HOUSE OF COMMONS LIBRARY

BRIEFING PAPER

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Brexit: product standards and safety marking

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Contents:

Contents

Summary

This briefing paper considers the UK's conformity with product standards and safety marking in the lead up to Brexit.

Currently, the CE mark is placed on a wide range of products to show they are compliant with EU regulatory requirements, including: toys, electrical equipment, and machinery. In most cases, the CE mark can be applied to products tested by the manufacturer. However, for some products, there is a legal requirement for the product to be assessed by a third-party assessment body (a "notified body") to confirm they meet relevant regulatory requirements.

In a "no-deal" scenario, the EU has said it will stop recognising the competency of UK-based notified bodies to assess products for the EU market. In effect, manufacturers who continue to use UK-based notified bodies will no longer be able to apply the CE mark.

The government intends to reclassify UK notified bodies as UK Approved Bodies. These bodies will be eligible to assess products against relevant UK requirements and issue the new "UKCA" mark to compliant products. For a time-limited period, manufacturers will be able to use the CE mark when placing their products on the UK market if their product meets the relevant EU requirements (including products assessed by an EU-recognised body). The government intends to consult with businesses before taking a decision on when this period would end.

UK Products being exported to the EU which currently require CE marking, will continue to require CE marking to demonstrate compliance with the relevant EU regulatory requirements.

In respect of the UK market – new UKCA mark.

In respect of the EU market – continued use of the CE mark.

1. Current EU standards and labelling requirements

1.1 Product conformity

Box 1: CE Marking

- The letters "CE" on a product which is traded in the EU and EEA signifies that it has been assessed to meet high safety, health and environmental protection requirements.
- By affixing the CE mark to a product, a manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EU and EEA.
- Not all products must bear a CE mark, only those product categories subject to specific directives.

Product conformity to established technical and quality standards is a hallmark of the EU product standardisation project. The adoption of harmonised standards for products - such as toys, medical devices and construction products - allows for free circulation of potentially highly sensitive goods while ensuring public safety in the Single Market.

To ensure that a product meets the prescribed standards, the EU has created a system where Member States provide accreditation to "notified bodies". The notified bodies undertake conformity assessments for manufacturers and issue CE marks to products that meet the required standard, as well as undertaking mandatory quality audits.

Notified body

In a nutshell, a notified body is an organisation (or private company) that has been designated by an EU Member State (the designating authority) to assess whether manufacturers and their products meet the requirements set out in legislation. For example, in respect of medical devices, the Medicines and Healthcare Products Regulatory Agency (MHRA) is the designating and competent authority in the UK.

Manufacturers can apply to any notified body in the EU and once they have the necessary certification their products can be sold anywhere in the EU. Following an appropriate assessment, the notified body will issue relevant certification allowing manufacturers to put CE-marks on their products and put them on the market in the EU (see below).

To protect consumers and facilitate cross-border trade, European standards currently set benchmarks for the safety and quality of products and services across multiple sectors, including:

- energy,
- construction materials,
- toys,
- medical devices, and
- transport.

For example, all medical device products must meet the essential requirements of all relevant European medical device directives. The directives outline the safety and performance requirements for medical devices in the EU. The CE mark is a legal requirement to place a medical device on the market in the EU and EEA.

According to CEN (the European Committee for Standardization) and CENELEC (the European Committee for Electrotechnical Standardization), European standards are initiated by business, with about 30 per cent mandated by the European Commission. European standards

European standards are drawn up by CEN and CENELEC, which are independent associations and not EU agencies. They provide a single model, whereby each European standard is adopted identically as a national norm. Currently, UK industry and the British Standards Institution (BSI) play a key role in setting European standards (see section 1.3 below).

1.2 CE Mark

A CE mark must be affixed to certain categories of products sold in the EU and in the EEA. A wide range of products are covered by EU laws that mandate CE marking. A CE mark is intended to serve as a sign of assurance for consumers and other end users of the products.

A CE mark is also a declaration by the manufacturer that the product complies with all relevant EU legislation that mandates compliance with specific standards and requirements concerning product safety, environmental impact, consumer protection, etc. It is the responsibility of the manufacturer to ensure that the product is appropriately marked.

Within the EU and the broader EEA, the marketing and use of products which carry a CE mark cannot be restricted unless there is evidence of non-compliance with the underlying EU legislation justifying such restriction.

