New EU Biocidal Regulation: Treated Articles

The Biocidal Product **Regulation** EU 528/2012 ("BPR") comes into effect on 1 September 2013[1]. It replaces the **Biocidal Directive** 98/8/EC. The BPR will be binding in its **entirety and directly applicable** in all Member States of the European Union. The BPR concerns companies **making biocidal products available on the EU market** and the placing on the market of **treated articles**. It also deals 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 BPR is to ensure that **biocidal products** and **treated articles** are authorised.

…Biocidal products should neither be made available on the market nor used unless authorised in accordance with this Regulation. Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation..

…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…

Before any biocidal product can be placed on the market in the EU, it must have an **authorisation**, and the **active substances** contained in that biocidal product **must be previously approved**. Please note there are exceptions:

- **Active substances** under the review programme;
- Biocidal products containing these active substances can be placed on the market while awaiting the **final decision** on the approval;
- **Provisional product authorisations** for new active substances that are still under assessment are also allowed on the market.

[1] A regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the European Union

In the BPR it states that:

Rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade.

Purpose of the BPR

This BPR lays down rules for:

- The **establishment at Union level** of a **list of active substances** which may be used in biocidal products;
- The **authorisation of biocidal products**;
- The **mutual recognition of authorisations** within the Union;
- The **making available on the market** and the **use of biocidal products** within one or more Member States or the Union;
- The **placing on the market of treated articles**.

What is a Biocidal Product?

Under the 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 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 Union.

- '**Authorisation**' means national authorisation, Union authorisation or authorisation in accordance with Article 26.

- '**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 by competent authorities, the Agency, or the Commission for the purposes of the BPR.

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

What is a Treated Article?

Under Article 3 the BPR, 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 BPR introduces mandatory data sharing obligations whilst encouraging the use of alternative testing methods.

The table below gives the HSE's current view of what a treated article and a biocidal product are (this is subject to change once further guidance is published at the European level)[2].

Type of article	**Treated Article or Biocidal Product**
Article treated with a biocide (e.g. a wooden bench painted with wood preservative) with the sole intention of controlling organisms harmful to the treated article/material itself	Treated Article must comply requirements in Article 58
Article is treated with a biocide and the primary function of the article is **not** as a biocide (e.g. antibacterial sock)	Treated Article must comply requirements in Article 58
Article is treated with a biocide and the primary function of the article is as a biocide (e.g. antibacterial wipe)	Biocidal Product which requires authorisation

The 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.*

Under **REACH**, consumers may request from the supplier of a treated article information on the biocidal treatment of the treated article. This information must be provided with 45 days and free of charge.

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 (Article 92).

[2] Acknowledgement - table reproduced from HSE website

From 1 September 2013, the requirements of the BPR will also apply to such **authorisation/registration**.

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**.

In accordance with Article 3, 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 BPR, all products within the biocidal product family will be covered by one authorisation.

Key issues

With regard to the Biocidal **Directive** 98/8/EC, there have been less than 60 substance reviews completed, and around 12 or so products authorised. The point is that a number of active substances have been withdrawn due to the high costs of 'supporting' these products through the authorisation process.

The aim of the BPR is to **simplify and streamline existing EU requirements** whilst maintaining a high level of protection to health and the environment.

For companies currently marketing biocidal products or producing active substances, there is no need to take any action right now, particularly, if the application for an active substance and/or biocidal product is under review in accordance with the Biocidal **Directive** 98/8/EC and current UK regulations.

Gaining approval under the BPR follows the same **two-step procedure** as under the Biocidal **Directive** 98/8/EC:

- For the **approval** of active substances at EU level; and

- The **authorisation** of biocidal products in Member States.

Under the BPR, the current review programme of **active substances** will continue. There is a clear procedure for **evaluation and approval** of both biocidal products and active substances.

What are the changes under the BPR?

The changes brought about by the BPR will affect businesses selling biocidal products and/or producing active substances:

- Companies will have the option to **apply for authorisation of a biocidal product across the whole of the EU** by applying to the European Chemicals Agency (ECHA).

- The BPR provides for ECHA to deal with applications for the **approval of active substance**.

- The BPR makes allowances for companies to **source active substances from other companies** other than the suppliers of the active substances listed in support of applications. This means that when companies are making biocidal products available on the EU market the suppliers of the active substances must have access to the data that 'supports' the applications

- Improve the mutual recognition process by the introduction of **binding deadlines** and a stronger system for **mutual recognition dispute settlement**;

- A **database of suppliers** will be maintained by ECHA.

