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Antibacterial Soaps Have Phased Out Controversial Ingredients, But Concerns Remain About New Ones

The Food and Drug Administration has washed its hands of antibacterial soaps that contain certain active ingredients because manufacturers have not demonstrated their long-term safety and effectiveness.

Instead of conducting the research requested by the FDA nearly three years ago, most antibacterial soap makers simply replaced the ingredients in question. The problem is that the new ingredients *also* lack evidence of safety and effectiveness, according to the agency.

The latest development in this soap opera came on Friday, when the FDA issued a [final rule](#) that bans antibacterial washes containing one or more of 19 active ingredients, including the two that have been the most common—triclosan in liquid soaps and triclocarban in bar soaps. The “vast majority” of the more than 2,000 antibacterial hand soaps on the market contain at least one of those ingredients, Dr. Theresa Michele, director of the agency’s division of nonprescription drug products, told reporters on a conference call.

“A lot of the marketing has been over-the-top germophobia—kill all germs everywhere, and we will all be safer seems to be the thought,” [Jonathan Eisen](#), a University of California,



Davis, evolutionary biologist who studies the ecology and evolution of microbial communities, told me.



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The FDA's new rule affects only consumer products that are meant to be rinsed off with water, not hand sanitizers or wipes or antiseptic products used in health-care settings, such as nursing homes. It also does not apply to the products marketed as both antibacterial dishwashing liquid and hand wash, which the Environmental Protection Agency [regulates](#) as pesticides. In addition, the rule doesn't cover any of the multitude of other products that contain triclosan, ranging from toothpaste to shampoos and body lotions.

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While many manufacturers of antibacterial soap have phased out the active ingredient triclosan, which the FDA banned Friday in such products, the Dial brand continues to use it. (Photographer: Andrew Harrer/Bloomberg)

“Consumers may think antibacterial washes are more effective at preventing the spread of germs, but we have no scientific evidence that they are any better than plain soap and water,” Dr. Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research, said in a prepared statement about the final rule. “In fact, some data suggest that antibacterial ingredients may do more harm than good over the long term.”

The ban did not exactly take manufacturers by surprise. In December 2013, the FDA issued a [proposed rule](#) spurred by data that suggested the now banned active ingredients could contribute to bacterial resistance or cause hormonal effects. The proposed rule required makers of antibacterial hand soaps and body

washes to demonstrate that they were safe to use every day and more effective than plain soap and water in keeping people healthy by preventing the spread of certain infections. If companies didn't comply, they'd have to formulate their products or remove the "antibacterial" claim from their labels.

A stroll down the soap aisle at the supermarket or pharmacy shows that a number of manufacturers must have chosen the first option, because "antibacterial" still appears on many product labels. "To give our consumers peace of mind, and despite triclosan having a long and extensive history of safe use, we decided in 2012 to phase out triclosan in our beauty and baby care products," Johnson & Johnson said in a [statement](#) released in July 2014. And in an undated [page](#) on its website, Procter & Gamble states, "We have eliminated triclosan from more than 99% of the products where it was used and have an exit plan for the few remaining uses."

I checked labels at a local CVS and scoured the internet in search of hand and body washes that still contain triclosan or triclocarban, the main brand that kept coming up was [Dial](#), made by Henkel Consumer Goods, a Scottsdale, Ariz.,-based subsidiary of Henkel, a German company.

But besides triclosan and triclocarban, the other 17 now-banned active ingredients "haven't been used in years and years," Brian Sansoni, a spokesman for the [American Cleaning Institute](#) (ACI), an industry group representing manufacturers of such products, told me. "Most of the antibacterial soaps in the consumer marketplace are using one of three ingredients: benzalkonium chloride, benzelthonium chloride and chloroxylonol," Sansoni said.

Here's the thing: While those three ingredients aren't among the 19 banned by the FDA's new final rule, the agency notes that they also lack evidence demonstrating their safety and effectiveness. But the agency has put off

deciding whether to ban them for another year to allow manufacturers to conduct studies and submit data.

“The FDA already has in its hands data that show the safety and effectiveness of antibacterial soaps,” the ACI said in a prepared response to the final rule.

“Manufacturers are continuing their work to provide even more science and research to fill data gaps identified by FDA. In the coming year, ACI and its member companies will submit additional safety and effectiveness data on the key ingredients in use in consumer antibacterial soaps today: benzalkonium chloride, benzelthonium chloride and chloroxylenol.”

The Environmental Working Group (EWG), a nonprofit advocacy organization, hailed the FDA’s final rule. “This decision by the FDA is a huge victory on behalf of human health and the environment,” Ken Cook, EWG co-founder and president, said in a [prepared statement](#). “EWG has been conducting research and advocating for this exact federal government action for nearly a decade.”

Meanwhile, triclosan remains in a bunch of other consumer products besides liquid soaps, such as [Colgate-Palmolive’s Total toothpaste](#). As the manufacturer notes, though, the FDA approved Colgate Total under the same regulatory framework used for prescription drugs.

“Triclosan in toothpaste has been shown to be effective in preventing gingivitis that’s caused by bacteria in the mouth,” Dr. Sandra Kweder, then deputy director of the FDA’s Office of New Drugs, said at a press briefing on the 2013 proposed rule. “They have done studies to show that use of triclosan in that setting is safe and effective.”

Biologist Eisen isn’t so sure. He was surprised to find triclosan in his toothpaste and [blogged](#) about it a couple of years ago.

“Overall, it seems like that (triclosan in toothpaste) was mostly about marketing, too,” Eisen told me. “And given that there is growing evidence that messing with the human microbiome has some risks, putting antimicrobials in toothpaste when the benefits are doubtful seems, well, unwise.”

He’s not calling for an immediate outright ban of triclosan and other questionable antibacterial ingredients from all consumer products, though. “In some situations, and in some products, it seems plausible that some of these chemicals have benefits that exceed the risks.”

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