Working with biocides after Brexit: actions and deadlines

Introduction

Following the end of the Transition Period on 31 December 2020, Great Britain is no longer part of the EU scheme for regulating biocides.

This guidance contains a series of fact sheets for businesses that want to gain, or maintain, access to the GB market after 31 December 2020. Each fact sheet addresses a different scenario and clearly presents what action you need to take, when you need to do it, and the consequences if you don't.

For information about Declarations of Interest and Notifications of intent to support active substances in the GB Review Programme, please contact us at biocidesenquries@hse.gov.uk with full details of your situation.

Applications

To submit an application or information as described in this guidance please use one of the following application forms, as appropriate:

- Product - Microsoft Word document – use this form to make new product/product family applications under GB BPR (including change of authorisation holder and active substance supplier), or resubmit pending applications for authorisation, renewal and changes.
- Active Substance - Microsoft Word document – use this form to make new applications for active substance approval under GB BPR or resubmit pending applications for approval and renewal.
- Article 95 - Microsoft Word document – use this form to apply to get on the GB Article 95 List or resubmit the information that supports your EU Article 95 listing to remain on the GB List beyond 31 December 2022.

Please email your application form to biocidesapplications@hse.gov.uk – companies may wish to mark emails as appropriate eg confidential. Please note that your application form may be returned if it is incomplete.

Only the application form should be submitted by email. All other relevant documentation/data must be submitted using the HSE Secure File Sharing Service.

All documents / attachments should be included within your IUCLID dossier, where relevant.

Using the HSE Secure File Sharing Service

Once we have received and processed your application form, you will be sent a link to upload the files associated with the relevant application – please do not use the link to upload files related to other applications.

Links will be sent out Monday – Friday and are valid for 5 working days – if the link expires before you are able to upload your files, please email biocidesapplications@hse.gov.uk to request a new link.

Please ensure you comply with the terms and conditions of using the HSE Secure File Sharing Service – these will be included in the email alongside the link.

Please check the spam settings on your email account to ensure our emails are not going to your junk folder.

GB Fact sheets

Use the links below to go to the fact sheets.

GB Fact sheet 1 – Existing BPR product authorisations in GB

All existing GB product authorisations will continue to be valid in GB after 31 December 2020, including:

- national authorisations (as well as those granted via mutual recognition and the same biocidal product route)
- simplified authorisations (as well as those granted via the same biocidal product route)
- Union authorisations (as well as those granted via the same biocidal product route)

All existing simplified notifications to the UK will be converted into a GB authorisation.

HSE will not charge for this process.

All existing Union authorisations will be treated as a national authorisation under GB BPR.

HSE may issue GB specific documentation but will not charge for this process.

Action 1		
Be established in the UK	Ensure you are established in the UK, if not already, or transfer your authorisation to a company that is established in the UK – inform HSE by admin change application.	By 31 December 2021
Failure to comply with action 1		
Authorisation will be cancelled and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB • additional 180 days for using the biocidal product in GB	From the date the authorisation is cancelled
Action 2		
Submit	Supply relevant scientific and authorisation data if requested by HSE.	Within 60 days of the request
Failure to comply with action 2		
Authorisation will be cancelled and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB	From the date the authorisation is cancelled
Action 3		
Read GB Fact sheet 8	The information and actions in GB Factsheet 8 (Article 95) also apply.	Read now

Note

Where an existing GB authorised product is the reference product for a new or pending GB same biocidal product application, you may be asked to submit the full data package that supports the reference product authorisation and any subsequent changes or renewals to enable HSE to evaluate the same biocidal product application.

Other fact sheets may also apply.

GB Fact sheet 2A – New applications for changes to existing BPR product authorisations in GB

You can continue to make changes to any valid BPR product authorisation in GB after 31 December 2020, including:

- national authorisations (as well as those granted via mutual recognition and the same biocidal product route)
- simplified authorisations (as well as those granted via the same biocidal product route)
- Union authorisations (as well as those granted via the same biocidal product route)

This fact sheet applies to any administrative, minor or major change to any valid BPR product authorisation in GB that is first submitted after 31 December 2020.

Any changes applied for in GB will only apply to the GB authorisation.

GB cannot mutually recognise changes made to EU BPR authorisations.

Action 1		
Submit	Submit the relevant change application to HSE. This includes the full data package supporting the authorisation and any subsequent changes or renewals.	Any time from 1 January 2021
	Where any part of your application or authorisation relies on a letter of access (including authorisations originally granted via the same biocidal product route), ensure that the data owner submits the relevant data to HSE.	By the time you submit your application
Failure to comply with action 1		
Change cannot be implemented	Your authorisation will remain valid* even if your change application is rejected.	Any time after submission
***HSE may take action to cancel your authorisation where there is a safety concern.		
Action 2		
Read GB Fact sheet 1	The information and actions in GB Fact sheet 1 (existing authorisations) also apply.	Read now
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

Some administrative changes, such as addition of trade names or change of product name/authorisation holder address, may not need the full original application to be submitted – you may wish to contact HSE to discuss whether this is applicable to your application.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 2B – Pending applications for changes to existing BPR product authorisations in GB

This fact sheet applies to any pending application for an administrative, minor or major change to any valid BPR product authorisation in GB, including:

- national authorisations (as well as those granted via mutual recognition and the same biocidal product route)
- simplified authorisations (as well as those granted via the same biocidal product route)
- Union authorisations (as well as those granted via the same biocidal product route)

where the UK was either the reference Member State (rMS), evaluating Competent Authority (eCA) or a concerned Member State (cMS).