- If you are importing an article into the EU that is treated with a biocide, you will have to ensure that the **active substance** of the **biocide** is **approved under the BPR**. Any biocidal **claims** for the **treated article**, should carry a **label** with information about the biocide;

- The BPR has a **two-step approach** for evaluation;

- Some biocidal products can be authorised at the Union level granting direct access to the entire Union market.

- Obligatory **data sharing** is intended to reduce the number of animal tests in relation to vertebrate animal studies;

- Any person placing biocidal products on the market will be required to **hold the data** on active substances.

In most cases there are transitional arrangements before these provisions apply fully.

Simplified Authorisation Procedure for Biocidal Products

There is a distinction between the **approval** of **active substances** and **biocidal products.** The **approval of active substances** takes place at Union level and the authorisation of biocidal products at Member State level, the HSE in this case. The list of active substances can be found in Annex I of the BPR.

The process is extended to other Member States by mutual recognition. The BPR allows for authorisation at Union level. Article 27 of the BPR provides that once a **product** is authorised in at least one Member State, the product can be **made available** on the market in all Member States without the need for mutual recognition, provided certain conditions are met.

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 ECHA in accordance with its procedure.

If the application or prospective authorisation holder fails to pay the fees to the competent authority in 30 days, the application will be rejected.

…Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder..

It is worth noting that:

…A biocidal product authorised in accordance with Article 26 may be made available on the market in all Member States without the need for mutual recognition. However, the authorisation holder shall notify each Member State no later than 30 days before placing the biocidal product on the market within the territory of that Member..

Member States can restrict the marketing of biocidal products in the EU:

Where a Member State has valid reasons to consider that a biocidal product authorised in accordance with Article 26 does not meet the criteria laid down in Article 25 and a decision pursuant to Articles 35 and 36 has not yet been taken, that Member State may provisionally restrict or prohibit making available on the market or use of that product on its territory.

Submission and validation of New Applications for Active Substances

Under Article 7 of the BPR, the approval of an **active substance** will be carried out by the Agency:

The applicant shall submit an application for approval of an active substance, or for making subsequent amendments to the conditions of approval of an active substance, to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do

so. That competent authority shall be the evaluating competent authority.

The '**Agency**' means the **European Chemicals Agency** established by Regulation (EC) No 1907/2006.

The **application for approval of an active substance** must meet certain requirements laid down in the 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 Health and Safety Executive ("HSE")[3] as the **competent authority**. The HSE will evaluate the application within the timeframe and procedures laid down by the BPR.

Approved active substances shall be included in a Union list of approved active substances. The Commission shall keep the list up to date and make it electronically available to the public.

'Union authorisation' allows an application to be made via a single authorisation, avoiding the need for mutual recognition of a national authorisation.

Union authorisations are for biocidal products with **similar conditions of use** across the Union (certain exceptions apply).

Depending upon the product types, Union authorisation will be available in three different stages:

- From **1 September 2013** for product types 1, 3, 4, 5, 18 and 19.
- From **1 January 2017** for product types 2, 6 and 13.
- From **1 January 2020** onwards to the remaining products types 7, 8, 9, 10, 11, 12, 16 and 22.

Product Types

Under the BPR, biocidal products are classified into **22 biocidal product-types**, grouped into four main areas. It is worth noting that preservatives for food and feedstock are not within the scope of the BPR[4].

[3] In the UK

[4] The full list of product types can be found in Annex V of the BPR.

…Biocidal products intended to be used not only for the purposes of this Regulation, but also in connection with medical devices, such as disinfectants used to disinfect surfaces in hospitals and medical devices, may pose risks other than those with which this Regulation is concerned. Therefore, such biocidal products should comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements set out in Annex I to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([1]), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([2]) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices …

Therefore, the present Regulation should not apply to food and feed used as repellents or attractants.

Product Type	Examples
MAIN GROUP 1: Disinfectants	These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.
Product-type 1: Human hygiene	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
Product-type 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.
Product-type 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.
Product-type 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 impregnate materials which may enter into contact with food.
Product-type 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.
Product-type 6: Preservatives for products during storage	Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, 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 other baits.
Product-type 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.
Product-type 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.
Product-type 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.
Product-type 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.
Product-type 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.
Product-type 12: Slimicides	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
Product-type 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	
Product-type 14: Rodenticides	Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.
Product-type 15: Avicides	Products used for the control of birds, by means other than repulsion or attraction.
Product-type 16: Molluscicides, vermicides and products to control other invertebrates	Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion or attraction.
Product-type 17: Piscicides	Products used for the control of fish, by means other than repulsion or attraction.
Product-type 18: Insecticides, acaricides and products to control other arthropods	Products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.
Product-type 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.
Product-type 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	
Product-type 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.
Product-type 22: Embalming and taxidermist fluids	Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

Submission and Acceptance of Renewal Applications for Active Substances

Under Article 13 of the BPR, the renewal of the approval of an active substance will be carried out by the Agency:

Applicants wishing to seek renewal of the approval of an active substance for one or more product-types shall submit an application to the Agency at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.

