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Companies Warned to Heed Cutoff Dates in EU Biocides Regulation

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BNA Snapshot

EU Biocidal Products Regulation

Key Development: Companies urged to act ahead of deadlines related to biocidal substances and products and goods treated with biocides, under the 2012 EU law on biocides.

Potential Impact: Companies might face negotiations to obtain letters of access for substance authorization dossiers.

What's Next: Companies wishing to sell biocidal substances and products in the EU must be listed by Sept. 1, 2015; companies that want to sell some goods treated with biocides must apply by Sept. 1, 2016.

Companies that import biocidal substances or products into the European Union, or import goods that incorporate biocidal products, need to be aware of two cutoff dates that could affect their ability to do business in the 28-country bloc, according to legal experts and EU officials.

The first date, Sept. 1, 2015, was introduced by Article 95 of the EU's 2012 Biocidal Products Regulation (BPR, 528/2012/EU), which was intended to harmonize the approvals process for biocidal products and substances put onto the EU market.

The second date, Sept. 1, 2016, applies to so-called "treated articles" under the BPR, which are goods that intentionally incorporate a biocidal product, such as wooden items treated with preservatives.

Under the BPR, after Sept. 1, 2015, biocidal products such as insecticides and preservatives traded in the EU can only be sourced from EU companies that are included on a so-called Article 95 list held by the European Chemicals Agency (ECHA).

Pierre Choraine, biocides team coordinator in the environment directorate-general of the European Commission, the EU's executive arm, said that it was "really very important to understand the implications of this Article 95."

Choraine was speaking during a webinar organized July 9 by the Brussels office of Steptoe & Johnson LLP.

Article 95 List

To get onto the Article 95 list, companies must be producers or importers of biocidal substances or products that have been approved, or are in the process of being approved, for the EU market.

Under the BPR, approval must be sought for both biocidal substances and products. Products can only contain active substances that have already been assessed and authorized, or that are already part of an assessment program that was underway when the BPR entered into force.

In addition, to be included on the Article 95 list, companies must have participated in the submission of a dossier for approval of a substance, or must have a "letter of access" to a dossier submitted by another company.

This rule, introduced by the BPR, is designed to ensure that companies that use the same active substance in their products make a fair financial contribution to the process of seeking approval for the substances.

Lucas Bergkamp, a partner with Hunton & Williams LLP in Brussels, told Bloomberg BNA July 10 that companies must be listed "to avoid a situation where one company pays all the costs of the approval dossier, but other suppliers benefit from the approval of the active substances at no cost."

Substance approval dossiers "must contain, among other things, toxicological and eco-toxicological data, which may be very costly for an applicant to generate," Bergkamp said.

Data Sharing Negotiations

ECHA told Bloomberg BNA July 10 that after Sept. 1, 2015, new companies can join the Article 95 list, but they "will be able to access the EU market only after they are listed," and "in case of products containing new active substances, they will need to wait for the approval of the active substance and the authorizations of the products before accessing the market."

Darren Abrahams, a partner with Steptoe & Johnson LLP, said during the July 9 webinar that the 2015 deadline in effect gives companies a limited time to conduct "mandatory data sharing negotiations."

Companies that are unable to agree terms for letters of access with companies that have filed biocide authorizations and are already included on the Article 95 list would not be able to sell their products on the EU market after the cut-off date.

"The timelines for data-sharing negotiations are extremely short under the BPR," Johnson said.

Industry Grappling With Process

Claudio Mereu, a partner with Field Fisher Waterhouse LLP in Brussels, told Bloomberg BNA July 10 that "everyone in the business is aware" of the need to act by the Sept. 1, 2015 cut-off date, but they did not necessarily know what steps they have to take.

"That's the principle preoccupation of industry at the moment," Mereu said. "They are confronted with complex regulatory schemes and they are a bit lost."

Smaller companies in particular could be at a disadvantage because they potentially face the need to negotiate for a letter of access with companies that have submitted approval dossiers for biocidal substances, Mereu said.

This could be both time-consuming and costly, Mereu said. He added that is was "not totally unheard of" for a letter of access to cost "several hundred thousand euros."

Abrahams said that non-EU companies cannot be included in the Article 95 list, and must therefore ensure that the EU importers of their substances or products are listed, to avoid being cut off from the market.

Treated Articles

The second cutoff date of Sept. 1, 2016, applies to treated articles, which can only be sold in the EU if the biocide with which they have been treated has been approved for that use.

Under transitional measures introduced by the BPR, treated articles that contain substances that have not been authorized for that use or are not in the process of authorization, can continue to be sold in the EU if the manufacturers or importers of the treated article file an application with ECHA by Sept. 1, 2016.

Without such an application, treated articles containing unauthorized biocides must be taken off the market by March 1, 2017.

Choraine said that manufacturers and importers of goods treated with unauthorized biocides "need to take action." They could either switch to a biocide that has the relevant authorizations, or file an application for authorization, he said.

Market Disruption Risk

Bergkamp said that provisions on treated articles had already been amended "to rectify certain unintended consequences," though the BPR only entered into force on Sept. 1, 2013.

The European Parliament approved in February amendments to the BPR designed to correct errors in the original text (37 INER 357, 3/12/14).

"In addition to a very substantial compliance cost, the Biocides Regulation is very complex and not without unintended consequences for industries," Bergkamp said.

He added that “in this context, it is difficult for companies to understand their obligations and it cannot be excluded that certain companies will be caught off guard with the risk of market disruption.”

For More Information

Information from the European Chemicals Agency on the BPR is available at http://echa.europa.eu/regulations/biocidal-products- regulation.