

# EU to Pace Nanotechnology Latest Study Fuels Concerns Over Health; Setting a Standard

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BRUSSELS -- Mounting concern and new scientific evidence that nanoparticles could threaten human health are ratcheting up the pressure on European officials to produce regulations governing the use of the technology.

Nanoparticles are molecules of usually harmless substances that have been manipulated into special shapes to give them desirable properties such as strength or flexibility.

Companies already sell hundreds of products containing nanomaterials and say they believe these products are safe. But a major study released this month found that at least one nanomaterial, carbon nanotubes, appears to mimic the behavior of cancer-causing asbestos in the lung.

Critics of the industry say nanotechnology companies have little safety data about their products that addresses the unique health concerns raised by nanotechnology. "Research and business communities continue to invest heavily in carbon nanotubes for a wide range of products under the assumption that they are no more hazardous than graphite," the researchers wrote in their study, published in the journal *Nature Nanotechnology*. "Our results suggest the need for further research and great caution before introducing such products into the market if long-term harm is to be avoided."

European Union regulators didn't reach any conclusions on nanotechnology as they prepared the new law on chemical standards -- known as REACH -- that comes into force on June 1. They must now decide when nanotechnology turns an ordinary substance into a whole new material that needs to be tested, as well as what new tests might be needed to gauge nanomaterials' impact on human health.

They also must decide whether additional laws will be needed to assess the potential health dangers of nanomaterials, EU officials say.

The decisions on nanomaterials are likely to affect how nanomaterials are regulated across the world, because Europe is one of the world's largest export markets for chemicals.

"REACH in Europe is setting the pace on chemicals regulation around the world," said Andrew Maynard, a scientist at the Woodrow Wilson Center in Washington and one of the lead authors of the new study on carbon nanotubes. "Any multinational is having to adhere to what REACH says ahead of whatever their local regulations are."

Nanomaterials already appear in more than 600 products, such as sunscreen, paints, disinfectants, pharmaceuticals and cosmetics, said Mark Wiesner, a professor of civil environmental

engineering at Duke University in North Carolina. The nanotechnology industry accounts for \$50 billion in sales annually and is growing at double-digit rates, he said.

Nanoparticles are used in sunscreen, for example, so the cream can be rubbed into the skin and disappear more easily. Carbon nanotubes -- the type of nanomaterial that one study has said mimics the behavior of asbestos -- are now being used in sports equipment to make them stronger and lighter.

Nanotechnology companies range from small start-ups to some of the world's biggest chemical makers. [BASF](#) AG, for example, has opened a nanomaterials research center in Singapore, and it owns a stake in U.S. nanomaterials firm SDCmaterials Inc.

The nanotechnology industry says its products should be regulated under REACH. The industry says nanotechnology is safe and will pass the requirements of the new regulatory regime.

"We are not saying that before REACH, our products were not safe," said Steffi Friedrichs, executive director of the Nanotechnology Industries Association. "There have always been a lot of requirements for safety in various markets."

Ms. Friedrichs said the study on carbon nanotubes isn't surprising, and it doesn't mean workers or consumers are at risk. Workers in the industry use protective equipment, while nanotubes used in consumer products are usually embedded in hard materials, preventing them from being inhaled, she said.

Critics say that nanomaterials producers and users are already selling hundreds of products containing nanomaterials that lack safety data.

"We're at a point right now where words don't count for much, you've got to see some action," said Mr. Maynard of the Woodrow Wilson Center. "Clearly the information the industry is working with in its health and safety data is completely out of step with information coming out of the laboratory."

The debate over how the EU should regulate nanomaterials is just beginning. In one of its first decisions, the European Commission is set to propose within the next few weeks whether REACH should keep carbon and graphite on a list of natural substances that are exempt from safety testing.

Environmentalists say carbon and graphite should be removed from the list of exempted substances to ensure that all their nanofoms are tested before being sold in Europe.

"We fear that new loopholes will be created in further exemptions from REACH," said Ninja Reineke, senior policy adviser at WWF, an environmental group.

The chemical industry, however, says carbon and graphite should stay on the list, because nanomaterials have separate classification numbers from the carbon or graphite they are derived from. They would therefore be subject to safety testing under REACH.

"We have always been saying that nanomaterials and nanoforms are perfectly covered by the REACH legislation," said Erwin Annys of the European Chemical Industry Council.

But the Woodrow Wilson Center's Mr. Maynard said there are nanomaterials that simply have the classification numbers of carbon and graphite and so would be exempt from REACH safety testing rules if carbon and graphite remain exempted.

In the next few weeks, the commission plans to issue a report that will review the various EU regulations surrounding nanomaterials and identify possible gaps, EU officials say. Then a working group will meet in July to discuss more broadly how nanomaterials should be regulated under REACH and other EU health and safety laws.

The group will also examine what kinds of new tests may be needed to gauge the impact of exposure to nanomaterials on humans.

"Nanomaterials should be treated like any other substance, and therefore will be subject to the information requirements under REACH," said Ton Van Lierop, spokesman for the commission's business directorate, which is partly responsible for implementing the new rules.

He adds, however, that some issues do need clarification. "How to characterize nanomaterials? Should they be seen as separate substances? And how to refine testing methods?" he asks.