

Biocidal products and treated articles: requirements for manufacturers and importers under the European Regulation BPR 528/2012

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The transition period allowed for compliance of articles treated with biocides in Article 58 of the European Regulation on Biocidal Products (EU BPR 528/2012) ended March 1, 2017.

This article summarizes the requirements for producers and importers for placing treated articles on the EU market.

The EU Biocides Regulation 528/2012 (EU BPR) contains provisions which apply not only to biocidal products, which are classified in 22 product types based on their intended use, but also to all articles which have been treated with or incorporate a biocidal product.



While biocidal products may be placed on the EU market subject to approval and registration, treated articles do not undergo a registration process; however they may only be placed on the EU market if all the biocidal active substances they have been treated with are either approved/included in Annex I of BPR, or are under evaluation in the review programme. Treated articles must carry a label providing information as to the biocidal treatment received.

When should a compound containing biocides be considered a treated article rather than a biocidal product? Should all items that have been treated with biocides, at any step of their manufacturing process, be considered to be treated articles?

This article gives some indication on how to distinguish between treated articles, biocidal products and articles which, despite the content of some biocides, do not fall into either of the two categories.

DEFINITIONS

Treated article

Article 3 of the EU BPR defines a treated article as “any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products”.

Treated articles must comply requirements in Article 58 of EU Biocides Regulation 528/2012

Biocidal product

Article 3 of the EU BPR defines a biocidal product as “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”.

Biocidal products and treated articles: requirements for manufacturers and importers under the European Regulation BPR 528/2012

Elena Conti

Biocidal products require authorization and registration under EU Biocides Regulation 528/2012.

Biocidal function/biocidal property

Articles may be treated with biocides to be conferred either biocidal properties or biocidal functions.

Biocidal property: articles that are treated with the sole intention of controlling organisms harmful to the treated article itself, e.g. wooden garden furniture painted with wood preservative, has a biocidal property.

Biocidal function: antimicrobial treatments made, for example, to computer keyboards to prevent bacterial growth on the surface, to hospital furniture to kill germs on contact, to door handles to prevent cross-infection and to textiles to prevent odours, confer a biocidal function to the treated articles, whose primary function, however, will remain the one determined by their shape and design.

A treated article is different from a biocidal product, in that its biocidal function is not its primary function. On the other hand, a treated article that has a primary biocidal function shall be considered a biocidal product.



The definition of treated article implies that the treatment with or incorporation of a biocidal product is made with the intention of conferring a biocidal property (or even a biocidal function) to the treated article, and can thus be expected to lead to a beneficial and desired effect in the finished good (e.g. protecting it from bio-degradation during storage or use). Following this logic, the scope of treated articles shall exclude such biocidal treatments or incorporation of biocides which were made in the course of manufacturing merely in order to perform a specific biocidal function at that stage of the process, but will not have an intended biocidal effect in the finished good as placed on the EU market. Examples of such exclusions are:

- goods and packaging materials which have been treated with biocidal fumigants or disinfectants to comply with international laws regulating import from extra UE countries, where no residues are expected to remain, are not considered to be treated articles.
- The presence of traces of a biocidal product that has been used to preserve some of the components, e.g. in-can preservatives of a paint used for coating a window frame, does not imply that the window itself is a treated article.
- Finished good incorporating a substance which is known to have some biocidal activity, but which has been used for reasons unrelated to this biocidal activity (e.g. essential oils, such as lavender oil, that may be used to perfume certain articles) are not considered treated articles.

These concepts are summarized in Table n. 1.

REQUIREMENTS FOR MANUFACTURERS AND IMPORTERS

Treated articles with either biocidal function or biocidal property must comply requirements in Article 58 of EU Biocides Regulation 528/2012.

EU BPR prohibits placing on the market of the treated article unless all active substances in the biocidal pro-

Biocidal products and treated articles: requirements for manufacturers and importers under the European Regulation BPR 528/2012

Elena Conti

Type of article	Requirements
Article treated with/incorporates 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 with biocidal property must comply requirements in Article 58 of EU Biocides Regulation 528/2012
Article is treated with/incorporates a biocide and the primary function of the article is not as a biocide (e.g. odour free/ stay fresh antibacterial sock).	Treated Article with biocidal function must comply requirements in Article 58 of EU Biocides Regulation 528/2012.
Article is treated with /incorporates a biocide and the primary function of the article is as a biocide (e.g. antibacterial wipe).	Biocidal product which requires authorization and registration in compliance with EU Biocides Regulation 528/2012.
Article contains biocidal products that do not perform a biocidal function and do not confer biocidal properties to the article in use, or has undergone treatments that do not leave biocide residues (e.g. window frame painted with paint containing in-can preservative; wooden pallet that has been fumigated according to phytosanitary legislation).	The article has neither biocidal property nor function and is not subject to any requirements.

Table 1.

duct it was treated with/incorporates are approved for the relevant product-type and use under EU BPR, and any specified conditions or restrictions relating to the active substances are met.

For example, if a textile has been treated with a biocidal product which will preserve the article as well as prevent the development of bad odours, the active substance(s) shall have been approved for product-type 9, as this product-type covers both products used for the preservation of fibres as well as products which antagonise the settlement of micro-organisms and thus prevent the development of odours.

