Furniture Industry Research Association

FIRA Guide to European Biocidal Products Regulations



Published by

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on behalf of the **Furniture Industry Research Association**
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Foreword

This guide has been prepared by FIRA International Ltd on behalf of the Furniture Industry Research Association to assist FIRA members in various sectors of the furniture industry which may use biocidal products or treated articles such as kitchen, office, bedding, children's or healthcare sectors. FIRA is issuing this guide in order to help its members and their suppliers to comply with the obligations they may have under the Biocidal Products Regulations (B P R) Regulation (EU) 528/2012).

It does not replace any legislative documents that are available and is simply additional information to help achieve compliance. As such, the regulation and relevant supporting documentation (details of which can be found at the end of this document) must also be understood.

The dates and titles of standards and regulations referenced within this document were current at the time of publication. It is advised that advice be sought on the status of these and any other applicable documentation when assessing product conformity.

All efforts have been made to ensure this document is correct at the time of going to press. The opinions and advice expressed are given in good faith. However, the authors cannot be held responsible for any action resulting from the content of this guide as the ultimate interpretation of the regulations rests with the courts. Where serious doubt occurs professional legal opinion should be sought.

We recommend that you review and monitor the regulation(s) and standards, details of which can be found at the end of this document.

For the purposes of this guide, and with specific reference to the placing of product on the market, making available any products and distribution of products etc. this is only considered to the extent that it relates to placing product for use on the EU market. This may of course change in the event of a Brexit no-deal situation.

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1. Terms and definitions

Knowledge of the following terms and their definitions is essential to understand how the BPR affects your products.

Active ingredient is the active component or mix in a formulation that confers the efficacy of a product. It is now often used as a synonym to ''active substance' see below.

Active Substance is a substance or a micro-organism that has an action on or against harmful organisms. Hence, the biocidal function of an active substance is an intrinsic property.

Micro-organism is any microbiological entity, cellular or non-cellular, capable of *replication* or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoan and microscopic parasitic helminths.

Harmful organism is an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment.

Biocidal product is 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. For example – anti-fungal, anti-mould, anti-bacterial, anti-viral.

Primary biocidal function is not defined in the legal text of the Biocidal Product Regulations but is addressed in the note for guidance on treated articles from the European Commission as “a biocidal function of first rank, importance, or value compared to other functions of the treated article”.

Treated article which has a primary biocidal function shall be considered a biocidal product. The Commission Guidance defines the “function” of a treated article as the “intended purpose” for which the treated article is supplied. A treated article with a “biocidal function”, by analogy, is a treated article whose intended primary function is to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any harmless organism by means other than mere physical or mechanical action

Efficacy of a biocidal product can be defined as the power to produce an effect, and is related to the intrinsic efficacy of the active substance/s of the product and is influenced by the presence of non-active substances and the use pattern (e.g. efficacy rate against a given target organism).

Natural Biocide. Many biocides are synthetic, but there are naturally occurring biocides classified as natural biocides, derived from, e.g., bacteria and plants.

Nanomaterial is a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100nm.

Pathogenic Agents or infectious agents are a biological agent that causes disease or illness to its host. Typical pathogens include bacteria, viruses, fungi and protists.

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2. Scope and objectives of the BPR

The BPR aims to harmonise EU rules on the making available on the market and use of biocidal products, while ensuring a high level of protection of both human and animal health and the environment. It does this by laying down rules for:

- Establishing a harmonised EU list of approved active substances that may be used in biocidal products
- Authorisation of biocidal products and making them available on the EU market
- Mutual recognition of authorisations within the EU
- Placing on the market of treated articles.

The BPR applies to products intentionally marketed as “biocidal products” and the active substances they contain, consist of or generate. The Regulation also includes some exemptions in Article 2.2., as it does not apply to products falling under the scope of the Cosmetics Regulations and the Medical Device Directive.

The regulation can be found at:-

EU Biocidal Products Regulation (https://echa.europa.eu/regulations/biocidal-products-regulation/legislation)

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3. Introduction

The introduction of the new EU Biocides Regulation in September 2013 (528/2012) revoked the previous Biocidal Products Directive (98/8/EEC) across Europe. These new Regulations incorporated, for the first time, the 'use' phase of biocidal products as well as articles that have been treated with biocides.

A 'biocidal product'; is defined in the EU BPR 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*****"***

Biocide treatment is used in the marketing of a multitude of consumer products such as household appliances, furniture, building products and textiles, often citing specific protection against microorganisms such as E. coli, Salmonella and MRSA. Correspondingly, all active biocidal agents intended for use in the treatment of goods sold on the EU market must now receive prior authorization. Upon approval of the active substance it is included in the Union List of Approved Active Substances and must also be authorised for each in the member state where the products is to be sold.

A list of the approved active substances can be found at:-

EU Article 95 Union List of Approved Active Substances (https://echa.europa.eu/information-on-chemicals/active-substance-suppliers)

The EU BPR also contains provisions which apply not only to biocidal products but also to all articles, which have been treated with or incorporate a biocidal product. In particular, articles can only be treated with active substances which have been approved in the EU for that purpose.

