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# Food chemical regulations rely heavily on industry self-policing and lack transparency

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Safety decisions concerning one-third of the more than 10,000 substances that may be added to human food were made by food manufacturers and a trade association without review by the U.S. Food and Drug Administration (FDA), according to an analysis spearheaded by the Pew Health Group.

The report, published today in the peer-reviewed journal *Comprehensive Reviews in* Food Science *and* Food Safety, illustrates potential problems with the U.S. food additive regulatory program.

"Congress established our food additive regulatory program more than 50 years ago, and it does not stand up well to scrutiny based on today's standards of science and public transparency," said Tom Neltner, Food Additives Project director in the Pew Health Group.

The research also found that the FDA developed an expedited process in the mid-1990's that essentially eliminated the opportunity for public involvement in decision making prior to FDA's safety determination. This shift doubled the rate of industry requests for FDA review. In contrast, standard operating procedure for other federal regulatory decisions regarding drug, workplace, and environmental safety requires public notice and an opportunity to comment.

"While the shift to a new regulatory process–one in which companies make safety decisions and ask FDA to confirm them–has sped up agency review, it has also bypassed the public," Neltner said. "Subjecting safety

decisions to comment from competitors, academic scientists, public interest groups, and the general public can result in stronger protections for consumers. In an age of growing demand for government transparency, there is virtually no meaningful opportunity for participation in decisions about large classes of substances added to the food supply."

When Congress passed the Food Additives Amendment of 1958, it created a structure that has limited the FDA's ability to effectively regulate substances added to food because the law:

1. Allows manufacturers to determine that the use of an additive is "generally recognized as safe" (GRAS), and then use that substance without notifying the FDA. As a result, the agency is unaware of many substances that may be added to food and lacks the ability to ensure that safety decisions were properly made.

2. Does not require that manufacturers inform the FDA when health reports suggest new hazards associated with additives already used in food. Therefore, the agency has no access to unpublished reports and must expend limited resources sifting through published information to identify potential problems and set priorities.

In addition to the article examining the state of the food additive regulation, a piece in the same publication summarizes a workshop, co-sponsored by the Institute of Food Technologists and the journal Nature, examined how FDA evaluates the potential hazards posed by substances added to food. The two-day session, held in April 2011, brought together science and food policy experts from government, industry, academia, and public interest organizations. Issues discussed at the workshop and presented in the journal article include:

-- The need for clear procedures to develop validated toxicological tests

and regularly revise guidance documents to reflect advances in science.

-- Opportunities to improve academic research to make it more usable for regulatory decision making and enhance coordination between federal agencies.

-- Challenges to reassessing a chemical's safety after it is on the market.

Provided by Pew Health Group