Food additive safety often determined by those with food industry ties, study finds

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Review finds strong conflict-of-interest issues in the approval process; experts call for changes.

(HealthDay)—Experts selected by the food industry have often been the ones approving the safety of food additives for the past 15 years, a new report claims.

In a study of conflict-of-interest issues in food safety evaluations, researchers from The Pew Charitable Trusts found that employees of food additive manufacturers wrote one of every five safety determinations submitted to the U.S. Food and Drug Administration by the industry between 1997 and 2012.

Another 13 percent of the determinations were written by someone working for a consulting firm selected by the manufacturer. And the remainder of the reviews were conducted by expert panels selected either by the manufacturer or a consultant to the manufacturer, according to the report published online Aug. 7 in the journal *JAMA*

Internal Medicine.

The study also found that the expert panels conducting a majority of the safety assessments tend to feature the same experts repeatedly.

"There's a cadre of 10 people that serve on almost all of these expert panels," said study author Thomas Neltner, director of Pew's food additives project. "Three-quarters of the panels contained at least one of these people. One person served on 44 percent of the panels, which tells us there's not only conflicts of interest, but there's a very small group of people making these decisions."

The study used conflict-of-interest criteria developed by a committee of the Institute of Medicine to analyze 451 "generally recognized as safe," or GRAS, determinations that the food industry submitted to the FDA over a 25-year period.

The Food Additives Amendment of 1958 allows manufacturers to determine when an additive is GRAS. Manufacturers are not legally required to notify the FDA about GRAS determinations, but in some cases they do, the authors wrote.

"For right now, the law doesn't even require a company to tell the FDA that it's going to start marketing or using a new food ingredient," said Michael Jacobson, executive director of the Center for Science in the Public Interest. "The FDA may not even have the chance to evaluate the safety of new ingredients."

The researchers found that employees of additive manufacturers made about 22 percent of the GRAS determinations submitted to the FDA.

And the expert panels that made GRAS determinations included 10 experts who served on at least 27 of 290 panels, and one person who

served on 128 panels, the study revealed.

"These committees give a very superficial, one-sided review," Jacobson said. "They want to please the sponsor, and then maybe they will get more business because they've proven themselves trustworthy, but it's no way to run a food safety review process."

In a related commentary in the journal, Marion Nestle of New York University wrote: "The lack of independent review in GRAS determinations raises serious questions about the public health implications of unregulated additives in the food supply, particularly the additives that the FDA does not even know about. It also raises questions about conflicts of interest in other regulatory matters."

An FDA official said the agency encourages companies to notify the FDA about food ingredients they have determined are GRAS.

"While notification is not required, it is a way for companies to ensure that their GRAS determinations are based on sound data and information," said FDA spokeswoman Theresea Eisenman. "For example, the addition of caffeine to a widening array of products like chewing gum, waffles and syrup is an example of where notification of a company's GRAS determination would have been useful for both government and industry."

She added, "FDA plans to issue guidance to industry on meeting the GRAS criteria established under the Act."

Jacobsen said a complete overhaul of the system might be required.

"It really dramatizes the extent to which the people who are evaluating many new food ingredients have severe conflicts of interest," he noted. "That should make the public and Congress think about revising the

whole system by which new food ingredients enter the food supply."

Jacobsen said that the FDA has been reluctant to act on concerns over the validity of the additive safety review process, believing that Congress should step in.

However, the FDA could rewrite the rules for choosing experts to serve on the GRAS panels, Neltner noted.

"They define the qualifications of these people. One of those qualifications can be that they have no conflicts of interest," Neltner said. "If this person would be disqualified from being on an FDA advisory committee due to conflicts, they shouldn't be allowed to serve on these panels."

More information: For more information on GRAS, visit the U.S. Food and Drug Administration.