Does FDA approval mean that GMOs are safe?

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The decisions made by the FDA concerning genetically modified food (GMOs) have been based on politics and not science. The official FDA policy on GMOs was first written by Michael R. Taylor who is currently Deputy Commissioner for Foods at the FDA. This position was created in 2009 and filled by Taylor in 2010. At the time Taylor wrote what has since become the FDA policy on GMOs, he was working for the law firm King & Spalding. Among his clients were Monsanto and the International Food Biotechnology Council (IFBC). It was for the IFBC that he wrote the document that eventually, with some editing, became the official FDA policy. In 1991, Taylor left the law firm for the newly created post of Deputy Commissioner for Policy at the FDA. This was his second stint at the FDA. Between 1994-1996 he was the Administrator of the Food Safety & Inspection Service at the USDA. Following that, he accepted the post of Vice President for Public Policy at Monsanto before taking his current job at the FDA.

A federal law was written in 1958 banning chemical additives in food that are known carcinogens. In 1988, Taylor wrote a paper arguing that this law can be interpreted to allow carcinogenic chemicals in food so long as they are present in low amounts presenting minimal risk. FDA policy states that GMO crops are not even considered additives, but they are "substantially equivalent" to conventional crops and they need no separate category.

Before new drugs are approved by the FDA they must go through a series of rigorous animal testing. If adverse effects are not found in the animal tests, they must then proceed to a series of rigorous clinical trials with human beings. The chemical companies who have developed the genetically engineered (GE) seeds have made the claim to the FDA that their products do not qualify as a new drug because they are essentially identical to non-GMO crops and therefore do not require the same rigorous testing. The EPA agreed and as a result, the FDA's GMO policy is that the biotechnology companies can determine if their own foods are safe. There are no required safety studies. [See excerpts from the FDA Federal Register at the end of this article.]

A genetically modified plant may or may not require FDA approval (depending on whether or not the modification can be considered an "additive" as in some yeasts, for example). If it does require approval, it is up to the producer to perform the tests to insure safety. The tests that have been performed for FDA approval have all been performed and/or paid for by the petitioner *and those data are not published in journals or subjected to peer review*. Most of these studies were done on rats, none were undertaken for more than 90 days and many were much less; not nearly long enough for adverse effects to show. There have been no safety studies done by any federal agencies.

Excerpts from the Statement of Policy - Foods Derived from New Plant Varieties

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"In most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food,..."

"Finally, the principles discussed in this notice do not apply to "new drugs" as defined by section 201 (p) of the act (21 U.S.C. 321(p)), "new animal drugs" as defined by section 201(w) of the act (21 U.S.C. 321(w)), or to "pesticide chemicals" as defined by section 201(q) of the act. As discussed in section IX., EPA is responsible for pesticide chemicals, including those produced in plants as a result to genetic modification." [note "the act" is the Federal Food, Drug, and Cosmetic Act]

"Any genetic modification technique has the potential to alter the composition of food in a manner relevant to food safety, although, based on experience, **the likelihood of a safety hazard is typically very low**. The following paragraphs describe some potential changes in composition that may require evaluation to assure food safety."

"Section 402(a)(1) of the act imposes a legal duty on those who introduce food into the market place, including food derived from new crop varieties, to ensure that the food satisfies the applicable safety standard."
"In enacting the amendment [food additive amendment, 1958], Congress recognized that **many substances intentionally added to food do not require a formal premarket review by FDA to assure their safety,** either because their safety had been established by a long history of use in food or because the nature of the substance and the information generally available to scientists about the substance are such that the substance simply does not raise a safety concern worthy of premarket review by FDA. Congress thus adopted a two-step definition of "food additive." The first step broadly includes any substance the intended use of which results in its becoming a component of food. The second step, however, **excludes from the definition of food additive substances that are GRAS [generally recognized as safe].** It is on the basis of the GRAS exception of the "food additive" definition that many ingredients derived from natural sources (such as salt, pepper, vinegar, vegetable oil, and thousands of spices and natural flavors), as well as a host of chemical additives (including some sweeteners, preservatives, and artificial flavors), **are able to be lawfully marketed today without having been formally reviewed by FDA** and without being the subject of a food additive regulation. The judgment of Congress was that subjecting every intentional additive to FDA premarket review was not necessary to protect public health and would impose an insurmountable burden on FDA and the food industry. **It is the responsibility of the producer of a new food to evaluate the safety of the food and assure that the safety requirement of section 402(a)(1) of the act is met."**

"With respect to transferred genetic material (nucleic acids), **generally FDA does not anticipate that transferred genetic material would itself be subject to food additive regulation.** Nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans or animals, and do not raise a safety concern as a component of food. **In regulatory terms, such material is presumed to be GRAS.** Although the guidance provided in section VII. calls for a good understanding of the identity of the genetic material being transferred through genetic modification techniques, **FDA does not expect that there will be any serious question about the GRAS status of transferred genetic material."**

"Section VII. of this notice provides guidance to producers of new foods for conducting safety evaluations. This guidance is intended to assist producers in evaluating the safety of the food that they market, regardless of whether the food requires premarket approval by FDA. **This guidance also includes criteria and analytical steps that producers can follow in determining whether their product is a candidate for food additive regulation** and whether consultation with FDA should be pursued to determine the

regulatory status of the product. **Ultimately, it is the food producer who is responsible for assuring safety."**