

EXPLANATORY MEMORANDUM TO
THE CONFORMITY ASSESSMENT (MUTUAL RECOGNITION AGREEMENTS)
REGULATIONS

2019 No. 392

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 Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations will provide explicit recognition in UK legislation for conformity assessment (product safety compliance) against EU regulations carried out by bodies in third countries that have entered into a Mutual Recognition Agreement (MRA), or a trade agreement including provisions on conformity assessment (collectively referred to as Agreements), with the European Union (EU).

2.2 These Regulations will provide certainty that relevant goods that are conformity assessed by bodies in third countries that are recognised under the Agreements, can be placed on the UK market pre-exit. By making it clear that conformity assessment by certain bodies in these third countries should be treated as if it had been carried out by a body under EU law, these Regulations will also ensure that these products can continue to be placed on the UK market after exit, under the relevant EU Exit legislation.

2.3 The countries with Agreements covered by this measure are Australia, New Zealand, Canada, USA, Japan, Switzerland, Turkey, South Korea and Israel.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales, Scotland and Northern Ireland.

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

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 The purpose of product safety legislation is to ensure that products that are placed on the market are safe and compliant with relevant regulatory requirements. To this end, EU legislation places obligations on economic operators throughout the supply chain (manufacturers, importers, distributors and, in certain product legislation, authorised representatives appointed by manufacturers). The key obligations are that products are safe and/or accurate and meet certain requirements. Generally, there is a requirement that the product is assessed to demonstrate compliance with the relevant requirements (conformity assessment), sometimes by a third party, prior to being placed on the market. Product safety legislation is enforced by market surveillance authorities, which have a duty to evaluate products believed to present a risk. Should products be found to be unsafe or otherwise non-compliant, corrective action will be required and they ultimately may have to be withdrawn from the market.
- 6.2 As a Member State of the EU, the UK is subject to bilateral Agreements between the EU and third countries which allow certain bodies (designated under the Agreements) in these third countries to carry out conformity assessment, for certain product sectors (under legislation specified in the Agreements) against EU regulations or (in the case of Switzerland, Turkey and Israel) equivalent national regulations.
- 6.3 These Regulations will give these Agreements explicit grounding in UK law before exit day, making it clear that conformity assessment by certain bodies in these third countries should be treated as if it had been carried out by the requisite body under the relevant updated EU law.
- 6.4 These Regulations provide that where Swiss or Turkish-based conformity assessments are conducted as against updated Swiss, or Turkish law, the output of those assessments will be treated as if the assessments had been made as against equivalent updated EU law.
- 6.5 Some of the Agreements include references to outdated EU legislation, so the references to updated law ensure that the current law is taken into account, as would be the case in practice. It was not necessary to refer to updated Israeli law because the provisions of EU law notified under the Agreement between the EU and Israel do not require updating as at the date these Regulations were made.
- 6.6 These Regulations will also enable recognition of existing Authorised Representatives (legal entities that perform certain statutory functions on behalf of a manufacturer) based in Switzerland and Turkey (rather than only in the EU, as EU law would otherwise require), where the respective Agreements allow for this. It will do this by treating persons based in Turkey and Switzerland as if they are based in the EU, for the purpose of deciding whether they are or can become Authorised Representatives.
- 6.7 For product-specific legislation, UK legislation follows a framework developed at EU level and applied with adaptations to many product areas. There are a number of pieces of EU Exit legislation which will come into effect if the UK leaves the EU on 29 March 2019 without a deal agreed by both Parties covering different product areas, that (subject to outstanding Parliamentary processes or approvals) will amend this product-specific legislation so that the UK statute book functions effectively after the UK has left the EU (for example removing EU references to reflect the fact that the UK will no longer be a member of the EU and setting up a parallel UK-only regime).
- 6.8 In some cases, this EU Exit legislation would enable the UK to continue to accept goods made and assessed against EU requirements after exit. These provisions are

intended to be time-limited and to provide certainty in order to reduce the risk of disruption to businesses, consumers and the public.

