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Potential stormy CEs ahead for product compliance

If the UK departs the EU on 29 March 2019 without an agreement in place, manufacturers and importers of industrial and consumer goods selling into the UK and/or EU will face a range of compliance and market access challenges. With fewer than five weeks remaining, 'no-deal' contingency plans should be implemented.

Although dependent on product type and route to market, points to consider in a no-deal Brexit scenario could include:

- products placed on the UK market post-Brexit may need to meet new UK-centric standards and marking obligations;
- products manufactured in, or imported into the UK, for onward supply into the EU will be deemed to be 'imported' into the EU – placing additional risks and obligations on the EU distributors (as 'importer');
- certain higher risk products authorised by a UK notified body will need a new EU 'notified body approval' for continued supply into the EU (a potentially lengthy and/or expensive process);
- businesses with UK-based 'authorised representatives' for EU product compliance will need to substitute to EU-based entities;
- additional complications likely to arise under more specific product and chemical regimes (e.g. transferring UK REACH substance registrations for chemicals).

FUTURE USE OF THE CE MARK

Since 1993 UK consumers and industrial product users have become accustomed to seeing CE marking on their goods as an indication that the product in question meets requisite EU safety and compliance standards. In response to the threat of a 'no-deal', the UK Government published guidance on 2 February 2019 informing manufacturers of plans to replace (at an unspecified future date) the CE marking with the new UK Conformity Assessed (UKCA) marking. This proposal remains subject to parliamentary approval.

Although there is still significant uncertainty as to how the UKCA marking will work in practice, and indeed whether it will be necessary at all (although see divergence below for why it is likely to be required), products not placed on the UK market before 29 March 2019 may need at a future point to be re-certified, re-labelled and/or modified in order to comply with new reciprocal UK regulations. As it stands, advice from the UK Government is to, in the short-term following a 'no-deal' Brexit, continue to manufacture and label products in accordance with existing EU derived CE marking rules.



It is important to emphasise that there is currently no reciprocity in this potential future arrangement: the UKCA marking will not be recognised on the EU market and, therefore, all products currently requiring a CE marking will continue to require it for sale into the EU.

A British Standards Institute official stated that the UKCA marking "*provides flexibility for government should there be a divergence of regulations to insist that manufacturers were committing to that UK regulatory practice in future.*" Flexibility is key to manufacturers, yet it may simultaneously cause complications when selling cross-market between the UK and the EU Customs Union, even if a no-deal scenario is avoided.

ECONOMIC OPERATORS, AUTHORISED REPRESENTATIVES AND RESPONSIBLE PERSONS

From an EU product legislation perspective, the UK's exit would leave UK-based importers and manufacturers as third-party economic operators and similarly their EU distributors and/or customers, who previously relied on UK entities in the supply chain, will become importers to the EU market for compliance purposes. As a result of this change, these new 'importers' will be subject to more rigorous product compliance obligations. An importer is required to undertake more diligent checks to ensure that products fulfil all EU safety, health and environmental protection requirements unlike the less onerous conditions placed on distributors and suppliers.

Businesses can appoint nominated persons (commonly known as 'authorised representatives'), based in the EU, to carry out certain tasks on their behalf. The tasks a nominated person can carry out are defined in different pieces of EU product legislation. It is mandatory for some products (such as medical devices, marine equipment and cosmetics). UK-based nominated person will no longer be recognised by the EU if there is 'no deal'. Businesses with an authorised representative based in the UK or those who have UK entities as the labelled importer of record will need to establish or find a new EU representative.

NOTIFIED BODIES

The EU has made it clear that in the event of the UK leaving without an agreement in place, product conformity assessments carried out by UK assessment bodies will no longer be recognised. This means that in a 'no-deal' scenario after 31 March products destined for the EU will need to be assessed by an EU

TRIVERS SMITH

recognised conformity assessment body. Products assessed by UK bodies, but not yet 'placed on the market' prior to the UK's departure, will need to have their assessments transferred to an EU recognised body.

PRODUCT SPECIFIC CHALLENGES

There are a number of more detailed EU industrial and consumer product and chemical regimes, such as those relating to electronic and electrical equipment, batteries, medical devices, toys, construction materials, chemicals, etc. Each regime will require careful analysis with regard to potential market access and labelling issues in the event of a 'no-deal' Brexit.

For example, companies with UK registrations under the chemicals regime, REACH, would no longer be able to sell into the EEA market without transferring the registrations to an EEA-based organisation. The chemicals industry has already seen the transfer of a significant number of registrations to EEA-based organisations, with more expected in the coming month. This may have wider impacts to those in the supply chain who either manufacture or import chemicals or are reliant on them for their manufacturing or industrial processes.

DIVERGENCE

Regardless of where we end up, product standards and compliance will remain critical issues between the UK and EU over the coming years. The EU fears that the UK could become a back door into the customs union for products which do not meet its standards. With regulatory divergence at some stage a real possibility, the days of a single symbol representing product conformity look to be numbered, as even if a deal and transitional period are agreed it is difficult to imagine the CE marking regime could be maintained on both sides of the Channel when competing trade interests will surely emerge. That said, UK businesses exporting to the EU are likely to lobby the UK Government to avoid, or at least minimise, this divergence to reduce additional compliance cost. Indeed, where faced with two regimes with differing standards, experience shows us that manufacturers frequently choose the higher standard, in a so-called "race to the top".

In addition to direct regulatory enforcement risks (which in the short term at least may be unlikely to materialise), contractual liabilities should be considered. Technical breaches of law may enable parties to look to re-negotiate or terminate supply contracts, for example.

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