IS THE US FDA REGULATION AND EVALUATION OF GENETICALLY ENGINEEERED FOODS SUFFICIENT?

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INTRODUCTION

Opponents to genetically engineered foods in the United States (US) have raised many concerns over the past years. Many claim the foods are not safe because unexpected or unintended effects will occur and be introduced into the food.[1] Others claim the foods are not evaluated sufficiently by government agencies.[2] The US Food and Drug Administration (FDA) claims that genetically engineered foods on the market are safe and their evaluation of genetically engineered foods is no different than the evaluation of foods that are not genetically engineered.[3] The FDA has held its position steadfast over the years in light of controversy and criticism; claiming that genetically engineered foods are just as safe as their conventional counterparts.[4]

In light of this and other criticism which will be addressed later in this paper, this paper will argue the FDA should enhance the way they regulate, evaluate and approve genetically engineered foods in order to gain consumer confidence and approval. The future prospects for genetic engineered plants to improve health and the potential to grow fruits and vegetables that can contain a vaccine to fight a common disease, will be a missed opportunity for the advancement of science and health if consumers continue to oppose this technology. The general public needs a better understanding of genetic engineering and genetically engineered foods and only then can there be an expectation for a better acceptance of this technology.

Sections I and II of this paper will explain the technology of genetically engineered foods and review the current FDA regulation, evaluation and safety process. Section III and IV will discuss opposition and proponent views. Section V, will conclude with recommended changes and enhancements

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[1] FDA's Policy for Foods Developed by Biotechnology, US Food and Drug Administration, Center for Food Safety and Nutrition handout (1995). *available at*:http://www.cfsan.fda.gov/~dms/biolabgu.html

[2] Center for Science in the Public Interest: Biotechnology, Frequently Asked Questions. *available at:* http://www.cspinet.org/biotech/faq (last visited Apr 21,2008).

[3] "*Supra* note 1 at 3."

[4] Linda Bren, FDA Consumer Magazine, Genetic Engineering: The Future of Foods? (November-December 2003).

the FDA should take to improve on their current oversight in order to instill consumer confidence.

This paper will address only genetically engineered (GE) plant foods, and will be labeled as GE or GE foods, throughout this paper.

I. THE TECHNOLOGY OF GENETIC ENGINEERING

This section will explain how GE crops are developed and compare the process to the traditional method that was used by farmers for hundreds of years prior. It will explain some benefits of the technology of genetic engineering and discuss some of the first GE foods that made it to the US market in the 1990's.

GE crops are developed from biotechnology, by inserting a gene into a plant to give it a specific or desired trait.[5] The process is called recombinant DNA, or gene splicing.[6] Through this process a specific gene can be inserted into a plant to provide a benefit. This process directs the production of a specific protein that makes the plant different.[7] This method is faster than the traditional method of genetic modification which farmers have successfully used over the years. Genes can come from any organism--plant, animal or microbe.[8] Cross-fertilization is one such method that farmers have used over the years; this method requires mixing of thousands of genes from several plants and requires many attempts and years of testing in order to weed out an unwanted trait.[9] Gene splicing is much quicker and a more precise method; saving years of testing.[10]

Many of the first GE crops were intended to help the farmer by controlling insects.[11] For example,

a corn gene from the bacterium Bacillus thurigiensis (BT) was inserted into a corn plant to help farmers control destruction of their crop from caterpillars.[12] This reduced the amount of chemical pesticides used on the crop as well. [13]

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[5] Larry Thompson, Are Bioengineered Foods Safe? FDA Consumer, (January-February 2000). *available at*: http://www.cfsan.fda.gov/~dms/fdbioeng.html
[6] *Id.*
[7] *Id.*
[8] Raymond Formanek, FDA Consumer Magazine, Proposed Rules Issued for Bioengineered Foods, (March-April 2001).
[9] "*Supra* note 4 at 9."
[10] "S*upra* note 4 at 10."
[11] "*Supra* note 4 at 11."
[12] "*Supra* note 5 at 12."
[13] "*Supra* note 5 at 13

The first genetically modified food, "Flavr Savr" tomato was sold on the US market in 1994.[14] The goal was to grow a tomato that remained on the vine longer for enhanced flavor.[15] In the mid-1990's there was an insect virus threatening the papaya crop in Hawaii. Because traditional plant breeding failed to produce a virus resistant papaya, researchers from Cornell University were able to isolate a specific gene and by integrating this gene into the papaya, the crop and subsequent crops became resistant to the virus.[16] This genetic engineered procedure saved the papaya crop and possibly the farmers' livelihood.

