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Upcoming Deadlines for Biocides in the EU

In the European Union the manufacturing, import, sale, and use of chemical substances are highly regulated. Biocidal products are regulated under (EU) No. 528/2012 (EU Biocides Regulation).[1] The EU Biocides Regulation entered into force in EU Member States on Sept. 1, 2013. However, the European legislature has provided for a gradual implementation of the rules on biocides, biocidal products, and articles that contain or have been treated with biocides (so-called "treated articles"). Producers and importers of biocides should be aware of the relevant deadlines to ensure timely compliance. The next important deadline is Sept. 1, 2016.

Existing EU Authorization Requirements for Active Substances in Biocides

Biocides are used to protect humans, animals, materials, or articles against harmful organisms (*e.g.*, against pests and bacteria). The EU Biocides Regulation covers biocidal products and "treated articles". It applies to substances or micro-organisms that have an effect on or against harmful organisms, and products containing those substances or micro-organisms. This is called an "active substance." Under the EU Biocides Regulation, the active substances in biocides generally require prior authorization by the European Chemicals Agency (ECHA) if the manufacturer wants to place the biocide on the European market.

As of Sept. 1, 2015, a biocide is allowed only on the European market if the producer or supplier of the *active substance* in a biocide, combined with the specific product type, is included on a list of approved substances.[2] National regulators (who decide whether a biocidal product will be authorized in a specific Member State) can only authorize a biocide if both the biocide's active substance and either the substance supplier or the product supplier are included in that list.

[1] Regulation (EU) No. 528/2012 of the European Parliament and of the Council of May 22, 2012, concerning making biocidal products available on the market and the use of biocidal products.

[2] The Article 95 list is a list of relevant substances and product suppliers and can be found here: http://echa.europa.eu/documents/10162/17287015/art_95_list_en.pdf, as of May 4, 2016. The suppliers on the Article 95 list include participants in the Review Programme, supporters of new active substances, who have submitted a "biocide dossier."

Upcoming Deadlines for Treated Articles– Sept. 1, 2016, and March 1, 2017

Active substances in "treated articles" (*e.g.*, wood treated with arsenic or sofas treated with DMF) also require authorization by ECHA. The application for authorization of the active substance in a treated article must be filed before Sept. 1, 2016, with ECHA (with some exceptions). A "treated article" is defined as "any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products." If a treated article contains an active substance which is not approved already (*e.g.,* included in the list of approved substances), or for which an application for approval has not already been made, an application needs to be made before Sept. 1, 2016 in order to keep selling the "treated article" on the European market.

After March 1, 2017, a "treated article" can no longer be placed on the European market if the active substance has not been authorized, also with some exceptions. Noncompliance with these deadlines has the potential to lead to a forced recall and substantial fines.

For the authorization application, companies must use a standard application portal called "R4BP 3". To apply, a "biocides dossier" must be prepared. This dossier must include, among others things, a full and detailed description of the conducted studies of the active substance as well as extensive information regarding the properties of the active substance. This procedure does not apply if the active substance has already been included in Annex I of the EU Biocides Regulation. Those substances are exempted and do not require authorization. An application and authorization for an active substance can only be used by the applicant/receiver (substance supplier or the biocidal product supplier) of the authorization. This is to prevent "free-riding" by subsequent applicants. If a subsequent applicant wants to make use of the data of a previous application it will need permission from the previous applicant (data owner) or ECHA. The application and authorization must specify the use of the active substance in a biocide, combined with the specific product type as well.

The authorization procedure further does not apply if the substance is already included in the Review Programme.[3] The Review Programme focuses on the close examination of existing active substances contained in biocidal products that were already on the EU Market as of May 14, 2000, to ensure compliance with the new regulations. Under the Review Programme, existing active substances may be banned. The Review Programme is foreseen to be completed by 2024, according to ECHA.

Labeling Requirements for Biocides and Treated Articles

If the active substance is approved, the treated articles must be labeled in accordance with the EU Biocides Regulation. The EU Biocides Regulation contains national language requirements for labeling (unless the Member State provides otherwise). According to the EU Biocides Regulation, among other requirements, the label of the product must state which biocides were used, identify relevant biocides, and indicate any necessary precautions.

Regarding proper precautions to ensure your company's compliance, please consult with your counsel or contact a Greenberg Traurig attorney.

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[3] Commission Delegated Regulation (EU) No. 1062/2014 of Aug. 4, 2014, concerning the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No. 528/2012.

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