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U.S. regulators lack data on health risks of most chemicals

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This summer, when Kellogg recalled 28 million boxes of Froot Loops, [Apple](#) Jacks, Corn Pops and Honey Smacks, the company blamed elevated levels of a chemical in the packaging.

Dozens of consumers reported a strange taste and odor, and some complained of nausea and diarrhea. But Kellogg said a team of experts it hired determined that there was "no harmful material" in the products.

Federal regulators, who are charged with ensuring the safety of food and consumer products, are in the dark about the suspected chemical, 2-methylnaphthalene. The Food and Drug Administration has no scientific data on its impact on human health. The Environmental Protection Agency also lacks basic health and safety data for 2-methylnaphthalene -- even though the EPA has been seeking that information from the chemical industry for 16 years.

The cereal recall hints at a larger issue: huge gaps in the government's knowledge about chemicals in everyday consumer products, from furniture to clothing to children's products. Under current laws, the government has little or no information about the health risks posed by most of the 80,000 chemicals on the U.S. market today.

[\(As product recalls pile up, consumers risk getting lost\)](#)

"It is really troubling that you've got this form of naphthalene that's produced in millions of pounds a year and we don't have some of the basic information about how toxic it is," said Erik Olson, an expert at the Pew Charitable Trusts, which is advocating an overhaul of U.S. chemical laws. "In so many cases, government agencies are missing data they need on even widely used chemicals about whether they pose a health risk."

The information gap is hardly new. When the Toxic Substances Control Act was passed in 1976, it exempted from regulation about 62,000 chemicals that were in commercial use -- including 2-methylnaphthalene. In addition, chemicals developed since the law's passage do not have to be tested for safety. Instead, companies are asked to volunteer information on the health effects of their compounds, and the government can decide whether additional tests are needed.

In 1994, the EPA invited the chemical industry to submit health and safety data for 2-methylnaphthalene because it was being produced in large quantities, said Mary F. Dominiak of the EPA. Chemical manufacturers have yet to disclose that information, she said.

And they may not even have it. If a manufacturer possesses data showing that a chemical harms health or the environment, it is required to turn over the findings to the EPA. Critics say that creates a disincentive for manufacturers to test their chemicals.

Kellogg responded to a request for comment by referring to the statement it issued with its recall, which said, "While the potential for serious health problems is low, some consumers are sensitive to the uncharacteristic off-flavor and smell and should not eat the recalled products because of possible temporary symptoms including nausea and diarrhea."

Bills pending in Congress would revamp the way the government regulates chemicals, forcing companies to prove that new chemicals are safe before using them and requiring health and safety assessments of existing chemicals, such as 2-methylnaphthalene. The chemical industry has said it agrees the law should

be revamped, but it also has expressed concern that new restrictions might hamper innovation and competitiveness.

One federal agency has minimal information about 2-methylnaphthalene -- the Agency for Toxic Substances and Disease Registry, which reviewed the scientific literature on the chemical in 2005. It concluded that nothing is known about its use related to food. "You are not likely to be exposed . . . eating foods or drinking beverages" and risk exposure only "if you live near a hazardous waste site," according to the agency's Web site.

A natural component of crude oil, 2-methylnaphthalene is structurally related to naphthalene, an ingredient in mothballs and toilet-deodorant blocks that is considered a possible human carcinogen by the EPA. Kay Cooksey, a packaging expert at Clemson University, said 2-methylnaphthalene likely ended up in cereal because something went awry in the manufacturing of the foil-lined bags. The foil is attached to the paper bag with an adhesive that is heated, she said. If too much heat is applied or if the composition of the adhesive is incorrect, 2-methylnaphthalene could form, she said.

The chemical "is not supposed to be in food," said Mitchell Cheeseman of the FDA's office of food safety. The agency allows a minute amount of the chemical in food packaging if it is produced as a "contaminant" during the manufacturing process, but it is not supposed to transfer to the food, he said.

Because the FDA does not know anything about the toxicity of 2-methylnaphthalene, the agency set its limit based on what it knows about the toxic effects of similar chemicals, Cheeseman said.

He added that the FDA does not know what caused the Kellogg contamination, how much 2-methylnaphthalene might have migrated into the cereals or if it was the only contaminant. The agency did not perform its own tests on the cereals.

Roberta Wagner of the FDA's Office of Regulatory Affairs said Kellogg destroyed most of the tainted liners before it contacted the agency and announced a recall.

"Basically, Kellogg's investigated the situation before they made the decision to do the recall," Wagner said. "They did their own testing." She said the agency continues to investigate.

The company submitted a copy of its health risk assessment to the FDA, but neither Kellogg nor the agency would release it.

Cheeseman said it is unusual for contaminants to migrate from packaging into foods.

But others are less certain. "In this case, it had an odor and it had a taste, so it was detected," said David Andrews, a senior scientist at the Environmental Working Group, an advocacy organization. "But there are hundreds of other potential impurities that we can't smell and taste, chemicals that we know very little about and the government knows little about."

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