

## UK releases new technical guidance for manufacturers

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The United Kingdom (UK) will leave the European Union's (EU) Single Market and Customs Union on 31 December 2020, marking the end of the transition period. The UK will begin a new economic relationship with the EU - either with a trade deal (Free Trade Agreement or FTA) or by reverting to World Trade Organization terms. Leaving the EU's Single Market and Customs Union entails a number of changes that businesses need to navigate, including to the conditions under which products may be made available in each territory (referred to as being "placed on the market").

On 1 September 2020, the UK Government released four new technical guidance documents for UK businesses who trade certain products between the UK and EU or use regulated chemicals in their manufacturing processes or products.

The four technical guidance documents are:

- ▶ [Placing manufactured goods on the EU market from 1 January 2021](#)
- ▶ [Acting as a Responsible Person \(import\) from 1 January 2021](#)
- ▶ [Using the UKCA mark from 1 January 2021](#)
- ▶ [How to comply with REACH chemical regulations](#)

Specific technical guidance for life sciences and medical businesses was also released on 1 September and can be found [here](#).

There are a number of issues that will impact UK to EU trade from 1 January 2021, and over the longer term for EU to UK trade flows. One of the biggest shifts will be for those manufacturers whose products currently use the CE mark.<sup>1</sup>

## **CE and conformity assessment – products traded from the UK to the EU**

The main changes businesses need to consider are:

- From 1 January 2021, there will be restrictions as to which notified bodies may carry out conformity assessments for UK-manufactured products being traded into the EU. In the event of no FTA between the UK and EU, only EU-recognized conformity assessment bodies may carry out such assessments.

Several UK-based notified bodies have taken steps to become recognized by the EU, but not all have. Manufacturers holding their conformity assessment certificates with a non-EU recognized body will either need to get their products re-assessed, in the event of no deal between the UK and EU, by an EU-recognized body or transfer the existing certificates to an EU-recognized body.

- Companies trading into the EU and with authorized representatives or responsible persons based in Great Britain will need to appoint one based in the EU, the European Economic Area (EEA) or Northern Ireland to satisfy the relevant EU regulations.
- For products being traded from the UK to the EU via an EU-based distributor, the EU-based distributor will become the “importer.” The EU-based distributor will need to comply with a variety of additional regulatory obligations including ensuring that the correct conformity assessment procedures have been followed (which includes being named on product labels and packaging as well as the requirement to maintain a copy of the declaration of conformity for 10 years).

## **CE and conformity assessment – products traded from the EU to the UK**

For products being traded from the EU to the UK, the CE mark will continue to be accepted as valid until 31 December 2021, with the exception of Northern Ireland which will continue to accept the CE mark or UK(NI) mark as per the Northern Ireland Protocol (see separate guidance [placing goods on the Northern Ireland market](#)).

Companies are encouraged by the UK Government to adopt the new UK Conformity Assessed mark (or UKCA) to replace the EU’s CE mark from 1 January 2021 but most companies, unless in restricted circumstances, will have until 1 January 2022 before they must do so. Any businesses which do choose to adopt the UKCA during 2021 should be aware that doing so will also require them to obtain separate conformity assessment certificates from both UK-recognized and EU-recognized bodies if selling both in the UK and EU.

Most products which currently require a CE mark to be directly applied to the product will be allowed to satisfy UKCA marking requirements by including details on a label fixed to the product or in accompanying documentation, rather than directly on the product, until 1 January 2023.

The new UKCA will apply to the vast majority of products that currently use the CE mark, with the addition of aerosol products. Additional rules will apply to medical devices, rail interoperability, construction products and civil explosives. Hose products currently use the CE mark.

## **Chemicals and Brexit**

The UK’s new chemical regulatory framework will start on 1 January 2021 and will be known as UK REACH, to replace the EU’s REACH framework. The implementation of the new framework will be phased in with the UK Government announcing that it will be extending the deadline for companies to submit the necessary data under the UK REACH transitional arrangements.

UK holders of EU REACH registrations must complete the grandfathering process over to the new UK REACH by providing data to the UK Health and Safety Executive (HSE) within two, four or six years of 28 October 2021, depending on their [Tonnage Band Deadlines](#). Downstream users in the UK who have traditionally relied on an EU/EEA-based company which holds an EU REACH registration granted prior to 1 January 2020 will need to take action by 27 October 2021 to notify the HSE if they wish to continue importing that substance and ensure that the necessary registrations are made for UK REACH purposes.

Companies wishing to import chemicals which have been granted EU REACH registrations after 1 January 2020 must be submitted to UK REACH as well.

## Next steps

Businesses should work with their local tax professional(s) to:

- ▶ Evaluate sector and product/service specific regulatory changes associated with new and altered compliance regimes
- ▶ Quantify the associated impact, including safety harmonization and conformity checks, labelling, professional qualifications, importer/distributor obligations, notified bodies, and authorized representatives
- ▶ Optimize supply chains
- ▶ Transform business models post-Brexit
- ▶ Identify alternative locations in which to perform activities

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## Endnote

1. The CE mark is placed on a product to demonstrate that it conforms with all of the relevant EU legal requirements.

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