Pending applications are those that were submitted to and accepted by the UK or ECHA under EU BPR prior to 1 January 2021 and no decision on the change for the UK market was taken by 31 December 2020.

Any changes applied for in GB will only apply to the GB authorisation.

GB cannot mutually recognise changes made to EU BPR authorisations.

Action 1		
Submit	Resubmit the full original change application to HSE. This includes the full data package supporting the authorisation and any subsequent changes or renewals.	By 29 June 2021
	Where any part of your application or authorisation relies on a letter of access (including authorisations originally granted via the same biocidal product route), ensure that the data owner submits the relevant data to HSE.	By the time you submit your application
Failure to comply with action 1		
Change cannot be implemented	Your authorisation will remain valid* even if your change application is rejected.	Any time after submission
***HSE may take action to cancel your authorisation where there is a safety concern.		
Action 2		
Read GB Fact sheet 1	The information and actions in GB Fact sheet 1 (existing authorisations) also apply.	Read now
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

Some administrative changes, such as addition of trade names or change of product name/authorisation holder address, may not need the full original application to be submitted – you may wish to contact HSE to discuss whether this is applicable to your application.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 3A – Pending product applications in GB – UK was rMS or eCA

This fact sheet applies where the UK was, at any time prior to 1 January 2021, evaluating an application:

- for national authorisation in the UK, including those with related mutual recognitions in an EU Member State(s)
- on behalf of the EU, including simplified and Union authorisation applications

This fact sheet does not apply to pending same biocidal product applications (go to GB Fact sheet 4)

Pending applications are those that were submitted to and accepted by the UK under EU BPR prior to 1 January 2021 and no decision on authorisation for the UK market was taken by 31 December 2020.

Action 1		
Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 31 March 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
Application will be rejected and products must be removed from the GB market	Phase out periods will apply to existing products* only: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date the application is rejected
Action 2		
Be established in the UK	Ensure the prospective authorisation holder is established in the UK, if not already.	By the time HSE is ready to grant the authorisation
Failure to comply with action 2		
Authorisation cannot be granted and products must be removed from the GB market	Phase out periods will apply to existing products* only: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date of the decision not to grant the authorisation
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

*Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR) prior to the submission of your original UK application under EU BPR and the approval date given to the last active substance in the product.

Partial evaluations done by HSE under EU BPR prior to 1 January 2021 are considered valid under GB BPR.

Applications resubmitted by 31 March 2021 will continue to be evaluated under GB BPR from the point they were paused prior to 1 January 2021.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 3B – Pending product applications in GB – UK was not rMS or eCA

This fact sheet applies where, prior to 1 January 2021, the UK was a concerned Member State (cMS) for applications that have, or are being, evaluated by an EU Member State, including:

- mutual recognitions, either in sequence or in parallel
- simplified authorisation applications
- Union authorisation applications

This fact sheet does not apply to pending same biocidal product applications (go to GB Fact sheet 4).

Pending applications are those that were submitted to and accepted by:

- the UK previously acting as a concerned Member State (cMS), for mutual recognition in sequence or in parallel
- an EU Member State (not the UK), for simplified and Union authorisation applications

under EU BPR prior to 1 January 2021 and no decision on authorisation for the UK market was taken by 31 December 2020.

Action 1		
Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 29 June 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
Application will be rejected and products must be removed from the GB market	Phase out periods will apply to existing products* only: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date the application is rejected
Action 2		
Be established in the UK	Ensure the prospective authorisation holder is established in the UK, if not already.	By the time HSE is ready to grant the authorisation
Failure to comply with action 2		
Authorisation cannot be granted and products must be removed from the GB market	Phase out periods will apply to existing products* only: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date of the decision not to grant the authorisation
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

***Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR) prior to the submission of your original application to the UK (or relevant EU Member State for Union and simplified authorisations) under EU BPR **and** the approval date given to the last active substance in the product.

Providing your application is resubmitted by 29 June 2021, the date of your original application to the UK (or relevant EU Member State for Union and simplified authorisations) under EU BPR will be recognised for the purposes of meeting any legal deadlines for application submission.

