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Regulatory system called into question

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By Scott Streater, Staff Reporter

Picture this scenario: You own the Wonderful Chemical Co., and you have developed a new compound that when added to dishwasher detergent promises to help make plates remarkably clean every time.

> Photo: Certified medical assistant Zoraida Rodriguez with a patient. Rodriguez was not surprised to learn from the Star-Telegram study that she has low levels of many toxic substances in her blood.

You want to put it on the market as quickly as possible.

Lucky for you, the federal approval process for new chemicals is suited to companies like yours.

All you have to do is apply to the Environmental Protection Agency's new-chemicals program, an overworked corner of the agency that handles an average of about 142 applications a month. Staff members have 90 days to review your application and determine whether the chemical poses a risk to human health or the environment.

You're not required to test your chemical for health effects unless evidence already exists of potential harm. You do not have to develop computer models that demonstrate what happens to your chemical once it enters the environment, how long it stays in the air or soil or whether it could get into people.

And if problems are discovered after it is in widespread use, it's up to the EPA to prove that your chemical is to blame. If you find a problem, you're required to tell the government.

To industry, the beauty of the U.S. chemical-regulatory system is that it gives manufacturers the upper hand in a competitive global economy.

"We have new chemical introductions at a rate four times greater than Europe because our system creates a climate where new chemicals can be introduced and markets developed," said Steve Russell, a senior director at the American Chemistry Council, the chemical industry's national trade group.

But to many medical researchers and health experts, the system is a growing cause for concern. They are asking whether the United States regulates toxic chemicals in a way that adequately protects people.

Even the government's own watchdog agency questioned why the burden is on the public, not industry, to ensure that chemicals in production are safe.

Critics point out that very little information exists on the potential health effects of many of the nearly 82,000 chemicals in commercial use.

"We have lots of products that are still being sold every day that we really don't know enough about to be confident that they're safe," said Dan Esty, a senior EPA administrator for former President George H.W. Bush who now directs the Yale Center for Environmental Law and Policy at Yale Law School.

Others disagree.

Many regulations control how industry uses chemicals on the market and limit the amounts that can be emitted into the air and water, said Paul Rubin, a professor of economics and law at Emory University in Atlanta.

What's more, many of those regulations were implemented "in the absence of a lot of good scientific evidence," said Roger Meiners, a professor of economics and law at the University of Texas at Arlington.

"It's not because the people doing the work are not competent or intend to have any negative consequences as a result," Meiners said. "But a lot of regulation, when it is imposed, is a reflection of the knowledge that exists at that point in time, which is limited."

And Congress, he said, has little interest in funding research.

The Toxic Substances Control Act, implemented in 1976, dictates how new chemicals are approved and regulated. It also says chemicals must not pose an "unreasonable risk to health or the environment."

But the definition of "unreasonable risk" is vague, and it's up to the EPA to do the costly research to show that a chemical poses a risk.

People have to be dropping like flies, critics say, before federal regulators can limit or ban the use of a chemical.

That's the opposite of what most scientists would consider a comprehensive chemicals policy, said Michael Wilson, a research scientist with the Center for Occupational and Environmental Health at the University of California, Berkeley. "You sort of wait for the airplanes to fall out of the air before you design an air traffic system."

In July, the Government Accountability Office criticized the toxic-substances act for placing the burden of testing new chemicals for human risks on the EPA instead of on industry. In August, the Senate Environment & Public Works Committee held hearings to determine whether the act needs to be amended to better protect human health and the environment.

The committee declined to act. But some lawmakers have proposed changes.

One is the Kids Safe Chemical Act, which among other things would require chemical manufacturers to provide health and safety information on chemicals used in a wide array of products. The bill, introduced last year by Sens. Frank Lautenberg, D-N.J., and Jim Jeffords, I-Vt., is stalled in committee, and observers say its prospects for approval do not look good.

The European Union adopted legislation that starting July 1 banned the use of two kinds of flame retardants in electrical equipment and components sold in Europe.

But that's minor compared with the EU's Registration, Evaluation & Authorization of Chemicals initiative. It will require chemical manufacturers who want to do business in Europe to submit health hazard data, most of which is not available today, for thousands of chemicals. The U.S. government has joined a number of other governments and industry leaders in lobbying against the proposal, saying it would restrict chemicals that could be harmful no matter how remote the risk. .

The initiative could receive final approval soon.

If data submitted by U.S. manufacturers show potential health hazards no one knew of before, that would put tremendous pressure on chemical companies to develop cleaner alternatives, said Esty, the Yale Center director.

"I suspect that chemicals that are found to be unacceptably toxic based on European testing will be withdrawn from the U.S. market as well," he said. "I suspect that the presence of tort lawyers looking for opportunities to bring cases would make it untenable to continue to sell any chemicals that had, in effect, flunked European testing."

Industry leaders say the EPA already has an effective system, the High Production Volume Challenge. It's a voluntary program in which companies have agreed to gather and submit hazard data for chemicals of which more than 1 million pounds a year are manufactured in or imported into the U.S. The program will ultimately yield information about some 2,200 chemicals, said Charles Auer, director of the EPA's Office of Pollution Prevention & Toxics.

That information, some of it already available on the EPA's Web site, is more than enough, said Russell, the American Chemistry Council official.

"It's just simply not accurate to say that information doesn't exist on these chemicals," he said.

But Auer concedes that the information is limited to basic screening data, not in-depth research on long-term health effects.

Jane Houlihan, vice president of research at the Environmental Working Group, a national advocacy organization, said, "It's better than nothing. But is it what we need in order to know whether these chemicals are safe? Absolutely not."

Berkeley researcher Wilson says a good chemical-regulation policy would consist of improving the flow of information about chemical toxicity, strengthening the government's ability to protect public health and devoting more public money to develop cleaner chemical alternatives.

"We can create a market that moves steadily toward the design and production of safer chemicals," he said. "We can do that if that's what we decide to do."

Good intentions

Many man-made chemicals are sources of concern today. But most have or had beneficial uses:

Polychlorinated biphenyls (PCBs): They were used extensively as coolants and lubricants in transformers and other electrical equipment because they don't burn easily and are good insulators. Their manufacture stopped in the U.S. in 1977.

Polybrominated diphenyl ethers (PBDEs): Compounds designed to prevent the chemical reaction that ignites a fire. They are used in seat cushion foam and computer wiring insulation and are added to plastics. Two of the three most widely used PBDEs were voluntarily withdrawn in the U.S. in 2004.

Perfluorooctanoic acid (PFOA): Designed to help make nonstick cookware, it is also used on fast-food wrappers and in microwave popcorn bags to keep food from sticking. DuPont and eight other companies worldwide have agreed to phase out its use by 2015.

Perfluorooctane sulfonate (PFOS): It was widely used on carpets and on sofas and other furniture to protect against staining. It was also in aerosol spray that repelled water when applied to items like camping gear and shoes. 3M voluntarily stopped making it in 2000.

DDT: A pesticide used extensively against mosquitoes, it helped control the spread of malaria and other illnesses. It was banned in the U.S. in 1972.

SOURCES: Environmental Protection Agency, federal Agency for Toxic Substances and Disease Registry. Posted on Tue, Dec. 05, 2006.