Nutrition Therapy Highlights

Genetically-Modified Organism

Just Say No To **GMO**
Genetically modified organism

Genetically-modified foods (GM foods) have made a big splash in the news lately. European environmental organizations and public interest groups have been actively protesting against GM foods for months, and recent controversial studies about the effects of genetically-modified corn pollen on monarch butterfly caterpillars1, 2 have brought the issue of genetic engineering to the forefront of the public consciousness in the U.S. In response to the upswelling of public concern, the U.S. Food and Drug Administration (FDA) held three open meetings in Chicago, Washington, D.C., and Oakland, California to solicit public opinions and begin the process of establishing a new regulatory procedure for government approval of GM foods3. I attended the FDA meeting held in November 1999 in Washington, D.C., and here I will attempt to summarize the issues involved and explain the U.S. government's present role in regulating GM food.

What are genetically-modified foods?
The term GM foods or GMOs (genetically-modified organisms) is most commonly used to refer to crop plants created for human or animal consumption using the latest molecular biology techniques. These plants have been modified in the laboratory to enhance desired traits such as increased resistance to herbicides or improved nutritional content. The enhancement of desired traits has traditionally been undertaken through breeding, but conventional plant breeding methods can be very time consuming and are often not very accurate. Genetic engineering, on the other hand, can create plants with the exact desired trait very rapidly and with great accuracy. For example, plant geneticists can isolate a gene responsible for drought tolerance and insert that gene into a different plant. The new genetically-modified plant will gain drought tolerance as well. Not only can genes be transferred from one plant to another, but genes from non-plant organisms also can be used. The best known example of this is the use of B.t. genes in corn and other crops. B.t., or Bacillus thuringiensis, is a naturally occurring bacterium that produces crystal proteins that are lethal to insect larvae. B.t. crystal protein genes have been transferred into corn, enabling the corn to produce its own pesticides against insects such as the European corn borer. For two informative overviews of some of the techniques involved in creating GM foods, visit Biotech Basics (sponsored by Monsanto) http://www.biotechknowledge.monsanto.com/biotech/bbasics.nsf/index or Techniques of Plant Biotechnology from the National Center for Biotechnology Education http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/techniques.

What are some of the advantages of GM foods?

The world population has topped 6 billion people and is predicted to double in the next 50 years. Ensuring an adequate food supply for this booming population is going to be a major challenge in the years to come. GM foods promise to meet this need in a number of ways:

- **Pest resistance**
  Crop losses from insect pests can be staggering, resulting in devastating financial loss for farmers and starvation in developing countries. Farmers typically use many tons of chemical pesticides annually. Consumers do not wish to eat food that has been treated with pesticides because of potential health hazards, and run-off of agricultural wastes

from excessive use of pesticides and fertilizers can poison the water supply and cause harm to the environment. Growing GM foods such as B.t. corn can help eliminate the application of chemical pesticides and reduce the cost of bringing a crop to market[4, 5].

