.

### Costs:

**Conformity assessment.** The Department's central estimate of conformity assessment costs is £3.7 million under option 1. In order to calculate the additional costs against the counterfactual, the Department assumes that under option 1 all businesses would be required to seek new conformity assessment certificates within the first year, compared to within a 10-year period in the counterfactual.

**Conformity marking.** The Department's central estimate of additional conformity marking costs in the 12-month period, relative to the counterfactual, is £25.7 million under option 1. This arises mainly where manufacturers have to add UK conformity marking outside of the product development cycle, which the Department states could cost "...between £100s to tens of £1000s" (page 22). This cost is estimated to have an impact on between 10,000 and 17,000 businesses. Given the range of costs and businesses affected the Department has provided low (£14.4 million) and high (£41.8 million) estimates with a wide differential, suggesting a high level of uncertainty. The estimates do not account for the mitigating impact of transitional measures, such as adding removable, rather than permanent, markings to products, which may reduce costs for manufacturers. Given the uncertainty over the behaviour of firms, the IA does not quantify this cost, instead providing a qualitative

assessment of the impact of the transitional measures. The Department expects this cost to business to be minimised where businesses can incorporate the permanent marking into their product-development cycle.

**Familiarisation costs.** The IA recognises that firms will have to familiarise themselves with the new legislation for their specific product area. The Department provides a central estimate for this one-off familiarisation cost of £6.6 million for businesses. This central estimate assumes that a manager takes two hours, on average, to read and prepare for the new legislation, and that there are 85,000 UK retailers and wholesalers operate in sectors within scope of the regulations. The IA presents a range between £1.8 million and £15.1 million, which reflects the uncertainty around the total familiarisation costs.

### Benefits

The Department presents a qualitative description of the benefits of ending the deeming provision. The Department indicates that benefits would increase over time if the UK and EU requirements were to diverge in the future. For example, should the UK choose to introduce higher levels of protection in future, then automatic continued acceptance of EU goods could mean that products manufactured to lower standards could still be sold in the UK. This could also potentially undermine the competitiveness of UK businesses.

The IA details benefits for both UK businesses and consumers, arising through the certainty of ending the deeming provision. The Department argues this will allow businesses to plan their adaption to the UK's product safety and metrology requirements, after the end of the transition period, around the timetable specified by this proposed amending legislation.

Further, the Department suggests that by ensuring all products sold in the UK meet high safety and performance requirements and, where relevant, are assessed by UK recognised approved bodies, the regulations would also reduce the risk of consumers, businesses and others buying faulty, unsafe, non-compliant or inaccurate products.

## Quality of submission

### Issues addressed following the RPC's initial review

The Department has revised the IA in response to comments from the RPC, enabling the IA now to be regarded as fit for purpose. The substantive improvements in the assessment, mainly around the need to provide further explanatory detail, are as follows:

**Level and reporting of evidence from stakeholder consultation.** The RPC noted that the Department needed to provide further evidence, or at least demonstrate that the information provided is representative of industry and a sufficient basis to produce reasonably reliable aggregate estimates. The Department has now provided much more information on businesses consulted, by size and sector coverage (mainly at pages 7-8 of the IA). This includes:

- stakeholder consultation over the last year, with 40 UK manufacturers and 33 UK notified bodies (NBs);
- that manufacturers interviewed collectively produce products covered by 15 out of the 20 directives and regulations in scope of the IA;
- that the NBs consulted covered 20-25 per cent of the UK NBs and included interviews with three of the UK's largest NBs providing conformity assessment services against the majority of directives; and
- interviews with seven trade associations for sectors with potential conformity assessment capacity issues.

**Use of averages.** The RPC commented, in particular, on the IA originally submitted, that the Department must explain why averages from more-segmented populations had not been used, given the diversity of sectors and businesses affected. The Department has now explained how averages presented in the IA have been constructed (pages 16-20 for conformity assessment and pages 22-23 for conformity marking), and how they have been underpinned by more detailed sector-specific average costs, where possible. For example, where sectoral data are available, sector specific conformity assessment costs have been applied.

**Familiarisation costs.** The RPC commented in its initial review that the Department must clarify how fully it has considered familiarisation costs, including whether areas such as record keeping and staff communication have been taken into account. The Department has provided further explanation and justification of its familiarisation cost estimates (pages 26 and 27), including that they are based on estimates from similar legislative changes.

### **Possible additional costs in relation to civil explosives and pyrotechnics**

**sectors.** In its initial review, the RPC commented that the Department must address explicitly the likelihood and potential impact on any UK manufacturers and importers should there be no emerging UK NB for pyrotechnics or risks around the Health and Safety Executive's plans to sustain its conformity assessment facility. The Department has provided significant additional information on pages 24 to 26.

