UK Biocidal Regulation:
Treated Articles

The Biocidal Product Regulation EU 528/2012 ("**EU BPR**") has been copied into GB law and amended accordingly.

Therefore, most aspects of EU BPR have been adopted into the **new UK Biocidal Products Regulation** ('**UK BPR'**), which came into force on 31 December 2020.

Biocidal Products

1. Introduction

The **EU BPR** came into effect on 1 September 2013. It replaced the **Biocidal Directive** 98/8/EC. The EU BPR was binding in its **entirety and directly applicable** in all Member States of the European Union. The EU BPR concerned companies **making biocidal products available on the EU market** and the placing on the market of **treated articles**. It also dealt with the **use of the active substances contained in biocidal products** to protect humans, animals, materials or articles against harmful organisms, such as pests or bacteria, writes Dr Rosanna Cooper.

The idea behind the EU BPR was to ensure that **biocidal products** and **treated articles** were authorised.

> …The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment…

2. Active Substance(s)

The **active substance** in a biocidal product must gain **authorisation** from the Health and Safety Executive ("HSE"). Suppliers of active substances are on the GB Article 95 list:

> **The GB Article 95 List**
> The GB Article 95 list provides details of the suppliers for active substance / product type combinations that can be used in biocidal products in Great Britain (GB).

3. Placing a biocidal product on the market in the UK

Before any biocidal product can be placed on the market in the UK, it must have an **authorisation**.

4. What is a Biocidal Product?

Under the UK BPR, a biocidal product means:

…any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action…

Under the UK BPR:

- An '**active substance**' means a **substance** or a **micro-organism** that has an **action** on or **against harmful organisms**.
- '**Making available on the market**' means any **supply of a biocidal product** or of a **treated article** for **distribution or use in the course of a commercial activity**, whether in return for payment or free of charge.
- '**Placing on the market**' means the first making available on the market of a biocidal product or of a treated article.
- '**Use**' means all **operations carried out with a biocidal product**, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the UK.
- '**Authorisation**' means national authorisation.
- '**Letter of access'** means an **original document, signed by the data owner** or its representative, which states that the data may be used for the benefit of a third party ...

It is important to note that any treated article that has a **primary biocidal function** will be deemed a **biocidal product**.

5. Biocidal Product Types

Under the UK BPR biocidal products are grouped into 22 product types comprising 4 main groups. It is worth noting that preservatives for food and feedstock are not within the scope of the UKBPR.

Number	Product type	Description
MAIN GROUP 1: Disinfectants These product-types exclude cleaning products that are not intended to have a biocidal effect, such as washing liquids and powders.		
1	Human hygiene	Biocidal products used for human hygiene purposes, applied on or

Number	Product type	Description
		in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
2	Disinfectants and algaecides not intended for direct application to humans or animals	Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities. Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
3	Veterinary hygiene	Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function. Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.
4	Food and feed area	Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals. Products used to be incorporated into materials which may enter into contact with food.
5	Drinking water	Products used for the disinfection of drinking water for both humans and animals.
MAIN GROUP 2: Preservatives Unless otherwise stated these product-types include only products to prevent microbial and algal development.		
6	Preservatives for products during storage	Products used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life. Products used as preservatives for the storage or use of rodenticide, insecticide or

Number	Product type	Description
		other baits.
7	Film preservatives	Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
8	Wood preservatives	Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product-type includes both preventive and curative products.
9	Fibre, leather, rubber and polymerised materials preservatives	Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.
10	Construction material preservatives	Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack.
11	Preservatives for liquid-cooling and processing systems	Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.
12	Slimicides	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, such as on wood and paper pulp and porous sand strata in oil extraction.
13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.
MAIN GROUP 3: Pest control		
14	Rodenticides	Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.
15	Avicides	Products used for the control of birds, by means other than repulsion or attraction.
16	Molluscicides, vermicides and products to control	Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion

Number	Product type	Description
	other invertebrates	or attraction.
17	Piscicides	Products used for the control of fish, by means other than repulsion or attraction.
18	Insecticides, acaricides and products to control other arthropods	Products used for the control of arthropods (insects, arachnids and crustaceans), by means other than repulsion or attraction.
19	Repellents and attractants	Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.
20	Control of other vertebrates	Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction.
MAIN GROUP 4: Other biocidal products		
21	Antifouling products	Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
22	Embalming and taxidermist fluids	Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

6. Authorisation

6.1 Biocidal Product Families

An authorisation may be granted for a biocidal product or a **biocidal product family**. An authorisation will be granted for a **maximum period of 10 years**.

