

# What Brexit means for regulated product conformity assessment

## Summary

Assessing the conformity of products with specific legislation is the role of 'Notified Bodies'. This process builds confidence and enables market access. Brexit brings challenges to the role of UK-based Notified Bodies and this paper explores different options for those organizations.

BSI, as a UK Notified Body under 15 EU directives and regulations, has been working with its business

clients to understand their needs for regulated product conformity assessment. The clear view of business has been to support solutions that enable continuity, market access and regulatory clarity.

BSI endorses this view and proposes the UK government seeks to implement a solution where there can be an element of recognition of UK Notified Bodies post-Brexit.

## What is regulated product conformity assessment?

**Product conformity assessment is the process by which a manufacturer demonstrates that a product meets set performance, safety and environmental parameters.**

**It is **regulated** conformity assessment when those parameters are set in the law.**

Regulated product conformity assessment:

- Gives an assurance that products meet legal requirements
- Builds supply chain confidence
- Enables market access where that conformity assessment is recognized
- All the above facilitates international trade

The majority of European Union technical harmonization legislation<sup>1</sup> requires 'CE marking' and covers a broad range of household and workplace products including toys, machinery, electrical equipment and medical devices.

This legislation requires a manufacturer to undertake conformity assessment, often delivered by a third-party organization: a 'Notified Body'. Notified Bodies therefore play a critical role in the technical infrastructure, enabling compliant products to reach the market and preventing non-compliant products from endangering consumers and other end users. Notified Bodies are designated by Member State authorities; the UK has nearly 200 Notified Bodies across a broad range of legislation.

<sup>1</sup>This also applies in the rest of the European Economic Area

## What are the possible outcomes from Brexit for UK Notified Bodies?

Post-Brexit, there are **four options** for UK Notified Bodies. These have different impacts on UK industry and consumers/end users and are considered here:

- 1. WTO rules:** the UK falls back on WTO rules and UK Notified Bodies no longer have a role in regulated product conformity assessment across the EU/EEA. Products must be re-certified to enter the EU market from the UK, as with any other 'third' country.

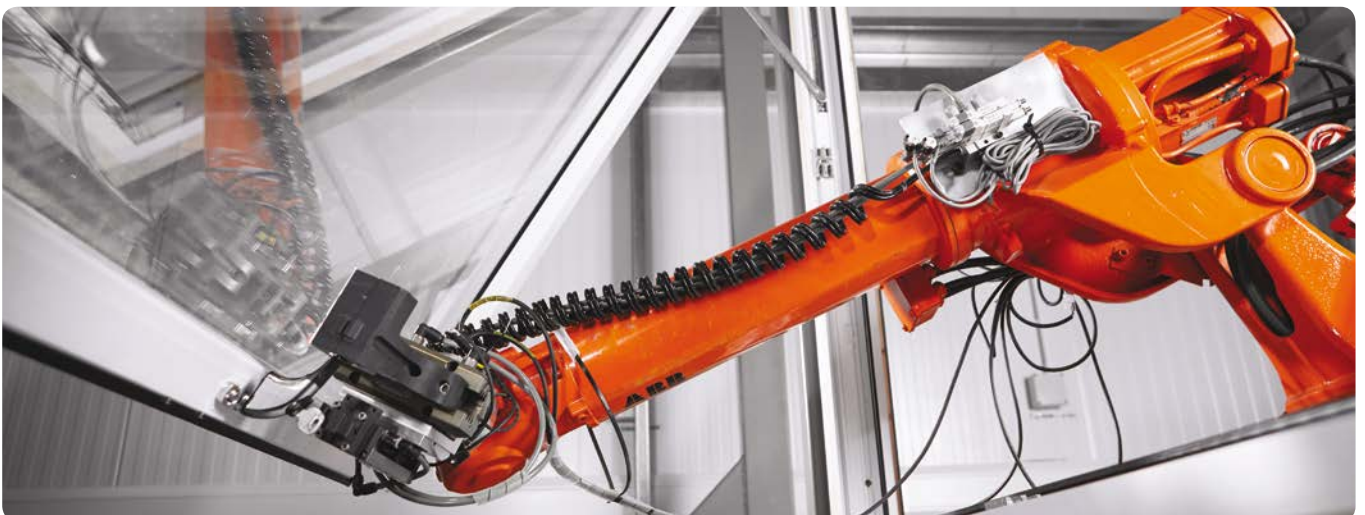
### Impacts of this option:

For UK industry: this would mean that UK industry would still bear the existing costs of compliance for export purposes to our major market in the EU, as well as the costs of creating and complying with the new UK infrastructure. Lack of recognition of certification between the EU Notified Bodies and UK organizations performing the same function would necessitate two product conformity certificates for each product. Delays in the implementation of new technologies in a smaller UK market with a differing regulatory regime could negatively impact the competitiveness of UK industry globally. This would lead to job losses in the regulatory and conformity assessment bodies and possible limitations to inward investment.