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

Submission and Acceptance of Applications

An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation must be submitted to the Agency 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 BPR

Submission and Validation of Applications

Applicants wishing to apply for Union authorisation in accordance with Article 42(1) shall submit an application to the Agency, including a confirmation that the biocidal product would have **similar conditions of use across the Union**, informing the Agency of the name of the competent authority of the Member State that they propose should evaluate the application and providing **written confirmation** that the

competent authority has agreed to do so.

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

Authorisation through Mutual Recognition in Sequence

All Member States receiving applications for **mutual recognition** of a national authorisation for a biocidal product shall **authorise the biocidal product** under the **same terms and conditions** as the national authorisation

Applicants wishing to use the **mutual recognition in sequence** for the national authorisation of a biocidal product already granted in another Member State, in accordance with Article 17, have to **submit an application to each of the competent authorities of the Member States concerned**.

Authorisation through Mutual Recognition in Parallel

Applicants wishing to use the **mutual recognition in parallel** for a biocidal product which has not yet been authorised in accordance with Article 17 in any Member State, must **submit the application to the competent authority of the Member State of its choice**.

Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 of a particular product type.

The Union authorisation may be granted from **1 September 2013**, for biocidal products containing one or more new active substances and biocidal products of specific product-types. In January 2017 and 2020, Union authorisation may be granted for other biocidal product types.

Classification, Packaging and Labelling of Biocidal Products

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

…In accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008.

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 the indications '**low-risk biocidal product**', '**non-toxic**', '**harmless**', '**natural**', '**environmentally friendly**', '**animal friendly**' or **similar indications**.

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

    - The **identity of every active substance** and its concentration in metric units;

    - The **nanomaterials** contained in the product, if any, and any specific related risks, and, following each reference to nano-materials, the word 'nano' in brackets;

    - The **authorisation number allocated** to the biocidal product by the competent authority or the Commission;
    - The name and address of the authorisation holder etc.

- 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.

- Member States may require:
  - The provision of models or drafts of the packaging, labelling and leaflets;
  - That biocidal products made available on the market in their territories be labelled in their official language or languages.

Register for Biocidal Products

An **application for the authorisation of biocidal products** should be submitted via he **Register for Biocidal Products**. From 1 September 2013, ECHA will be responsible for coordinating the evaluation of applications.

The Agency is therefore obliged to maintain the **Register for Biocidal Products.**

Applicants for the authorisation of biocidal products:

- Should submit applications and data for all procedures covered by the BPR. The Agency will then check that correct format was followed and notify the relevant competent authority accordingly without delay or reject the application;
- Once the application has been validated or accepted by the HSE in this case, the details shall be made available via the Register for Biocidal Products to all other competent authorities and to the Agency;
- The HSE will update the information in the Register for Biocidal Products relating to biocidal products which it has authorised or refused, amended, renewed or cancelled;
- The Commission shall update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.

Making available on the Market and Use of Biocidal Products

Under Article 17 of the BPR, there are some important points to note:

- Biocidal products **shall not be made available on the market** or used unless authorised in accordance with the BPR.
- **Applications** for authorisation shall be made by, or on behalf of, the prospective authorisation holder.
- Applications for national authorisation in a Member State shall be submitted to the competent authority of that Member State i.e. the HSE.
- Applications for **Union** authorisation shall be submitted to the **Agency**.
- An authorisation may be granted for a **single biocidal product** or a **biocidal product family**.
- An authorisation shall be granted for a maximum period of **10 years**.
- Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69;
- Instructions for **safe disposal** of the product and its packaging;
- The conditions for **storage and shelf-life** of the biocidal product under normal conditions of storage;
- Any other information about the biocidal product.

Applicants wishing to apply for a national authorisation in accordance with Article 17 shall submit an application to the HSE.

Placing on the Market of Treated Articles

Article 58 of the 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 BPR for this product-type and any conditions or restrictions specified that are specified in the Annex are met.

Labelling of treated articles must comply with the provisions of the BPR.

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** including the following information:
  - The **trade name** of the biocidal product;
  - The **name and address of the authorisation holder;**
  - The **date of authorisation** and its expiry;
  - The **authorisation number** of the biocidal product;
  - **Qualitative and quantitative composition** in terms of the active substances and non-active substances;
  - The **manufacturers of the biocidal product** (names and addresses including location of manufacturing sites);
  - The **manufacturers of the active substances** (names and addresses

including location of manufacturing sites);

- The **type of formulation** of the biocidal product;
- The **hazard and precautionary statements**;
- The **product-type**;
- The target **harmful organisms**;
- The application **doses** and instructions for use;
- The categories of **users**;
- The particulars of likely direct or indirect **adverse effects.**

Advertising under the BPR

An '**advertisement'** is defined as a means of **promoting the sale** or **use of biocidal products** by printed, electronic or other media.

