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Brexit Law – your business, the EU and the way ahead

What a disorderly Brexit means for product conformity assessments and marking

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Introduction

In the EU, manufacturers of a wide variety of products can currently demonstrate compliance with essential EU requirements by having a so-called "notified body" carry out a product conformity assessment and affix a conformity marking (most commonly, the CE marking). These actions are often a pre-requisite to placing products on the EU market.

If the EU and the UK do not reach a consensus on the withdrawal agreement [1] and the UK leaves the EU at 11 pm (GMT) on 29 March 2019 with no deal (i.e., a hard or disorderly Brexit), EU legislation will cease to apply to the UK and the UK will become a third country for trade purposes[2].

Such a disorderly Brexit may have far reaching consequences for certain businesses, particularly those looking to place certain products on both the EU-27 and UK markets.

This article discusses the consequences of a disorderly Brexit on product conformity assessments and conformity marking, and the immediate actions to be taken by businesses in light of recent guidance issued by the European Commission and the UK's Department of Business, Energy and Industrial Strategy (**BEIS**).

Placing products on the EU-27 market

Earlier this year, the EU Commission published guidance on the implications of the UK's withdrawal from the EU with regard to "industrial products"[3]. We summarise the key elements of the EU Commission's guidance below, as well as a number of the practical implications for businesses.

Economic operators and their role in supply chains

Most EU product legislation channels regulatory obligations towards "manufacturers", "importers" and "authorised representatives" operating from, or established in, an EU Member State.

In the event of a hard Brexit, with effect from 11 pm (GMT) on 29 March 2019 (the **Withdrawal Date**), a person established in the UK will no longer be deemed to be an economic operator established in an EU Member State. This may result in businesses further down your supply chains (such as distributors or downstream users) becoming the importer of the products for regulatory purposes and having to fulfil related product obligations.

In cases where EU legislation allows for the appointment of an "authorised representative" (e.g. RoHS[4]) or "responsible person" (e.g. cosmetic products[5]) in the EU (which is often offered as a solution for manufacturers established outside of

1 The draft "agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community as endorsed by leaders at a special meeting of the European Council on 25 November 2018" can be found here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/759019/25_November_Agreement_on_the_withdrawal_of_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_from_the_European_Union_and_the_European_Atomic_Energy_Community.pdf

2 At the time of writing this article, negotiations are still on-going between the UK and the EU, with a view of reaching a consensus on the withdrawal agreement.

3 http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=612136 and https://ec.europa.eu/info/sites/info/files/qa_brexit_industrial_products_en.pdf. The EU Commission guidance applies primarily to the EU legislation outlined in Annexure A.

the EU to comply with their relevant obligations), the appointment of UK-based authorised representatives or responsible persons will no longer be possible after the Withdrawal Date, and existing representatives/persons established in the UK will no longer be recognised as such for the purposes of the applicable EU product legislation.

Operators relying on a UK-based authorised representative or responsible person are therefore advised to take the necessary steps to ensure that, as from the Withdrawal Date, their authorised representative or responsible person is established in one of the EU-27 Member States.

Conformity assessment procedures and CE marking

For many product areas, EU legislation requires the involvement of a third-party technical expert, a so-called "notified body", to assess the conformity of products before they can be CE-marked and placed on the market.

The aim of these procedures, and the affixing of the CE-mark on products, is to ensure that such products may be placed on the EU market and move freely within the EU without obtaining multiple approvals across a range of regulatory areas.

EU product legislation requires that notified bodies are established in an EU Member State and are designated by a Member State as the competent authority to carry out the conformity duties. In the case of a disorderly Brexit, as from the Withdrawal Date, the UK-based notified bodies will lose their status as EU-recognised notified bodies and with it their ability to perform conformity assessments as regards EU requirements.

The extent to which goods certified by a UK-based notified body can continue to circulate in the EU-27 market after the Withdrawal Date will depend on whether these goods have been "placed on the market" before the Withdrawal Date. For example, goods held by an EU-27 wholesaler, or goods sold to an EU-27 customer (even where the goods have not yet been delivered), prior to the Withdrawal Date may continue to be made available in the EU-27 market after the Withdrawal Date.

