

<b>Title: Preparing product safety and metrology legislation for EU Exit in a no-deal scenario</b>  <b>IA No: BEIS030(F)-18-OPSS</b> <b>RPC Reference No:</b> <b>Lead department or agency:</b> Office for Product Safety and Standards, BEIS <b>Other departments or agencies:</b> Health & Safety Executive - Department for Work & Pensions, Department of Health and Social Care	<b>Impact Assessment (IA)</b> <b>Date: 04/02/2019</b> <b>Stage: Final</b> <b>Source of intervention:</b> <b>Type of measure:</b> Secondary legislation <b>Contact for enquiries:</b> Policy: Christine Knox <a href="mailto:Christine.Knox@beis.gov.uk">Christine.Knox@beis.gov.uk</a>  Analyst: Ivan Bishop <a href="mailto:Ivan.Bishop@beis.gov.uk">Ivan.Bishop@beis.gov.uk</a>
<b>Summary: Intervention and Options</b>	<b>RPC Opinion:</b> Not sought as IA is de minimis

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANDCB in 2014 prices)	One-In, Three-Out	Business Impact Target Status
-£25.02m	-£25.02m	£2.4m	Not in scope	N/A

**What is the problem under consideration? Why is government intervention necessary?**  
 On exit from the EU we want to ensure that the UK has an effective and robust product safety and metrology regime in place, which will continue to provide reassurance and continuity to consumers and UK businesses. The current UK product safety and metrology framework is underpinned by EU law, which would not apply to the UK once it is no longer a Member State of the EU. Without action, the current regime would no longer function properly. We need to correct this before we leave the EU so that our legal system continues to function to protect consumers, workers and provide continuity for business.

**What are the policy objectives and the intended effects?**  
 The objective is to convert the EU-derived product safety and metrology legislation into UK law so that it continues to function on Day One after exit if the UK were to leave the EU without a deal. Delivering the deal negotiated with the EU remains the Government's top priority, but this SI is planning for a contingency and is the responsible approach to exit preparations. This will ensure that products are safe to use and will not cause harm to consumers, workers and others. It will also ensure that unsafe products can continue to be removed from the market. This will provide UK businesses and consumers with continuity and 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)**

0.Current arrangements up to 29 March 2019: the UK operates a product safety and metrology regime based mostly on EU legislation, enabling the free trade of goods which meet EU-wide product safety and metrology specifications and mutual recognition for accredited bodies. This is the baseline against which the other scenario is assessed.

0.1 Do Nothing: We have reflected on the consequences of leaving the EU if we do not introduce this legislation. If we left without action, the current regulations would no longer function correctly, leading to the potential to compromise product safety and risking consumer safety, causing confusion for business, consumers and market surveillance authorities.

1.To introduce legislation for a 'no deal' scenario to fix product safety and metrology legislation into UK domestic legislation so that it continues to operate effectively and maintain safety and accuracy requirements protecting consumers and workers and also providing continuity for UK business and market surveillance authorities.

**Will the policy be reviewed? TBC. If applicable, set review date: N/A**

Does implementation go beyond minimum EU requirements?				
Are any of these organisations in scope?	Micro	Small	Medium	Large
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> 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:



Date:

4<sup>th</sup> February 2019

# Summary: Analysis & Evidence

## Policy Option 1

Description: Preparing product safety and metrology legislation for EU Exit

### FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2019	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -17.87	High: -32.77	Best Estimate: -25.02

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	13.7	1	0.5	17.9
High	28.6		0.5	32.8
Best Estimate	20.8		0.5	25.0

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

We have costed the familiarisation time for economic operators as they identify the new legislation applying to their product area for manufacturers, importers and distributors. This is estimated to affect around 241,000 businesses. Based on a corporate manager or director taking three hours to familiarise themselves with the new legislation – the labour cost would be around £19.6m. In addition, the costs of notification and re-notification of cosmetic products are estimated at £1.2m in transition and £0.5m annually.

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

N/A

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 ensure that the current product safety and metrology system for the UK market is maintained, and therefore relative to the static acquis baseline there are no quantifiable benefits.

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

By maintaining a strong product safety and metrology regime in the UK, UK businesses and consumers will be reassured that products placed on the UK market will continue to be safe to use. The UK Trading Standards estimate that the benefit of the UK product safety and metrology regime in stopping unsafe and non-compliant products is substantial (£70 million in 2017-18).

Key assumptions/sensitivities/risks rate (%)	Discount	3.5
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#### BUSINESS ASSESSMENT (Option B)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 2.4	Benefits: N/A	Net: -2.4	
			N/A

# Evidence Base (for summary sheets)

## Leaving the EU

1. On the 23<sup>rd</sup> June 2016 the UK voted to leave the European Union (EU). As a result of this, the Government gave notification of the UK's intention to leave the EU under Article 50 of the Treaty on the European Union, on 29<sup>th</sup> March 2017. Under Article 50, the UK has two years from the date of notification to make arrangements to leave the EU; including negotiating a withdrawal agreement with the EU, after which our membership of the EU will end.
2. Whilst negotiations are ongoing to develop a future relationship with the EU that allows the most free and frictionless trade in goods possible, contingency planning is underway to prepare for all scenarios. It is in everyone's interests to secure a good deal with the EU. We believe that this will be achieved, and this is the preferred outcome, but we have a duty to plan for the alternative. This is the responsible approach to planning for exit.

## Background information

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, 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 and must cooperate with other economic operators if problems with their products arise.
4. The current legislative framework consists of general requirements that apply to all consumer (non-food) goods, and specific requirements that apply to a number of individual product categories, ranging from electrical goods to toys. At the heart of the product safety legislation is a requirement that all products are safe under normal or reasonably foreseeable use. This general safety requirement is set out in the General Product Safety Regulations 2005.
5. In the case of product specific legislation, the regulations set out particular provisions for the product type through the specification of essential requirements for the design and the conformity assessment that must be undertaken to provide assurance of compliance. Essential requirements are specifications that have to be met for the product to be compliant. For example, the legislation specifies that electrical products should not produce temperatures that could pose a danger, and that they must be adequately insulated. Toys must be designed so that they do not present a choking hazard.
6. For these products, an assessment needs to be undertaken to demonstrate that the product is compliant with the relevant legislation. For some products this means that 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) who will undertake a conformity assessment to determine if the product or processes meet the necessary specifications. Currently UK business can use any NB in any EU Member State (or another country where the EU has a Mutual Recognition Agreement) to carry out their conformity assessment and this also applies to businesses in the rest of the world who can use any EU NB, including those based in the UK. The conformity assessment process can cover checks that should be undertaken on product design, construction and performance, and how those checks should be performed. NBs are usually accredited by a national accreditation body nominated by the Member State where they wish to register. In the case of the UK, accreditation activity for most NBs is undertaken by the United Kingdom Accreditation Service (UKAS).
7. In many cases manufacturers can refer to published and recognised standards to help guide product design and construction and to help them achieve conformity with the legislation. In the UK these are published by the British Standards Institution (BSI) and largely based on international standards or European harmonised standards. In some cases, there is a presumption of conformity with the essential requirements if a manufacturer follows a European

harmonised standard that has been published in the Official Journal of the European Union (OJEU). For the products considered here, these standards are voluntary, and businesses can demonstrate conformity with regulation in other ways if they wish.

