Title: Impact Assessment for the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020 **IA No:** **RPC Reference No:** **Lead department or agency:** BEIS **Other departments or agencies:** Office for Product Safety and Standards – BEIS Health & Safety Executive	**Impact Assessment (IA)** **Date:** 25/08/2020 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** **Analyst:** leena.tessa@beis.gov.uk **Policy:** faye.skelton@beis.gov.uk

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Option 1 (in 2019 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
- £35.9m	-£35.9m	-£4.0m	Non qualifying provision

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

The UK needs an effective and robust product safety and metrology regime in place, which provides reassurance to consumers and clarity to business on their legal requirements. If Parliament were not to bring in this legislation, the UK would continue to accept products compliant with EU regulations with no defined time-limit on this, and this would not be in line with the UK's Government commitment to having an independent UK regulatory regime. The UK would not be able to ensure that products on the market meet UK safety and performance requirements. The Statutory Instrument (SI) introduces other changes, without which the UK regime would not operate effectively.

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

The objective is to implement the UK's own product safety and metrology regime from 1st January 2021 and end the automatic acceptance of products which comply with the EU product safety and metrology legislation (except in Northern Ireland who will continue to follow EU law as per the requirements of the Northern Ireland Protocol). This legislation will ensure the UK has a meaningful regulatory framework for product safety and legal metrology, including the ability to amend its own regulations in the future in the interests of UK business and consumers and to provide adequate protection to UK consumers. It will also ensure that unsafe and non-compliant products can continue to be removed from the market. This will provide businesses and consumers with reassurance about the safety and accuracy of products.

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

Option 0: Do nothing: The UK will have its own regulatory regime, but will accept goods made and assessed under the EU regulatory frameworks for an undefined time-limited period.

Option 1 (preferred option): 12-month continued acceptance of goods assessed against EU rules: End acceptance of goods assessed against EU rules after a 12-month period for all sectors.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** N/A

Does implementation go beyond minimum EU requirements?		N/A		
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, Paul Scully MP

Date: 29/10/2020

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)		
2019	2020	10	Low: -16.2	High: -89.4	Best Estimate: -35.9

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	N/A	**16.2**
High	N/A	N/A	N/A	**89.4**
Best Estimate	N/A	N/A	N/A	**35.9**

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

We estimate between 10,000 and 17,000 UK manufacturers and up to 135,000 UK wholesalers and retailers will be impacted by the implementation of the accompanying SI. Under Option 1, we estimate there will be costs of £25.7m for conformity marking, £3.7m for conformity assessment and £6.6m for familiarisation for businesses. The total net present value for businesses is a cost of £35.9m under Option 1. The monetised costs do not take into account the potential cost savings of the transitional measure related to removable labels.

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

UK and non-UK manufacturers that will incur additional costs as a result of the SI could pass on these costs to UK consumers and businesses through increased prices or reduced product availability.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	N/A		N/A	**N/A**

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

The SI will provide benefits for both UK businesses and consumers. However, we have not been able to quantify the benefits, which are therefore described in the key non-monetised section below.

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

The SI will reduce the risk to consumers and businesses of buying faulty, unsafe, non-compliant or inaccurate products. The SI provides certainty for manufacturers about the incoming UK product safety and metrology regime. Additionally, GB importers (these provisions are only applicable when a product is placed on the GB market and not the UK market which also encompasses NI), will have an additional 6 months to ensure that products are adequately labelled, and for the first 24 months, manufactures can use removable labelling, rather than printed/engraved/moulded marks. These measures should reduce the cost compliance for the affected business population (but have not been quantified).

Key assumptions/sensitivities/risks	Discount rate	3.5%

We have limited data with which to estimate costs to business. In total we have consulted with 33 UK conformity assessment bodies and 40 manufacturers that are in-scope of these regulatory measures. To account for uncertainty around the representativeness of the data for this heterogeneous industry, we have consulted policy experts, external literature, and public databases.
We assume costs first occur in 2021, when the legislation takes effect after the end of the transition period.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 4.0	**Benefits:** 0	**Net:** -4.0	N/A

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Background

1. In autumn 2019, as contingency for a no deal scenario, the UK government legislated for a UK product safety and metrology regime to come into force on the 1st January 2021 (in the 2019 Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 SI No. 696, and which is referred to as SI 2019/696 from now on). The UK domestic regime converted EU legislation on product safety and metrology into UK law. Since then we have laid an amending SI to ensure the legislation for Northern Ireland is unchanged, separating the GB market, and therefore implementing the relevant EU law in NI, as per the requirements of the Northern Ireland Protocol. The original SI 2019/696 also legislated for a so-called 'deeming provision'[1], 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 Government was clear at the time that the period where manufacturers can continue to place CE marked goods on the UK market would come to an end in order for the UK to regain full regulatory sovereignty, but did not at the time specify the timing for the removal of the provision.

2. The SI we are now planning is seeking to end the deeming provision to ensure the UK regime works effectively, and the UK is meaningfully able to set its own regulations in the interests of UK business and consumers. All businesses selling products in GB will have to meet its safety and performance requirements, and where required have products tested by a UK-recognised body. The deeming provision where manufacturers can continue to place CE marked goods on the UK market will be ended after a period of 12-months, which will give businesses time to prepare.

3. In general terms, product safety and metrology legislation places requirements on any business involved in the import, manufacture and supply of goods. Manufacturers, and where relevant, importers and distributors, must ensure that the products they place on the market are safe, conform with the relevant regulatory requirements and are provided with instructions for safe use. They must also have measures in place to identify risks once a product is on the market, so that quick corrective action can be taken where needed, including a recall if required. Distributors must not supply goods that they believe to be dangerous or non-compliant with essential safety requirements and must cooperate with other economic operators if problems with their products arise.

4. 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 some products the manufacturer will self-certify that the product meets all requirements. For products that present a greater risk, the manufacturer is required to submit the product to a Notified Body (NB – a third party) who 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 (or another country where the EU has a Mutual Recognition Agreement)[2] to carry out their conformity assessment and this also applies to businesses in the rest of the world.

5. The conformity assessment process can cover checks that should be undertaken on product design, construction and performance, and how those checks should be performed. 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 UK) where they wish to register. In the case of the UK, accreditation activity for most Notified Bodies is undertaken by the United Kingdom Accreditation Service (UKAS). A CAB is a more general

[1] A section or clause of a statute, regulation or other legal instrument that explicitly states how something is to be treated or regarded. In this case the deeming provision provides for unilateral recognition of certain goods meeting EU requirements, including the acceptance of the conformity mark (CE mark) and use of EU notified bodies to assess goods for the UK market.

[2] A Mutual Recognition Agreement is an annex within a free trade agreement through which countries aim to align their regulatory standards and will accept the results of conformity assessment bodies from the partner country as a legal demonstration that a product complies with its own regulations

term which refers to all businesses which provide conformity assessment, product testing and consultancy/advisory services on product compliance.

6. From 1st January 2021, all UK Notified Bodies will be converted into UK Approved Bodies which will allow them to conformity assess products for the UK market.

7. In some cases, following assessment, the product is then required to be marked to demonstrate its compliance with the legal requirements. This is commonly with a CE marking[3] which indicates that it has either undergone conformity assessment by a Notified Body, or the manufacturer self-declares that they have met the legal requirements and carried out appropriate conformity assessment. In cases where a Notified Body's involvement is required, the CE marking must be accompanied by the relevant Notified Body's four-digit Notified Body number. There are other markings applied for certain products, for example: the reversed epsilon '3' on aerosol dispensers, 'M' for measuring instruments and 'Ex' for equipment used for explosive atmospheres.

8. All products are also required to be labelled with the address of the UK manufacturer or importer which is responsible for first placing the product on the UK market.[4]

9. All requirements also apply to non-UK and non-EU manufacturers which export products into the UK and EU. There is an additional requirement on these manufacturers for certain products. A non-UK and non-EU manufacturer can choose to have an Authorised Representative (AR) within the UK or European Economic Area (EEA). This is a person with which the manufacturer has a contractual arrangement in order that the AR legally represents a manufacturer in the UK or EU and will provide details of a product's compliance with the relevant product safety and metrology regulations if needed. For the Cosmetics Regulation (EC) No. 1223/2009 a non-UK or non-EU manufacturer is required to have a Responsible Person (RP) within the UK or EU. A Responsible Person is similar to an AR but they have additional responsibilities such as adding product details to the European cosmetic ingredient database.

10. Responsibility for adhering to these requirements lies with business but enforcing authorities such as local authorities and government departments have a key role in checking compliance with these requirements to ensure the safety of products on the market. The Office for Product Safety and Standards (OPSS) within the Department of Business, Energy and Industrial Strategy (BEIS) has responsibility for transposing and implementing current EU Directives covering product safety and metrology, in the UK. OPSS is responsible for introducing and implementing this, bringing current EU Directives into UK law, covering around 30 specific pieces of associated product safety and legal metrology legislation.

Problem under consideration and rationale for intervention

11. Currently, the UK's product safety and metrology regime is reliant on a framework based on EU law and EU-nominated bodies. The UK left the EU on the 31st January 2020 and the transition period, which allows the UK and EU more time to make additional arrangements, comes to an end on the 31st December 2020.

12. In Autumn 2019, as contingency for a no deal scenario, the UK government legislated for a UK product safety and metrology regime to come into force on the 1st January 2021 - SI 2019/696. The UK domestic regime converted EU legislation on product safety and metrology into UK law. It also legislated for a so-called 'deeming provision', under which businesses could continue to place products assessed against EU rather than UK rules on

[3] The CE marking is a European conformity marking.

[4] Placing a product on the market refers to the moment when an individual product is first made available for sale in the UK. For example, this could be when a product is displayed for sale in a shop or online, when a product is stockpiled in a warehouse but is already covered by a contract of sale, or when a business has imported a product to use in its production/service.

the UK market for an undefined time-limited period. The Government was clear at the time that the period where manufacturers can continue to place CE marked goods on the UK market would come to an end in order for the UK to regain full regulatory sovereignty but did not at the time, specify the timing for the removal of the provision.

13. For the UK's new regime to be effective, this SI will end the deeming provision after a period of time where manufacturers can continue to place CE marked goods on the UK market. This period will confirm by when businesses need to comply with the GB regime, and give businesses time to prepare.