EU BPR also states that:

"***a treated article that has a primary biocidal function shall be considered a biocidal product*****."**

The notes for guidance related to treated articles can be found at:-

(https://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles)

The BPR keeps a two-step approach for the authorisation of biocidal products. All active substances which biocidal products are consisting of, containing or generating should be approved for the relevant application/product type before the associated biocidal products may be authorised. Biocidal products are subject to a prior authorisation procedure before placed on the market for a specific application in the Member States of the EU.

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4. Biocidal Products vs Treated Articles

4.1 Biocidal Products

As previously described a biocidal product is

“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.”

4.1.1 Approval of Active Substances

As previously alluded to, biocidal product authorisation is a 2 step process and involves the approval and renewal of active substances. The provisions of the BPR concerning approval of active substances are contained in Chapter II (Articles 4-11) while the renewal of their approval is dealt with in Chapter III (Articles 12 16). The approval of an active substance is for an initial period of maximum 10 years, which can be renewed.

An active substance supplier must put together an active substance dossier with the data listed in Annex II to the BPR, as well as a dossier for requesting at least one biocidal product authorisation representative of the active substance used in the relevant product type. This dossier has to be sent to ECHA, which allocates it to an agreed national competent authority.

The national competent authority reviews and evaluates the dossier. ECHA will submit its opinion on the evaluating authority’s conclusions to the Commission. The latter will adopt an implementing decision approving, or not, the active substance. For more information on Registering substances either for active assessment or to Amend Annex 1 of the BPR please visit the ECHA website. They have guidance on preparing your dossier.

Approval of Active Substances:-

https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances

A list of all approved substances is made available to the public via the link in ‘Introduction’.

At least 550 days before the end of the approved period, the applicant has to submit a renewal dossier including all relevant data generated since the approval together with an assessment of whether the active substance still qualifies to be approved under the conditions laid down in the BPR.

NOTE – It is unlikely that any FIRA members manufacture / supply active substances but it is important to understand the authorisation process.

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4.1.2 Authorisation of Biocidal Products

As noted previously, all Biocidal products require authorisation before they can be made available on the market. There are several processes that can be used depending on the product and the countries in which they are to be sold.

- **National authorisation and mutual recognition** - If the product is placed only in a single market, country authorisation is sufficient and submit an application on ECHA's website.
- **Mutual recognition -** If a company wishes to place the product on the market in several countries, it can apply for mutual recognition for the product authorisation.
- **Union authorisation -** The BPR has an alternative for companies that need to apply for an EU-wide authorisation in one go.
- **Simplified Authorisation -** There is a simplified procedure for products which meet certain criteria specified in the regulation e.g. do not contain any substance of concern.
- **Same biocidal product authorisation -** Applying for an authorisation of biocidal product, which is either identical to an already authorised biocidal product or identical to a biocidal product for which an application for authorisation is ongoing.

Detailed information on authorisation of biocidal products can be found at:-

https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products

HSE are the enforcement authority in the UK, covering REACH as well as biocides – see section 8. The HSE website offers about registering a product and FAQ's. Information can be found here http://www.hse.gov.uk/biocides/marketing.htm

4.1.2 Biocidal Product Groupings

In Annex V of the BPR the biocidal products are classified into 22 biocidal product-types, grouped in four main areas.

GROUP 1 – DISINFECTANTS and GENERAL BIOCIDES		
PT1	**Human Hygiene**	**Products in this group are biocidal products used for human hygiene purposes applied or in contact with human skin for the primary purpose of disinfecting the skin.**
PT2	**Disinfectants and algaecides not intended for direct application to humans or animals**	**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.** **Used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.**

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		Used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. **Used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.**
Biocides used in furniture components with the intended purpose of treating or being incorporated into materials, surfaces or articles and adding disinfectant properties to that material surface or article. Biocides used in furniture products with the purpose of treating or being incorporated into materials surfaces or articles with the purpose of preventing microbial growth.		
GROUP 2 – PRESERVATIVES		
PT6	**Preservatives for Product during Storage**	**Biocidal products of PT6 are widely used to preserve products during storage. If the preserved goods (a chemical substance or mixture or an article) itself is placed on the market it qualifies as a treated article.** **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 ingredient 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.** **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**	**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.**
PT8	**Wood Preservatives**	**Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-**

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		destroying or wood-disfiguring organisms, including insects. **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.**
PT9	**Fibre, leather, rubber and polymerised materials preservatives**	**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.** **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**
Common materials used in the construction of furniture may contain Biocidal preservatives for preservation purposes or related to anti-odour claims.		
GROUP 3 PEST CONTROL		
PT18	**Insecticides, acaricides and products to control other arthropods**	**Used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.**
Biocidal Furniture products that contain insecticides to control dust mite or bed bugs leading to anti- allergy or anti-microbial claims		
GROUP 4 OTHER BIOCIDAL PRODUCTS – EMBALMING and ANTIFOULING PRODUCTS – It is unlikely that this group would apply to furniture.		

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A full list of product groupings can be found at:-

https://echa.europa.eu/regulations/biocidal-products-regulation/product-types

It is expected that the range of biocidal products manufactured by FIRA members will be limited and that the majority of products falling under the scope of the BPR would be classed as 'Treated Articles' (See section 4.2). Nevertheless, it is important to understand the product groupings associated with biocidal products.

