EXPLANATORY MEMORANDUM TO

THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Business, Energy and Industrial Strategy and is laid before Parliament by Act.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 Whilst negotiations are ongoing to develop a future relationship with the EU that delivers in our national interest, the Department must take a responsible approach in preparing for all scenarios, including the outcome that we leave the EU without any deal in March 2019. This instrument is being made as a contingency measure to ensure that the UK has a functioning statute book that will ensure certainty irrespective of the outcome of the negotiations.

2.2 The objective of this instrument is to ensure that there is no reduction in product safety or accuracy, or consumer protections, as a result of EU exit. The Government wants to make sure that the effectiveness of the current legislative framework continues. The requirements for product safety and metrology legislation will be maintained by retaining the appropriate EU obligations in UK law. This aims to provide continuity and certainty for business and maintain consumer confidence in the safety and accuracy of the relevant products. This instrument amends 38 product safety and metrology measures to correct deficiencies which arise in those measures on EU Exit. It includes changes to 4 measures that are currently directly applicable EU instruments (EU Regulations) which place obligations on economic operators to ensure that products are safe, and the instrument also includes the revocation of 4 EU instruments that will be redundant in UK legislation once the UK leaves the EU.

2.3 Three measures that only apply to Northern Ireland, are included in the instrument. This is because in the continued absence of a Northern Ireland Executive, UK Government Ministers have decided that in the interest of legal certainty, the UK Government will take through the necessary Northern Ireland secondary legislation at Westminster. This is being done in close consultation with the Northern Ireland departments.

2.4 Conformity assessment processes, to demonstrate that the product conforms with the requirements of the legislation, can be undertaken by conformity assessment bodies or through self-certification by the manufacturer – the legislation specifies which routes are permitted. Where the process currently involves a third-party conformity assessment body, the instrument provides for a parallel UK regime mirroring that of the EU regime, where conformity assessment procedures can be carried out by approved conformity assessment bodies in the UK. Additionally, it creates a framework for UK marking to be affixed instead of the CE marking which indicates conformity with the requirements of the legislation. It also provides for unilateral

recognition of EU requirements and the CE marking, so that products that meet these requirements can continue to circulate in the UK after exit. As explained in the Technical Notices referred to below in paragraph 7.1, it is intended that these arrangements will be for a time limited period, but this instrument itself does not limit the duration of this provision.

2.5 The instrument amends references and definitions contained within those regulations which need to be updated so they can continue to function appropriately on EU Exit. For example, this includes adaptations to reflect the fact that the UK will no longer be an 'EEA State' or a 'Member State'.

Explanations

What did any relevant EU law do before exit day?

2.6 25 of the 38 measures that are corrected, implement EU Directives. Four are directly applicable EU law ("direct EU legislation") and the 4 that are being revoked are also retained direct EU legislation. The majority follow a legislative framework which sets out 'essential requirements' that products must meet before they are placed on the EU market. This provides a legal basis that products placed on the market within the EU will meet certain safety and accuracy standards. The EU law places obligations on economic operators (manufacturers and their authorised representatives, importers and distributors). They must take steps in order to ensure that they do not make products available on the market that do not meet the essential requirements and take action if they consider they may have made such products available.

2.7 The products range from toys to simple pressure vessels, but the framework is the same and all products need to be assessed before placing on the market – either by self-certification or by a conformity assessment body. Generally, as the associated risk and product complexity increases the product is more likely to have to undergo assessment by third party conformity assessment bodies known as Notified Bodies (NBs). The NB will attest that the product meets certain specifications and the manufacturer then provides a Declaration of Conformity saying that the product meets the requirements of the legislation. The purpose is to ensure that products placed on the market in the EU are safe or accurate to use and will not cause harm to consumers or other end-users. The legislative framework provides a means to ensure that unsafe and non-compliant products can be made safe and compliant, or ultimately removed from the market. The framework is backed up by criminal offences for non-compliance.

Why is it being changed?