14. The period where manufacturers can continue to place CE marked goods on the UK market and the other components of the SI will affect all manufacturers, importers and distributors who produce and/or sell products covered by product safety and metrology regulations owned by OPSS and the Health and Safety Executive (HSE).

15. If Parliament does not bring in this regulation, then the UK would be required to continue to accept products assessed against EU regulations with no defined time-limit. This would not be in line with the UK's Government commitment to having an independent UK regulatory regime and the UK would not be able to ensure that products coming onto the UK market meet its safety and performance requirements. For example, CE marked goods which do not comply with the UK regulations could continue to be sold in the UK for an undefined time-limited period even if UK rules were to change. It would also mean EU-based bodies which the UK has not approved, and over which it has no ongoing oversight, could continue to approve goods for the UK market indefinitely. While in the short term this poses no significant issues due to the initial alignment of rules on the 1st January 2020, over time this would become an increasing cause for concern as the UK will have no ability to assure itself that these bodies are competent to test against UK rules, particularly if, as expected, UK rules do not match EU rules in the future. By fully enforcing the UK product safety and metrology regime and ending the acceptance of products assessed against EU rules, the UK government will have the ability to ensure the regime reflects the UK national interests.

16. The counterfactual (Option 0) for this assessment is based on the current legislation: on the 1st January 2021, the deeming provision in the 2019/696 will be implemented (when that legislation comes into force). The UK will have its own regulatory regime which mirrors EU requirements, and the UK would continue to accept goods that have been assessed against EU rules on the market for an undefined time-limited period. The counterfactual also incorporates relevant provisions in the Northern Ireland Protocol and for NI businesses to have unfettered access to the GB market.[5]

[5] The Protocol applies certain EU product safety legislation to NI, and unfettered access enables NI businesses to place products that meet these EU rules on the GB market without any additional approvals.

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

Businesses affected

17. The SI covers a substantial part of the UK manufacturing sector from consumer products like toys, personal protective equipment (PPE) and electronics, to industrial products, such as lifts and machinery. Broadly, we estimate that around 10,000-17,000 UK manufacturers are involved in these industries and will be affected by this SI (8-13% of UK manufacturers). We estimate that there are between 40,000 and 135,000 retailers and wholesalers in the UK which sell these products in the UK (best estimate 85,000).[6] 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. The UK manufacturing sector has a gross value added (GVA) of £184bn.[7] Businesses who will be affected by the SI represent a large proportion of UK manufacturing GVA. For example, fabricated and basic metals and machinery and equipment both represent 7.9% of manufacturing GVA, and electronics represents 10.7%.[8] The products in scope of the SI also represent a large proportion of UK trade flows. For example, we estimate that £44.8bn worth of goods from these industries were exported to other countries in 2018[9]. The UK also relies heavily on imports of these goods, with £70.8bn imported in 2018. For sectors such as Electronics, Personal Protective Equipment (PPE) and Pyrotechnics, most products are imported into the UK, rather than domestically produced.

19. To inform the quantification of impacts, we have drawn on a wide range of data and evidence obtained from industry since 2017. Our primary source of evidence are interviews with 40 UK manufacturers and 33 UK Notified Bodies between June 2019 and June 2020 on their preparations for leaving the EU. We have endeavoured to provide a quantified assessment of impacts where possible. Given the diversity of business in-scope of the measures, we understand this sample is not representative of the overall population. We describe in detail in the 'Costs and benefits of each option' section how we have made best use of the available evidence to estimate the overall cost to business.

Notified Bodies

20. We interviewed 20-25% of the UK's Notified Body population between June 2019 and August 2020. This included interviews with three of the UK's largest Notified Bodies which provide conformity assessment services against the majority of directives. Based on the companies' characteristics, we are confident that we have captured a large proportion of the Notified Body sector which is affected by the measure. We also interviewed a wide range of smaller Notified Bodies which reflects the composition of the Notified Body industry. Our evidence suggests the UK Notified Bodies industry is comprised mostly of SMEs[10]. Collectively, these 33 Notified Bodies provide services for all of the 16 directives and regulations which require third party conformity assessment.

21. In addition to our long-term engagement, we carried out further interviews with 23 Notified Bodies throughout July and early August in order to fill in data gaps around the costs of

[6] ONS (2019) – including agri-food manufacturers. CE marking and equivalent marking covers a wide range of sectors, however this IA relates to sectors regulated by BEIS/OPSS and HSE as per the SI and therefore we do not account for manufacturers producing products in-scope of other regulations/directives. See annex 1 for a full list of directives/regulations in-scope of this assessment. See Table 6 for explanation of how the number of businesses affected is calculated.

[7] ONS GDP output approach – low-level aggregates 2019 (accessed August 2020)

[8] SIC sectors 25Other, 28 and 26+27 respectively.

[9] HMRC (2018)

[10] 98% of the technical testing and analysis industry is SMEs (ONS, 2019)

conformity assessment and ending the acceptance of EU compliant goods in the UK. This included an interview with an EU pyrotechnics Notified Body as there are no Notified Bodies for this sector in the UK. We also drew on information from previous surveys we conducted with Notified Bodies in 2017 and 2019, which provided data on the costs of conformity assessment.

Manufacturers

22. We interviewed manufacturers which collectively produce products covered by 15 out of the 20 directives and regulations in scope of this assessment. Interviews focused on gathering evidence on the costs of conformity assessment, conformity marking and leaving the EU. We were not able to engage with manufacturers in five sectors; aerosols, lifts, non-automatic weighing instruments, recreational craft and measuring container bottles. These sectors represent around 8% of the manufacturer population in scope of the assessment.

23. Given that businesses were not always able to provide us with comprehensive data on costs because they had not yet considered these impacts, and the information obtained from business cannot be considered representative of all the different businesses and products, we also discussed different assumptions with the relevant technical experts in OPSS and HSE. Having identified sectors with potential conformity assessment capacity issues, we also interviewed 7 trade associations. These associations tend to represent the majority of manufacturers in their sectors.[11]

Policy Objective

24. The first policy objective is to end the so-called 'deeming provision' after a 12-month period in which manufacturers can continue to place CE marked goods on the UK market. This is delivering the UK government's commitment to having an independent UK regime, with a meaningful ability to diverge from EU rules where this is in the interests of UK businesses and consumers, and to ensure that products placed on the market in GB comply with the safety and performance requirements set out under that regime.

25. The 12-month period will allow businesses to adapt to the UK's regulatory regime at a lower cost than if they had to comply immediately from 1st January 2021. Additionally, for two years after 1st Jan 2021, business will be permitted to add UK conformity marking to products on a detachable label or on an accompanying document. After this period, all products put on the GB market will have to comply with UK regulations and, where relevant, be assessed by a UK-recognised conformity assessment body.

26. The SI makes some other changes, which are minor, such as to correct deficiencies or capture existing EU law which would otherwise not be retained. These include changes in respect of cosmetics and also toys (to ensure certain existing chemical thresholds that will apply at prior to the end of the transition period remain applicable); to RAMS[12] (to allow us to update underlying product regulations as needed if the national UK accreditation body is ever changed); to lifts (to update some existing references to 'Member State' not already picked up by 2019/696); and weighing instruments (to mirror the 12-month period whereby manufacturers can place CE marked goods on the UK market for provisions concerning recognition of European Economic Area testing certificates).

27. The final policy objective is to implement some measures related to the Northern Ireland Protocol. At the end of the transition period, goods complying with product safety and

[11] Four trade associations represent over 70% of the turnover or businesses in their sectors. One trade association represents around half of the businesses in their sector. The proportion of the sector represented by the final trade association is not known.

[12] Regulation of Accreditation and Market Surveillance

metrology regulations and placed on the Northern Ireland market may also use a new UK(NI) mark alongside the CE mark to indicate that a UK-based third-party body has been used to test against the EU regulatory requirements. Such goods may be placed on the NI market but not sold in the EU. CE+UK(NI) marked goods will be valid on the GB market under 'unfettered access' if placed by a 'qualifying' NI business. The SI will introduce the design of the UK(NI) mark and the approach to the sanction regime should the mark be misused. This SI also legislates for some unfettered access provisions for NI businesses to place specific goods on the GB market. These measures resulting from the Northern Ireland Protocol are out of scope of assessment. The Northern Ireland Protocol has already been placed in legislation through the European Union (Withdrawal Agreement) Act 2020, amending powers of the European Union (Withdrawal) Act 2018.

28. Impacts on related EU-exit measures which have already been legislated for as part of the 2019 Product Safety SI are out of scope of this assessment. This is an assessment of the costs to businesses of bringing forward conformity marking changes and conformity assessment for the UK market as a result of the 2020 Product Safety SI which will end the acceptance of EU compliant goods in the UK from 1st January 2022. Similarly, impacts on non-UK businesses from the implementation of the accompanying 2020 Product Safety SI are out of scope. However, we consider impacts on non-UK businesses and the consequent impacts on UK businesses and consumers in the 'wider impacts' section (Paragraph 113).

Descriptions of options considered

29. **Option 0: Do nothing**: If we do not introduce this legislation, on the 1st January 2021, the deeming provision in the 2019/696 SI will come into force. The UK will have its own regulatory regime, but in GB there would be continued acceptance of goods assessed against EU regulations (and where relevant by EU recognised bodies) on the market for an undefined time-limited period.

30. **Option 1: 12-month period of time where manufacturers can continue to place CE marked goods on the UK market**: This option would be introduced via legislation which would come into force alongside Product Safety SI 2019/696. This will end the deeming provision after a 12-month period where CE marked goods can continue to be placed on the UK market by manufacturers for all sectors. After this period, on the 1st January 2022, all products sold in GB will have to comply with the UK regulations.[13]Businesses would have to comply with the UK regime at the end of this period which requires them applying UK conformity marking to products and where necessary having UK conformity certificates issued by UK-recognised Approved Bodies. This will also legislate for a 24-month period of transitional measures, which will provide businesses with flexible options for meeting UK conformity marking requirements. See page 15 onwards for the assessment of Option 1.

Option 0: Do nothing

31. This is the baseline against which the legislation scenario is assessed: The Product Safety SI 2019/696 will come into force on 1 January 2021, introducing the UK's own product safety and metrology regulatory regime. There would be a deeming provision which allows businesses to continue to sell goods assessed against EU regulations in the GB market until further legislation ends this provision.

