March 2019

Biocidal Products Regulation - What businesses need to do in the event of a no-deal Brexit

The table below outlines the steps companies would need to take with respect to their biocidal products authorisations and active substance approvals in the unlikely event the UK leaves the EU with no agreement in place.

This information reflects the position at the time of publication. Please check the HSE website regularly for any updates.

	Your company is…	You want to…	You need to…	By when…
1.	a company with an EU Article 95 listing	maintain a listing on the UK Article 95 list after exit day	Your EU Article 95 entry, if in place before exit day, will be transferred to the UK Article 95 list on exit day. You need to submit supporting information to HSE in the form of a supporting dossier or letter of access as previously submitted to ECHA. HSE will not charge for the resubmission of this information. HSE will publish information on which companies have submitted the relevant information	by exit day + 24 months
			If you are submitting a letter of access, HSE may refuse the application if it does not hold the relevant data. Therefore, in this case make sure the data owner also submits a full dossier to HSE by the same date.	by exit day + 24 months
			Ensure you are established in the UK, if you are not already	by exit day + 24 months

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2.	a company with an existing UK biocidal product authorisation, including simplified and Union authorisations	maintain UK market access	**Establishment in the UK**	
			Ensure that you are established in the UK if you are not already, or that you transfer your authorisation to a company that is established in the UK	by exit day + 12 months
			UK Article 95	
			Ensure that your active substance supplier is listed on the UK Article 95 list (if you are not listed on Article 95 yourself) and has made a submission to HSE which will allow them to remain on the list after that time (see above, point 1). HSE will make this information publicly available.[1]	by exit day + 24 months
			If your active substance supplier has not made such a submission, change your supplier to one remaining on the UK Article 95 list and apply for a change to your product authorisation to reflect your new supplier	with the permission of HSE, by a date specified by HSE, normally no later than (exit day + 24 months) + 180 days

[1] Not applicable for active substances listed, before exit day, in Annex I of BPR, categories 1-5 or 7.

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			Submission of data Supply relevant scientific and authorisation data if requested by HSE	within 2 months of the request
3.	a company with an authorisation under the simplified procedure that was granted in another Member State, and then notified to the UK to gain access to the UK market	Maintain UK market access	As per 2, but HSE will convert your notification into a UK authorisation. HSE will not make a charge for this process	
4.	a company intending to submit a new UK active substance approval or product authorisation application after exit day	gain access to UK market	**Submission of application** Submit a national application to HSE (in addition to any EU application). **Establishment in the UK** for a product authorisation, ensure you are established in the UK, if you are not already **UK Article 95** for a product authorisation, ensure that your active substance supplier is listed	any time after exit day by the time of the application by the time of application

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			on the UK Article 95 list (if you are not listed on Article 95 yourself) ensure the active substance supplier has made a submission to HSE which will allow them to remain on the list after exit day + 24 months (see above, point 1). HSE will make this information publicly available.[2] if your active substance supplier has not made such a submission, change your supplier to one remaining on the UK Article 95 list and apply for a change to your product authorisation to reflect your new supplier. HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks	by exit day + 24 months with the permission of HSE, by a date specified by HSE, normally no later than (exit day + 24 months) + 180 days
5.	a company with an application for: • National authorisation or renewal of a national authorisation in the UK	Complete the process to get a UK national authorisation (or amendment to a national authorisation)	**Resubmission of application** Re-submit the full original application to HSE.	by exit day + 90 days

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• mutual recognition or renewal of a mutual recognition where UK is the reference Member State • Union authorisation where UK is the evaluating Member State • Simplified authorisation where UK is the evaluating Member State • Application to the UK for 'same biocidal product' authorisation • A change to an existing authorisation where no decision on the authorisation, renewal, or change has been taken on or before exit day	Where you rely on a letter of access, ensure the data owner submits the relevant data by the same time. For 'same biocidal product' applications or changes to existing authorisations, also re-submit all required information on the reference product at the same time. HSE will not charge for the resubmission of this information. **Establishment in the UK** Ensure the authorisation holder is established in the UK, if they are not already	for changes, by exit day + 180 days for renewals or changes, by the expiry date of the authorisation or exit day + 12 months, whichever is the earlier For new authorisations, by the time HSE grants the authorisation

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	UK Article 95	
	If your active substance supplier was on the EU Article 95 list, you can assume they will be included in the UK list until exit day + 24 months.	
	Ensure your active substance supplier has made a submission to HSE which will allow them to remain on the list after exit day + 24 months (see above, point 1). HSE will make this information publicly available.[3]	by exit day + 24 months
	If your active substance supplier has not made such a submission, change your supplier to one remaining on the UK Article 95 list and apply for a change to your product authorisation to reflect your new supplier.	with the permission of HSE, by a date specified by HSE, normally no later than (exit day + 24 months) + 180 days
	HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks.	