8. In some cases, the product is then required to be marked to demonstrate its compliance with the legal requirements, commonly with a CE marking 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 (such as the reversed epsilon '3' on aerosol dispensers). In addition, for measuring instruments and equipment used for explosive atmospheres, supplementary markings are provided ie M and Ex which respectively denotes compliance to metrology essential requirements or denotes a specific explosion protection.
9. Responsibility for adhering to these 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.
10. The Office for Product Safety and Standards is responsible for implementing this SI which affects 38 pieces of product safety, metrology and associated legislation. The SI covers a wide range of products in the UK – the specific pieces of legislation are listed in Annex A.

### **Problem under consideration**

11. Currently, the UK's product safety and metrology regime is reliant on a framework based on EU law and EU-nominated bodies. It is largely based upon meeting the requirements as set out in a number of EU Directives. In many cases, the UK has transposed the Directives into UK regulations which reference back to EU law. However, when the UK leaves the EU on March 29<sup>th</sup> it will no longer be subject to EU law.
12. This impact assessment covers what will happen if the UK were to leave the EU without a deal.
13. If Parliament were not to bring in this contingency legislation, then the UK product safety and metrology regime would not operate effectively. This could lead to a risk of unsafe or inaccurate products being placed on the market with no legal means of removing them. This would pose a potential risk to the safety of consumers, workers and others and could affect the purchasing confidence of UK consumers.

### **Rationale for intervention**

14. The UK's existing product safety and metrology regulatory regime is based on EU legislation and is aligned with the regime practiced across the EU. This provides a legal basis that products sold within the EU will meet certain safety and accuracy standards. Manufacturers, importers or distributors can each have obligations to ensure traceability in the supply chain. Depending on the product, they are either subject to assessment by Notified Bodies to confirm that the product conforms with the requirements as set out in the relevant legislation; or manufacturers (or their authorised representative in some cases) will self-certify that the product meets the legislative requirements, through undertaking internal procedures. When the UK leaves the EU, it will be important that the UK continues to regulate the safety and accuracy of products sold in the UK, to ensure that:

- a) products are safe to use and will not cause harm to consumers, workers and others;
- b) businesses and individuals retain confidence that (non-food) consumer products sold in the UK will meet safety and accuracy requirements; and
- c) the UK market is not undermined by the widespread availability of products for which there is no verifiable quality assurance.

15. By fully defining the UK product safety and metrology regime in UK legislation this will give the UK government the ability to ensure that the regime reflects the UK national interests.

## **Policy objective**

16. The policy objective in drafting the SI is to maintain as far as possible the same requirements for products on the market as currently exist in respect of product safety and metrology in contingency planning in a 'no deal' scenario. This will ensure that products are safe and compliant and weighing instruments accurate, and will not cause harm to consumers, workers and others. It will also ensure that unsafe products can continue to be removed from the market. We aim to minimise burdens, in particular, costs to economic operators.
17. We intend to follow the principle of bundling the deficiency fixes to all 38 regulations into one large SI which covers all the individual SIs. We are bundling where possible, to ensure effective use of Ministerial and Parliamentary time.

## **UK manufacturing**

18. The SI covers a substantial part of the manufacturing sector – producers of consumer products (and other products such as machinery, civil explosives, pressure equipment, electronic and electrical equipment etc.)<sup>1</sup> Broadly, we estimate that around 63,000 UK manufacturers are involved in these industries, accounting for around £54 billion GVA (ONS Annual Business Survey 2016). We estimate that £63 billion worth of goods from these industries was exported to other EU countries in 2017, with around £104 billion imported from these EU countries (ONS, UK trade in goods<sup>2</sup>).

## **Consultation**

19. The Department recognised that there will be widespread interest in how the UK plans to ensure an operable product safety and legal metrology framework on EU Exit and has held informal discussions with a range of industry stakeholders (including trade associations, other industry representative bodies, and consumer advocacy bodies) across the product areas covered by this SI. The main concerns raised by stakeholders were around the establishment of a UK mark and what lead in time businesses will have to implement and adapt to any new marking requirements. The majority of stakeholders the Department engaged with were broadly supportive of the need to maintain a functioning product safety and legal metrology regime on EU Exit which mirrors the framework in operation the day before EU Exit as closely as is possible.
20. Through this engagement the Department has been able to understand the main concerns and requirements of business, industry experts and enforcement agencies and has been able to provide reassurance to maintain industry confidence and continuity. On 13<sup>th</sup> September 2018 the Department published a Technical Notice<sup>3</sup> on how the product safety and metrology system would operate for goods to be placed on the UK and EU market. The Office for Product Safety

<sup>1</sup> The industries covered include the safety requirements for pyrotechnic articles, cosmetics, leisure craft (boats), protective equipment, pressure equipment, aerosols, radio equipment and other electronic equipment, measuring instruments, non-electric weighing instruments, gas appliances, machinery (including construction and agricultural machinery), toys and games, simple pressure vessels, jewellery and lifts - these all relate to specific regulations. The General Product Safety Regulations covers all products used by consumers (though if there are specific product regulations these would take precedence). We have broadly tried to identify which other manufacturing industries would produce consumer products. It is difficult from the available data, either from official sources or from trade associations to precisely match industries with the specific products covered by the regulations, so we have attempted to get as close as possible using official data via Standard Industrial Classifications.

<sup>2</sup> <https://www.ons.gov.uk/economy/nationalaccounts/balanceofpayments/datasets/publicationtablesuktradecpa08>

<sup>3</sup> <https://www.gov.uk/government/publications/trading-goods-regulated-under-the-new-approach-if-theres-no-brexiteal/trading-goods-regulated-under-the-new-approach-if-theres-no-brexiteal>

and Standards (OPSS) has followed this publication with further engagement with businesses and business representative groups to ensure that they are informed and get their feedback.

## **Description of options considered**

21. Option 0.1: We have not provided a quantitative assessment of a 'do nothing' option but have qualitatively assessed the consequences of not passing this legislation to Parliament. If we left the EU but took no further action to prepare our domestic statute book, we would have an incomplete and confusing legal system alongside an unworkable framework, in particular across conformity assessment and testing. Without action, the current regulations would no longer function correctly to ensure only compliant and accurate products were placed on the market, and would also lose the ability to remove them from the market if issues were identified. This could lead to unsafe products being available resulting in potential harm to consumers, workers and others. It would also cause confusion for business, Government and wider society. There is therefore only one option explored in this impact assessment.
22. Option 1: To maintain substantially the same regulatory framework. Fixes will be made to any parts of the existing legislation that won't work in a 'no deal' scenario. These amendments will be made by introducing a Statutory Instrument to amend product safety and metrology measures so that from day one of exit it continues to operate effectively and maintain current safety and accuracy requirements.

## **Current arrangements**

23. This is the baseline against which the legislation scenario is assessed:

- a) There is free and unlimited access to EU markets for products manufactured in the EU compliant with product safety and metrology regulations;
- b) To be compliant, products must meet essential requirements, undergo conformity assessment by Notified Bodies (where required), and ensure CE markings (where required) are properly affixed
- c) UK Notified Bodies are recognised across the EU as bodies providing conformity assessments for the products they are entitled to assess; and
- d) For certain products, harmonised EU standards can provide a presumption of conformity with the essential requirements.

24. Assumptions are that:

- a) The IA will baseline against the current UK static acquis as expected before EU exit in March 2019; and
- b) All publicly announced legislation is passed successfully through parliament.

