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APPLICATION: Industrial products placed on the EU market as from UK withdrawal date

Type of ships:

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL PRODUCTS

Following notification of the United Kingdom submitted on 28 March 2017 of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union, as from 30 March 2019 the United Kingdom will be treated as a “third country”, having direct impact on the manufacturers or importers established in the United Kingdom, with additional consequences related to conformity assessment procedures and UK Notified Bodies.

Notice to stakeholders released by European Commission on 22 January 2018 on withdrawal of the United Kingdom and the EU rules in the field of industrial products, attached to this Newsletter should be observed for more details.

However, and notwithstanding the above stated, it is to be noted that 30 March 2019 as the date of the withdrawal of the United Kingdom from the Union, the European Council in agreement with the United Kingdom may unanimously decide that the Treaties cease to apply at a later date.

ATTACHMENT:
- European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Notice to Stakeholders, dated 22 January 2018

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs

Brussels, 22 January 2018
Rev1

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL PRODUCTS[1]

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that, unless a ratified withdrawal agreement[2] establishes another date, all Union primary and secondary law will cease to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ('the withdrawal date').[3] The United Kingdom will then become a 'third country'.[4]

Preparing for the withdrawal is not just a matter for EU and national authorities but also for private parties.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, all interested parties, and especially economic operators, are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.[5]

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of non-food and non-agricultural products, whether for use by consumers or professionals (hereinafter referred to as "Union product legislation"), no longer apply to the United Kingdom. This has, in

[1] See the annex for the detailed list of Union product legislation.

[2] Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

[3] Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

[4] A third country is a country not member of the EU.

[5] For goods placed on the EU market *before* the withdrawal date, the EU is trying to agree solutions with the United Kingdom in the withdrawal agreement. The essential principles of the EU's position on goods placed on the market under Union law before the withdrawal date are available here: https://ec.europa.eu/commission/publications/position-paper-goods-placed-market-under-union-law-withdrawal-date_en.

particular, the consequences presented below for products **placed on the EU-27 market**[6] **as from the withdrawal date.**[7] An indicative list of Union product legislation to which this notice applies can be found in the annex.[8]

This notice should be read in conjunction with any complementary, more specific notices on the legal consequences of the United Kingdom's withdrawal that may be published with regard to any of the Union acts listed in the annex.

1. CONSEQUENCES FOR THE IDENTIFICATION OF ECONOMIC OPERATORS

According to Union product legislation, the **importer** is the economic operator[9] established in the Union who places a product from a third country on the Union market. As from the withdrawal date, a manufacturer or importer established in the United Kingdom will no longer be considered as an economic operator established in the Union. As a consequence, an economic operator established in the EU-27 who, prior to the withdrawal date, was considered as an EU distributor will become an importer for the purposes of Union product legislation in relation to products from a third country that this economic operator places on the EU-27 market as from the withdrawal date. This operator will have to comply with the specific obligations relevant to an importer, which are different from those of a distributor.[10]

Currently, Union product legislation does not generally oblige the manufacturer to designate an **authorised representative**.[11] However, if the manufacturer chooses to do so, the applicable legislation requires the authorised representative to be established in the Union. In addition, specific Union legislation does provide for the obligation to have

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6 The concept of placing on the market refers to each individual product and not to types of products, and whether it was manufactured as an individual unit or in series. For more information on the concept of placing on the market, see Chapter 2 of Commission Notice 2016/C 272/01 "The Blue Guide on the implementation of EU product rules 2016", OJ C 272, 26.7.2016, p. 1 (hereinafter referred to as "the Blue Guide").

7 This note does not deal with the placing on the UK market as from the withdrawal date.

8 Several elements are commonly present in the different pieces of EU product legislation, regardless of the harmonisation technique adopted by the legislator (e.g. the notion of placing on the market and making available of a product; the definitions of the economic operators). In addition to such common elements, Union legislation based on the so-called New Approach also shares the same approach to technical harmonisation, by setting out common requirements ("essential requirements", expressed in the form of performance requirements or objectives to be attained) on how a product has to be designed and manufactured to meet the required level of e.g. health, safety or environmental protection as well as the conformity assessment procedure, which is chosen from among a common set of modules, that has to be followed to demonstrate compliance with such requirements. For more information in this regard, please see the Blue Guide.