Article 72 deals with advertising. A biocidal product holder must comply with the provisions of the Rregulation on classification, labelling and packaging ("CLP Regulation") and that of the BPR.

Article 72 states that:

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.

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 and the Agency or, in the case of a Union authorisation, the Commission and the Agency. 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**.

Data Protection

With regard to the **protection of data** held by the HSE or the Agency, such data shall not be used by the HSE or the Agency 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**.

When **submitting data to the HSE or to the Agency** under the BPR, the applicant must:

- Indicate the **name and contact details of the data owner** for all data submitted;

- Specify whether it is the data owner/holds a **letter of access**.

- Applicant shall, without delay, inform the competent authority or the Agency about any **changes to the ownership of the data**;

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

Existing **active substance**	The **protection period** for data submitted with a view to the approval of an existing **active substance shall end 10 years** from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.
New active substance	The protection period for data submitted with a view to the approval of a **new active substance** shall end **15 years** from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.
Renewal or review of the approval of an active substance	The protection period for new data submitted with a view to the **renewal or review of the approval of an active substance** shall end five years from the first day of the month following the date of the adoption of a decision in accordance with Article 14(4) concerning the renewal or the review.

A biocidal product containing only existing active substances	The protection period for data submitted with a view to the authorisation of **a biocidal product containing only existing active substances** shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), Article 34(6) or Article 44(4).
A biocidal product containing a new active substance	The protection period for data submitted with a view to the authorisation **of a biocidal product containing a new active substance** shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), Article 34(6) or Article 44(4).
renewal or amendment of the authorisation of a biocidal product	The protection period for new data submitted with a view to the **renewal or amendment of the authorisation of a biocidal product** shall end five years from the first day of the month following the decision concerning the renewal or amendment of the authorisation.

Data Sharing

The BPR states that in order to avoid animal testing, **testing on vertebrates shall be undertaken only as a last resort.** Testing on vertebrates shall not be repeated for the purposes of the BPR.

Therefore, any person intending to perform tests or studies in the case of data involving tests on vertebrates must submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency

or to HSE in connection with a previous application. The Agency shall verify whether such tests or studies have already been submitted.

Where such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, under BPR or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant.

To encourage the development of new active substances and biocidal products containing them, it is necessary to provide for a period of protection with respect to the proprietary information submitted in support of the approval of such active substances or the authorisation of biocidal products containing them which is longer than the period of protection for information concerning existing active substances and biocidal products containing them.

Parallel Trade

According to Article 53,1, at the request of the applicant the HSE shall grant a **parallel trade permit** for a biocidal product that is authorised in another Member State to be made available on the market and used in the Member State of introduction, if it determines that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction. There is a fee payable.

A competent authority of a Member State ('Member State of introduction') shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another Member State ('Member State of origin') to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction ('the reference product').

The applicant who intends to place the biocidal product on the market in the Member State of introduction shall submit the application for a parallel trade permit to the competent authority of the Member State of introduction.

The HSE may request additional information necessary to determine whether the products are identical. There are specified timeframes for the delivery of this information.

A biocidal product shall be considered as identical to the reference product only if all the following conditions are met:

(a) they have been manufactured by the same company, by an associated undertaking or under license in accordance with the same manufacturing process;

(b) they are identical in specification and content in respect of the active substances and the type of formulation;

(c) they are the same in respect of the non-active substances present; and

(d) they are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human health, animal health or the environment.

4.An application for a parallel trade permit shall include the following information and items:

(a) name and authorisation number of the biocidal product in the Member State of origin;

(b) name and address of the competent authority of the Member State of origin;

(c) name and address of the authorisation holder in the Member State of origin;

(d) original label and instructions for use with which the biocidal product is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction;

(e) name and address of the applicant;

(f) name to be given to the biocidal product to be distributed in the Member State of introduction;

(g) a draft label for the biocidal product intended to be made available on the market in the Member State of introduction in the official language or languages of the Member State of introduction, unless that Member State provides otherwise;

(h) a sample of the biocidal product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

(i) name and authorisation number of the reference product in the Member State of introduction.

Under Article 95 (3) of the BPR, after the **1st September 2015,** biocidal products cannot be made available on the EU market **if the active substance manufacturer/importer is not on the list**.

*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.*

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