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Precaution before Profits: An Overview of Issues in Genetically Engineered Food and Crops

by

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ARTICLES

PRECAUTION BEFORE PROFITS: AN OVERVIEW OF ISSUES IN GENETICALLY ENGINEERED FOOD AND CROPS

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I. INTRODUCTION

The introduction of genetically engineered crops into our food supply has become a major controversy provoking debate in the media, in federal, state, and local governments, on college campuses, in grocery stores, and throughout the world. Those within the industry argue that genetically engineered ("GE") food and crops are a natural extension of traditional breeding methods and that any negative reaction by consumers is based on fear and a lack of understanding. As this article shows, the position of the industry is manipulative. By raising fear and ignorance as rebuttals to valid concerns, the industry shifts the debate away from the merits and substance of argument. At a minimum, the risks and benefits of genetically engineered food are inconclusive, and the technology itself is so new that the full implications of its widespread use cannot possibly be predicted. In addition, the current regulatory structure is inadequate and unable to protect individuals from potential risks. These facts, coupled with a major imbalance in power and financial resources between industry and consumers, lead to the conclusion that the only reasonable option for the use of genetic engineering in agriculture is to move with extreme caution.

Part Two of this essay explains the science behind the technology used to create genetically modified food and crops. A brief overview of the technology is necessary to understand the risks posed and evaluate any benefits claimed. Part Three explores the nature of the controversy, evaluating the potential risks and benefits of the technology by looking at the major claims on both sides of the debate. Part Four of this article examines the existing regulatory structure for GE food and crops in the United States and concludes that the structure is not adequate to protect consumers from the potential risks of these products. Though evidence exists to suggest that GE food and crops may have serious risks for human and environmental health, no one is currently guaranteeing the safety of these products. The article concludes that in light of the potential health risks, lack of benefits, and inadequate regulation of genetically engineered food and crops, the only reasonable approach is to place the burden of safety on those creating the risks, whatever they may be, and to call for a moratorium on the sale of genetically modified food and crops until adequate safety testing answers the questions the technology raises.

II. GENETICALLY ENGINEERED FOOD: TECHNOLOGY AND APPLICATIONS

Part of the problem with debates about genetically engineered food is that the discussions must revolve around the science. It is the scientific technique that creates the risks and supposed benefits associated with genetically engineered food. For many people who have not taken science since the required high school biology class, the scientific discussions can be intimidating. At the same time, scientists who have had years of expert training in their field of study can feel threatened by the thought of decisions being made about this technology by people who are not educated as scientists. This leads to a division where those working within science hold their discussions and debates, and consumers and advocates hold their debates on the policy separately. This is an unfortunate situation, and it need not be the model. Consumers can get enough of a scientific understanding of the technique to debate the issue directly with the scientists, and hearing the opinions of the general public can only help the scientists broaden their perspectives. The following overview will provide a good background for the discussion of risks and benefits of genetically engineered food and crops.

Genetically engineered crops are plants into which scientists have inserted pieces or strands of foreign genetic material in an effort to change or supplement one or more of the plant's traits.[1] Genetically engineered food contains ingredients made from genetically engineered crops.[2] In the United States, more than sixty million acres of farmland are covered in GE crops,[3] including soybeans, maize (corn), canola (rape seed), and cotton.[4] These crops are used

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[1] Skip Spitzer, *Genetically Engineered Crops and Foods*, Pesticide Action Network North America 1, *at* http://www.panna.org/geTutorial/geTutorialComplete.html (last visited Dec. 10, 2000) [hereinafter Spitzer].

[2] *See id.*

[3] Ronnie Cummins, *Hazards of Genetically Engineered Foods and Crops: Why We Need a Moratorium*, Fact sheet of the Organic Consumers Ass'n 1, *at* http://www.purefood.org (last visited Feb. 12, 2001) [hereinafter Organic Consumer Ass'n Fact Sheet].

[4] GREENPEACE, QUESTIONS AND ANSWERS: FREQUENTLY ASKED QUESTIONS, *at*

in the production of food products widely available in supermarkets in the United States from Kellogg's and General Mills cereals to Heinz ketchup, Carnation chocolate milk, Coca-Cola, and Beech Nut baby food.[5]

A. The Technology

Genetic engineers are still experimenting with the best ways to get plants to take up foreign DNA. It is a complex challenge, requiring genetic engineers to isolate the genetic and chemical basis of the quality they want the new plant to have, find a way to get the foreign genetic material into the new plant at the appropriate spot, functioning at the right time in the appropriate sequence of development, and at the appropriate level of expression—all without affecting any of the other processes of the living plant. With so many variables, it is understandable that the technology is still experimental.