For pyrotechnics, the Department has explained that it will work with the United Kingdom Accreditation Service (UKAS) and third-country CABs, with an aim of designating a third-country CAB in advance of 1 January 2022. In the unlikely event that a third-country CAB does not want to take on responsibility for certifying against the UK Conformity Assessed mark, the Department would work with stakeholders on a solution that would ensure important pyrotechnic products could still be placed on the UK market. For civil explosives, the Department has provided further details on how the Health and Safety Executive has developed and identified a viable operating model for the conformity assessment of civil explosives, and the ongoing work to ensure operational capability for after the standstill period.

**Unjustified assumptions.** The RPC asked for evidence about the assumption that UK NBs would minimise the burden on clients of issuing UK certificates by not requiring a full re-assessment. The Department has provided further information on pages 16-17. This explains that many UK NBs have already transferred their certificates to their EU branches and, as the EU and UK NB are part of the same company or legal entity, it expects that they would have confidence in their respective assessments and would issue UK certificates without a full re-assessment. The Department has also explained that businesses that do not have EU branches have formed partnerships with EU NBs and, due to the partnerships and contracts, many would be willing to issue certificates without a full re-assessment. The Department has made it clear that this assessment is based on stakeholder engagement with NBs.

**Transition costs.** The Department has now made it clearer why there will be no further transitional costs after 1 January 2023, as business, which adopt the transitional measure of removable marking/labelling, will need to switch to permanent labels by then.

On the basis of the changes made to the IA in response to the RPC's initial review, the RPC can now confirm that the IA is fit for purpose. The Department acknowledges that there is significant uncertainty in its estimates, in part due to constraints on gathering evidence, and has sought to address this, for example, through use of cost

ranges. Overall, although noting the uncertainty in the estimates, the RPC now considers the Department's assessment to be reasonable and proportionate.

### **Other areas addressed in the revised IA**

The RPC identified a number of less-significant areas for improvement in the initial review and the Department's revised IA helpfully addresses these. These include:

**Costs to government.** The RPC asked for more detail on the potential costs to government, including the risks of having to set up, and fund, a UK body for pyrotechnics and cost of accreditation with UKAS. The Department has now provided a fuller explanation of these costs on pages 25 and 30. Further, the Department has added more detail on why cost for civil explosives conformity assessment capacity is out of scope as a result of UK leaving the EU. The RPC also welcomes the Department's increased discussion around their expectations for the body becoming self-sustaining, information on the impact on trading standards, and an explanation for why the expected costs to UKAS are small.

**Development of case studies.** The Department has now provided more detail on the three case studies on page 22, and how they are used as examples of the different timeframes for businesses to make marking changes every 2, 5 and 10 years.

**Explanation of cost calculations.** The RPC suggested it would be better to present the cost calculations more clearly, particularly for the £3.7 million conformity assessment costs on page 19. The Department has now strengthened significantly the presentation of these calculations by moving them to the main body of the IA, utilising tables and text boxes in order to demonstrate clearly how costs have been calculated. The Department have also provided further clarification on the 10-year appraisal period and the counterfactual.

**Competition assessment.** The RPC suggested that, while a fully quantified competition assessment would not be feasible, nor proportionate, a qualitative assessment of the potential impacts on competition would be helpful. The Department has now provided a thoughtful qualitative consideration for competition impacts on page 32, in line with the Competition and Markets Authority guidance on assessing competition impacts<sup>1</sup>.

**Environmental costs.** The Department has now included a qualitative assessment of environmental impacts on page 33, particularly those costs arising from the use of adhesive labels.

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<sup>1</sup> <https://www.gov.uk/government/publications/competition-impact-assessment-guidelines-for-policymakers>

**Trade and investment.** The Department has provided within the IA (page 21), more detail on the impact on non-UK manufacturers including the estimated value of the imports affected. In addition, the Department has made clear that it cannot assess reliably in which circumstances the non-UK exporters will be able to pass easily the additional cost on UK consumers.

#### Departmental assessment

Classification	Non-qualifying provision
Equivalent annual net direct cost to business (EANDCB)	£4.0 million
Business net present value	-£35.7 million
Overall net present value	-£35.7 million

#### RPC assessment

Classification	Under the framework rules for the 2017-19 parliament: non-qualifying provision ( <i>de minimis</i> )  To be determined once the framework rules for the current parliament are set
EANDCB	£4.0 million  To be determined once the framework rules for the current parliament are set
Small and micro business assessment	Not required but sufficient