

Brexit and Biocides

The Future of the Biocidal Products Regulation (BPR) in the UK and EU
September 2019



Under current plans, the UK will leave the European Union on October 31st 2019 and is currently negotiating the terms of a Withdrawal Agreement with the EU27.

ERM has an experienced team of Regulatory Affairs Consultants who have established a reputation for delivering high quality and successful active substance and product dossiers across the range of Product Types within scope of EU BPR (Regulation (EU) 528/2012).

ERM can help your company navigate and manage the changes implemented by Brexit.

ERM can assist with asset and case transfers, Article 95 listing amendments, and dossier submissions within the EU and UK.



Transposition of European Union Law

Upon withdrawal of the UK from the European Union, activities in the UK market will no longer be subject to EU chemicals legislation but will be regulated by UK legislation.

The UK government will incorporate all current EU chemicals regulations without substantive change into UK law through the EU Withdrawal Bill. This will repeal the 1972 European Communities Act and transfers all existing EU legislation into UK domestic law, ensuring market continuity, through common product standards, and aiding future trade negotiations.

EU law will continue to apply in the UK until the leaving date and may continue to be applied in certain legislative areas under any transitional arrangements that may be implemented as part of the Withdrawal Agreement.

Future Regulation of Biocidal Products in the UK

UK HSE state that an implementation period has been agreed subject to final conclusion and ratification of the draft Withdrawal Agreement.

Upon UK withdrawal, the UK will revert to a 'third country' status under EU BPR. UK companies will still be able to contact the ECHA Helpdesk to resolve issues regarding BPR obligations in relation to conducting business in the EU but the UK will have no obligation to operate a national Helpdesk for the purposes of EU BPR. HSE will assume responsibility for many roles previously administered by ECHA and will develop IT infrastructure to replace systems such as ECHA's R4BP3 tool.

Data requirements and standards implemented by the UK after EU exit are expected to remain the same as they were prior to withdrawal.

UK companies will no longer be recognised as EU legal entities under EU BPR; either immediately at withdrawal on October 31st 2019 in the event of no Withdrawal Agreement, or at a predetermined point in the implementation period if agreed under the Withdrawal Agreement. The loss of legal entity status has ramifications for UK companies who have active substance approvals and/or biocidal products authorisations under EU BPR.

In the event of no Withdrawal Agreement: Article 95 Obligations

Article 95 of EU BPR requires that companies listed on the Article 95 list of approved substance and product suppliers must be established within the Union (including EEA countries and Switzerland). In order for UK companies to remain on the EU BPR Article 95 list they must establish a representative based within the Union and must communicate this to ECHA at least one month prior to the UK's withdrawal ('request for correction').

HSE will establish a UK version of the Article 95 list that will be based on the EU list at the point of UK withdrawal from the EU. Continued inclusion on the UK list will be subject to provision of appropriate information: a supporting dossier or letter of access as previously submitted to ECHA will need to be submitted to HSE by October 2021¹. Non-UK companies will have to establish a UK-based representative in order to be included on the UK list.

¹ HSE will not charge for the resubmission of this information. For companies that submitted a LoA, that LoA will only be valid if the data owner also submits the relevant dossier to HSE by October 2021.

Existing Approvals and Authorisations

Biocidal product authorisations and active substance approvals valid in the UK on the day of withdrawal will remain valid in the UK until their normal expiry date. By 30th October 2020, Authorisation Holders of UK authorisations will need to be established in the UK if not already, or that authorisation will need to be transferred to a company established in the UK².

By 30th October 2021, active substances will need to be supplied by companies listed in the UK Article 95³.

Authorisations issued in a Member State on the basis of the recognition of a UK authorisation will remain valid. Under EU BPR Authorisation Holders must be established within the EU, EEA countries or Switzerland. UK companies who wish to retain their BPR Authorisations within the EU will be required to transfer assets to a new Authorisation Holder established within the EU.

Ongoing Approvals and Authorisations

Applications for national authorisations being processed by HSE on the day of EU exit will continue to be processed; however, the original application will need to be re-submitted to HSE by 29th January 2020.

For ongoing active substance and Union Authorisation applications currently being led by the UK CA, but which will not be completed before EU-exit, transfer to another Member State is required. Applicants in this position should have been contacted by ECHA in relation to this transfer and should liaise with HSE for further details of the process.

For ongoing applications being led by other EU Member States (e.g. MR, UA), it will be necessary to re-submit an application for UK national authorisation to HSE by 28th April 2020⁴. In order to ensure compliance with legal deadlines the UK have confirmed that the date of the original application will be recognised. The authorisation can only be granted to a UK-based company.

For mutual recognition applications based on a national authorisation led by the UK it may be necessary to submit applications for national authorisations to relevant EU Member States, dependent on the status of the UK evaluation. Authorisations can only be granted to EU-based companies.

In instances where the original application was not made to the UK it will be necessary to re-submit information from the original application. HSE will no longer have access to ECHA IT systems. For an active substance application, resubmission with all active substance dossier will need to be submitted by 29th January 2020 where UK was eCA, or by the 28th April 2020 where another MS was the eCA.

New Approvals and Authorisations

After UK withdrawal there will be no alterations to application processes under EU BPR. UK-based and EU-based companies

can continue to submit applications for product authorisations and active substances. However, it should be noted that biocidal product authorisations can only be granted to an EU-based company.

Companies needing to apply for an active substance approval or for a biocidal product authorisation in the UK will apply to HSE, instead of ECHA. Active substance approvals and biocidal product authorisations will be UK-specific and can only be granted to a UK-based company³.

After EU exit there is no reciprocal agreement to enable mutual recognition in the UK of an authorisation granted by an EU Member State, or vice versa. It is understood the UK may consider an MR-like process for incoming applications but this is not confirmed. There can be no guarantee that EU MS will consider UK evaluations.



Fees

HSE will continue to operate a cost recovery fee structure charged on an hourly basis. Fees will be levied for evaluation processes but will not be made for resubmissions of applications previously submitted to ECHA under EU BPR.

Fees may be due to ECHA and/or EU Member State Competent Authorities in relation to processing new applications for biocidal products and amendments of existing authorisations which result from the withdrawal of the UK from the EU.

Data sharing

Companies may own the rights to studies that are not publicly available and have been used in substance and product registration dossiers. UK legal entities will be required to resubmit detailed substance or product information to the UK. This may be a reasonable expectation where UK companies own the relevant data but could be problematic for UK legal entities relying on Letter of Access agreements for data owned by non-UK legal entities as these agreements often stipulate data use within an EU BPR context and not for other regulatory jurisdictions.



Disclaimer: the information in this document is ERM's current understanding of available information and does not constitute a legal interpretation.

For further information:

Biocidal Products Regulation

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² HSE may request for submission of relevant scientific data and authorisation data within a 2 months deadline.

³ If the active substance supplier has not submitted additional data to HSE by that date and not listed in the UK Article 95, companies will need to change supplier and apply

for a change of supplier of product authorisation (by date set by HSE but no later than 28th April 2022).

⁴ In a no-deal scenario the UK will not be able to complete mutual recognition procedures for evaluations undertaken by other Member States. Where relying on LoA, data owner will also need to submit relevant data at the same time.