

Should genetically modified foods be abandoned on the basis of allergenicity?

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Introduction

In October of 2006, Indian Prime Minister Manmohan Singh urged for a second green revolution in rice, encouraging scientists “[to use] the potential of biotechnology to meet the requirements of hungry people” [1]. Biotechnology, and genetic engineering in particular, has the potential to positively impact billions of lives; as Prime Minister Singh aptly highlighted, the proliferation of genetically modified rice can help the 780 million people suffering from hunger worldwide [2]. In addition to potentially reducing world hunger, genetic modification provides solutions to many of the United Nations’ Millennium Development Goals, such as the following: combating infectious diseases, reducing child mortality, improving maternal health, improving child nutrition, and ensuring environmental sustainability [3]. In short, the humanitarian profits of utilizing biotechnology are immense. Plagued with not only world hunger issues, but also the plummet in world food stocks, a viable solution to the world’s food problems is required, and quickly, to ensure the safety and sustainability of future generations [4]. As Norman Borlaug, a Nobel Peace Prize Laureate and

father of the Green Revolution, states “we’re 6.6 billion people [worldwide] and could feed 4.4 billion. I don’t see 2 billion volunteers to give up food” [5]. More low-maintenance crops, and, consequently, larger quantities of food, need to be produced to economically and nutritionally aid the millions of impoverished people worldwide. Borlaug advocates the use of biotechnology to solve world hunger, stating that by modifying wheat grains, he produces “the food that’s needed for the people today” [5]; in his opinion, genetically modified foods are essential in order to allow humanity to enjoy a prosperous and healthy twenty-first century.

While many people agree with the viewpoints of Prime Minister Singh and Norman Borlaug, some groups—such as Greenpeace and Friends of the Earth—are wary of the possible health consequences of this new genre of food [6–9]. A major concern for Greenpeace, as well as for individuals of the general public, is the possible allergenicity of genetically modified (GM) foods by the manipulation of genes and, particularly, the insertion of coding for new proteins [8]. To produce GM plants, a sequence of amino acids encoding for a protein is transposed onto the DNA of a particular plant (e.g., corn). Essentially, the genetic information encoding for a protein from one plant is transferred to another plant, thus giving the receiving plant the ability to express the desired protein [9, 10]. This particular process was highlighted in the mainstream media in 2000, when Friends of the Earth initiated a campaign against Aventis CropScience, stating that Starlink, a breed of corn originally deemed safe for only animal feed, had migrated into the human food supply [7]. The scientific significance of the levels of this corn—and its potential allergenic properties—found in mainstream food is ques-

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tionable, but the argument raised by Friends of the Earth is valid. This opposition group's findings led to further testing and evaluation of current regulations, illustrating the importance of regulation in the GM food sector.

Although “no allerg[en]ic effects have been found relative to genetically modified foods currently on the market” [8], scientific testing has shown allergic responses to new genetically engineered foods in the developmental stages [8]. As the editors of *New Scientist* strongly state, “opponents of GM foods [Greenpeace et al.] may try to use this finding to damn all transgenic crops. That would be silly...every crop must be judged individually” [11]. As with all scientific research, GM foods should be tested extensively and regulated to ensure that they are safe; however, the issue of allergenicity is not key to the future of GM foods [12]. Allergenicity remains a major concern due to the severe impact allergic reactions can have on people [12–14]; however, with modern technology, this issue can be managed and addressed, leading to an even larger variety of safe GM foods. Further, GM foods remain a viable means of solving a multitude of world problems, such as hunger and nutrient/vitamin deficiency, regardless of the outlier case studies of allergic response [15, 16]. In short, the development and regulation of this technology is tantamount; with careful screening and testing, the potential risks associated with the genetic alteration of foods can be avoided, leaving a crop with vast humanitarian benefits. Allergenicity should not be a make-or-break issue in the GM food debate.

Allergenicity in food

Food-induced allergic responses are categorized into two main groups: food intolerance and food hypersensitivity [17]. These types of sensitivity can vary greatly, with allergic responses ranging from extremely mild to extremely severe (e.g., peanut allergies can be mild, or can lead to death). With food intolerance, a patient has a negative reaction to food, unrelated to an immune response; simply put, the patient lacks the necessary enzymes to digest the irritant (e.g., patients with lactose intolerance lack the enzyme to digest the milk sugar lactose). However, with food hypersensitivity, the immune system plays an integral role. In response to an allergenic food, the body elicits a heightened immunological response via the IgE mechanism [17] (Fig. 1). IgE-based immunologic responses occur immediately upon exposure to the irritant—within a few minutes—and include hypersensitivity reactions such as “hives, asthma, gastrointestinal problems, and anaphylaxis” [11]. Anaphylaxis is a severe allergic response causing breathing difficulty and, potentially, death [12]. This specific type of response is multi-level, and depends upon a previous