2.8 On exit from the EU we want to ensure that the UK has an effective and robust product safety and metrology system in place, which will continue to provide reassurance and continuity to consumers and UK businesses. The current legislative measures are drafted in terms that reflect membership of the EU. For example, various obligations must be met before a product is placed on the EU market, which post exit will not include the UK. This means that if left uncorrected these instruments will not apply to the UK market. Without action, the current regime would no longer function properly which could lead to unsafe products being placed on the market and no effective framework in place to effect their removal from the market. We need to correct this before we leave the EU so that our current legal and regulatory system continues to function to protect consumers, workers and provide continuity for business.

What will it now do?

2.9 The instrument will fix deficiencies in the UK legislation arising from EU Exit. This will ensure that products placed on the UK market must continue to meet substantially the same essential requirements. As well as fixing EU references that will no longer be appropriate, the instrument creates an independent UK regime for checking that products meet these requirements and creates a framework for UK marking by which a manufacturer indicates that the product is in conformity with the requirements of the relevant enactment. The instrument also aims to ensure that the availability of products to consumers and other end-users is not diminished, by providing for products that meet the pre-exit EU (and UK) requirements to be allowed to continue to be placed on the market, intended to be for a time limited period.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The product safety and metrology legislation across the range of products is grouped within this one instrument. This ensures that the types of deficiency identified and the way of correcting those deficiencies, is replicated across the legislation. Having all the amendments in one instrument will enable Parliament to consider these in the round. In addition, technical annexes from EU Directives which pre-exit were subject to (sometimes ambulatory) cross references have been reproduced in schedules, with minimum necessary change to remove deficiencies, to make the UK regime non-reliant on the EU, ensuring users have a single piece of domestic legislation that contains all relevant requirements. We have maintained continuity in the use of language and form that is familiar to the industry and demonstrates there is no change in the essential duties required. These Schedules can extend over several pages as they set out detailed provisions, which has contributed to the size of the instrument, so that a large proportion of the instrument is given over to replicating these existing legislative requirements. The logic for including these in the schedules is to keep all the domestic legislation in one place.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument varies between provisions. For the purposes of Standing Order No. 83P, the instrument does not apply to England only, or England and Wales only.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument varies between provisions. There are 3 measures that are being amended which apply to Northern Ireland only and 7 that apply to England, Scotland and Wales only.

4.2 The territorial application of this instrument is the same as its extent.

5. European Convention on Human Rights

5.1 The Minister for Small Business, Consumers and Corporate Responsibility, Kelly Tolhurst, has made the following statement regarding human rights:

"In my view the provisions of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the convention rights."

6. Legislative Context

6.1 The purpose of product safety and metrology legislation is to ensure that products that are placed on the market are safe and compliant. To this end, the legislation places obligations on economic operators throughout the supply chain (manufacturers, importers and distributors). The key obligation is that products are safe or accurate and meet certain requirements. This may create a requirement that the product is tested to demonstrate compliance with the requirements prior to be being placed on the market. Should products be found to be unsafe they ultimately may have to be withdrawn from the market.

6.2 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 – examples include electrical goods and toys. The overriding purpose of the legislation is to require all products to be safe under normal or reasonably foreseeable use. This general safety requirement is set out in the General Product Safety Regulations 2005.

6.3 In the case of product specific legislation, the legislation follows a framework developed at EU level and applied with adaptations to many product areas. A manufacturer or importer must not place products on the market that do not meet the essential requirements, which can cover requirements at design as well as manufacturing stages. 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.

6.4 The manufacturer is responsible for undertaking an assessment of the product and to make a declaration that the product is compliant with the essential requirements. For some products this means that the manufacturer will self-certify that the product meets all requirements. For products deemed to present a greater risk, the manufacturer pre-exit is required to submit the product to an NB who will undertake a conformity assessment providing the evidence for the manufacturer to provide the Declaration of Conformity.

