Treated Articles under Biocidal Products Regulation

Calling for a practical interpretation of provisions on treated articles as applied to complex articles and treated mixtures

Executive summary

With the entry into force of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR) on 1 September 2013, new provisions affecting 'treated articles' are in place in the EU that raise a series of concerns for members of the American Chamber of Commerce to the European Union (AmCham EU). Some of these concerns have been addressed by the recent adoption of amending Regulation (EU) No 334/2014. However, others remain that should be addressed. In particular, the interpretation in the current version of the Note for Guidance on Treated Articles dated September 2013 regarding 'complex articles' and 'treated mixtures' are unclear and legally contestable.

AmCham EU fully supports the European Commission in its recent efforts to provide a suitable solution to these issues. However, AmCham EU emphasises that a legislative amendment to the BPR should be prepared to bring full legal certainty on these issues.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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POSITION PAPER

American Chamber of Commerce to the European Union (AmCham EU)
Avenue des Arts 53, B-1000 Brussels, Belgium
Register ID: 5265780509-97
Tel: +32 (0)2 513 68 92 | www.amchameu.eu

Secretariat Point of Contact: Julie Linde Kjeldsen; jlk@amchameu.eu +32 (0)2 289 10 15

16 July 2014

Treated articles under the Biocidal Products Regulation (BPR)

The Regulation defines a 'treated article' as any substance, mixture or article that has been treated with, or intentionally incorporates, one or more biocidal products.

Treated articles are subject to several requirements, and can only be placed on the EU market if:

1. Tthe active substance(s) in the biocidal product they incorporate or have been treated with have been approved in the EU for the relevant biocidal product type; and
2. They bear specific labelling if claims are made regarding their biocidal properties or this is required in the active substance approval.

These provisions raise a considerable number of questions of interpretation that led the European Commission to draft and adopt the Note for Guidance at the September 2013 meeting of Member State Competent Authorities (MSCA) for the implementation of the Biocidal Products Regulation.

AmCham EU attends as observer the MSCA meetings on the implementation of the BPR and has repeatedly voiced concerns at these meetings that the proposed interpretation of the provisions of the BPR on treated articles, and in particular on 'complex articles' was legally questionable, unworkable and would lead to barriers to importation in the EU.

Complex Articles

The Note for Guidance essentially provides that the treatment of any component in the supply chain of an article before importation in the EU would subject it to the regulation, even if the active substance has no effect on the imported article or is no longer present in such article.

More specifically, the Note for Guidance provides (FAQ Answer No 24): '*The BPR defines a treated article as 'any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products'. This is to be understood as covering both treatment of the article itself as well as the treatment of any of its components further back in the supply chain. Thus complex articles such as cars, ships, planes are subject to the provisions of Article 58. It is however recognised that such earlier treatments of components might be difficult to identify, especially for complex articles. Practical enforcement is therefore likely to concentrate on articles where man or the environment can be exposed to the treated components.*'

Industry, including AmCham EU, has indicated to the Commission and the MSCA that, considering the complex supply chain for many products, this interpretation implies that any product imported into the EU may be suspected of being a treated article without companies having the systems in place to ensure compliance.

The European Commission has recognised the problem in its ***Note for Discussion on Treated articles*** published on 2 May 2014, where it provides a new interpretation that is more consistent with the legal text and legislative intent. More specifically, the European Commission proposes to:

- Interpret the '***intentionally incorporating***' element of definition as only applying to biocidal products having a biocidal function in the final good, therefore excluding incorporation of biocidal products with biocidal functions at intermediate stages of the manufacturing process;
- Interpret the '***treated with***' element of definition as only applying to treatment of the finished goods as placed on the market.

AmCham EU fully supports these two interpretations of the Commission, which will not only make the treated articles provisions of the BPR more workable but also more compatible with both the letter and the spirit of the legislation. AmCham EU requests the MSCA to likewise support this interpretation of the legislation.

Treated mixtures

Concerns have also been raised by stakeholders regarding the application of the labeling requirements for treated articles to treated mixtures that are also subject to labeling.

On 28 February 2014, the European Commission responded to such concerns that the labeling provisions on treated articles would only apply to **treated articles in the REACH sense**, not to substances and mixtures, and therefore that they would be no need to duplicate such labeling with the CLP labeling already required for such products.AmCham EU also fully supports this interpretation by the European Commission.

Legislative changes needed

While AmCham EU welcomes and supports the European Commission in its proposed interpretations of the BPR as discussed above, AmCham EU is greatly concerned that these interpretations may not be fully accepted and adopted by all the Member States, with resulting distortions of the internal market and of trade of articles into and in the EU.

AmCham EU therefore strongly believes that the provisions of the BPR on treated articles should be redrafted to reflect such interpretations in a new amendment to the BPR to ensure full legal certainty and protect the importation and free circulation of many products that could be considered as treated articles in the EU.