## **Option 1 - Continuation of UK product safety and metrology legislation through the SI**

25. The SI would ensure that products regulated under the relevant product safety and metrology measures currently required under EU legislation, would continue to be required to meet substantially the same essential requirements under the sole authority of UK law. It would also ensure that there is an independent UK regime for checking products meet the requirements, which is as robust as the existing EU regime. It will make provision for new UK markings which will show that the product complies with the relevant UK statutory requirements. This new system will allow products that bear the UK marking to be placed on the UK market, as long as any third-party assessment required has been carried out by a UK-recognised conformity assessment body.

26. This SI is required to ensure that there is continuation of UK product safety and metrology legislation in a 'no deal' scenario. The following approaches, which are provided for in the SI, will be needed if the current arrangements cease to exist:
- i. Continued recognition by the UK of EU Notified Bodies and associated conformity assessments
  - ii. Establishment of a new system of UK Approved Bodies
  - iii. Continued recognition and continued acceptance of the 'CE' marking in UK markets
  - iv. Establishment of a new system of UK conformity marking
  - v. A new 'designated' standards approach where UK identifies which standards are relevant to demonstrating a presumption of conformity with UK regulations
27. Goods already placed on the market will be able to continue to circulate in the UK. Additionally, goods that meet EU requirements (and were assessed by an EU recognised conformity assessment body where third-party assessment is required) can still be placed on the UK market. This is intended to be a time-limited measure<sup>4</sup>.
28. The results of conformity assessment carried out by UK notified bodies will no longer be recognised in the EU. This means that products assessed by a UK Notified Body will no longer be able to be placed on the EU market without reassessment and re-marking by an EU recognised conformity assessment body.
29. Notified Bodies based in the UK will be granted new UK 'Approved Body' status and listed on a new UK database. Approved Bodies will be able to assess products for the UK market against UK essential requirements (which, immediately after exit day in a 'no deal' scenario, will be substantially the same as EU essential requirements).
30. Manufacturers selling goods on the UK market will then be able to affix a new UK conformity marking before placing a product on the UK market. Manufacturers will not need to use these markings from the point of exit in a 'no deal' scenario if they have used the relevant EU marking after having their product assessed by an EU recognised body, where third-party assessment is required. This is intended to be a time-limited arrangement.
31. In practice this means that products that meet EU requirements can continue to be placed on the UK market without any need for reassessment or re-marking, including where they have demonstrated compliance with EU requirements after exit day. This is intended to apply for a time-limited period and sufficient notice will be given to businesses before that period ends.
32. Products that meet UK requirements and bear a UK conformity marking can be placed on the UK market, as long as any third-party assessment required has been carried out by a UK-recognised conformity assessment body.
33. The United Kingdom Accreditation Service's role as the UK's national accreditation body, including for most UK conformity assessment bodies, will remain as it is now.
34. Existing harmonised standards (used to demonstrate conformity with EU essential requirements) will become UK 'designated standards', which can be used to demonstrate conformity with UK essential requirements<sup>5</sup>. As noted above, immediately following exit these will be substantially the same as EU essential requirements.
35. As UK requirements will be identical to EU requirements at the point of departure, the documentation required will be the same (though products made expressly against the UK version of the requirements, e.g. products which are then UK marked on the basis of self-declaration of use of a UK Approved Body, will require a UK Declaration of Conformity, rather than an EU Declaration of Conformity, referencing the relevant UK legislation).

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<sup>4</sup> This is specifically stated in the Government's Technical Notice. However, this SI does not itself limit the time that such goods would be accepted in the UK market, or include powers to enable the time to be limited. It would therefore be a separate legislative process.

<sup>5</sup> While following these standards will help to ensure compliance, goods that don't follow the relevant standards could still be compliant, though they will need to demonstrate this through testing and potentially conformity assessment.



36. For the vast majority of economic agents affected by this change, we expect costs to be small and limited to familiarisation with the changes introduced by this SI. As set out above, the SI is designed to ensure that the product safety and metrology system for the UK market remains unchanged as far as possible if the UK leaves the EU without a negotiated agreement. Products already on the UK market will not require new documentation (however, specific to the cosmetics industry, businesses will be required to notify the appropriate UK body of the products they already have on the market. New products will need to go through the same procedures as they currently do. Where changes are introduced, such as UK marking, they will be introduced in a way to minimise costs to business by trying to ensure the changes can be made as part of normal production processes (for instance the design process for new products) by providing businesses with sufficient notice of the new marking and allowing them to continue using the CE marking in most circumstances (until such time as separate legislation is enacted to end the continued acceptance of CE marked products). UK businesses may face additional costs due to the EU no longer recognising UK bodies operating in the product safety and metrology system, but these costs are not due to the SI and are therefore not in scope of this impact assessment. More details are given in paragraphs 61 and 62.

### **Amendments made by the SI to implement Option 1**

37. Under the European Union (Withdrawal) Act there are many pieces of legislation relating to product safety and metrology that are being maintained in UK law. We need to make additional secondary legislation to ensure that the regulations still work post exit if the current arrangements cease to exist. The SI will amend deficiencies ranging from the simple removal of invalid references (such as to EU bodies and institutions) to setting out the need for a new domestic system of conformity assessment while giving some form of ongoing recognition the EU system (using the existing CE marking for products manufactured for the EU market and a new UK conformity mark for products manufactured for the UK market only).
38. Of the 38 pieces of legislation being revised by this SI, 3 deal with general and cross-cutting requirements, 21 relate to specific product safety requirements, 7 to metrology, 3 are Primary legislation and 4 are being revoked/will cease to have effect.

#### *General and cross cutting requirements*

39. The three regulations affected here have a broader basis and include one EU regulation - the EU Regulation for Accreditation and Market Surveillance 765/2008 (RAMS) - plus two sets of UK regulations - the Accreditation Regulations 2009 and the General Product Safety Regulations 2005 (GPSR)
40. The GPSR set out a general safety requirement which stipulates that all products must be safe for normal or reasonably foreseeable use. The SI will fix deficiencies by removing EU references such as to the European Commission, the EEA and Member States. It will also remove references to EU legislation and copy out the existing requirements into UK legislation or refer to the new UK version of the legislation eg to the UK version of RAMS.
41. The Accreditation Regulations designate UKAS as the UK national accreditation body and the SI will remedy deficiencies in relation to the EU references in the regulations.
42. Changes to GPSR are limited to technical fixes which enable the current product safety regime to continue to operate. Therefore, we expect familiarisation to be the only cost associated with these changes.
43. RAMS sets out the requirements for national accreditation bodies and provides a framework for the market surveillance of products and sets out the general principles for use of the 'CE' marking. The European Union (Withdrawal) Act will retain RAMS in UK law. Additionally, this SI will allow for unilateral recognition of 'CE' marking and of EU Notified Bodies and their associated conformity assessments where there is no divergence between the EU and UK requirements and will provide for the establishment of a new UK conformity assessment marking (with new UK NB and technical documentation references).

44. Introducing a new domestic system for conformity assessment will enable UK accredited Approved Bodies to continue providing conformity assessments for the UK market. The new UK marking will be able to be applied to products placed on the UK market after exit day that are assessed by UK Approved Bodies and potentially some that self-certified where the manufacturer is content for that product to only be eligible for placing on the UK market.