- 6.9 These Regulations will provide certainty of the existing position, which is that relevant goods that are conformity assessed by bodies in third countries that are recognised under the agreements set out in paragraph 2.3 can be placed on the UK market pre-exit. By making it clear that conformity assessment by certain bodies in these third countries should be treated as if it had been carried out by a body under EU law, these Regulations will also ensure that these products can continue to be placed on the UK market after exit, under the relevant EU Exit legislation.
- 6.10 For example, after exit, existing Authorised Representatives based in Turkey and Switzerland will be acceptable under UK law due to the Product Safety and Metrology Etc. (Amendment Etc.) (EU Exit) Regulations 2019. However, Swiss and Turkish-based Authorised Representatives that are appointed after the UK exits the EU will not be recognised under UK law (due to the operation of the Product Safety and Metrology Etc. (Amendment Etc.) (EU Exit) Regulations 2019) and instead new Authorised Representatives appointed post-exit will have to be based in the UK (as will also be the case for new Authorised Representatives based in the EU).
- 6.11 In enacting these measures, these Regulations affect, but do not directly amend, a number of different areas of product legislation, which are covered within sectoral chapters in each of the Agreements¹. However, where other sector-specific product legislation already provides for recognition of conformity assessment under the Agreements or does so in future, then the relevant operative provision(s) of these Regulations will not apply to that product.

7. Policy background

What is being done and why?

- 7.1 Conformity assessment, or product safety compliance, is a process that determines whether a product meets certain requirements that allow it to be legally placed on the market. For example, a product must undergo conformity assessment against EU regulatory requirements before it can be placed on the EU market.
- 7.2 The EU has several bilateral Agreements that relate to conformity assessment with third countries. The Agreements promote trade in goods between the EU and third countries by reducing technical barriers to trade. One of the main technical barriers to trade that the Agreements address is around the conditions under which one party (the EU) will accept outputs of conformity assessment undertaken by conformity assessment bodies based in the territory of the other party (e.g. in Canada). The

¹ The product-specific legislation covered by each Agreement varies, but in summary these Regulations will, through the Agreements, affect legislation relating to Biocidal products, Automotive and Motor products, Agricultural and forestry tractors, Cableway installations, Marine equipment, Explosives for civil use, Construction plant and equipment (noise), Construction products, Pharmaceutical Good Manufacturing Practice and Medicinal (human and veterinary) Products, Medical devices, Electrical products, electrical safety and low voltage equipment, Electromagnetic compatibility (EMC) and electromagnetic equipment, Telecommunications equipment and/or radio, Lifts, Gas appliances and boilers, Machinery, Pressure equipment (including transportable pressure equipment and transport of dangerous goods) and simple pressure vessels, Measuring instruments and packaged/pre-packaged goods, Personal protective equipment, Recreational craft, Toys, Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX), and Pyrotechnics.

conformity assessment outputs demonstrate compliance with the first party's (the EU's) product requirements and vice versa. Each agreement is a bilateral trade deal between, in this instance, the EU and a third country (e.g. Canada).

- 7.3 Each bilateral agreement specifies the products or sectors to which it applies (e.g. machinery or electrical and telecommunications equipment) and the conditions under which conformity assessment outputs will be accepted.
- 7.4 While the UK remains an EU Member State, it is subject to these bilateral Agreements. This means products can be conformity assessed against EU regulations, or (in some cases) regulations recognised as equivalent, by designated bodies in these third countries and then be placed on the UK market.
- 7.5 The purpose of these Regulations is to clarify the existing legal position related to EU-recognised third country conformity assessments by ensuring that outputs of conformity assessment by bodies covered by the Agreements will be treated as if issued by an EU body. These Regulations will also enable recognition of existing Authorised Representatives (legal entities that perform certain statutory functions on behalf of a manufacturer) based in Switzerland and Turkey, where the respective Agreements allow for this.
- 7.6 In order to reduce potential disruption to businesses and consumers, the UK Government will continue to accept some goods made and assessed by EU bodies against EU regulations on the UK market in the event that the UK exits the EU on 29 March 2019 without a deal agreed by both Parties. It is intended that this ongoing recognition will be for a time-limited period. This approach is being enacted through various pieces of EU Exit legislation, covering different product areas.
- 7.7 These Regulations ensure that outputs of conformity assessment by bodies covered by the Agreements will be treated as if issued by a body under EU law. This, in turn, will also ensure that products within scope of the Agreements where conformity assessment has been carried out by specific third country bodies can continue to be placed on the UK market after exit under the separate relevant EU Exit legislation (subject to any outstanding Parliamentary approvals and procedure).
- 7.8 Without these Regulations there could be ambiguity and legal uncertainty for companies wishing to export certain products, covered by these Agreements, to the UK, meaning it is possible that the availability of products from these countries in the UK could diminish. Without the legal certainty provided by these Regulations companies may also decide to have their product undergo conformity assessment by a UK or EU-based body (rather than a third country body). Where non-UK manufacturers choose to have their products re-tested by a UK body (or an EU-based body) in order to continue to supply the UK market, they may pass on the additional testing, certification and labelling/marketing costs to consumers.
- 7.9 The policy intent is to ensure that products within scope of the conformity assessment provisions in the Agreements can be placed on the UK market and that, under the relevant EU Exit legislation, this remains the case after exit.
- 7.10 Separately, new trading arrangements, including new Agreements concerning conformity assessment, as between these third countries and the UK only, are being progressed and will provide a reciprocal and more permanent arrangement once they are concluded.