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 4 – Pending same biocidal product applications in GB

This fact sheet applies to all types of same biocidal product applications for the GB market, including:

- same biocidal products of any existing or pending GB national authorisation (as well as those originally granted via mutual recognition or the same biocidal product route)
- same biocidal products of any existing or pending simplified authorisation
- same biocidal products of any existing or pending Union authorisation (as well as those originally applied for as a Union authorisation or a national authorisation in the UK)

Product applications are considered to be pending if they were submitted to and accepted by the UK or ECHA under EU BPR prior to 1 January 2021 and no decision on authorisation for the UK market was taken by 31 December 2020.

Action 1		
Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 29 June 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
Application will be rejected and products must be removed from the GB market	Phase out periods will apply to existing products* only: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date the application is rejected
Action 2		
Be established in the UK	Ensure the prospective authorisation holder is established in the UK, if not already.	By the time HSE is ready to grant the authorisation
Failure to comply with action 2		
Authorisation cannot be granted and products must be removed from the GB market	Phase out periods will apply to existing products* only: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date of the decision not to grant the authorisation
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

*Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR) prior to the submission of your original application to the UK or ECHA under EU BPR and the approval date given to the last active substance in the product.

Providing your application is resubmitted by 29 June 2021, the date of your original application to the UK or ECHA under EU BPR will be recognised for the purposes of meeting any legal deadlines for application submission.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 5A – Pending product renewals in GB – UK was rMS or eCA

This fact sheet applies where the UK was, at any time prior to 1 January 2021, evaluating an application for renewal of:

- any valid UK national authorisation, including those with related applications for renewal via mutual recognition in an EU Member State(s) and those originally granted via the same biocidal product route
- any valid Union authorisation, including those originally granted via the same biocidal product route

Pending applications are those that were submitted to and accepted by the UK under EU BPR prior to 1 January 2021 and no decision on renewal for the UK market was taken by 31 December 2020.

Action 1

Submit	Resubmit the renewal application to HSE. This includes the full data package supporting the authorisation and any additional data generated since the original authorisation, including any subsequent changes and previous renewals.	By 31 March 2021
	Where any part of your application or authorisation relies on a letter of access (including authorisations originally granted via the same biocidal product route), ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application

Failure to comply with action 1

Application will be rejected and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB	From the current expiry date of the authorisation*

*If you have received a UK certificate for your authorisation with the reference '**BPR38**' or '**BPR38BPF**' in the bottom right-hand corner, your authorisation will be cancelled and the phase out period will start from the date of the cancellation.

Action 2

Be established in the UK	Ensure you are established in the UK, if not already, or transfer your authorisation to a company that is established in the UK – inform HSE by admin change application.	By 31 December 2021

Failure to comply with action 2

Authorisation will be cancelled and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB	From the date the authorisation is cancelled

Action 3

Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

Partial evaluations undertaken by HSE under EU BPR prior to 1 January 2021 are considered valid under GB BPR.

Applications resubmitted by 31 March 2021 will continue to be evaluated under GB BPR from the point they were paused prior to 1 January 2021.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 5B – Pending product renewals in GB – UK was not rMS or eCA

This fact sheet applies where, prior to 1 January 2021, the UK was a concerned Member State (cMS) for applications that have, or are being, evaluated by an EU Member State, including:

- renewal of a valid UK national authorisation via mutual recognition
- renewal of a valid Union authorisation (as well as those originally granted via the same biocidal product route)

Pending applications are those that were submitted to and accepted by:

- the UK previously acting as a concerned Member State (cMS), for renewal of a valid UK national authorisation via mutual recognition
- an EU Member State (not the UK), for renewal of a valid Union authorisation, including those originally granted via the same biocidal product route

under EU BPR prior to 1 January 2021 and no decision on renewal for the UK market was taken by 31 December 2020.

Action 1		
Submit	Resubmit the renewal application to HSE. This includes the full data package supporting the authorisation and any additional data generated since the original authorisation, including any subsequent changes and previous renewals.	By 29 June 2021
	Where any part of your application or authorisation relies on a letter of access (including authorisations originally granted via the same biocidal product route), ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
Application will be rejected and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB	From the current expiry date of the authorisation*

*If you have received a UK certificate for your authorisation with the reference '**BPR38**' or '**BPR38BPF**' in the bottom right-hand corner, your authorisation will be cancelled and the phase out period will start from the date of the cancellation.

Action 2		
Be established in the UK	Ensure you are established in the UK, if not already, or transfer your authorisation to a company that is established in the UK – inform HSE by admin change application.	By 31 December 2021
Failure to comply with action 2		
Authorisation will be cancelled and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB	From the date the authorisation is cancelled
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

Providing your application is resubmitted by 29 June 2021, the date of your original application to the UK or ECHA under EU BPR will be recognised for the purposes of meeting any legal deadlines for application submission.

