

Upcoming EU Requirements on Goods Treated with Biocidal Substances

By Peter Bogaert and Candido García Molyneux (Covington & Burling LLP)

The Council of the European Union has adopted a position at First Reading on a proposal for a Regulation on Biocidal Products that would impose new requirements on goods treated with biocidal products (“Council First Reading”).¹ The new rules would apply to a wide variety of consumer goods, such as furniture and other wood products, packaging, electronic equipment, plastic materials, paper and tissue products, absorbent hygiene products, apparel, paints, and kitchen accessories, and are likely to have a significant impact on goods imported into the European Union or European Economic Area.

The Council First Reading would significantly change the EU regulatory framework for materials (i.e., articles, mixtures, and substances) treated with or incorporating biocidal products. On the one hand, the new rules would limit the scope of the strict requirements that apply to biocidal products to only those materials that have a primary biocidal purpose. On the other hand, however, they would also create a new category of rules for all materials that intentionally incorporate or have been treated with biocidal products (so-called “treated articles”) even if such materials do not have a primary biocidal purpose.

These new rules would facilitate the making of biocidal claims for materials that are not themselves biocidal products, while also imposing approval and disclosure requirements on the active biocidal substances used even if they are only intended to preserve the materials or their ingredients and no biocidal claims are made. Importantly, the approval requirements may also significantly limit the number of suppliers from whom producers of these materials may purchase biocidal substances.

While the European Parliament and Council may still amend the Council First Reading and eventually could even fail to adopt the Regulation, this seems unlikely, and the Council First Reading’s requirements could apply in substantially their current or even stricter form as of January 2013.

This article briefly reviews the scope of “treated articles” and the requirements that will apply to them

Peter Bogaert is a Managing Partner of Covington & Burling’s Brussels office, and has a broad European life sciences practice. He has detailed regulatory expertise under EC and national laws, handles legislative and other policy assignments and provides strategic advice. (pbogaert@cov.com) Cándido García Molyneux is a Spanish Of Counsel in the Brussels office. His practice focuses on EU environmental law, Spanish food and drug law, and international trade law. (cgarciamolyneux@cov.com)

under the Council First Reading, and makes some recommendations for producers marketing or intending to market goods treated with active biocidal substances in the EU/EEA.

The new rules would limit the scope of the strict requirements that apply to biocidal products to only those materials that have a primary biocidal purpose.

Treated Articles

The proposed Regulation is intended to replace the current Biocidal Products Directive.² This Directive broadly defines biocidal products as “active substances and preparations containing one or more active substances [...] intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.”

Although the Biocidal Products Directive does not regulate “treated articles” as such, the European Commission’s Manual of Decisions on the Directive provides that articles treated with active biocidal substances are deemed to be biocidal products if the biocidal substances in the articles are intended to have an external effect. In particular, an article is considered to be a biocidal product if its biocidal ingredient is intended to be released from the article to control harmful organisms outside the article or to control only organisms that are not harmful to the article itself.

In that event, the article will be classified as a biocidal product even if it does not have a primary biocidal purpose. Where the active biocidal substance is intended only to control organisms that are harmful to the article itself (internal effect, such as a preservative), the article is not deemed a biocidal product and is outside the scope of the Biocidal Products Directive.

In contrast to this current approach, the Council First Reading explicitly regulates both biocidal products and “treated articles.” It limits the scope of biocidal products to include only materials “with the primary intention” of having a biocidal action (i.e., “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.

“Treated articles” are defined broadly to cover any “substance, mixture or article” (“materials”) that “has been treated with, or intentionally incorporates, one or more biocidal products.” (emphasis added) Thus, an article (i.e., object) or mixture would be a “treated article” if it has been treated with or intentionally incorporates a substance or mixture that has the primary intention of having a biocidal action even if the article or mixture itself is not primarily intended to have such action.

For example, a facial tissue treated with a biocidal product (e.g., tissues with anti-viral claims) would likely be classified as a “treated article” even if the main purpose of the tissue is not to kill bacteria. Where the “treated article” has the main purpose of killing harmful organisms (e.g., a mosquito net treated with a biocidal product), it would be classified as a biocidal product.

Materials would be classified as “treated articles” independently of whether their active biocidal substances are intended to have an external or internal effect. For example, paint treated with a preservative would be classified as a “treated article” even if the preservative is solely intended to protect the paint from harmful organisms, provided that its mode of action is not simply physical or mechanical. Importantly, products could be classified as treated articles even if no biocidal claims are made.

Materials with active biocidal substances would also likely be classified as “treated articles” even if the presence of the active biocidal substances is solely due to the use of ingredients treated with biocidal products in the manufacture of the materials. For example, this could arguably be the case with electronic equipment made of plastic materials treated with preservatives. Furthermore, the European Commission’s current interpretation of the term “treated with” is that goods that have been treated with biocidal products (e.g., disinfected) could also be classified as “treated articles” even if the biocidal products are no longer present in the goods when they are marketed.

The new requirements for “treated articles” would not apply to several specific categories of exempted products, including foods, cosmetics, and medicinal products. They would also not apply to medical devices, but biocidal products used to exert a controlling effect on any harmful organisms present on medical devices would have to comply with the essential requirements of the medical devices directives.