- **Herbicide tolerance**
  For some crops, it is not cost-effective to remove weeds by physical means such as tilling, so farmers will often spray large quantities of different herbicides (weed-killer) to destroy weeds, a time-consuming and expensive process, that requires care so that the herbicide doesn't harm the crop plant or the environment. Crop plants genetically-engineered to be resistant to one very powerful herbicide could help prevent environmental damage by reducing the amount of herbicides needed. For example, Monsanto has created a strain of soybeans genetically modified to be not affected by their herbicide product Roundup ®[6]. A farmer grows these soybeans which then only require one application of weed-killer instead of multiple applications, reducing production cost and limiting the dangers of agricultural waste run-off[7].
- **Disease resistance**
  There are many viruses, fungi and bacteria that cause plant diseases. Plant biologists are working to create plants with genetically-engineered resistance to these diseases[8, 9].
- **Cold tolerance**
  Unexpected frost can destroy sensitive seedlings. An antifreeze gene from cold water fish has been introduced into plants such as tobacco and potato. With this antifreeze gene, these plants are able to tolerate cold temperatures that normally would kill unmodified seedlings[10]. (Note: I have not been able to find any journal articles or patents that involve fish antifreeze proteins in strawberries, although I have seen such reports in newspapers. I can only conclude that nothing on this application has yet been published or patented.)
- **Drought tolerance/salinity tolerance**
  As the world population grows and more land is utilized for housing instead of food production, farmers will need to grow crops in locations previously unsuited for plant cultivation. Creating plants that can withstand long periods of drought or high salt content in soil and groundwater will help people to grow crops in formerly inhospitable places[11, 12].
- **Nutrition**
  Malnutrition is common in third world countries where impoverished peoples rely on a single crop such as rice for the main staple of their diet. However, rice does not contain adequate amounts of all necessary nutrients to prevent malnutrition. If rice could be genetically engineered to contain additional vitamins and minerals, nutrient deficiencies could be alleviated. For example, blindness due to vitamin A deficiency is a common problem in third world countries. Researchers at the Swiss Federal Institute of Technology Institute for Plant Sciences have created a strain of "golden" rice containing an unusually high content of beta-carotene (vitamin A)[13]. Since this rice was funded by the Rockefeller Foundation[14], a non-profit organization, the Institute hopes to offer the golden rice seed free to any third world country that requests it. Plans were underway to develop a golden rice that also has increased iron content. However, the grant that funded the creation of these two rice strains was not renewed, perhaps because of the vigorous anti-GM food protesting in Europe, and so this nutritionally-enhanced rice may not come to market at all[15].
- **Pharmaceuticals**
  Medicines and vaccines often are costly to produce and sometimes require special storage conditions not readily available in third world countries. Researchers are working to develop edible vaccines in tomatoes and potatoes[16, 17]. These vaccines will be much easier to ship, store and administer than traditional injectable vaccines.

- **Phytoremediation**
  Not all GM plants are grown as crops. Soil and groundwater pollution continues to be a problem in all parts of the world. Plants such as poplar trees have been genetically engineered to clean up heavy metal pollution from contaminated soil18.

How prevalent are GM crops?

What plants are involved?

According to the FDA and the United States Department of Agriculture (USDA), there are over 40 plant varieties that have completed all of the federal requirements for commercialization (http://vm.cfsan.fda.gov/%7Elrd/biocon). Some examples of these plants include tomatoes and cantalopes that have modified ripening characteristics, soybeans and sugarbeets that are resistant to herbicides, and corn and cotton plants with increased resistance to insect pests. Not all these products are available in supermarkets yet; however, the prevalence of GM foods in U.S. grocery stores is more widespread than is commonly thought. While there are very, very few genetically-modified whole fruits and vegetables available on produce stands, highly processed foods, such as vegetable oils or breakfast cereals, most likely contain some tiny percentage of genetically-modified ingredients because the raw ingredients have been pooled into one processing stream from many different sources. Also, the ubiquity of soybean derivatives as food additives in the modern American diet virtually ensures that all U.S. consumers have been exposed to GM food products.

The U.S. statistics that follow are derived from data presented on the USDA web site at http://www.ers.usda.gov/briefing/biotechnology/. The global statistics are derived from a brief published by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) at http://www.isaaa.org/publications/briefs/Brief_21.htm and from the Biotechnology Industry Organization at http://www.bio.org/food&ag/1999Acreage.

Thirteen countries grew genetically-engineered crops commercially in 2000, and of these, the U.S. produced the majority. In 2000, 68% of all GM crops were grown by U.S. farmers. In comparison, Argentina, Canada and China produced only 23%, 7% and 1%, respectively. Other countries that grew commercial GM crops in 2000 are Australia, Bulgaria, France, Germany, Mexico, Romania, South Africa, Spain, and Uruguay.

