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Navigating the U.S. Food Additive Regulatory Program

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Due to publishing restrictions, the full text of this article can be accessed online here.

Abstract: The Food Additives Amendment of 1958 is the foundation for the U.S. food additive regulatory program, which oversees most substances added to food.

This article is a comprehensive review of the program, including original analysis of pre- and postmarket safety standards for various categories and subcategories of substances and their uses; assigning the more than 10000 substances currently allowed in human food to those categories; and analyzing the U.S. Food and Drug Administration's (FDA) review of more than 1900 petitions and notifications received from 1990 to 2010.

Overall, federal agencies made approximately 40% of the 6000 safety decisions allowing substances in human food. These decisions allowed an estimated 66% of the substances currently believed to be used in food. Manufacturers and a trade association made the remaining decisions without FDA review by concluding that the substances were generally recognized as safe (GRAS).

Robust premarket safety decisions are critical since FDA has limited resources to monitor potentially significant scientific developments and changing uses of a substance after it enters commerce and only has access to published data or data submitted to it. In the late 1990s, FDA moved from promulgating rules for its decisions for food contact and GRAS substances to reviewing manufacturer safety decisions and posting the results of the review on the agency's website.

This shift appears to have encouraged manufacturers to submit their decisions to FDA for review but has limited public opportunity to provide input.

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Learn more about the Pew Health Group's Food Additives Project.