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2019

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL PRODUCTS¹

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INTRODUCTION

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a ‘third country’.² The Withdrawal Agreement³ provides for a transition period ending on 31 December 2020.⁴ Until that date, EU law in its entirety applies to and in the United Kingdom.⁵

During the transition period, the EU and the United Kingdom will negotiate an agreement on a new partnership, providing notably for a free trade area. However, it is not certain whether such an agreement will be concluded and will enter into force at the end of the transition period. In any event, such an agreement would create a relationship which in terms of market access conditions will be very different from the United Kingdom’s participation in the internal market,⁶ in the EU Customs Union, and in the VAT and excise duty area.

Therefore, all interested parties, and especially economic operators, are reminded of the legal situation as of the end of the transition period (Part A below). This notice also explains certain relevant separation provisions of the Withdrawal Agreement (Part B below), as well as the rules applicable to Northern Ireland as of the end of the transition period (Part C below).

Advice to stakeholders:

To address the consequences set out in this notice, manufacturers are in particular advised to:

- ensure certification by an EU notified body where such certification is required under the EU product legislation;
- ensure compliance with establishment requirements for ‘responsible persons’ for regulatory compliance and authorised representatives, and
- adapt product labelling, where necessary.

² A third country is a country not member of the EU.

³ Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 (“Withdrawal Agreement”).

⁴ The transition period may, before 1 July 2020, be extended once for up to 1 or 2 years (Article 132(1) of the Withdrawal Agreement). The UK government has so far ruled out such an extension.

⁵ Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

⁶ In particular, a free trade agreement does not provide for internal market concepts (in the area of goods and services) such as mutual recognition, the ‘country of origin principle’, and harmonisation. Nor does a free trade agreement remove customs formalities and controls, including those concerning the origin of goods and their input, as well as prohibitions and restrictions for imports and exports.

Please note:

This notice does not cover EU rules in the field of agro-food, medicinal products, motor vehicles, aviation safety and most chemicals. These areas are addressed in separate notices.

An indicative list of Union product legislation to which this notice applies can be found in the Annex.⁷

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

A. LEGAL SITUATION AS OF THE END OF THE TRANSITION PERIOD

As of the end of the transition period, 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.⁸ This has in particular the following consequences:

1. IDENTIFICATION OF ECONOMIC OPERATORS

According to Union product legislation, the **importer** is the economic operator⁹ established in the Union who places a product from a third country on the Union market.¹⁰ As of the end of the transition period, a manufacturer or importer established in the United Kingdom will no longer be considered as an economic

⁷ Several elements are commonly present in the different pieces of Union 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 product 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 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").

⁸ Regarding the applicability of the EU law on industrial products to Northern Ireland, see Part C of this notice.

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

¹⁰ In the case of lifts, there are no importers or distributors as lifts only come into existence as finished products once they have been installed in buildings or constructions. Consequently, lifts are only placed on the market by the installer when, after installation and completion of the applicable conformity assessment procedure, affixing of the CE marking and issuance of the Declaration of Conformity, they are supplied for use. See Article 2(5) and recital 4 of Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts, OJ L 96, 29.3.2014, p. 251.

operator established in the Union. As a consequence, an economic operator established in the EU who, prior to the end of the transition period, was considered as an EU distributor of products received from the United Kingdom will become an importer for the purposes of Union product legislation in relation to such products as of the end of the transition period. This operator will have to comply with the more stringent obligations applicable to an importer, as regards in particular verification of product compliance and, where applicable, the indication of his contact details on the product or its label.¹¹

In some product areas, Union product legislation foresees '**responsible persons**' who have specific tasks in relation to ensuring continued regulatory compliance and interfacing with market surveillance authorities. These 'responsible persons' must be established in the Union, for example:

- the responsible person for cosmetic products¹² and, as of 16 July 2021, products subject to the legislation referred to in Article 4(5) of Regulation (EU) 2019/1020¹³; or
- authorised representatives, whose appointment by the manufacturer is generally voluntary, with the exception of medical devices¹⁴ and marine equipment¹⁵

UK-based responsible persons will lose their status for the purposes of the applicable Union product legislation as of the end of the transition period, regardless of when products were placed on the market. Therefore, manufacturers need to ensure that, as from the end of the transition period, their designated responsible persons are established in the EU.

¹¹ See Chapter 3 of the Blue Guide.

¹² 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.