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

8.1 These Regulations are not being made under the European Union (Withdrawal) Act 2018, but they relate to the withdrawal of the United Kingdom from the European Union. These Regulations are being made to clarify the existing legal position related to EU-recognised third country conformity assessments, under the powers contained in section 2(2) of the European Communities Act 1972. The Regulations therefore must be made before the UK exits from the EU.

8.2 The Regulations relate to the UK's withdrawal because, as explained above, some EU Exit legislation will enable the UK to continue to accept goods made and assessed against EU (and EU-recognised) requirements post-exit. As these Regulations provide certainty that conformity assessment under the Agreements will be treated as if done under EU law, then goods assessed under the Agreements may be accepted in the UK post-exit where the other requirements of the relevant EU Exit legislation are met.

9. Consolidation

9.1 These Regulations do not raise any issues of consolidation.

10. Consultation outcome

10.1 The Government did not undertake a formal public consultation given that this instrument's provisions are limited to clarifying the existing legal position related to EU-recognised third country conformity assessments ahead of EU exit.

10.2 The aim of these Regulations is to give certainty that the EU's Agreements with third countries, to which the UK is currently subject, are clarified in domestic law. This is intended to contribute to maintaining the same requirements for products coming on to the UK market, that have been assessed by relevant third countries bodies after the UK exits the EU, as currently exists.

10.3 There has been engagement with the Northern Ireland Executive, the Scottish Government and the Welsh Government on this measure. This has included sharing draft legislation and receiving their acknowledgment of the proposed instrument in areas where Northern Ireland, Scotland and Wales are able to legislate separately.

11. Guidance

11.1 Guidance on the UK's approach to importing, exporting and transporting products is available on the GOV.UK website. The Technical Notices published in September 2018 on the GOV.UK website also set out guidance on the approach to imports and exports in the event that the UK leaves the EU on 29 March 2019 without a deal agreed by both Parties. For example, the Technical Notice on 'Trading goods regulated under the 'New Approach' if there's no Brexit deal' contains details of the continuity approach in relation to goods regulated under the 'New Approach' framework. There are other Technical Notices on the GOV.UK website explaining the approach in other sectors and products.

11.2 This information is regularly being updated for EU exit and will reflect the provisions contained in these Regulations. Further support and advice on specific product legislation is available by contacting goodsregulation@beis.gov.uk.

12. Impact

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 An Impact Assessment has not been prepared for this instrument because it does not impose any costs to business, charities, voluntary bodies or the public sector. The legislative changes made by the instrument do not constitute a change in policy for UK business, charities, voluntary bodies or the public sector.

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 businesses as no new costs are anticipated.
- 13.3 The basis for the final decision on what action to take to assist small businesses is the absence of any anticipated new costs.

14. Monitoring & review

- 14.1 These Regulations do not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, the Minister for Small Business, Consumers and Corporate Responsibility, Kelly Tolhurst, has made the following statement:

“The Department has not included a statutory review clause. This is because a review would be disproportionate when taking into account the economic impact of this instrument. The application of the instrument post-exit is intended to be time-limited and, in relation to the Government’s approach of accepting goods made and assessed against EU requirements post-exit described above, the Government has committed to providing sufficient notice to businesses before this period ends.”

15. Contact

- 15.1 Simon Lawrence at the Department for Business, Energy and Industrial Strategy. Telephone: 0207 215 3910 or email: simon.lawrence@beis.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Kathryn Boyd, Deputy Director for Trade in Goods, 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.