EPA's process to OK pesticides raises health concerns

By Katia Savchuk, Center for Investigative Reporting

Tiny particles of silver could appear soon in children's toys and clothing, embedded inside plastics and fabrics to fight stains and odors.

No one knows how the germ-killing particles, part of a new pesticide called Nanosilva, affect human health or the environment in the long run. But regulators have proposed letting Nanosilva on the market for up to four years before the manufacturer has to submit studies on whether the particles pose certain dangers.

That's because the U.S. Environmental Protection Agency has backed approving Nanosilva through conditional registration, a fast-track process that recently has drawn criticism for oversight problems. Unlike regular registration, it allows a pesticide to be sold before all required safety studies are in. In this case, manufacturer Nanosilva LLC can move ahead even though it hasn't explored fully the potential health risks if the product were to seep out of plastic or be inhaled.

Nanosilva's approval, which could be finalized early this year, has renewed focus on the loophole, designed mainly to help the EPA speed up approvals of pesticides nearly identical to those already being sold.

Recent reviews have found vast problems with the EPA's oversight of conditional registration. An internal audit showed in 2011 that 70 percent of all active pesticides had been conditionally approved. The audit also concluded that the

agency used the label too broadly. Since then, its use has increased. Figures the EPA provided in December put the number at 80 percent.

Thousands of pesticides kept conditional status for more than 20 years, the Natural Resources Defense Council, a nonprofit environmental advocacy group, found in 2010. The EPA says studies typically are due within four years.

And last year, federal auditors found the agency couldn't reliably track how many products were conditionally registered or whether safety studies were submitted. As a result, pesticides could linger on the market for years without critical tests, the Government Accountability Office warned in August.

These aren't new problems. At least seven independent reviews dating back to 1980 have noted flaws with the agency's systems for tracking pesticide registrations.

The EPA said it has enough data on Nanosilva to know that it's safe while the manufacturer finishes testing, as the law requires. But some scientists and environmentalists say the agency is taking a risk on products that are hardly essential, like sports clothing that doesn't stain or stink or toys that last longer.

"You could allow some uses that are justified based on human well-being, such as medical implements, but to allow the possibility that nanosilver would be released in plastic on children's toys, and your kid could chew on it and ingest that material before we understand its toxicity — that's unnecessary risk," said Samuel Luoma, a research ecologist at the University of California, Davis. "It doesn't make any sense."

Conventional silver has been used as an antibacterial product for centuries. It releases ions that are deadly for many bacteria and fungi. Recently, scientists have broken down silver into particles more than 1,000 times smaller than the width of a human hair — some not much wider than a DNA strand. They're called nanosilver. Nanosilva is just one brand that contains them.

Nanosilver can be embedded directly into plastics, fabrics and other materials. Companies say this helps products last longer. It also allows them to call items antibacterial and attract germ-conscious consumers. Nanosilver needs to be registered as a pesticide because it claims to kill bacteria and other live organisms.

Regular silver is highly toxic to fish and other aquatic life but isn't usually dangerous for humans. But scientists say nanosilver could pose unique hazards, and they know little about its long-term risks.

Animal studies show that nanosilver can slip into cells and build up in the brain, heart and other organs. The EPA doesn't know whether nanosilver causes reproductive harm or cancer because there are no valid studies. Research on animals suggests that it can collect in the male reproductive system, potentially harming fertility, and may cause genetic mutations, which sometimes are linked to cancer.

Scientists have warned that nanosilver may be more toxic than regular silver and act as a carrier for other poisonous chemicals. Besides human health risks, researchers worry that nanosilver could kill fish and disrupt food chains if it makes its way into the environment.

The EPA argues that approving Nanosilva promotes innovation and lets consumers enjoy better products. The agency also says it didn't give the manufacturer enough time to do safety tests. The EPA didn't ask for those tests until nearly four years after an independent scientific advisory panel counseled the EPA on how it should evaluate nanosilver in 2009.

And, in evaluating Nanosilva, the EPA ignored some of that

panel's advice.

The scientists told the agency to evaluate every nanosilver product separately. Just because one is safe doesn't mean others will be, they said. The agency instead figured out many health and environment risks based on studies on particles that were different from those in Nanosilva. The EPA said the tests were "scientifically appropriate."

Nanosilva officials couldn't be reached for comment.

This isn't the first time the EPA has conditionally approved pesticides containing nanosilver.

In November, a federal appeals court overturned the approval of two nanosilver products, ruling that the EPA had incorrectly found they posed no risks to toddlers. That decision didn't affect Nanosilva because the EPA used different calculations in each case.

Regulators still are grappling with how to deal with nanomaterials. While only two companies have asked for EPA approval, hundreds of products containing nanosilver already are on the market, according to an inventory by The Project on Emerging Nanotechnologies.

The EPA also has fast-tracked other controversial pesticides, including ones linked to the collapse of honeybee colonies and tree deaths.

All conditionally registered pesticides meet legal safety standards, the EPA said. The agency said it's taken steps to prevent staff from coding registrations incorrectly, which it said was the main reason numbers appeared high.

The EPA also has reviewed some conditionally approved products to look for missing data and other problems. But it hasn't traced the paper trail for all pesticides, as it told federal auditors it would do by last fall. The EPA also doesn't have a concrete plan for the main fix auditors prescribed, an automated tracking system to guarantee that studies arrive and get reviewed. Currently, pesticide managers sometimes rely on handwritten notes and memory to keep track.

"Until they figure out the system, they shouldn't be using conditional registration," said Mae Wu, an attorney for the Natural Resources Defense Council.

The EPA first told federal auditors it would develop an automated tracking system more than 25 years ago.