However, if products assessed by a UK-based notified body will not be placed on the EU-27 market by the Withdrawal Date, businesses are advised to either apply for a new certificate issued by an EU-27 notified body or, prior to the Withdrawal Date, arrange for a transfer – on the basis of a contractual arrangement between the manufacturer, the UK-based notified body and the EU-27 notified body – of the relevant file and the corresponding certificate from the UK-based notified body to the EU-27 notified body.

Where products destined for the EU-27 market have not been assessed by a notified body prior to the Withdrawal Date, businesses are advised to take the necessary steps to ensure that you hold certificates issued by an EU-27 notified body to demonstrate product compliance.

Placing products on the UK market

On 13 September 2018, the UK's BEIS published guidance on "Trading Goods regulated under the 'New Approach' if there's no Brexit deal" [6] This was followed on 2 February 2019 with guidance on a new UK conformity mark ("Using the UKCA marking if the UK leaves the EU without a deal")[7], and on 15 February 2019 with guidance on the regulatory requirements applying to manufactured goods in a hard Brexit scenario ("Manufactured goods: regulatory requirements if the UK leaves the EU without a deal")[8].

4 Article 8 of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast).

5 Article 4 and 5 of Regulation (EC) No 1223 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast).

6 The September 2018 BEIS guidance can be found at: 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. It does not cover the following areas: (i) automotive (vehicle type approval), (ii) aerospace, (iii) pharmaceutical products (batch testing medicines, medicines, medicinal devices and clinical trials, submitting regulatory information on medical products), (iv) medical devices (medicines, medical devices and clinical trials, submitting regulatory information on medical products), (v) chemicals, and (vi) goods subject to national regulations (non-harmonised goods). The BEIS guidance covers the EU legislation outlined in Annexure B.

7 The 2 February 2019 BEIS guidance can be found at: https://www.gov.uk/government/publications/prepare-to-use-the-ukca-mark-after-brexit/using-the-ukca-marking-if-the-uk-leaves-the-eu-without-a-deal.

8 The 15 February 2019 BEIS guidance can be found at: https://www.gov.uk/government/publications/manufactured-goods-regulatory-requirements-after-brexit/manufactured-goods-regulatory-requirements-if-the-uk-leaves-the-eu-without-a-deal.

The BEIS guidance clarifies that, in the case of a disorderly Brexit, (i) goods already lawfully placed on the EU market before the Withdrawal Date will be able to freely circulate in the UK, and (ii) goods that meet EU requirements (and which were tested by an EU-27 recognised conformity assessment body) can still be placed on the UK market for a limited period of time. After this period (which the BEIS guidance indicates will be determined in consultation with industry), all products placed on the UK market will need to comply with the UK's new conformity assessment (or UKCA)[9] marking regime.

The UKCA marking regime will cover most of the products subject to, and will apply the same general rules as, the CE marking regime. For example:

- products placed on the UK market will be required to satisfy certain "essential requirements", which will be the same, immediately after the Withdrawal Date, as the requirements under the current EU CE marking regime;
- some products will require a third party conformity assessment by a UK approved body to confirm they satisfy the UK's essential requirements. The Government intends to reclassify current UK-based notified bodies to UK approved bodies under the UKCA marking regime; and
- the manufacturer will be required to affix the UKCA marking before the product can be placed on the UK market.

As such, businesses manufacturing or supplying products which may be placed on either (or both of) the EU-27 and UK markets will need to ensure that they satisfy the requirements of the parallel UKCA and EU-27 CE marking regimes after the Withdrawal Date. This will require a careful review of product (and packaging) labelling, amongst other things.

Product conformity should therefore be a key part of your Brexit contingency planning. For many businesses, this may bring additional time and costs as you seek to minimise the impacts of a no-deal Brexit. The immediate priority is to ensure that there is no disruption to your ability to sell or distribute your products into key markets. You should also carefully monitor the UK's proposal for a phase-in of the new UKCA mark. For many businesses, it will take time (and costs) to ensure their products carry all necessary conformity markings.

If you have questions on any aspect of this briefing, please get in touch with the contacts below or your usual contacts within Allen & Overy LLP.