For UK consumers/end users: critically, this option would likely mean that the UK would have slower access to new life-saving or life-enhancing technologies: the costs

of developing these technologies in a smaller market as well as in the much larger neighbouring European market would be prohibitive in the early stages. Also, UK patients and consumers would not reap the large scale epidemiological benefits to risk management arising from the pooling of EU and UK data in areas such as life sciences.

For UK public policy: UK government will lose influence over the regulatory policy concerning product conformity assessment in the EU and UK companies will still need to meet EU-set requirements for trading into the EU Single Market. The UK government will be able to set national regulatory policy, although there will be pressure to maintain requirements to that of the EU to prevent placing additional burdens on UK manufacturers.



- 2. Full recognition:** UK Notified Bodies are still recognized in the EU/EEA and the UK plays a partial role in determining regulatory policy. This would be a similar option to that of the non-EU EEA members such as Norway or Iceland.

This business as usual situation would provide continued seamless integration into the Single Market.

However the Prime Minister appears to have ruled out this option; it is therefore not considered in more detail.

- 3. FTA with mutual recognition of regulated conformity assessment:** UK Notified Bodies would meet UK requirements, which in turn would be deemed sufficient to meet EU requirements.

#### Impacts of this option:

For UK industry: this would mean that UK industry would bear the costs of creating and complying with the new UK infrastructure. Once that is achieved, the results of national regulated conformity assessment would be sufficient to also place products on the market in the EU.

For UK consumers/end users: as with Option 1, critically, this option would could result in negative outcomes for UK consumers arising from the cessation of data sharing arrangements with the EU.

For UK public policy: UK government will lose influence over the regulatory policy concerning product conformity assessment in the EU. The UK government will be able to set national regulatory policy, although there will be pressure to mirror the requirements of the EU in order to maintain reciprocity of access and to prevent placing additional burdens on UK manufacturers.



- 4. FTA with recognition of regulated conformity assessment:** this is a 'hybrid' possibility of Options 2 and 3. In this option, in most areas mutual recognition of conformity assessment would apply, as in Option 3. For more complex products, where a Notified Body certificate is always required, UK Notified Bodies would be recognized as equivalent to EU Notified Bodies, as in Option 2: they would be able to apply the same standards (which are European and international standards<sup>2</sup>) and to issue certificates stating that products meet EU laws. It would be similar to arrangements with Canada, Australia and Turkey. The areas to be chosen would reflect the importance of the sectors and would need to be negotiated specifically.

#### Impacts of this option:

For UK industry: for less complex products, with lower safety risks, as with Option 3, this would mean that UK industry would bear the costs of creating and complying with the new UK infrastructure (which would need to be in line with the EU infrastructure in order to give reciprocity of access). UK Notified Bodies could continue to carry out regulated conformity assessment against EU laws for more complex products, where the UK government recognizes the importance of stricter controls and the need to ensure market access under the same conditions. In conversations with BSI, **UK industry has supported options of this type as it would be the closest option to continued seamless market access.**

For UK consumers/end users: unlike Options 1 and 3, in this case market access to the EU would enable data sharing in areas such as life sciences, leading to the benefits in risk management noted above for UK patients and consumers.

For UK public policy: UK government should have a limited degree of influence over regulatory policy in those areas where UK Notified Bodies continue to perform their functions, although that degree of influence would need to be negotiated as part of the UK-EU settlement. For all other sectors, the situation would be the same as Option 3.

<sup>2</sup> It is worth noting that BSI's ambition is to remain a full member of the European Standards Organizations post-Brexit, in which case UK experts would continue to influence the content of European standards.