6.5 The system of NBs is currently based on a system of mutual recognition whereby notifying authorities within Member States ensure that the bodies meet the requirements set at EU level ("notified body requirements") and then notify the bodies that are assessed as meeting them, to the Commission and other Member States, who then have a period in which to object to the notification. This is to ensure consistency and continuity of competence of these bodies across the EU. Any business can use any approved NB in any Member State to carry out their conformity assessment before placing products on the EU market. The system of notification provides that where a body has been accredited by a national accreditation body and a certificate has been issued, this certificate can be used by the notifying authority to verify that the conformity assessment body meets the notified body requirements. In the case of the UK, the national accreditation body is the UK Accreditation Service (UKAS), which is appointed as such by legislation.

6.6 In many cases the legislation provides that manufacturers can use "harmonised standards" to give rise to a presumption of conformity with the essential requirements. There is a system whereby the Commission can request the European standardisation organisations to devise standards and a system whereby Member States can object to

standards becoming or remaining harmonised standards giving rise to a presumption of conformity with the essential requirements.

6.7 In many cases, once the relevant conformity assessment procedures have been carried out and the manufacturer is satisfied the product meets the essential requirements, they should make a Declaration of Conformity and the product can be marked with a conformity marking to demonstrate that the manufacturer attests that the product complies with the legal requirements. In the EU this is commonly the CE marking, which is by legal definition the manufacturer's attestation that the product complies with the EU requirements. There are other marks 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 i.e. M and Ex respectively.

6.8 The manufacturer must make a declaration of conformity and must ensure that other technical documentation is drawn up, as well as safety instructions for the end user. There are obligations on other operators in the supply chain (such as distributors) to verify that the other economic operators (manufacturers or importers) have complied with the requirements imposed on them by the legislation. There are also requirements on all economic operators in the supply chain to comply with request for information from enforcing authorities. Enforcing authorities include the Secretary of State, local authority trading standards and the Health and Safety Executive (HSE) who have specific duties and powers in regard to checking compliance with these requirements to ensure the safety of products entering and circulating 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.

7. Policy background

What is being done and why?

7.1 The legislative framework is dependent on a complex system of mutual recognition. The Government has committed to minimise disruption for business, consumers and citizens to ensure the continued operation of business, infrastructure and public services on EU Exit. In some areas the Government has taken the decision to provide continuity intended to be for a time limited period after March 2019. For goods on the market, the Government's approach on continuity (as announced in the Technical Notices the Government published in September 2018) is that the UK will continue to recognise EU product requirements as valid for sale on the UK market after March 2019, irrespective of whether the EU reciprocates. To align with that general approach, the policy objective for the measures this instrument amends is that they should function on EU Exit as they currently do now, which includes the unilateral recognition of CE marking (as well as other conformity markings, like the "3" for aerosols), conformity assessment and Notified Bodies.

7.2 In parallel this instrument creates a UK only regime which mirrors the requirements at EU level but replaces the requirements to use an EU notified body with a requirement to use a UK approved body. The instrument also introduces a framework for a UK marking, to replace the CE marking, and the Secretary of State will publish the prescribed form of this UK marking on the GOV.UK website prior to exit day.

7.3 Products which satisfy the EU requirements post exit, will be deemed to satisfy the UK requirements. This means that products that lawfully bear the CE marking or the "3" marking will be able to circulate on the market, as well as those that lawfully bear the UK marking.

Transfer of powers

7.4 In some of the EU legislation that is either implemented by the retained EU law that is being corrected, or is direct retained EU legislation (EU Regulations) that is being corrected by this instrument, there are powers for the Commission to update some of the requirements where it is considered necessary to do so to reflect technical or scientific development or where risks are identified. These powers are being transferred to the Secretary of State to amend the retained EU law by secondary legislation (regulations). These powers are contained in 9 of the pieces of EU law and are being transferred across to the Secretary of State. For example, in the Pressure Equipment (Safety) Directive, in order to take into account of very serious safety concerns that may arise, the Commission is able to re-classify pressure equipment so as to make it subject to different conformity assessment procedures to address these. So that the UK is not at risk of having unsafe products dumped on its market if there are serious safety concerns, the power of the Commission has been transferred to the Secretary of State, so that the Secretary of State can make the same type of amendments to the UK legislation post exit.