Your Allen & Overy contacts

Matthew Townsend
Partner – London/Brussels
+44 20 3088 3174
matthew.townsend@allenovery.com

Fee Goossens
Senior Associate – Brussels
+32 2 780 2601
fee.goossens@allenovery.com

Jochem Spaans
Counsel – Amsterdam
+31 20 674 1500
jochem.spaans@allenovery.com

Isabella Kelly
Associate – London
+44 20 3088 1717
isabella.kelly@allenovery.com

If you would like to discuss the issues raised in this paper in more detail, please contact any of the experts above or your usual Allen & Overy contact.

[9] UK Conformity Assessed.

Annexure A

Legislation to which the EU Commission's "Notice to stakeholders – Withdrawal of the United Kingdom and the EU rules in the field of industrial products" applies:

- Products within the scope of Directive 2001/95/EC on general product safety (OJ L 11, 15.1.2002, p. 4)
- The restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU, OJ L 174, 1.7.2011, p. 88) and Directive 2012/19/EU on waste electrical and electronic equipment (OJ L 197, 24.7.2012, p. 38)
- Batteries and waste batteries (Directive 2006/66/EC, OJ L 266, 26.9.2006, p. 1)
- Appliances burning gaseous fuels (Directive 2009/142/EC, OJ L 330, 16.12.2009, p. 10, replaced as of 21 April 2018 by Regulation (EU) 2016/426, OJ L 81, 31.3.2016, p. 99)
- Ecodesign requirements for energy-related products (Directive 2009/125/EC, OJ L 285, 31.10.2009, p. 10, and all implementing Regulations for specific product groups that have been adopted under this Framework Directive)
- Simple pressure vessels (Directive 2014/29/EU, OJ L 96, 29.3.2014, p. 45)
- Toys' safety (Directive 2009/48/EC, OJ L 170, 30.6.2009, p. 1)
- Electrical equipment designed for use within certain voltage limits (Directive 2014/35/EU, OJ L 96, 29.3.2014, p. 357)
- Machinery (Directive 2006/42/EC, OJ L 157, 9.6.2006, p. 24)
- Electromagnetic compatibility (Directive 2014/30/EU, OJ L 96, 29.3.2014, p. 79)
- Measuring instruments (Directive 2014/32/EU, OJ L 96, 29.3.2014, p. 149)
- Non-automatic weighing instruments (Directive 2014/31/EU, OJ L 96, 29.3.2014, p. 107)
- Cableway installations designed to carry persons (Directive 2000/9/EC, OJ L 106, 3.5.2000, p. 21, replaced as of 21 April 2018 by Regulation (EU) 2016/424, OJ L 81, 31.3.2016, p. 1)
- Radio equipment (Directive 2014/53/EU, OJ L 153, 22.5.2014, p. 62)
- Medical devices and Active implantable medical devices (Directives 93/42/EEC, OJ L 169, 12.7.1993, p. 1, and 90/385/EEC, OJ L 189, 20.7.1990, p. 17, to be replaced as of 26 May 2020 by Regulation (EU) 2017/745, OJ L 117, 5.5.2017, p. 1, with the exception of the provisions of Directives 93/42/EEC and 90/385/EEC listed in Article 122 of Regulation 2017/45, for which a later date of repeal is provided for)
- In vitro diagnostic medical devices (Directive 98/79/EC, OJ L 331, 7.12.1998, to be replaced as of 26 May 2022 by Regulation (EU) 2017/746, OJ L 117, 5.5.2017, 6 p. 176, with the exception of the provisions of Directive 98/79/EC listed in Article 112 of Regulation 2017/46, for which a later date of repeal is provided for)
- Cosmetics (Regulation (EC) 1223/2009, OJ L 342, 22.12.2009, p. 59)
- Pressure equipment (Directive 2014/68/EU, OJ L 189, 27.6.2014, p. 164)
- Transportable Pressure equipment (Directive 2010/35/EU, OJ L 165, 30.6.2010, p. 1)
- Aerosol Dispensers (Directive 75/324/EEC, OJ L 147, 9.6.1975, p. 40)
- Lifts and safety components for lifts (Directive 2014/33/EU, OJ L 96, 29.3.2014, p. 251)
- Recreational craft and personal watercraft (Directive 2013/53/EU OJ L 354, 28.12.2013, p. 90)
- Equipment and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU, OJ L 96, 29.3.2014, p. 309)
- Explosives for civil uses (Directive 2014/28/EU, OJ L 96, 29.3.2014, p. 1)
- Construction products (Regulation (EU) No 305/2011, OJ L 88, 4.4.2011, p. 5)
- Pyrotechnics (Directive 2013/29/EU, OJ L 178, 28.6.2013, p. 27)
- Regulation on the Labelling of Tyres (Regulation (EC) No 1222/2009, OJ L 342, 22.12.2009, p. 46)

