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BLOG

FDA Bans Common Antibacterial Agent; Will EPA Follow Suit?

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On September 2, 2016, the U.S. Food and Drug Administration (FDA) issued a final rule banning the sale of over-the-counter consumer antiseptic wash products containing certain active ingredients. After September 6, 2017, companies will no longer be able to market antibacterial washes with these ingredients because, according to FDA, manufacturers failed to demonstrate that the ingredients are both safe for long-term daily use and more effective that non-antibacterial soap and water in preventing illness and the spread of certain infections. One of the 19 banned active chemicals is triclosan, an antibacterial and antifungal agent commonly found in soaps.

Certain consumer uses of triclosan, such as in hand soaps and toothpaste, are regulated by the FDA. However, triclosan is also registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use as a bacteriostat, mildewstat, and fungistat in plastics, polymers, textiles, and other products. FIFRA is administered by EPA.

EPA has been under pressure from certain environmental and consumer safety groups to ban the use of triclosan in the products under EPA's jurisdiction. EPA completed a Reregistration Eligibility Decision for triclosan in September 2008 which concluded that, with the exception of preservative use of triclosan in paints, pesticides containing triclosan met the statutory safety standard in FIFRA, provided that risk mitigation measures as outlined in the Decision were implemented, confirmatory data gaps were addressed, and label amendments were incorporated as presented in the Decision. Although FIFRA requires that registrations of pesticides be reviewed every 15 years, EPA had opened the public comment period for triclosan's registration review in 2013, only five years after the prior Reregistration Eligibility Decision had been issued. The registration review's final work plan was published in April 2014, but a new Reregistration Eligibility Decision has not yet been issued. Manufacturers and end users of products containing triclosan should closely follow these developments, as EPA will likely face continued pressure to follow FDA's lead and cancel registrations of triclosan-containing products.

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