Treated articles and the BPR

Firms still face legal uncertainty and complex supply chain communications

In late 2011, when the Biocidal Products Regulation (BPR) was about to be adopted, we reviewed its provisions on the new concept of “treated articles” and their possible impacts on industry. We highlighted several concerns, notably those concerning the classification of products as biocidal products or treated articles, the vagueness of the labelling requirements, and the absence of de minimis thresholds for non-listed active substances (GBB Dec. 2011/Jan 2012).

The provisions of the BPR will apply throughout the EU from 1 September 2013 and the European Commission plans to address these, and other, concerns through a Note for Guidance (CW 10 January 2013) and changes to several articles in the BPR, including the transition period for treated articles (article 94).

Here, we highlight some of the issues that are addressed by both Commission documents and the concerns that remain or are raised by the proposed interpretations. The BPR provisions on treated articles are much more complex than anticipated, and their application in practice using the interpretation proposed by the Commission will be burdensome (notably in terms of supply chain communications) and will not bring legal certainty.

The BPR includes new provisions on “treated articles” defined as “any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products”. By contrast, a treated article that has a “primary biocidal function” is considered to be a biocidal product. Essentially, a “treated article” must not be placed on the EU market unless all active biocidal substances (used to treat that article or incorporated in that article) are included in the Regulation’s list of approved active substances for the relevant product type. There are also labelling requirements under some conditions. Thus from 1 September 2013, companies importing any product (substance, mixture or article) into the EU that has been treated with, or incorporates, biocides must ensure that the active substances so used are authorised under the BPR. Does that seem easy enough? Please read on.

Primary biocidal function

The draft guidance includes criteria to determine when a product has the “primary function” of a biocide and should therefore be considered as a “biocidal product” in its own right, rather than a “treated article”. First, it says that “if a substance or mixture has a biocidal function, it is covered by the definition of a biocidal product in the first indent of article 3(1)(a) of the BPR. It is therefore irrelevant whether the biocidal function is primary or secondary”. This means that any substance or mixture that has a biocidal function, even if only secondary, would require approval as a biocide and would not be considered a treated article. Only substances and mixtures treated with a biocide which was used to preserve the substance or mixture itself (as opposed to performing a function external to the substance or mixture) would be considered as “treated articles”, while “articles” (in the sense of REACH) could still be considered as “treated articles” if they contain a biocide with a secondary function. This means that a curtain (article) and a wall paint (mixture) treated with, or incorporating, a biocide purely to act as a preservative would both be considered as “treated articles”, while “articles” (in the sense of REACH) could still be considered as “treated articles” if they contain a biocide with a secondary function. In this case, the wall paint would be considered a biocidal product but the treated curtain...
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would be considered a treated article. The shape, design, and all other criteria defined for articles under REACH, will thus matter under the BPR as well.

This interpretation has significant consequences for a number of products with secondary biocidal functions, but will be difficult to challenge.

Second, the draft guidance says the primary biocidal function of a treated article can be determined on the basis of the prominence of the claim made, or if a “public health claim” is made. The Commission justifies the latter by saying treated articles with no primary biocidal function will not be subject to any efficacy assessment. Therefore, it says, “whenever any averagely well-informed consumer gets the impression that a treated article has a biocidal function of public health relevance (ie an action against one or more organisms of public health relevance), in the interest of making the article subject to an efficacy assessment at product authorisation stage, that biocidal function should be regarded as a primary biocidal function and the treated article as a biocidal product.”

Public health claims, as described in the draft document, cover a variety of cases where a treated article is claimed to protect against specific pathogenic microorganisms, or disease vectors such as ticks or mosquitoes, as well more generic claims such as “fights germs”, “kills 99% of bacteria”, “provides antibacterial protection”, “antibacterial” or “controls fungus”.

This health claim criterion, if confirmed, will have far-reaching results, as it implies that even where no “claim” is made, wording on the package that could give the impression that the product has a biocidal function of public health relevance could lead to the reclassification of a treated article as a biocidal product requiring approval. For example, coming back to our previous example of a curtain treated with an insect repellant, this product could be considered as a biocidal product because the biocidal function might be perceived as a health claim of public relevance, should there be risks of diseases that can be transmitted, for example, by mosquitoes.

The BPR does not itself refer to health claims in any way, and the Commission’s interpretation appears quite subjective.

The draft guidance goes even further by suggesting that other criteria may be developed and that “there might also be specific circumstances where a treated article would not meet any of these criteria, but where these circumstances would confer to the treated article a primary biocidal function.” With such a broad set of conditions, and should this interpretation be kept as the final rule, it would seem almost impossible for companies to place any treated article on the EU market with any legal certainty.

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**Labelling**

The draft guidance clarifies that treated articles with no biocidal function, but associated with statements (even when these are part of the technical documentation of the article only) indicating or implying a biocidal property, such as preservation of the article, must also comply with the labelling requirements of BPR Article 58(3). Examples of statements are given, most relating to the use of preservatives to protect an article’s shelf life. Again, this reflects a very broad concept of “claims”.

However, the draft document clears up what has to be included in the label when the biocidal product that the article has been treated with contains more than one active substance, and confirms that only those substances that contribute to the biocidal properties claimed, or for which the conditions for the approval so require, have to be mentioned on the label.

**Compositional issues**

We discussed last year that no threshold/cut-off limit was set in the BPR for active substances in treated articles. This is confirmed in the draft guidance, which also confirms that the 0.1% threshold for substances of very high concern in articles under REACH does not apply to treated articles under the BPR. The Commission’s rationale for this is that “the purpose of the rules in BPR relating to treated articles is to make sure that non-approved biocidal active substances are not present in Europe at all, and the percentage of a substance in relation to a treated article is irrelevant for this purpose.”

