



Review of the Scientific Basis for Safety Decisions on Hazards of Substances Added to Food

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 its production system have grown increasingly complex, especially with the growth of processed foods in the mid-20th century. As a result, a significant number of the foods that make up the modern diet contain added chemicals. These chemicals are commonly known as food additives and perform many roles, including preserving and enhancing flavor, enhancing taste, preventing spoilage, and packaging the food.

The Food Additives Amendment of 1958 requires either the Food and Drug Administration (FDA) or a manufacturer to determine that a chemical's use is safe before it is added to or comes in contact with food. The law specifies that a chemical is safe when there is "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."² This language is wrought with ambiguity, and many in the scientific and public interest communities have questioned how FDA utilizes and interprets data when the agency determines the safety of a chemical's use in food.³

To help answer this question, in April 2011 Pew Health Group convened a workshop bringing together more than 80 experts from government, industry, academia and public interest organizations to examine the principles underlying the development and use of scientific evidence to identify and characterize chemical hazards. The workshop, "Enhancing FDA's Evaluation of Science to Ensure Chemicals Added to Human Food Are Safe," was cosponsored by the Institute of Food Technologists and the journal *Nature*. In the November 1, 2011, issue of the peer-reviewed journal *Comprehensive Reviews in Food Science and Food Safety*, Pew published a proceeding of the discussions.⁴

Based on the workshop discussions, Pew observed that:

- FDA's guidance regarding safety decisions does not reflect the latest developments in science and academic research. Since manufacturers are themselves permitted to determine that a new substance is "generally recognized as safe" based on FDA's testing guidelines without actually involving the agency, it is essential that these guidelines be kept current.
- FDA often has to make premarket safety decisions based on incomplete information. Once a chemical is approved, however, FDA does not have the resources to systematically evaluate scientific developments relevant to that chemical among the thousands of substances within its purview. Furthermore, manufacturers are under no obligation to notify the agency of potential health problems to which they might become aware.

Enhancing FDA's Evaluation of Science

Scientists participating in the workshop generally agreed that FDA's evaluation of science to ensure that chemicals in or on food are safe could be improved.⁵ Although there was no intention for participants to reach a consensus, Pew noted that several topics emerged repeatedly, including:

Definition of "harm"

Congress did not include formal definitions of "harm" and "safe" in the Food Additives Amendment of 1958, and FDA's regulations implementing the law do not provide much clarification. As a result, stakeholders had a broad range of views about what constitutes an adverse effect and how to identify and characterize harm.

Need for Transparency

Without well-communicated decisions and a clear decision-making process, scientists find it difficult to conduct research most useful for FDA or share their data with the agency in an effective and timely manner. It is important that FDA be transparent in its decision, in the criteria it uses to evaluate submitted scientific data and in strategies to keep its toxicology tests current and relevant.

Postmarket Assessment

A current shortcoming of FDA's approach to ensure the safety of food chemicals is its apparent lack of a structured process to perform reviews of previously approved chemicals. Developing strategies and priorities for periodic reevaluations of chemicals already in commerce will help the regulatory system keep current with scientific advances.

Validating New Research Methods

Scientific understanding of what causes harm or contributes to diseases in humans is constantly changing. New research methods need to be validated and incorporated in a timely manner into FDA's Redbook—an electronically available document that contains guidelines for assessing the potential hazards of chemicals in or on food. To do so, strategies are needed for keeping regulatory science abreast with broader scientific developments.

Open Communication

Cutting-edge research can change scientific understanding about a particular chemical's use. A frequent consultation between key groups, including FDA, the academic and government scientific communities, and industry could enhance the regulatory usefulness of new advances.

Supporting Innovation

Reduce the time it takes to validate new guidelines through innovation by making better use of academic research, stimulating public and private funding, and enhancing collaboration between federal and international agencies.

Improving Academic Research

With proper incentives, academic researchers could modify their studies to better support the needs of regulators. Specifically, funding agencies could create incentives for this shift in research focus.

Pew Health Group's Food Additives Project

In 2010, Pew Health Group launched the Food Additives 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, the project's staff consults with its team of expert advisers, holds workshops, and publishes peer-reviewed journal articles.⁶⁷ 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 21 CFR §170.3(i), 2011.

³ *Nature* (editorial), "The Weight of Evidence: Better chemical-control legislation is a good start, but scientific reform should parallel legal reform." *Nature* 464:1103–1104, April 22, 2010.

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.

⁵ *Ibid.*

⁶ *Ibid.*

⁷ 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.