

Trading goods regulated under the ‘New Approach’ if there’s no Brexit deal

Summary

How trading in harmonised goods regulated under the ‘New Approach’ would be affected if the UK leaves the EU with no deal.

Detail

If the UK leaves the EU in March 2019 without a deal, find out how this would affect you if you are a business trading in those harmonised goods (where common EU-wide rules apply) currently regulated by the EU under the ‘New Approach’.

A scenario in which the UK leaves the EU without agreement (a ‘no deal’ scenario) remains unlikely given the mutual interests of the UK and the EU in securing a negotiated outcome.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it’s our duty as a responsible government to prepare for all eventualities, including ‘no deal’, until we can be certain of the outcome of those negotiations.

For two years, the government has been implementing a significant programme of work to ensure the UK will be ready from day 1 in all scenarios, including a potential ‘no deal’ outcome in March 2019.

It has always been the case that as we get nearer to March 2019, preparations for a no deal scenario would have to be accelerated. Such an acceleration does not reflect an increased likelihood of a ‘no deal’ outcome. Rather it is about ensuring our plans are in place in the unlikely scenario that they need to be relied upon.

This series of technical notices sets out information to allow businesses and citizens to understand what they would need to do in a ‘no deal’ scenario, so they can make informed plans and preparations.

This guidance is part of that series.

Also included is an [overarching framing notice] (<https://www.gov.uk/government/publications/uk-governments-preparations-for-a-no-deal-scenario/>) explaining the government's overarching approach to preparing the UK for this outcome in order to minimise disruption and ensure a smooth and orderly exit in all scenarios.

We are working with the devolved administrations on technical notices and we will continue to do so as plans develop.

Purpose

This notice explains the future arrangements for the regulation of most goods covered by the EU's New Approach, which includes those regulated under the 'New Legislative Framework' as well as machinery. In particular it covers arrangements for conformity assessment (the testing of goods to ensure they meet relevant requirements). These goods are subject to EU-wide product specific rules. These arrangements will apply in the unlikely event that the UK exits the EU without a deal in March 2019.

This notice does not cover the following areas:

- Automotive - [Guidance available here] (insert link to Vehicle Standards TN)
- Aerospace
- Pharmaceutical products - Guidance available here: [Batch testing medicines] (<https://www.gov.uk/government/publications/batch-testing-medicines-if-there-s-no-brex-it-deal>), [Medicines, Medical Devices and Clinical Trials] (<https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-there-s-no-brex-it-deal>), [Submitting regulatory information on medical products] (<https://www.gov.uk/government/publications/submitting-regulatory-information-on-medical-products-if-there-s-no-brex-it-deal>)
- Medical devices - Guidance available here: [Medicines, Medical Devices and Clinical Trials] (<https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-there-s-no-brex-it-deal>) and Submitting regulatory information on medical products] (<https://www.gov.uk/government/publications/submitting-regulatory-information-on-medical-products-if-there-s-no-brex-it-deal>)
- Chemicals
- Goods subject to national regulations (non-harmonised goods) - [Guidance available here] (insert link to non harmonised goods TN)

Annex A sets out the specific EU goods regulations and directives covered by this notice. This list may be updated over time.

Annex B provides additional detail regarding civil explosives.

Before 29 March 2019

For the products covered by this notice EU legislation sets out the rules, or ‘essential (safety) requirements’, which products must meet before they are placed on the EU market.

For some of these product areas, manufacturers can choose to demonstrate compliance with the essential requirements set out in legislation by following ‘harmonised standards’. Harmonised standards that can be used to demonstrate that a product meets essential requirements are published in the [Official Journal of the European Union] (<https://eur-lex.europa.eu/oj/direct-access.html>).

For construction products, use of the harmonised standards is mandatory.

The relevant EU legislation sets out how products within its scope can be tested to prove that they conform with the essential requirements. Typical ways of showing conformity include:

- self-declaration by the manufacturer that they have taken appropriate steps to ensure their product is compliant (for example, for most toys)
- assessment of the final product by an EU-accredited body (known as a ‘notified body. A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market.)
- assessment of a product’s design (or a prototype) by a notified body, followed by testing of either a sample of the final product or quality assurance of production processes

For many products, a manufacturer must affix a ‘conformity marking’, most commonly the CE marking (CE marking is defined in EU law as “a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in [EU] harmonisation legislation providing for its affixing”). This acts as a declaration that the product complies with the relevant requirements. For marine equipment, the wheel mark (The Wheel Mark (Mark of Conformity) is the European regulatory marking of all marine equipment, as defined in the Marine Equipment Directive, 2014/90/EU) is used.