Table 1: Current Arrangements

Issue	Until 31/12/2020 (end of transition period)	1/1/2021onwards for a time-limited period
Conformity marking	Businesses must use EU conformity markings where relevant to place products on the UK market	Businesses can use the UK conformity marking (e.g. UKCA) or the EU conformity marking (e.g. CE) to place products on the GB market. Businesses must use EU conformity marking to place products on the Northern Ireland market.
Conformity assessment	Businesses can use UK or EU Notified Bodies to conformity assess products for both the UK and EU markets.	Businesses can use UK Approved Bodies or EU Notified Bodies to conformity assess products for the UK market.
Importer/ Manufacturer addresses	Addresses can be in UK or EU. A product with a UK or EU manufacturer address does not need an importer address.	For the UK market, an importer address must be in the UK although for 12 months this can be on a separate document. A product with an EU manufacturer address will generally need a UK importer address.
Authorised Representatives	Authorised Representatives for the UK and EU markets can be based in the UK or EU.	New Authorised Representatives for the UK market must be based in the UK.

[13] With the exception of products which are compliant with EU regulations and are flowing from Northern Ireland to Great Britain, these products can continue to freely circulate once in Great Britain.

Option 1: 12 month continued acceptance of goods assessed against EU rules

32. Option 1 would make the following changes to the 'do nothing' Option 0:

I. End the deeming provision for all sectors from the 1st January 2021. From the 1st January 2022, GB businesses would no longer be able to put CE marked, or equivalent, products on the GB market (unless they were appropriately marked under the UK regime also). All products will have to comply with the UK regime:

   i. Products requiring conformity assessment will need assessment with a UK Approved Bodies and will require UK certificates to prove their compliance to UK regulations.
   ii. UK conformity marking (e.g. UKCA) will have to be applied to all products which require it (all sectors other than Cosmetics).
   iii. UK importer/manufacturer addresses will need to be applied to all products.
   iv. A Responsible Person in the UK will have to upload the details of Cosmetic products onto the UK's database.

II. Introduce transitional measure from 24 months between 1st January 2021 and 31st December 2022 to allow businesses to meet UK requirements more flexibly. Business will be able to:

   i. Put new UK importer/manufacturer addresses on an accompanying document.
   ii. Add UK conformity marking to products on a detachable label or on an accompanying document.

III. Authorised Representatives (AR) can currently be located in the UK or EEA. From 1st January 2021 the UK will require all Authorised Representatives (AR) to be located within the UK.

33. The SI also makes some other minor changes to correct deficiencies or capture existing EU law which would otherwise not be retained. These include changes in respect of cosmetics, toys, Regulation Accreditation & Market Surveillance (RAMS), weighing instruments and lifts.

Table 2: Timeline of SI measures for Option 1

Measure	Until 31/12/2020 End of transition period	1/1/2021 – 31/12/2022 Option 1	1/1/2023 onwards UK regime (for the GB market)
Conformity marking	Businesses can use the EU conformity marking (i.e. CE mark) to place products on the UK market.	All businesses can use the UK conformity marking or the EU conformity marking to place products on the GB market until 31st December 2021. For 24 months until January 2023, UK conformity marking can be on a detachable label or an accompanying document.	All businesses must apply UK conformity marking to products in line with the requirements to place products on the GB market. These must be permanent markings.
Conformity assessment	Businesses can use a UK or EU CAB to conformity assess products.	Businesses can use the UK or EU CAB to conformity assess products until 31st December 2021. From 1st January 2022 all businesses can only use a UK CAB to conformity assess product for the GB market.	All businesses can only use a UK CAB to conformity assess products for the GB market.
Importer/ Manufacturer addresses	Addresses in the EU are accepted in the UK.	Addresses in the EU are accepted in the UK until 31st December 2021. From 1st January 2022 all addresses must be in the UK. For the entire period, new UK addresses can be placed in an accompanying document.	New UK addresses must be applied to products in line with regulation.
Authorised Representatives	Authorised representatives will be recognised in the UK even if based in EEA.	Authorised representatives from 1st January 2021 will need to be based in the UK.	

Costs and benefits of each option

34. This assessment considers the effect of implementing the SI with a 12-month period where businesses can continue to place CE marked goods on the UK market for all sectors (Option 1), relative to the counterfactual of time-limited continuity (Option 0).

35. Guidance on the 12-month period where manufacturers can continue to place CE marked goods on the UK market and 24 month transitional measure period was published on 1 September 2020 providing businesses with details of the new UK conformity marking and conformity assessment as well as the date when goods assessed against EU rules will no longer be accepted in GB.

Impacts in scope of this IA

36. Impacts in scope of this assessment are those which directly result from ending the deeming provision in the accompanying SI, and also transitional measures designed to help businesses adjust to this change.

37. For the purposes of this assessment, we assume that – in the absence of a change in policy – businesses will adapt their processes to comply with the UK regime as part of their normal business process, in order to minimise additional cost. We assess the cost for businesses of complying with the UK regime outside of their usual business process. For example, for conformity marking, businesses might have to add new UK conformity marking outside of their normal marking changes, and for conformity assessment, businesses might require UK certificates before their EU certificates are due for reassessment.

Impacts not in scope of this IA

38. Impacts not in scope of this assessment are those that relate to the UK's product safety and metrology regime which was enacted by SI 2019/696. Impacts of adjusting to the new regime for current products (administrative/organisational costs) or new products (assessment and conformity marking) are out of scope. These costs include:

    i. Adding UK conformity marking to newly designed products

    ii. Conformity Assessment by UK Approved Bodies for newly designed products

    iii. Administrative and organisational costs to UK manufacturers, which sell in the UK and the EU, of complying with two different regulatory regimes

    iv. On-going conformity marking and conformity assessment costs for UK manufacturers after the initial change in preparation for the end of the period where manufacturers can continue to place CE marked goods on the UK market which are in scope of the assessment

    v. Administrative and organisational costs to UK importers of ensuring products have UK importer addresses and are complaint with UK regulation

    vi. Administrative and organisational costs to UK distributors and retailers of ensuring products are compliant with UK regulations

39. Impacts not in scope of this assessment are also those related to the implementation of the Northern Ireland Protocol. The Northern Ireland Protocol has already been placed in legislation through the European Union (Withdrawal Agreement) Act 2020, amending

powers of the European Union (Withdrawal) Act 2018 and any businesses impacts are included in the counterfactual. This covers:

i. Provisions introducing the design of the UK(NI) mark

ii. The approach to the sanction regime should the mark be misused;

iii. And some product specific provisions that enable NI businesses to place certain goods that meet the EU rules on the GB market without any additional approvals (unfettered access)

Evidence for calculations

40. Due to the heterogeneity of the businesses and sectors affected by the SI, where possible we have calculated sector-specific assumptions at each step in the cost calculations, and scaled up by the number of business tested to be in each sector. Where data was not sufficiently detailed at the sector level, we estimated broad averages from the data collected across all sectors. We developed low, central, and high cost estimates to take account of the uncertainties here. This is described in the more detail in the relevant section below, and Table 6 page 29 explains the key assumptions in more detail. 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 and policy experts. We have highlighted any uncertainties or assumptions that our assessment includes.

Option 0: Do nothing

41. In the 'do nothing' scenario, from 1st January 2021 businesses will be able to choose to comply with the new UK regulatory regime, or continue to place EU compliant products on the UK market.

42. Following the publication of the draft EU exit legislation, guidance was issued for businesses on the introduction of the UKCA mark and the acceptance of CE marked products on the UK market for an unspecified time-limited period. It specified that if businesses chose to comply with the UK regime, they would need to add UK conformity marking to their products and, where necessary, get products assessed by UK Approved Bodies.

43. We assume that businesses would choose to comply with the UK regime as part of their normal product development cycle in order to minimise cost. We assess the costs of Option 1 against this baseline.

Conformity Assessment

44. Certificates of manufacturers issued by UK Notified Bodies will automatically roll-over and be compliant with UK requirements. Certificates issued by EU Notified Bodies will not be accepted in the UK and manufacturers will require new UK certificates to sell products in Great Britain.[14]

45. As part of the outgoing EU legislation, engagement with manufacturers suggests that manufacturers are required to get products recertified on average every 2-10 years. We assume that manufacturers will choose to have new UK certificates issued at the point when

[14] Northern Ireland businesses can choose to continue to use an EU Notified Body to comply for conformity assessment as part of the Northern Ireland Protocol

existing EU certificates expire. This is because manufacturers that export would naturally be required to get a new certificate for the EU market when their certificate expires or when new products are developed, and there would be cost efficiencies to obtaining both UK and EU conformity certificates at the same time in the product development process. We assume that all businesses which export to the EU also supply the UK market and will require new UK certificates.[15]

Conformity marking

46. If the SI were not implemented, we assume that businesses would choose to apply UK conformity markings to products at the point at which they would make normal marking or labelling changes to products as part of their product development cycle and if necessary at a point when products had been assessed for the UK market. We assume that manufacturers will also incorporate any manufacturer address changes into this process. There will be costs associated with these changes, however these costs relate to existing legislation that was implemented as a result of the UK leaving the EU, and these are not in scope of this assessment.

Option 1: 12-month continued acceptance of goods assessed against EU rules

47. Option 1 will legislate to end the deeming provision from 1st January 2022. Before this date, businesses will be able to place goods assessed against EU rules (including using the CE marking) on the UK market. After this date (12-months after the end of the transition period), all GB businesses will have to ensure goods are assessed against UK rules, and use UK conformity marking and (where necessary) have UK certificates of conformity from a UK-recognised body. There will also be a 24-month period which will allow businesses to add the UK conformity marking and new importer addresses to products with a removable label or in an accompanying document. However, from 1st January 2023, all products will require permanent UK conformity marking as specified in the respective regulation.