Examples of products falling into specific biocidal groupings may include:-

- Mattresses with ticking / fillings using Anti- Microbial, Anti-Allergy active substances – PT18
- Furniture with fabrics / fillings using Anti- Microbial, Anti-Allergy active substances – PT18.
- Furniture / Divans constructed of materials (Wood) that incorporates a preservative or insecticide – PT8 and PT18
- Furniture constructed of materials (Fibre / Leather) incorporating a biocidal product intended to reduce odours – PT9
- Work-surfaces incorporating biocidal disinfectant – PT1

See Annex A – Potential Furniture Products with Biocidal Properties.

4.2 Treated Articles

Most furniture suppliers will not directly manufacture a chemical biocidal product but will likely import materials that fall under the scope of the EU BPR due to the treated article clause.

As previously described the EU BPR states that:

"*a treated article that has a primary biocidal function shall be considered a biocidal product*."

Therefore any treated article that has a primary biocidal function shall be considered a biocidal product. A primary biocidal function is not defined in the legal text but is addressed in the Note for Guidance on treated articles from the European Commission as "a biocidal function of first rank, importance, or value compared to other functions of the treated article".

The Commission Guidance defines the "function" of a treated article as the "intended purpose" for which the treated article is supplied. A treated article with a "biocidal function", by analogy, is a treated article whose intended primary function is to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any harmless organism by means other than mere physical or mechanical action. The Commission Guidance also states that a treated article has more than one function if it serves more than one intended purpose.

Determining whether the biocidal function of a treated article is its primary function, however, is complex. A treated article whose exclusive function (resulting from the treatment with or intentional incorporation of biocidal products) is to control harmful organisms has a primary biocidal function. However, in cases where a treated article has multiple functions, at least one of which is biocidal, the following elements are currently proposed as criteria for determining whether the biocidal function is primary:

- Intended use and purpose of the treated article
- Prominence of claims made: If a claim refers to the biocidal function and is given greater prominence than other claims, the biocidal function could be considered primary
- Whether a public health claim is made
- Concentration of the active substance(s) in the treated article is important, whether it is comparable to an existing biocidal product
- Mode of action of the active substance(s) or the treated article (in particular whether it would be identical to that of an existing biocidal product)

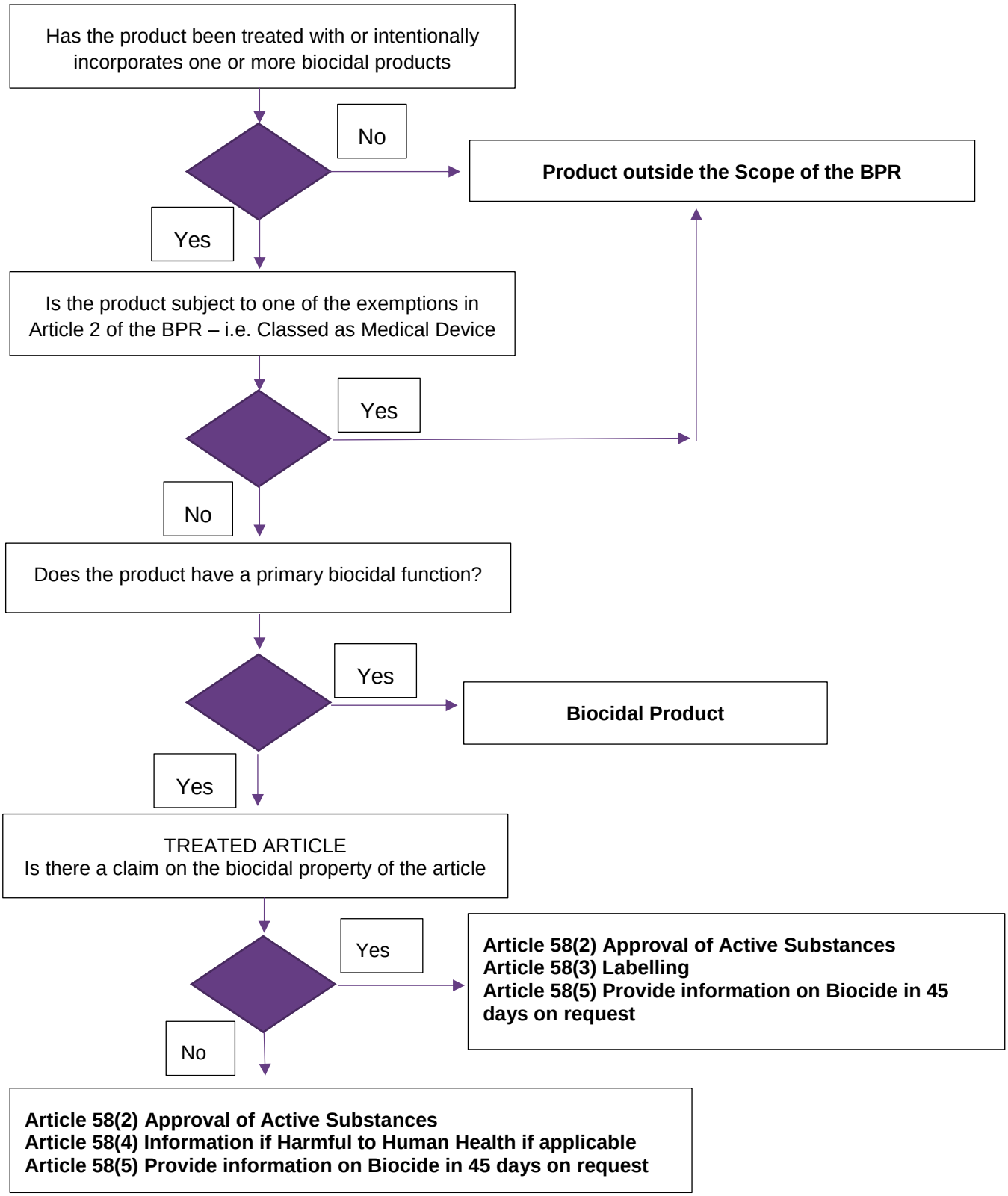
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The relevance of the above determination is that treated articles with a primary biocidal function are regulated as biocidal products and must meet all associated requirements. However, a treated article with no primary biocidal function is still subject to the provisions of the BPR.