HSE will conduct its own renewal evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 5C – New applications for product renewal in GB with a submission deadline after 31 December 2020

To maintain access to the GB market after 31 December 2020 you will still need to apply for renewal of valid GB authorisations at least 550 days before their current expiry dates, including:

- national authorisations (as well as those originally granted via mutual recognition or the same biocidal product route)
- Union authorisations (as well as those originally granted via the same biocidal product route), which HSE will convert to GB national authorisations (go to GB Fact sheet 1)

Action 1		
Submit	Submit a renewal application to HSE. This includes the full data package supporting the authorisation and any additional data generated since the original authorisation, including any subsequent changes and previous renewals.	At least 550 days before the current expiry date of the authorisation
	Where any part of your application or authorisation relies on a letter of access (including authorisations originally granted via the same biocidal product route), ensure that the data owner submits the relevant data to HSE.	By the time you submit your application
Failure to comply with action 1		
Authorisation cannot be renewed and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB	From the current expiry date of the authorisation
Action 2		
Be established in the UK	Ensure you are established in the UK, if not already, or transfer your authorisation to a company that is established in the UK – inform HSE by admin change application.	By 31 December 2021
Failure to comply with action 2		
Authorisation will be cancelled and products must be removed from the GB market	Phase out periods will apply: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB	From the date the authorisation is cancelled
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

Separate applications will need to be submitted under EU BPR if you also want to renew any existing authorisations in the EU or Northern Ireland.
HSE will conduct its own renewal evaluation, separate from any EU evaluation.
Applications may be rejected if HSE does not hold all of the relevant data.
Other fact sheets may also apply.

GB Fact sheet 6A – New applications for GB BPR product authorisation – new products not currently on the GB market

If all of the active substances in your product are already approved in GB or included on the GB Simplified Active Substance List, you can apply for either national or simplified product authorisation in GB, including via the same biocidal product route.

This fact sheet does not apply if you wish to add a new trade name to a product that is already authorised in GB under BPR (go to GB Fact sheet 2A).

Where your product is already legally on the market in GB (e.g. regulated under other national legislation such as COPR) and you are applying for GB BPR product authorisation following active substance approval (go to GB Fact sheet 6B for further information), any new trade names included in your BPR application that have never been on the GB market cannot be supplied in GB until your authorisation is granted.

GB cannot mutually recognise EU BPR authorisations.

Action 1		
Submit	Submit an application to HSE for GB authorisation.	Before placing the product on the market*
	Where any part of your application or authorisation relies on a letter of access (including same biocidal product applications), ensure that the data owner submits the relevant data to HSE.	By the time you submit your application
Failure to comply with action 1		
No sale, supply or use	An authorisation cannot be granted and the biocidal product cannot be supplied and/or used in GB.	Immediate effect
Action 2		
Be established in the UK	Ensure that the prospective authorisation holder is established in the UK.	Before submitting your application
Failure to comply with action 2		
No sale, supply or use	Your application will not be accepted and the biocidal product cannot be supplied and/or used in GB.	Immediate effect
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

*No sale, supply or use of products (including new trade names) in GB until product authorisation is granted by HSE.

A separate application will need to be submitted under EU BPR if you also want to supply your product in the EU or Northern Ireland.

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 6B – New applications for GB BPR product authorisation following active substance approval – existing products already legally on the GB market

This fact sheet applies to products (including individual trade names) that were already legally on the market in GB (e.g. regulated under other national legislation such as COPR) prior to the approval date given to the last active substance in the product.

Once the last active substance in your product is given an approval date under GB BPR you will need to apply for product authorisation in GB, including via the same biocidal product route, in order to keep the product on the market.

This fact sheet does not apply to products (including individual trade names) that were **not** legally on the market in GB (e.g. regulated under other national legislation such as COPR) prior to the approval date given to the last active substance in the product (go to GB Fact sheet 6A).

GB cannot mutually recognise EU BPR authorisations.

Action 1		
Submit	Submit an application to HSE for GB authorisation.	By the approval date that is given to the last active substance in your product
	Where any part of your application or authorisation relies on a letter of access (including same biocidal product applications), ensure that the data owner submits the relevant data to HSE.	By the time you submit your application
Failure to comply with action 1		
Authorisation cannot be granted and existing products must be removed from the GB market	Phase out periods will apply to existing products: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date of approval of the last active substance
Action 2		
Be established in the UK	Ensure that the prospective authorisation holder is established in the UK.	Before submitting your application
Failure to comply with action 2		
Application will be rejected and existing products must be removed from the GB market	Phase out periods will apply to existing products: • 180 days for supplying the biocidal product in GB; and • 365 days for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date the application is rejected
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

A separate application will need to be submitted under EU BPR if you also want to supply your product in the EU or Northern Ireland.

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 7A – Products not currently requiring authorisation under GB BPR – new products not currently on the GB market

New products may not yet need authorisation under GB BPR if all of the active substance(s) they contain were supported in the review programme (or under Article 93) for the relevant product type and an approval decision (positive or negative) has not yet been taken under GB BPR.

New products include any trade names that are not already legally on the GB market (e.g. regulated under other national legislation such as COPR).