A biocidal product family is defined as:

> … a group of biocidal products having similar uses, the active substances of which have the same specifications, and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products…

Under the UK BPR, all products within the biocidal product family will be covered by one authorisation.

Authorisation types

Product authorisations can be granted for single products or product families.

Single product authorisations:

- are for a fixed formulation
- can include an unlimited number of trade names

- can include products that are marketed by several different companies but have a single authorisation holder – that authorisation holder is legally responsible for all of those products

Product family authorisations:

- are for a group of biocidal products that have:
  - similar uses
  - the same active substances
  - similar formulations within a defined range
  - similar levels of risk and efficacy
- can include an unlimited number of trade names
- can include products that are marketed by several different companies but have a single authorisation holder – that authorisation holder is legally responsible for all of those products
- group products into different meta-Summary of Product Characteristics (meta-SPCs) depending on their properties and use patterns – every product within a meta-SPC must have the same classification
- cover every product in the family under a single authorisation (each product will receive a unique suffix to the authorisation number)
- allow for new products to be added into the authorised family – you need to notify HSE of the exact composition, trade name and suffix to the authorisation number, 30 days before placing the new product on the GB market (except where the product is explicitly identified in the original family authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations in the original family authorisation)

Application types

Both single product and product family authorisations may be able to be authorised by the following application types:

National authorisation

Allows biocidal products / biocidal product families that are not eligible for simplified authorisation to be made available on the market in GB.

…

6.2 Simplified Authorisation Procedure for Biocidal Products

The application for authorisation of certain **biocidal products** may be eligible under the **simplified authorisation procedure**, provided the conditions are met:

- All the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;

- The biocidal product does not contain any substance of concern;
- The biocidal product does not contain any nanomaterials;
- The biocidal product is sufficiently effective; and
- The handling of the biocidal product and its intended use do not require personal protective equipment.

If all of the conditions above are met by the applicant, the applicant will be required to submit an application to the HSE accordance with its procedure.

If the application or prospective authorisation holder fails to pay the fees, the application will be rejected.

Simplified authorisation

Is only available to biocidal products / biocidal product families containing an active substance(s) on the GB Simplified Active Substances List and meeting certain other criteria.

Simplified product authorisation is intended to encourage the use of products with a more favourable environmental or human or animal health profile and they can therefore be granted based on a limited data package.

…

Same biocidal product authorisation

Allows for the authorisation of a biocidal product / biocidal product family which is identical to another biocidal product / biocidal product family / part of a biocidal product family which is already authorised in GB, either by national or simplified authorisation.

You need to seek agreement from the authorisation holder of the biocidal product / biocidal product family that you want to base your application on before you apply.….

6.3 Content of an Authorisation

An authorisation for a biocidal product shall include the following:

- Stipulation of the **terms and conditions** for making the biocidal product available on the market;
- **Use** of the single biocidal product or the biocidal product family;
- Summary of the **biocidal product characteristics**

6.4 Biocidal Products already Authorised under the UK BPR

Any **authorisation/registration** granted under the UK BPR will be valid and all existing conditions and restrictions will continue to apply until the expiry of the authorisation or it is revoked or cancelled. There are specific requirements that have to be adhered to:

Existing GB products: transfer to GB BPR

Article 89 of the GB Biocidal Products Regulation (GB BPR) lets biocidal products, which are currently allowed to be made available on the market under other national law in Great Britain (GB), transition to authorisation under GB BPR.

Such products will contain existing active substances that are under review for the relevant product type as part of the GB Review Programme.