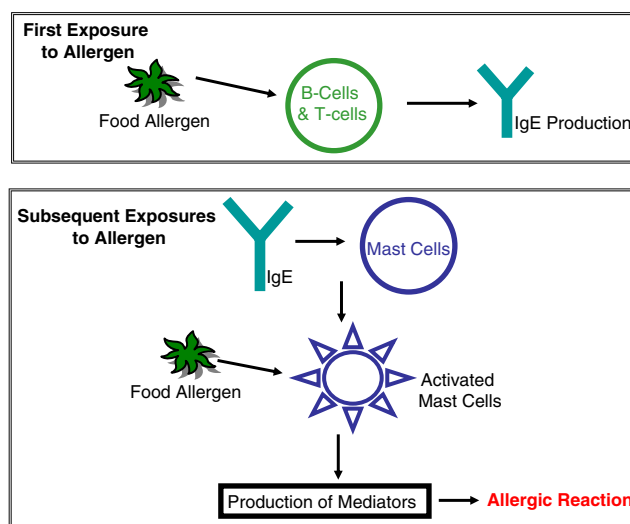


Fig. 1 Immunological response of food allergens via the IgE mechanism

exposure to the antigen [17]. During this previous exposure, the Th2 cells (helper T white blood cells that aid in antibody-mediated immunity, including responses to irritants) [13] collaborate with the body's natural antigen processing to produce IgE, which then becomes affixed to the high-affinity receptors of the mast cell and basophiles (white blood cells) [9]. Upon re-exposure to the antigen, the mediators created in the IgE process are released; this release and instigation is the allergic response [11].

In November of 2005, this particular immune response was highlighted in the popular media for its association with GM peas. Over a ten-year span, a \$2 million project was devoted to the development of genetically engineered peas that are resistant to their primary pest, the pea weevil [18]. The weevil “was eating up to 30 percent of pea yields, [a sum] potentially worth millions [of dollars].” Not only is this animal an annoyance to farmers, but it is also a hindrance to the Australian agriculture business. In order to kill the weevils, scientists inserted the genetic coding for an anti-nutrient native to kidney beans “that interferes with the bugs’ digestion, thereby starving them to death” [18, 19] into the DNA of peas [18]. In kidney beans, this anti-nutrient is denatured during the cooking process and is therefore safe for human digestion [18, 19]. However, when inserted into the pea, this same portion of genetic code produced vastly different effects. In clinical tests, mice fed both cooked and uncooked GM peas exhibited an allergic response [18]. How could this same protein be harmless in kidneys yet allergenic in peas? Recall that glycoproteins (a protein combined with a sugar) are responsible for IgE-mediated allergic responses, and that glycosylation is the process in which sugar chains become attached to proteins. Thus, in glycosylation, a benign protein can be transformed

into a severe allergen [18, 19]. After studying the GM pea case in depth, a team of Australian scientists led by Simon Hogan discovered that the glycosylation of the kidney protein and the GM pea protein were slightly different [18, 19]; thus, even the same genetic sequence can produce slight variations of proteins in different plants, and, consequently, cases of allergenicity.

Testing and regulation

While the possible allergenicity of GM foods presents a legitimate problem, in actuality, comprehensive testing of the crops in development prevents the introduction of potentially harmful foods into the public market. For example, without the in-depth and thorough analysis of GM peas, the allergenic properties of the slightly modified protein would not have surfaced. Present in all aspects of science, extensive testing serves as a checks-and-balances system; in food biotechnology, a team of researchers develops a crop and then applies a plethora of chemical and pharmacological tests to the product, ensuring its safety and effectiveness. As Professor Terri Lomax of the Oregon State University Department of Botany and Plant Pathology aptly states, “these GM crops are actually the most highly tested crops that we’ve ever had. They’re regulated by the EPA [testing for pesticides], the FDA [safeness to consumers], and the USDA [where they are grown and how they will affect the environment]” [5]; thus, with these “millions of dollars worth of testing” [5], a product is not introduced into the market unless it has been repeatedly and reproducibly proven to be completely safe to consumers. Consequently, condemning the entire field of genetically modified foods based on a few findings of allergenicity is absurd. With the thorough testing of all GM crops, a few cases of potentially allergenic genetic insertions are sure to arise; and, as with the Australian pea example, the projects should and will be abandoned [18], placing human safety over profit and convenience.

Furthermore, the actual occurrence of these allergen-inducing insertions is rare. According to the World Health Organization, “no allerg[en]ic effects have been found relative to genetically modified foods currently on the market” [20]; thus, the first generation of GM foods has been proven safe for human consumption. At present, GM foods in the public market include soybean, maize, canola, cocoa beans, potato, and cottonseed oil, all of which have shown to improve productivity and yield of farms [20].

