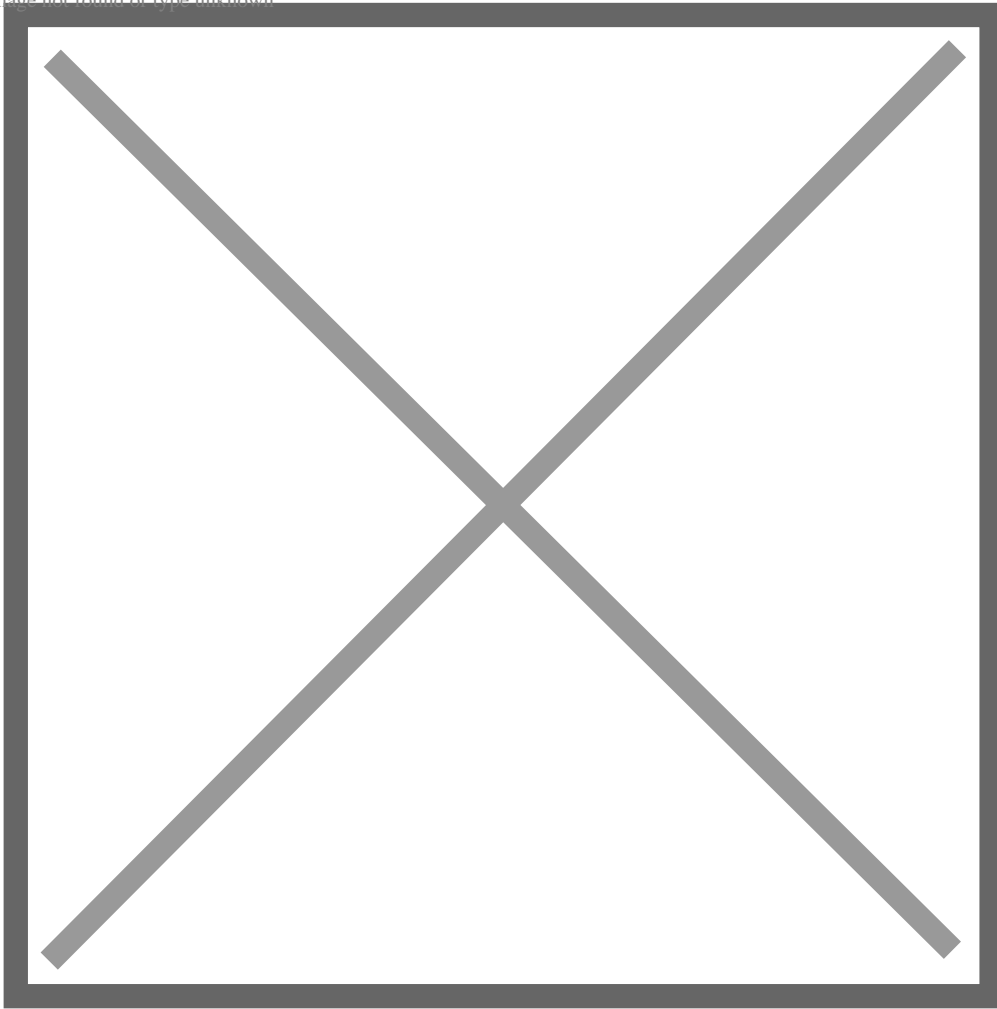


Are GMO foods ‘substantially equivalent’ to non-GMO foods, as the FDA maintains?

Since the mid 1990s, critics of crop biotechnology have alleged that genetic engineering could make unintended, harmful changes to a food crop’s DNA. As a result, “.... genetically modified crops have the potential to introduce new toxins or allergens into our food ” organic industry group [Just Label It has claimed](#). Critics further allege that the FDA could accidentally allow dangerous crops onto the market because the agency universally declared GMO crops “substantially equivalent” to their conventional counterparts in 1992. Anti-GMO Green America summarized activist concerns in this infographic:

Image not found or type unknown



However, this is a mischaracterization of the FDA’s position on substantial equivalence and GMOs. The FDA did not determine that all GMO crops are, by definition, substantially equivalent and thus do not merit special labels or regulations. Rather, the policy states that new crops that are found to be substantially equivalent do not merit special oversight. According to the agency:

The regulatory status of a food is dependent upon objective characteristics of the food and the intended use of the food .

It should be noted that substantial equivalence, though often associated with biotech crops, is a regulatory concept used by safety regulators to analyze a broad range of new products, including [medical devices](#) and [generic and biosimilar drugs](#). It was extended to [food safety in 1993](#). Substantial equivalence isn't a universal assumption; it's a science-based conclusion embraced only after extensive testing of the product.