The process of genetic engineering has the ability to save years of testing to produce a specific benefit to a plant or crop. Reducing the amount of chemical pesticides, growing a better tasting tomato and saving an entire crop, are benefits to farmers, consumers and to the environment. Consumers need to be educated on the benefits of genetic engineering and they must see the benefits before they will attempt to accept the technology.

II. US FDA REGULATION AND EVALUATION

This section will discuss the current process used by the FDA to evaluate and regulate GE foods and discuss the first FDA regulation for a GE food. GE foods are not subject to an evaluation or pre-market approval by any federal agency; this has opponents outraged. This non-mandatory approval is highly criticized and creates a stumbling block for consumer approval. Unless this process is changed, consumer acceptance may continue to be negative.

The FDA has the primary responsibility under the Federal Food, Drug, and Cosmetic Act (FDCA) to ensure the safety and wholesomeness of most foods. Under the FDCA, the FDA regulates all food and food ingredients excluding meat and poultry, even those developed by genetic engineering.[17] Under this act the FDA requires that manufacturers ensure all of the food they sell meet specific safety standards, whether genetically engineered or conventional food.[18] The FDA claims that GE foods on the market are safe and that their evaluation of GE foods is no different than the evaluation of foods that are not GE.[19]

In 1986, the US published a "Coordinated Framework for the Regulation of Biotechnology", which announced the policy of federal agencies involved in reviewing biotechnology research and products

[14] "*Supra* note 8 at 14."
[15] "*Supra* note 8 at 15."
[16] "*Supra* note 4 at 16."
[17] "*Supra* note 3 at 17."
[18] "*Supra* note 4 at 18."
[19] "*Supra* note 3 at 19."

and outlined the framework for oversight and review of products developed using biotechnology.[20] This established that the agencies responsible for developing GE foods were also responsible for their evaluation.[21]

The FDA ensures that all foods, traditional and GE, are safe to eat for humans and animals, the USDA ensures that all plants, traditional and GE plants are safe to grow, and the EPA ensures that pesticides used on these plants are safe for human and animal consumption and the environment. FDA under the FDCA has the authority to remove any food from the market they feel is not safe, this applies to all food, traditional and GE.

In March 1990, the first regulation was issued by the FDA for the use in a food of a substance produced by recombinant DNA techniques.[22] It was for chymosin, (rennet) which is a milk clotting enzyme used in making dairy products. FDA affirmed that chymosin was "generally recognized as safe" (GRAS) meaning it was exempt from pre-market approval. The source of the new enzyme, E.Coli K-12, was affirmed as GRAS and therefore exempt from any requirements as a food additive.[23] The FDA's approval was based on the following factors:

> The introduced chymosin gene encoded a protein that had the same structure and function as animal-derived chymosin; the manufacturing process removes most impurities; the production microorganisms are destroyed or removed during processing and are non-toxigenic and non-pathogenic; and any antibiotic resistance marker genes (e.g., ampicillin) are destroyed in the manufacturing process.[24]

This establishes that a manufacturer need only prove a GE food is safe as its conventional counterpart and they are exempt from any additional requirement or approval from the FDA.

Although three government agencies have an oversight for GE foods, no one agency is required to evaluate, review and approve GE foods prior to marketing. The FDA relies on manufacturers of GE foods to ensure these foods meet FDCA standards. Even though this is the same requirement of manufacturers for traditional foods, this has been a controversial point for many opponents.

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[20] Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology, 51 FR 23302 (June 26, 1986).
[21] *Id.*
[22] "*Supra* note 3 at 22."
[23] "*Supra* note 3 at 23."
[24] "*Supra* note 3 at 24."

A. FDA SAFETY EVALUATION PROCESS

This section will explain the FDA's role in the evaluation of the safety of GE foods.

There is uncertainty and controversy in the eyes of many opponents about the safety of GE foods, and how the FDA evaluates its safety. Without confidence in the safety evaluation of GE foods, consumers will be reluctant to support the technology and the benefits may go unknown. Future benefits will be unrealized.

In 1992 the FDA published a policy statement in the Federal Register (57 FR 22984) that explained how GE foods are regulated under the FDCA.[25] This policy statement provided "guidance to industry" which established a standard of care for GE foods. This standard of care was to ensure safety and wholesomeness.[26] The guidelines address the way manufacturers should evaluate the safety of GE foods they develop, including testing for any potential health risks.[27] This was the first guidance that addressed the safety evaluations for new proteins produced by bioengineered plants.[28] The FDA policy statement and testing guidelines specified that new proteins that differed substantially in function and structure would be considered a food additive and must go through the process review for food additives.[29] This is the only circumstance where a GE food would require pre-market approval by the FDA.