Making available on the market means any supply of a biocidal product, whether in return for payment or free of charge, at all stages of the supply chain. Some examples of this could include:

- manufacturer to distributor
- distributor to retail store
- retail store to user

Biocidal products that are already available on the GB market under other national law fall into two categories:

- those with approval under the Control of Pesticides Regulations (COPR)
- those not needing HSE approval under COPR - but they may need to comply with other national law in GB

6.5 Product received Authorisation

Once authorisation is obtained there are ongoing requirements:

Other requirements

Once you have received product authorisation, you will need to:

- ensure you comply with any deadlines associated with the authorisation, such as for any post authorisation data requirements, or your authorisation may be cancelled
- note your authorisation expiry date - the authorisation will expire on the date shown unless the authorisation holder submits a valid application for renewal at least 550 days before the expiry date

There are additional requirements placed on biocidal products by GB BPR which include (but are not limited to):

- packaging and labelling requirements …
- advertising requirements …
- record keeping requirements …
- notification of unexpected or adverse effects … all authorisation holders must notify HSE without delay of any information they become aware of concerning the biocidal product, or the active substance(s) it contains, that may affect the authorisation, for example:
  - new data or information on the harmful effects of the active substance or biocidal product on humans, animals or the environment
  - any data indicating the potential development of resistance to the active substance or biocidal product
  - new data or information indicating that the product is not sufficiently effective

In addition to complying with GB BPR you should ensure you comply, where applicable, with general chemical and product safety law which continues to operate such as:

- GB Classification, Labelling and Packaging of Substances and Mixtures (GB CLP) Regulation
- General Product Safety (GPS) Regulations

6.6 Submission and validation of New Applications for Active Substances

The **application for approval of an active substance** must meet certain requirements laid down in the UK BPR, including the submission of a **dossier** and payment of a **fee**.

The **evaluation of the application** in the United Kingdom will be carried out by the HSE. The HSE will evaluate the application within the timeframe and procedures laid down by the UK BPR.

6.7 Submission and Acceptance of Renewal Applications for Active Substances

Under the UK BPR, the renewal of the approval of an active substance will be carried out by the HSE

The **evaluation of the renewal application** will be carried out by HSE within the timeframe and procedures laid down by the UK BPR

…Persons placing active substances on the market, they should be required to hold a dossier, or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products. Biocidal products containing active substances for which the relevant person does not comply with that obligation should no longer be made available on the market. In such cases, there should be appropriate phase-out periods for disposal and use of existing stocks of biocidal products…

6.8 Submission and Acceptance of Applications

An application by or on behalf of an authorisation holder wishing to seek the renewal of a authorisation must be submitted to the HSE before the expiry date of the authorisation.

The **evaluation of the application** will be carried out by HSE within the timeframe and procedures laid down by the UK BPR

7. Classification, Packaging and Labelling of Biocidal Products

All authorisation holders must ensure that their biocidal products are classified, packaged and labelled:

…In accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements….

In addition:

- Products **which may be mistaken for food**, including drink, or feed shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they must contain components to discourage their consumption and, in particular, shall not be attractive to children. ##

- Authorisation holders must ensure that **labels are not misleading** in respect of the risks from the product to human health, animal health or the environment or its efficacy;

- Authorisation holders must ensure that labels do not mention certain **indications**.

- The label must show **clearly and indelibly** specific information as laid down by the UK BPR.

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- Where due to the size of the biocidal product specific information cannot be included in the label, this may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

8. Advertising under the UK BPR

An '**advertisement'** is defined as a means of **promoting the sale** or **use of biocidal products** by printed, electronic or other media. A biocidal product holder must comply with the provisions of the Regulation on classification, labelling and packaging and that of the UK BPR.

Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences 'Use biocides safely. Always read the label and product information before use.'. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

…Advertisers may replace the word 'biocides' in the prescribed sentences with a clear reference to the product-type being advertised.
Advertisements for biocidal products shall not refer to the
product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication.

9. Obligation for Notification of Unexpected or Adverse Effects

Once a biocidal product holder becomes aware of information that **may affect the authorisation** of an **authorised biocidal product** or its **active substance(s)**, the holder of the authorisation must **promptly notify** the HSE. In particular, the following must be notified:

- **New data** or information on the **adverse effects of the active substance** or **biocidal product** for humans, in particular vulnerable groups, animals or the environment;

- Any data indicating the **potential of the active substance** for the development of resistance;

- **New data** or information indicating that the **biocidal product is not sufficiently effective**.