48. To comply with the regulatory changes, businesses will incur costs within a 2-year period. This is because:

    i. In the first 12 months, GB businesses, who still hold conformity assessment certificates with EU Notified bodies will incur costs of conformity assessment: These businesses will need to transfer any conformity assessment certificates held with EU Notified Bodies to UK Approved Bodies.

    ii. In the first 12 months, manufacturers will incur costs of adding new conformity marking: Adding UK conformity marking to products, and adding new importer address to products and/or product accessories (in this time manufacturers can use removable labels or accompanying documents for conformity marking or importer addresses).

    iii. Manufacturers can adopt the transitional measure of removable marking/labelling across a 2-year period (this includes throughout the 12-month standstill arrangement in 2021 and an additional 12 months in 2022). At the end of the 2 years, all manufacturers will have to apply permanent UK conformity marking to all products being sold in GB and (where relevant) will have to apply new importer addresses to products and/or product accessories.

[15] There may be some businesses which only export products to the EU and do not sell within the UK, this is expected to be a very small proportion of exporters, and there is no available data to test this assumption.

49. We have assessed the policy over a 10-year period rather than a 2-year period as this policy requires business to bring forward their conformity assessment and conformity marking changes. Under Option 0, manufacturers would make these changes over a period of up to 10 years as part of their normal product development cycle. Under Option 1, some businesses will incorporate these costs as part of their normal product development cycle in the 2-year period, but for many businesses these costs will fall outside of their normal product development cycle and will consequently face additional costs.

Conformity Assessment

50. Under Option 1, there will be an impact on businesses who would otherwise not have sought UK conformity assessment until after 1st January 2022. Due to the change in legislation, these businesses will incur the costs associated with UK conformity assessment over a 1-year period; legislation brings forward demand for conformity assessments in the UK, compared to the profile in the counterfactual.

51. There are 16 directives/regulations in scope of the SI (see Annex 1) 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 either the UK or the EU to access both markets. Option 1 will end the deeming provision and certificates issued by EU Notified Bodies will not be recognised by GB from 1st January 2022. Manufacturers will be required to use a UK-recognised body (which will be known as an 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 business affected

52. If the manufacturer already has certificates with a UK Notified Body before the end of the transition period, these certificates will automatically become valid UK certificates and there will be no new conformity assessment cost to these manufacturers for the GB market. However, manufacturers who have certificates with EU Notified Bodies will need to have UK certificates issued by a UK Approved Body for 1st January 2022.

53. Currently, only businesses which place goods on the market in both the UK and the EU are likely to use an EU Notified Body rather than a UK body. We assume that all other businesses already have UK-based conformity assessment, since engagement with businesses suggests it is less costly and more efficient to use a local CAB for assessment, and there is no benefit to using an EU CAB if a business does not export to the EU. The exception is for manufacturers of pyrotechnics products, since there is no UK CAB for pyrotechnics. We estimate that around 1,500 to 3,000 UK manufacturers may be affected (central estimate 2,300): those which require conformity assessment with a CAB and sell within both the UK and EU.[16]

54. In preparation for no-deal, engagement with businesses suggests that manufacturers who sell within the UK and the EU have moved their certificates to EU Notified Bodies, since due to the deeming provision, by moving certificates to an EU Notified Body manufacturers are able to access both markets (EU certificates would still be accepted in the UK but certificates issued by UK Notified Bodies would no longer be recognised by the EU).

55. Businesses that have their current certificates with an EU body will face additional costs to acquiring a UK certificate if they continue to sell within GB. Data on the precise proportion of UK manufacturers which have certificates with EU Notified Bodies is unavailable for most

[16] ONS (2019) – please refer to Table 6 for methodology details

sectors. However, engagement with 33 UK CABs (23% of the total UK population) suggests the majority of manufacturers have done so. We segment this data across sectors where possible. Since there is no UK Notified Body for pyrotechnics, all pyrotechnics manufacturers in the UK must currently use an EU Notified Body and evidence from the civil explosives industry suggests all UK civil explosives manufacturers currently hold certificates with EU Notified Bodies. Therefore, for these two sectors 100% of UK manufacturers hold certificates with EU Notified Bodies. For all other sectors, we estimate that around 60 – 90% of manufacturers who sell to the EU and UK (1,500 to 3,000) have certificates with EU Notified Bodies (central estimate 75%). Our estimate for the number of businesses facing additional costs is therefore 900 – 2,700 (central estimate 1,700).

Cost to business

56. In order to calculate the additional cost under Option 1, we assume that in the absence of a change, all businesses would seek new conformity assessment certificates within a 10-year period. Under option 1 this is reduced to 1 year.

57. From engagement with manufacturers, we have estimated the typical cost of conformity assessment. The costs businesses face depends on whether UK Approved Bodies will require them 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.

58. UK Approved Bodies will be able to accept the results of EU Notified Bodies and will be able to issue new certificates at an estimated cost of around £100 to £2,000 per certificate (central estimate £200), according to research with UK Bodies. However, UK Approved Bodies will have the right 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.

59. We have limited evidence on the intentions of UK Notified Bodies and the proportion of which will require products to have a full assessment before UK certificates are issued. Engagement with Notified Bodies suggests there are several reasons why some Notified Bodies could require a full re-assessment:

    i. Legal risks of accepting the results of another Notified Body

    ii. Reports supplied by other Notified Bodies contain insufficient detail

    iii. Assessment by another Notified Body is of an unsatisfactory standard

60. To take account of these factors, we make an assumption that 40% of manufacturers will be required to have a full reassessment for UK certificates to be issued, with a range of 20-60% to account for the uncertainty here. We assume that the majority (up to 80%, central estimate 60%) will face a reduced cost, to account of the likelihood of a lower burden on GB manufacturers if UK bodies accept some testing and documentation previously reviewed by EU bodies (e.g. a full conformity assessment process including testing of prototypes and audits where applicable is not needed). We expect that the majority of manufacturers do not require a full assessment for two reasons:

    i. Firstly, many UK bodies operate under large global or European wide businesses. Engagement with these large bodies and data from the European Commission's database[17] on EU Notified Bodies suggests a quarter of UK Notified Bodies have branches located in the EU. Engagement with these bodies suggests they transferred many of their clients to their EU branches in preparation for a no deal

[17] NANDO (2020)

scenario.[18] Engagement also suggests they would be able to replicate new UK certificates for their clients. This is because, being part of the same overarching business, they can have confidence in each other's assessment services and have access to past assessment reports.

ii. Secondly, engagement also suggests that many UK Notified Bodies, which do not have branches in the EU but do have clients which export to the EU, formed partnerships with EU Notified Bodies. This allowed clients to transfer certificates to the EU in preparation for a no deal. Since these UK Notified Bodies are already familiar with the manufacturers and have partnerships or contracts with EU Notified Bodies, many would be willing to issue new UK certificates for manufacturers without having to carry out a full reassessment of products. However, some form of review would be common before a certificate is issued.

61. Overall, our evidence suggests that most Notified Bodies interviewed would not require manufacturers to have a full reassessment. However, a small number of bodies suggested that they might have to carry out full assessments if past assessment reports were not satisfactory or they were concerned that accepting the results of other bodies may impact their legal position or reputation.

62. Therefore, we expect the majority of manufacturers to face lower costs as they won't require a full reassessment. However, the scale and cost of the assessment required will depend on each manufacturer, product and CAB. There will also be a scale of assessment required from the minimum where a CAB reviews reports and issues a new certificate to a full assessment when audits and product check are carried out. Due to a lack of data and the variety of products and businesses in scope we are not able to quantify this heterogeneity.

63. If UK Approved Bodies do require full assessment, evidence from Notified Bodies suggests this could cost manufacturers between £500-£100,000 per product range, depending on the type of product and regulatory requirements being assessed. Costs are most likely to fall within the range £2,000 to £15,000 (central assumption £12,000). The precise cost for each manufacturer and product range[19] is dependent on the product type, type of assessment required and the manufacturer's characteristics such as size, assessment history and level of in-house expertise. For example, if a manufacturer has used the same CAB for a long time and is experienced in carrying out internal product assessments and providing their CAB with information, the conformity assessment fee is likely to be lower. Therefore, there is a wide variation in the costs of conformity assessment, and true costs for individual manufacturers could fall outside this range.

64. We have collected sufficient data from notified bodies and businesses to provide average conformity assessment costs for each directive and regulations. We use these to calculate a weighted average across all sectors based on the number of business requiring conformity assessment for each regulation, in order to estimate the average conformity cost to the entire manufacturer population for a low, central and high scenario. Engagement with businesses suggests that businesses will generally sell between 2-20 product ranges in the UK for which they will require conformity assessment. We expect the majority of businesses to have relatively few product ranges (up to 5) since 99% of manufacturers impacted by the SI are small and micro businesses. However, evidence suggests that some large manufacturers will require conformity assessment for a large number of product ranges, for example 60. Reflecting this variation, we estimate that the average number across all businesses is between 6 and 8 product ranges (central estimate 7).[20] To estimate these

[18] Our engagement shows that following the 2019 no deal guidance and 2019 Product Safety SI, businesses expected goods conformity assessed by EU Notified Bodies to be accepted in the UK from 1st January 2021 for an undefined time-limited period and expected that goods conformity assessed by UK CABs would no longer be accepted in the EU.

[19] A product range refers to one type of product which requires third-party conformity assessment in order to be sold in the UK or EU.

[20] Particular businesses may have a greater or lesser number of products than this.

averages, in the central scenario, we assume that 55% of businesses have 2 products, 30% have 10 products, and 15% have 20 products. This generates a weighted average of 7. The low scenario assumes a greater proportion of businesses have 2 products and a lesser number have 10 or 20 products. For the high scenario, the opposite applies. See figure 1 for details.

65. Considering all the available evidence and bringing these assumptions together, our central estimate is that the average cost per business is around £4,800. This assumes c.40% of 1,500 – 3,000 businesses require full reassessments for their products, at an average cost of £11,600 per product), and that c.60% of businesses require new certificates only, at an average cost of £200.

66. To account for the uncertainty, for the lower end of our estimated range, we assume that c.20% of businesses require full reassessments for their products, at an average cost of £2,200, and that c.80% of businesses require new certificates only, at an average of £100. For the high scenario, we assume that c.60% of businesses require full reassessments for their products, at an average cost of £15.500, and that c.40% of businesses require new certificates only, at an average cost of £2,000.

67. Combining with the estimated average number of product ranges per business (6-8), the total conformity assessment costs for UK manufacturers under option 1 is therefore estimated to be between £2.7m (low scenario) and £235.8m (high scenario), with a central estimate of £58.6m (See Table 3 for an illustration of the central scenario estimate).