The first step in creating a genetically engineered crop is isolation of the genetic material that will hopefully produce a specific result in the new plant. Plant traits like color, size, life span, and ripening speed, as well as plant processes are all influenced to some extent by proteins that are made inside the plant. The plant's genes determine the production of these proteins. Though environmental elements like soil quality, air temperature, toxicity, and the amount and quality of water available also influence the appearance and functioning of plants, genetic engineers are mainly concerned with the role of genes. On December 13, 2000, an international team of researchers announced that they had sequenced the approximately 26,000 genes of a basic plant, *Arabidopsis thaliana*.[6] In addition, in late January, 2001, two companies announced the sequencing of the rice genome, the first crop to have its genome sequenced.[7] The scientists added that they would immediately launch a ten-year project to find out what each gene does.[8] This type of research is done with the hopes that genes can be linked to specific traits,

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www.truefoodnow.org/speak_out/generalfaq.html (last visited Dec. 13, 2000) [hereinafter GREENPEACE FAQ].

[5] GREENPEACE, TRUE FOOD SHOPPING LIST 11, 16, 17, 20, 26, 42, *at* http://www.truefoodnow.org (Oct. 2000).

[6] Maggie Fox, *Scientists Map Genes of Basic Plant*, Yahoo News 1 (Dec. 13, 2000), *at* http://dailynews.yahoo.com/h/nm/20001213/sc/plant_dc_1.html [hereinafter Fox].

[7] Andrew Pollack & Carol Kaesuk Yoon, *Rice Genome Called a Crop Breakthrough*, N.Y. TIMES, Jan. 27, 2001, at A10.

[8] Fox, *supra* note 6.

allowing scientists to manipulate those genes in other organisms.

Once scientists have isolated the genetic material linked to a trait or process, the scientist must get that material integrated into the cells of the new plant. Scientists are experimenting with several different ways to do this including using recombinant DNA, microinjection, electro-and chemical poration, and bio-ballistics.[9] Each technique uses a slightly different method for getting the isolated genetic material into the recipient cell. Plasmids and viruses, two biological vectors, are used in the recombinant DNA technique to carry genetic material into cells. Plasmids and viruses typically move between cells of different organisms, and they take the new genes with them as they go about their normal routine; though in the case of viruses, the viruses own biological function (to infect the recipient cell with disease) must be disabled. Plasmids and viruses bring the new genetic material into the recipient cell's nucleus, and sometimes the recipient cell will integrate the new genetic material into its own genes and begin to produce the protein for which the gene codes.[10]

Other ways to get the new genetic material incorporated into the recipient cell's DNA include microinjection, where the new genetic material is injected directly into the cell, and electro and chemical poration, where scientists create pores or holes in the recipient cell membrane that allow the new genes to enter. A final method is technically known as Bioballistics, and uses a type of gun to shoot the DNA into the recipient cell.[11] The gene gun technique uses projectiles of very small slivers of metal (like gold) coated with the foreign genetic material.[12] If all goes as planned, the projectiles are shot into the cell with the gene gun, and the foreign DNA is carried into the nucleus.[13]

Luck plays a role in each of these insertion techniques. It is common for the insertion technique to kill the recipient cell, and it is also very difficult to predict if and where the new genetic material will be incorporated into the DNA of the recipient cell. Often the insertion methods described above will lead to insertion of multiple

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[9] UNION OF CONCERNED SCIENTISTS, GENETIC ENG'G TECHNIQUES: FACT SHEET (2000), *at* http://www.ucsusa.org/agriculture/gen.techniques.html [hereinafter UCS FACT SHEET].

[10] *See id.*

[11] MARTIN TEITEL & KIMBERLY WILSON, GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE, 10 (1999) [hereinafter TEITEL & WILSON].

[12] *See id.*

[13] UCS FACT SHEET, *supra* note 9, at 2.

copies of the foreign genetic material either at a single site, or in multiple locations of the recipient cell.[14] Scientists also have to deal with the fact that the genes, once incorporated, do not always perform as predicted, and results can be surprising. In the ideal situation, the new gene is incorporated into the recipient cell's DNA and the production of the protein associated with the new gene begins. The trait or process controlled by the protein then becomes evident in the recipient plant, proving that successful genetic engineering has occurred.

B. Applications

Using the general technological framework discussed above, genetic engineers are able to avoid the reproductive limitations inherent in nature. The technique opens up a whole range of genetic exchanges that could never be possible without human interference. For example, consider a hypothetical population of fish that live in an extreme cold-weather environment. Scientists who study these fish, might find a gene specific to the population that produces a protein making the fish impervious to cold temperatures. In natural circumstances, this gene would be passed on in the fish population through breeding and natural evolution. In particularly cold winters, when many non-protected fish would die, those fish with the gene would survive in higher numbers, and a larger proportion of the fish population would eventually carry this useful gene. It would not be possible for the fish population to pass the genetic trait on to other organisms or plants that might benefit from cold protection since it is impossible for a fish to reproduce with anything but another of its kind. However, with genetic engineering, scientists could isolate the gene from the fish and transfer it into any other living organism—including a person or a plant. If the recipient cell incorporates the foreign gene, it is assumed that the production of the protein would begin, and the recipient organism would show the effects of the protein from the foreign gene. Though this is a hypothetical example, the possibilities it implies demonstrate both the promise and the risk of this technology.

