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Treated articles under the biocidal products regulation

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Abstract Under the BPR any substance, mixture or article which intentionally incorporates a biocide must use a biocidal product containing a compliant active substance. The case-by-case nature of defining treated articles and the issues surrounding the evaluation and approval of active substances that are used principally in treated articles are examined in this review. The challenge of reconciling the 'one-safe use' principle for BPR active substance approval within a risk assessment that covers the diverse nature of treated articles uses is also considered.

INTRODUCTION

Unlike the Biocidal Products Directive (BPD) (1), the Biocidal Products Regulation (BPR) (2) includes treated articles within the scope of the legislation, specifically in Article 58 with respect to the rules for placing articles on the market, but also more generally. The reason to regulate treated articles was to increase the overall protection of human health, animal health and the environment from the use of biocidal products, and to address potential discrimination between treated articles originating from within the European Union (EU) and those imported from countries outside the EU.

The definition of a treated article is stated clearly in the BPR: it means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products. The terms substance, mixture and article take their definition from the REACH regulation (3) and include solid objects and liquid materials.

In practice, defining a treated article can sometimes be uncertain because the action of treating an article could impart a biocidal property to the article. The property may be unintended, for example, a biocidal product may remain in the article as a residue from manufacturing, or the property may be intended, with the treatment giving a known biocidal function to the article. If the treated article has a biocidal property that is the primary function, the article will be regarded as biocidal product and consequently authorisation of the article will be required under the BPR.

To enable consumers to make informed choices regarding the properties of treated articles and to facilitate enforcement, treated articles are required to be labelled, according to Article 58. Labels should include information such as the purpose of the treatment and any hazards associated with the active substance(s) being used. The dividing line between treated article and biocidal

product is not always certain and Authorities may judge on a case-by-case basis, taking into account factors such as intended use and claims, the function of the article and consideration of the concentration, mode of action and efficacy of the active substance(s). To enable industry to comply with their Regulatory obligations the guidance applicable to treated articles in this respect should be unambiguous and applied consistently.

APPROVED ACTIVE SUBSTANCES

The BPR will have a significant impact on the market for treated articles. Since 01 March 2017 it is no longer possible to place on the EU market treated articles containing an active substance which is not already approved, which is not under evaluation for approval, or is not listed in Annex I to the BPR and therefore eligible for simplified authorisation according to Article 25 of the BPR. It is important to remember that in each case the substance should be approved for the intended use (Product Type).

Since the regulation of active substances used in treated articles is a new requirement under the BPR an allowance is made for substances that were not previously in scope. A transition period was established in Article 94 (4) until 01 September 2016 up to which point interested companies needed to submit to the European Chemicals Agency (ECHA) a complete dossier for the active substance. Acceptance of the dossier as complete allows continued market access for the substance pending evaluation and ultimate approval.

If an active substance is not given approval, treated articles containing the substance may no longer be placed on the market from a point starting 180 days from the substance non-approval decision date.

DEFINITION AND REGULATION

As stated previously, the dividing line between treated article and biocidal product is open to case-by-case interpretation and the use of biocidal products in the treatment of textiles is an illustration of this point. Textiles are treated for many reasons depending on the end use. Antimicrobial substances are included to prevent deterioration (e.g. mould suppression), or to act as odour control agents in clothing, or to provide some form of antimicrobial barrier in healthcare applications. Insecticides may be applied as repellents to benefit human health (e.g. to repel mosquitoes) or to protect the textile itself from deterioration (e.g. moths). The primary purpose of the textile will almost always be a physical intention: to function within an item of clothing, or to act as a covering of some type, etc. The inclusion of a biocide to provide a chemical action will usually be secondary, even if its presence is announced, hence the strength of any claim associated with the biocide is seen as the key factor in deciding if the article is a biocidal product.

It is important to note, that within Article 3(3) of the BPR the opportunity exists for Member States to request the Commission to decide, by means of implementing acts, whether a specific product or group of products is a biocidal product or a treated article or neither. To date, there are only eight such implementing acts (decisions) published on the ECHA website (5) and these all relate to individual products, no group decisions have yet been published. With respect to treated textiles, the decision given in EU 2016/903 (6) concerning a horse rug impregnated with permethrin is an interesting and clear example of the Commission's analysis of the use, intention and action of the active substance. In this particular example the horse rug (treated article) was considered to be a biocidal product – whether this resulted in a subsequent application for authorisation is unknown. It may be supposed that defining treated articles as biocidal products will be isolated events because of the primary physical function of any article. Regulation of treated articles will most likely be achieved via authorisation of the biocidal product used to treat the article and this is workable for the internal EU market where the use of the biocidal product can be monitored and controlled. For treated articles coming from outside the EU the equivalent control of the biocidal product will not be possible and regulation of treated articles via the active substance approval may be an option that is considered by the Authorities.