7.5 Furthermore, in relation to harmonised standards, the instrument sets out a system of UK "designated standards", which the Secretary of State will designate by publishing the reference to them. These designated standards will give rise to a presumption of conformity with the UK requirements, in the same way that harmonised standards do now in respect of the EU requirements. The substance of designated standards and harmonised standards will, immediately after exit at least, be the same. As under the EU regime, the standards have to be adopted by a European Standardisation body but under the UK regime they can also have been adopted by the British Standards Institute. In the Standardisation Regulation (the post exit UK law version of which is being revoked by this instrument) there is a power for the Commission to amend the Regulation to update the list of standardisation bodies in order to take into account any change in their name. This power is being transferred to the Secretary of State for those measures that will include provisions as to designated standards.

7.6 Finally, in the EU Regulation on Accreditation and Market Surveillance there are duties for Member States to appoint a national accreditation body (and to ensure that the body continues to meet various requirements) and to ensure that market surveillance authorities have the powers necessary for the proper performance of their functions. These duties are being maintained post-exit and in order to ensure that the Secretary of State can continue to meet these duties, the instrument creates powers to make legislation to give effect to these duties.

Other deficiencies being corrected

7.7 Additionally, to achieve this, this instrument makes appropriate minor amendments to EU and EEA references and definitions contained within these regulations to reflect the fact that after EU Exit the United Kingdom will no longer be a member of the EU or the EEA.

7.8 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.

7.9 Of the 38 measures being revised by this instrument, 3 deal with general and cross-cutting requirements, 28 relate to specific product safety and metrology requirements, 3 are primary legislation and 4 are being revoked.

General and cross cutting legislation

7.10 The 3 measures affected here have a broader basis and include 2 EU regulations – the General Product Safety Regulations 2005 (GPSR) and the EU Regulation for Accreditation and Market Surveillance 765/2008 (RAMS) - plus one UK regulation, the Accreditation Regulations 2009.

7.11 The GPSR set out a general safety requirement which stipulates that all products must be safe for normal or reasonably foreseeable use. The instrument will fix deficiencies by removing EU references such as to the European Commission, the EEA and Member States. It will also create a national database on market surveillance, to replace the one currently used at the EU level.

7.12 RAMS sets out the requirements for national accreditation bodies and will continue to set out the same requirements for the UK national accreditation body post exit. The requirements include for example that the national accreditation body must be independent of the conformity assessment bodies that it assesses. The 2009 Accreditation Regulations name UKAS as the national accreditation body for the UK, and the instrument maintains their appointment as well as many minor drafting changes.

7.13 RAMS also provides a framework for the market surveillance of products, which are retained for the UK market. Finally, it sets out the general principles for use of the 'CE' mark, which the instrument amends so that it will set out the (same) principles for the UK mark, post exit.

Specific product safety and metrology legislation

7.14 Most of the product safety regulations covered in these provisions are the responsibility of the Department for Business, Energy and industrial Strategy. However, the instrument also covers 3 Department for Work and Pensions regulations and 3 Northern Ireland regulations as they cover related product safety areas and allow for a package of changes to be introduced to completely cover all the civil explosives requirements across the whole of the United Kingdom.