A CE mark does not mean that a product complies with all other EU legislation that applies to that product. A CE mark only signifies compliance with a certain set of EU legislation that specifically mandates CE marking. CE marking is in addition to other legal requirements in respect of: consumer protection, product safety, environmental protection etc.

1.3 UK participation in setting standards

UK industry and the BSI play a key role in setting European standards.

The BSI is the National Standards Body

As the government appointed National Standards Body, BSI is responsible for the UK's catalogue of national standards, over 84% of which are identical to international and European standards. Many of these directly support the regulatory requirements for product safety and environmental protection. Importantly, the BSI represents UK interests at the:

- International Organisation for standardisation (ISO);
- International Electrotechnical Commission (IEC); and
- European Standards organisations (CEN, CENELEC and ETSI).

According to the BSI, its role is to help improve the quality and safety of products, services and systems by enabling the creation of standards and encouraging their use. It outlined its position as follows:

> We publish over 2,700 standards annually, underpinned by a collaborative approach, engaging with industry experts, government bodies, trade associations, businesses of all sizes and consumers to develop standards that reflect good business practice.[1]

[1] BSI website [online] (accessed 12 June 2019]

2. "No-deal" Brexit: product safety standards

2.1 European Commission Notice

On 22 January 2018, the European Commission (EC) issued a Notice setting out the effect Britain's withdrawal from the EU may have on product safety standards in the event of a no deal, Notice to stakeholders – Withdrawal of the UK and EU rules in the field of industrial products. In this Notice, the EC stated that for industrial products to demonstrate compliance with CE Marking requirements for products placed on the EU market as from Brexit 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".

In the absence of any other arrangement, the EC outlined its position as follows:

> "[…] 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 to apply for a new certificate issued by an EU-27 Notified Body or organising a transfer […] of the file from the UK Notified Body to an EU Notified Body".

Simply put, EU legislation requires a notified body to be based in the EU. As from 31 October 2019, UK manufacturers wishing to sell to the EU would have to instruct EU based notified bodies. To demonstrate the potential impact of this Notice, a good example is medical devices. According to EU Commission data, almost half of all medical device products certified in the EU currently use UK notified bodies.

The validity of hundreds of thousands of established UK conformity assessments may be called into question. In addition, some economic operators (i.e. manufacturers, importers and authorised representatives) currently operating from the UK, might see their designation change under CE marking legislation as well as their relevant obligations. For example, after Brexit, EU distributors established in the UK may become importers under CE marking legislation in relation to the products that they place on the EU market.

Of course, some UK notified bodies may already have contingency plans in place to ensure that after Brexit global clients can continue to use them as their European notified body (see BSI and section 2.2 below).

2.2 BSI continued membership of CEN and CENELEC

The UK Government's position has been to call for a comprehensive system of mutual recognition and a commitment to maintain UK regulatory standards in line with the EU's. Greg Clark, the Business

Secretary, has supported moves to keep the UK a full member of European standard setting bodies. In June 2018, Greg Clark wrote to Scott Steedman, director of the BSI, urging him to "take the steps you feel are necessary" to maintain national influence in the setting of European and international benchmarks.

The BSI announced in November 2018 that it had reached an agreement with its counterparts in the European standards organisations - CEN and CENELEC – that secures its full membership and participation in the European standards system post-Brexit. The BSI set-out its position as follows:

BSI continues as a member of CEN and CENELEC

> A transition period for the CEN and CENELEC statutes will begin on the date of the UK's effective withdrawal from the EU, until the end of 2020. The delayed date of Brexit does not affect the end date of this transition period.
>
> This transition period introduces a derogation for BSI from certain eligibility clauses of the statutes. CEN and CENELEC have created a working group to determine a permanent solution for the statutes, to apply as of the end of 2020. At the same time BSI will undergo a review of its fulfilment of the membership criteria of CEN and CENELEC. BSI sees the decisions taken by the General Assemblies of CEN and CENELEC as a pragmatic solution that provides stability for the European standards system while meeting the needs of our stakeholders. BSI experts will be entitled, as now, to participate in CEN and CENELEC technical committees while BSI will continue to enjoy full voting rights in the decision-making bodies of both organizations. Crucially, furthermore, standards users in the UK can continue to be confident that these standards will meet their needs as they will be influenced, as they are now, by UK stakeholders.[2]

According to this statement, the UK, through the BSI, will continue to commit to the fundamental membership principles of CEN and CENELEC, meaning that all member countries of CEN and CENELEC have a consistent and coherent catalogue of national standards for industry, consumers and regulators.

