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

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QUESTIONS AND ANSWERS RELATED TO THE UNITED KINGDOM'S WITHDRAWAL FROM THE EUROPEAN UNION WITH REGARD TO INDUSTRIAL PRODUCTS

On 22 January 2018, the European Commission services published a "*Notice to stakeholders – withdrawal of the United Kingdom and EU rules in the field of industrial products*" ('the Notice').[1] An indicative list of Union product legislation to which the Notice applies can be found in its Annex.

This list of Questions and Answers (Q&A) gives further guidance on the basis of the Notice in a situation where the United Kingdom (UK) becomes a third country on 30 March 2019 at 00:00h (CET) ('the withdrawal date') without a ratified withdrawal agreement and hence

- without the transition period provided for in the draft Withdrawal Agreement; and

- without the provisions in relation to "goods placed on the market" provided for in the draft Withdrawal Agreement.

The list of Q&A may be further updated and complemented as necessary and should be read in conjunction with any complementary, more specific notices or Q&A on the legal consequences of the UK's withdrawal that have been or may be published with regard to any of the Union acts listed in the Annex to the Notice.

A. CONCEPT OF GOODS PLACED ON THE UNION (EU-27) MARKET BEFORE THE WITHDRAWAL DATE

The relevant criterion to determine the extent to which there may be consequences from the UK withdrawal for a specific product covered by the Notice is whether a product was placed on the Union (EU-27) market before the withdrawal date.

The concept of placing on the market refers to each individual product, not to a type of products, whether it was manufactured as an individual unit or in series. It relates to the first making available on the Union (EU-27) market, i.e. the first supply of a good for distribution, consumption or use after the manufacturing stage. Placing on the market

[1] https://ec.europa.eu/info/sites/info/files/file_import/industrial_products_en_1.pdf

does not require physical delivery of the product but does require that the manufacturing stage has been completed.[2]

1. **Goods physically in the distribution chain or already in use in the EU-27 market on the withdrawal date.**

   Example: a cosmetic product held in the EU-27 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 held in the EU-27 by a wholesaler or already supplied to a hospital in the EU-27, where it is in use.

   These goods are considered as placed on the Union (EU-27) market before the withdrawal date and can therefore continue to be made available in the EU-27 market or remain in use with no need for re-certification, re-labelling or product modifications. This is without prejudice to the obligation to appoint a new 'responsible person' established in the EU-27 where the current one is UK-based as set out under Section B below.

2. **Goods manufactured either in the EU or in a third country, sold to an EU-27 customer before the withdrawal date after the manufacturing stage was completed but not yet physically delivered to the EU-27 customer on that date.**

   Example: an X-ray machine manufactured in the US and certified by a UK Notified Body has been sold to a Dutch hospital on 15 March 2019 (=date of placing on the market, i.e. date of the transaction) but will only arrive at Dutch customs on 5 April 2019.

   Same as the goods under Q&A No. 1. The date of placing on the Union (EU-27) market is the date of the transaction between the manufacturer and the EU-27 customer after the manufacturing stage was completed. Placing on the market does not require physical delivery of the product.

3. **Goods imported into the UK from a third country or manufactured in the UK, subsequently sold to an EU-27 customer before the withdrawal date but physically delivered to the EU-27 customer as of that date.**

   Example A: an X-ray machine manufactured in the US and certified by a UK Notified Body is sold to a UK wholesaler on 15 February 2019 and imported by the latter into the UK on 15 March 2019. The UK wholesaler then sells it to a Dutch hospital on 25 March 2019 and the X-ray machine arrives at Dutch customs on 5 April 2019.

   Example B: an X-ray machine manufactured in the UK and certified by a UK Notified Body is sold either directly to the Dutch hospital or via a UK

[2] 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.

distributor, in both cases the date of the transaction with the Dutch hospital is 25 March 2019, arrival at Dutch Customs on 5 April 2019.

In both examples, same as the goods under Q&A No. 1 and 2. The date of placing on the Union (EU-27) market is the date of the transaction between the UK economic operator (manufacturer, importer or distributor) to the EU-27 customer. Placing on the market does not require physical delivery of the product.

4. Goods imported into the UK from a third country or manufactured in the UK before the withdrawal date, subsequently sold to an EU-27 customer as of the withdrawal date.

Example A: a circular saw (machinery) manufactured in the US and certified by a UK Notified Body is sold to a UK wholesaler on 15 February 2019 and imported by the latter into the UK on 15 March 2019. The UK wholesaler then sells it to a Dutch factory on 5 April 2019 and the circular saw arrives at Dutch customs on 15 April 2019.

Example B: a circular saw manufactured in the UK and certified by a UK NB is sold either directly to the Dutch factory or via a UK wholesaler, in both cases the date of the transaction with the Dutch factory is 5 April 2019, arrival at Dutch Customs on 15 April 2019.