Action 1		
Check if you need to apply	Some biocidal products need product approval from HSE under the Control of Pesticides Regulations (COPR) and/or to comply with other legislation or approval schemes in GB e.g. Defra's disinfectant approval scheme. Check: https://www.hse.gov.uk/biocides/uk-existing-law.htm	Before placing the product on the market
Failure to comply with action 1		
No sale, supply or use	The biocidal product cannot be supplied and/or used in GB.	Immediate effect
Action 2		
Check other general legal requirements	All biocidal products must comply with other general legal requirements. Check: https://www.hse.gov.uk/biocides/uk-existing-law.htm	Before placing the product on the market
Failure to comply with action 2		
No sale, supply or use	Enforcement action may be taken where products do not comply with the relevant legislation.	At any time
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

Once the last active substance in the product is given an approval date, you must apply for product authorisation under GB BPR by this approval date to keep your product on the GB market (go to GB Fact sheet 6B).

Other fact sheets may also apply.

GB Fact sheet 7B – Products not currently requiring authorisation under GB BPR – existing products already legally on the GB market

Existing products may not yet need authorisation under GB BPR if all of the active substance(s) they contain were supported in the review programme (or under Article 93) for the relevant product type and an approval decision (positive or negative) has not yet been taken under GB BPR.

Existing products are those trade names that are already legally on the GB market (eg regulated under other national legislation such as COPR).

Action 1		
Continue to comply	Continue to comply with the requirements of any applicable legislation or approval schemes in GB, such as the conditions of the product approval under COPR.	At all times
Failure to comply with action 1		
No sale, supply or use	Enforcement action may be taken where products do not comply with the relevant legislation.	At any time
Action 2		
Continue to comply	All biocidal products must comply with other general legal requirements. Check: https://www.hse.gov.uk/biocides/uk-existing-law.htm	At all times
Failure to comply with action 2		
No sale, supply or use	Enforcement action may be taken where products do not comply with the relevant legislation.	At any time
Action 3		
Read GB Fact sheet 8	The information and actions in GB Fact sheet 8 (Article 95) also apply.	Read now

Note

Once the last active substance in the product is given an approval date, you must apply for product authorisation under GB BPR by this approval date to keep your product on the GB market (go to GB Fact sheet 6B).

Other fact sheets may also apply.

GB Fact sheet 8 – GB Article 95 – Impact on biocidal products

Active substance and product suppliers that are on the EU Article 95 List on 31 December 2020 will be included on the GB Article 95 List on 1 January 2021 and remain on the list for at least 2 years.

They will need to complete certain actions to remain on the list beyond this initial 2-year period (go to GB Fact sheet 14).

This fact sheet does not apply to products containing active substances:

- in categories A or C of the GB Simplified Active Substance List (equivalent to categories 1-5 or 7 of Annex I of EU BPR)
- successfully notified into the GB Review Programme but a dossier has not yet been submitted under GB BPR.

Action 1		
Check GB Article 95	Ensure that either you or your active substance supplier are on the GB Article 95 List.	From 1 January 2021
Failure to comply with action 1		
No sale or supply	Products containing an active substance supplied by a company that is not included on the GB Article 95 List on 1 January 2021 cannot be supplied in GB*.	From 1 January 2021
Action 2		
Talk to your supplier or action GB Fact sheet 14	Confirm with your active substance supplier that they will complete all of the required actions (go to GB Fact sheet 14) to remain on the GB Article 95 List by 31 December 2022. Alternatively, if you are on the GB Article 95 List yourself, start preparing to complete all of the required actions (go to GB Fact sheet 14) to remain on the GB Article 95 List by 31 December 2022.	As soon as possible
Failure to comply with action 2		
No sale or supply	Products containing an active substance supplied by a company that does not take the necessary actions to remain on the GB Article 95 List beyond 31 December 2022 cannot be supplied in GB*.	From 1 January 2023
Action 3 – if relevant		
Change supplier or get included on the GB Article 95 List	If necessary, change to an active substance supplier that will remain on the GB Article 95 List or apply to be included on the GB Article 95 List yourself. Apply to update your GB BPR authorisation or COPR approval if you change supplier. You should discuss any issues with HSE as soon as possible.	By 31 December 2022
Failure to comply with action 3		
No sale or supply	Products containing an active substance supplied by a company that does not take the necessary actions to remain on the GB Article 95 List beyond 31 December 2022 cannot be supplied in GB*. Enforcement action may be taken where products are not supplied in accordance with the conditions of their GB BPR authorisation or COPR approval.	From 1 January 2023

Note

*Products containing an active substance supplied by a company that is not included on the GB Article 95 List on 1 January 2021 or does not take the necessary actions to remain on the GB Article 95 List beyond 31 December 2022 can continue to be used in GB – but not supplied – (where relevant, in accordance with any GB BPR authorisation or COPR approval), until any relevant authorisation or approval expires or is cancelled, whichever is the earlier, or other regulatory action is taken.

Information about which active substance suppliers have completed all of the required actions to remain on the GB Article 95 List beyond 31 December 2022 will be available on the HSE website from 1 January 2021 and updated regularly.

Other fact sheets may also apply.

