

What Did Pew Health Group Find in Its Review of the U.S. Food Additive Regulatory Program?

In 2010, supermarkets carried an average of 38,718 different items on their shelves.¹ Such diversity did not appear overnight—our modern food supply and the food production system have grown increasingly complex since the mid-20th century, especially with the growth of processed foods. Often this variety is achieved through the use of added chemicals. These substances, commonly known as food additives, are found in items we consume every day. They perform many roles, including preserving flavor, enhancing taste or appearance, preventing spoilage, and packaging the food.

The safety of more than 3,000 chemicals added to human food has not been reviewed by FDA.

How many chemicals are allowed in human food?

In the November 1, 2011, edition of the peer-reviewed journal *Comprehensive Reviews in Food Science and Food Safety (CRFS)*, Pew Health Group published a rigorous analysis of the U.S. food additive regulatory program.² For this examination, Pew developed two novel methods to estimate the number of chemicals allowed in human food and the number of affirmative safety decisions for these substances. Key among the findings is that more than 10,000 chemicals were allowed in human food as of January 2011.

One-third of these chemicals (more than 3,000) were approved by manufacturers or the Flavor and Extract Manufacturers Association (FEMA) Expert Panel. The remaining two-thirds were cleared by a federal agency—either the Environmental Protection Agency (EPA) (in the case of pesticides) or the U.S. Food and Drug Administration (FDA) (for all other chemicals). Since many of FDA’s safety decisions covered multiple chemicals (sometimes hundreds of them), simply counting the number of chemicals overestimates the agency’s contribution. Therefore, the article includes a complementary method that suggests that manufacturers and a trade association may have made the majority of affirmative safety decisions.

How do most chemicals get clearance to be added to human food?

No chemical may be used in or on food unless there has been a decision that it is safe for consumers. There are three ways for a food company to obtain clearance to begin using a chemical in or on food.

1. The manufacturer or a trade association decides a chemical’s use is “generally recognized as safe” or, in industry parlance, a “GRAS substance,” based on the opinion of experts in the field using published studies. In this case, it need not notify FDA, and the public has no involvement in the safety decision.
2. FDA (or EPA in the case of pesticides) approves the use of a chemical by issuing a new or amended regulation. FDA usually makes this safety decision in response to a petition by a manufacturer or its representative and provides the public with the opportunity to comment before the chemical use is approved and a regulation is issued. Before 1995, FDA made all of its safety decisions this way, but from 2006 to 2010 this route accounted for less than 3 percent of the agency’s decisions.

3. A manufacturer asks FDA to review a chemical it wants to use in food. In response, FDA sends a letter stating that it has “no objections” or “no questions.” The public is not notified prior to the agency’s decision and does not have an opportunity to comment. FDA developed this expedited approach in 1995, and Congress later approved this method for certain types of substances. From 2006 to 2010, more than 97 percent of FDA’s decisions used this method.

What is done to make sure a chemical is safe after it has been cleared?

When Congress established the food additive regulatory program in 1958, it focused on ensuring a chemical was safe *before* a food company could market or use the substance. It did not establish specific requirements to ensure continued safety. Currently, there is no requirement for FDA to regularly review chemicals added to food to ensure their safety *after* their initial approval. Also, unlike pesticides, industrial chemicals, and chemicals in consumer products, manufacturers are *not* required to inform FDA of the amount of these chemicals they are using in food or new scientific data suggesting potential health safety issues associated with the chemicals.

Conclusions

Pew’s analysis found that the legal framework Congress created in 1958 has not kept pace with science and the food industry, essentially limiting FDA’s ability to effectively regulate chemicals added to food. The gaps in regulatory safeguards suggest that in many cases public safety is in the hands of the food manufacturers rather than FDA.

Four primary areas of concern were revealed through this analysis.

1. FDA is unaware of a large number of chemical uses in food and, therefore, cannot ensure that safety decisions regarding these uses were properly made.
2. Food manufacturers are not required to notify FDA of relevant health and safety studies, thereby placing FDA in the difficult position of tracking safety information for more than 10,000 chemicals with limited resources and information.
3. The agency’s expedited approach to reviewing safety decisions since 1995 occurs with little public engagement.
4. FDA lacks the resources and information needed to identify and prevent potential health problems or to set priorities for systematic reevaluation of safety decisions made during the past half-century.

About Pew Health Group’s Food Additive Project

In 2010, Pew Health Group launched its Food Additive Project. Its purposes are to: (1) conduct a comprehensive analysis of the existing regulatory program; (2) determine whether that system ensures that chemicals added to food are safe as required by law; and (3) develop policy recommendations. Through a transparent process that engages industry, academic, government, and public interest stakeholders, project staff consult with a team of expert advisors, hold workshops, and publish peer-reviewed journal articles.^{3,4} See www.pewtrusts.org/foodadditives for more information on the initiative.

¹ Food Marketing Institute, “Supermarket Facts: Industry Overview 2010,” www.fmi.org/facts_figs/?fuseaction=superfact, accessed October 2011.

² Neltner et al., “Navigating the U.S. Food Additive Regulatory Program.” *Comp Rev Food Sci Food Safety* [serial online], 10(6):342–370, 2011. Available from www.pewtrusts.org/our_work_detail.aspx?id=1203.

³ Ibid.

⁴ Maffini et al., “FDA’s Evaluation of Science to Ensure Chemicals Added to Human Food Are Safe: Workshop Proceedings.” *Comp Rev Food Sci Food Safety* [serial online], 10(6):321–341, 2011. Available from www.pewtrusts.org/our_work_detail.aspx?id=1203.