The process flowchart overleaf may help in the decision making process.

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Process Flow Chart for Treated Articles



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4.2.1 Requirements for Treated Articles

Article 58 of the BPR explains the requirements a treated article needs to comply with before it can be placed on the market.

BPR Art. 58 (2):

"A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met."

Note: The list drawn up in accordance with Art. 9(2) is the list of approved active substances

After 1 March 2017 it was no longer possible to place on the EU market articles treated with a biocidal product (or intentionally incorporating a biocidal product) containing an active substance which is not already approved, listed in Annex I, or under assessment.

Article 94 of the BPR details the transitional measures which are applicable to active substances contained in biocidal products that a treated article was treated with or incorporates, will have to be taken into account.

Treated articles may be treated with or incorporate any biocidal products which consist of active substances that are:

- Listed in BPR Annex 1
- On the approved active substances list
- Under evaluation

4.2.2 Labelling and Consumer Information Requirements for Treated Articles

Other than the approval of active substances, Article 58 provides for the requirements a treated article needs to comply with before it can be placed on the market. Treated articles have to be labelled according to Art. 58 (3) only if:

- A claim is made about the biocidal properties of the treated article
    - e.g.: biocide is added intentionally, with claim and/or market positioning regarding its biocidal properties gained from using biocides (e.g. Mattress with anti-microbial claim)
- When the conditions associated with the approval of the active substance concerned requires specific labelling provisions.

BPR Art. 58 (3):

"The label shall provide the following information:

(a) a statement that the treated article incorporates biocidal products;
(b) where substantiated, the biocidal property attributed to the treated article;
(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, 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.

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Therefore, a compliant label must bear the following information:

- A statement that the treated article incorporates biocidal products
- The biocidal property attributed to the treated article where a claim is made
- The name of all actives substances contained in the biocidal products
- The name of all nanomaterials contained (indicating they are 'nano')
- Any relevant instruction for use

4.2.3 Examples of Labelling

How the article is labelled depends on the type of claim manufacturers are making about the article.

For example, if a manufacturer wants to claim the biocidal properties of a mattress with insecticide treatment then they must label the article in accordance with Article 58 (3) of the regulation.

Mattress with Cover claiming Anti – Allergy Properties

- Mattress ticking treated with insecticide "X" to prevent dust mites.
- Claim on biocidal property is made: 'anti-allergy mattress'
- No primary biocidal function = Treated Article

Treated Article Labelling – Implementation of article 58 (3)

BPR Article 58 (3) The label […] shall provide the following information	How to Address
a) a statement that the treated article incorporates biocidal products;	**Include 'contains insecticide' X in the labelling**
(b) where substantiated, the biocidal property attributed to the treated article;	**Include 'contains insecticide X' in the labelling and the biocidal property – Anti Allergy – within boundaries of substantiated claims related to the efficacy of the biocide used.**
(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;	**Name of Active substance(s) used**
(d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets;	**None in this product – N/A**
(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.	**Any relevant instructions for use & any precautions to be taken related to particular biocidal product used.**

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Sofa with a preservative treatment in the timber frame with no claims as a biocidal product

- Sofa timber frame contains preservative to prevent spoilage in storage along the supply chain
- No primary biocidal function = Treated Article
- No biocidal claims nor claims on the biocidal property gained are made

Since no biocidal claims nor claims on the biocidal property gained are made on the product, the treated article label is not required

CAUTION!

There may be a stipulation in the approval conditions of the biocide active substance approval that means that the article must be labelled (regardless of a claim being made or not) with any relevant instruction for use, including precautions to be taken if this is necessary to protect humans, animals or the environment.

This is detailed in Article 58(4) of the BPR that states

“additional labelling requirement for all treated articles (not subject to the limitation of Article 58(3)) in the form of any relevant instructions for use and precautions to be taken if necessary for the protection of animal and human health and the environment.”

4.2.4 Treated Article information requests

Finally, Article 58(5) provides that the supplier of a treated article must provide information (free of charge) on the biocidal treatment of a treated article within 45 days of a request from a consumer. Therefore, if you are in the downstream supply chain of a treated article it is a legal requirement to supply the information upon request from the upstream supplier.

