FDA to Deliver Review of Triclosan

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This Tuesday, April 30, 2013, photo, shows Dawn Ultra antibacterial soap in a kitchen Tuesday in Chicago. Federal health regulators are deciding whether triclosan, the germ-killing ingredient found in an estimated 75 percent of anti-bacterial liquid soaps and body washes sold in the U.S. is harmful. The ruling, which will determine whether triclosan continues to be used in household cleaners, could have broader implications for a $1 billion industry that includes hundreds of anti-bacterial products from toothpaste to toys **(AP Photo/Kichiro Sato)**

WASHINGTON (AP) — It's a chemical that's been in U.S. households for more than 40 years, from the body wash in your bathroom shower to the knives on your kitchen counter to the bedding in your baby's basinet.

But federal health regulators are just now deciding whether triclosan — the germ-killing ingredient found in an estimated 75 percent of antibacterial liquid soaps and body washes sold in the U.S. — is ineffective, or worse, harmful.

The U.S. Food and Drug Administration is planning to deliver a review this year of whether triclosan is safe. The ruling, which will determine whether triclosan continues to be used in household cleaners, could have implications for a $1-billion industry that includes hundreds of antibacterial products from toothpaste to toys.

The agency's review comes amid growing pressure from lawmakers, consumer advocates and others who are concerned about the safety of triclosan. Recent studies of triclosan in animals have led scientists to worry that it could increase the risk of infertility, early puberty and other hormone-related problems in humans.

"To me it looks like the risks outweigh any benefit associated with these products right now," said Allison Aiello, professor at the University of Michigan's School of Public Health. "At this point, it's just looking like a superfluous chemical."

The concerns over triclosan offer a sobering glimpse at a little-known fact: Many chemicals used in everyday household products have never been formally approved by U.S. health regulators. That's because many germ-killing chemicals were

developed decades ago before there were laws requiring scientific review of cleaning ingredients.

The controversy also highlights how long it can take the federal government to review the safety of such chemicals. It's not uncommon for the process to drag on for years, since regulators must review volumes of research and take comments from the public on each draft.

In the case of triclosan, Congress passed a law in 1972 requiring that the FDA set guidelines for dozens of common antibacterial chemicals found in over-the-counter soaps and scrubs. The guidelines function like a cookbook for manufacturers, detailing which chemicals can be used in what products, and in what amounts.

In 1978, the FDA published its first tentative guidelines for chemicals used in liquid hand soaps and washes. The draft stated that triclosan was "not generally recognized as safe and effective," because regulators could not find enough scientific research demonstrating its safety and effectiveness.

The FDA published several drafts of the guidelines over the years, but the agency never finalized the results. So, companies have not had to remove triclosan from their products.

Meanwhile, the agency did approve triclosan for use in Colgate's Total toothpaste in 1997, after Colgate-Palmolive Co. submitted data showing that the ingredient helped fight gingivitis.

Then, last summer, the FDA said its review of triclosan would be complete by late 2012. That target date then slipped to February, which has also come and gone. But pressure on the agency from outside critics didn't let up.

In March, a federal appeals court said a lawsuit by the nonprofit Natural Resources Defense Council aimed at forcing the FDA to complete its review could move forward. A three-judge panel reinstated the 2010 lawsuit, which had been tossed out by a lower court, saying the nonprofit group presented evidence that triclosan could potentially be dangerous.

Now, four decades after it was charged with reviewing triclosan, the FDA is planning to complete its review. FDA spokeswoman Stephanie Yao said evaluating triclosan and other antibacterial agents is "one of the highest priorities" for the agency, but did not offer an explanation for the delay.

The FDA's website currently states that "the agency does not have evidence that triclosan in antibacterial soaps and body washes provides any benefit over washing with regular soap and water."

The American Cleaning Institute, a cleaning products trade organization, says it has provided reams of data to FDA showing that triclosan is both safe and effective.

"Triclosan is one of the most reviewed and researched ingredients used in

consumer and health care products," says Brian Sansoni, a spokesman for the group, whose members include Colgate-Palmolive and Henkel Consumer Goods Inc., maker of Dial soap.

While it can take years for the government to make rules, members of Congress say there is little precedent for the FDA's four-decade review of triclosan.

"When FDA first started evaluating the rules governing triclosan's use, Richard Nixon was still president," said Rep. Edward Markey, D-Mass, who asked the FDA to take a closer look at triclosan in 2010 after the European Union banned the chemical from products that come into contact with food.