Current applications of genetic technology are pervasive in the food supply. When you buy a product in a supermarket that is not organic, you may be eating food made with ingredients that are genetically engineered with new properties. Currently, the most

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14 Michael K. Hansen, *Genetic Eng'g is not an Extension of Traditional Plant Breeding* 4 (Jan. 2000), *at* http://www.biotech-info.net/wide_crosses.html [hereinafter Hansen].

common purposes of genetic engineering are: (1) herbicide resistance, (2) pesticide resistance, and (3) forcing expression or suppression of different traits, which includes anything from using genetic engineering to attempt to alter the nutritional qualities or reproductive cycle of a crop, to improving shelf-life or a plant's ability to grow at different temperatures.[15]

Seventy percent of the croplands devoted to genetically engineered crops are herbicide resistant.[16] Herbicides are powerful toxic chemicals[17] used to kill unwanted plants.[18] Traditionally, farmers had to be very careful when applying herbicides to their crops, because the herbicide would kill weeds and valued crops indiscriminately. Monsanto, the company that produced Roundup, also developed a line of crops resistant to it, called Roundup Ready.[19] These seeds are genetically engineered to withstand Roundup, allowing the farmer to spray the entire plant without killing it. Monsanto's Roundup Ready products include genetically engineered corn, soy, oil producing canola (rape seed), and cotton, all resistant to the herbicide Roundup.[20]

Another commercial use of genetic engineering in agriculture is pesticide resistance. Scientists (and organic farmers) found that a naturally-occurring soil bacterium, called *Bacillus thuringiensis* (*B.t.*), produced proteins that acted as a natural insecticide, killing caterpillars as well as beetle and fly larvae.[21] Though organic farmers had been spraying *B.t.* on crops with success, genetic engineers decided to try to insert the genetic material that triggered the production of *B.t.* into crops to induce the production of an internalized insecticide. *B.t.* crops produce the insect toxin

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15 *See* Steven H. Yoshida, *The Safety of Genetically Modified Soybeans: Evidence and Regulation*, 55 Food Drug LJ 193, 193 (2000) [hereinafter Yoshida] (quoting Maurizio G. Paoletti & David Pimentel, *Genetic Eng'g in Agric. and the Env't Assessing Risks and Benefits*, 47 BIOSCIENCE 665, 668-70 (1996)).

16 *See* Greenpeace FAQ, *supra* note 4.

17 *See* STEPHEN R. PADGETTE ET AL., *New Weed Control Opportunities: Dev. of Soybeans with a Roundup Reading Gene, in* HERBICIDE RESISTANT CROPS, 53, 55 (1996). The most widely used herbicide in the U.S. is Glyphosate, sold commercially as Roundup.

18 *See id.* at 193.

19 *See* TEITEL & WILSON, *supra* note 11, at 52. Monsanto, like many of the ag-biotech companies, has a complicated history of mergers and acquisitions. On March 31, 2000 Monsanto merged with Pharmacia & Upjohn, and since then Monsanto has been the agricultural division of Pharmacia. *See* Monsanto, *Co. Timeline/History*, *at* http://www.monsanto.com/monsanto/about_us/company_timeline/index6.html (last visited Feb. 6, 2001).

20 *See* TEITEL AND WILSON, *supra* note 11, at 52.

21 *See id.* at 24.

throughout the plant's life cycle, in all parts of the plant.[22] As a result, farmers who buy genetically engineered seeds no longer have to spray the *B.t.* on the plants, though they must continue to use other pesticides and/or herbicides for pests resistant to *B.t.*.[23]

In addition to using genetic engineering in crops to create herbicide tolerance and pest resistance, scientists are trying to manipulate the genetic material of plants directly. This direct manipulation produces qualitative differences in new crops, so that the new crop expresses certain traits at certain times or in certain amounts.[24] An early example of this was the genetically engineered FLAVR SAVR tomato that Calgene created in an attempt to extend the shelf life and supposedly improve the flavor of the tomato. The Calgene scientists isolated a gene associated with an enzyme involved in the ripening process of the tomato plant. They reversed the gene, blocking the expression of the enzyme and extending the time it took before picked tomatoes became soft. Theoretically, this would allow for extended shelf life and make transport easier, as the tomatoes could be picked and shipped while they were still hard.[25] Though actual production and sale of the FLAVR SAVR tomatoes did not go as planned, this model—of isolation of a gene and insertion into another species to affect some trait or process—is still considered valid by genetic engineers in the field.[26]

