HM Government

BREXIT 31 OCTOBER

Manufactured goods regulation

Preparing for a no deal Brexit

Summary

- Overview of key considerations for UK businesses
- Regulation of ‘New Approach’ goods in no deal scenario
- Regulation of ‘Old Approach’ goods in no deal scenario
- Key contacts
- Further resources

Key considerations if you make, sell or trade manufactured goods (1)

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 Brexit but action may still be needed.

Key considerations if you make, sell or trade manufactured goods (2)

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.

Key considerations if you make, sell or trade manufactured goods (3)

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

Check which regulations apply to your product

‘Old Approach’: goods such as cars, medicines, chemicals and aerospace, with standalone models of regulation

‘New Approach’: a common toolkit of regulatory measures covering goods such as toys and machinery

‘Non-harmonised goods’: subject to national rather than EU-wide product rules

Examples: toys, electronics, machinery, pressure equipment, personal protective equipment, construction products, medical devices, domestic appliances, lifts, pyrotechnic articles, recreational craft

Regulation of ‘New Approach’ goods

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’).

CE marking and UKCA marking for the UK market

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 system of Approved Bodies and a UK database will replace Notified Bodies and the EU 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.

CE marking for the EU market

- 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. This applies to mandatory 3rd party assessment only. Voluntary testing is not impacted.
- As an alternative, manufacturers can transfer their files to an EU-recognised body pre-Brexit as long as this is before exit day
- However, most manufacturers of CE marked goods self-declare conformity. This will not be affected.

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 – not mirrored by the EU.

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.

Products already on EU27 market by exit day will not be impacted

Placing on the market refers to each **individual** product, not a type of products / product line

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.

Regulation of ‘Old Approach’ goods

How does the ‘Old Approach’ work now?

- Product sectors include aerospace, automotive, chemicals and pharmaceuticals.
- Sector specific regulatory frameworks, with detailed requirements set out in legislation
- National authorities usually oversee performance and granting of approvals.
- Please visit **gov.uk/euexit** for the latest information.

Arrangements for ‘Old Approach’ goods in a no deal scenario

	The UK will have its own REACH regime post Brexit for **chemicals** manufactured in or exported to the UK.
	EC type-approvals no longer automatically accepted for **motor vehicles** on the UK market – the UK Vehicle Certification Agency (VCA) will issue provisional UK type approvals.
	**Medicines** with a 'centralised' authorisation will be given a UK authorisation.
	In various areas (**cosmetics, chemicals, medicines**) - companies may need to appoint new UK representatives.
	Exact arrangements will depend on specific goods – lots of guidance available on GOV.UK.

Automotive: Checklist of actions for selling into the EU

- ☐ To continue placing products on the EU market, existing VCA-issued EC type-approvals need to be transferred to an EU-based type-approval authority. The application to do this needs to be **started** prior to Brexit.
- ☐ UK manufacturers based outside EU must appoint a representative established in the EU to represent them before EU type-approval authorities.
- ☐ New products to be placed on the EU market will require EC type-approval, with full testing and certification conducted by an EU-based type-approval authority and designated technical service.

Automotive: Checklist of actions for selling into the UK

- ☐ Motor vehicles to be placed on the UK market will need to convert their existing EC type-approvals to UK type-approval by applying to VCA for a provisional UK type-approval, valid for two years.
- ☐ New vehicle approvals will require VCA-issued UK type-approval after Brexit day (subject to new legislation).
- ☐ For manufacturers with valid EC type-approval post-Brexit: duplicate testing is not required, but manufacturers will need to supply documentary evidence to prove compliance.
- ☐ Read the detailed guidance on gov.uk.

Chemicals: checklist of actions to maintain UK market access

UK REACH:

- ☐ Those with ‘grandfathered’ UK held EU REACH registrations would need to open an account on the new UK REACH IT system and provide some basic information in the first 120 days after Exit.
- ☐ If their EU/EEA supplier does not appoint a UK Only Representative, UK downstream users will need to notify their continued use of substances covered by an EU held registration within 180 days.
- ☐ Both of these groups are then able within 2 years to provide the full technical information appropriate to the tonnage band to ensure continued use after that time.

PIC:

- ☐ Exporters will need to provide prior notifications to HSE for hazardous chemicals, and receive explicit consent from HSE.

Chemicals: UK exports to the EU will need to fulfil third country regulatory requirements

EU REACH:

UK-based companies need to transfer their registration to an EEA-based organisation to retain market access.

Alternatively, UK companies can appoint an EU-based 'Only Representative' (OR).

PIC:

UK-based companies will no longer have access to the ePIC notification system.

UK-based companies will need to pre-notify for listed chemicals, and receive explicit consent.

Where to find more information

Available guidance

- Placing manufactured goods on the UK market

- Placing manufactured goods on the EU market after Brexit

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

Other contacts

Sector	Contact(s)
New Approach goods	Goodsregulation@beis.gov.uk
Chemicals	General Brexit enquires: EU-exitchemicals@hse.gov.uk Biocides: biocidesenquiries@hse.gov.uk CLP: ukreachca@hse.gov.uk PIC: ukdna@hse.gov.uk
Automotive	VCA: UKTA@vca.gov.uk DfT: IVS.ENQUIRIES@dft.gov.uk
Medical devices	devices.regulatory@mhra.gov.uk

Additional information beyond this presentation

- There may be other issues not addressed in this material
- In some areas, policy content is still being developed
- Please visit **gov.uk/brexit** for the latest information