Food safety regulators in the US, Canada, Australia, New Zealand and many other countries use substantial equivalence to assess how much scrutiny a new food product requires before being commercialized. If a new food is judged to be substantially equivalent to foods that are already considered safe, either through previous testing or, more often, through a long history of use, then regulators do not require animal feeding studies or other long, expensive demonstrations of safety. If not, the product is evaluated as a new food additive and [faces further](#) safety scrutiny.

All crops vary from generation to generation. Variation can occur as an evolutionary process or from breeding techniques. Corn, for example, contains more [nucleotide polymorphisms](#) (small variations in gene sequence) than a tomato. Substantial equivalence looks at where a cultivar falls within the range of variation found within the domesticated species.

USDA scientist Owen Hoekenga, in an [important 2008 paper](#), wrote that the variation in corn is so high that “two maize varieties may be as different from each other as humans are from chimpanzees on the DNA level.” But these varieties can still be considered “substantially equivalent” because they clearly fall within the range of what we recognize as maize, whether that is color, shape of the ear, or nutritional content.

Determining substantial equivalence depends first on establishing the extent of this range of variation within the species the new plant belongs to. In order to establish substantial equivalence, scientists perform what's called a compositional analysis of a wide range of samples of the parent plant variety. They [map the range](#) of macro- and micro-nutrients, anti-nutrients and toxic molecules produced by this plant and compare these results to those of the new crop.

It's much the same for new genetically engineered crops. Existing data is examined for original crop variation, and then a new trans- or cisgenic crop is compared along the same metrics. If the new crop lies within that original range of variation, then it is “substantially equivalent.” Note that even after a finding of substantial equivalence, most new GE crops go through extensive testing, with federal regulators reviewing reams of data before the products are introduced, a process covering on average seven years and costing \$135 million.

Before the GMO Rainbow papaya, engineered to resist ringspot virus, was released to Hawaiian growers, it was subjected to [compositional analysis](#) to compare it to its conventional counterpart. Summarizing the evaluation process, the authors of a [2011 study explained](#):

The nutritional composition of Rainbow papaya and a non-transgenic control were analyzed to address GE [food](#) safety concerns regarding the potential for altered nutritional composition and altered expression of inherent [allergens](#) and [toxic proteins](#). Rainbow papaya fruit were analyzed at three ripening stages and the data compared to that of a non-transgenic papaya which shares a similar pedigree. No differences were observed between GE and non-GE papaya for 36 [nutrients](#) at any of the tested fruit ripeness stages. Our data show that the Rainbow cultivar is substantially similar to the non-GE cultivar.

Opponents of substantial equivalence (which include EU member states that do not use this concept in their regulation of GE crops) object to this [standard because](#) there's no clear statistical ["hard" basis](#) and no quantitative range of effects (such as a standard deviation, or p-value) that determines the border of "equivalent." Furthermore, they claim there is no way to predict unintended (or unexpected) surprise effects. For example, activist critics complain that GMO crops sometimes appear to contain substantially more (or less) of a given nutrient found in conventional crops. Jeffrey Smith, head of the one-man Institute for Responsible Technology, has argued that GMO soybeans contain 14 percent less isoflavones, a class of nutrients that affects [hormone](#) production.

However, Smith didn't address the fact that plants can [naturally contain](#) varying amounts of the same nutrient, depending on how and where they were grown. Scientists, therefore, set a [range of variation](#) deemed acceptable when evaluating the nutrient content of new GMO crops. GMO crops sometimes contain more of a particular nutrient than they otherwise would, or contain a nutrient they normally wouldn't contain at all, such as beta-carotene in Golden Rice, engineered to combat vitamin A deficiency in developing countries. These products are nonetheless subjected to [rigorous testing](#) to ensure they are safe for human consumption.

Regulations governing GMO crops are far more strict when a plant is engineered to contain a trait its conventional counterparts lack. Insect-resistant Bt crops, for instance, which possess genes from the soil bacterium *Bacillus thuringiensis*, [underwent extensive testing](#) beyond substantial equivalence before they were approved. Animal feeding trials were required to establish the safety of these crops. Any potential environmental impacts were further assessed separately by the EPA, the federal agency that regulates pesticide use in the US. The [Rainbow papaya](#) was also subjected to additional review by the EPA since it conferred virus resistance to the fruit.

Substantial equivalence has an impressive safety record, [according to the authors of a 2013 study](#). "The compositional equivalency between genetically modified (GM) crops and nontransgenic comparators has been a fundamental component of human health safety assessment for 20 years," they noted." After two decades, suspect unintended compositional effects that could be caused by genetic modification have not materialized." In 2016, the [prestigious National Academies of Science agreed](#):

Statistically significant differences in nutrient and chemical composition have been found between GE and non-GE plants by using traditional methods of compositional analysis, but the difference have been considered to fall within the range of naturally occurring variation found in currently available non-GE crops.