Soybeans and corn are the top two most widely grown crops (82% of all GM crops harvested in 2000), with cotton, rapeseed (or canola) and potatoes trailing behind. 74% of these GM crops were modified for herbicide tolerance, 19% were modified for insect pest resistance, and 7% were modified for both herbicide tolerance and pest tolerance. Globally, acreage of GM crops has increased 25-fold in just 5 years, from approximately 4.3 million acres in 1996 to 109 million acres in 2000 - almost twice the area of the United Kingdom. Approximately 99 million acres were devoted to GM crops in the U.S. and Argentina alone.

In the U.S., approximately 54% of all soybeans cultivated in 2000 were genetically-modified, up from 42% in 1998 and only 7% in 1996. In 2000, genetically-modified cotton varieties accounted for 61% of the total cotton crop, up from 42% in 1998, and 15% in 1996. GM corn and also experienced a similar but less dramatic increase. Corn production increased to 25% of all corn grown in 2000, about the same as 1998 (26%), but up from 1.5% in 1996. As anticipated, pesticide and herbicide use on these GM varieties was slashed and, for the most part, yields were increased (for details, see the UDSA publication at http://www.ers.usda.gov/publications/aer786/).

What are some of the criticisms against GM foods?

Environmental activists, religious organizations, public interest groups, professional associations and other scientists and government officials have all raised concerns about GM foods, and criticized agribusiness for pursuing profit without concern for potential hazards, and the government for failing to exercise adequate regulatory oversight. It seems that everyone has a strong opinion about GM foods. Even the Vatican[19] and the Prince of Wales[20] have expressed their opinions. Most concerns about GM foods fall into three categories: environmental hazards, human health risks, and economic concerns.

Environmental hazards

<u>Unintended harm to other organisms</u>
Last year a laboratory study was published in Nature[21] showing that pollen from B.t. corn caused high mortality rates in monarch butterfly caterpillars. Monarch caterpillars consume milkweed plants, not corn, but the fear is that if pollen from B.t. corn is blown by the wind onto milkweed plants in neighboring fields, the caterpillars could eat the pollen and perish. Although the Nature study was not conducted under natural field conditions, the results seemed to support this viewpoint. Unfortunately, B.t. toxins kill many species of insect larvae indiscriminately; it is not possible to design a B.t. toxin that would only kill crop-damaging pests and remain harmless to all other insects. This study is being reexamined by the USDA, the U.S. Environmental Protection Agency (EPA) and other non-government research groups, and preliminary data from new studies suggests that the original study may have been flawed[22, 23]. This topic is the subject of acrimonious debate, and both sides of the argument are defending their data vigorously. Currently, there is no agreement about the results of these studies, and the potential risk of harm to non-target organisms will need to be evaluated further.

<u>Reduced effectiveness of pesticides</u>
Just as some populations of mosquitoes developed resistance to the now-banned pesticide DDT, many people are concerned that insects will become resistant to B.t. or other crops that have been genetically-modified to produce their own pesticides.

<u>Gene transfer to non-target species</u>
Another concern is that crop plants engineered for herbicide tolerance and weeds will cross-breed, resulting in the transfer of the herbicide resistance genes from the crops into the weeds. These "superweeds" would then be herbicide tolerant as well. Other introduced genes may cross over into non-modified crops planted next to GM crops. The possibility of interbreeding is shown by the defense of farmers against lawsuits filed by Monsanto. The company has filed patent infringement lawsuits against farmers who may have harvested GM crops. Monsanto claims that the farmers obtained Monsanto-licensed GM seeds from an unknown source and did not pay royalties to Monsanto. The farmers claim that their unmodified crops were cross-pollinated from someone else's GM crops planted a field or two away. More investigation is needed to resolve this issue.
There are several possible solutions to the three problems mentioned above. Genes are exchanged between plants via pollen. Two ways to ensure that non-target species will not receive introduced genes from GM plants are to create GM plants that are male sterile (do not produce pollen) or to modify the GM plant so that the pollen does not contain the introduced gene[24, 25, 26]. Cross-pollination would not occur, and if harmless insects such as monarch caterpillars were to eat pollen from GM plants, the caterpillars would survive.