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5. Responsibilities in the supply chain

A company is an article producer if it makes or assembles an article within the EEA, regardless of how the articles are produced and where they are placed on the market. An article importer is any company located inside the EEA that is responsible for the physical introduction into the EEA customs territory of an article.

If an article producer, for example, purchases substances inside the EEA for use in the production process of his articles, he also has to fulfil downstream user requirements. If the substances are instead purchased outside of the EEA, the article producer has the role of importer of substances along with the related obligations, such as registration.

5.1 Importing a Treated Article into the EU

Importing a treated article into the EU is classed as “Placing a Product on the Market”, therefore you must ensure treated articles you place on the market comply with the requirements of the BPR before you commence importing.

5.2 Placing a Biocidal Product on the Market

As described earlier in this section, if you intend on importing a treated article into the EU whether claiming biocidal properties or not you must treat the article as if it were a biocidal product. This means you will need to do the following:

- Check the status of the active chemicals
- If your active substance is not one of the following, you cannot place the active substance on the market at this time:
    - Approved for Product Type;
    - Under review for your product type; or
    - Listed in the Annex 1 of the EU BPR

In respect of the treated article itself, this means you cannot import an article with an active substance that fails to meet the above.

and you will need to take action through one of two routes to be able to bring the article in to the EU:

- Support the substance through the active assessment and approval process

or

- Submit an application to amend Annex I of the BPR and gain authorisation for the product

Where the active substance has already been approved for the product type you will need to get the product authorised before you can place it on the market. Furthermore, you will need to decide if you need National Authorisation (for example you only intend to sell in the UK) or Union Authorisation. Explained in section 4.1.2

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5.3 Placing a Treated Article on the Market

If you are not directly importing an article containing a biocidal product and you do not manufacture biocidal products for use in your own products, then you are dealing with a treated article – see section 4.1.

Articles can range from simple to complex pieces. Articles are affected even if only one component of the article contains a biocide such as preservative in the wooden frame of a divan base.

As explained in section 4.2.1 previously

Article 58 of the BPR outlines responsibilities to the regulations, below is a list of requirements:

- Your Article must contain Biocidal Products that have been registered and have an active substance that is approved for use and with the correct product type approval
- Manufactures or Importers may have to include specific information about the treated articles they place on the market
- Suppliers of Treated Articles must provide, free of charge when requested, information on the biocidal treatment of the treated article. This information must be provided within 45 day

As above, to achieve compliance depends on if you import treated articles (either as component or finished article) from outside of the EU or manufacture inside the EU using treated articles also sourced within the EU. The below table outlines the required actions and if the route to market is applicable:

Action	Imported Treated Article	EU Treated Article
Check Active Substance Approval Status	**Yes**	**No ***
If Active Substance not Approved then either: • **Active Substance Approval or** • **Application to amend Annex 1 BPR if applicable**	**Yes**	**No ***
If your substance gains approval or is already approved for type and use then you must have the product authorised for use	**Yes**	**No ***
Check Biocidal Product for approval and use type	**No**	**Yes**
Biocidal Claim made on treated article, full label required (Article 58)	**Yes**	**Yes**
No Biocidal Claim made on treated article, label required if necessary protect to human, animal or environment	**Yes**	**Yes**
Information of biocidal treatment to be provided free of charge and within 45 days if requested	**Yes**	**Yes**

*Verify with supplier diligence check – see section 7

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6. Substantiating Claims

Use of label claims as a communication tool towards the end-user seems to be current practice, particularly in some product-types placed on the market. A number of companies are making anti-allergy, anti-odour and anti-dust mite claims on bedding products in particular. Most companies making these claims are purchasing these treated articles from a supplier who has gone down a rigorous product authorisation route to register their product. This supplier is known as the Authorised Holder (AH).

While product labels are not part of the product authorisation by the AH, submission of example labels with each application for product authorisation is required. Therefore, any intended label claim may be identified by applicants at the submission stage.

Article 69 of the BPR gives the authorisation holder the full responsibility of ensuring that biocidal products are classified, packaged and labelled in accordance with the summary of the product characteristics (SPC). Article 69(2) further specifies the minimum information that shall be provided on the labels. Thus other information, such as claims, can be added by the AH to the label. This means that AH's are responsible for the substantiation of any claim made on the label from an enforcement point of view. Although Article 69(1) of the BPR requires that label claims referring to the technical features of the product should be in accordance with the SPC, the objective of this provision is not that the label claims have to be listed in the SPC, but to ensure that the label claims are consistent with the uses authorised in the SPC and are not misleading

Enforcement of label claims should be performed against the information available in the authorised uses of the SPC (e.g. target organisms) first. Where relevant (e.g. "marketing" label claims), enforcement can also be based on other information made available to the enforcement authorities provided by the AH, in order to conclude whether those claims are substantiated and compliant with the above-mentioned EU legislation.

It is important that the manufacturer applying the product label for marketing purposes to the end user understands the claims that are made by the authorised holder so as comply with trading standards and avoid being visited by enforcement authorities. For example, making marketing claims that a mattress kills 99.9% of bed bugs may not fit with the efficacy rate (see section 6.2) against a given target organism that resulted in the AH being granted the product authorisation against

It is important that the manufacturer / producer / applying the product label, for purposes of marketing to the end user, fully understands and clearly communicates the claims that are made by the authorised holder. For example, making marketing claims that a mattress kills 99.9% of bed bugs may not fit with the efficacy rate (see section 6.2) against a given target organism that resulted in the AH being granted the product authorisation against the BPR.

