Treated Articles

What are treated articles?

Whilst, similarly to the Biocidal Products Directive, the Biocidal Products Regulation (BPR) predominantly creates obligations around biocidal products and the active substances they contain, it also brings into scope those who manufacture, import or place on the market treated articles.

Despite what the name may suggest, the term treated article under the BPR covers any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal product. The obligations only apply however, where the treated substance, mixture or article is not itself a biocidal product, so before clarifying the duties associated with treated articles it must be established where such a material will be a treated article, and where it will be a biocidal product.

Biocidal Products Vs Treated Articles

Treating a substance, mixture or article with a biocidal product; or intentionally incorporating a biocidal product into them may be done for a number of reasons, but it is the properties conferred on the material that will determine whether it meets the definition of a biocidal product or a treated article.

Substances and mixtures

For substances and mixtures, the question is as to whether the biocidal treatment or incorporation imparts a biocidal function to the material or not. A biocidal function is one aimed at destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism. If the substance or mixture does have any sort of biocidal function (eg an anti-mould paint) then it will be a biocidal product rather than a treated article. If on the other hand, the treated substance or mixture does not have any sort of biocidal function, and the treatment is purely for the protection of that substance or mixture (eg a paint containing an in-can preservative) then it will be a treated article.

Articles

In the case of materials meeting the definition of articles under the REACH Regulation, which have been treated with, or incorporate, a biocidal product the question is again down to the function of the material, however now it is slightly more complex. For an article to be defined as a biocidal product, it not only needs to have a biocidal function but this must be the primary function of the article. If the treatment does not give the article a biocidal function (ie treated wood), or the biocidal function conveyed is secondary to its principal intended purpose, then the article will be a treated article.

Whether the biocidal function of an article is primary or not will need to be evaluated on a case-by-case basis, and any decision made should be clearly documented. Suggested criteria for determining whether the function is primary or not include:

- the target species, and whether it would be harmful to the article itself;
- the concentration of the active substance, compared to its concentration in biocidal products;
- the mode of action of the active substance, compared to its mode of action in biocidal products;
- the intended use and purpose of the article; and
- claims made regarding the function of the article, particularly the prominence of such claims.

Legal obligations

The key objectives behind incorporating treated articles into the scope of the legislation are: to avoid discrimination between treated articles originating in the EU and treated articles imported from third countries; and to enable customers to make informed choices about the products they buy. For these reasons the duties relate to the choice of biocidal product used in the treatment, and the labelling of the treated article. These are covered below.

Biocidal treatment

Article 58(2) of the BPR requires that where a substance, mixture or article has been treated with or incorporates a biocidal product, the active substances within that product are approved. Approval of active substances under the BPR is based not only on the substance, but also the product type in which it may be used, so it must be ensured the approval is for use in the type of biocidal product used to treat the treated article. Approved active substances, and the product type for which they are approved are listed on the website of the European Chemicals Agency (ECHA).

The legislation does not specify that the active substance must remain in the treated article, so for those importing substances, mixtures and articles, it won't be sufficient to simply look at the constituents of the product. Specific questions about biocidal treatment will need to be asked of the supplier. The only exception to the obligations is for treated articles "where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment."

Labelling

Article 58 also sets requirements for the labelling of treated articles. There are two conditions under which specific labelling of a treated article under the BPR is required: firstly, the approval of an active substance may specify a labelling requirement, for example the approval of the skin sensitising substance bromoacetic acid includes the condition that the label on treated articles provides information on the risk to human health. Secondly, specific labelling requirements apply where a claim is made as to the biocidal properties of a treated article, for example the statement 'contains an insecticide to prevent deterioration'.

If one of these conditions is fulfilled, then the label must state: that the treated article incorporates biocidal products; the property they attribute; the names of active substances and any nanomaterials in the biocidal product; and any relevant instructions for use. Where a claim as to a biocidal property is made, this must be substantiated and supported through appropriate data.

These obligations fall upon those placing the treated article on the market; that is the company who first supply a treated article for distribution or commercial use. The labelling duties do not apply to subsequent actors in the supply chain, however these suppliers must, within 45 days of a consumer request, provide information on the biocidal treatment of a treated article.

Transitional measures

Applications for the approval of existing active substances were made under the Biocidal Product Directive and continue to be evaluated, however as this directive did not legislate treated articles, it is possible that where such substances, mixtures and articles are imported the active substances may not be included in the review program. The Biocidal Product Regulation therefore allows for treated articles which were available on the market on 1 September 2013 to continue to be placed on the market provided an application for approval of the active substance in the relevant product type is submitted by 1 September 2016.

Where any decision is made not to approve an active substance for the relevant product-type, substances, mixtures or articles treated with or incorporating a biocidal product containing the active substance, must no longer be placed on the market as of the 1 September 2016, or 180 days after the decision is made, whichever is later.

Need further help?

If you require further information about your duties under the Biocidal Products Regulation, or you would like to know more about the legislation that effects you as a producer or importer of treated articles, email our Helpdesk at enquiries@reachready.co.uk or call us on +44 (0) 207 901 1444.