Where EU rules require third party testing, that notified body’s four-digit identification number (as listed on the EU’s New Approach Notified and Designated Organisations database, known as [NANDO](<http://ec.europa.eu/growth/tools-databases/nando/index.cfm>)) must also be affixed to the product.

Notified bodies are usually given the right to carry out conformity assessment following assessment by a national accreditation body (in the UK, the [United Kingdom Accreditation Service](<https://www.ukas.com/>)). They are then formally 'notified' to the European Commission and other EU countries by the relevant public body and listed on the New Approach Notified and Designated Organisations (NANDO) database.

After March 2019 if there's no deal

Goods already placed on the market will be able to continue to circulate in the UK. Additionally, goods that meet EU requirements (and were tested by an EU recognised conformity assessment body) can still be placed on the UK market. This is intended to be a time-limited measure.

The results of conformity assessment carried out by UK notified bodies will no longer be recognised in the EU. This means that products tested by a UK notified body will no longer be able to be placed on the EU market without retesting and re-marking by an EU recognised conformity assessment body.

For the areas within scope of this notice (see Annex A), notified bodies based in the UK will be granted new UK 'approved body' status and listed on a new UK database. Approved bodies will be able to assess products for the UK market against UK essential requirements (which, immediately after exit day in a 'no deal' scenario, will be identical to EU essential requirements).

Manufacturers selling goods on the UK market will then be able to affix a new UK conformity marking before placing a product on the UK market. A separate UK marking to replace the wheel mark will be in place for marine equipment. Manufacturers will not need to use these markings from the point of exit in a 'no deal' scenario if they have used the relevant EU marking after having their product assessed by an EU recognised body. This will be a time-limited arrangement. Details of these markings will be published later in 2018 and with sufficient time to allow businesses to prepare.

The United Kingdom Accreditation Service's role as the UK's national accreditation body, including for most UK conformity assessment bodies, will remain as it is now.

Existing harmonised standards (used to demonstrate conformity with EU essential requirements) will become UK 'designated standards', used to demonstrate conformity with UK essential requirements. As noted above, immediately following

exit these will be identical to EU essential requirements.

Implications

All manufacturers intending to place products on the UK market on or after 29 March 2019 will want to consider the actions outlined below.

All manufacturers placing products on the EU market will need to take the actions outlined below if they intend to place products on the EU market on or after 29 March 2019

Actions for businesses and other stakeholders

Manufacturers placing products on the UK market should note:

- Products that meet EU requirements can continue to be placed on the UK market without any need for retesting or re-marking, including where they have demonstrated compliance with EU requirements after exit day. This will apply for a time-limited period and sufficient notice will be given to businesses before that period ends.
- Products that meet UK requirements and bear a UK conformity marking can be placed on the UK market, as long as any third-party testing required has been carried out by a UK-recognised conformity assessment body.
- For product areas covered by this notice, UK-based notified bodies will become UK approved bodies after March 2019 and will be listed on a new UK database.

Manufacturers placing products on the EU internal market should note:

- Products which were tested by a UK-based notified body will need to be retested by an EU-recognised conformity assessment body before placing on the EU internal market (A list of EU-recognised conformity assessment bodies can be found on the [NANDO database] (<http://ec.europa.eu/growth/tools-databases/nando/index.cfm>). After March 2019, in a no deal scenario UK-based bodies will no longer be listed on this database).
- Alternatively, manufacturers can seek to arrange for their files to be transferred to an EU-recognised notified body to allow for certificates of conformity issued by a UK-based notified body to continue to be valid.
- In either of the scenarios above, products where third-party testing is required would need to be re-marked with the new EU-recognised notified body's four-digit number.

More information

The government will provide further information later in 2018 setting out the practical arrangements for how UK-based notified bodies will be granted status as UK approved bodies and on the new UK markings.

Where the government makes changes to any of the above arrangements, for example, regarding the ongoing recognition of conformity assessment activities carried out by EU bodies – it will ensure businesses are provided with adequate notice.

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

It is part of the government's ongoing programme of planning for all possible outcomes. We expect to negotiate a successful deal with the EU.

The UK government is clear that in this scenario we must respect our unique relationship with Ireland, with whom we share a land border and who are co-signatories of the Belfast Agreement. The UK government has consistently placed upholding the Agreement and its successors at the heart of our approach. It enshrines the consent principle on which Northern Ireland's constitutional status rests. We recognise the basis it has provided for the deep economic and social cooperation on the island of Ireland. This includes North-South cooperation between Northern Ireland and Ireland, which we're committed to protecting in line with the letter and spirit of Strand two of the Agreement.

The Irish government have indicated they would need to discuss arrangements in the event of no deal with the European Commission and EU countries. The UK would stand ready in this scenario to engage constructively to meet our commitments and act in the best interests of the people of Northern Ireland, recognising the very significant challenges that the lack of a UK-EU legal agreement would pose in this unique and highly sensitive context.