Unsubstantiated or unrealistic claims may result in enforcement action, therefore good communication is advised between the AH and the manufacturer or importer making product label claims to ensure they match the original scope of the SPC.

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6.1 Efficacy of biocidal products

Efficacy (in layman's terms, effectiveness) of a biocidal product can be defined as the power to produce an effect that is related to the intrinsic efficacy of the active substance/s of the product and is influenced by the presence of non-active substances and the use pattern (e.g. efficacy rate against a given target organism). The aim of the product authorisation is to assess the efficacy of biocidal products, to ensure that only effective products enter the market. A full assessment of efficacy is conducted for applications for product authorisations.

Factors, which are taken into consideration during assessment of the efficacy for a biocidal product to control, repel or attract insects and other arthropods for which authorisation is sought, are:

- the target organism to be controlled, repelled or attracted;
- the physical state in which the product is applied (e.g. liquid/powder/bait);
- the areas of use, these may be in and around residential homes and other spaces in which people are accommodated;
- in and around spaces in which animals are accommodated
- in spaces intended for the preparation, processing or storage of food and beverages;
- in empty stores, ship's holds, factories and silos.

Information on effectiveness and intended uses of the product, together with its active substances, must be sufficient to permit an evaluation of the product, including the nature and benefits that accrue following use of the product in comparison to suitable reference products or damage thresholds, and to define its conditions of use.

A combination of laboratory studies, rigorous simulated-use laboratory studies, or field studies can be used to evaluate whether the product is effective for the requested use(s) at the specified doses. Data from these studies are compared with the specified criteria. Assessment will be made mainly in relation to the claims for the effectiveness of the product made on the product label. This assessment will take into account the

- pest(s) to be controlled
- indoor or outdoor use
- the method(s) of application
- application rates and use patterns of the product
- maximum storage period of the product

6.1.1 Examples of Specific label claims related to furniture

For specific target pests where only efficacy against one insect/arachnid order or a certain family within that order is claimed, data against only a limited number of pest species will normally be required. For example

- FOR USE AGAINST DUST MITES - Data against *Dermatophagoides sp*. should be available

Broad label claims, such as "crawling insect killer" or "flying insect killer", should be accompanied by qualification of the range of pests against which the product may be used. When broad claims are made, data on representative pest species will need to be provided for the range of pests against which efficacy is claimed.

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6.1.2 Mites Example

Mites are among the most diverse and successful of all the invertebrate groups. They have exploited an incredible array of habitats, and because of their small size (most are microscopic) most go totally unnoticed. Perhaps the best-known mite, is the house dust mite (family Pyroglyphidae), the faeces of which can cause asthma and allergic symptoms.

The house dust mite is widespread in human habitation. House dust mites thrive in the indoor environment provided by homes, specifically in bedrooms and kitchens. Dust mites survive well in mattresses, carpets, furniture and bedding.

For dust mites a clear label claim should have been be submitted in the product authorisation phase. The results of laboratory or field trials should demonstrate the efficacy of the product, based on the submitted label claim. As mentioned previously a biocidal product may only be authorised if it "possesses a sufficient level of efficacy"

This is implemented for mites in the following way.

A biocide against mites is normally considered to be sufficiently "effective" if the following results can be achieved:

- laboratory tests: ≥90% mortality in 24 hours;
- simulated-use tests: ≥90%mortality in 1 week;

6.1.3 Bed bugs example

Bedbugs are small, wingless blood feeding insects. Bedbugs are not known to transmit disease in Europe, but infestations can cause painful and irritating bites on the skin while humans sleep. Once infested, treatment and control is very difficult. Bedbugs harbour themselves in very confined areas in wall cracks, furniture joints, along lining of mattresses, behind pictures and in seams of furnishings. For bed bugs a clear label claim should be submitted. The study results of laboratory or field trials should demonstrate the efficacy of the product, based on the submitted label claim.

A biocidal product may only be authorised if it "possesses a sufficient level of efficacy".

An insecticidal product intended for the control of bedbugs is considered to be sufficiently

"effective" if the following results are achieved:

- ≥ 90% knockdown within a few minutes after contact with the product (or according to the claim), direct after application and at the end of the residual period;
- mortality according to the label claim, preferably ≥90% in 1 hour.