2.3 The Product Safety and Metrology (Amendment etc.) (EU Exit) Regulations 2019

This Statutory Instrument (SI) would amend UK product compliance legislation in the event of a no-deal Brexit.

In brief, the Product Safety and Metrology (Amendment etc.) (EU Exit) Regulations 2019 would correct deficiencies in UK legislation that gives effect to EU laws applicable to product safety so that the legislation would continue to operate effectively when the UK leaves the EU. The Regulations, made under section 8 of the European Union (Withdrawal) Act 2018, were made on 27 March 2019 and will come into force on Brexit day (in the event of no-deal).

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2 "BSI: Brexit and Standards: BSI continues as member of CEN and CENELEC", BSI EU Exit update 11 April 2019, [online] (accessed 12 June 2019)

The Regulations are extensive, running to **37 detailed schedules**. The Explanatory Memorandum that accompanies the Regulations, states that the substantive law relating to product safety will continue to apply as before Brexit day. Most changes are therefore consequential in nature. To give a flavour, I would highlight the following points. The Regulations would:

- Amend primary and secondary legislation in the field of product safety by removing or amending references to EU legislation from UK legislation and revoking measures that would no longer be needed after exit day.

  The amended legislation includes the Consumer Protection Act 1987 and the General Product Safety Regulations 2005 (SI 2005/1803) as well as numerous sector-specific regulations, such as the Toys (Safety) Regulations 2011 (SI 2011/1881) and the Electrical Equipment (Safety) Regulations 2016 (SI 2016/1101).

- Amend some secondary legislation pertaining to health and safety at work (such as the Lifting Operations and Lifting Equipment Regulations 1998 (SI 1998/2307).

- Revoke some direct EU legislation, including:

  Regulation (EU) 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation; and

  Regulation (EC) 764/2008 rules to products lawfully marketed in another member state 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 Directive 3052/95/EC.

- Amend references and definitions in affected legislation to ensure that they are appropriate after exit day. For example, substituting the "UK" for "CE" and empowering the Secretary of State (rather than European bodies) to act as the relevant authority, for approval or accreditation purposes (see below).

- Address metrology and make minor changes to the Weights and Measures Act 1985, subordinate legislation concerning weights and measures, and also to the Hallmarking Act 1973.

Changes to compliance processes

In the event of a no-deal Brexit, changes to compliance processes will need to be implemented to ensure that UK products have UK markings and the relevant UK guidance and processes are followed where there is a question over product safety. Specifically, the following points should also be noted:

- **The market** - definitions of "placing on the market" and "making available on the market" would be restricted to the UK market alone, as opposed to the whole EEA market. This is aimed at ensuring that UK product safety laws are focused on goods sold to consumers in the UK.

- **UK Compliance** - the European CE marking regime, which signifies compliance with product safety laws, would be replaced in the UK with a new "UK Conformity Assessed" marking regime ('UKCA'). Information on the use of this marking can be found on the Gov.UK website.

  If Britain exits the EU without a deal, in most cases CE marking would still be used for products being placed on the UK market for a time-limited period. However, where a product requires a third-party assessment of conformity, and if that assessment is carried out by a UK notified body, the new UKCA mark should be applied.

A new "UK Conformity Assessed" marking

- **Powers of the Secretary of State** – in the event of a no-deal, the Secretary of State would take on the role of EU authorities for the regulation of product safety. This means that the Secretary of State would issue UK standards, guidelines and provide a UK database of product safety and market surveillance information to replace the current EU structures, such as reporting to Rapex.

  The current EU standards published in the Official Journal of the EU and the European Commission's guidelines would no longer be relevant on the day of Brexit. However, there is currently no indication of where and when UK standards will be published and therefore, in practice, it is likely that EU guidelines will continue to be followed until the UK guidance is produced.

2.4 New UK legislative framework and new UKCA mark

Box 2: The UK Conformity Assessed (UKCA) marking

This is the design for the UK marking for certain products to be sold in the UK, which would replace the CE marking in the event the UK leaves the EU without a deal.