Another possible solution is to create buffer zones around fields of GM crops27, 28, 29. For example, non-GM corn would be planted to surround a field of B.t. GM corn, and the non-GM corn would not be harvested. Beneficial or harmless insects would have a refuge in the non-GM corn, and insect pests could be allowed to destroy the non-GM corn and would not develop resistance to B.t. pesticides. Gene transfer to weeds and other crops would not occur because the wind-blown pollen would not travel beyond the buffer zone. Estimates of the necessary width of buffer zones range from 6 meters to 30 meters or more30. This planting method may not be feasible if too much acreage is required for the buffer zones.

Human health risks

- Allergenicity Many children in the US and Europe have developed life-threatening allergies to peanuts and other foods. There is a possibility that introducing a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals. A proposal to incorporate a gene from Brazil nuts into soybeans was abandoned because of the fear of causing unexpected allergic reactions31. Extensive testing of GM foods may be required to avoid the possibility of harm to consumers with food allergies. Labeling of GM foods and food products will acquire new importance, which I shall discuss later.
- Unknown effects on human health There is a growing concern that introducing foreign genes into food plants may have an unexpected and negative impact on human health. A recent article published in Lancet examined the effects of GM potatoes on the digestive tract in rats32, 33. This study claimed that there were appreciable differences in the intestines of rats fed GM potatoes and rats fed unmodified potatoes. Yet critics say that this paper, like the monarch butterfly data, is flawed and does not hold up to scientific scrutiny34. Moreover, the gene introduced into the potatoes was a snowdrop flower lectin, a substance known to be toxic to mammals. The scientists who created this variety of potato chose to use the lectin gene simply to test the methodology, and these potatoes were never intended for human or animal consumption.

On the whole, with the exception of possible allergenicity, scientists believe that GM foods do not present a risk to human health.

Economic concerns

Bringing a GM food to market is a lengthy and costly process, and of course agri-biotech companies wish to ensure a profitable return on their investment. Many new plant genetic engineering technologies and GM plants have been patented, and patent infringement is a big concern of agribusiness. Yet consumer advocates are worried that patenting these new plant varieties will raise the price of seeds so high that small farmers and third world countries will not be able to afford seeds for GM crops, thus widening the gap between the wealthy and the poor. It is hoped that in a humanitarian gesture, more companies and non-profits will follow the lead of the Rockefeller Foundation and offer their products at reduced cost to impoverished nations.

Patent enforcement may also be difficult, as the contention of the farmers that they involuntarily grew Monsanto-engineered strains when their crops were cross-pollinated shows. One way to combat possible patent infringement is to introduce a "suicide gene" into GM plants. These plants would be viable for only one growing season and would produce sterile seeds that do not germinate. Farmers would need to buy a fresh supply of seeds each year. However, this would be financially disastrous for farmers in third world countries who cannot afford to buy seed each year and traditionally set aside a portion of their harvest to plant in the next growing season. In an open letter to the public, Monsanto has pledged to abandon all research using this suicide gene technology35.

How are GM foods regulated and what is the government's role in this process?

Governments around the world are hard at work to establish a regulatory process to monitor the effects of and approve new varieties of GM plants. Yet depending on the political, social and economic climate within a region or country, different governments are responding in different ways.

In Japan, the Ministry of Health and Welfare has announced that health testing of GM foods will be mandatory as of April 200136, 37. Currently, testing of GM foods is voluntary. Japanese supermarkets are offering both GM foods and unmodified foods, and customers are beginning to show a strong preference for unmodified fruits and vegetables.

India's government has not yet announced a policy on GM foods because no GM crops are grown in India and no products are commercially available in supermarkets yet38. India is, however, very supportive of transgenic plant research. It is highly likely that India will decide that the benefits of GM foods outweigh the risks because Indian agriculture will need to adopt drastic new measures to counteract the country's endemic poverty and feed its exploding population.

