

Appointing nominated persons to your business if there's no Brexit deal

Summary

How appointing a nominated person to carry out duties on your behalf when selling certain goods would be affected if the UK leaves the EU with no deal.

Detail

If the UK leaves the EU in March 2019 without a deal, find out how this would affect your business using a 'nominated person' to carry out certain tasks on your behalf.

A scenario in which the UK leaves the EU without agreement (a 'no deal' scenario) remains unlikely given the mutual interests of the UK and the EU in securing a negotiated outcome.

Negotiations are progressing well and both we and the EU continue to work hard to seek a positive deal. However, it's our duty as a responsible government to prepare for all eventualities, including 'no deal', until we can be certain of the outcome of those negotiations.

For two years, the government has been implementing a significant programme of work to ensure the UK will be ready from day 1 in all scenarios, including a potential 'no deal' outcome in March 2019.

It has always been the case that as we get nearer to March 2019, preparations for a 'no deal' scenario would have to be accelerated. Such an acceleration does not reflect an increased likelihood of a 'no deal' outcome. Rather it is about ensuring our plans are in place in the unlikely scenario that they need to be relied upon.

This series of technical notices sets out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario, so they can make informed plans and preparations.

This guidance is part of that series.

Also included is an [overarching framing notice] (<https://www.gov.uk/government/publications/uk-governments-preparations-for-a-no-deal-scenario/>) explaining the government's overarching approach to preparing the UK for this outcome in order to minimise disruption and ensure a smooth and orderly exit in all scenarios.

We are working with the devolved administrations on technical notices and we will continue to do so as plans develop.

Purpose

The purpose of this notice is to explain future arrangements for nominated persons ('authorised representatives' and 'responsible persons') in relation to manufactured goods. These arrangements will apply in the unlikely event that the UK exits the EU without a deal in March 2019.

This notice does not cover the following areas:

- The role of Qualified Persons and Qualified Persons Responsible for Pharmacovigilance (QPs and QPPVs) for pharmaceuticals. Guidance available here: [Batch testing medicines if there's no Brexit deal] (<https://www.gov.uk/government/publications/batch-testing-medicines-if-there-s-no-brex-it-deal>) and [Medicines, Medical Devices and Clinical Trials] (<https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-there-s-no-brex-it-deal>)
- The role of the Only Representative for chemicals
- Authorised Representatives for medical devices

For the purposes of this notice, references to EU countries should be read as references to EEA states (Iceland, Liechtenstein and Norway).

Before 29 March 2019

Businesses can appoint nominated persons 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. Individuals who can carry out the role of nominated person may also be known as authorised representatives and responsible persons.

For example, an authorised representative must hold technical documentation about a product and provide this to market surveillance authorities in EU countries upon request. In some cases, they may affix a marking, such as the CE marking, to a product to indicate that the product meets the relevant requirements set out in legislation [[link to notice on conformity assessment \(harmonised\)](#)].

Generally, the appointment of an authorised representative is optional. It is mandatory in the following circumstances:

- For some products (such as medical devices and marine equipment) where the manufacturer is not based in an EU country; and
- For cosmetics: a responsible person carries out specific duties, including ensuring that the product is safe for human health. Where a business is based

in an EU country and placing cosmetics on the EU market, the responsible person is usually the manufacturer itself.

After March 2019 if there's no deal

Any UK-based nominated person will no longer be recognised under EU law(<https://ec.europa.eu/docsroom/documents/27241/attachments/1/translations/en/renditions/native>). This means they will not be recognised as able to carry out tasks on the manufacturer's behalf.

To minimise disruption immediately after exit, existing authorised representatives based in an EU country will continue to be recognised in the UK for a time-limited period. However, new authorised representatives will need to be based in the UK to be recognised under UK law. Examples of EU production regulations that include the role of authorised representatives can be found at Annex A of the [technical notice on 'New Approach' product regulation] (INSERT LINK)

For cosmetics, responsible persons based in an EU country will no longer be recognised by the UK after March 2019 ([Regulation (EC) N° 1223/2009] (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20160812&from=EN>) is the main EU legislation covering cosmetics and covers the role of the responsible person). Businesses wishing to place cosmetics on the UK market will need to appoint a UK-based responsible person. This is due to specific legal duties assigned to the responsible person and their importance on ensuring the safety of products placed on the market.

Implications

The implications outlined below relate to UK, EU and third country businesses in the event of the UK leaving the EU in a 'no deal' scenario.

This notice does not apply to medical devices. [A separate notice has been published for medical devices] (<https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexite-deal>), although some details are subject to forthcoming consultation.

Businesses with an existing authorised representative based in an EU country will not be impacted in the short term and can continue to place products on the EU and UK markets in the same way.

Businesses with an authorised representative based in the UK will no longer be able to rely on that representative to carry out all the required tasks for products placed on the EU market.

Businesses wishing to appoint a new authorised representative to carry out tasks on their behalf in the UK should be aware that the authorised representative must be located in the UK but will be unable to carry out tasks relating to products being placed on the EU market.

Businesses placing cosmetic products on the EU market will not be able to use a responsible person located in the UK to place a product on the EU market.

Businesses placing cosmetic products on the UK market will not be able to use a responsible person located in an EU country to place a product on the UK market.

Actions for businesses and other stakeholders

The actions outlined below relate to UK, EU and third country businesses in the event of the UK leaving the EU in a 'no deal' scenario. These businesses may want to discuss their requirements and necessary actions with their counterparts in the country they wish to establish representation.

Businesses with an authorised representative based in the UK will need to establish a new authorised representative in an EU country if they want an authorised representative to carry out tasks on their behalf within the EU.

Businesses wishing to appoint a new authorised representative to carry out tasks on their behalf in the UK will need to appoint a representative located in the UK.

Businesses placing cosmetic products on the EU market will need to appoint a responsible person located in an EU country.

Businesses placing cosmetic products on the UK market will need to appoint a responsible person located in the UK.

More information

This notice is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations.

It is part of the government's ongoing programme of planning for all possible outcomes. We expect to negotiate a successful deal with the EU.

The UK government is clear that in this scenario we must respect our unique relationship with Ireland, with whom we share a land border and who are co-signatories of the Belfast Agreement. The UK government has consistently placed upholding the Agreement and its successors at the heart of our approach. It enshrines the consent principle on which Northern Ireland's constitutional status rests. We recognise the basis it has provided for the deep economic and social cooperation on the island of Ireland. This includes North-South cooperation between Northern Ireland and Ireland, which we're committed to protecting in line with the letter and spirit of Strand two of the Agreement.

The Irish government have indicated they would need to discuss arrangements in the event of no deal with the European Commission and EU countries. The UK would stand ready in this scenario to engage constructively to meet our commitments and act in the best interests of the people of Northern Ireland, recognising the very significant challenges that the lack of a UK-EU legal agreement would pose in this unique and highly sensitive context.

It remains, though, the responsibility of the UK government, as the sovereign government in Northern Ireland, to continue preparations for the full range of potential outcomes, including no deal. As we do, and as decisions are made, we'll take full account of the unique circumstances of Northern Ireland.