In the event of the UK leaving the EU without a deal, preparations are taking place across government to ensure regulatory continuity. This involves the introduction of regulations under the New Legislative Framework including, for certain legislation, a new UK regulatory mark that will be affixed to products or their packaging. The purpose of this new UKCA mark will be to support the authorities and provide clarity to manufacturers placing products on the UK market post-Brexit – but only in the case that the UK leaves the EU without a deal. It is important to note that if a UKCA mark is required, it will be underpinned by the same British standards as current legislation.

A new UKCA mark

New designated standards

In addition, the concept of "harmonised standards" will be transferred into the UK legal order to become identical "designated standards". From exit day the Secretary of State will cite designated standards for the purposes of providing a presumption of conformity with the applicable regulation, in the same way as the European Commission cites European standards.

3. Want does this mean for UK businesses and consumers?

3.1 Overview

This section (and **Box 3** below) considers the possible implications of a no-deal Brexit on manufacturers who place products on both the UK and EU markets. It should be noted that the following technical guidance has been issued by the UK government:

- Placing of manufactured products on the UK market if there is a no-Brexit deal, 19 March 2019.
- Placing manufactured goods on the EU internal market if there's no Brexit deal, 9 March 2019.
- On 26 February 2019, the Government issued similar advice in respect of construction products and medical devices.

Box 3: Obligations on UK manufacturers

Current position

- Currently, the CE mark is required to be affixed on many products (including medical devices, toys, machinery and electrical equipment) placed on the market in the EU to indicate compliance with the relevant EU legislation on product safety.
- In many cases, products can be self-declared as compliant by the manufacturer, who can then affix the CE marking. For some products, however, the product needs to be assessed by a third-party conformity assessment body (a so-called "notified body") to ensure that the EU safety requirements are met.

In the event of a no-deal Brexit

- The government has published guidance on the **new "UKCA" product mark**, which mirrors the CE mark for certain products placed on the UK market in the event of a no-deal Brexit.
- To the extent possible, the UK government has sought to minimise the disruption caused by a no-deal Brexit by continuing to allow CE marked products to be placed on the market in the UK, albeit for an unspecified time-limited period.
- The most serious disruption will be caused to manufacturers/importers who have until now used UK notified bodies (or indeed UK-based authorised representatives). Because such bodies will no longer be recognised by the EU, conformity assessments carried out by them can no longer support the affixing of **a CE mark, which remains a pre-requisite for placing products on the market in the EU**.
- Affected manufacturers/importers will therefore need to make plans to switch to EU-recognised conformity assessment bodies if they wish to continue to market in the EU after a no deal Brexit.

3.2 Placing products on the UK market after a no-deal Brexit

Box 4: Placing products on the UK market in the event of a no-deal Brexit

"UKCA" (UK Conformity Assessed) marking is the new UK product marking that will be used for certain goods placed on the UK market, if the UK leaves the EU without a deal.

The UKCA marking is concerned with the UK market only. As such, the marking will not be recognised on the EU market and products for sale in the EU that currently need a CE marking will continue to need a CE marking.

Following a no-deal Brexit and for a **time-limited period**, the manufacturer/importer has a choice when placing goods on the UK market:

- continue to rely (for the time being at least) on the CE mark to place the products on the market in the UK, or
- apply the new UKCA mark.

During the time-limited period, to place CE marked goods on the UK market after the UK leaves the EU, the manufacturer/importer will need to ensure that these goods:

- meet the essential requirements as set out in the EU legislation;
- have undergone the relevant conformity assessment procedure (including by an EU recognised body, where required); and
- display the relevant EU conformity marking (such as the CE marking).

In addition, the manufacturer/importer must ensure that technical documentation and an EU declaration or attestation of conformity are available on request. This documentation must be presented to the relevant national authorities, such as a market surveillance authority, on request.

It is important to note that the manufacturer/importer will still be able to use CE marking based on self-declaration of conformity, when placing products on both the UK and EU markets.

Once this time-limited period ends, only UKCA marking will be recognised in respect of the UK market. A product bearing a CE mark would still be valid for sale in the UK so long as it was also UKCA marked and complies with the relevant UK rules.