¹³ Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, OJ L 169, 25.6.2019, p. 1. Article 4(1) of Regulation (EU) 2019/1020 provides that the products subject to the legislation referred to in Article 4(5) can be placed on the market only if there is a person established in the Union who is responsible for the regulatory compliance tasks set out in Article 4(3). Article 4(2) provides that the responsible person can be any of the following: (a) the manufacturer; (b) the importer; (c) an authorised representative; (d) a fulfilment service provider. Pursuant to Article 4(4), the name, registered trade name or registered trade mark, and contact details of the responsible person must be indicated on the product or on its packaging, the parcel or an accompanying document. These provisions will start applying as from 16 July 2021.

¹⁴ 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).

¹⁵ 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.

Where sector-specific databases exist (e.g. the Cosmetic Registration Portal, Eudamed for medical devices), the information on responsible persons is recorded in those databases and any change will therefore be traceable there.

Goods placed on the EU market as of the end of the transition period will have to fully comply with the provisions of Union law applicable at the time of their placing on the market. This means, *inter alia*, that when required they will have to indicate the details of an EU 'responsible person'.

2. CONFORMITY ASSESSMENT PROCEDURES AND NOTIFIED BODIES¹⁶

In some product areas, Union legislation requires the intervention of a qualified third party, known as Notified Body, in the conformity assessment procedure. Notified Bodies must be established in a Member State and designated by a Member State notifying authority for performing the conformity assessment tasks set out in the relevant act of Union product legislation.

As of the end of the transition period, 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 database¹⁷). As such, UK bodies will not be in a position to perform conformity assessment tasks pursuant to Union product legislation as of the end of the transition period.

When the applicable conformity assessment procedure requires or provides for the possibility of third party intervention, a certificate delivered by a body which is 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 of the end of the transition period.

It will therefore be necessary for economic operators to either apply for a new certificate issued by an EU Notified Body, or arrange for a transfer of the file and the corresponding certificate from the UK Notified Body to an EU 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 transfer of certificates from a UK Notified Body to an EU Notified Body needs to take place before the end of the transition period, on the basis of a contractual arrangement between the manufacturer, the UK Notified Body, and the EU Notified Body.

¹⁶ The legal consequences set out in this section also apply, *mutatis mutandis*, in relation to:

- (a) European Technical Assessments issued by Technical Assessment Bodies designated by the UK authorities under Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 88, 4.4.2011, p.5;
- (b) certificates or approvals issued by a user inspectorate or a recognised third-party organisation designated by the UK authorities under Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment, OJ L 189, 27.6.2014, p. 164.

¹⁷ <http://ec.europa.eu/growth/tools-databases/nando/>

When a certificate has been transferred, both the EU Declaration of Conformity (drawn up by the manufacturer) and the Notified Body Certificate must be updated accordingly: these documents will need to mention that the certificate is now under the responsibility of an EU Notified Body and indicate both the old UK and the new EU Notified Body's details / identification numbers.

If the above mentioned product documentation is in order, there is no need to change the Notified Body number for products already placed on the EU or the UK market or manufactured before the transfer of certificate has taken place and not yet placed on the EU or the UK market. However, products manufactured after the transfer of the certificate has taken place should be marked with the new EU Notified Body number and it will not be possible to continue to use the UK Notified Body number.¹⁸

3. ACCREDITATION

Accreditation is an attestation issued by a national accreditation body that a conformity assessment body meets the applicable requirements to carry out a specific conformity assessment activity. Accreditation is the preferred means of demonstrating the technical competence of Notified Bodies, unless Union product legislation provides otherwise. Regulation No 765/2008¹⁹ sets out the legal framework for the organisation and operation of the European accreditation system.

The UK Accreditation Service will cease to be a national accreditation body within the meaning and for the purposes of Regulation No 765/2008 as from the end of the transition period. As a consequence, its accreditation certificates will no longer be considered as 'accreditation' within the meaning of Regulation No 765/2008 and no longer valid or recognised in the EU pursuant to that Regulation as of the end of the transition period.²⁰

¹⁸ Please also note that in the field of recreational craft and personal watercraft, each watercraft placed on the EU market must also bear a unique code of the manufacturer assigned by Member State authorities or authorised national bodies. For more information, please refer to the applicable “Notice to stakeholders – withdrawal of the United Kingdom and EU rules in the field of recreational craft and personal watercraft” published here: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#grow.

¹⁹ Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30.