GB Fact sheet 9A – Pending Review Programme active substance applications in GB – UK was eCA

This fact sheet applies to any Review Programme active substance application where the UK was the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

Review Programme active substances are those that were:

- on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development; and
- included in Annex II of the Review Regulation (EU) No 1062/2014 for that product type prior to 1 January 2021. Check: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02014R1062-20190330&from=en

Pending applications are those where a dossier was submitted and accepted under EU BPR prior to 1 January 2021 and no decision on the approval was taken by 31 December 2020.

Action 1		
Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 31 March 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
Open invitation	HSE will publish an open invitation allowing any business to notify their intention to take over the role of supporting the active substance / product type combination for assessment in the GB Review Programme. Go to GB Fact sheet 9C.*	From 31 March 2021

***Failure to comply with GB Fact sheet 9C may result in a non-approval decision. Phase out periods will apply to existing products** only.

Note

**Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR) prior to the non-approval decision.

Partial evaluations undertaken by HSE under EU BPR prior to 1 January 2021 are considered valid under GB BPR.

Applications resubmitted within the relevant deadline will continue to be evaluated under GB BPR from the point they were paused prior to 1 January 2021.

Once all relevant resubmission deadlines have passed, HSE will consider the totality of the evaluations required under the GB Review Programme. Once determined, further information will be made available regarding the scheduling of those evaluations as appropriate.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 9B – Pending Review Programme active substance applications in GB – UK was not eCA

This fact sheet applies to any Review Programme active substance application where the UK was **not** the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

Review Programme active substances are those that were:

- on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development; and
- included in Annex II of the Review Regulation (EU) No 1062/2014 for that product type prior to 1 January 2021. Check: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02014R1062-20190330&from=en

Pending applications are those where a dossier was submitted and accepted under EU BPR prior to 1 January 2021 and no decision on the approval was taken by 31 December 2020.

Action 1

Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 29 June 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application

Failure to comply with action 1

Open invitation	HSE will publish an open invitation allowing any business to notify their intention to take over the role of supporting the active substance / product type combination for assessment in the GB Review Programme. Go to GB Fact sheet 9C.*	From 29 June 2021

*Failure to comply with GB Fact sheet 9C may result in a non-approval decision. Phase out periods will apply to existing products** only.

Note

**Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR) prior to the non-approval decision.

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Once all relevant resubmission deadlines have passed, HSE will consider the totality of the evaluations required under the GB Review Programme. Once determined, further information will be made available regarding the scheduling of those evaluations as appropriate.

Other fact sheets may also apply.

GB Fact sheet 9C – New notifications in GB following failure to comply with GB Fact sheets 9A or 9B

This fact sheet applies where the full original application for a pending Review Programme active substance has not been resubmitted to HSE (go to GB Fact sheets 9A and 9B) by either 31 March 2021 or 29 June 2021, as applicable, and an open invitation has been published by HSE.

The publication of an open invitation allows any business to notify an intention to take over the role of supporting the relevant active substance / product type combination for assessment in the GB Review Programme.

Action 1

Submit	Submit a compliant notification to HSE.	By the deadline of the open invitation

Failure to comply with action 1

Non-approval decision	Phase out periods will apply to existing products* only: • 12 months for supplying the biocidal product in GB; and • 18 months for using the biocidal product in GB	From the date of the non-approval decision

Note

***Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR).

If your notification is declared to be compliant by HSE, you will need to submit a full active substance dossier within 2 years of the date your notification is declared compliant.

Other fact sheets may also apply.

GB Fact sheet 10A – Pending Article 93 active substance applications in GB – UK was eCA

This fact sheet applies to any Article 93 active substance application where the UK was the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

Article 93 active substances are those that were originally supported under the transitional measures of Article 93 of EU BPR.

Pending applications are those where a dossier was submitted and accepted under EU BPR prior to 1 September 2016 and no decision on the approval was taken by 31 December 2020.

Action 1		
Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 31 March 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
Non-approval decision	Phase out periods will apply to existing products* only: • 12 months for supplying the biocidal product in GB; and • 18 months for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date of the non-approval decision

Note

***Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR).

Partial evaluations undertaken by HSE under EU BPR prior to 1 January 2021 are considered valid under GB BPR.

Applications resubmitted by 31 March 2021 will continue to be evaluated under GB BPR from the point they were paused prior to 1 January 2021.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 10B – Pending Article 93 active substance applications in GB – UK was not eCA

This fact sheet applies to any Article 93 active substance application where the UK was **not** the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

Article 93 active substances are those that were originally supported under the transitional measures of Article 93 of EU BPR.

Pending applications are those where a dossier was submitted and accepted under EU BPR prior to 1 September 2016 and no decision on the approval was taken by 31 December 2020.

Action 1		
Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 29 June 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
Non-approval decision	Phase out periods will apply to existing products* only: • 12 months for supplying the biocidal product in GB; and • 18 months for using the biocidal product in GB HSE will revoke any existing COPR approval.	From the date of the non-approval decision

Note

***Existing products are those trade names that were legally on the GB market (eg regulated under other national legislation such as COPR).