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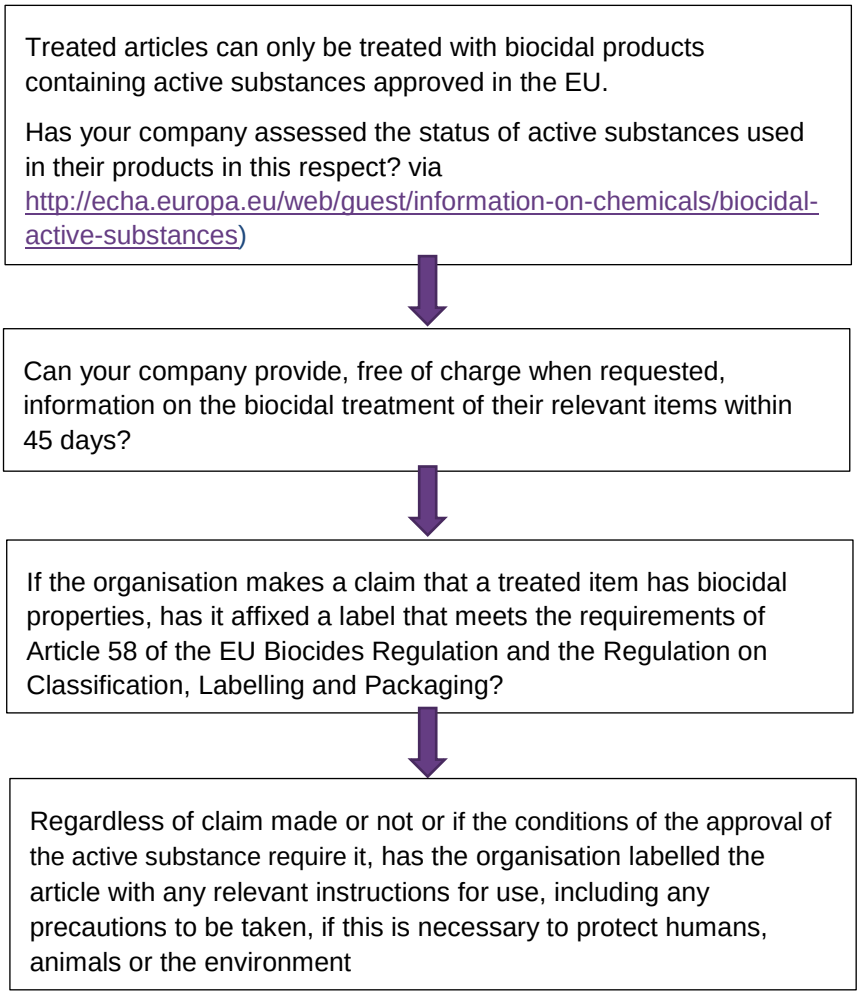
7. Retailers - Best practice and Due Diligence

For the majority of FIRA members the products effected would not be outright biocidal products (See annex A classification) with the sole intended purpose as a biocide but dual purpose products with biocide as an intended function and therefore classed as treated article. These treated articles may be supplied as components to be incorporated or manufactured into more complex final furniture products or potentially imported as complete products with biocidal claim. Possible claims may relate to odour-controlling, disinfecting properties or anti-microbial reduction of a finished good. The classification of such a product as a treated article will always depend on the intended effect in the finished good and (even indirect) claims.

Companies should also be aware of the product type(s) of the active substances used in the finished product and ensure that they can get this information from their suppliers. Depending on the product type, the classification can take place for individual product types. Please note that some product types can trigger a classification as treated articles, biocidal products or neither of these.

Therefore, it is recommended that suppliers, manufacturers, importers and retailers of products and components with biocidal claims follow the flow chart below and evaluate suppliers to control capture details using an in-house database related to the individual product or component.

Flow Chart - Due diligence check for Treated Articles



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7.1 BPR Supplier Evaluation, Selection and Control

It is recommended that companies such as downstream users and retailers put in place procedures to evaluate current and existing suppliers of component or products for their BPR credentials. Those companies that are already certified to an ISO management scheme (ISO14001) can add this check easily into their current supplier approval procedure.

For example:

BPR SUPPLIER EVALUATION, SELECTION AND CONTROL PROCEDURE

The Purchasing department evaluates new suppliers BPR status. The purchasing manager has the responsibility and authority to approve and disapprove suppliers that do not comply with BPR regulations.

New suppliers are evaluated in accordance with the following criteria against BPR, if applicable, to prove due diligence has been undertaken

- Do they supply products or components with Biocidal properties
- If, no have they provided a declaration stating that they do not supply products which require conformance with the BPR
- If, yes Is the component / product a treated article of biocidal product
- Is the active substance used been approved in the UK
- Can the supplier provide MSDS sheet for the active substance
- Has the supplier provided all information related to the Biocide used, to be kept on file in case downstream user requests (45 day rule)
- If a treated article is can they provide a copy of the label to check it meets requirements of article 58.
- Can the supplier provide Risk Assessments related to the product
- Provide claims information, what has been approved in authorization process
- Provide detail of the authorisation, registration provided to and from ECHA
- Product specification and bill of materials
- Results of quality in process checks
- Identification of product batches - traceability

In some cases a formal risk assessment should be conducted as part of the evaluation and selection of a potential supplier of BPR products.

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8. Enforcement

There are several bodies that are responsible for investigating incidents and undertaking enforcement activities under the EU Biocides Regulation 528/2012 (EU BPR) including the Health & Safety Executive, local authorities and other bodies. Exactly which body enforces in a particular situation is broadly split between local authority trading standards officers who enforce the advertisement and sale of biocides, while the use of products is enforced by either HSE inspectors or local authority environmental health officers, depending where the product has been used.