Table 3: Total conformity assessment cost calculation (central estimate)

Estimate number of businesses affected	Average cost to business (per product range)	Average no. of product ranges per business	Total cost*
1,700 ("A")	**£4,800** ("B")	**7** ("C")	**~£58.6m** (A x B x C)

**Figures do not sum precisely due to the use of unrounded figures for each assumption in the calculations.*

Figure 1: Conformity assessment cost calculation

A. Number of businesses affected: 900 – 2,700 (central est. **1,700**)

Number of UK manufacturers exporting to the EU and where conformity assessment applies: 1,500 – 3,000 (central est. 2,300)
× *Proportion of businesses which currently hold certificates with EU Notified Bodies: 60-90% (central est. 75%)*

B. Average cost to business (per product range) £500 - £10,100 (central est. **£4,800**)

Proportion of businesses that require full reassessment: 20-60% (central est. 40%)
× *Cost of full assessment per product range: £2,200 – £15,500 (central est. £11,600)*
+
× *Proportion of businesses that require new certificate only: 40-80% (central est. 60%)*
× *Cost of new certificate issuance: £100 - £2,000 (central est. £200)*

C. Typical no. of product ranges per business: 6-8 (central estimate **7**). *Weighted average based on*

Average number of products on the market per business (2/10/20)
× *% of manufacturers with 2/10/20 ranges (55/30/15% in the central scenario)*

A x B x C = £58.6m when costs in 1 year (option 1) and £54.8m when spread over 5 years (option 0) in central scenario

Net cost of option 1 is £58.6 - £54.8m = **£3.8m** (*using unrounded raw figures).* (£3.7m in 2019 prices)

68. £58.6m is the total conformity assessment costs for UK manufacturers. The equivalent total cost in option 0, when costs are spread over 5 years[21] rather than 1 (e.g. 20% of businesses

[21] We assume that products require reassessment every 5 years for our central scenario (our low to high range is every 2-10 years).

getting products reassessed each year, and total costs discounted accordingly) in the central scenario is £54.8m. This is an estimated £11.7m annual cost (rounded) over 5 years, discounted to 2021. For the low scenario, the total cost is estimated as £2.7m; £1.4m in year one and year two, discounted to 2021. For the high scenarios, the total cost is estimated as £203m; £23.6m annual cost over 10 years, discounted to 2021. Therefore the net additional cost of option 1 is £3.8m (£58.6m - £54.8m) in our central scenario, or £3.7m in 2019 prices.

69. £3.7m is the estimated additional conformity assessment costs for UK manufacturers; the cost of bringing forward the issue of new certificates to before 1st January 2021, compared to applying for new certificates when they require renewal or when new products are developed (every 5 years on average for our central scenario). This estimate is highly uncertain, and the true cost could be much higher or much lower than we estimate here, as shown by the lower and higher estimates. See Table 5: Estimated costs of Option 1 for the estimated range.

Table 4: Conformity assessment costs (£m)

	Year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Total *(Discounted to 2021, deflated to 2019)*
Option 0	Low	1.4	1.4	-	-	-	-	-	-	-	-	2.6
	Central	11.7	11.7	11.7	11.7	11.7	-	-	-	-	-	52.7
	High	23.6	23.6	23.6	23.6	23.6	23.6	23.6	23.6	23.6	23.6	195.0
Option 1	Low	2.7	-	-	-	-	-	-	-	-	-	2.6
	Central	58.6	-	-	-	-	-	-	-	-	-	56.3
	High	235.8	-	-	-	-	-	-	-	-	-	226.6

The net additional cost in 2019 prices for the low, central and high scenario is <£100k, £3.7m and £31.5m. This is calculated by taking the 2019 costs under Option 0 from the 2019 cost under Option 1. Figures may not sum due to rounding.

Conformity marking

70. The legislation also brings forward the requirement for new UK conformity marking. We estimate that between 10,000 and 17,000 (central estimate is 14,000) UK manufacturers will need to add UK conformity marking to their products.[22] This estimate is based on the number of businesses which comply with the regulations in scope of this SI. See table 6 for further details on this estimate. In the counterfactual, we assume that businesses will add conformity marking as part of their product development cycle. Any additional costs to businesses of the UK conformity marking were already considered in the previous SI and do not require a formal assessment in line with guidance on EU-exit related impacts.

71. Engagement with businesses suggests that businesses change their marking/labelling on products as part of their product development cycle, for example, when products are redesigned, or machinery and tools are upgraded. Under Option 1, businesses will be required to add the UK conformity marking from the 1st January 2022. Though it is likely some businesses will apply markings as part of their product development cycle and will therefore apply the UK conformity marking with little or no additional cost, many manufacturers may have to add the UK conformity marking outside of their normal product development cycle.

72. Research suggests usual marking changes can occur as often as every year for some businesses, up to around every 10 years. We do not have sufficient data to precisely estimate the frequency of business-as-usual marking or labelling changes across sectors. Therefore data we have collected at a directive/regulation level has been aggregated across all sectors and tested with technical policy experts for each directive/regulation to check that they are realistic assumptions, as an additional layer of validation. Our evidence shows that the frequency with which normal marking changes are made varies across product types and businesses, however we do not have sufficient data to assess precisely how this varies across sectors. The following case studies illustrate the frequency of marking changes for different products:

> **Case Study 1:** A manufacturer which produces equipment regulated by the ATEX Directive 2014/34/EU changes their marking every year.

> **Case study 2**: A manufacturer which produces products regulated by the Personal Protective Equipment Directive 89/686/EEC can have supply-chain commitments (requiring labelling) 18-24 months before distribution.

> **Case study 3**: According to an industry representative, marking/labelling tools for Electronics manufacturers can run for 4-5 year cycles. These businesses are typically regulated by the Electromagnetic Compatibility and Radio Equipment Directives.

73. From the data collected, to account for the variation in business behaviour, we assume that the likelihood of businesses making a marking/labelling change in any given year is 10-50% (central estimate 20%). We estimate that 60% of manufacturers make a change every 2 years, 30% every 5 years, and 10% every 10 years (central scenario). From this assumption, we estimate that the proportion of businesses making changes outside of their normal product development cycle is around 60-67% (central estimate 63%).

74. Engagement with manufacturers suggests that adding the UK conformity marking outside of the product development cycle could cost between £100s to tens of £1000s. Two out of 40 manufacturers interviewed reported that the cost of adding the UKCA mark would be

[22] ONS (2019)

minimal. One manufacturer suggested a new printer for labels would cost around £1,000. Other costs can come from change labelling software, purchasing new marking tools or hiring engineers to redesign labels. However, costs depend heavily on the type of products and manufacturing process and engagement suggests that some businesses will face larger costs. 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. However, it is not clear what the additional cost would be of (for some businesses) investing in new tools or software outside of their usual product development/investment cycles.

75. Due to a lack of data at the sector level, we aggregated data across all sectors we assume that the typical cost of new marking per business is £1,000 (low) - £10,000 (high) (central est. £5,000), and that the proportion of manufacturers with low, central, or high costs is 60%, 30% and 10% respectively. The low scenario assumes a greater proportion of businesses have low costs (£1,000), and a lesser number have high costs (£10,000). For the high scenario, the opposite applies.

Figure 2: Marking/labelling cost calculation

A. Number of businesses affected: 10,300 – 17,100 (central est. **13,700**)

B. Proportion of businesses making changes outside of the product development cycle: 60 – 67% (central est. **63%**)

Marking change rate (likelihood of change in any given year): 10-50% (central est. 20%)
× *% of manufacturers changing labels every 2/5/10 years (60/30/10% in central scenario)*

C. Typical cost of adding new marking outside of product development cycle: £2,450 - £3,750 (central est. **£3,100**)

Cost of new marking per business: £1,000 - £10,000 (central est. £5,000)
× *% of manufacturers with low/medium/high costs (60/30/10% in central scenario)*

A x B x C = **£26.2m** = additional costs from 100% of labelling changes occurring in year 1 (option 1)

(£25.7m in 2019 prices)

76. GB importers will also need to ensure that all imported products are labelled with official UK importer addresses at the end of the 12-month period where manufacturers can continue to place CE marked goods on the UK market. There will be a further 12 months of transitional measures where business can put new addresses in an accompanying document.

77. Where products are not already labelled with UK addresses, businesses will incur the cost of adding this information. In some cases, non-UK manufactures will undertake this change and costs; in others, GB importers will have to add this information. Due to lack of data on the behaviour of businesses, it is not possible to assess how the costs will be distributed across GB and non-GB businesses. In any case, the cost to GB businesses of implementing this change now, compared to at some point in the future, is likely to be very small.

78. Like GB manufacturers, non-GB manufacturers will have to add UK conformity marking to their products destined for the UK market. As the costs fall on non-GB businesses, we do not quantify the cost (out of scope) but provide some qualitative assessment in the wider impacts section given that there could be some pass-through effects (see paragraph 119).

79. The total additional cost of marking/labelling in this 12-month period, relative to the counterfactual, is estimated to be £25.7m (central scenario). However this estimate does not account for the mitigating impact of transitional measures, which may reduce costs for manufacturers. This is not quantified, but we provide a qualitative assessment of the transitional measures below.

Transitional Measures

80. Although manufacturers have to add UK conformity marking for the 1st January 2022, they have a further 12 months, as part of the 24-month transitional measure period, where they can apply UK conformity marking on removable labels (e.g. sticky labels) or in an accompanying document. These measures will mean that businesses do not necessarily need to re-design products and packaging, and these will therefore reduce costs for business. However, we do not have any data on what proportion of businesses will choose to use the transitional measure, and so this impact is excluded from the quantitative analysis. Engagement with manufacturers suggests that many businesses can make marking/labelling changes within the first 12 months, whether as part of their product development cycle or as an additional cost to their business.

81. It may be that if businesses are able to do so, they will choose to add permanent UK conformity marking to all of their products rather than face the cost of adding removable labels to one group of their products and permanent marking to a second group of products. However, some businesses will not be able to add permanent UK conformity labels within the first 12 months as it will take them longer to prepare. These businesses can place removable labels on products or attach an accompanying document from 1st January 2022, as an interim measure to allow more time to add permanent labels before 1st January 2023.