Starlink corn, a GM breed originally deemed unsafe for human ingestion due to allergenic properties [21–23], underwent further testing. This further testing was in part due to the Friends of the Earth’s allegations of finding

traces of Starlink in Kraft Taco Bell taco shells. The Friends of the Earth is a strong anti-GM group that cites allergenicity as a major reason to abandon GM foods [5]. Although the actual levels of Starlink found in the samples may not be statistically significant [24], the media coverage certainly illustrated the importance of strict testing and regulation of GM foods. Feed livestock studies performed at the University of Guelph (Netherlands), at the University of Missouri, and in Japan involving chickens, cattle and dairy cows concluded that [1] there is no difference between StarLink corn and conventional corn in terms of the dietary effects on the animals (e.g., weight gain, feed intake, etc.), [2] no difference was observed between the composition of the milk produced by dairy cows fed with StarLink and that yielded by with conventional corn, and [3] no extraneous protein was present in the milk of these cows nor in organ samples—liver, kidney, fat or muscle—collected from the animals fed with Starlink [25, 26].

With its somewhat inconclusive allegations of allergenicity, the Starlink corn debate illustrates the rarity of allergen-inducing GM foods. To date, the two main examples of allergen-inducing genetically engineered crops are the Australian pea and plants bearing an insertion of the Brazil nut gene. As previously mentioned, the pea was allergenic due to a slight change in the glycosylation process of its kidney bean protein; however, the case of the Brazil nut gene is entirely different. Whereas the coding for an originally benign protein was inserted into the pea gene, the Brazil nut protein itself is already allergenic (at the time of original research, this particular protein was not yet known to be allergenic) [27]. Thus, unless a change in glycosylation occurred in the GM crops—in this case, the change in the glycoprotein structure would be a positive outcome, as opposed to that in the pea—the new plants could quite probably be expected to illustrate the same irritating properties [27]. In short, GM foods are generally safe, with very few occurrences of allergenicity; furthermore, this allergenicity is discovered in the laboratory during development, and unsafe foods are not introduced to the public sector.

Therefore, the extensive testing and regulation of GM foods is paramount in ensuring public safety. Many worldwide efforts have been employed to ensure the testing of genetically engineered crops. In 1963, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) formed Codex Alimentarius, a program aimed at “protecting the health of consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international government and non-governmental organizations” [28]. The expansive Codex provides guidelines for all types of food, ranging from instant noodles to food-grade salt [29]. In recent years, the

Codex has been augmented to encompass the new field of GM foods. However, the majority of these GM-related directives and regulations reflect new European Union rulings regarding labeling and the environmental effects of GM foods [30]. In 2003, Codex “develop[ed] principles for the human health risk analysis of GM foods...including an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene)”. With the new guidelines, the Codex states that the following steps are essential when assessing GM foods: hazard identification, hazard characterization, exposure assessment, and risk characterization [31]. Models of the occurrence of these potential hazards are constructed and utilized to predict the potential risk associated with a particular gene insertion, and these potential risks are evaluated through epidemiological studies [31]. Essentially, the potential effects of a certain GM food are studied and assessed, and then the GM foods are pushed through extensive scientific testing to ensure their safety.

The standardization of GM food testing has proven essential in the GM food debate; by providing a universal set of rigid guidelines for all GM food research, the FAO and WHO impose a worldwide standard for genetically engineered crops. Unfortunately, now, “in the [United States] government, the term is ‘voluntary testing [of GM foods]’, but everyone tests in the lab” [5]; the fact that the government does not impose strong regulations upon biotechnology companies causes much discontent in anti-GM groups (e.g., Greenpeace). Though the GM products themselves are generally safe, extensive testing adds another level of assured security and acts as an anodyne, reassuring the general public that the food is actually harmless.

The United States government should follow the lead of the FAO and WHO, and develop a Codex of sorts specifically regarding GM foods. Among the techniques utilized could be the analysis of glycosylation in transgenic plants. As illustrated with the pea case study, identical genetic encoding can actually produce slight variations of the same glycoprotein, and can potentially result in allergenicity of the modified plant. Also, the Food and Drug Administration should employ a serum bank containing a database of all known allergens (e.g., Allermatch™ [32]) in order to avoid inserting already allergenic proteins into plants, such as the Brazil nut's gene in soybean [27]. Allermatch™ is a recently developed bank containing the profiles of many glycoproteins that are known to be allergenic, providing a database for scientists to access the structures of known allergens for comparison with new GM plant proteins, as well as to assess the viability of possible proteins that are to be encoded for in GM plants (as per the Brazil nut case study, allergenic proteins should not be inserted into new plants, as this could cause potential cases of allergenicity)

[32]. These examples of safety evaluation techniques are merely a few among a barrage of tests currently utilized by the biotechnology industry. Essentially, the United States government simply needs to study the tests currently in use and develop regulatory laws that compel all corporations and researchers to follow the same *modus operandi*.