Some states in Brazil have banned GM crops entirely, and the Brazilian Institute for the Defense of Consumers, in collaboration with Greenpeace, has filed suit to prevent the importation of GM crops39,. Brazilian farmers, however, have resorted to smuggling GM soybean seeds into the country because they fear economic harm if they are unable to compete in the global marketplace with other grain-exporting countries.

In Europe, anti-GM food protestors have been especially active. In the last few years Europe has experienced two major foods scares: bovine spongiform encephalopathy (mad cow disease) in Great Britain and dioxin-tainted foods originating from Belgium. These food scares have undermined consumer confidence about the European food supply, and citizens are disinclined to trust government information about GM foods. In response to the public outcry, Europe now requires mandatory food labeling of GM foods in stores, and the European Commission (EC) has established a 1% threshold for contamination of unmodified foods with GM food products40.

In the United States, the regulatory process is confused because there are three different government agencies that have jurisdiction over GM foods. To put it very simply, the EPA evaluates GM plants for environmental safety, the USDA evaluates whether the plant is safe to grow, and the FDA evaluates whether the plant is safe to eat. The EPA is responsible for regulating substances such as pesticides or toxins that may cause harm to the environment. GM crops such as B.t. pesticide-laced corn or herbicide-tolerant crops but not foods modified for their nutritional value fall under the purview of the EPA. The USDA is responsible for GM crops that do not fall under the umbrella of the EPA such as drought-tolerant or disease-tolerant crops, crops grown for animal feeds, or whole fruits, vegetables and grains for human consumption. The FDA historically has been concerned with pharmaceuticals, cosmetics and food products and additives, not whole foods. Under current guidelines, a genetically-modified ear of corn sold at a produce stand is not regulated by the FDA because it is a whole food, but a box of cornflakes is regulated because it is a food product. The FDA's stance is that GM foods are substantially equivalent to unmodified, "natural" foods, and therefore not subject to FDA regulation.

The EPA conducts risk assessment studies on pesticides that could potentially cause harm to human health and the environment, and establishes tolerance and residue levels for pesticides. There are strict limits on the amount of pesticides that may be applied to crops during growth and production, as well as the amount that remains in the food after processing. Growers using pesticides must have a license for each pesticide and must follow the directions on the label to accord with the EPA's safety standards. Government inspectors may periodically visit farms and conduct investigations to ensure compliance. Violation of government regulations may result in steep fines, loss of license and even jail sentences.

As an example the EPA regulatory approach, consider B.t. corn. The EPA has not established limits on residue levels in B.t corn because the B.t. in the corn is not sprayed as a chemical pesticide but is a gene that is integrated into the genetic material of the corn itself. Growers must have a license from the EPA for B.t corn, and the EPA has issued a letter for the 2000 growing season requiring farmers to plant 20% unmodified corn, and up to 50% unmodified corn in regions where cotton is also cultivated41. This planting strategy may help prevent insects from developing resistance to the B.t. pesticides as well as provide a refuge for non-target insects such as Monarch butterflies.

The USDA has many internal divisions that share responsibility for assessing GM foods. Among these divisions are APHIS, the Animal Health and Plant Inspection Service, which conducts field tests and issues permits to grow GM crops, the Agricultural Research Service which performs in-house GM food research, and the Cooperative State Research, Education and Extension Service which oversees the USDA risk assessment program. The USDA is concerned with potential hazards of the plant itself. Does it harbor insect pests? Is it a noxious weed? Will it cause harm to indigenous species if it escapes from farmer's fields? The USDA has the power to impose quarantines on problem regions to prevent movement of suspected plants, restrict import or export of suspected plants, and can even destroy plants cultivated in violation of USDA regulations. Many GM plants do not require USDA permits from APHIS. A GM plant does not require a permit if it meets these 6 criteria: 1) the plant is not a noxious weed; 2) the genetic material introduced into the GM plant is stably integrated into the plant's own genome; 3) the function of the introduced gene is known and does not cause plant disease; 4) the GM plant is not toxic to non-target organisms; 5) the introduced gene will not cause the creation of new plant viruses; and 6) the GM plant cannot contain genetic material from animal or human pathogens (see http://www.aphis.usda.gov:80/bbep/bp/7cfr340).