82. Removable labels should therefore reduce the overall cost of complying fully with the UK regime before 2023. By using the removable labels, businesses who cannot add permanent labels in the 12-month period where manufacturers can continue to place CE marked goods on the UK market or can only do so at a very high cost, will be able to add removable UK conformity marking at a more feasible cost and sell their products in GB in 2022, whilst adding permanent marking before 2023. It is possible that business could incur procurement costs associated with applying removable labels, however we assume businesses would only select this option if it was less costly than adding permanent marking.

83. With the option to use removable labels or an accompanying document between 1st January 2022 and 31st December 2023, some businesses will choose to delay costs in this second 12-month period. However, overall, we would expect this measure to create a reduced cost to business because more businesses will be able to incorporate the permanent marking into their product development cycle.

Testing capacity in the UK

84. The UK civil explosives and pyrotechnics sectors warrant special attention, since engagement suggests there is currently limited conformity assessment capacity in the UK.

Civil Explosives

85. The civil explosive sector is small relative to other sectors in scope of this assessment. There are 13 UK manufacturers of civil explosives, all of which we estimate sell within the UK and EU and currently have certificates with EU Notified Bodies.[23] HSE have estimated that there are £100m of explosives exported to the EU and £500m imported from the EU.[24] The Civil Explosives directive applies to sectors such as mining, construction and offshore industries, and covers products such as propellant powders and safety and detonating fuses.

86. The UK civil explosives Notified Body (ENB) was originally established by HSE's Science Division (SD) following a Ministerial steer at the time, that it should be set up and, in time,

[23] Estimated by HSE

[24] Estimated by HSE. Data on trade with non-EU countries is not available.

would then be taken on and owned by a commercial provider. This has not happened, and the commercial arm within HSE remain the UK's only providers of civil explosives conformity assessment. The lack of market appetite is perceived to be as a result of the highly technical facilities required, running costs and low profit margins. There is no legal requirement for HSE to operate the civil explosives CAB. However, it is the only provider in the UK and, given the impact of the end of the transition period and the Government's intention to end unilateral recognition of EU conformity assessment, HSE plan to sustain the facility.

87. HSE has developed and identified a viable operating model for the conformity assessment of civil explosives. Assessment of civil explosives, as now, will be delivered by the commercial arm of HSE's Science Division (SD). The service will be operational from the end of the transition period.

88. The main risk identified relates to testing for new products not having previously undergone any form of conformity assessment procedure and marking. Explosives conformity assessment is a technically niche area and currently none of the limited number of EU notified bodies offer a comprehensive service for the assessment of all product types and rely on sub-contracting out to each other which is included in the final costs to the dutyholder.

89. Looking beyond the end of the 12-month standstill period, SD is considering how it may provide conformity assessment for the full range of civil explosive products and this may include sub-contracting the testing to third parties and then reviewing/assessing the outcomes prior to issuing the UKCA mark. Work is ongoing to develop operational capability and identifying any additional work required.

Pyrotechnics

90. UK businesses that place pyrotechnic articles on the UK market currently have their products conformity assessed to the CE marking requirements by EU based Notified Bodies. There are very few manufacturers of pyrotechnics (including fireworks, stage pyrotechnics and also products such as Christmas crackers) in the UK. There are no UK manufacturers of fireworks and we estimate that there are around 4 UK manufacturers of other pyrotechnic products in the UK.[25] The majority of pyrotechnics are manufactured in China and imported into the UK. The UK imported £26m of pyrotechnics in 2018 which represents a very small proportion of the UK's manufactured goods imports (0.02%).[26] However, some UK distributors of fireworks put their own branding on products and are therefore considered 'manufacturers' according to the regulation. We estimate that there could be around 60 distributors in the UK which are responsible for ensuring that imported products comply with the pyrotechnics regulation.[27]

91. There is no Notified Body for pyrotechnics in the UK. Engagement with the UK pyrotechnics industry suggests the industry is in decline as in 2019 there were so few UK manufacturers for pyrotechnics, and to date there hasn't been market appetite to set up a UK Notified Body. All UK and non-UK manufacturers selling pyrotechnics in the UK use one of the twelve[28] EU pyrotechnic Notified Bodies to have products conformity assessed to EU regulations. Many of these NBs have satellite offices based in China, where the majority of fireworks are manufactured for logistical reasons. Without a UK body in place that is ready to act as an Approved Body, these manufacturers cannot get products assessed to UK regulations and will not be able to sell fireworks in the UK after recognition of CE marked goods ends.

[25] ONS (2019) data suggests there are around 4 manufacturers of relevant products in the UK

[26] HMRC (2018) Excludes agri-food manufacturers

[27] British Pyrotechnics Association website and British Fireworks Association website (2020)

[28] NANDO (2020)

92. This SI includes provisions which allow the Secretary of State to designate approved bodies who are based outside the UK, and includes provisions for the approved body to allow a sub-contractor or subsidiary (in conjunction with the approved body, or not) which is capable of carrying out all the conformity assessment activities required as per the regulations. The Department will work with UKAS and third country CABs, with an aim of designating at least one third country CAB in advance of January 2022.

93. In the even that a third country CAB does not want to take on responsibility for certifying against the UKCA mark, which we consider unlikely given existing third country CABs already certify for the UK market, then we would work with stakeholders on an alternative solution that would ensure important pyrotechnic products could still be placed on the GB market.

Familiarisation Costs

94. Manufacturers, Notified Bodies, UKAS, [29] importers, retailers and enforcement bodies will have to familiarise themselves with the new legislation. The Impact Assessment accompanying The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 titled 'Preparing product safety and metrology legislation for EU Exit in a no-deal scenario'[30] considered the impact of these organisations familiarising themselves with the new UK regime, including the UKCA mark and the deeming provision. There will be no additional costs associated with record keeping to demonstrate compliance, which businesses may already incur as part of the existing arrangements. However, with this SI, manufacturers, Notified Bodies, importers, retailers and enforcement bodies will have to read and understand the following changes: the end date of the deeming provision, the transitional measures, and the minor amendments to specific regulations (e.g. Toys).

95. We estimate that in total over 100,000 businesses may need to familiarise themselves with these changes. This total includes manufacturers, retailers/wholesalers, Notified Bodies, and local authorities. Our best estimate is that there are around 85,000 UK retailers and wholesalers operating in sectors affected by this SI,[31] plus around 14,000 manufacturers, Notified Bodies and other relevant organisations. See table 6 for further details.

96. We estimate that it will take between 1-3 for a corporate manager or director to familiarise themselves with the new legislation and communicate this to staff. Three hours is a reasonable upper estimate for the amount and complexity of this new legislation. The 2019 no-deal legislative changes estimated three hours which included a longer list of legislation subject to amendment than is included in this SI. Three hours is also similar to the estimated familiarisation time for the 2014 product safety regulation that consolidated, modernised and clarified 20 previous regulations relating to the manufacture and storing of explosives, which similarly covers the ground of multiple existing regulations without fundamentally changing the approaches taken.[32]

97. Some businesses may take longer than three hours to read and comprehend the changes, whereas others may take only a few minutes, and others may not need to take any time at all (many business that we estimate could be affected, particularly retailers/wholesalers, many not in fact deal with products in scope of the measures). Our central scenario assumes

[29] UKAS is the UK's accreditation body

[30] https://www.legislation.gov.uk/uksi/2019/696/impacts

[31] ONS Annual Business Survey (2018)

[32] This estimate familiarisation time for the 2014 regulation was tested in consultation. *Impact Assessment on Proposals to consolidate and modernise explosives legislation and to withdraw the Approved Code of Practice to the Manufacture and Storage of Explosives Regulations 2005 https://www.legislation.gov.uk/ukia/2014/197/pdfs/ukia_20140197_en.pdf*

an average of two hours familiarisation time per business, which corresponds to an aggregate cost estimate of £6.6m.[33]

98. The Department published guidance on 1 September 2020, which set out the actions businesses needed to take to place product on the market for Great Britain. The guidance is concise and is written in easy to read language. Familiarisation time for businesses should therefore be limited.

99. As stated in para 94, the total estimated familiarisation costs take into account reading and understanding the transitional measures, which include for instance temporary marking and labelling until 2023. If firms decide to take this approach to meeting the regulatory requirements, there may be specific costs of understanding the particular marking/labelling requirements and what is permissible, however we are not able to quantify this aspect specifically as the take-up of this voluntary option is unknown.

Table 5: Estimated costs of Option 1

Option 1 – Net Present Value (2019 prices)	Low	Central	High
Additional Conformity Assessment Costs	<£100k	£3.7m	£31.5m
Additional Marking/Labelling Costs	£14.4m	£25.7m	£41.8m
Additional Familiarisation Costs	£1.8m	£6.6m	£15.1m
Total	**£16.2m**	**£35.9m**	**£89.4m**

Figures may not sum due to rounding.

Benefits

100. The benefits on businesses and individuals of the UK's new product safety and metrology regime are out of scope as this was considered as part of SI 2019/696. However, we explain below the benefits of ending the deeming provision.

101. The SI will provide benefits for both UK businesses and consumers. Ending the deeming provision after a specified period provides certainty for manufacturers, allowing them to plan their adaption to the UK's product safety and metrology requirements post-departure from the EU around the timetable specified in this SI. By ending the deeming provision, the UK will meaningfully be able to set its own regulations in the interests of UK business and consumers and to provide adequate protection to UK consumers.

102. 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 SI also reduces the risk of consumers, businesses and others buying faulty, unsafe, non-compliant or inaccurate products. National Trading Standards 2017-18 Annual Report[34] states that NTS's enforcement activities prevented over 800,000 unsafe and 1.4 million non-compliant items entering the UK supply chain. NTS calculated that the cost to society if these items had not been removed would have been £70 million.

103. This risk is higher whilst the UK continues to accept EU requirements with no additional UK requirements: Should the UK choose for example to introduce higher levels of protection in future, then automatic continued acceptance of EU goods could mean that products manufactured to lower standards (than set out by UK legislation) could still be sold in the UK, and could undermine the competitiveness of UK businesses.