## Summary of the options

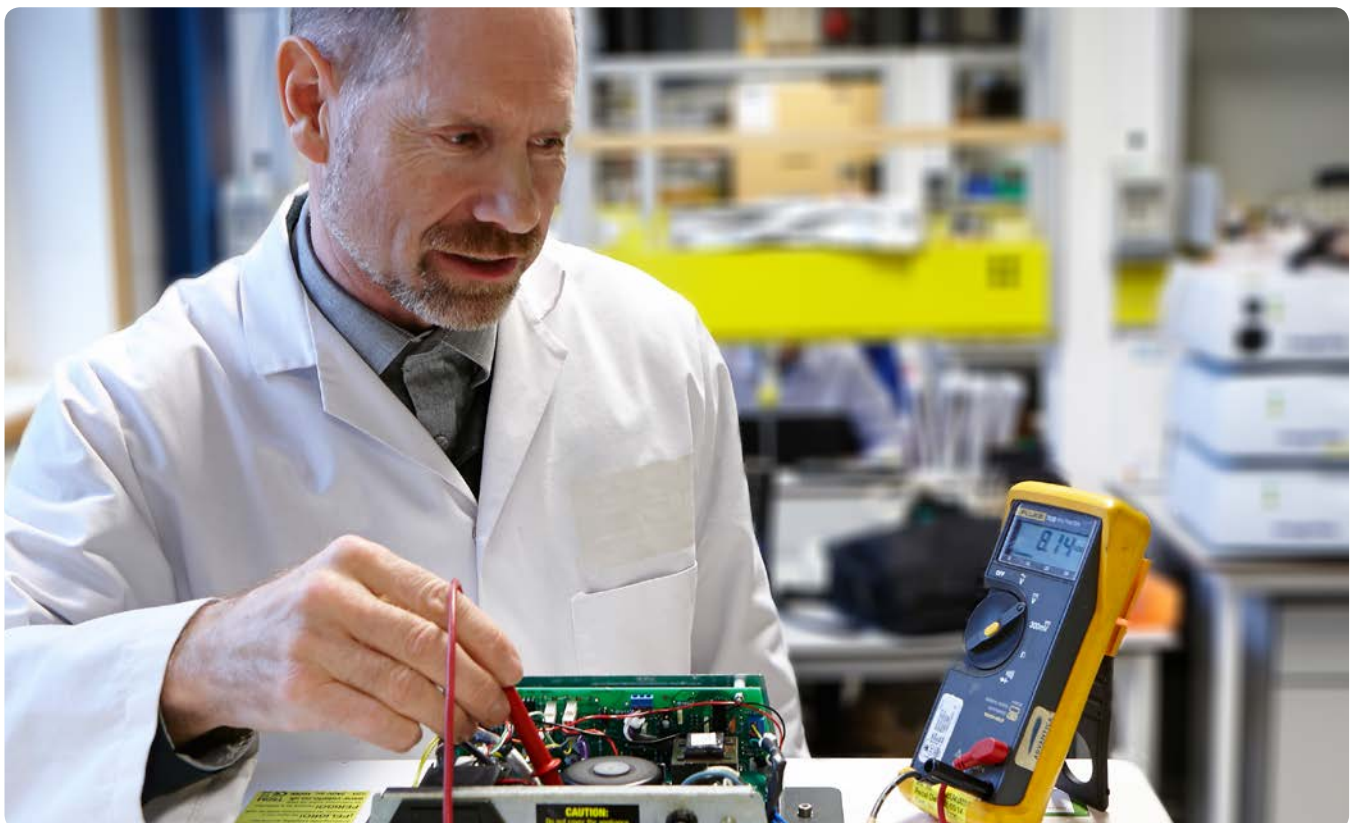
The UK Government appears to be leaning towards a free trade agreement with the EU; a UK-specific deal of a type not previously negotiated. Continued membership of the EU Single Market through, for example, EEA membership appears unlikely. The WTO rules option seems a last resort.

For UK product conformity bodies, which are currently Notified Bodies, this leaves two options. The first is a mutual recognition option, where the UK and EU systems run in parallel and each recognize the other's competence. This would bring market access, but significantly reduces our ability to influence the product conformity requirements and process and to include the UK perspective, as well as bringing possible negative impacts from the lack of pooling of data across Europe.

The second is a partial recognition option, where UK Notified Bodies could play a full role in enabling market

access in the UK and the EU, in certain sectors where the role of the Notified Body is critical. This would retain the attractiveness of the UK as the gateway to Europe in these sectors, preserving some elements of UK influence and maintaining benefits for UK consumers.

These final two options encompass the strong views of UK industry as shared with BSI: a wish to maintain the simplest possible access to markets in the UK as well as to post-Brexit EU.



## Background

### Regulated product conformity assessment in the EU

BS EN ISO/IEC 17000:2004 defines conformity assessment as the “demonstration that specified requirements relating to a product, process, system, person or body are fulfilled”. Conformity assessment of a certain type and performed by certain organizations can be required in law. This is the case in the European Union under the New Legislative Framework for

product harmonization, more commonly still known as the ‘New Approach’. This legislation, which usually also requires manufacturers to affix the ‘CE marking’ once the conformity assessment has been successfully completed, covers a broad range of household and workplace use products, as outlined in the box below.

#### EU ‘New Approach’/CE marking legislation includes:

- Machinery
- Gas appliances
- Toys
- Pressure equipment
- Medical devices
- Pyrotechnics
- Electrical equipment
- Construction products
- Radio equipment
- Personal protective equipment
- Cableways
- Equipment for explosive atmospheres
- Measuring instruments
- Non-automatic weighing instruments
- Electromagnetic compatibility
- Recreational craft

Under the New Approach the manufacturer is responsible for conformity assessment that must be carried out according to certain modules specified in the relevant legislation. This conformity assessment may involve a simple self-declaration of conformity, or it may require the intervention of a third-party conformity assessment body, known as a ‘Notified Body’.

Notified Bodies are designated by Member States’ competent authorities and are included in a European Commission database (‘Nando’).

Regulated conformity assessment within the Single Market brings a level of control to the compliance of products. Notified Bodies have to meet a level of

competence that is regulated by the Member States, usually through accreditation.

#### Notified Bodies outside the EU

There are mutual recognition agreements with the EU that permit conformity assessment bodies from other territories to act as Notified Bodies. The EEA permits conformity assessment bodies from signatories who are not EU Member States (e.g. Norway, Iceland) to be Notified Bodies, as does the Customs Union with Turkey. Specific mutual recognition agreements permit a limited number (in total, under 50 organizations) of conformity assessment bodies in Japan, Australia, Switzerland and the US also to act as Notified Bodies, for specified legislation.



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