### *Product Safety*

45. We are looking to effect changes to 21 regulations relating to safety requirements for specific groups of products (these are regulations numbered 4 – 24 in Annex A). They largely set out product safety and conformity assessment requirements for specific products ranging from toys, cosmetics, motor yachts, household appliances and equipment for use on offshore platforms. For these regulations the SI will make the following changes:
- i. **Ensure the scope of the Regulations reflect that the UK is no longer a Member State of the EU** - the regulations are currently drafted by reference to the EU market, which post exit will not include the UK;
  - ii. **Remove EU references** such as to the European Commission, the EEA and Member States;
  - iii. Remove references to **EU legislation** and copy out the existing requirements into UK legislation or refer to the new UK version of the legislation eg to the UK version of RAMS;
  - iv. Set out a **new UK system for conformity assessment while giving ongoing recognition to the EU system**. We will have a UK only system but also make clear that where the EU requirements relating to the product are met, this also satisfies the UK requirements. This will mean establishing a new UK conformity assessment marking (with new UK Notified Body equivalents (to be known as “approved bodies”) and technical documentation references) and recognising the CE marking for products;
  - v. Allow for existing **authorised representatives (AR)**<sup>6</sup>, where used, to continue to be based either in the EEA or the UK. New ARs for the UK market would be based in the UK;
  - vi. **Responsible persons** (cosmetics only) must be based in the UK;
  - vii. Replace references to **European harmonised standards** with a reference to UK designated standards which on exit day will be the same as European standards;
  - viii. Replace references to language used by Member State with “**English**”;
  - ix. Remove inoperable **obligations for Secretary of State** to inform Commission and Member States when taking certain actions; and
  - x. Ensure the definitions of the various economic operators reflect the fact that the UK will no longer be in the EU / EEA (for example ensuring “**importers**” are persons who import into the UK (rather than the EU / EEA as currently drafted).
46. Additional changes are required for some regulations such as pressure equipment and toys which contain ambulatory references<sup>7</sup> to Directives which will be broken post exit. Further changes will also be needed in respect of the regulations governing civil explosives. Minor amendments have been made to the provisions relating to ‘tracking and traceability’ of civil explosives to enable their continued operation but identifying the EU as a third country. The requirement to add two letters identifying the state of production or import will remain. We propose an amendment to recognise the traceability codes placed on civil explosives imported from the EU to the UK, to link them to a UK based importer. This will avoid the need for additional GB/NI codes to be added at significant cost to manufacturers, where the EU code already exists, but will preserve a UK importer contact for traceability purposes.
47. The provisions relating to transfers of civil explosives into GB have been amended to ensure they continue to operate. HSE continues to be responsible for providing an authorisation to import any civil explosive into GB. After Exit, the UK will come out of the Intra-Community Transit (ICTs) system. However, HSE will retain the requirement for permission to transport explosives that will operate in the same way. Duty holders apply for ICTs from each country in an explosive’s journey

<sup>6</sup> A manufacturer can appoint an authorised representative (known as responsible persons in the cosmetics industry) based in the EU to take on some of the responsibilities of the manufacturer (such as retaining documentation, labelling and marking products, and dealing with any product safety issues) for products brought to the EU market.

<sup>7</sup> Ambulatory references allow updates to an underlying EC Directive to have automatic effect in the UK.

currently, and HSE intends to retain the same basic form and information requirements after Exit, **so the administrative burden should not change at all.**

48. Currently, civil explosives manufactured in, or imported to, the EU must be marked with a unique site code provided by an EU country to the manufacturer or EU-based importer. This code is recognised by all EU countries. An accompanying record must be held to enable traceability of the civil explosive through the supply chain.
49. In a 'no deal' scenario, the UK will recognise existing site codes on civil explosive products imported to the UK where the site code has been issued by another Member State. The UK will not require importers to add a new code. However, to continue effective traceability through the supply chain, all importers will need to contact a UK competent authority (Great Britain or Northern Ireland depending on the place of import) to notify them of any existing site code on the civil explosives being imported. The competent authority will then link this existing code to the UK based importer
50. The Lifting Operations and Lifting Equipment Regulations (LOLER) place duties on people and companies who own, operate or have control over lifting equipment. Most lifting equipment and lifting accessories fall within scope of the Machinery Directive, implemented by the UK Supply of Machinery (Safety) Regulations and will therefore have been subject to conformity assessments before being placed on the EU market. After Exit, most lifting equipment and lifting accessories would still be required to have the appropriate conformity assessment undertaken for the market it is being placed on; this may include the CE marking, a UK equivalent, or both. Any differences in costs from the change in conformity assessment would be a cost of the Supply of Machinery Regulations and not a cost of changes to LOLER. LOLER would be amended to reflect the fact that when HSE inspectors look for evidence of conformity assessments, they will check for the appropriate marking based on the market these goods would be sold on. **There would be no additional costs to dutyholders.**
51. The Offshore Installations Safety Case Regulations (SCR) aim to reduce the risks from major accident hazards to the health and safety of the workforce employed on offshore installations or in connected activities. The regulations state that an examination by the verifier of any design, specification, certificate, CE marking or other document, marking or standard is required when establishing a verification scheme. After Exit, the examination required should now look at the appropriate marking; this may be the CE marking, a UK equivalent, or both. Any differences in costs from the change in markings, would be a cost of the Supply of Machinery Regulations and not a cost of SCR. The Offshore Installations Regulations would be amended to reflect the fact that when HSE inspectors look for conformity assessments, verifiers will check for the appropriate marking. **There would be no additional costs to dutyholders.**
52. Many of the product safety regulations also set out the responsibilities and requirements of manufacturers, importers and distributors and Notified Bodies. Certain regulations require that an accredited Notified Body provides a conformity assessment to indicate that a product meets the requirements of the relevant legislation. In some cases, it is possible for manufacturers to self-certify that their products or processes meet the requirements, though they will still need to have the evidence of testing that has been carried out to show that they meet the standards. These are the number of Notified Bodies in the respective product groups, as set out on the NANDO<sup>8</sup> database in March 2018:

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<sup>8</sup> NANDO: **New Approach Notified and Designated Organisations**; Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive.

	UK accredited	EU total
Lifts	6	233
Personal Protective Equipment	13	40
ATEX Equipment and systems for use in potentially explosive atmospheres	8	71
Civil Explosives	1	11
Electromagnetic Compatibility	17	111
Gas Appliances	3	11
Machinery	24	146
Measuring Instruments	27	88
Non-automatic weighing instruments	31	66
Equipment for use outdoors (Noise emissions in the environment)	7	61
Pressure Equipment	28	178
Pyrotechnic Articles	0	13
Recreational Craft and Personal Watercraft	4	24
Radio Equipment	9	47
Simple Pressure Vessels	6	75
Toys	9	42

53. The CE marking is an EU marking that denotes that the manufacturer considers their product complies with the applicable EU legislation. In the absence of a mutual recognition agreement, the conformity assessments undertaken by UK Notified Bodies will not be recognised as valid for the EU27 market. In light of this, a UK marking to be applied to products being placed on the UK market alone, will be need to be provided for by legislation. The SI now refers to recognition of this mark as opposed to the CE marking alone and includes a deeming provision allowing for continued recognition of the CE marking, EU Notified Bodies and their associated conformity assessments. This is intended to be a time limited measure.