Key elements in allergy evaluation

Genetic modification can cause allergenicity in two ways: it can introduce allergens or it can change the level or nature of an allergen [33]. Current procedures employed for assessing allergenicity in modified foods are not fully scientifically validated. However, these protocols can still raise red flags, thereby providing warnings against potentially allergenic foods. The assessment of allergenicity involves evaluating the gene source, bioinformatics analysis, serum IgE binding studies, and investigating the stability of new proteins to pepsin digestion [34, 35] (Fig. 2).

If the origin of the gene for the transferred protein is a food commonly known to be allergenic, then blood sera of patients allergic to this source are tested against the modified food to evaluate IgE binding. However, several factors such as demographics, gender, age, and prevalence of allergy may affect this mode of evaluation. Additionally, bioinformatic analysis is performed to compare the sequence of the transferred protein against the amino acid sequences of all known allergens. If the sequence of the transferred protein has greater than 35% identity with known allergens over an 80 amino acid segment, then IgE testing is performed [28, 36]. Bioinformatics analysis is fairly simple and can

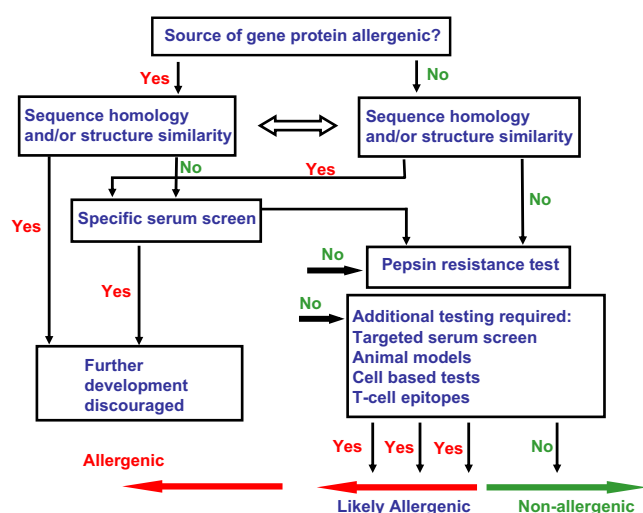


Fig. 2 Assessment of allergenicity. The figure is adapted from the reference [14] with permission from the Proceedings of the Nutrition Society

yield rapid results. However, the use of an appropriate allergen database (<http://www.allergenonline.com>) is critical for this study.

Serum screening is important when both the source of the gene is known to be allergenic and the bioinformatics analysis shows sequence homology of the new protein with a known allergen [27, 37–40]. In serum screening, sera of people known to be allergic to the source is evaluated, with specific quantification of the new protein's immunoreactivity with IgE [41]. ELISA methods and Western blotting are also commonly used for this study [41–43]. Appropriate positive and negative controls are essential in this evaluation and false positives are a major concern. Other factors, such as protein abundance and resistance to pepsin digestion are also considered potential allergenic traits [44, 45]. Digestion with pepsin can be performed in vitro and is a simple test. Along with the stability of the protein, the quantity of the food consumed is an important factor because a stable nonabundant food can become allergenic if consumed in high quantities [34].

In addition to the aforementioned key elements, there are some new approaches that require further research in terms of their usefulness in allergenicity evaluation. These approaches include assessing the effect of transferred proteins on the endogenous allergenicity of known allergenic foods, evaluating allergenicity in animal models, and evaluating the cross-reactivity of potential allergens with diverse food sources [28, 46, 47].

Conclusion

As with the universal Codex Alimentarius of the FAO/WHO, thorough United States governmental guidelines would decrease consumer skepticism by quantitatively demonstrating the safety and nonallergenicity of GM foods to the general public. The promise of GM foods is great, and their possible benefits are boundless. From decreased use of pesticides to increased nutritional value, biotechnology can serve a multitude of humanitarian purposes, improving both food and the environment. The genetic engineering of plants can even turn so-called waste into effective nourishment: the ultimate form of recycling. Currently, research into the genetic alteration of cotton is changing inedible cottonseed into a protein-rich food source, quite similar to chickpea [48]. The future of GM foods holds much promise, and the rare cases of allergenicity should not impede upon this scientific development. With strict regulation and extensive testing, the issue of allergenicity becomes nonexistent, and it certainly should not prove a hindrance to the advancement of science, nutrition, and farming.

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