"Science has evolved, and so should FDA's regulations guiding the use of this chemical in consumer products," he says.

U.S. scientists agree that the FDA's review is overdue. The Endocrine Society, a group of doctors and scientists who specialize in the hormone system, flagged triclosan four years ago as an ingredient that alters levels of thyroid hormones and reproductive hormones like testosterone and estrogen.

"I think the FDA is behind the curve," said Dr. Andrea Gore of the University of Texas at Austin, who was the lead author of the Endocrine Society's statement on hormone disrupting chemicals. "At what point do you draw a line and say we need to take this out of products that are being applied to our skin? What is enough evidence?"

Some Americans are shocked that the FDA has taken so long. Mallory Smith is troubled to learn that the government has never confirmed the safety of antibacterial soap's key ingredient.

Smith, who works for the federal government, says she keeps antibacterial soap in the kitchen to clean her hands after she's handled raw meat.

"As a regular consumer I rely on the government to identify products that are safe for me to use," Smith said. "If something is brought to their attention, they should look into it, and ban the chemical if necessary."

Others are less surprised by the government's multi-decade review. "It sounds like a typical government agency to me: totally unproductive," said David Fisher, who sells restaurant equipment in Arizona.

Ironically, triclosan first became widely used because it was considered safer than an older antibacterial ingredient, hexachlorophene. That chemical was banned from household items in 1972 after FDA scientists discovered that toxic levels could be absorbed through the skin. Several infant deaths in France were connected to baby powder that contained unsafe levels of the chemical, due to a manufacturing error.

Triclosan was initially used in hospitals in the 1970s as a scrub for surgeons preparing to perform an operation. It was also used to coat the surfaces of

catheters, stitches and other surgical instruments.

Beginning in the 1990s, triclosan began making its way into hundreds of antibacterial consumer goods, ranging from soap to socks to lunchboxes. The growth has in part been fueled by Americans who believe that antibacterial ingredients provide an added level of protection against germs.

As the use of triclosan has expanded, more scientists have questioned its effectiveness. In 2007, researchers at the University of Michigan and other universities compiled data from 30 studies looking at the use of antibacterial soaps. The results showed soaps with triclosan were no more effective at preventing illness or reducing bacteria on the hands than plain soap.

Other studies have shown that longer hand-washing improves results far more than adding antibacterial ingredients. The Centers for Disease Control recommends washing hands at least 20 seconds. The CDC also recommends using hand sanitizer — most of which use alcohol or ethanol to kill germs, not chemicals like triclosan — if soap and water are not available.

Troclosan's safety also has become a growing concern in recent years. To date, nearly all of the research on triclosan's health impact comes from animal studies —which are not necessarily applicable to humans — but the findings still have researchers concerned.

A 2009 study by scientists at the Environmental Protection Agency showed that triclosan decreases levels of testosterone and sperm production in male rats. Female rats exposed to triclosan showed signs of early puberty and altered levels of estrogen and thyroid hormones.

And 2010 study by University of Florida researchers found that triclosan interfered with the transfer of estrogen to growing fetuses in pregnant sheep. Estrogen is important in both male and female development because it promotes growth of organs like the lungs and liver.

Sansoni, the soap and detergent industry spokesman, says those animal studies can't be applied to humans and "make exaggerated claims about the damaging effects" of triclosan.

But safety concerns over triclosan don't just involve rats and other animals. Some experts argue that routine use of antibacterial chemicals like triclosan is contributing to a surge in drug-resistant germs, or superbugs, that are immune to antibiotics. Few studies have attempted to track antibiotic resistance tied to Triclosan in the real world. But laboratory studies have shown that antibiotic-resistant strains of E. coli and other bacteria can grow in cultures with high levels of triclosan.

As a result of the growing concerns, some leading medical societies, hospitals and companies have abandoned the chemical.

Kaiser Permanente pulled triclosan from its 37 hospitals across the country in 2010, switching to traditional soaps and alcohol-based hand sanitizers. Kathy Gerwig, Kaiser Permanente's vice president for workplace safety, said the hospital chain decided to phase out triclosan as part of its "precautionary approach" to safety issues.

"If there is credible evidence that a product we're using might have some disadvantages from a health or environmental standpoint, then it's our obligation to look for a safer alternative," Gerwig said.

Johnson & Johnson has pledged to remove triclosan from all of its adult products by the end of 2015. The company says none of its baby products currently contain the ingredient.

"We want people to have complete peace of mind when they use our products," Susan Nettesheim, vice president of product stewardship, said when the company made the announcement last summer.

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