

Scientific evidence shows need to regulate antimicrobial ingredients in consumer products

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Does the widespread and still proliferating use of antimicrobial household products cause more harm than good to consumers and the environment? Evidence compiled in a new feature article published in the journal *Environmental Science & Technology* by Arizona State University professor Rolf Halden shows that decades of widespread use of antimicrobials has left consumers with no measurable benefits.

Worse yet, lax regulation has caused widespread contamination of the environment, wildlife and human populations with compounds that appear more toxic than safe, according to recent scientific research.

After 40 years of unfinished business, the Food and Drug Administration (FDA) has revisited the issue regarding the safety of some of the most common antibacterial additives of household products, chemicals called triclocarban (TCC) and triclosan (TCS), used in soaps and toothpaste.

"It's a big deal that the FDA is taking this on," said Rolf Halden, who has been tracking the issue for years. Halden is the director of the Center for Environmental Security, a joint research hub created with support from Arizona State University's Biodesign Institute, Fulton Schools of Engineering and the Security and Defense Systems Initiative.

The FDA has given soap manufacturers one year to demonstrate that the

substances are safe or to take them out of the products altogether. The FDA rule is open for public comment until June.

"The FDA's move is a prudent and important step toward preserving the efficacy of clinically important antibiotics, preventing unnecessary exposure of the general population to endocrine disrupting and potentially harmful chemicals, and throttling back the increasing release and accumulation of antimicrobials in the environment," said Halden.

TCC and TCS were first introduced into the market in 1957 and 1964, respectively.

"This multi-billion dollar market has saturated supermarkets worldwide and vastly accelerated the consumption of antimicrobial products," wrote Halden in the *ES&T* paper. "Today, TCC and more so TCS can be found in soaps, detergents, clothing, carpets, paints, plastics, toys, school supplies, and even in pacifiers, with over 2,000 antimicrobial products available."

Antimicrobial soaps are very effective if used properly in health care settings. However, in households they don't work because hardly anyone uses them as originally intended. To be effective, public health officials recommend scrubbing your hands with the soap to a verse of "Row, row, row your boat" for about 20-30 seconds.

In reality, Halden says, [consumers](#) use antimicrobials in hand soap for far too short a period of time, 6 seconds on average. This pattern of use voids any potential health benefits but allow TCC and TCS to contaminate the environment and expose wildlife for a lifetime and multiple generations.

Using modern research technology and more sophisticated detection methods pioneered by his lab team, Halden has examined both the

human health and environmental consequences of the widespread use of antimicrobials. His research has added to the growing worldwide scientific evidence of TCC and TCS collateral damage, including:

- TCC and TCS are the most abundant drugs in wastewater treatment plant sludge (60 percent of the mass of all drugs detectable in sewage sludge);
- TCC and TCS do not degrade easily and have persisted for more than 50 years in U.S. sediments;
- TCC and TCS contaminate lakes and rivers, exerting lifetime exposure to aquatic organisms, with endocrine disruptive and immunotoxic effects;
- Approximately 310,000 lbs/yr of TCC and 125,000 lbs/yr of TCS are applied inadvertently on U.S. agricultural land as a result of sewage sludge disposal, presenting a pathway for contamination of food with antimicrobials and drug resistant microbes;
- Traces of toxic dioxin are present in commercial grade TCS and additional dioxins are known to form upon disposal down the drain and during sludge incineration.

And that's just the environmental and wildlife consequences. Among the human health risks are promoting the development of drug-resistant infections and altering hormone levels in developing children, possibly leading to the early onset of puberty.

The Centers for Disease Control (CDC) has found the chemicals in the urine of three-quarters of Americans, and an industry-funded study detected TCS in the breast milk of 97 percent of U.S. women tested.

In the U.S., regulating TCS and TCC has been challenging. In 1974, a single umbrella guidance document, called the topical antimicrobial drug products Over-the-Counter (OTC) Drug Monograph of the FDA,

attempted to regulate all uses and best practices.

And yet, 2014 marks the 40th anniversary of the OTC FDA issuance, with this piece of federal legislation still not being finalized to protect consumers from ill effects of TCC and TCS.

Halden points out that ultimately, innovation holds the key toward solving the current worldwide antimicrobial issues. He envisions a more sustainable future with 'green' next-generation antimicrobials on the horizon that offer broad-spectrum effectiveness against pathogens but possess low toxicity and potential for fostering antimicrobial drug resistance; they also will degrade rapidly in wastewater treatment plants, thus limiting unwanted exposure and contamination of the environment following use.

With a multi-billion dollar market potential, next-generation compounds should be a highly competitive industry and the source of new jobs to fuel the 'green economy.'

"Sustainability considerations already are informing the design of green pharmaceuticals and adopting this approach for antimicrobials promises to yield important benefits to people and the planet," he concludes in the *ES&T* paper.

In the interim, Halden will be off to Washington, D.C. to exchange information with scientists and lawmakers at the FDA and the U.S. Environmental Protection Agency.

More information: pubs.acs.org/doi/abs/10.1021/es500495p

Provided by Arizona State University

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