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Biotech Crops' Seal of Safety Does Not Convince Skeptics

By Bryan Keogh

Genetically modified organisms (GMOs) have become nearly ubiquitous in U.S.-produced corn, soybeans, and canola, and more than two-thirds of the processed foods Americans consume contain such ingredients. Government agencies and international bodies have repeatedly approved the foods for human consumption while arguing that such bioengineered crops help preserve the environment and could save millions from hunger. Yet many consumers and some scientists remain skeptical, particularly in Europe. GMOs' skeptics worry that prolonged exposure to such foods promotes allergies and even cancer.

Hundreds and some say thousands of studies have examined the health effects of bioengineered products, most concluding that GMOs are as wholesome as other foods, persuading 60 countries to approve the importation of genetically engineered crops for food or animal feed and 29 led by the U.S. to allow their production, according to the International Service for the Acquisition of Agri-biotech Applications (ISAAA)—a nonprofit group that encourages using GMOs to alleviate hunger and poverty. The World Health Organization, the National Academies, and the European Commission describe them to be as safe as their conventional counterparts, helping worldwide market growth for biotech foods to reach $160 billion.

But doubts persist. Opponents and those merely urging caution point to a few studies—which biotechnology backers discount—indicating cancerous or other effects in rats. The lingering concerns have prompted countries, including Germany, France, Peru, and a county in California to ban the crops and have led to labeling campaigns, such as those in Europe, to give consumers the option to avoid foods containing such organisms. A chief complaint about the research declaring GMOs safe is that the studies are too short to assess the long-term toxic effects of consuming foods genetically manipulated to promote herbicide tolerance, insect resistance, or other traits, and that longer-term studies are needed to truly demonstrate safety.

In 1992, the U.S. Food and Drug Administration called foods containing ingredients derived from the recombinant DNA technology used to make GMOs "substantially similar" to conventional ones and deemed them "generally recognized as safe." Since then, proponents and government agencies have insisted that the more extensive tests required for drugs or pesticides aren't necessary. Only a latent trend—such as an inexplicable spike in cancer rates—could signal that consuming GMOs over several decades may lead to health problems stemming from the buildup of toxins in the body.

Parsing the Evidence

"There's really very little evidence one way or another," said Lawrence Kushi, associate director and nutritional epidemiologist at Kaiser Permanente in Oakland, Calif. "Part of the problem from an epidemiological perspective is that it's difficult to actually study this question because people don't know whether they've actually consumed [GMOs]."

The stakes are high. Apart from those who stand to profit most from the increased use of biotechnology, in its starkest terms the debate pits the potentially substantial but thus far unproven health risks against the need for a "food revolution" that may be essential to feeding the world's population in the 21st century and beyond. It's estimated that current productivity will have to surge by some 70% to feed a global population that the United Nations expects to swell to 9.3 billion by 2050.

The FDA's stance on GMOs allowed the industry to push their seeds from lab to soil with less regulation than that for food additives. But GMOs have nonetheless been heavily analyzed, according to Val Giddings, a senior fellow at the Information Technology and Innovation Foundation, who has been involved in the issue for nearly three decades. Crops and foods improved through biotechnology have been more scrutinized than any other crops in the history of humanity," he said.

"It completely baffles me to hear this claim made by some of the professional opposition groups that nobody has done any safety studies and that what few there are have been done by scientists working for industry and therefore are tainted as if the facts don't speak for themselves," said Giddings, who spent 8 years as vice president for food and agriculture at the Biotechnology Industry Organization and a decade performing risk assessments at the U.S. Department of Agriculture's Animal and Plant Health Inspection Service unit.

"There are thousands upon thousands of studies that have been done, most by independent academics," he argued. "Folks who say that really isn't enough—to them I say when is enough?" Giddings also takes issue with the term "genetically modified," which implies that foods derived from bioengineering are inherently different from their traditional counterparts. All foods are genetically modified, he says, just using different methods, such as classical agricultural breeding.

José L. Domingo, professor and director of the Laboratory of Toxicology and Environmental Health at the University Rovira i Virgili School of Medicine in Spain, argued the "substantial equivalence" concept has led to insufficient research on the toxicological impact of transgenic plants. Domingo reviewed the available scientific literature concerning GMOs first in 2000 and again in 2006 and 2010, and he found that the number of studies that focused on a safety assessment of GMOs remained "limited."

Domingo reported that most research that deals with the topic—commonly conducted by biotechnology companies and

associated groups—found certain types of GMO products, particularly maize and soybeans, to be as safe and nutritious as their conventional counterparts. Several recent studies, however, pointed to signs of adverse effects in the kidney and liver, he noted.

"To date, risk assessment of GM crops for human nutrition and health has not been systematically performed," Domingo wrote in a June 8 editorial for *Human and Ecological Risk Assessment*, of which he is also co-editor-in-chief. "Although the most common result is that GM and conventional sources induce similar nutritional performance and growth in animals, adverse microscopic and molecular effects of some GM foods in different organs or tissues have been reported."

Biotech Crops and Policy Worldwide

Biotech crops have been available commercially since 1996, when U.S. farmers planted the first 1.7 million hectares. That figure has ballooned to 160 million hectares in 2011, planted by 16.7 million farmers, covering about 11% of all used land. Thus, these crops are the fastest adopted technology of modern agriculture, according to the latest edition of *Global Status of Commercialized Biotech/GM Crops*, an annual review of the industry by the ISAAA.

The U.S. is by far the biggest planter, with 69 million hectares in 2011, more than double Brazil's 30.3 million and Argentina's 23.7 million, according to the report. Soybeans, particularly ones with herbicide tolerance, are the most dominant seed, making up 47% of the total, followed by maize and cotton. At least three-quarters of the cotton, corn, and soybeans planted in the U.S. have at least one bioengineered trait, according to the U.S. Department of Agriculture, one of the three agencies that regulate GMOs. In Europe, where a 4-year moratorium on GMOs ended in 2004, farmers in six countries currently plant bioengineered crops, led by Spain and Portugal.