Continued use of CE mark for a time - limited period

As outlined in **Box 4** above, the government has made provision for a new UKCA mark. Most, but not all, products to which a CE mark must currently be applied will fall within scope of the new UK product marking regime following a no deal Brexit. The rules around using the new UKCA mark will mirror those which currently apply for the application of the CE mark.

After the UK leaves the EU, manufacturers will still be able to place on the UK market goods which have been made and assessed against EU regulatory requirements and then CE marked. However, this is intended to be for a **time-limited period only**. The UK Government has said it

will consult with industry and provide notice before ending this time-limited period.

During this time-limited period, it will be possible in most cases to use only the CE mark for products being placed on the UK market. However, there is one exception. This is where the products in question require third party assessment of conformity, and that has been carried out by a UK conformity assessment body. In such circumstances, it will be necessary to apply the new UKCA mark as from exit day. This will not be the case however if the certificate of conformity has been transferred to an EU-recognised body before then (in which case the CE mark could still be applied, making the products acceptable for the UK market).

For products which currently only require self-declaration of conformity for the CE mark to be applied, it is possible to apply the new UKCA mark based on that self-declaration. In these cases, it would be possible to use either marking, or to use both CE and UKCA marking on the same product.

During this time-limited period, the new UKCA mark is intended to be complimentary to the CE mark and not replace it. It is envisaged that the UKCA mark could be used where the manufacturer is unable to apply a CE mark (for example, where the manufacturer has used a UK Approved Body rather than an EU notified body, and only wishes to place their products on the UK market).

After the time-limited period, only the UKCA mark will be recognised in respect of the UK market. A product bearing the CE mark would still be valid for sale in the UK so long as it was also UKCA marked and complies with the relevant UK rules.

3.3 Placing products on the EU market after a no-deal Brexit

Box 5: Placing products on the EU market in the event of a no-deal Brexit

- Products currently requiring CE marking will continue to require a CE mark if they are to be offered for sale in the EU. The UKCA mark will not be recognised on the EU market,
- Some goods made in the UK and exported to the EU may have to be stamped with two marks: a CE mark for EU markets and a UKCA mark for the UK. For some products that could also mean two sets of tests, as the EU may not recognise ones done by UK organisations.

There are other implications UK manufacturers/importers should consider, including:

- Manufacturers/importers who use a UK Approved Body may wish to contact that body to understand their post Brexit position and whether the new UKCA mark is more appropriate for their product.
- Manufacturers/importers who distribute through an EU supply chain should bear in mind that the "economic operator" status of that supply chain will change which may require changes to packaging.
- Manufacturers/importers of machinery who intend to place products on the EU market following a no-deal Brexit, should nominate a person who is responsible for compiling the Technical File who must be based in the EU.

The crucial point to note is that all CE marking rules will continue to apply until the UK has left the EU. CE marking is integral to the Single Market so, in the absence of any other arrangement, the UK will need to apply the rules if it wants to continue to trade with the EU, even if it adopts a new UKCA marking system in respect of internal trade. The new UKCA mark will not be recognised in the EU.

UK products placed on the EU market will still need to carry the CE mark.

The following points should also be noted:

- Products which only require self-declaration to affix the CE mark, can continue to be exported to, and placed on, the EU market. However, UK notified bodies will no longer be recognised in the EU after a no deal Brexit.
- This means that where the CE mark has been applied to products after a conformity assessment carried out by a UK notified body, these products will need to be re-assessed and marked by an EU-recognised notified body to be placed on the EU market.
- It follows from this that some manufacturers/importers may arrange for assessments to be transferred to an EU-recognised body before the UK leaves the EU.

3.4 Conclusion

In the event of a no-deal Brexit, the UK Government has sought to minimise the disruption caused by continuing to allow CE marked products to be placed on the UK market in the UK, albeit for an unspecified time-limited period.

Some commentators have suggested that the most serious disruption will be caused to manufacturers/importers who have until now used UK conformity assessment bodies (or UK-based authorized representatives). Because such bodies will no longer be recognised by the EU, conformity assessments carried out by them can no longer support the affixing of a CE mark, which remains a pre-requisite for placing products on the market in the EU. In effect, if these manufacturers/importers want to continue to place goods on the EU market after a no-deal Brexit, they will need to switch to an EU-recognised conformity assessment body.

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