In both examples, the goods are placed on the Union (EU-27) market after the withdrawal date as the date of their first making available to an EU-27 customer is on or after the withdrawal date. The goods are considered as imports from a third country and will have to fully comply with the provisions of Union law applicable at the time of their placing on the market. This means in particular that the goods will have to have been certified by an EU-27 Notified Body, where a third-party intervention in their conformity assessment is required. Where applicable, they will also have to indicate the details of the EU-27 importer and of an EU-27 'responsible person'.[3]

5. How can proof of placing on the market before the withdrawal date be given?

Proof of placing on the market can be given on the basis of any relevant document 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).

In practice, such proof will need to be given in case of checks upon importation into the Union (EU-27) 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

[3] Please note that, in addition, the EU rules for imports set out in the Union Customs Code, as well as in the EU VAT legislation apply. For more information, please refer to the applicable "Preparedness notices" published here: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#tradetaxud.

by market surveillance authorities, for example, with the reference to the specific identification element of the goods.

B. RESPONSIBLE PERSONS

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 products;[4] or authorised representatives, whose appointment by the manufacturer is generally voluntary but mandatory in a few sectors, notably: medical devices, transportable pressure equipment, marine equipment. UK-based responsible persons will lose their status as from the withdrawal date, regardless of when products were placed on the market. Therefore, manufacturers need to ensure that, as from the withdrawal date, their designated responsible persons are established in the EU-27.

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.

1. **Goods placed on the Union (EU-27) market before the withdrawal date**

   No need for relabelling with the contact details of the new EU-27 responsible persons. The information available in the existing databases or, absent those, information provided by economic operators to the competent national authorities concerning the appointment of a new EU-27 based responsible person shall suffice.

2. **Goods placed on the EU-27 market as of the withdrawal date, whether coming from the UK or another third country**

   These goods 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-27 'responsible person'.

C. IMPORTERS

According to Union product legislation, the importer is the economic operator 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. Union legislation generally requires the contact details of the importer to be provided on the product itself or its label.

1. **Products which were imported into the EU-28 via the UK and placed on the Union (EU-27) market before the withdrawal date**

[4] Regarding the EU rules for cosmetic products, see also the "Notice to stakeholders – withdrawal of the United Kingdom and EU rules in the field of cosmetic products" (https://ec.europa.eu/info/sites/info/files/cosmetic_products_en_0.pdf).

Q&A No. 1 of Section A applies. No change to the labels is required.

2. **Goods imported into the UK market before the withdrawal date and made available to the EU-27 market as of that date.**

   For products entering the EU-27 market as from the withdrawal date in respect of which the EU-28 importers used to be UK-based, EU-27 economic operators which were previously mere distributors of those products will become importers for the purposes of Union law when making those products available in the EU-27 market for the first time (i.e. placing them on the EU-27 market). This will require them to meet more stringent obligations as regards in particular verification of product compliance and, where applicable, the indication of their contact details on the product.

   Regarding the labelling of the importer, Q&A No. 4 of Section A applies: these goods are placed on the Union (EU-27) market after the withdrawal date and, will need to be relabelled with the indication of the EU-27 importer.

D. TRANSFER OF NOTIFIED BODY CERTIFICATES

In some product areas, Union product 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.

The Notice recalls that for the purposes of placing products on the EU-27 market as of the withdrawal date a certificate of an EU-27 Notified Body will be required. It will therefore be necessary for economic operators to either apply for a new certificate with another EU-27 Notified Body, or arrange for a transfer of the file and the corresponding certificate to an EU-27 Notified Body, which would then take over the responsibility for that certificate. The transfer of certificates from a UK Notified Body to an EU-27 Notified Body needs to take place before the withdrawal date, on the basis of a contractual arrangement between the manufacturer, the UK Notified Body, and the EU-27 Notified Body.

1. **I am a manufacturer of a product for which the certificate has been transferred from a UK Notified Body to an EU-27 Notified Body. Do the EU Declaration of Conformity and the actual Notified Body Certificate need to be updated to document this change?**

   Yes, for products placed on the EU-27 market after the withdrawal date 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-27 Notified Body and indicate both the old UK and the new EU-27 Notified Body's details / identification numbers.

2. **Does the Notified Body number on the product itself need to be changed also for products already on the market or manufactured before the transfer of the certificates occurred?**

If the above mentioned product documentation is in order, no need to change the Notified Body number for products already placed on the EU-27 market or manufactured before the transfer of certificate has taken place and not yet placed on the EU-27 market. However, products manufactured after the transfer of the certificate has taken place should be marked with the new EU-27 Notified Body number and it will not be possible to continue to use the UK Notified Body number until the end of the validity of the original certificate issued by it.

E. 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 765/2008[5] sets out the legal framework for the organisation and operation of the European accreditation system.

1. **What is the legal status under Union law, as from the withdrawal date, of accreditation certificates delivered by the UK Accreditation Service (UKAS)?**

   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 withdrawal date. 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-27 pursuant to that Regulation as of the withdrawal date.[6]

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[5] 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.

[6] 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" (https://ec.europa.eu/info/sites/info/files/file_import/fluorinated-gases_en.pdf).