54. Not all of the regulations use a CE conformity mark. Aerosol dispensers use a reversed epsilon **3** **conformity marking** and cosmetics are not required to carry a conformity mark. These regulations will also be captured by the new dual system proposed in the SI. Products where the EU requirements are satisfied will also satisfy the UK requirements. This will mean establishing a new UK conformity assessment marking (with new UK NB and technical documentation references) and accepting the **3** or other conformity marking.

55. UK product safety law references European Harmonised standards, the latter of which when the reference is published in the Official Journal, carry a presumption of conformity with product safety regulations in some cases. These references will be changed to refer to designated standards with all oversight requirements falling to the Secretary of State.

56. These changes are predominantly technical fixes to enable the current product safety regime for the UK market to operate solely for the UK market in a 'no deal' scenario. Therefore, we expect the primary direct cost incurred by businesses as a result of this SI to be familiarisation costs. UK importers of products from the EU will in many cases have to ensure that their details are included on the product or packaging, and keep copies of relevant documentation. The cost of labelling should largely be incorporated into the normal processes for the importing of new products. Documentation should be provided by the manufacturers.

### *Metrology*

57. The seven metrology regulations (numbered 25 - 31 in Annex A) that will be amended by the SI set out accuracy and conformity assessment requirements. Changes to these regulations will be as those described in paragraph 45 above. **Therefore, apart from familiarisation costs, no additional administrative burden is expected from this change.**

## *Primary legislation*

58. The SI will introduce minor deficiency fixes to three pieces of Primary Legislation. These are the Product Liability provisions in Part 1 of the Consumer Protection Act 1987; the Hallmarking Act 1973; and the Weights and Measures Act 1985. In all cases the SI will remove references in the Acts to EU related terminology and maintain the same requirements for products on the market as currently by retaining their provisions in UK legislation. **Therefore, apart from familiarisation costs, no additional administrative burden is expected from this change.**

## *For revocation*

59. The effect of the European Union (Withdrawal) Act is to retain current EU technical requirements and administrative practices in UK law. The provisions of some of these regulations will no longer make sense following EU Exit and consequently they will be revoked by the SI. This applies to the Standardisation Regulation (definitions of standards will be now in each piece of product safety legislation), the Mutual Recognition Regulation, the Decision on the Common Framework for marketing products, and Regulation 2679/98 “the strawberry regulations”. They all make references to provisions that are only applicable as long as the UK is a Member State of the EU.
60. The impact of these EU regulations no longer applying to UK business is not an impact of this SI, but a direct consequence of the UK leaving the EU. **Therefore, these impacts are not in scope of this impact assessment.**

## **Monetised and non-monetised costs and benefits of each option (including administrative burden)**

61. The impact analysis provides an indication of the costs and benefits that would arise from a ‘no deal’ regulated product safety and metrology regime fully based on UK law compared to the static *acquis*, current arrangements baseline. We have regularly engaged with stakeholders and wherever possible we have provided quantitative evidence. However, this sort of evidence and data has been limited and difficult to source. In this unprecedented event, businesses are still unsure how they will respond in a ‘no deal’ situation and it is difficult to predict how they might behave. Costs may be commercially sensitive and therefore not available and many of the products affected do not have sector focussed manufacturing or trade data making it difficult to provide quantifiable direct costs. For example a recently published report by EURIS<sup>9</sup> conducted by the University of Sussex found that 81% of firms do not know how much it would cost them to prove their products comply with regulations on leaving. “The complex nature of our supply chains means it is nearly impossible to calculate the ultimate cost and impact [of EU Exit] to associated parts of the economy”.
62. Where evidence and data was not available we have provided a qualitative assessment.

## *Direct costs*

### *Familiarisation costs*

63. The IA identifies the costs for business, directly associated with the instrument, to be largely familiarisation costs. We have costed the familiarisation time for economic operators as they identify the new legislation applying to their product area for manufacturers, importers and distributors. This is estimated to affect around 241,000 businesses. Based on a corporate manager or director taking three hours to familiarise themselves with the new legislation – the one-off labour cost would be around £19.6m. Details of how the estimate was arrived at are in the paragraphs 64 – 70 below.

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<sup>9</sup> The EURIS Taskforce is an advisory body on the potential impacts of the changing relationship between the UK and EU for the UK manufacturers. It represents industrial product suppliers covered by the Single Market covering sectors responsible for over 25% of total UK goods imports and exports.

64. The regulations being covered by this SI tend to refer to product types or groups of products. There is no data source that provides information on the number of businesses that produce detailed types of product. Therefore, to estimate the number of businesses involved, we used the detailed industries defined under the official industry classifications (SIC 2007), which are defined by activity, and matched them with the groups of products covered by the specific regulations. It needs to be noted that the specific industry classifications don't always precisely match the groups of products covered by the regulations, but the data provides an approximate estimate of the number of businesses affected. Given that even at the detailed level of classification, individual manufacturing and distribution industries are often defined by a range of activities, of which businesses classified to that industry may just carry out one. As we have tried to include all industries that may count among its activities the production or distribution of any product covered by the regulations dealt with by this SI, it is likely that our estimate of businesses affected is an overestimate (including businesses that are not involved in the distribution or manufacture of the relevant products. This is because of the wider definitions used in the Standard Industrial Classification compared to product regulations. Hence, the number of businesses is based on conservative estimates. Based on the Annual Business Survey we estimate that around 63,000 manufacturers, 47,000 wholesalers, 124,000 retailers and 393 organisations involved in the product safety and metrology regime (Notified Bodies, market surveillance authorities etc) would be affected.
65. The Lifting Operations and Lifting Equipment Regulations cover all organisations that use lifting equipment. This could account for a large number of businesses in many sectors, from agriculture to manufacturing to construction to transport, to handling cargo to distribution to building management to health and social care to arts and entertainment. However, most businesses will not be changing the lifting equipment they use or changing their operations so will likely not familiarise themselves with the health and safety requirements except when such changes occur. They will already be aware of the safety requirements required in using the equipment that they have (and these will not change). LOLER will be changed to enable the products that are conformity assessed to have a 'UK' marking, as well as the existing 'CE' marking. It is likely that most businesses would become aware of this change when they are purchasing new equipment – as part of the purchasing activity. Some research by HSE suggests that when HSE's online guidance changes to reflect regulatory change, an additional 7,000 looking at the guidance (compared with regular usage). We therefore estimate that 7,000 businesses will familiarise themselves with the revised guidance as a conservative estimate for familiarisation for this SI.
66. Similarly, around 75 UK business operate offshore<sup>10</sup>, and would need to be aware that the equipment used could have a 'UK' marking.
67. This SI covers a number of Regulations, and essentially ensures that the processes for placing products on the UK market will remain the same as before once the UK has departed the EU. We estimate that for each business affected on average a corporate manager or director would take three hours to familiarise themselves with this SI. This is similar to 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<sup>11</sup>. This estimate familiarisation time for the 2014 regulation was tested in consultation.
68. The estimated familiarisation cost for Scenario 1<sup>12</sup> is set out below in Table 2. These costs are relative to the static acquis, current arrangements baseline. To provide some sensitivity around the estimate of three hours familiarisation time, we take it as the basis for a central estimate, and provide a high and low range around it. The approach used to estimate business numbers is set out in Annex B.