[3] Not applicable for active substances listed, before exit day, in Annex I of BPR, categories 1-5 or 7.

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6.	a company with an application for: • Mutual recognition in sequence or in parallel where UK is a concerned Member State (ie another Member State is carrying out the lead evaluation) • Renewal of a mutual recognition where the UK is a concerned Member State • Union authorisation where UK is not the evaluating Member State • Simplified authorisation where UK is not the evaluating competent authority where no decision on authorisation or renewal has been taken on or before exit day	gain UK national authorisation	**Resubmission of application** re-submit an application for UK national authorisation to HSE. NB in a no-deal scenario the UK will not, after the UK leaves the EU, be able to complete mutual recognition procedures for evaluations undertaken by other Member States. Where you rely on a letter of access, ensure the data owner submits the relevant data by the same time. HSE will not charge for the resubmission of the information. **Establishment in the UK** Ensure the authorisation holder is established in the UK, if they are not already	by exit day + 180 days by exit day + 180 days for renewals or changes, by the expiry date of the authorisation or exit day + 12 months, whichever is the earlier

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		For new authorisations, by the time HSE grants the authorisation
	Article 95	
	If your active substance supplier was on the EU Article 95 list, you can assume they will be included in the UK list until exit day + 24 months.	-
	Ensure your active substance supplier has made a submission to HSE which will allow them to remain on the list after exit day + 24 months (see above, point 1). HSE will make this information publicly available.[4]	by exit day + 24 months
	If your active substance supplier has not made such a submission, change your supplier to one remaining on the UK Article 95 list and apply for a change to your product authorisation to reflect your new supplier.	with the permission of HSE, by a date specified by HSE, normally no later than (exit day + 24 months) + 180 days
	The date of your original application to another EU Member State would be	

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	recognised for the purposes of meeting any legal application submission deadlines. HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks.

[4] Not applicable for active substances listed, before exit day, in Annex I of BPR, categories 1-5 or 7.

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7.	a company with a UK product authorisation where the deadline for applying for renewal is shortly after exit day	Apply for a renewal in the UK	**Submission of application**	
			If you apply before or on exit day, do so under the current EU arrangements. Transitional arrangements under paragraphs 5 or 6 will apply.	any time up to and including exit day
			If you apply after exit day, apply to HSE for renewal. Ensure the renewal application contains all supporting data from your original application.	by the BPR renewal submission deadline for your product
			Where you rely on a letter of access, ensure that the data owner submits the data to HSE	by the BPR renewal submission deadline for your product
			Establishment in the UK	
			If you are not based in the UK, ensure you are established in the UK or that you transfer the authorisation to a company that is established in the UK	by the expiry date of the authorisation or exit day + 12 months, whichever is the earlier

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	UK Article 95	
	If your active substance supplier was on the EU Article 95 list, you can assume they will be included in the UK list until exit day + 24 months.	
	Ensure your active substance supplier has made a submission to HSE which will allow them to remain on the list after exit day + 24 months (see above, point 1). HSE will make this information publicly available.[5]	by exit day + 24 months
	If your active substance supplier has not made such a submission, change your supplier to one remaining on the UK Article 95 list and apply for a change to your product authorisation to reflect your new supplier.	with the permission of HSE, by a date specified by HSE, normally no later than (exit day + 24 months) + 180 days
	HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks.	

[5] Not applicable for active substances listed, before exit day, in Annex I of BPR, categories 1-5 or 7.

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8.	a company with a UK product authorisation that is valid after exit day	Amend the authorisation	Apply to HSE for a change to the authorisation Supply your full original application to authorise the product. Where the original application relied on a letter of access, the data owner must supply the data to HSE HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks	 at the time of the application at the time of the application
9.	a company intending to renew an active substance approval where the deadline for applying for renewal is shortly after exit day	Apply for renewal in the UK	Apply to HSE for renewal. This will need to include the full original active substance dossier together with any additional data generated since the original approval HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks.	By the BPR renewal deadline for your active substance

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10.	A company that is a participant in the EU's review programme of active substances	Be included in the UK's review programme after exit and benefit from the transitional arrangements in Article 89 of BPR – allowing products to be kept on the market under national rules while the active substance is being evaluated	Submit your full application to HSE including the active substance dossier HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks	By exit day + 90 days where UK was the evaluating Member State under the EU's programme by exit day +180 days where another Member State was evaluating the active substance
11.	A company that has made an application for an active substance to be approved, <u>not</u> as part of the EU's review programme of active substances (eg. a new active substance), where no decision on whether to approve the substance has been taken on or before exit day	Apply for the active substance to be approved in the UK	Submit, or re-submit the full application including the active substance dossier to HSE HSE will develop its own systems for receiving and processing applications, we will share further information in the coming weeks	By exit day + 90 days where UK was the evaluating Member State for the active substance by exit day + 180 days where another Member State was evaluating the active substance