Biocidal Products or Treated Articles: Imports and Exports

1. Are you looking to import biocidal products into the UK?

There is GB legislation in place that you must **comply** with if you intend to place a **biocidal product or treated article on the UK market**. Therefore, the first step is to ensure that the biocidal product is compliant, writes Dr Rosanna Cooper.

See excerpts from an article on **UK Biocidal Regulation: Treated Articles** by Dr Rosanna Cooper of **RT Coopers Solicitors** below:

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…

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**.

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.

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.

The full **article** on **UK Biocidal Regulation: Treated Articles** is available **here**.

2. Excerpts from Health and Safety Executive

We have also reproduced excerpts from the HSE website where relevant in this article:

If you are importing biocidal products or treated articles into Great Britain (England, Wales and Scotland), you must comply with all relevant GB legislation **before** you place the product or treated article on the market. Find out if the **biocidal product** or **treated article** you want to import complies with GB laws on biocides.

If you are importing biocidal products into Great Britain from Northern Ireland, you may need to notify HSE. **Find out about unfettered access for biocides.**

Placing on the market means making the product or treated article available on the market for the first time. This means the first act of supply of a biocidal product or 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

- You should **find out if UK REACH applies** to the biocidal product or treated article you want to import.

If you are importing biocidal products or treated articles into Great Britain with the sole intention of re-exporting it outside of Great Britain, this is **not** considered as placing on the GB market where:

- the biocidal product or treated article is not released for free circulation
- has not left the stocks of the importer, for example, it's not supplied for distribution or use on the GB market

If the product or treated article is not placed on the market in GB prior to export, GB BPR does not apply.

3. Are you looking to export biocidal products from the UK to Northern Ireland, the EU, the EEA or Switzerland?

If you intend to export your biocidal product to Northern Ireland, the EU, the EEA or Switzerland you must comply with their legislation. Remember the UK adopted the EU Biocidal Regulations from January 2021:

If you are exporting biocidal products or treated articles to Northern Ireland, the EU, the EEA or Switzerland, you must comply with all legislation applicable in that country, including the **EU Biocidal Products Regulation (EU BPR).**

You may also need to comply with GB legislation such as **GB Prior Informed Consent (GB PIC)** or specific **customs and export rules**.

4. Are you looking to export biocidal products from the UK to a non-EU country (outside of the EU, EEA or Switzerland)?

In addition to checking that your biocidal product ios compliant with the legislation in the respective country, you may require a Certificate of Free Trade (see below).

If you are exporting biocidal products or treated articles outside of the EU, the EEA or Switzerland, you should check any relevant legislation in the importing country. You may be asked by the importing country to provide a Certificate of Free Sale (CFS) if you are exporting a biocidal product or an active substance.

A CFS is an official document confirming that the product complies with the relevant laws on biocides and may be freely sold across Great Britain. HSE can issue various **CFS or Export Statements** depending on the status of the biocidal product or active substance, for example, whether it is already authorised or approved under GB BPR or being evaluated.

The author is **Dr Rosanna Cooper** of RT Coopers Solicitors. She is an expert in all aspects of regulatory law. Dr Cooper is a chartered chemist and a fellow of the Royal Society of Chemistry. She may be contacted on +44 (0) 207 488 9947 or by email: enquiries@rtcooperssolicitors.com. For more information on the services provided by RT Coopers on regulatory law, visit http://www.rtcoopers.com/regulatorylaw.php and www.rtcoopers.com/practice_biocides.php.