7.15 This instrument applies to 3 measures which are reserved or a transferred matter for Northern Ireland under the Northern Ireland Act 1998 the Equipment for Use in potentially Explosives Atmospheres Regulations (Northern Ireland) 2017, the Identification and Traceability of Explosives (Northern Ireland) Regulations 2013 and the Making Available on the Market and Supervisions of Transfer of Explosives (Northern Ireland) Regulations 2016. The UK Government remains committed to restoring devolution in Northern Ireland. This is particularly important in the context of EU Exit where we want devolved Ministers to take the necessary actions to prepare Northern Ireland for exit. We have been considering how to ensure a functioning statute book across the UK including in Northern Ireland for exit day absent a Northern Ireland Executive. With exit day less than one year away, and in the

continued absence of a Northern Ireland Executive, the window to prepare Northern Ireland's statute book for exit is narrowing. UK Government Ministers have therefore decided that in the interest of legal certainty in Northern Ireland, the UK Government will take through the necessary secondary legislation at Westminster for Northern Ireland, in close consultation with the Northern Ireland departments. This is one such instrument.

7.16 The instrument is making changes to 29 pieces of legislation relating to safety requirements for specific groups of products and weighing and measuring equipment. They set out product safety and conformity assessment requirements for specific products ranging from toys, cosmetics, motor yachts, household appliances and equipment for use on off-shore platforms. The relevant regulations are:

(a) Aerosol Dispensers Regulations 2009/ 2824

(b) Cosmetics (EU Regulation) 1223/2009 & Cosmetic Product Enforcement Regulations 2013 (2013/1478)

(c) Electrical Equipment (Safety) Regulations 2016/1101

(d) Electromagnetic compatibility Regulations 2016/1091

(e) Equipment for use in potentially explosive atmospheres Regulations GB 2016/1107

(f) Equipment for use in potentially explosive atmospheres Regulations NI 2017/90

(g) Explosives Regulations 2014/1638 [HSE/DWP]

(h) Gas Appliances (Enforcement) Regs 2018/389 & Gas Appliances (EU Reg) 2016/426

(i) Identification and Traceability of Explosives Regulations (NI) 2013/449

(j) Lifting Operations and Lifting Equipment Regulations 1998/2307 [HSE/DWP]

(k) Lifts Regulations 2016/1093

(l) Making Available on the Market & Supervisions of Transfers of Explosives (NI) 2016/366

(m) Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001/1701

(n) Offshore Installations (Offshore Safety Directive) (Safety Case etc) 2015/398 & Offshore Installations (Safety Case) Regulations 2005/3117 [HSE/DWP]

(o) Personal Protective Equipment (Enforcement) Regulations 2018/390 & PPE (EU Reg) 2016/425

(p) Pressure Equipment (Safety) Regulations 2016/1105

(q) Pyrotechnic Articles (Safety) Regulations 2015/1553

(r) Radio Equipment Regulations 2017/1206

(s) Recreational Craft Regulations 2017/737

(t) Simple Pressure Vessels (Safety) Regulations 2016/1092

(u) Supply of Machinery (Safety) Regulations 2008/1597

(v) Toys (Safety) Regulations 2011/1881

(w) Measuring Container Bottles (EEC Requirements) Regulations 1977/932

(x) Measuring Instruments (EEC Requirements) Regulations 1988

(y) Measuring Instruments Regulations 2016/1153

(z) Non-automatic weighing instruments Regulations 2016/1152

(aa) Weights & Measures (Intoxicating Liquor) Order 1988/2039

(bb) Weights & Measures (Packaged Goods) Regulations 2006/659

(cc) Weights and Measures (Revocations) Regulations 2015/356

7.17 In addition to the changes set out above, this instrument will make the following changes:

(a) allow for existing authorised representatives (AR), where used, to continue to be based either in the EU27 or the UK. New ARs would be based in the UK. Responsible persons (cosmetics only) must be based in the UK;

(b) Replace references to language used by Member State with "English";

(c) Remove obligations for Secretary of State to inform Commission and Member States when taking certain actions;

(d) 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). Current UK distributors who get products from EU27 operators will become UK importers on exit;

(e) Introduce an 18 month transitional period for distributors to take on 'importer' responsibilities for labelling, by allowing importer information to be produced on accompanying documentation instead of on the product itself. This would allow lead-in time for any re-labelling needed on the article;

(f) Existing offences will continue to apply – on economic operators, including importers post exit (who pre-exit would have been subject to the less onerous duties of distributors);

(g) Provides that an existing criminal offence of providing false or misleading information applies when a responsible person follows the lesser notification requirements for Cosmetics, on the basis that the product is already available on the EEA or UK market, and that notification under the EU Regulation has already taken place; and

(h) Creates new UK only databases for market surveillance and public protection purposes, to replace the Commission databases to which we will no longer have access post exit.