However, if a textile has been treated with a biocidal product preserving the article as well as giving it a disinfecting function, the active substance(s) shall have been approved for both product-types 2 and 9, as product-type 2 covers products used to be incorporated in textiles with the purpose of producing treated articles with a disinfecting function, whilst product-type 9 covers products used for the preservation of fibres.

Manufacturers, importers or others who place treated articles on the market also have to include specific information on labels on the treated articles they place onto the market. These include:

- a. a statement that the treated article incorporates biocidal product(s)
- b. where substantiated, the biocidal property attributed to the treated article
- c. the name of all active substances contained in the biocidal products
- d. the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets
- e. any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates

Finally, anyone supplying treated articles on the market must provide, free of charge when requested, information on the biocidal treatment of the treated article. This information must be provided within 45 days.

In Table n. 2 examples are given of articles that qualify as treated articles, relative to each biocidal product-type (adapted from EC Note for Guidance CA-Sept 13-Doc.5.1e Revision 1, December 2014).

Biocidal products and treated articles: requirements for manufacturers and importers under the European Regulation BPR 528/2012

Elena Conti

PT1 (human hygiene disinfectants)	Any chemical substance, mixture or article containing biocides that fall into these PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.
PT2 (disinfectants) PT3 (veterinary hygiene products) PT4 (food and feed area disinfectants)	Any chemical substance, mixture or article containing biocides that fall into these PTs are likely to be classified as biocidal products due to their use and the nature of the biocidal effect. The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles.
PT5 (drinking water disinfectants)	Any chemical substance, mixture or article containing biocides that fall into these PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.
PT6 (preservatives for products during storage)	Biocidal products of PT6 are widely used to preserve products during storage. If the preserved good (a chemical substance, a mixture or an article) itself is placed on the market it qualifies as a treated article. An exceptional case are biocidal products (examples given in BPR, Annex V are rodenticides, insecticides, other baits, but in principle applicable to all BPs), preserved with PT6 preservatives, which qualify as biocidal products due to the presence of other biocidal active substances. Chemical substances and mixtures containing an in-can preservative may however be further used as ingredients in the manufacturing process of other finished goods. If the in-can preservative of such an ingredients in such cases has no further intended biocidal function later in the finished good, the residual presence of preservatives stemming from preserved ingredients should not qualify the finished good as a treated article. Also solid components used in the manufacture of a complex finished article may incorporate a PT6 preservative. In such cases it needs to be considered whether the preservation is relevant only during storage of this component (and not later in the finished article), or whether the preservation is also beneficial during the storage and possibly use of the finished article. In the first case, the finished article does not qualify as a treated article. In the latter case, the finished article would have to be considered a treated article.
PT7 (film preservatives)	The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles.
PT8 (wood preservatives)	Biocidal products of PT8 (wood preservatives) will usually be used with the intention to provide long-term preservation of the wood, which would continue to be effective in the finished good, which would thus qualify as a treated article. Exceptions to this may be PT8 biocidal products used at saw-mill stage or during initial storage, which only serve to protect the wood at this stage from harmful organisms (e.g. short-term preservation of freshly cut wood with fungicides to prevent the discoloration caused by blue stain forming fungi until further processing), or curative treatments of wood before being manufactured into a finished good. Articles made at a later stage from wood that has undergone such treatments should not be considered treated articles.

Biocidal products and treated articles: requirements for manufacturers and importers under the European Regulation BPR 528/2012

Elena Conti

<p>PT9 (fibre, leather, rubber and polymerised materials preservative)</p> <p>PT10 (construction material preservatives)</p>	<p>The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles.</p>
<p>PT11 (preservatives for liquid-cooling and processing systems)</p>	<p>Biocidal products of PT 11 are likely to be used mainly in closed systems. Any traces of such preservatives in finished goods produced in the facility using these biocidal products should be considered unintentional and thus do not qualify the good as a treated article.</p>
<p>PT12 (slimicides)</p>	<p>Biocidal products of PT12 are used in industrial processes to control slime growth at certain stages. Any traces of the AS in a finished good should be considered unintentional and thus do not qualify the good as a treated article. However, any liquids, fluids etc. containing slimicides, when placed themselves on the market, have to be considered treated articles.</p>
<p>PT13 (working or cutting fluid preservatives)</p>	<p>Cutting or working fluids are used at certain stages of the production process. Any traces of such preservatives in finished goods produced in the facility using these biocidal products, should be considered unintentional and thus do not qualify the good as a treated article. However, any working or cutting fluids containing preservatives, when placed on the market, have to be considered treated articles.</p>
<p>PT4-17,20 (vertebrate pest control)</p>	<p>Any chemical substance, mixture or article containing AS that fall into these PTs are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.</p>
<p>PT18 (insecticides)</p>	<p>Chemical substances or mixture containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.</p>
<p>PT19 (repellents and attractants)</p> <p>PT21 (antifouling products)</p> <p>PT22 (embalming and taxidermist fluids)</p>	<p>The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles.</p>

Table 2.

REFERENCES AND SOURCES:

<https://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles>

<https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr>

EC Note for Guidance CA-Sept 13-Doc.5.1e Revision 1, December 2014

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