The ISAAA estimates that farmers and biotechnology companies have reaped $78 billion in economic benefits since 1996. The group also argues that using biotech crops benefits the environment by reducing water and pesticide use while decreasing the need to chop down forests for more farmland. Even the Vatican has joined the debate, convening a panel in 2009 that sided with proponents in arguing for a moral imperative to use GMOs to help eradicate hunger.

The World Health Organization's take is encouragement coupled with caution, emphasizing that the seeds have many genes that are new to the food supply. "GM foods currently available on the international market have undergone risk assessments and are not likely to present risks for human health any more than their conventional counterparts," the group concluded in a 2005 report. "The potential risks associated with GMOs and GM foods should be assessed on a case-by-case basis."

The FDA recommends that biotech companies consult with the agency at least 120 days before marketing new GM foods. In the EU, the European Food Safety Agency is required to assess the health and environmental risks of such products and seeds before they can enter the region.

"The [safe] record of biotech crops and foods in actual practice is formidable. Billions upon billions of meals have been consumed consisting in part of biotech foods and feed by humans since 1996."

The Cartagena Protocol on Biosafety, adopted by 162 countries and the EU since 2000 (not including the U.S.), governs the movements of living modified organisms resulting from modern biotechnology from one nation to another and prescribes a precautionary principle for importing GMOs. The agreement, inforce since 2003, requires a certain amount of country-to-country labeling, advance export notification, and documentation.

Studies on Safety

But some experts argue that countries' own checks and balances on GMOs are not enough. Gilles-Eric Séralini, a professor of molecular biology at the University of Caen in France and president of the scientific board of the Committee of Independent Research and Information on Genetic Engineering, says the risks of getting it wrong are too great and could be avoided if government agencies demanded longer studies before approving GM plants and foods.

"In order to study gastrointestinal effects or any kind of chronic toxicity, you need 2-year-long tests on mammals in order to know whether there's a possibility of cancer," said Séralini, who helped the European Commission prepare its case in 2003 defending the moratorium then in place to keep GMOs out of the region. "This has not been done."

Séralini analyzed a 90-day toxicity study of Monsanto's MON 863 maize variety, which was approved in Europe in 2005. He reported that after consuming the corn, rats in the study showed slight but dose-related variations in growth, signs of toxic effects in the liver and kidney, and an increase in triglycerides. The paper concluded that longer tests were needed. Another study, by Joël Spiroux de Vendômois, published in the *International Journal of Biological Sciences* in 2009, compared three corn varieties and reported sex- and often dose-dependent toxic effects in the kidney and liver. The research also indicated effects in the heart, adrenal glands, spleen, and blood cell production system, concluding that the pesticides specific to each type of corn may have caused the kidney and liver problems. The European Commission convened an expert panel to review Séralini's findings, as well as the original study, and concluded that Séralini's analysis offered no reliable evidence of adverse effects. The de Vendômois study has not yet been scientifically questioned, according to Domingo.


Val Giddings

"None of them stand up to scrutiny," Giddings said. "The [safe] record of biotech

crops and foods in actual practice is formidable. Billions upon billions of meals made of meals have been consumed consisting in part of biotech foods and feed by humans and animals since 1996. None of these claims of potential harm by opponents have actually been confirmed in this experience and certainly have not been corroborated by replicable studies by other researchers."

In spelling out its policy on biotechnology in 1992, the FDA said that it expected the proteins, carbohydrates, fats, and oils in bioengineered foods to be substantially similar to those in conventional products and thus unlikely to raise any safety questions. The focus of studies to ensure that GM foods remain safe is on the molecular differences between the organisms, which are then studied for toxicological and other health effects.

"Proteins are also present in all biological systems, and proteins are not considered to be causes of cancer," according to Monsanto, the largest producer of genetically engineered seed and the herbicide glyphosate, marketed as Roundup. "Certain protein hormones or toxins may have the potential to influence cancer rates as a result of their specific biological activity. However, such biological activity is predictable from protein structure and will be easily recognized in acute toxicology studies."

Monsanto and others also argue that biotech foods shouldn't be subject to long-term cancer tests for the same reason that conventional foods aren't, as well as that the current

standard of testing only the component that is different in the bioengineered product is sufficient to determine its safety.

Challenges of Long-Term Studies

Long-term studies on the health impact of GMOs may be impossible, however, without traceability, which only product labeling can accomplish. Although the EU currently mandates a GMO label for all foods that contain ingredients at least 0.5% genetically modified, such disclosures aren't required elsewhere. The FDA recently rejected a proposal to mandate labeling. Some states, such as Washington and California, are considering their own measures.

Kaiser's Kushi notes the "cautionary tale" of hydrogenated oils, which were once ubiquitous in the processed foods and home-cooked pies—in the guise of Crisco—that Americans consumed for much of the 20th century, particularly in fast-food restaurants, and they were deemed perfectly safe. Only in recent years did scientific scrutiny of the health hazards of hydrogenating oils to create artificial *trans* fats lead the industry and government to acknowledge risks such as coronary heart disease, eventually leading to boycotts, mandatory labeling, and restaurants' and companies' ridding the ingredients from their foods. An estimate in 1994 put the annual U.S. death toll from the consumption of partially hydrogenated vegetable fat at 30,000.

"When one is talking about new things, probably better to go slowly and err on the side of caution," Kushi said. "The thing about the GMOs is that they are new organisms in terms of how the DNA is combined, so they would not have not necessarily existed in nature."

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