<sup>10</sup> [http://www.legislation.gov.uk/ukia/2015/170/pdfs/ukia\\_20150170\\_en.pdf](http://www.legislation.gov.uk/ukia/2015/170/pdfs/ukia_20150170_en.pdf)

<sup>11</sup> 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](https://www.legislation.gov.uk/ukia/2014/197/pdfs/ukia_20140197_en.pdf)

<sup>12</sup> Scenario 1 refers to the introduction of legislation for a 'no deal' scenario to fix product safety and metrology legislation into UK domestic legislation so that it continues to operate effectively and maintain current safety and accuracy requirements protecting consumers and workers and also providing continuity for UK business and market surveillance authorities.

**Table 2: Familiarisation cost for Scenario 1**

Hourly labour cost for corporate manager or director <sup>13</sup>		£27.11	
<u>Business type</u>	<u>Number of businesses</u>	<u>Familiarisation time (hours)</u>	<u>Cost ( £000s)</u>
Manufacturers requiring 'CE' or other EU marking	22,323	3	1,816
Other manufacturers affected by specific product regulations	1,832	3	149
Manufacturers affected by general regulations only	38,632	3	3,142
Wholesalers importing from outside EU and also exporting	4,704	3	383
Other wholesalers	42,207	3	3,433
Retailers	123,762	3	10,066
LOLER	7,000	3	569
Offshore operators	75	3	6
Notified Bodies, UKAS, BSI, enforcement organisations	393	3	32
Total			19,595

69. For a low estimate of familiarisation costs, we reduce the time taken to familiarise to 2 hours. This produces a low estimate for familiarisation of £13,063,000.

70. For the high estimate, we increase the time taken to 4 hours. This produces a high estimate for familiarisation of £26,126,000.

71. There are three additional costs to consider specifically for the cosmetics sector. This includes the cost on business to notify the UK equivalent of the Cosmetic Product Notification Portal (CPNP) of new products placed on the market, as well as the cost on business to provide UK-CPNP with limited information on all the products they already have on the market. Also, there is a requirement that businesses wishing to place a cosmetic product on the UK market will need to appoint a UK-based responsible person. These proposals are estimated to cost £1.2 million in transition and £0.5 million annually. These costs are relative to the static acquis, current arrangements scenario.

#### *Costs resulting from changes to conformity assessment*

72. After the UK's departure from the EU, new UK markings for products for the UK market will be introduced. However, products already on the market including those from EU-accredited Notified Bodies will be accepted on the UK market. UK accredited Notified Bodies would become UK Approved Bodies authorised to provide conformity assessments for products to be placed on the UK market. Conformity assessment carried out prior to exit day would still be valid for the UK market post-exit.

<sup>13</sup> Including non-wage labour cost uplift

73. If the EU decides not to accept conformity assessments from UK accredited Notified Bodies once the UK has departed the EU, UK manufacturers who have used a UK Notified Body will face a cost<sup>14</sup> from either getting conformity assessed by an EU recognised Notified Body or switching to a UK marking. This decision will depend on which option is more cost effective for each manufacturer. Where UK manufacturers have used a UK Notified Body, any goods that are not placed on the market by exit day will need to either be reassessed by an EU Notified Body, or the manufacturer will need to arrange for a transfer of files to an EU recognised Notified Body, if those goods are to be placed on the EU market subsequent to exit day.
74. However, this impact is not a consequence of this policy change introduced by this SI. It is a consequence of the EU no longer not accepting conformity assessments from UK Notified Bodies. Therefore, these impacts are out of scope of this impact assessment.
75. The significant change introduced by this SI (i.e. the introduction of a UK marking) will allow UK businesses to switch to the UK marking where it would be more expensive to arrange a conformity assessment with an EU-accredited Notified Body, and where they do not intend to place those goods on the EU market.
76. Examples from industry suggest that for the aerosols sector relabelling is considered 'a matter of course' and is expected at least every two years<sup>15</sup>, while around a third of toy products placed on the EU market each year are products new to market<sup>16</sup> (with around an 18-24 month development period<sup>17</sup>).
77. In the future, if the UK wanted to end the unilateral recognition of the CE marking for a given product type (and the underlying conformity assessment where applicable) and therefore require UK manufacturers to use the UK marking, a separate legislative process would be required. The relevant impacts would be captured alongside the associated legislation.
78. The cost of designing the new UK markings is expected to be negligible and will fall on the public sector.

#### *Indirect costs*

79. There are potential impacts to trade with the EU if the costs of getting products to market increases due to changes to the UK product safety and metrology regime. In 2017, trade in goods data shows that the manufacturing industries affected by this SI exported around £63bn worth of goods to the EU, while around £104bn worth of such goods were imported from the EU<sup>18</sup>.

#### *Costs not in scope of this IA*

80. There are a number of wider impacts caused by the interaction between the UK's departure from the EU and the UK's new product safety and metrology regime. These costs are out of scope of this IA as they are not caused by the SIs, but are included for context. These wider costs include:
- i. UK manufacturers exporting to the EU may be required to arrange conformity assessments from an EU recognised notified body
  - ii. UK Notified Bodies could face a loss of revenue due to losing conformity assessment work from EU and non-EU customers and UK exporters to the EU.
  - iii. UK businesses operating as Authorised Representatives (AR) or Responsible Persons (RP) for the EU market would lose revenue if they were no longer able to perform this role. Similarly, UK exporters to the EU may have to take on an EU based AR or RP.

<sup>14</sup> There will be no additional cost to manufacturers who already choose to have their products accredited by EU-based Notified Bodies.

<sup>15</sup> [https://www.legislation.gov.uk/ukia/2009/268/pdfs/ukia\\_20090268\\_en.pdf](https://www.legislation.gov.uk/ukia/2009/268/pdfs/ukia_20090268_en.pdf)

<sup>16</sup> <https://www.toyindustries.eu/wp-content/uploads/2018/01/TIE-EU-Toy-Sector-Facts-and-Figures-FINAL.pdf>

<sup>17</sup> British Toy and Hobby Association

<sup>18</sup> <https://www.ons.gov.uk/economy/nationalaccounts/balanceofpayments/datasets/publicationtablesuktradecpa08>. As noted, the SIC industry definitions used are broader than the specific products covered by the regulations covered by this SI.



- iv. UK businesses who choose to adopt the new UK marking, in order to continue to make use of UK Notified Bodies who will no longer be recognised by EU27, may have additional labelling costs (paragraphs 72 - 73 give more details of why these are out of scope)
- v. Increased burdens on UK importers of EU products. For example, having to re-label products to include their contact details<sup>19</sup>.

**81. These impacts are not a direct consequence of the changes that this 'no deal' SI introduces. They are a consequence of the UK leaving the EU or of negotiated outcomes and therefore out of scope of this assessment and not discussed further.**

### *Benefits*

- 82. The aim of the SI is to ensure that the current product safety and metrology system for the UK market is maintained, and so there are no quantifiable benefits relative to the static acquis baseline. Potentially, there may be some benefit to UK businesses from acting as authorised representatives or responsible persons for products imported to the UK market.
- 83. Compared with not legislating, the SI will provide assurance to business and consumers that products brought to the UK market will continue to need to meet high levels of product safety. It will also provide manufacturers with continuity and certainty that their existing testing regimes for manufacturing processes and products will remain compliant with the UK's product safety requirements post-departure from the EU.
- 84. Having the regulated product safety framework in place will mitigate the danger to consumers, workers and others of buying faulty, unsafe, non-compliant or inaccurate products. The National Trading Standards 2017-18 Annual Report<sup>20</sup> 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.