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 11A – Pending new and non-Review Programme existing active substance applications in GB – UK was eCA

This fact sheet applies to any new or non-Review Programme existing active substance application where the UK was the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

New active substances are those that were not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development.

Non-Review Programme existing active substances are those that were:

- on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development; and
- being assessed outside of the EU Review Programme for that product type prior to 1 January 2021

These are usually active substances that were identified as existing (check Annex I of Commission Regulation (EC) No 1451/2007: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007R1451&from=EN) but the dossiers were not submitted by the relevant deadlines that would have allowed them to be included in the EU Review Programme.

This also includes where an active substance may have been included in the EU Review Programme for some product types but dossiers for other product types were submitted after the relevant deadlines had passed and so those active substance / product type combinations that didn't meet the relevant deadline are being assessed outside of the EU Review Programme.

This fact sheet does not apply to Article 93 active substance applications (go to GB Fact sheet 10A).

Pending applications are those where a dossier was submitted and accepted under EU BPR prior to 1 January 2021 and no decision on the approval was taken by 31 December 2020.

Action 1		
Submit	Resubmit the full original application to HSE. This includes the full original data package and any additional data gathered or generated since the original submission.	By 31 March 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application
Failure to comply with action 1		
No approval can be granted*	The active substance cannot be used in biocidal products in GB*.	Immediate effect

*Where relevant, a non-approval decision may be taken for the active substance. Any authorisations or derogations allowing products containing the relevant active substance to be supplied in GB will be cancelled.

Note

Partial evaluations undertaken by HSE under EU BPR prior to 1 January 2021 are considered valid under GB BPR.

Applications resubmitted by 31 March 2021 will continue to be evaluated under GB BPR from the point they were paused prior to 1 January 2021.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 11B – Pending new and non-Review Programme existing active substance applications in GB – UK was not eCA

This fact sheet applies to any new or non-Review Programme existing active substance application where the UK was **not** the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

New active substances are those that were not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development.

Non-Review Programme existing active substances are those that were:

- on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development; and
- being assessed outside of the EU Review Programme for that product type prior to 1 January 2021

These are usually active substances that were identified as existing (check Annex I of Commission Regulation (EC) No 1451/2007: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007R1451&from=EN) but the dossiers were not submitted by the relevant deadlines that would have allowed them to be included in the EU Review Programme.

This also includes where an active substance may have been included in the EU Review Programme for some product types but dossiers for other product types were submitted after the relevant deadlines had passed and so those active substance/product type combinations that didn't meet the relevant deadline are being assessed outside of the EU Review Programme.

This fact sheet does not apply to Article 93 active substance applications (go to GB Fact sheet 10B).

Pending applications are those where a dossier was submitted and accepted under EU BPR prior to 1 January 2021 and no decision on the approval was taken by 31 December 2020.

Action 1

Read GB Fact sheet 13	There are no legal deadlines for resubmission of applications but, to gain or maintain access (eg copper) to the GB market, you will need to make an application for active substance approval under GB BPR (go to GB Fact sheet 13).	Read now

Failure to comply with action 1

Where an application is not submitted under GB BPR, a non-approval decision may be taken for the active substance where relevant. Any authorisations or derogations allowing products containing the relevant active substance to be supplied in GB will be cancelled.

Note

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 12A – Pending active substance renewals in GB – UK was eCA

This fact sheet applies to any active substance renewal application where the UK was the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

Pending applications are those that were submitted and accepted under EU BPR prior to 1 January 2021 and no decision on the renewal was taken by 31 December 2020.

Action 1

Submit	Resubmit the full original application to HSE. This includes the full data package supporting the approval and any additional data generated since the original approval, including any post-approval data and previous renewals.	By 31 March 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application

Failure to comply with action 1

Approval cannot be renewed and existing product authorisations will be cancelled	The active substance approval will remain valid until its current expiry date*, following which, any product authorisations will be cancelled. Phase out periods will apply for any product with a valid BPR authorisation in GB: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB**	From the date the authorisation is cancelled

***Active substances that had their expiry date postponed by the EU Commission prior to 1 January 2021 for the purposes of completing the renewal evaluation will have their approvals cancelled.

****Products containing the active substance and without a BPR authorisation valid in GB before the decision on the active substance cannot be supplied in GB and phase out periods will not apply.

Note

Partial evaluations done by HSE under EU BPR prior to 1 January 2021 are considered valid under GB BPR.

Applications resubmitted by 31 March 2021 will continue to be evaluated under GB BPR from the point they were paused prior to 1 January 2021.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 12B – Pending active substance renewals in GB – UK was not eCA

This fact sheet applies to any active substance renewal application where the UK was **not** the evaluating Competent Authority (eCA) at any time prior to 1 January 2021.

Pending applications are those that were submitted and accepted under EU BPR prior to 1 January 2021 and no decision on the renewal was taken by 31 December 2020.

