



Department for
Business, Energy
& Industrial Strategy

Preparing your Business for EU Exit

September 2019



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Regulation of New Approach goods in a no deal scenario

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If you make, sell or trade manufactured goods



In a no deal scenario the UK would fall outside of the EU regulatory frameworks. You will need to take action to continue selling many manufactured goods in the EU, and may need to act to continue selling in the UK too.

1 Check which regulations apply to your product



To determine what steps you or others in your supply chain need to take, identify what EU regulations are relevant to you. Think about inputs as well as end products, for example chemicals.

2 Check if you need a new product approval or to transfer/convert an existing one



If your product requires third-party approval, you may need a new one or to transfer the one you have. The EU will stop recognising UK approvals. The UK will recognise EU approvals immediately after exit but action may still be needed.

If you make, sell or trade manufactured goods

- 3 Check if you need a nominated person or other representative to act on your behalf
 -  UK businesses, facilities and nominated persons (i.e. authorised reps, qualified persons) will no longer count as established in the EU, and vice-versa. You may need to appoint someone to undertake certain tasks in the EU or UK.

- 4 Speak to your supply chains / distributors and understand new legal duties
 -  Make sure your suppliers understand the actions they need to take. If you distribute EU goods, or have your goods distributed by someone in the EU, you may acquire new legal duties. You may face new UK reporting requirements.

If you make, sell or trade manufactured goods

- 5 Consider what marking / labelling changes apply to your product



You may need to make changes to the information or regulatory markings that appear on your product, for example to reflect changes to product approvals or new representatives you appoint in the EU.

- 6 More details on [regulatory requirements for UK](#) and [EU markets](#) on gov.uk

How does the 'New Approach' work now?



High-level requirements in legislation and use of harmonised standards to achieve compliance



Conformity with requirements of 'New Approach' legislation shown by use of the CE marking



In most cases manufacturers take sole legal responsibility for compliance and can self-declare



In other cases manufacturers need to use a third party assessment body (a 'Notified Body')

Selling goods into the UK



New approach goods meeting EU regulations and CE marked can still be sold in UK for time-limited period.



UK will directly recognise conformity assessment carried out by EU notified bodies.



A new UK database will replace the EU's NANDO database.



Products assessed against UK rules by a UK 'Approved Body' will need the UKCA marking.



We will consult with businesses before making any changes to these arrangements.

Selling into the EU



Conformity assessments by UK notified bodies will no longer be recognised in the EU



Goods assessed by a UK body cannot be sold in the EU without reassessment by an EU body*



As an alternative, manufacturers can transfer their files to an EU-recognised body pre-exit



CE marking needs to be used for goods sold into the EU. Self-declaration unaffected

* This applies to **mandatory** third part assessment. Voluntary testing against European or international standards is not impacted.

Transfer of files to EU notified bodies



EU Commission suggest files and certificates can be transferred to an EU notified body



Transfer must take place by exit day



Goods would need to bear the new four-digit notified body number



Declaration of Conformity and Notified Body certificate will need details of both bodies

Declarations of conformity



For new approach goods an EU declaration of conformity should be drawn up and available



For UKCA marked products - a UK declaration of conformity will be needed



For CE marked products an EU declaration will still be needed - even for UK market



DoCs may need updating with new Notified Body and/or authorised representative/importer details

Authorised Representatives



Businesses can appoint Authorised Representatives to carry out tasks on their behalf -



UK-based Authorised Representatives will no longer be recognised in EU in the event of no deal.



Existing Authorised Representatives in an EU country will continue to be recognised in the UK.



New Authorised Representatives will need to be based in the UK to be recognised under UK law.

Importing and Distributing



An EU-based distributor of UK goods may become an ‘importer’ - and vice-versa



Compared to a distributor, importers have a stronger duty to ensure products are compliant



The importer’s address also often has to be put on the product or its packaging



18 month transitional period during which UK importers can put information identifying them on an accompanying document.

Definition of products placed on the market



Placing on the market refers to each individual product, not a type of products.



Placing refers to the first supply of a good for distribution, consumption or use after the manufacturing stage is completed



European Commission: placing does not require the physical delivery of a product



Proof can be a contract of sale, invoice, distribution or shipping documents.

Checklist of actions for new approach goods

- Check whether you need to change your conformity assessment body and/or the conformity marking on your goods
- Check whether you need to appoint a new Authorised Representative or equivalent in the EU
- Determine if you or your EU-based distributor will become an importer and understand your new legal duties
- Update your product's labelling and declaration of conformity based on the above actions

Any questions?

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Further information

- Please visit [gov.uk/brexit](https://www.gov.uk/brexit) for the latest information.
- If you are unsure what guidance is relevant to you or if you have general queries relating to the regulation of manufactured goods, email: goodsregulation@beis.gov.uk

BEIS Product Safety Regulation Survey

- BEIS is running a survey on how businesses demonstrate that the products meet EU product safety requirements.
- The survey asks about the costs of compliance as well the process.
- It will help us assess how businesses might be affected by any changes in the regulatory compliance process necessary to export products to the EU after the UK leaves the Single Market for Goods.
- It will also be used to inform internal and cross government policy decisions.
- It takes around 15 minutes to complete and is available at: <https://www.smartsurvey.co.uk/s/BEISPRODUCTSAFETY/>