### **Risks and assumptions**

- 85. This SI assumes that the UK will leave the EU with 'no deal' in place. This is not an event we expect but a contingency we have prepared as part of sensible planning for EU Exit.
- 86. Our assumption is that the proposed SI will put in place a product safety and metrology system based in UK law that, at the point of the UK's departure from the EU, will maintain substantially the same requirements for products brought to the UK market, in terms of documentation, conformity assessment, labelling details and product standards as the current system.

### **Small and Micro Business Assessment**

- 87. Based on data from the ONS, we estimate that around 95% of manufacturing businesses and over 96% of distributors in the industries affected by the SI are small or micro businesses. Estimates from a survey of Notified Bodies conducted by BEIS suggests that around 60% of Notified Bodies may be small or micro businesses. It is currently unclear if and to what extent small and micro businesses might be disproportionately affected due to lack of data. We are therefore unable to identify any mitigating options to reduce the burden on SMEs.
- 88. The legislation is necessary to ensure that the UK maintains a strong product safety and metrology system allowing for only compliant and accurate products to be placed on the UK market. Manufacturers and distributors will benefit from the certainty that the requirements for

<sup>19</sup> Currently, as EU-made products are not imported to the single market, they are not considered as imports under the product safety and metrology system. Following the UK's exit from the EU, businesses importing products from the EU will be deemed importers rather than distributors. As set out in Annex B, importers have additional responsibilities compared to distributors; primarily, they will need to place their contact details on the product, and keep copies of the product documentation (testing, conformity assessments etc).

<sup>20</sup> <http://www.nationaltradingstandards.uk/uploads/annual%20report%202017-18%20final.pdf> , p57

product safety and metrology standards and documentation will be the same once the UK has left the EU as they are currently. They will also benefit from the reassurance this will provide to customers (distributors, as customers of manufacturers will benefit from having that reassurance).

89. The extent to which manufacturers and distributors who import goods from the EU may face costs in adjusting to changes to the product safety and metrology system. There is a risk that in some circumstances the costs might disproportionately affect small and micro businesses. However, the data is not available to analyse this in more detail.
90. Most Notified Body organisations also obtain revenue from other activities, such as product testing. A higher proportion of micro and small Notified Bodies are more dependent on revenue from notified body activity than medium or large Notified Bodies. Therefore, if the eventual outcome of the negotiations results in reduced Notified Body activity for UK organisations, it might disproportionately affect small and micro Notified Bodies.

### **Summary and description of implementation plan**

91. The SI ensures that if the UK leaves the EU in a 'no deal' scenario, it 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**

92. This legislation is intended to allow the continuation of the regulated product safety system for products brought to the UK market following its departure from the EU. These circumstances mean that the Government takes the view that a post-implementation review of such correcting regulations would be impractical, and any potential benefit would be outweighed by the potential adverse effects in terms of cost and use of resource.
93. 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.

## Legislation which is subject to amendment by the proposed SI

1. GPSR General Product Safety Regulations 2005/1803
2. RAMS (EU Regulation) 765/2008 – Accreditation + Market Surveillance
3. Accreditation Regulations 2009
4. ATEX Equipment for use in potentially explosive atmospheres Regulations 2016/1107 and NI ATEX Regulations (SR 2017 No 90)
5. Electromagnetic compatibility Regulations 2016/1091
6. Lifts Regulations 2016/1093
7. LVD Electrical Equipment (Safety) Regulations 2016/1101
8. Pressure Equipment (Safety) Regulations 2016/1105
9. Pyrotechnic Articles (Safety) Regulations 2015/1553
10. Recreational Craft Regulations 2017/737
11. Radio Equipment Regulations 2017/1206
12. SPV Simple Pressure Vessels (Safety) Regulations 2016/1092
13. Toys (Safety) Regulations 2011/1881
14. Explosives Regulations 2014/1638 [HSE/DWP]
15. Lifting Operations and Lifting Equipment Regulations 1998/2307 [HSE/DWP]
16. Offshore Installations (Offshore Safety Directive) (Safety Case etc) 2015/398 and Offshore Installations (Safety Case) Regulations 2005/3117 [HSE/DWP]
17. MAMSTER Making Available on Market & Supervision of Transfers of Explosives (NI) 2016/366
18. The Identification and Traceability of Explosives Regulations (NI) 2013/449 [NIO]
19. Aerosol Dispensers Regulations 2009/ 2824
20. Cosmetics (EU Regulation) 1223/2009 and Cosmetic Products Enforcement Regulations 2013/1478
21. Gas Appliances (EU Regulation) 2016/426 and Enforcement Regulations (2018/389)
22. Supply of Machinery (Safety) Regulations 2008/1597
23. Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001/1701
24. Personal Protective Equipment (EU Regulation) 2016/425 and Enforcement Regulations (2018/390)
25. Measuring Instruments Regulations 2016/1153
26. Non-automatic weighing instruments Regulations 2016/1152
27. Measuring Container Bottles (EEC Requirements) Regulations 1977/932
28. Weights & Measures (Packaged Goods) Regulations 2006/659
29. Intoxicating Liquor Order 1988
30. Measuring Instruments (EEC Requirements) Regulations 1988
31. Weights and Measures (Revocations) Regulations 2015/356
32. Consumer Protection Act 1987 (Part 1) – Product Liability
33. Hallmarking Act 1973
34. Weights and Measures Act 1985
35. Standardisation (EU Regulation) 1025/2012
36. Mutual Recognition Regulation 764/2008
37. Common Framework for Marketing Products 768/2008 (“NLF Decision”)
38. Regulation 2679/98 (“Strawberry Regulations

### Estimated numbers of Businesses affected

1. The European Commission has set out the key obligations for different actors in the supply chain.
  - Manufacturers: - a manufacturer placing a product on the EU market is responsible for designing and manufacturing the product in accordance with the essential or legal requirements set out in EU legislation, obtaining a conformity assessment, and producing and maintaining the required technical documentation and certificate of conformity. It must ensure instructions and safety information accompany the product, and label the product with the required information, including a conformity marking (such as a 'CE' marking) for some products.
  - Authorised Representatives (Responsible Persons in the Cosmetics industry): - a manufacturer can appoint an authorised representative based in the EU to take on some of the responsibilities of the manufacturer (such as retaining documentation, labelling and marking products, and dealing with any product safety issues) for products brought to the EU market.
  - Importer bringing products into the EU market from outside the EU: - the importer must ensure that the manufacturer has fulfilled its obligations, label the product with its own business details, and retain copies of the relevant product documentation. The importer may become the authorised representative, and if the importer markets the product under its own name then it would take on the manufacturer's responsibilities. They must be able to identify the suppliers of the products they import.
  - Distributors: - distributors must check that products they are placing on the market have the required marking, labelling and documentation. They must be able to identify the suppliers of products they make available.
2. As discussed in the main body of the document, manufacturers and distributors have responsibilities under the product safety regime set out in the regulations being amended by the SI.
3. Some of the regulations relate to specific groups of products, while others cover consumer products more broadly.
4. For the specified products, these include quite broad areas like machinery (supply of machinery (safety) regulations) and electronic and electrical products (low voltage regulations and electromagnetic compatibility), alongside more narrowly defined groups such as lifts, toys, measuring instruments, non-automatic weighing instruments, cosmetics, aerosols, simple pressure vessels, pressure equipment, personal protective equipment, recreational craft (boats), gas appliances, pyrotechnics, outdoor equipment (construction and agricultural machinery), hallmarked products (jewellery etc) and radio equipment.
5. Official statistics tends to classify business numbers by the activity of the business as defined by the Standard Industrial Classification (SIC). The SIC doesn't easily match the descriptions or lists of products or groups of products specified in the regulations covered by this SI. However, by looking at the detailed activities set out for each industry in SIC it can be used to broadly identify which industries are potentially affected by the SI. We have used the SIC definitions to identify which industry classes would be relevant (as manufacturers or distributors of the products covered). For the regulations covering specified products, we have also used the government data source PRODCOM (which links detailed product classifications to SIC to identify which manufacturing industry class produces the products covered. We have estimated the business numbers using the industries we have identified as potentially affected by the SI. Because even at a disaggregated level of SIC individual industries can include multiple activities this is likely to overestimate the number of businesses affected, as some businesses included in the industries identified will not actually produce or distribute the products covered. However this will be partially balanced by businesses allocated to industries that we haven't included who do produce or distribute such products among their portfolio. For instance, we have not been able to identify specific industries for the equipment used in potentially explosive atmospheres as these are general products specifically adapted to be effective in these environments; a wide range of industries could be covered, though maybe only a few manufacturers actually adapt the products to work in explosive environments.