Action 1

Submit	Resubmit the full original application to HSE. This includes the full data package supporting the approval and any additional data generated since the original approval, including any post-approval data and previous renewals.	By 29 June 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you resubmit your application

Failure to comply with action 1

Approval cannot be renewed and existing product authorisations will be cancelled	The active substance approval will remain valid until its current expiry date*, following which, any product authorisations will be cancelled. Phase out periods will apply for any product with a valid BPR authorisation in GB: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB**	From the date the authorisation is cancelled

***Active substances that had their expiry date postponed by the EU Commission prior to 1 January 2021 for the purposes of completing the renewal evaluation will have their approvals cancelled.

**Products containing the active substance and without a BPR authorisation valid in GB before the decision on the active substance cannot be supplied in GB and phase out periods will not apply.

Note

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 12C – New applications for active substance renewal in GB with a submission deadline after 31 December 2020

To maintain access to the GB market after 31 December 2020 you will still need to apply for renewal of valid GB active substance approvals at least 550 days before their current expiry dates.

Action 1

Submit	Submit a renewal application to HSE. This includes the full data package supporting the approval and any additional data generated since the original approval, including any post-approval data and previous renewals.	At least 550 days before the current expiry date of the approval
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you submit your application

Failure to comply with action 1

Approval cannot be renewed and existing product authorisations will be cancelled	The active substance approval will remain valid until its current expiry date, following which, any product authorisations will be cancelled. Phase out periods will apply for any product with a valid BPR authorisation in GB: • 180 days for supplying the biocidal product in GB; and • additional 180 days for using the biocidal product in GB*	From the date the authorisation is cancelled

***Products containing the active substance and without a BPR authorisation valid in GB before the active substance approval expires cannot be supplied in GB and phase out periods will not apply.

Note

Separate applications will need to be submitted under EU BPR if you also want to renew any existing approvals in the EU or Northern Ireland.

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Other fact sheets may also apply.

GB Fact sheet 13 – New applications for GB BPR active substance approval

New applications can be made under GB BPR for active substances, including those that:

- are new to the market
- are new product types that have not already been supported
- have already been given a non-approval decision under EU BPR
- are new or non-Review Programme existing active substances where an application was submitted under EU BPR prior to 1 January 2021 and the UK was **not** the evaluating Competent Authority (eCA) at any time (go to GB Fact sheet 11B)

Action 1		
Submit	Submit an application to HSE for GB approval.	From 1 January 2021
	Where any part of your application relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you submit your application
Failure to comply with action 1		
No approval can be granted	The active substance cannot be used in biocidal products in GB.	Immediate effect

Note

A separate application will need to be submitted under EU BPR if you also want to gain approval in the EU or Northern Ireland.

HSE will conduct its own full evaluation, separate from any EU evaluation.

Applications may be rejected if HSE does not hold all of the relevant data.

Products containing the active substance cannot be supplied in GB until they gain GB BPR product authorisation.

Other fact sheets may also apply.

GB Fact sheet 14 – GB Article 95 List

Active substance and product suppliers that are on the EU Article 95 List on 31 December 2020 will be included on the GB Article 95 List on 1 January 2021 and remain on the list for at least 2 years.

You will need to complete certain actions to remain on the list beyond this initial 2-year period.

This fact sheet does not apply to active substances:

- in categories A or C of the GB Simplified Active Substance List (equivalent to categories 1-5 or 7 of Annex I of EU BPR)
- successfully notified into the GB Review Programme but a dossier has not yet been submitted under GB BPR.

Action 1		
Submit	Resubmit the dossier or letter of access supporting your EU Article 95 listing to HSE.	By 31 December 2022
	Where any part of your EU Article 95 listing relies on a letter of access, ensure that the data owner submits the relevant data to HSE.	By the time you submit your application
Failure to comply with action 1		
You will be removed from the GB Article 95 List	Biocidal products containing your source of active substance cannot be supplied in GB*. Enforcement action may be taken where products are not supplied in accordance with the conditions of their GB BPR authorisation or COPR approval.	From 1 January 2023
Action 2		
Be established in the UK	Ensure you are established in the UK, if not already, and inform HSE either by email or as part of your data resubmission. Alternatively, you may appoint a UK representative for the purposes of GB Article 95 and inform HSE either by email or as part of your data resubmission.	By 31 December 2022
Failure to comply with action 2		
You will be removed from the GB Article 95 List	Biocidal products containing your source of active substance cannot be supplied in GB*. Enforcement action may be taken where products are not supplied in accordance with the conditions of their GB BPR authorisation or COPR approval.	From 1 January 2023

Note

*Products can continue to be used in GB – but not supplied – (where relevant, in accordance with any GB BPR authorisation or COPR approval), until any relevant authorisation or approval expires or is cancelled, whichever is the earlier, or other regulatory action is taken.

Information about which active substance suppliers have completed all of the required actions to remain on the GB Article 95 List beyond 31 December 2022 will be available on the HSE website from 1 January 2021 and updated regularly.

Other fact sheets may also apply.

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

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