10. Data Protection

With regard to the **protection of data** held by the HSE, such data shall not be used by the HSE for the benefit of a subsequent applicant, except where:

- The subsequent applicant submits a **letter of access**; or

- The relevant time **limit for data protection has expired**.

The UK BPR provides for protection of data up to a maximum limit. Once the protection expires, it is lost.

Data protection

The GB Biocidal Products Regulation (GB BPR) specifies protection periods for data submitted **for the first time** in support of active substance approvals and biocidal product authorisations. This is intended to protect the interests of companies that have submitted proprietary information. It also allows them to recover some of the cost of generating data from other companies who wish to use the data in support of their own applications.

Under these protections, the data may only be used by HSE for the benefit of another applicant if one of the following conditions is met:

- that applicant provides a letter of access from the original data submitter
- the data protection has expired

The data protection periods begin when the data are submitted **for the first time** and vary in length depending on the circumstances of the data submission.

Once the data protection has expired, HSE may grant permission for subsequent applicants to refer to the data. However, data which are no longer protected are still the property of the original data owner and HSE will not give copies of such data to other applicants.

Data protection cannot be granted for:

- data that are published / available in the public domain
- data that have already been submitted in support of an active substance approval or product authorisation
- data that were already protected following an approval or authorisation decision before the end of the Transition Period which followed the UK leaving the EU – the existing protection periods remain valid and extensions to the existing expiry dates or new data protection periods will not be granted

Active substances

If the data are submitted for …	and the active substance is	the data protection will end
active substance approval	new	**15 years** from the first day of the month following the date of approval or inclusion onto the GB Simplified Active Substance List
	existing	**10 years** from the first day of the month following the date of approval or inclusion onto the GB Simplified Active Substance List
renewal of an active substance approval	new or existing	**5 years** from the first day of the month following the date of renewal

Biocidal products

If the data are submitted for …	and the active substance is	the data protection will end
product authorisation	new	**15 years** from the first day of the month following the date of authorisation
	existing	**10 years** from the first day of the month following the date of authorisation
renewal of a product authorisation	new or existing	**5 years** from the first day of the month following the date of renewal
change of a product authorisation	new or existing	**5 years** from the first day of the month following the date of authorisation of the change

Treated Articles

11. What is a Treated Article?

A treated article is defined as:

> …A treated article means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products……

The HSE's current view of what a treated article and a biocidal product are as follows:

> **Treated article or biocidal product?**
>
> To determine if you are dealing with a treated article or a biocidal product, you need to decide if the article has primary biocidal function.
>
> As a general principle, a function of an article is:
>
> - **primary** if the biocidal action cannot be removed without fundamentally altering the purpose or intended use of the article, for example, if you remove the biocides from a disinfectant wipe, the wipe no longer has any purpose – the disinfecting action is the primary biocidal function

- **secondary** if the biocidal action can be removed and the article can still be used for the non-biocidal purpose by the same intended user, for example, a chopping board which incorporates a disinfectant can still be used to prepare food if the disinfectant is removed – the disinfecting action is a secondary function as the primary function is to prepare food

A treated article which only has one function, and when this function is also biocidal, has by default a primary biocidal function. For example, mosquito nets which are treated with insecticide or insect repellent are intended solely to control mosquitoes. Removing the insecticide or insect repellent does not fundamentally alter the purpose or intended use of the net as it will still control mosquitoes.

Some articles might be both a biocidal product **and** a treated article.

Complex articles are those that are made up of several parts eg a sofa is made up of a frame, cushions, fabric cover etc. Complex articles can be treated articles too, even if only one of the parts has been treated with or incorporates a biocidal product.