7.18 Additional changes are required for some regulations such as measuring instruments and toys, which contain (sometimes ambulatory) cross references to Annexes of Directives which will be broken post exit by including the Annexes in the UK Regulations. This will make sure UK legislation is not reliant on the EU's post exit, but without changing the obligations on exit day. It also accounts for some of the length of the instrument, since the Annexes in some cases are tens of pages long.

7.19 For cosmetics this instrument will make further amendments to ensure the continued protection of UK consumers after exit. In a 'no deal' scenario it is likely that the UK will no longer have access to the EU Cosmetics Products Notification Portal which provides essential information to National Poison Centres to protect public health. Work has already begun on a UK replacement database.

7.20 Cosmetic products already on the market will not be required to fully notify but will be required to provide basic information on the Responsible Person in the UK, the name of the product and its frame formulation within a 90-day period after exit.

7.21 Additionally, for cosmetics there will be a transitional period of two years for labelling, during which time products will not be required to revise the labelling to identify a UK Responsible person.

7.22 The instrument also introduces a transitional period in respect of labelling for 'new' importers. Once the UK has left the EU, former distributors who brought products in from the EU27 to the UK, will now be classified as 'importers' bringing in products from a third country. This change in status brings new obligations such as the requirements for importers to label their products with their name and address. It is important that we understand the implications for business and seek to minimise the impact on them. While it is not possible to remove 'importer' responsibilities without reducing the protection for UK consumers, given stakeholder feedback, we can seek to ease the burden of compliance by considering how the labelling requirement in regard to name and address could be implemented.

7.23 This instrument will amend the legislation so that for an 18 month transitional period the information can routinely be placed on an accompanying document. This would be a less burdensome way of meeting labelling requirements and we propose using guidance and wider stakeholder engagement to increase awareness of this to encourage and support business to implement 'new' importer obligations in the most cost-effective way.

7.24 This approach only applies to product areas which do not require a 'responsible person' to be present in the UK, so would not apply to cosmetic products

7.25 Further changes are also being made 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 existing requirement to add two letters identifying the state of production or import will remain. The instrument includes 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 costs to manufacturers, where the EU code already exists, but will preserve a UK importer contact for traceability purposes.

Primary legislation

7.26 The instrument will also introduce deficiency fixes to 3 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. The instrument will remove reciprocal recognition arrangements and 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.

Revocations

7.27 The effect of the European Union (Withdrawal) Act is to maintain EU Regulations in UK law. The provisions of some of the EU Regulations for which the Department is responsible will no longer make sense following EU Exit and consequently they are being revoked. 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. The amendments also revoke the corresponding EEA provisions.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 There are no plans at this time to consolidate the legislation amended by this instrument.

10. Consultation outcome

10.1 The Department did not undertake a public consultation given that its provisions are limited to addressing failures in retained EU and UK law to operate effectively as a result of EU Exit and in order to minimise any sensitivities in advance of negotiations with the EU.

10.2 The aim of this instrument is to maintain the same requirements for products on the market as currently exists in respect of the product safety and metrology framework; to provide UK businesses and consumers with continuity and reassurance about the safety and accuracy of products placed on the UK market on exit day. Technical input required for this instrument has been provided by the Office for Product Safety and Standards, the HSE and interested government bodies.

10.3 Informal consultation has taken place with a good cross-representation of stakeholders, including trade associations and other industry representative bodies across the product areas covered by this instrument. Stakeholders were supportive of the need to maintain a functioning product safety and metrology regime on EU exit which mirrors the framework in operation the day before EU exit as closely as is possible. The main interest of stakeholders has been the establishment of a UK marking and what lead-in time business will have to implement and adapt to any new marking requirements.

