WINSTON & STRAWN LLP

BLOG

# Biocidal Products: A Reinforcing of Regulatory Obligations

JULY 20, 2012

Regulation no. 528/2012, dated May 22, 2012, of the European Parliament and Council concerning "the placing on the market and use of biocidal products," jointly adopted by the European Council and Parliament, was published in the *Official Gazette of the European Union* on June 27, 2012 and replaces Directive 98/8/EC.

The following products now fall within the scope of the definition of biocidal products: "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of 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", as well as "any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of 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"; thus explicitly and for the first time referring to biocidal products that are generated "in situ". In addition, Regulation no. 528/2012 provides that "a treated article that has a primary biocidal function shall be considered a biocidal product", thus amending the scope of previous rules.

In addition, the new regulation specifies and completes certain provisions that previously applied under Directive 98/8/EC; it is also innovative as it provides for:

- a stricter regulatory framework for treated articles, defined as "any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products" and which may be placed on the market only if the active substances with which it has been treated or which it incorporates are included in the list established by the European Union. These new provisions might be difficult to apply with regard to business relationships with some non-European manufacturers of treated articles;
- a modified system of mutual recognition between Member States, by which the existing procedure is replaced by procedures of mutual recognition "in sequence" or mutual recognition "in parallel" within the European Union, aiming at reducing administrative constraints.

Regulation no. 528/2012 shall apply as of September 1, 2013, with the exception of certain provisions to which a

transitional implementation period shall apply.

*One environmental lawyer's opinion*: Considering the forthcoming implementation date, a precise inventory of the products, substances, and particularly the treated articles (which may be affected by this text) should be established promptly, in order to quickly anticipate the significant consequences of this new system.

This analysis should thereby allow for adjustment of regulatory and administrative follow-up of these products, to reinforce warranties that sometimes exist in this regard, particularly in the context of business agreements that are already in force with non-European suppliers (entities that may not be informed of such new provisions), and thus to avoid significant risks of supply shortage.

2 Min Read

## Related Topics

Rulemaking

## Related Capabilities

Environmental