

## **Regulating biocidal products if there's no Brexit deal**

### **Summary**

How biocidal products like industrial disinfectants and wood preservatives would be regulated if the UK leaves the EU in March 2019 with no deal.

### **Detail**

If the UK leaves the EU in March 2019 with no deal, find out how this would affect the regulation of products that control harmful or unwanted organisms through chemical or biological means, including industrial disinfectants and wood preservatives.

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 outline the arrangements that would come into force to regulate chemicals in the unlikely event the UK leaves the EU on 29 March 2019 with no agreement in place, with respect to the Biocidal Products Regulation (EU) No 528/2012 (BPR).

## **Before 29 March 2019**

Biocidal products control harmful or unwanted organisms through chemical or biological means. The BPR regulates the EU biocides market.

BPR puts in place a two-stage process for authorising biocidal products. First, active substances (the active ingredients in biocidal products) are approved at an EU level. The evaluation work for active substances is shared amongst EU countries.

Once an active substance is approved for a specific product type, companies may apply for biocidal products of that product type, and containing that substance, to be authorised in individual EU countries.

Businesses wishing to place biocidal products on the market in more than one EU country have two options. They can either apply for EU-wide 'Union' authorisation, or authorisation in a 'lead' EU country followed by authorisation in other EU countries by a 'mutual recognition' process.

The Health & Safety Executive (HSE) authorises biocidal products for the UK market on behalf of the Secretary of State and the devolved administrations.

The process is facilitated by a central IT system, known as the 'Register for Biocidal Products' (R4BP3) that is run by the European Chemicals Agency (ECHA).

## **After March 2019 if there's no deal**

The UK would establish an independent standalone biocidal products regime.

The UK would put in place a stable regulatory framework for biocidal products from the point of exit, by retaining the BPR and its subsidiary regulations in national law using the provisions of the EU Withdrawal Act. At the time of exit, the national regime would be essentially the same as the current EU framework, with changes made

only where they are required to enable the regime to operate effectively in a national context.

This would ensure continued levels of protection for human health and the environment and give certainty to UK businesses putting biocidal products on the market.

## **Implications**

HSE would continue to act as the competent authority for the UK on behalf of the Secretary of State and the devolved administrations, building on its existing capacity and capability.

Companies wishing to apply for an active substance to be approved or for a biocidal product to be authorised in the UK would apply to HSE, instead of ECHA. Active substance approvals and biocidal product authorisations would be UK-specific. Companies wishing to apply for active substance approvals or product authorisations in the EU-27 would continue to apply to ECHA.

HSE would take on the functions that ECHA currently performs, where these are still relevant in the UK. For example, HSE would co-ordinate the UK-specific active substance evaluation process, in liaison with the various administrations of the UK, and would undertake technical equivalence assessments (determining whether a new source of an active substance, or material produced by a different manufacturing process, is sufficiently similar to one that has already been evaluated, so that the evaluation conclusions remain valid).

HSE would introduce its own processes and systems for receiving and processing applications. Companies would use these instead of ECHA's systems. In the longer term HSE would build an IT system for handling applications, with interim arrangements for receiving and processing applications put in place from exit day while it is developed.

HSE would store the information and data required to support biocidal product authorisations and active substance approvals, replacing ECHA's databases. To enable HSE to operate the biocides authorisation regime on a UK-only basis, companies may need to submit supporting data or other information to HSE that had previously been submitted to ECHA. This would be the same information as was previously submitted and HSE would not impose additional charges.

If you hold a biocidal product authorisation that is valid in the UK on exit day, it would remain valid in the UK after exit day until its normal expiry date. Active substance approvals would also remain valid until their normal expiry date.

If you have a biocidal product being processed by HSE on exit day, HSE would, where possible, continue to process this to grant a national authorisation. HSE may, however, need to ask you to re-submit the information supporting original application to enable it to complete its evaluation.

If you have an application being processed by another EU country on exit day as part of an EU-wide authorisation process (for example, a mutual recognition or union authorisation application), you would need to re-apply to the UK for a national authorisation. However, the date of your original application would be recognised for the purposes of meeting any application submission deadlines.

A UK version of the EU list of approved active substance suppliers (the so-called 'Article 95' list) would be established. It would operate the same way as the current EU list. Companies already on the EU list would, on exit day, be included in the UK's list. However, to remain on the list they would need to submit supporting information to HSE. This would be the same information as was submitted to ECHA, for example, an active substance dossier or a letter of access. Companies would also have to ensure they are established in the UK. A phase-in period would be provided to give businesses time to meet these requirements.

Under the BPR authorisation holders have to be established in the EU. In the standalone national regime, authorisation holders would need to be established in the UK. There would be a phase-in period to give businesses time to make any necessary arrangements.

These arrangements will ensure there would be minimal changes at the time of exit from the current system, and that the transition will be as smooth for businesses as possible.

### **More information**

Further information and instructions will be published in the coming months. We aim to give businesses and individuals as much certainty as possible as soon as we can, and to ensure that any new requirements are not unduly burdensome.

We also recommend reading the following technical notices:

- [Regulating chemicals (REACH) if there's no Brexit deal](<https://www.gov.uk/government/publications/regulating-chemicals-reach-if-theres-no-brexite-deal>)
- Classifying, labelling and packaging chemicals if there's no Brexit deal
- Export and import of hazardous chemicals (PIC) if there's no Brexit deal
- Control on mercury if there's no Brexit deal
- Control on Persistent Organic Pollutants if there's no Brexit deal
- Regulating pesticides if there's no Brexit deal

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 Member States. 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.

Norway, Iceland and Liechtenstein are party to the Agreement on the European Economic Area and participate in other EU arrangements. As such, in many areas, these countries adopt EU rules. Where this is the case, these technical notices may

also apply to them, and EEA businesses and citizens should consider whether they need to take any steps to prepare for a 'no deal' scenario.