10.4 On 13th September 2018 the Department published a Technical Notice[1] on how the product safety and metrology system would operate for goods to be placed on the UK and EU market in the event of a 'no deal' scenario. The Department and HSE have followed this publication with further engagement with businesses and business representative groups to ensure that they are informed and get their feedback.

11. Guidance

11.1 There is existing guidance on the UK's product safety and metrology framework, provided to support businesses, enforcement agencies and consumers, which can be found on the Office for Product Safety and Standards section of the GOV.UK website

[1] https://www.gov.uk/government/publications/trading-goods-regulated-under-the-new-approach-if-theres-no-brexit-deal/trading-goods-regulated-under-the-new-approach-if-theres-no-brexit-deal

(https://www.gov.uk/government/organisations/office-for-product-safety-and-standards) and also on the Business Companion website (https://www.businesscompanion.info/en/in-depth-guides). This information will be updated for EU Exit in due course and additional advice and support will be available to stakeholders as needed.

12. Impact

12.1 The impact on business has been looked at in an Impact Assessment (IA) for this instrument. There is no significant impact on charities or voluntary bodies.

12.2 The impact on the public sector is not significant. There will some internal processes and administration systems that need to be put in place as a consequence of transferring some functions and operations to existing UK entities, that are currently carried out within the EU.

12.3 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. In addition, the proposals on new notifications and re-notifications on cosmetics products are estimated to cost £1.2m in transition and £0.5m annually.

12.4 Despite the relatively low ongoing impacts we recognise that the length of the instrument and the number of areas covered suggests that parliament would benefit from further analysis when considering the instrument and the IA will be published to inform those debates.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise the regulatory burdens on small business.

13.3 The legal requirements on the industry do not differentiate between businesses in terms of their size, they are dependent on the type and nature of product being produced and placed on the market and therefore we are unable to take any mitigating actions to reduce burdens on small business.

14. Monitoring & review

14.1 The Department does not intend to monitor this instrument. However, some of the underlying measures include review clauses to review the regulatory provisions made under them. Furthermore, the Government will review the provisions allowing products that meet EU requirements on the UK market over time to decide whether these should be retained in the longer-term.

14.2 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Christine Knox at the Department for Business, Energy and Industrial Strategy, Telephone: 020 7215 3465 or email: OPSSbrexit@beis.gov.uk can be contacted with any queries regarding the instrument.

15.2 Rebecca Bradfield, Deputy Director for EU Exit team in the Office for Product Safety and Standards, at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.

15.3 Kelly Tolhurst, Minister for Small Business, Consumers and Corporate Responsibility at the Department for Business, Energy and Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Minister for Small Business, Consumers and Corporate Responsibility, Kelly Tolhurst, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because the instrument provides for maintaining the status quo as far as appropriate in that it keeps substantially the same obligations on economic operators for the UK market, enables manufacturers to use UK designated standards and UK approved bodies to test their products, whilst at the same time allowing products meeting the EU requirements, which were agreed whilst the UK was a member of the EU, to continue to be placed on the UK market.

2. Good reasons

2.1 The Minister for Small Business, Consumers and Corporate Responsibility, Kelly Tolhurst, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 We are making appropriate amendments to domestic legislation to address deficiencies arising from the withdrawal of the United Kingdom from the European Union. The amendments are limited to achieving that purpose.

3. Equalities

3.1 The Minister for Small Business, Consumers and Corporate Responsibility, Kelly Tolhurst, has made the following statement(s):

"The instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts".

3.2 The Minister for Small Business, Consumer and Corporate Responsibility, Kelly Tolhurst, has made the following statements regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Kelly Tolhurst, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010".

3.3 "This instrument does not extend to Northern Ireland, and as the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 extend to Northern

Ireland, I have given equivalent due regard to the need to eliminate discrimination, harassment and victimisation in relation to Northern Ireland".

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.