The current FDA policy was developed in 1992 (Federal Register Docket No. 92N-0139) and states that agri-biotech companies may voluntarily ask the FDA for a consultation. Companies working to create new GM foods are not required to consult the FDA, nor are they required to follow the FDA's recommendations after the consultation. Consumer interest groups wish this process to be mandatory, so that all GM food products, whole foods or otherwise, must be approved by the FDA before being released for commercialization. The FDA counters that the agency currently does not have the time, money, or resources to carry out exhaustive health and safety studies of every proposed GM food product. Moreover, the FDA policy as it exists today does not allow for this type of intervention.

How are GM foods labeled?

Labeling of GM foods and food products is also a contentious issue. On the whole, agribusiness industries believe that labeling should be voluntary and influenced by the demands of the free market. If consumers show preference for labeled foods over non-labeled foods, then industry will have the incentive to regulate itself or risk alienating the customer. Consumer interest groups, on the other hand, are demanding mandatory labeling. People have the right to know what they are eating, argue the interest groups, and historically industry has proven itself to be unreliable at self-compliance with existing safety regulations. The FDA's current position on food labeling is governed by the Food, Drug and Cosmetic Act which is only concerned with food additives, not whole foods or food products that are considered "GRAS" - generally recognized as safe. The FDA contends that GM foods are substantially equivalent to non-GM foods, and therefore not subject to more stringent labeling. If all GM foods and food products are to be labeled, Congress must enact sweeping changes in the existing food labeling policy.

There are many questions that must be answered if labeling of GM foods becomes mandatory. First, are consumers willing to absorb the cost of such an initiative? If the food production industry is required to label GM foods, factories will need to construct two separate processing streams and monitor the production lines accordingly. Farmers must be able to keep GM crops and non-GM crops from mixing during planting, harvesting and shipping. It is almost assured that industry will pass along these additional costs to consumers in the form of higher prices.

Secondly, what are the acceptable limits of GM contamination in non-GM products? The EC has determined that 1% is an acceptable limit of cross-contamination, yet many consumer interest groups argue that only 0% is acceptable. Some companies such as Gerber baby foods42 and Frito-Lay43 have pledged to avoid use of GM foods in any of their products. But who is going to monitor these companies for compliance and what is the penalty if they fail? Once again, the FDA does not have the resources to carry out testing to ensure compliance.

What is the level of detectability of GM food cross-contamination? Scientists agree that current technology is unable to detect minute quantities of contamination, so ensuring 0% contamination using existing methodologies is not guaranteed. Yet researchers disagree on what level of contamination really is detectable, especially in highly processed food products such as vegetable oils or breakfast cereals where the vegetables used to make these products have been pooled from many different sources. A 1% threshold may already be below current levels of detectability.

Finally, who is to be responsible for educating the public about GM food labels and how costly will that education be? Food labels must be designed to clearly convey accurate information about the product in simple language that everyone can understand. This may be the greatest challenge faced be a new food labeling policy: how to educate and inform the public without damaging the public trust and causing alarm or fear of GM food products.

In January 2000, an international trade agreement for labeling GM foods was established44, 45. More than 130 countries, including the US, the world's largest producer of GM foods, signed the agreement. The policy states that exporters must be required to label all GM foods and that importing countries have the right to judge for themselves the potential risks and reject GM foods, if they so choose. This new agreement may spur the U.S. government to resolve the domestic food labeling dilemma more rapidly.
Conclusion

Genetically-modified foods have the potential to solve many of the world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides and herbicides. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, international policy and food labeling. Many people feel that genetic engineering is the inevitable wave of the future and that we cannot afford to ignore a technology that has such enormous potential benefits. However, we must proceed with caution to avoid causing unintended harm to human health and the environment as a result of our enthusiasm for this powerful technology.

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