New Requirements for Treated Articles

The Council First Reading would impose new approval and disclosure requirements on the new category of “treated articles” even if they are not biocidal products. These requirements would apply as of January 2013, with some limited transitional periods.

Approval Requirements

“Treated articles” marketed in the EU/EEA would only be allowed to incorporate, or be treated with, active biocidal substances that are listed in the EU list of approved active biocidal substances for the specific product-types and uses, or in Annex I to the Regulation, subject to the applicable defined conditions and restrictions. However, under certain conditions, the Council First Reading would provide for a transitional period for “treated articles” that are already available on the market as of 20 days after the publication of the adopted Regulation (i.e., some time in 2012).

The new rules would create a new category of rules for all materials that intentionally incorporate or have been treated with biocidal products (so-called “treated articles”) even if such materials do not have a primary biocidal purpose.

Labeling and Other Disclosure Requirements

The Council First Reading would also require that “treated articles” marketed in the EU/EEA be labeled with particular biocidal information. The specific kind of information would depend on whether the active biocidal substances are intended or expected to be released from the “treated articles” under their normal or reasonably foreseeable conditions of use.

Where the active biocidal substances are intended or expected to be released from the “treated articles,” these would have to be labeled with: (i) a statement that the product “incorporates biocidal products;” (ii) the biocidal property attributed to the product if it can be substantiated; (iii) the name of the active substances that are contained in the product or were used to treat it; and (iv) relevant instructions for use. For example, these labeling requirements would likely apply to sport socks with anti-odor claims.

Where the active substances are not intended or expected to be released from the “treated articles,” the Council First Reading would require that the “treated articles” be labeled with: (i) a statement that the treated article was “treated with biocidal products,” and (ii) the address of a website containing the name of the active substances used for the treatment. In this case, however, the label must not claim any biocidal property. For example, these labeling requirements are likely to apply to furniture treated with preservatives but for which no biocidal claims are made.

In addition, the Council First Reading would empower the Commission to adopt procedures that eventually could require producers to notify the active biocidal substances

EU Requirements, continued on page 8

EU Requirements *(from page 7)*

they use in their goods to the European Chemicals Agency (“ECHA”). These notification requirements would complement the requirement to notify ECHA where an article contains a REACH Candidate List Substance of Very High Concern for Authorization.³

Next Steps and Recommendations

On the basis of the Council First Reading, the European Parliament is expected to adopt its Second Reading on the proposal in January 2012. The Council could then also introduce amendments, and the Regulation could be finally adopted and published by the summer of 2012.

In this context, producers marketing consumer goods in the EU/EEA may want to consider the following steps, among others:

1. Assess the presence of active biocidal substances in goods marketed in the EU/EEA. In some cases, producers may have to request their ingredient suppliers to provide a determination whether their ingredients incorporate or have been treated with biocidal substances.
2. Where goods incorporate or have been treated with active biocidal substances, consider shifting to substances and their uses that are already approved or are being reviewed for approval under Directive 98/8/EC on Biocidal Products. This will increase the likelihood that the goods may continue to be marketed in the EU/EEA or benefit from the transitional period.
3. Consider shifting the procurement of active biocidal substances to suppliers that support the EU review of the substances. This will increase the likelihood that the goods may continue to be marketed in the EU/EEA once the Regulation is adopted.
4. Consider launching new products with active biocidal substances and biocidal claims before the summer of 2012. This may allow the products to benefit from the transitional periods once the requirements of the Regulation enter into force.
5. Closely monitor developments in the Parliament and Council during their second readings, and eventually third reading. In particular, the Parliament may try to re-introduce a requirement on all producers of “treated articles” to obtain a “letter of certification” from the holder of the authorization of the biocidal product used. The Council and Parliament may also amend the details that must be contained in the label of “treated articles” and the dates of entry into force and transitional periods of the requirements. □

1 Council of the European Union, Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products 5032/11 (Brussels, 10 June 2011), available on the Internet here.

2 Directive 98/8/EC of the European Parliament and Council on the Placing of Biocidal Products on the Market O.J. L123/1 (24 April 1998), available on the Internet here.

3 The Reach Regulation and Substances of Very High Concern, available on the Internet here.

Practical International & US/Domestic Tax Strategies Series

PROVEN, PRACTICAL WAYS TO MANAGE YOUR INTERNATIONAL TAX BURDEN

The *Practical International and US Domestic Tax Strategies* series shows you, in clear and practical terms, how the world’s most successful companies are managing their tax liabilities.

You will learn:

- Strategic choices as the result of recent legislation or rulings.
- Ways to handle transfer pricing issues.
- How to manage issues involving joint ventures and strategic alliances.
- How companies use international and U.S. tax incentives.
- Holding company strategies.

Articles and case studies from leading practitioners. Separate periodicals covering:

- U.S. Domestic • Asia • International
- Mexico • Europe • Latin America • China

◆ Practical US/Domestic

◆ Practical International

◆ Practical Latin American

◆ Practical Mexican

◆ Practical Asia

◆ Practical European

◆ Practical China

To receive 3 **FREE** trial issues
-visit-

www.wtexec.com/tax.html