9 Union product legislation defines as economic operators the manufacturer, the importer, the distributor and the authorised representative.

10 See Chapter 3 of the Blue Guide.

11 The Commission proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products (COM (2017) 795 final of 19.12.2017: https://ec.europa.eu/docsroom/documents/26976) provides for the obligation to have a person responsible for compliance information established in the Union in respect of all products that are subject to the Union harmonisation legislation set out in the Annex to the proposed Regulation.

an authorised representative (e.g. Union legislation on medical devices[12], transportable pressure equipment[13] or marine equipment[14]) or a responsible person (cosmetic products[15]) established in the Union.

Authorised representatives or responsible persons established in the United Kingdom will not, as from the withdrawal date, be recognised as authorised representatives or responsible persons for the purposes of the applicable Union product legislation. Therefore, manufacturers are advised to take the necessary steps to ensure that, as from the withdrawal date, their designated authorised representatives or responsible persons are established in the EU-27.

2. CONSEQUENCES FOR CONFORMITY ASSESSMENT PROCEDURES AND NOTIFIED BODIES

In some product areas, Union legislation requires the intervention of a qualified third party, known as Notified Body, in the conformity assessment procedure.

Union product legislation requires Notified Bodies to be established in a Member State and be designated by a Member State notifying authority for performing the conformity assessment tasks set out in the relevant act of Union product legislation. Therefore, as from the withdrawal date, UK Notified Bodies will lose their status as EU Notified Bodies and will be removed from the Commission's information system on notified organisations (NANDO database[16]). As such, UK bodies will not be in a position to perform conformity assessment tasks pursuant to Union product legislation as from the withdrawal date.

When the applicable conformity assessment procedure requires or provides for the possibility of third party intervention, a certificate delivered by a body recognised as an EU Notified Body at the time of the placing of that product on the market will be required for products placed on the market as from the withdrawal date.

Economic operators are advised to take the necessary steps to ensure that, where the applicable conformity assessment procedures require the intervention of a Notified Body, they will hold certificates issued by an EU-27 Notified Body to demonstrate compliance for their products placed on the market as from the withdrawal date.

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[12] Article 14 of Council Directive 93/42/EEC concerning medical devices, OJ L 169, 12.7.1993, p.1, Article 10a of Council Directive 90/385/EEC concerning active implantable medical devices, OJ L 189, 20.7.1990, p. 17 (both Directives to be replaced as of 26 May 2020 by Regulation (EU) 2017/745 of the European Parliament and of the Council, OJ L 117, 5.5.2017, p. 1, where the corresponding provision is Article 11) and Article 10 of European Parliament and Council Directive 98/79/EC on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1 (to be replaced as of 26 May 2022 by Regulation (EU) 2017/746 of the European Parliament and of the Council, where the corresponding provision is Article 11, OJ L 117, 5.5.2017, p. 176).

[13] Article 5 of Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC, OJ L 165, 30.6.2010, p. 1.

[14] Article 13 of Directive 2014/90/EU of the European Parliament and of the Council on marine equipment, OJ L 257, 28.8.2014, p. 146.

[15] Articles 4 and 5 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59.

[16] http://ec.europa.eu/growth/tools-databases/nando/

Where economic operators hold certificates issued by a UK Notified Body prior to the withdrawal date and plan to continue placing the product concerned on the EU-27 market as from the withdrawal date, they are advised to consider either applying for a new certificate issued by an EU-27 Notified Body or arranging for a transfer – on the basis of a contractual arrangement between the manufacturer, the UK Notified Body, and the EU-27 Notified Body - of the file and the corresponding certificate from the UK Notified Body to an EU-27 Notified Body, which would then take over the responsibility for that certificate. This responsibility depends on the specific conformity assessment procedure required for the product concerned under the applicable product legislation set out in Annex.

The websites of the Commission on the Single Market for Goods (http://ec.europa.eu/growth/single-market/goods_en and http://ec.europa.eu/growth/sectors_en) provide general information concerning Union harmonisation legislation applicable to non-food and non-agricultural products. These pages will be updated with further information, where necessary.

European Commission
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Annex: Indicative list of Union product legislation

This notice applies primarily to:

- 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, to be 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, to be 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,

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, to be 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 Directive (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)