6. For the regulations focussing on specific groups of products we have identified the following industry classes as relevant (Annual Business Survey 2016 data is used for business numbers):

**Table A1.1 manufacturing industries covered by specific product safety regulations**

Standard Industrial Classification	Description	Number of enterprises
20.42	Manufacture of perfumes and toilet preparations	569
20.51	Manufacture of explosives	20
25.21	Manufacture of central heating radiators and boilers	139
25.29	Manufacture of other tanks, reservoirs and containers of metal	147
25.3	Manufacture of steam generators, except central heating hot water boilers	97
25.92	Manufacture of light metal packaging	99
26.1	Manufacture of electronic components and boards	914
26.2	Manufacture of computers and peripheral equipment	867
26.3	Manufacture of communication equipment	1,192
26.4	Manufacture of consumer electronics	513
26.51	Manufacture of instruments and appliances for measuring, testing and navigation	2,074
27	Manufacture of electrical equipment	3,070
28	Manufacture of machinery and equipment n.e.c.	7,822
30.12	Building of pleasure and sporting boats	496
32.12	Manufacture of jewellery and related articles	1,263
32.4	Manufacture of games and toys	595
32.99	Other manufacturing n.e.c.	4,278

7. We consider that these other manufacturing industries produce consumer products.

**Table A1.2 Other manufacturing industries producing consumer products**

Standard Industrial Classification	Description	Number of enterprises
13.92	Manufacture of made-up textile articles, except apparel	2,050
13.93	Manufacture of carpets and rugs	117
14	Manufacture of wearing apparel	3,855
15.12	Manufacture of luggage, handbags and the like, saddlery and harness	381
15.2	Manufacture of footwear	189
16.29	Manufacture of other products of wood; manufacture of articles of cork, straw and plaiting materials	970
17.2	Manufacture of articles of paper and paperboard	1,251
18	Printing and reproduction of recorded media	12,106
20.41	Manufacture of soap and detergents, cleaning and polishing preparations	363
22.19	Manufacture of other rubber products	529
22.22	Manufacture of plastic packaging goods	475
22.29	Manufacture of other plastic products	2,593
23.13	Manufacture of hollow glass	47
23.4	Manufacture of other porcelain and ceramic products	282
24.41	Precious metals production	49
25.7	Manufacture of cutlery, tools and general hardware	1,749
25.99	Manufacture of other fabricated metal products n.e.c.	3,497
26.52	Manufacture of watches and clocks	74
26.7	Manufacture of optical instruments and photographic equipment	298
26.8	Manufacture of magnetic and optical media	35
30.92	Manufacture of bicycles and invalid carriages	164
30.99	Manufacture of other transport equipment n.e.c.	90
31	Manufacture of furniture	6,223
32.1	Manufacture of jewellery, bijouterie and related articles (excluding 32.12)	152
32.2	Manufacture of musical instruments	268
32.3	Manufacture of sports goods	772
32.9	Other manufacturing (excluding 32.99)	53

8. For wholesalers, we identified the following industries as relevant to the SI:

**Table A1.3 Wholesale industries affected by the SI**

Standard Industrial Classification	Description	Number of enterprises
46.14	Agents involved in the sale of machinery, industrial equipment, ships and aircraft	2,128
46.15	Agents involved in the sale of furniture, household goods, hardware and ironmongery	1,160
46.16	Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	1,762
46.41	Wholesale of textiles	2,392
46.42	Wholesale of clothing and footwear	4,712
46.43	Wholesale of electrical household appliances	2,115
46.44	Wholesale of china and glassware and cleaning materials	633
46.45	Wholesale of perfume and cosmetics	1,476
46.47	Wholesale of furniture, carpets and lighting equipment	2,453
46.48	Wholesale of watches and jewellery	1,242
46.49	Wholesale of other household goods	5,325
46.5	Wholesale of information and communication equipment	5,052
46.6	Wholesale of other machinery, equipment and supplies	13,078
46.74	Wholesale of hardware, plumbing and heating equipment and supplies	3,383

9. The following retail industries were also considered relevant.

**Table A1.4 Retail industries affected by the SI**

Standard Industrial Classification	Description	Number of enterprises
		Number
47.11	Retail sale in non-specialised stores with food, beverages and tobacco predominating	30,682
47.19	Other retail sale in non-specialised stores	6,759
47.41	Retail sale of computers, peripheral units and software in specialised stores	1,511
47.42	Retail sale of telecommunications equipment in specialised stores	1,020
47.43	Retail sale of audio and video equipment in specialised stores	702
47.51	Retail sale of textiles in specialised stores	1,764
47.52	Retail sale of hardware, paints and glass in specialised stores	6,167
47.53	Retail sale of carpets, rugs, wall and floor coverings in specialised stores	3,745
47.54	Retail sale of electrical household appliances in specialised stores	2,782
47.59	Retail sale of furniture, lighting equipment and other household articles in specialised stores	10,399
47.61	Retail sale of books in specialised stores	1,056
47.62	Retail sale of newspapers and stationery in specialised stores	3,434
47.63	Retail sale of music and video recordings in specialised stores	420
47.64	Retail sale of sporting equipment in specialised stores	5,159
47.65	Retail sale of games and toys in specialised stores	901
47.71	Retail sale of clothing in specialised stores	11,455
47.72	Retail sale of footwear and leather goods in specialised stores	2,709
47.75	Retail sale of cosmetic and toilet articles in specialised stores	1,300
47.77	Retail sale of watches and jewellery in specialised stores	4,228
47.82	Retail sale via stalls and markets of textiles, clothing and footwear	*
47.89	Retail sale via stalls and markets of other goods	*
47.91	Retail sale via mail order houses or via internet	23,574

10. To estimate the number of manufacturers requiring a 'CE' marking or other EU marking on their product, we subtract from the numbers affected by regulations covering specific products the number of cosmetics and jewellery manufacturers.