HSE, as the regulatory authority for biocides, can also assist other enforcing authorities through:

- advice on the legislation, and on how individual products are affected by the legislation;
- details of the approval status of individual products and the conditions that have to be met for each approval;
- copies of the approval documents;
- witness statements for use in prosecutions.

The HSE can request to see proof of compliance, i.e. diligence – see section 7. For treated articles that have been imported into the EU records must be kept for a minimum of 10 years in accordance with the requirement for Biocidal Products.

For EU treated articles, whilst there is no specific guidance, retaining records for a minimum of 6 years would seem reasonable as with other regulation.

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Annex A – Potential Furniture Products with Biocidal Properties

The examples below are indicative and refer to the typical categorisation of a listed product group. The assessment of whether any individual product is a treated article, a biocidal product or neither of the two must be made on a case-by-case basis, taking into account all its characteristics.

Finished Goods	Biocidal product	Treated article	Not a treated article
WORKSURFACES / DESKTOPS used in kitchen or related to foodstuffs.		**Article in which a disinfectant was incorporated to generate an antimicrobial surface**	**Any components or intermediate forms which were disinfected (not incorporated) which are not themselves placed on the EU market.**
FURNITURE/ COMPONENTS CONTAINING IMPREGNATED WOOD **Divan Base, Sofa Frame, Bench, Wooden Bed Frame.**		**Wooden furniture article, or wooden components of a complex article impregnated with an insecticidal wood preservative in order to protect it from becoming infested.**	**Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation.**
FINAL FURNITURE PRODUCT (NOT COMPONENT) CONTAINING WOOD **Divan Base, Sofa Frame, Bench, Wooden Bed Frame.**		**Wooden furniture article treated with an insecticide (e.g. by fumigation) in order to remove a present infestation**	
FURNITURE PRODUCTS USING PAINTS or GLUES WITH IN CAN PRESERVATIVE		**Mixtures like paints, glues, inks, detergents, etc. containing an in-can preservative**	**Complex articles containing e.g. glues, inks, paints which had in-can preservatives added in order to protect them during storage, where these preservatives have no further function in the finished good**

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FURNITURE PRODUCTS USING PAINTS or GLUES CONTAINING AN ADDITIVE			**Paint, detergents, etc. containing an additive, and that additive had an in-can preservative added in order to protect its during storage, where this preservative has no further preserving function in the final product**
FURNITURE PRODUCTS COATED IN FUNGICIDAL PAINT / COATINGS **Outdoor furniture**		**Paints and coatings containing a preservative that extends the durability of the applied layer**	
FURNITURE PRODUCTS USED IN HOSPITALS PAINTED WITH ANTIMICROBIAL PAINTS / COATING **Hospital Chair Metal Frame - examples**		**Paints and coatings intended to prevent microbial settlement and growth in order to provide a germ-free environment e.g. in hospitals**	
LEATHER FURNITURE **Leather Sofas, Chairs**		**Leather furniture treated with a fungicide protecting the leather from decay**	
FABRIC FURNITURE **Fabric Sofas, fabric Chairs**		**Textiles, or textile components of complex articles, treated with a preservative in order to increase durability of the fabric (also when used in multi-component articles)**	
FABRIC OUTDOOR FURNITURE TREATED WITH INSECTICIDE		**Textiles, or textile components of complex articles, treated with an insecticide in order to protect the fabric from destruction by insects**	
FABRICS, MATTRESS FILLINGS TREATED WITH ANTI MICROBIAL TECHOLOGIES		**Textiles or Fillings treated with a biocidal product in order to control dust mites or bed bugs (also when used in multi-component articles). A filling / fabric is incorporated into a**	

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Reduction of Dust Mites, Bed bugs in mattresses		**mattress. The filling / fabric has been treated with a biocidal product properties to reduce mites and bed bugs based on antimicrobial action. These properties will have an intended function in the finished good and the packaging of the product contains a claim about reduction of bugs and mites**	
FABRICS, MATTRESS FILLINGS TREATED WITH ODOUR CONTROLLING TECHNOLOGIES		**Textiles or fillings treated with a biocidal product in order to control odour-forming bacteria (also when used in multi-component articles). A filling / fabric is incorporated into a mattress. The filling / fabric has been treated with a biocidal product to give odour-controlling properties based on antimicrobial action. These properties will have an intended function in the finished product and the packaging of the product contains a claim about reduction of bad smells.**	
FOAMS USED IN FURNITURE / MATTRESSES FOR FILLINGS		**Foam treated to inhibit microbial growth during use.**	
FURNITURE / COMPONENTS using PLASTIC COMPONENTS incorporating PRESERVATIVES		**Plastic articles, or plastic components of complex articles, incorporating a preservative that protects them against harmful organisms and increases durability of the material**	**Plastic articles or plastic components of complex articles, made of ingredients (monomers, polymerisation aids, etc.) which contained preservatives in order to protect them during storage and manufacture, where these preservatives have no further function in the finished product**

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How we can help…

This guidance document represents a summary of key issues appertaining to the Biocidal Products Regulations.

Companies can access more detailed information and advice by attending one of FIRA's regular training courses in Stevenage **- www.fira.co.uk/training**

Alternatively organisations may prefer the added benefits of retaining a FIRA expert to provide support.

To find out more, please contact Bruce Lovell - blovell@fira.co.uk

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