In 2006, the FDA issued additional "guidance for industry" to further address the safety evaluation of new proteins in new plant varieties that are under development for human food.[30] The intent of the document was to provide the framework for the manufacturer to evaluate the food safety of new proteins, prior to the stage of development.[31] This is termed "early" food safety evaluation of new proteins.[32] Does this comes in response to public concerns for years that a new protein could cause an allergic reaction to susceptible populations?

The responsibility for the safety of a GE food product is placed in the hands of the developer

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[25] FDA, Q & A Sheet, FDA's Statement of Policy; Foods Derived From New Plant Varieties (June,1992). See 57 FR 22984 (May 29, 1992).
[26] "Supra note 3 at 26."
[27] "Supra note 3 at 27."
[28] CFSAN Office of Food Additive Safety; Recommendations for the Early Food Safety Evaluation of New-Non Pesticidal Proteins Produced by new Plant Varieties Intended for Food Use. (June 2006). Available at http: www.cfsan.fda.gov/guidance
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*

to ensure the foods are safe for consumption and comply with all legal requirements.[33] The FDA puts the safety evaluation process of GE foods in the hands of the manufacturer.

All crops undergo field testing for several years or seasons by the developer or manufacturer. Manufacturers that develop genetically engineered foods must also prove in their data studies that the food is as safe as its conventional counterpart.[34] This safety data is voluntarily sent to the FDA.[35] Approval and

pre-market notification is not mandatory or even required unless the food differs from its conventional counterpart.

"The primary legal tool that the FDA uses to ensure the safety of GE foods is the adulteration provisions of the FDCA section 402(a) (1)."[36] As well, the FDA relies on the food additive provision of the FDCA (section 409) for substances that are intentionally added to food.[37]

The FDA has maintained throughout the history of GE foods that if GE foods are as safe as their conventional counterpart, the new food produced is just as safe.[38] Many experts agree that this type of testing has been adequate in determining the safety of these foods, even though these tests have limitations.[39] In 2002 the FDA agreed that their review process of GE foods could be enhanced (GAO report-letter 5/2/02) by verifying test data that companies provide and by increasing the transparency of the evaluation process.[40]

The Center for Science in the Public Interest (CSPI) has expressed that the FDA's oversight is not as rigorous or independent as it should be in evaluating these foods.[41]CSPI believes the FDA should formally approve a crop is safe for human consumption through mandatory approval vs. voluntary.[42]

The evaluation process and safety testing of GE foods falls to the manufacturer. Manufacturer test results are not required to be sent to the FDA. The FDA does not conduct pre-market review for GE foods; they believe they pose no risks because the manufacturer has already conducted the safety tests as

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[33] "*Supra* note 3 at 33."
[34] "*Supra* note 5 at 34."
[35] "*Supra* note 5 at 35."
[36] "*Supra* note 1 at 36."
[37] "*Supra* note 1 at 37."
[38] "*Supra* note 5 at 38."
[39] Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced,General Accounting Office, Report 02-566. (May 2002).
[40] *Id.*
[41] Center for Science in the Public Interest: Biotechnology, Frequently Asked Questions. Available at http://www.cspinet.org/biotech/faq (last visited Apr 21,2008).
[42] *Id.*

recommended by the FDA. Opponents against GE believe this type of testing and process is insufficient and believe the FDA evaluation should be mandatory. Unless this testing is enhanced or explained and supported by fact that it is sufficient, opponents will continue to criticize the FDA and claim GE foods are not safe.

III. OPPOSITION

This section will state some of the opposition expressed by consumers regarding GE foods. It will also discuss some consumer survey results which state that many consumers are unaware of the exact technology, but believe it to be unsafe regardless.

Opponents to GE claim the foods to be unsafe and have expressed the following concerns:

- That foods are not evaluated properly by the FDA for safety
- The FDA does not properly review manufacturers' safety results
- The food may cause an allergic reaction to some individuals
- There is a possibility for toxin development in the new food
- There can/will be an environmental impact
- Long term health effects are not addressed
- Some consumers want mandatory labeling

Opponents are quick to recall the 2000 StarLink corn crop incident where the Cry9C protein was found in taco shells that reached supermarket shelves. This GE corn was intended for animal feed and industrial use only.[43] The corn found its way into product for human consumption such as taco shells and a recall resulted. The product was declared adulterated under the Federal Food, Drug and Cosmetic Act due to the unapproved pesticide it contained and removed from the market. For many Americans this may have been their first experience in hearing that GE foods were on the market. Thus an uncertainty began as to how GE foods are regulated.