But the guidance goes much further: first, the Commission takes the position that the provisions of the BPR also apply to the treatment of any “component” of an article further back in the supply chain. However, the term “component” is not defined, and may also apply to substances or mixtures used to make another mixture.

Second, the Commission indicates that Article 58 applies as soon as an article is treated with, or intentionally incorporates, a biocidal product, “whether the active substance contained in that biocidal product eventually remains in the treated article or not”. This applies except when the treatment consists of fumigation or disinfection of premises and/or containers and no residues are expected to remain, which must be demonstrated without any indication of a limit of detection. This interpretation was not that held by some EU member states, in particular the UK.

By contrast, when it relates to residues from the production process, the guidance is more flexible in its clarification because it says residues from production processes are not used to treat the article nor are they intentionally incorporated therein, and therefore do not need to be approved for the article to be placed on the market.

So, the requirement is for companies to identify any active biocidal substance that has been used at any stage in the supply chain of a substance, mixture or article, at whatever level, and even if that active is no longer present in the finished product. This is obviously a major burden on companies which will require yet another series of complex supply chain communications. The
guidance recognises the issue, especially for complex articles, of identifying all possible treatments that may have occurred up the supply chain and says that practical enforcement will probably focus on articles where exposure to the active substances is expected. But this does not provide any certainty of no enforcement, nor any assistance for companies seeking to ensure full compliance.

The guidance also addresses the possible presence of substances known to have active biocidal properties but which may be present in articles for other reasons. In such cases, the Commission says “the burden of the proof will be placed on the person placing the treated article on the market to demonstrate that the substance, if it is not approved in the EU for the relevant product-type and use, was not incorporated for its biocidal activity.” Given the number of substances with dual properties that may be used in consumer products, this is also a concern.

Transitional measures

The last issue we want to highlight concerns the transitional measures of the BPR for treated articles. (Article 94 says treated articles that were available on the market on 1 September 2013 may “continue” to be placed on the market until the date of approval of the active substance, if the application for approval is submitted by 1 September 2016. If this decision is negative, the treated article must be removed from the market 180 days after the decision, or by 1 September 2016, whichever comes later, unless a new application for the approval of the active substance has been submitted.)

This provision raises some questions from the link between this transition period and that for active biocidal substances. Article 94 appears to say that no “new” article could be placed on the market until the active substances it contains are approved, even if the substance is under evaluation either from the BPD review programme or through a new application.

This resulted in a Commission proposal to correct Article 94 to allow the continued marketing of treated articles until either 1 September 2017, or until the date of a decision concerning the approval, for the relevant product type, of the last active substance(s) contained in the biocidal products with which the treated articles were treated, or which they incorporate (and this applies whether the active substance is already in the pipeline for review, or if an application is made by 1 September 2016).

The proposed text clarifies the status of treated articles containing active substances under the review programme or petitioned by 1 September 2016, but in our view is still unclear regarding “new” articles; that is those that will not be on the market on 1 September 2013, when the BPR takes effect. The proposed new text still specifies that “by way of derogation from Article 58(2), treated articles may continue to be placed on the market” until, for example, 1 September 2017. Does this mean that only those articles already on the market on 1 September 2013 can “continue” to be placed on the market, but not “new” articles, or does it mean that “any” treated article can be placed on the market until 1 September 2017 in derogation to article 58(2)? In our opinion, the Commission text can be interpreted both ways and should be clarified.

If there are still uncertainties about “new” products marketed after 1 September 2013, the draft guidance, fortunately, gives industry some flexibility by allowing “limited” design changes (for example, to colour, shape, size) of existing products, provided that the “new article” is treated with, or incorporates, the same biocidal product, and that the use and foreseeable exposure and risks from the biocidal product incorporated into the article remain the same.

In practice, therefore, even if the more restrictive interpretation of the transitional period were to apply, innovations and modifications of treated articles on the EU market on 1 September 2013 could continue to be made until 2017 (or later if the active substance was still under review), provided that the changes do not affect the active substances used. Here again, however, case-by-case review will be needed to decide which changes can be made that can benefit from the transitional period.

To conclude, the application of the BPR provisions on treated articles, starting on 1 September 2013, will require significant work for companies, in particular through supply chain communications, to ensure that articles containing or treated with biocides, or containing components that themselves have been treated with biocides, or for which direct or indirect biocidal claims are made, comply with Article 58 requiring that only approved active biocidal substances have been used.

The current discussions and draft documents discussed above aim at ensuring that the BPR works effectively. However, there remains scope for improvement and several aspects of the proposed guidance should be corrected if the Commission wants to achieve its objective.

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**Key BPR provisions on treated articles**

The Regulation extends the scope of the former Directive to cover articles and materials treated with biocidal products, for example, furniture treated with wood preservatives, which are imported from third countries. The key provisions are set out in articles 58 and 94.

- A treated article that has a primary biocidal function is considered to be a biocidal product. “Treated article” means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.
- Treated articles must 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 (Article 58(2)).
- Article 58(3) sets out the information that must be included on the product label for a treated article. Article 58(5) requires suppliers to respond to consumer requests for information in a manner which is similar to REACH Article 33(2) on consumer requests for information on candidate list substances in articles.
- Article 94 sets out transitional measures, and allows treated articles to stay on the market until 1 September 2016 if they submit an application for the approval of its active substance(s) before that date.

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