

European Food Regulator Strikes Down Splenda Cancer Study

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By [*Tiffany Stecker*](#)

Europe's food safety regulator has taken aim at a study on a popular artificial sweetener and cancer, the latest rebuttal of questions about the safety of low-calorie sugar substitutes.

The European Food Safety Authority issued a [statement](#) May 8 on the validity of findings in a study last year of sucralose, the main ingredient in Splenda, saying the data in the study did not support the authors' conclusions that the sweetener could lead to cancer in laboratory mice.

The study was led by scientists at the Ramazzini Institute in Bologna, Italy, and continues a simmering debate on the methods the institute employs to study potentially carcinogenic substances.

It's not the first time EFSA has criticized the Institute's work. The regulatory agency has repeatedly downplayed Ramazzini's studies tying aspartame, another low-calorie additive, to cancer.

The U.S. government has also questioned the institute's studies. In 2010, the National Toxicology Program criticized the Institute's findings for three fuel additives, causing a delay in the Environmental Protection Agency's assessments of the chemicals. Earlier this year, the House Science, Space and Technology Committee said it would look into the National Institutes of Health's grants to the Ramazzini Institute and contracts. NIH has sent about \$92 million since 2009 to the institute.

The institute's methods stands out from the standard practices of cancer research, a position that has opened it to pans, but also praise from groups who say it better reflects human exposure.

Difficult Data, No Cause-Effect Link

"I think [the EFSA statement] adds to the skepticism that has existed," Alan Boobis, a professor of toxicology at Imperial College in London, told Bloomberg BNA. Boobis is

also a board member of the International Life Science Institute (ILSI) Europe, which counts a number of food and beverage companies as members.

Specifically, EFSA questioned the sucralose study's design, which considers sucralose intake from the fetal stage to the natural death of the test animals. This introduces a broad range of factors that could create misclassifications and make the data more difficult to interpret, said the panel that undertook the review.

The panel also noted a lack of a dose-response relationship between sucralose intake and the incidence of lymphomas and leukemias, and the failure to establish the cause-effect relationship for epidemiological studies. In addition, there was no reliable evidence that the mice's genes were affected by ingesting sucralose—a key consideration in the development of cancer.

“The available data did not support the conclusions of the authors ... that sucralose induced haematopoietic neoplasias in male Swiss mice,” the panel said in its statement. Haematopoietic neoplasias indicate the development of leukemia or lymphoma.

The institute uses a particular study design that is unusual for the type of research it does, Boobis said. There is no formal external quality assurance procedure, which is required under the “Good Laboratory Practices” standards set by the Organisation for Economic Co-operation and Development. Outside researchers have also pointed to the prevalence of similar infections in Ramazzini's test animals. The inflammation can confuse the results of the studies, he added.

A representative from the Institute could not be reached for comment. But Lisa Lefferts, a senior scientist with the Center for Science in the Public Interest, defended the institute's way of conducting its experiments.

Ramazzini's methods are tailored to the longer studies they conduct, Lefferts said. Humans are more likely to get cancer later in life, and experimental studies that end too soon are less likely to capture those incidences of cancer. The study, which ran for nearly 10 years, also accounted for exposure to fetuses.

“It mirrors the situation to consumers and is more likely to detect cancer,” Lefferts told Bloomberg BNA. “They exceed Good Laboratory Practices, in my view.”

EFSA 'Notorious' for Industry-Friendly Stance

The center, which maintains a ranking of food additives' safety, downgraded sucralose from “caution” to “avoid” last year as a result of the Ramazzini Institute's paper. The center announced May 9 it would continue to advise consumers to avoid the sweetener, despite EFSA's dismissal of the findings.

“EFSA is notorious for having industry-friendly opinions and for conflicts of interests on its panels,” the organization said in a statement. CSPI did add that risks of eating too

much sugar—diabetes, heart disease, and obesity—far outweigh the cancer risk posed by artificial sweeteners.

The bigger question, Boobis said, is whether such experiments on animals are appropriate for cancer studies. A study without the proper controls and methods raises ethical questions on the use of test animals, he said. The issue has greater significance in Europe, where animal welfare laws spur a higher standard for animal experiments.

If the study's design was flawed from the beginning, "why use the animals in the first place for this purpose?" Boobis said.

The EFSA move also drew praise from the maker of Splenda sweetener and critics of the Institute's practices.

"EFSA's decision puts good science first, and it is consistent with the movement to bring greater scrutiny to poorly designed studies that draw false conclusions and unjustifiably alarm consumers," said the Heartland Food Products Group, the Carmel, Ind., producer of zero-calorie sweeteners and water flavorings.

The Campaign for Accuracy in Public Health Research, an American Chemistry Council-funded campaign aimed at reforming certain European scientific bodies such as Ramazzini and the International Agency for Research on Cancer, also slammed the institute.

"We should all demand integrity in the scientific process particularly when used to determine public policy," spokeswoman Ana Heeren said in an email.

The European agency's statement is good news for the industry following a [study](#) published in the scientific journal *Stroke* that found a link between artificially sweetened soft drinks and stroke and dementia.

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