ONE SAFE USE PRINCIPLE

Regulation of treated articles at the active substance approval level presents a significant difficulty because, according to Article 6 of the BPR, approval need only be based on one acceptable 'reference use'. This situation is built on the understanding that other uses can be evaluated post approval through product authorisation. As we have seen, this mechanism captures articles treated within the EU, but excludes articles treated outside the EU, thereby creating a potential for discrimination in the market.

The discrimination will be enhanced if treated articles or groups of articles are subject to exclusion, but here the EU Commission guidance is clear "restrictions concerning the use of an active substance in treated articles shall only be introduced where a major concern is identified, indicating

which categories of articles can or, cannot be treated with a biocidal product containing the active substance. The restriction should not discriminate between treated articles manufactured in the EU and those manufactured in third countries and should be sufficiently specific so that the restriction only applies to those articles for which the major concern is relevant".



IDENTIFYING MAJOR CONCERNS

Active substances can be used extensively in treated articles and it may not always be apparent which particular use, or a group of uses, best represents the market whilst at the same time offering a relevant worst-case risk assessment scenario that can identify a 'major concern'. Yet this is a critical issue for active substance approval if the Commission's instruction to 'apply restriction only to those articles which identify a major concern' is to be followed. It is unrealistic to expect every treated article use to be evaluated, but it is a concern that perception of risk can be distorted if the assessment focuses solely on extreme worst-case examples.

As far back as 2013 proposals have been put forward to accommodate multiple treated article uses within the risk assessment framework. The proposals envisage use-categories (risk envelopes) within which conditions for approval could be defined. As an example, the table below indicates the potential scope for human exposure to certain types of articles, with the use-categories defining in broad terms the type of article and specifying for each type the purpose of treatment (claim) and the likely nature of exposure.

Examples for possible use-categories approved within a decision on active substance*

Area of use	Purpose	Exposure category	Example
Textiles with skin contact	Anti-odour treatment	Long term dermal contact	Sports T-shirt
Hard surfaces	Protection against infection transmission by splashes e.g. in hospitals	Short term dermal contact (no food contact)	Tables, trays, worktops
Porous surfaces	Protection against infection transmission by splashes e.g. in hospitals	Short term dermal contact (no food contact)	Wall-papers
Porous surfaces	Anti-bacterial treatment	Short-term oral contact	Tooth-brush, mouthguard
Textiles without skin contact	Anti-mold treatment	No skin contact	Shower-curtain, tarpaulin, awning

* CA-Feb13-Doc.5.1.h – Note for Discussion with Competent Authorities for Biocidal Products. Guidance on Treated Articles.

Proposals of this type have been used for a number of years in the evaluation of wood as a treated article and here the risk assessment framework is well established for active substances. In contrast, the proposal outlined above for textile and hard surface articles has yet to be officially endorsed and the areas of use and other parameters are not agreed in guidance documents. Without this guidance, active substance approval decisions will continue to be made on a case-by-case basis for treated articles, which leaves open the question of consistency between different substance evaluations and provides significant uncertainty for companies wishing to support treated articles.



CONCLUSION

Inclusion of treated articles within the scope of the BPR has added significant complexity to the Regulation of biocidal active substances. Whilst the definition of a treated article is clearly stated in the Regulation, in practice it can be harder to predict whether treatment will create a treated article or a biocidal product. The purpose of treatment and associated claims will be key factors in the decision and the EU Commission may be required as the ultimate arbiter in borderline cases.

Treated articles must now contain only those active substances that are captured within the scope of the Regulation; this includes already approved substances and substances still under review, either as existing active substances or those supported since 01 September 2016 through transitional arrangements set up under the BPR. Regulation of treated articles originating from inside the EU will likely occur via the biocidal product used to treat the article, however this is not relevant for articles originating from outside the EU which creates the potential for market discrimination. Regulation at the active substance level is a potential mechanism to capture both sources of treated articles, but restriction of treated articles via this route is not foreseen in Commission guidance and is only possible in the case of major concerns. The methods available to assess such concerns are not sufficiently established in the field of textile and hard surface articles to permit unambiguous and consistent evaluation of active substance. Further work by agencies is clearly needed in order to provide clarity in this complex area of chemical Regulation.

REFERENCES

1. DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 1998 concerning the placing of biocidal products on the market, Official Journal L 123, 24.4.98 p.0001-0063
2. REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products, Official Journal L167, 27.6.2012, p. 1)
3. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
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5. <https://echa.europa.eu/regulations/biocidal-products-regulation/legislation>.
6. COMMISSION IMPLEMENTING DECISION (EU) 2016/903 of 8 June 2016 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a horse rug impregnated with permethrin used for the purpose of controlling nuisance insects in the environment of the horse. 

About the author

Richard Elsmore (ERM Partner and Managing Director of JSC International Limited) is based in Harrogate in the UK. Richard has over 30 years' experience of working within the Chemical industry. He has a first degree and PhD in Microbiology from Cardiff University and also an MBA in Financial Studies from Nottingham University; he is a Chartered Biologist and a Fellow of the Royal Society of Biology.