[33] Average gross hourly wage is assumed to be £28.37 (ONS ASHE 2018), combined with a non-wage labour cost uplift of 22% calculated using Eurostat (2018) *https://ec.europa.eu/eurostat/documents/2995521/9720156/3-11042019-BP-EN/3240675b-5513-41a4-8b28-3f5e24c55b70*. This is multiplied by the estimated number of businesses (manufacturers plus retailers and wholesalers) – 99,000 in the central scenario - and the average time taken the read the legislated (1 to 3 hours). The total is £6.6m, expressed in 2019 prices.

[34] http://www.nationaltradingstandards.uk/uploads/annual%20report%202017-18%20final.pdf , p57

104. It is not possible to quantify the precise benefits to business and individuals of ending the deeming provision, but we expect this benefit would increase over time if the UK and EU requirements were to diverge in the future. In such a scenario, if we did not end the deeming provision, businesses would be able to sell products in the UK which did not meet UK rules.

105. The SI also makes some minor amendments to UK regulation on Toys, Lifts, RAMS, Weighing Instruments and Cosmetics. By correcting deficiencies in previous related legislation, this will provide certainty for businesses. We are not able to quantify the benefit of the amendments but estimate these to be very small as the amendments are minor.

Table 6 – Evidence for assumptions

Estimate	Source(s)	Assumption(s)	Description
Number of businesses impacted	ONS (2019), HMRC (2018)	Between around 10,000 and 17,000 manufacturers (central estimate 14,000), and – for familiarisation costs only - between 40,000 and 135,000 retailers and wholesalers (central estimate 85,000), up to around 200 UK Notified Bodies, and around 200 local authorities in GB enforcing product safety and metrology.	Manufacturers: It is not possible to measure the precise number of manufacturers affected, since publicly available data does not record business activity according to which directive/regulation applies to products that individual firms manufacture. In each industry, there will be many businesses who do not have to comply with the regulations/directives in scope of the policies assessed here. We therefore apply a scaling factor using HMRC trade data to produce a more informative estimate of the affected business population.[35] Retailers/Wholesalers: Whether a seller is affected depends on whether they sell products in scope of these regulations; this is not possible to determine from publicly available data. We start with ONS (ABS) data on business activity by sector (SIC4), and conservatively assume that around two-thirds may stock products in scope based on the descriptions of each sector, with the upper end of the assumed range including more varied sectors such as online/mail-order retailing. This is likely to be an overestimate. To account for the uncertainty, we scale down the point estimate by 50% for the low end of the assumed range. Notified Bodies: According to the EU NANDO database,[36] there are 160 UK Notified Bodies. Authorities: According to the OPSS there are c.196 local authorities enforcing product safety/metrology
Conformity assessment costs	2019/2020 Industry research	Average conformity assessment cost per product range: £2,000 to £15,000 (central estimate £12,000), with a likely range of £500-£100,000. Average fee for new UK certificate issuance: £100 to £2,000 per certificate (central estimate £200)	We have collected data on the costs of conformity assessment and issuing certificates from UK businesses and Notified Bodies. Costs vary depending on the type of product and regulatory requirements being assessed: 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 size, assessment history and in-house expertise.
Conformity marking costs	2019/2020 Industry research	Average marking/labelling cost per product range: £1,000 to £10,000 (central estimate £5,000).	We have collected data on the costs of adding new marks/labels to products from UK businesses and from external literature. Evidence suggests there is a wide range of potential costs to adding conformity marking outside of the product development cycle, 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.
Firm characteristics	2019/2020 Industry research	Average number of product ranges per business range: 6 to 8 (central estimate 7) Annual rate of marking/labelling changes: every 2 to 10 years (central estimate 5 years) Annual rate of recertification range: every 2 to 20years (central estimate 7 years)	We have collected data to estimate the number of product ranges in the UK per business, and the annual rate of marking/labelling changes and conformity assessment certification. This was collected from UK businesses, and tested with policy experts.
Familiarisation costs	ONS (2018)	We assume that it will take between 1-3 hours (central estimate 2 hours) for a manager/director to read guidance and pass on information to colleagues and clients.	We use ONS ASHE data (2018) on the average gross hourly wage of corporate managers and directors (£28.37), and apply an uplift to take account of non-wage labour costs (+22%)[37]

[35] We map the directives/regulations in-scope to individual 6-digit Harmonised System (HS6) tariff trade codes that apply to each one. We then match these to 4-digit Standard Industrial Classification (SIC4) codes to estimate the number of businesses impacted at the industrial 4-digit code level using ONS ABS data. To account for the overestimation, we scale down the estimates by using HMRC (2018) trade data to calculate the proportion of trade under each SIC4 sector that is products which fall under each directive/regulation. These proportions at SIC4 sector are then applied to the number of manufacturers to provide an estimate of the affected business population. The overall scaling factor (weighted average) is around 50%.

[36] https://ec.europa.eu/growth/tools-databases/nando/. Accessed May 2020.

[37] calculated using Eurostat (2018) https://ec.europa.eu/eurostat/documents/2995521/9720156/3-11042019-BP-EN/3240675b-5513-41a4-8b28-3f5e24c55b70

Wider impacts

Costs for government

106. It is businesses' responsibility to ensure that their manufactured products conform with the UK's regulatory regime. All costs for government of introducing the product safety regulations and associated policies are out of scope of this assessment as they relate to having a functioning UK regulatory system after the end of the EU Exit transition period.

107. Responsibility for adhering to the requirements lies with business, but enforcing authorities such as local authority Trading Standards, or the Health and Safety Executive (HSE), have a key role in checking compliance with these requirements to ensure the safety of products on the market. This enforcement role includes advising industry on their systems and processes to ensure compliance, carrying out market surveillance activities to check and test products, as well as specialist teams operating at points of entry to intercept unsafe and non-compliant goods as they enter the UK.

108. There may be some additional Trading Standards inspections (and associated costs) due to ensuring that products on the UK market comply with the UK regulations such as having UKCA marking from January 2022. Compared to the status quo, there may be some additional risk of non-compliance due to ending the deeming provision and businesses having to comply sooner than they may otherwise have expected to do so, however this should be offset somewhat by the transitional measures for marking/labelling which should ease the burden of complying with the regulations and therefore reduce the incidence of non compliance. For advising businesses and responding to requests for advice, we assume that costs to Trading Standards are fully recovered.

109. The UK government is developing policy in order to create conformity assessment capacity for pyrotechnics in the UK. OPSS plan to mitigate the risk of no conformity assessment capacity by allowing conformity assessment bodies outside of the UK to be designated. This would allow businesses selling pyrotechnics in the UK to continue to use EU Notified Bodies. Alternatively, the UK government might decide to fund a UK conformity assessment body if the private conformity assessment sector did not have the appetite for this. For example, the government might have to fund the expansion of the civil explosives conformity assessment body for pyrotechnics. This would include costs for the training of staff and investment in testing facilities and equipment, as well as the accreditation of the body. Interviews with bodies suggests accreditation from UKAS for one directive costs around £20,000 initially, with on-going annual costs.

110. Additionally, the UK Notified Body for civil explosives (ENB) sits within the commercial arm of the Health and Safety Executive (HSE) Science Division. HSE does not bear any of the costs of providing the conformity assessment service function, as since the early 1990s when it was established, it has delivered the conformity assessment of civil explosives as an independent self-sustaining commercial entity.

111. At the end the transition period, the ENB will become the UK Explosives Approved Body (EAB). Explosives conformity assessment is a niche area and so due to the limited number of Notified Bodies, some had areas of work where they were more specialised meaning that not all EU Notified Bodies had to provide assessment for all products. The EAB will therefore need to provide an expanded service compared to the ENB due to it being the only body able to assign the UKCA to place goods on the GB market and this will require additional set up costs. This is a cost of the UK leaving the EU itself, not of the 2020 Product Safety SI, and is therefore out of scope of the assessment.

112. It is anticipated that over time, the EAB should become self-sustaining as the increased volume of chargeable conformity assessment services will necessarily be over and above

current levels. HSE is also developing differing delivery models to ensure delivery of this essential service, while limiting exposure in the current uncertain circumstances."

113. UKAS, is the UK's sole accreditation body recognised by the UK government and is responsible with assessing the competence of the UK's assessment bodies (e.g. Approved Bodies). Consultation with policy officials in BEIS with responsibility for accreditation suggests there should be minimal or no additional costs to UKAS because the accreditation activities they will perform for the UK regime will not change. Accreditation is largely carried out to the international accreditation standard ISO17011, whether it is for the accreditation of an Approved Body, Notified Body, or for voluntary purposes. Given this, plus the fact that UKAS does not require government funding, we do not anticipate there to be additional costs to government. We have taken familiarisation costs for UKAS into account on page 26, however, there may be some additional administration costs.

Product Availability

114. Many UK and non-UK manufacturers will have to add UK conformity marking to their products outside of their normal product development cycle and might have to obtain UK certificates issued by UK Approved Bodies before products require re-certification by their current EU Notified Body. Since the costs of bringing forward conformity marking and conformity assessment to be compliant with the UK regime at the end of the period where manufacturers can continue to place CE marked goods on the UK market can be considerable, up to tens of thousands of pounds per business, some manufacturers may decide to reduce products or stop selling products on the GB market. This is more likely for non-UK manufacturers where UK sales are a small proportion of their total sales.

Non-compliant products

115. It is possible that manufacturers will continue to sell CE marked or equivalent goods in the UK which are not compliant with the new UK regulation (for example applying the UKCA mark).

116. Although the government has issued guidance to businesses on the length of the period where manufacturers can continue to place CE marked goods on the UK market and what this means for business on 1 September 2020, some businesses, in particular non-UK manufacturers, may not be aware of the new requirements. We have not been able to engage with non-UK manufacturers on their readiness for the UK regime and how ending the deeming provision will impact them.

117. Whilst we do not envisage any significant increase in market surveillance activities, and we will continue with an intelligence-led, risk-based approach to market surveillance, it is possible that the UK government may have to increase spending on market surveillance activities to continue to ensure that products are compliant with UK regulations and those which are not, can be taken off the market. 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.

Non-UK businesses

118. All non-UK manufacturers exporting products to the UK will also be subject to the requirements of this SI. Impacts on non-UK manufacturers could affect UK businesses and consumers: The additional costs they face from bringing forward conformity marking, and conformity assessment changes could be passed onto UK businesses and consumers through higher prices. There is also a risk that non-UK manufacturers, particularly those with a lower awareness of UK requirements, will not meet the requirements in time. This would lead to a reduction in UK imports.