It remains, though, the responsibility of the UK government, as the sovereign government in Northern Ireland, to continue preparations for the full range of potential outcomes, including no deal. As we do, and as decisions are made, we'll take full account of the unique circumstances of Northern Ireland.

Annex A - EU directives and regulations covered by this notice

[Regulation for Accreditation and Market Surveillance – 765/2008]

(<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>)

[Toy Safety - Directive 2009/48/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009L0048>)

[Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065&locale=en>
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[Construction products - Regulation (EU) No 305/2011]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011R0305>)

[Pyrotechnic Articles - Directive 2013/29/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0029&locale=en>)

[Recreational craft and personal watercraft - Directive 2013/53/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013L0053>)

[Civil Explosives - Directive 2014/28/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0028&locale=en>)

[Simple Pressure Vessels - Directive 2014/29/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0029&locale=en>)

[Electromagnetic Compatibility - Directive 2014/30/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0030&locale=en>)

[Non-automatic Weighing Instruments - Directive 2014/31/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0031&locale=en>)

[Measuring Instruments - Directive

2014/32/EU](<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0032&locale=en>)

[Lifts - Directive 2014/33/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0033&locale=en>)

[ATEX - Directive 2014/34/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0034&locale=en>)

[Radio equipment - Directive 2014/53/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1415980552970&uri=CELEX:32014L0053>)

[Low Voltage - Directive 2014/35/EU]

(<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0035&locale=en>)

[Pressure equipment - Directive 2014/68/EU]

(http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.189.01.0164.01.ENG)

[Marine Equipment - Directive 2014/90/EU]

(http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.257.01.0146.01.ENG)

[Personal protective equipment - Regulation (EU) 2016/425]

(http://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=uriserv:OJ.L_.2016.081.01.0051.01.ENG&toc=OJ:L:2016:081:TOC)

[Gas appliances - Regulation (EU) 2016/426]

(http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.081.01.0099.01.ENG&toc=OJ:L:2016:081:TOC)

[Machinery Directive – Directive 2006/42/EC]

(<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006L0042>)

[Noise emission in the environment by equipment for use outdoors – Directive 2000/14/EC]

(<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32000L0014>)

[Ecodesign directive – (2009/125/EC)]

(<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009L0125>)

Annex B – Additional information relating to civil explosives

Before 29 March 2019

Currently anyone importing civil explosives into the EU, or transferring them through the EU, requires an approval from the EU country where the transfer ends. This is called an Intra Community Transfer approval and each EU country through which the civil explosives transfers must also add their authorisation for the transfer to the Intra Community Transfer.

Civil explosives manufactured in, or imported to, the EU must be marked with a unique site code provided by an EU country to the manufacturer or EU-based importer. This code is recognised by all EU countries. An accompanying record must be held to enable traceability of the civil explosive through the supply chain.

After March 2019 if there's no deal

As the UK will not be an EU country for the purposes of transfers of civil explosives through the EU internal market, the UK will not be able to issue an Intra Community Transfer.

This means that any transfers (now imports) of civil explosives to the UK will need a standalone approval from a UK competent authority (Great Britain or Northern Ireland depending on where the transfer ends in the UK) before the civil explosives are imported. Intra Community Transfer approvals issued by UK competent authorities prior to exit for multiple transfers will continue to be recognised until they expire.

The UK will recognise existing site codes on civil explosive products imported to the UK where the site code has been issued by another Member State. The UK will not require importers to add a new code. However, to continue effective traceability through the supply chain, all importers will need to contact a UK competent authority (Great Britain or Northern Ireland depending on the place of import) to notify them of any existing site code on the civil explosives being imported. The competent authority will then link this existing code to the UK based importer.

The UK government will continue to work with the Northern Ireland Civil Service to ensure that a coherent civil explosives regime continues to operate across the UK.

Implications

Any UK business, who previously obtained an Intra Community Transfer (approval from a UK competent authority (Great Britain or Northern Ireland depending on where the transfer ended) for a transfer across the EU internal market, will now need to obtain an Intra Community Transfer from the final Member State where the transfer ends in the EU internal market.

A new UK approval for the transfer (now import) to the UK will then be required from the relevant UK competent authority (Great Britain or Northern Ireland depending on where the transfer ends in the UK).

Any importer of civil explosives to the UK will need to contact the relevant UK competent authority (Great Britain or Northern Ireland depending on where the civil explosives are imported to) to provide them with details of any existing site code on the civil explosive product.

More information

Businesses dealing with civil explosives may also want to consider the separate [technical notice on export controls] (<https://www.gov.uk/government/publications/exporting-controlled-goods-if-theres-no-brexite-deal>).