The introduction of a gene from unrelated species, or from two different plants, is a controversy that has been expressed by opponents early on. Some opponents argue that this type of genetic engineering can carry traits that were not previously in the food, thus creating unknown allergens, toxins or other

[43] *Id.*

undesirable effects.[44] FDA has specifically focused on allergen concerns due to consumer concern and if a new product comes from a common allergy causing food, FDA requires this be labeled. Through the manufacturers testing any irregular result of allergens and toxins must be brought forward to the FDA for further safety testing and FDA approval before releasing on the market.

Experts claim that all foods have uncertain risks and that GE foods pose the same risks as conventional foods.[45] Experts say that monitoring of long-term health risks is not necessary or feasible.[46] Absolute safety for any food cannot be achieved or expected.[47]

Surveys in the US show consumers have a limited and uneven knowledge and understanding of GE foods.[48] Surveys show that when asked, many consumers are unaware they may be consuming food that was genetically engineered.[49] Pubic polls in the US indicate insufficient confidence in the foods, and when asked, 62% to 70% of respondents desire the food be labeled as "genetically modified" or some indication of such.[50] Currently, there is no requirement by the FDA to label GE foods as such, only if the food has an allergy-causing protein. It is estimated that three-quarters of the processed foods in US supermarkets contain GE soybeans, corn or another GE crop.[51] The only way to avoid eating a product that may be genetically engineered is to consume only organic food, as organic food cannot contain food that was genetically engineered.[52]

All of the above opposition, if not in progress, must be formally addressed by the FDA. For each opposition or opposing view, the FDA must provide the information that an evaluation has been conducted with the results or conduct an evaluation based on a risk assessment of each food on the market.

IV. PROPONENTS VIEWS

This section will discuss some of the early benefits from GE foods as well as explore the future prospects of this technology. Unless the benefits are realized and consumer confidence in the safety of these foods grows, consumers may never see or reap the true benefits.

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[44] "*Supra* note 5 at 44."
[45] "*Supra* note 5 at 45."
[46] "*Supra* note 39 at 46."
[47] "*Supra* note 1 at 47."
[48] FDA, Report on Consumer Focus Groups on Biotechnology. (October 20, 2000).
[49] *Id.*
[50] CSPI, National Poll on Labeling of Genetically Engineered Foods. (May 16, 2001).
[51] "*Supra* 4 at 51."
[52] "*Supra* note 41 at 52."

Some early goals for developing genetically engineered plants were: to improve crop rotation by reducing insects that destroy crops, by reducing viruses which cause disease in plants and herbicide resistance and by reducing the amount of chemicals that are needed to keep weeds at a minimum.[53]

Some of the benefits we have seen from GE crops and foods are a better yield because plants are less resistant to drought, and a reduction of pesticide use, as plants are engineered to be resistant to certain pests.[54] There is also future opportunity for enhanced nutritional value and other disease fighting properties. Rice genetically engineered with beta carotene is being developed for developing countries as well as experimentation of plants with vaccines and antibodies.[55]

The World Health Organization (WHO) has cited the following benefits from GE foods: "reduced agricultural chemical usage and enhanced farm income, and improved crop sustainability and food security, particularly in developing countries."[56]

Not only are the above benefits not often seen by the consumer they are also not communicated effectively to consumers.

V. CONCLUSION

Opponents in some California towns and other states have banned GE foods. Polls and surveys show an uneven knowledge and poor perception of GE foods. Some opposing claims have been addressed but unsuccessful in changing public perception. The future success of genetic engineering is at stake. With such opposition, the FDA must make a stronger case for evaluating GE plants and foods. FDA should conduct a risk assessment for each GE food and publish their review. Benefits and risks must be made public. Mandatory testing must be done by someone other than the FDA, perhaps a third party vs. the manufacturer, as there may be too much mistrust that cannot be reversed. Unless all the facts are known, there may never be a change in consumer perception. As well, an education campaign must be begin to educate consumers. The mistrust must be minimized.

Future GE foods must also have the same evaluation and risk assessment; the benefits must be seen.

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[53] FAO/WHO. Safety Aspects of genetically Modified Foods of Plant Origin Joint FAO/WHO Expert Consultation report. (May-June 2000).
[54] *Id.*
[55] "*Supra* note 4 at 55."
[56] "Supra note 53 at 56."

Rapid growth is anticipated in biotechnology and more GE plants will be developed for future use. Public approval is vital in allowing GE foods to be more widely utilized. For many Americans in many cases, they must be able to see before they will accept. Although opposition may not disappear altogether, unless opponents have a better understanding of GE foods, advancements in genetic engineering may never take place and benefits may not be utilized.