119. We estimate that up to £70.9bn (17%) of the UK's imports may need to comply with the UK regime.[38] The likely impact on prices of imported products and product availability will depend on three key factors:

i. Costs to non-UK manufactures: we expect that the potential costs for non-UK manufactures will be very small compared to the value of their exports to the UK (as for UK businesses, the relevant costs are those that are in addition to complying with the UKCA regime as part of normal businesses processes)

ii. Readiness of non-UK manufacturers: We do not have evidence to reliably anticipate readiness of non-UK manufacturers in two years' time. However, it is likely that they have lower awareness of UK requirements, and thus, there is a greater risk of them being not ready to comply with the changes by the required deadlines. SMEs with low amount of exports to the UK are likely to be most at risk.

iii. Price elasticity of UK demand for imported product: non-UK manufactures are more likely to pass any additional costs to UK consumers and importers where UK consumers are less likely to switch away from their products in response to higher prices (i.e. due to limited choice of alternative products or strong preference for imported goods). Given the variability of products and sectors in scope we cannot reliably assess whether the non-UK exporters will be able to easily pass the additional cost on UK consumers.

Impact on competition

120. The measures from this SI may have the potential to drive some competition impacts primarily through some firms exiting the market (either through choice or non-compliance). As set out below, given the characteristics of the regulatory change we expect these impacts to be very small.

i. The number/range of suppliers: the measures unlikely to have a significant cost impact on firms (UK or non-UK businesses); however an increase in costs – if firms are unable to pass these on through higher prices - could lead to some firms exiting the market. Given we estimate there are up to 17,000 UK manufacturers, this should have a limited impact overall. Since the measures apply equally to all businesses, it is likely that any cost increase will be passed on, with the degree of competition in the market unchanged.

ii. Suppliers' incentives/ability to complete: the measures are unlikely to limit the number or range of suppliers since the measures do not introduce any restrictions or controls on particular suppliers' ability to compete. Additionally, we have no evidence that particular businesses will be more able to comply with the changes at lower cost than other businesses.

iii. Consumer choice: the measures will affect all businesses equally, including both UK and non-UK businesses supplying UK consumers, and so should not limit consumer choice as – assuming existing manufacturers decide to adapt to the new requirements and not discontinue supplying the UK market – consumers should have access to all the same variety of products. The measures should not increase the cost for consumers of changing supplier.

Consumer awareness

[38] HMRC (2018). Excluding agri-goods imports

121. The CE marking is not a consumer mark, however it's often seen as such when it comes to public led campaigns. Like the CE marking, the UKCA marking is the product marking to demonstrate conformity to the product's regulations, and therefore is not intended for consumers. The Department has not yet scoped or costed how the UKCA marking should be communicated to consumers.

Environmental Costs

122. We expect the Product Safety SI to have limited environmental costs.

123. The legislation could create environmental costs through two channels. The first is the cost to the environment of the option to businesses of using removable labels (e.g. sticky labels) or accompanying documents for UK conformity marking and manufacturer/importer addresses. Business will be able to use this transition measure from the 1st January 2021 until 31st December 2022. We do not have data to estimate how many businesses will make use of this voluntary measure. However, we expect it to be the minority because some businesses will incorporate permanent UK conformity marking or address changes into their normal marking changes in this period and many other businesses will choose to add permanent marking and addresses in this period in order to avoid having to add removable labels and then add permanent marking at a later date. Therefore, it is likely to be businesses which cannot add permanent marking or addresses to this product in this period which will use this measure. The environmental costs of this measure will be:

    i. The additional cost of greenhouse gas emissions from the production of the labels or documents relative to that of permanent marking, and the resulting impact on climate change.

    ii. The cost to UK citizen's health and the UK's biodiversity from labels or documents which are discarded (e.g. cost to local councils of waste collection, costs of treating water pollution).

124. The second environmental cost of the Product Safety SI is that many businesses will have to discard stockpiled EU conformity labels. For example, two manufacturers interviewed stockpile their conformity marking labels for several years. From the 1st January 2022 they will no longer be able to use labels with EU conformity marking and the stockpiles of these would have to be discarded. This would have an environmental cost to local authorities of having to put the labels in landfill. In some cases, sticky labels can be recycled but components such as ink and adhesive are contaminants and there would be costs of treating these.

Small and micro business assessment

125. The SI will affect many small and micro businesses. We estimate that 99% of UK manufacturers directly affected by this legislation are small and medium sized businesses (between 9,900 and 16,800 businesses), of which 78% are micro sized businesses (<10 employees). We do not have information about the market share of small and micro sized businesses in scope of the SI.[39]

126. These businesses could be disproportionately impacted by the changes. The costs to business of conformity marking and conformity assessment are relatively fixed. Costs depend on the type and design of products a business produces rather than the quantity produced. For example, costs will depend on whether products require moulded labels or require physical testing by a CAB.

[39] ONS (2019)

127. Due to the characteristics of these businesses, ending the deeming provision after a period where manufacturers can continue to place CE marked goods on the UK market will have impacts varying in size for each business. Engagement with businesses shows that some small manufacturers use just-in-time labels, often printed in-house, which makes adding a new conformity marking a relatively quick and low-cost change. However, for other small businesses, evidence suggests making this marking change outside of their normal product development cycle could cost up to tens of thousands of pounds.

128. To mitigate the impact, the government will introduce transitional measures as part of the SI. The 12-month period during which manufacturers can continue to place CE marked goods on the UK market will ensure that businesses have time to meet conformity assessment requirements and add the UK conformity marking to products. The 24-month transitional measure period allows businesses to apply removable labels to products or have accompanying documents with the UK conformity marking and importer/manufacturer addresses. This will give all manufacturers more time and flexibility to incorporate the permanent UK conformity marking and UK addresses into their production process. These measures will allow more businesses to meet requirements at a lower cost. For example, some businesses will be able to make marking changes in 2021 as part of their normal business process. It will also help businesses avoid the risk of not meeting requirements from 1st January 2022 and not being able to sell products in GB.

129. A permanent exemption for small and micro businesses would invalidate the purpose of the policy as the vast majority of businesses would be exempt. Also, all imports from the EU would be allowed regardless of whether they meet UK rules (regardless of whether they are large or small) as there would be no way of verifying if EU exporters are small or large businesses. This could create risks for UK consumers and could create an unlevel playing field for UK businesses.

Risks and assumptions

130. The Department recognised that there will be widespread interest in how and when the UK plans to ensure an operable product safety and legal metrology framework. The assessment is informed by the available evidence, both quantitative and qualitative. The Trade and Investment Negotiations team in BEIS has held engagement with manufacturers, trade associations and conformity assessment bodies over the last three years to understand their preparations for the UK's exit from the EU and how a mutual recognition agreement (MRA) of conformity assessment with the EU would benefit UK businesses.

131. Data limitations mean that there is a high degree of uncertainty about the precise impacts on business. Where available data was insufficient to provide a quantitative assessment with a sufficient degree of confidence, we have provided a qualitative assessment of expected impacts, for example, of how transitional measures could reduce the cost for businesses.

132. Since we have been unable to collect fully representative cost data across different businesses and sectors and the publicly available data is limited, we have made several assumptions as part of this assessment. Assumptions are supported by evidence we have collected through business interviews and surveys, descriptive statistics, empirical literature and consultation with government policy experts. We have also assessed three different scenarios, low, central and high to account for the uncertainty in our assumptions and assessment. Our Best Estimate as presented in the summary sheets on pages 1 and 3 is based on our central scenario. The assumptions made are explained in detail in the preceding section 'Costs and benefits of each option' (page 13).

133. Additionally, the regulations and directives in scope cover a wide range of product types. As businesses only manufacture products covered by a handful of directives/regulations in scope, the evidence we collected is at this level. Therefore, where possible we used a weighted average for assumptions based on the proportion of manufacturers estimated to manufacture products in-scope of each regulation/directive.

Summary and description of implementation plan

134. The SI ensures that the UK will continue to have a robust product safety and metrology system fully regulated through UK legislation in all scenarios. This will ensure that it will be necessary for manufacturers, importers and distributors to demonstrate that products brought to the UK market will continue to meet the essential requirements. The SI will enable the UK to put in place an effective product safety and metrology system if current arrangements are no longer recognised.

Post implementation review

135. This legislation intends to provide a period for 12 months where manufacturers can continue to place CE marked goods on the UK market, and then end, the acceptance of products which comply with the EU product safety and metrology legislation in the UK and to correct deficiencies in past EU exit legislation to ensure the UK's own product safety and regulatory regime is fully in place from 1st January 2021. These circumstances mean that the Government takes the view that a post-implementation review of such correcting regulations would not be proportional and is not required. There would be limited scope for change of the legislation following a review and the costs of undertaking a review would outweigh any potential benefits.

136. This does not remove the general need to review and improve legislation in due course and where appropriate, but rather removes rigid review requirements as they relate to this SI.

Annex 1 – List of Regulations/Directives amended by the SI

1. Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
2. Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019
3. The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020
4. The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020
5. GPSR General Product Safety Regulations 2005/1803
6. RAMS (EU Regulation) 765/2008
7. ATEX Equipment for use in potentially explosive atmospheres Regulations 2016/1107
8. Electromagnetic compatibility Regulations 2016/1091
9. Lifts Regulations 2016/1093
10. LVD Electrical Equipment (Safety) Regulations 2016/1101
11. Pressure Equipment (Safety) Regulations 2016/1105
12. Pyrotechnic Articles (Safety) Regulations 2015/1553
13. Recreational Craft Regulations 2017/737
14. Radio Equipment Regulations 2017/1206
15. SPV Simple Pressure Vessels (Safety) Regulations 2016/1092
16. Toys (Safety) Regulations 2011/1881
17. Explosives Regulations 2014/1638 [HSE/DWP]
18. Aerosol Dispensers Regulations 2009/ 2824
19. Cosmetics (EU Regulation) 1223/2009
20. Gas Appliances (EU Regulation) 2016/426
21. Supply of Machinery (Safety) Regulations 2008/1597
22. Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001/1701
23. Personal Protective Equipment (EU Regulation) 2016/425
24. Measuring Instruments Regulations 2016/1153
25. Non-automatic weighing instruments Regulations 2016/1152