²⁰ See also other relevant preparedness notices referring to accreditation, such as the "Notice to stakeholders – withdrawal of the United Kingdom and EU rules on fluorinated greenhouse gases" and the “Notice to stakeholders – withdrawal of the United Kingdom and the EU Emission Trading System” published here: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#clima.

B. RELEVANT SEPARATION PROVISIONS OF THE WITHDRAWAL AGREEMENT

1. INDUSTRIAL PRODUCTS PLACED ON THE EU OR THE UK MARKET BEFORE THE END OF THE TRANSITION PERIOD

Article 41 of the Withdrawal Agreement provides that an existing and individually identifiable good lawfully placed on the market in the EU or the United Kingdom before the end of the transition period may be further made available on the market of the EU or of the United Kingdom and circulate between these two markets until it reaches its end-user. Where provided in the applicable provisions of Union law, such a good may also be put into service in the EU or in the United Kingdom.

The notion of placing on the market applies to individual products. Accordingly, this provision will apply only to those individual products which have been placed on the market in the EU or the UK before the end of the transition period, but not to the type or series of products in a general manner.

The economic operator relying on that provision bears the burden of proof of demonstrating on the basis of any relevant document that the good was placed on the market in the EU or the United Kingdom before the end of the transition period.²¹ Such proof can be given on the basis of documents ordinarily used in business transactions (e.g. contract of sale concerning goods which have already been manufactured, invoice, documents concerning the shipping of goods to distribution or similar commercial documents). There is no need to create a new type of document for this purpose. In practice, such proof will need to be given in case of checks upon importation into the EU or the UK or in case of checks by market surveillance authorities. The documentary evidence provided must make it possible to verify that it corresponds to the individual goods and quantity presented to customs or checked by market surveillance authorities, for example, with the reference to the specific identification element(s) of the goods.

For the purposes of these provisions, “placing on the market” means the first supply of a good for distribution, consumption or use on the market in the course of a commercial activity, whether in return or payment or free of charge.²² ‘Supply’ means that ‘an existing and individually identifiable good, after the stage of manufacturing has taken place, is the subject matter of a written or verbal agreement between two or more legal or natural persons for the transfer of ownership, any other property right, or possession concerning the good in question, or is the subject matter of an offer to a legal or natural person or persons to conclude such an agreement.’²³ ‘Putting into service’ means ‘the first use of a good within the Union or the United Kingdom by the end user for the purposes for which it was intended, or in the case of marine equipment, placing on board.’²⁴

²¹ Article 42 of the Withdrawal Agreement.

²² Article 40(a) and (b) of the Withdrawal Agreement.

²³ Article 40(c) of the Withdrawal Agreement.

²⁴ Article 40(d) of the Withdrawal Agreement.

This means that an individual product placed on the UK market according to this definition before the end of the transition period can still be made available (e.g. can continue to be supplied for distribution, consumption or use), put into service²⁵ (where applicable) and used in the EU after the end of the transition period, and vice-versa.

Situations which are considered as placing on the market include, for instance:

- Contract of sale from manufacturer to importer, distributor (also intra-group provided a genuine transaction can be identified) or final customer, where the manufacturing of that good has been completed;
- On-line sales: only when the customer receives confirmation of his order which identifies the specific good already manufactured and subject of the transaction, ready to be shipped to the customer.

Conversely, the following situations are not considered as placing on the market:

- Pre-ordered goods, not yet manufactured
- Contract for the supply of fungible goods (e.g. x units of product y, not individually identifiable)
- Goods manufactured and held in the manufacturer's stock, but not yet supplied for distribution, consumption or use
- Generic offer of a product on-line (only after an order by a customer has been placed and confirmed, the specific good which is the subject of the transaction and is ready to be shipped is considered to have been placed on the market).

EXAMPLE 1: Goods physically in the distribution chain or already in use in the EU or the UK market before the end of the transition period:

- *A cosmetic product held in the EU by a wholesaler with a view to onward distribution or already on the shelf of a department store; an X-ray machine (medical device) certified by a UK Notified Body and held in the EU by a wholesaler or already supplied to a hospital in the EU, where it is in use.*

These products are placed on the EU market before the end of the transition period and may be further made available on the market of the EU or of the UK and circulate between these two markets until they reach their end-users, be put into service (where applicable) and continue to be used in the EU or the UK with no need for re-certification, re-labelling or product modifications. This is without prejudice to the obligation to appoint a new responsible person or authorised representative, as the case may be, established in the EU where the current one is UK-based as set out under Section A.1 above.

