

E-ALERT | Environment

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NEW EU REQUIREMENTS ON ARTICLES TREATED WITH BIOCIDAL PRODUCTS

As of September 1, 2013, the new rules of the EU Biocidal Products Regulation apply to goods manufactured in, or imported into, the European Union and European Economic Area (“EU/EEA”).¹ The Regulation imposes new approval, labeling and disclosure requirements on goods (*i.e.*, substances, mixtures, objects) that have been treated with or that intentionally incorporate biocidal products (so-called “treated articles”), even if such goods do not have a biocidal function.

The new requirements for treated articles will apply to a wide variety of consumer goods, such as electronic equipment, household products, plastic materials, textiles, furniture and other wood products, and paints. They are likely to have the biggest impact on goods manufactured outside the EU/EEA and will significantly limit the number of suppliers from whom producers may procure their biocidal products and components. The European Commission’s current interpretation of the new rules for treated articles is also likely to impose even more burdensome requirements on producers making public health claims on their products.

This note provides a brief summary of the new rules on treated articles as interpreted in the latest draft of the European Commission’s Guidance on Frequently Asked Questions on Treated Articles of July 2013 (“Draft Guidance”).

TREATED ARTICLES

The Regulation defines “treated articles” broadly to cover any “substance, mixture or article” that “has been treated with, or intentionally incorporates, one or more biocidal products.” Thus, an article (*i.e.*, object) or mixture of chemicals is a “treated article” if it has been treated with or intentionally incorporates a substance that has the primary intention of having a biocidal action by means other than physical or mechanical, even if the object or mixture itself does not have a biocidal function or no biocidal claims are made. 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 the preservative’s mode of action is not simply physical or mechanical. The same applies to clothing, detergents, furniture, electronics and many other products.

The Draft Guidance also takes the position that a material may be a treated article as soon as it has been treated with or intentionally incorporates a biocidal product independently of whether the active substances contained in that biocidal product remain in that material.

¹ Regulation (EU) No. 528/2012 of the European Parliament and Council Concerning the Making Available on the Market and Use of Biocidal Products, available on the Internet at (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF>).

NO CONCENTRATION LIMITS AND IMPACT ON COMPLEX ARTICLES

In its Draft Guidance, the Commission reads the Regulation literally and takes the position that the requirements for treated articles apply independently of the concentration of the biocidal product in the material. The Commission is also of the view that complex articles are treated articles even if only one of their small components has been treated with or intentionally incorporates a biocidal product. For example, under the Commission's current interpretation, imported electronic devices are subject to the new requirements for treated articles if the plastic of an internal cable of the devices has been treated with preservatives. This can have labeling consequences when the product is stated to have been treated with preservatives, as may for instance be the case for furniture (see below).

ALL ACTIVE BIOCIDAL SUBSTANCES USED IN TREATED ARTICLES MUST BE EU APPROVED

Manufacturers and importers marketing treated articles in the EU/EEA must ensure that all the active substances contained in the biocidal products used to treat or intentionally incorporated into their treated articles are EU approved. The active substances must be approved for the relevant product type and use in the treated article, and the article must also comply with any relevant conditions of the approval of the active substance.

The Regulation, however, provides transitional periods for this approval requirement. Substances and product type combinations that have not yet been approved are allowed to be used in treated articles that are already on the EU/EEA market if: (i) the substance/product type combination is still being subject to review under the Commission's review program for biocidal active substance; or (ii) an application for approval is submitted before September 1, 2016.

LABELING REQUIREMENTS

The Regulation also imposes labeling and information requirements on treated articles, which apply as of September 1, 2013 and are not subject to transitional periods. Treated articles that are placed on the market of the EU/EEA are subject to specific labeling requirements if: (i) a claim is made regarding the biocidal properties of the article, or (ii) such labeling is required in the conditions of approval of the active substance contained in the biocidal product used to treat or intentionally incorporate into the article. Among other things, the label must indicate the name of all active substances and nanomaterials contained in the biocidal products used with the article.

Importantly, labeling will be required as soon as a claim is made on the biocidal property of the treated article even if it has no specific biocidal function. The Draft Guidance provides that a treated article's biocidal property is that resulting from the fact that the article has been treated or intentionally incorporates a biocidal product. In contrast, a treated article has a biocidal function if at least one of its intended purposes is to control any harmful organisms outside the article. Thus, labeling will be required for claims on anti-odor socks (*i.e.*, treated articles with a biocidal function), but also where a claim is made that a piece of furniture has been treated to protect it against unwanted organisms (*i.e.*, treated articles with a biocidal property).

Moreover, treated articles must be labeled with any precautions to be taken and any relevant instructions for use if this is necessary to protect human health, animals, or the environment.

ADDITIONAL DISCLOSURE REQUIREMENTS

The Regulation also requires suppliers (e.g., manufacturers, distributors, retailers) of treated articles in the EU/EEA to provide consumers with information on the biocidal treatment of the supplied treated article within 45 days of the consumer's request. The Regulation also empowers the Commission to impose additional notification requirements on producers of treated articles.

TREATED ARTICLES WITH A PRIMARY BIOCIDAL FUNCTION ARE BIOCIDAL PRODUCTS

A "treated article" in the form of an object that has a primary biocidal function should no longer be classified as a treated article, but as a biocidal product subject to authorization and the Regulation's other more stringent requirements. Importantly, the Draft Guidance also provides that if a treated article in the form of a mixture has any biocidal function (and not simply a biocidal property), it must be considered a biocidal product unless it benefits from the Regulation's exemptions for products subject to specific legislation (e.g., cosmetics, medicines, food, feeding stuffs). Thus, wall paint with mosquito repellent properties would be considered a biocidal product, while wall paint with a preservative to preserve the paint would be considered a treated article.

Whether a treated article in the form of an object has a primary biocidal function must be decided on a case-by-case basis. The Draft Guidance provides that to decide this the following criteria should be taken into account: (i) concentration of the active substance in the treated article, (ii) mode of action of the active substance or treated article and whether such mode of action would be identical to that of a biocidal product, (iii) intended use of the treated article, (iv) claims made regarding the function of the treated article, and (v) the target species and whether such species would not be harmful to the treated article itself.

PUBLIC HEALTH CLAIMS ARE LIKELY TO RENDER A TREATED ARTICLE A BIOCIDAL PRODUCT

Importantly, the Commission takes the position that the assessment of claims to decide whether a treated article has a primary biocidal function, and therefore should be considered a biocidal product, will depend on: (i) the prominence of the biocidal claim, and (ii) whether the biocidal claim has a public health relevance. A public health claim is a statement that the treated article is expected to provide certain benefits against organisms of public health relevance if used as indicated or implied by the person placing the treated article on the market. The Commission's latest draft Guidance provides that health claims may include claims such as "fights germs," "kills 99% bacteria," "provides antibacterial protection," and "controls fungus."

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

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