- Personal protective equipment (Directive 89/686/EEC, OJ L 399, 30.12.1989, p. 18, replaced as of 21 April 2018 by Regulation (EU) 2016/425, OJ L 81, 31.3.2016, p. 51)
- Marine equipment (Directive 2014/90/EU, OJ L 257, 28.8.2014, p. 146)
- Noise emission in the environment by equipment for use outdoors (Directive 2000/14/EC, OJ L 162, 3.7.2000, p. 1)
- Energy labelling (Regulation (EU) No 2017/1369, OJ L 198, 28.7.2017, p. 1, and all delegated Regulations for specific product groups that have been adopted under this Framework Regulation and those adopted under Directive 2010/30/EU, OJ L 153, 18.6.2010, p. 1, the predecessor of Regulation 2017/1369).
- Regulation on textile fibre names and related labelling and marking of textile products (Regulation (EU) No 1007/2011, OJ L 272, 18.10.2011, p. 1)
- Directive relating to labelling of the materials used in the main components of footwear (Directive 94/11/EC, OJ L 100, 19.4.1994, p. 37)
- Metrology (Directive 2011/17/EU OJ L 71, 18.3.2011, p. 1 - Repeal of several directives – transition till 2025)
- Bottles as measuring containers (Directive 75/107/EEC, OJ L 42, 15.2.1975, p. 14)
- Making up of pre-packaged products (Directive 76/211/EEC, OJ L 46, 21.2.1976, p. 1)
- Hot-water boilers fired with liquid or gaseous fuels (Directive 92/42/EEC, OJ L 167, 22.6.1992, p. 17. The Directive was repealed by Commission Regulation (EU) No 813/2013 (OJ L 239, 6.9.2013, p. 136) implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters, except for Articles 7(2) and 8 thereof and Annexes III to V thereto)
- Interoperability of the rail system within the European Union (Directive 2008/57/EC, OJ L 191, 18.7.2008, p. 1, to be replaced as of 16 June 2020 by Regulation (EU) 2016/797, OJ L 138, 26.5.2016, p. 44)
- Interoperability of Electronic Road Toll Systems (Decision 2009/750/EC implementing Directive 2004/52/EC, OJ L 268, 13.10.2009, p. 11)
- Tachographs in road transport (Regulation (EU) No 165/2014, OJ L 60, 28.2.2014, p. 1)
- Interoperability of the European Air Traffic Management network (Regulation (EC) No 552/2004, OJ L 96, 31.3.2004, p. 26)

Annexure B

Legislation to which the BEIS guidance applies:

- Regulation for Accreditation and Market Surveillance (Regulation (EC) 765/2008, OJ L 218, 13.8.2008, p. 30)
- Toys' safety (Directive 2009/48/EC, OJ L 170, 30.6.2009, p. 1)
- The restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU, OJ L 174, 1.7.2011, p. 88)
- Construction products (Regulation (EU) 305/2011, OJ L 88, 4.4.2011, p. 5)
- Pyrotechnics (Directive 2013/29/EU, OJ L 178, 28.6.2013, p. 27)
- Recreational craft and personal watercraft (Directive 2013/53/EU OJ L 354, 28.12.2013, p. 90)
- Explosives for civil uses (Directive 2014/28/EU, OJ L 96, 29.3.2014, p. 1)
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- Radio equipment (Directive 2014/53/EU, OJ L 153, 22.5.2014, p. 62)
- Electrical equipment designed for use within certain voltage limits (Directive 2014/35/EU, OJ L 96, 29.3.2014, p. 357)
- Pressure equipment (Directive 2014/68/EU, OJ L 189, 27.6.2014, p. 164)
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- Batteries and waste batteries (Directive 2006/66/EC, OJ L 266, 26.9.2006, p. 1)
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