Examples

Article	**Treated article or biocidal product**	**Comments**
wooden bench painted with wood preservative	treated article	The bench can still be used as seating if the wood preservative is removed. The wood preservative used to paint the bench would be the biocidal product.
socks with odour free / stay fresh or antibacterial claim	treated article	The socks can still be used to keep feet warm if the biocide is removed. The product used to treat the socks / fibres would be the biocidal product.
mosquito repellent wrist band	biocidal product	The purpose of the wrist band would be fundamentally altered if the repellent was removed.
interior paint containing an in-can preservative	treated article	The paint can still be used to colour walls if the in-can preservative is removed. The preservative added to the paint would be the biocidal product.
sofa with a wooden frame treated with a wood preservative	complex treated article	The sofa can still be used as seating if the wood preservative is removed. The wood preservative used to treat the frame would be the biocidal product.
wood preservative paint also containing an in-can preservative	biocidal product **and** treated article	The purpose of the paint would be fundamentally altered if the wood preservative was removed, but the paint can still be used to preserve wood if the in-can preservative is removed. The preservative added to the paint would also be a biocidal product
disinfectant coating applied	biocidal product	The purpose of the coating would be fundamentally

Article	Treated article or biocidal product	Comments
to eg public transport grab bars / rails		altered if the disinfectant was removed.
disinfectant added as part of the manufacturing process eg public transport grab bars / rails	treated article	The public transport grab bar / rail can still be used to steady / assist someone if the disinfectant is removed. The biocidal function (to stop the spread of bacteria, viruses etc) should not be the prominent / primary claim as this would make it a biocidal product. The product added as part of the manufacturing process would be the biocidal product.
face mask that incorporates a disinfectant in the fabric to prevent the spread of bacteria, viruses etc	biocidal product	The only purpose of the mask is to prevent the spread of bacteria, viruses etc. Removing the disinfectant does not fundamentally alter the purpose or intended use of the mask.

Requirements of the law

The requirements relating to treated articles in GB BPR:

- only apply to treated articles that are **not** biocidal products
- prohibit the treated article from being placed on the market unless:
  - **all** the active substances in the biocidal product it was treated with / incorporates are approved for the relevant product type and use or are included on the GB Simplified Active Substance List **and**
  - any specified conditions or restrictions relating to the active substance(s) are met
- include if and how the article should be labelled
- allow consumers to request information on the biocidal treatment of the treated article

Placing on the market means the first making available on the market of a treated article. This means the first act of supply of a treated article, whether in return for payment or free of charge. Some examples of this could include:

- manufacturer to distributor, retail store or end user
- importer to distributor, retailer or end user

12. Manufacturers, importers, suppliers and distributors of Treated Articles

If you are a **manufacturer**, **importer, supplier or distributor** of Treated Articles, you ~~you~~ must make sure that the **active substance**(s) is approved for the relevant product type and use or is included on the **GB Simplified Active Substance List** before you place a treated article on the UK market:

Before you place a treated article on the GB market you must make sure that the active substance(s) is approved for the relevant product type and use or is included on the GB Simplified Active Substance List.

If the active substance is not yet approved for the relevant product type or included on the GB Simplified Active Substance List, you may still be able to place the treated article on the GB market – check the '**Can be used in treated articles**' column on the GB List of Active Substances. If this column is marked with '**Yes**' for the active substance / product type combination, you may place the treated article on the GB market until either:

13. Labelling of Treated Articles

Labelling of treated articles must comply with the provisions of the UK BPR. The UK BPR requires manufacturers and importers of treated articles to label their products when:

- A claim is made that the treated article has biocidal properties;
- The conditions of the approval of the active substance use to treat the article require specific labelling provisions to protect public health or the environment.

14. Placing on the Market of Treated Articles

The UK BPR applies exclusively to **treated articles** that are **not biocidal products**. It does not apply to treated articles where the sole treatment to be undertaken is the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.

Therefore, a treated article cannot be placed on the market unless **all active substances** contained in the biocidal products treating the article are included in the Annex to the UK BPR for this product-type and any conditions or restrictions specified that are specified in the Annex are met.

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Tags

RT Coopers Solicitors and our biocide lawyers providing regulatory law and biocides legal advice on biocidal product regulation including biocidal product authorisation, treated articles regulation, biocides, pesticides as well as the classification, labelling and packaging of

biocidal products, antibacterial, disinfectants, insecticides, veterinary products, antimicrobial products, furniture painted with wood preservatives and product regulation