EXAMPLE 2: Goods manufactured in the EU, the UK or in any other third country, sold to an EU customer before the end of the transition period after the manufacturing stage was completed but not yet physically delivered to the EU customer on that date:

²⁵ In line with the above, for marine equipment this means placed on board of an EU ship as defined in Article 2(2) of Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment, OJ L 257, 28.8.2014, p. 146.

- *A circular saw (machinery) manufactured in the US and certified by a UK Notified Body has been sold by the manufacturer to a Dutch factory on 15 December 2020 but will only arrive at Dutch customs on 15 January 2021.*

Same as the goods under Example 1. The date of placing on the EU market is the date of the transaction (first supply) between the manufacturer and the EU customer after the manufacturing stage was completed. Placing on the market does not require physical delivery of the product.

EXAMPLE 3: Goods imported into the UK from a third country or manufactured in the UK, subsequently sold to an EU customer before the end of the transition period but physically delivered to the EU customer as of that date.

- *An X-ray machine manufactured in the US and certified by a UK Notified Body is sold to a UK wholesaler on 15 December 2020 and imported by the latter into the UK on 15 January 2021. The UK wholesaler then sells it to a Dutch hospital on 30 January 2021 and the X-ray machine arrives at Dutch customs on 15 February 2021.*
- *an X-ray machine manufactured in the UK and certified by a UK Notified Body is sold either directly by the manufacturer to the Dutch hospital or via a UK distributor, in both cases the date of the transaction with the Dutch hospital is 15 December 2020, arrival at Dutch Customs on 15 January 2021.*

In both examples, the date of placing on the UK market is the date of the transaction (first supply) between the manufacturer and the UK customer (wholesaler/importer or distributor). Placing on the market does not require physical delivery of the product. The product is considered as placed on the UK market before the end of the transition period and may therefore be further made available on the market of the EU or of the UK and circulate between these two markets until it reaches its end-user, be put into service (where applicable) and continue to be used in the EU or the UK with no need for re-certification, re-labelling or product modifications. This is without prejudice to the obligation to appoint a new responsible person or authorised representative, as the case may be, established in the EU where the current one is UK-based as set out under Section A.1 above.

2. TRANSFER OF INFORMATION FROM A UK BODY TO AN EU NOTIFIED BODY AND VICE-VERSA

Article 46 of the Withdrawal Agreement lays down provisions to facilitate, if need be, the transfer of information related to conformity assessments between notified bodies established in the UK or in the EU in case of succession of notified bodies. According to Article 46(1), ‘the United Kingdom shall ensure that information held by a conformity assessment body established in the United Kingdom in relation to its activities as a notified body under Union law before the end of the transition period is made available at the request of the certificate holder, without delay, to a notified body established in a Member State as indicated by the certificate holder.’ Article 46(2) contains a mirror provision requiring Member States to ensure that information held by EU notified bodies is made available at the request of the certificate holder, to a conformity assessment body established in the United Kingdom.

C. APPLICABLE RULES IN NORTHERN IRELAND AFTER THE END OF THE TRANSITION PERIOD

As from the end of the transition period, the Protocol on Ireland/Northern Ireland ('IE/NI Protocol') applies.²⁶ The IE/NI Protocol is subject to periodic consent of the Northern Ireland Legislative Assembly, the initial period of application extending to 4 years after the end of the transition period.²⁷

The IE/NI Protocol makes certain provisions of EU law applicable also to and in the United Kingdom in respect of Northern Ireland. It also provides that insofar as EU rules apply to and in the United Kingdom in respect of Northern Ireland, the latter is assimilated to a Member State.²⁸

The IE/NI Protocol provides that most of the legislation listed in the Annex to this notice applies to and in the United Kingdom in respect of Northern Ireland.²⁹

This means that, insofar as EU law made applicable by the IE/NI Protocol to the United Kingdom in respect of Northern Ireland is concerned, references to the EU in Parts A and B of this notice have to be understood as including Northern Ireland, whereas references to the United Kingdom have to be understood as referring only to Great Britain.

More specifically, this means *inter alia* the following:

- Products placed on the market in Northern Ireland have to comply with the applicable EU legislation;
- A product manufactured in Northern Ireland and shipped to the EU is not an imported product for the purpose of labelling and identification of economic operators / responsible persons (see above, Section A.1);
- A product shipped from Great Britain to Northern Ireland is an imported product (see above, introduction to Section A and Section A.1);
- Importers, authorised representative and other 'responsible persons' may be established in Northern Ireland (see above, section A.1).
- Certificates issued by a Notified Body in Great Britain are not valid in Northern Ireland. A Notified Body in Northern Ireland, however, can continue to certify products in certain circumstances (see below).

However, the IE/NI Protocol excludes the possibility for the United Kingdom in respect of Northern Ireland to:

- participate in the decision-making and decision-shaping of the Union;³⁰

²⁶ Article 185 of the Withdrawal Agreement.

²⁷ Article 18 of the IE/NI Protocol.

²⁸ Article 7(1) of the Withdrawal Agreement in combination with Article 13(1) of the IE/NI Protocol.

²⁹ Article 5(4) and sections 8 to 19, 21, 23, 27, and 28 of annex 2 to the IE/NI Protocol.

- initiate objections, safeguard or arbitration procedures to the extent that they concern regulations, standards, assessments, registrations, certificates, approvals and authorisations issued or carried out by EU Member States;³¹
- act as leading authority for assessments, examinations and authorisations;³²
- invoke the country of origin principle or mutual recognition for products placed legally on the market in Northern Ireland; or for certificates issued by bodies established in the United Kingdom.³³

More specifically, this last point means *inter alia* the following:

- Bodies established in Northern Ireland may certify products, but certificates issued by Notified Bodies in Northern Ireland are valid only in Northern Ireland. By contrast, these certificates are not valid in the EU.³⁴
- Where a product is certified by a Notified Body in Northern Ireland, the indication ‘UK(NI)’ must be affixed next to the CE marking or any other applicable conformity marking.³⁵ This distinct marking allows the identification of products which can be legally placed on the market in Northern Ireland, but not in the EU.
- In the non-harmonised area, the principle of mutual recognition in one Member State of goods lawfully marketed in another Member State pursuant to Articles 34 and 36 of the Treaty on the Functioning of the European Union³⁶ will not apply in respect of goods lawfully marketed in Northern Ireland. This means that the lawful placing of a product on the market of Northern Ireland cannot be invoked when that product is placed on the market in the EU. However, the lawful marketing of a product in a Member State can be invoked when that product is placed on the market in Northern Ireland.

³⁰ Where an information exchange or mutual consultation is necessary, this will take place in the joint consultative working group established by Article 15 of the IE/Ni Protocol.

³¹ Fifth subparagraph of Article 7(3) of the IE/Ni Protocol.

³² Article 13(6) of the IE/Ni Protocol.

³³ First subparagraph of Article 7(3) of the IE/Ni Protocol.

³⁴ Fourth subparagraph of Article 7(3) of the IE/Ni Protocol.

³⁵ Fourth subparagraph of Article 7(3) of the IE/Ni Protocol.

³⁶ Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ L 218, 13.8.2008, p. 21. Regulation (EC) No 764/2008 will be repealed with effect from 19 April 2020 by Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, OJ L 91, 29.3.2019, p. 1.

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

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Directorate-General for Mobility and Transport

Directorate-General for Justice and Consumers

Directorate-General for Environment

Directorate-General for Energy

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 (“RoHS” Directive 2011/65/EU, OJ L 174, 1.7.2011, p. 88)
- Waste electrical and electronic equipment (“WEEE” Directive 2012/19/EU, OJ L 197, 24.7.2012, p. 38)
- Batteries and waste batteries (Directive 2006/66/EC, OJ L 266, 26.9.2006, p. 1)
- Packaging and packaging waste (Directive 94/62/EC, OJ L 365, 31.12.1994, p.10)
- Appliances burning gaseous fuels (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)
- Toy 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 and methods of metrological control (Directive 2009/34/EC, OJ L 106, 28.4.2009, p. 7)
- 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 (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 (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. Directive 2004/52/EC will be repealed as of 20 October 2021 by Directive 2019/520/EU. Decision 2009/750/EC will be repealed as of 19 October 2021 by Commission Implementing Regulation (EU) 2020/204. See also Commission Delegated Regulation (EU) 2020/203 laying down, *inter alia*, minimum eligibility criteria or notified bodies, applicable as of 19 October 2021)
- Tachographs in road transport (Regulation (EU) No 165/2014, OJ L 60, 28.2.2014, p. 1)