This brief overview of the techniques and applications of genetic engineering technologies in crops and foods provides a basis for discussion about the effects and implications of the technology. Genetic engineering has allowed scientists to manipulate genes directly and eliminate the natural barriers to reproduction between species. Although theoretically the processes described above have the potential to transform the role of humans in agriculture by allowing them to affect the substance of plants and foods at the genetic level, in actuality, the effects of the technology are even more widespread. The transformative nature of what genetic engineers are doing cannot be quantified. The full effects of moving foreign genes between different species and kingdoms are unknown, even to highly-trained genetic engineers.

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[22] GREENPEACE FAQ, *supra* note 4.

[23] *See* Andy Coghlan and Barry Fox, *Keep that Spray: Crops Made Resistant to Pests Still do Better With Chemicals*, NEW SCIENTIST, Dec. 18, 1999, at 5.

[24] *See* TEITEL & WILSON, *supra* note 11, at 19.

[25] *See id.*

[26] *See id.*

III. ISSUES IN THE GENETICALLY ENGINEERED FOOD DEBATE

The overview of the genetic engineering technology explored in Part Two of this article provides information necessary to comprehend the full spectrum of claims about genetically engineered food. Part Three makes clear that the transformative nature of genetic engineering technology has prompted consumers to question new risks and industry to promise new benefits. This section considers some of the biggest risks to human and environmental health created by the use of genetically engineered crops as well as some of the claims and benefits heralded by the industry. As this section illustrates, the current frame of the controversy—where one side raises risks and the other side raises benefits—has created a situation where the risks are not being addressed and the benefits are not being evaluated. A thorough look at the claims made on both sides makes it clear that neither side really knows what the full impact of genetically engineered food is or will be. At this time, however, the risks appear to be many and the benefits weak.

A. Concerns about Genetically Engineered Food

Concerns about genetically engineered food include risks to both human and environmental health. These concerns are being raised by consumers and several non-profit and advocacy organizations in the United States including the Council for Responsible Genetics,[27] Greenpeace,[28] the Union of Concerned Scientists,[29] the Center for Food Safety,[30] and the Organic Consumers Association.[31]

1. Risks to Human Health

a. Unpredictability

One of the greatest concerns about genetically engineered crops and food is the fact that so much is unknown and, at this time, unknowable. Though scientists have the skill to remove and insert gene sequences in living things, they are not able to control the many variables in the process. Scientists with a genetic map of a plant

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27 *See* THE COUNCIL FOR RESPONSIBLE GENETICS, CENTRAL PRINCIPLES OF CRG, *at* http://www.gene-watch.org (last visited Feb. 7, 2001).

28 *See* GREENPEACE FAQ, *supra* note 4.

29 *See* UCS FACT SHEET, *supra* note 9.

30 *See* THE CENTER FOR FOOD SAFETY, CITIZEN PETITION BEFORE THE U.S. FOOD AND DRUG ADMIN., *at* http://www.centerforfoodsafety.org/li/FDApetition.html (last visited Feb. 7, 2001).

31 *See* ORGANIC CONSUMERS ASS'N FACT SHEET, *supra* note 3.

cannot yet predict what each gene does. In addition, genes interact with other genes and with their environment in complex ways, making it impossible for a scientist to be able to predict completely the overall changes in an organism resulting from the transference of even just one gene.[32]

This unpredictability has led to surprising results in several experiments with genetically engineered plants. For example, in 1999, *Science* magazine reported on a study in which two groups of rats were fed potatoes.[33] One group was fed potatoes that had been genetically modified with a lectin gene to enhance the potatoes' resistance to insects, while the other group was fed non-genetically modified potatoes supplemented with the same lectin.[34] The rats that ate the genetically modified potatoes showed stunted growth and suppressed immune systems, while the rats that ate the non-genetically modified potatoes with the same lectin had none of those symptoms.[35]

In another experiment, scientists studied three strains of a mustard plant: one modified from conventional breeding and two that were genetically engineered.[36] Typically the mustard plant is self-pollinating with low rates of cross pollination, which would lead researchers to assume that if such a plant was genetically modified it would have a low chance of cross-pollinating with other plants.[37] Surprisingly, this experiment showed that the genetically engineered mustard plants were twenty times more likely to cross-pollinate than the non-genetically modified mustard plant with the same allele.[38] In yet another study involving petunia flowers, scientists inserted the gene associated with producing red petals. The genetically engineered plants not only produced red petals, they also showed decreased fertility and altered growth in their roots and leaves.[39]

These experiments show that attempts at genetic modification of

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32 Yoshida, *supra* note 15, at 205.

33 Martin Enserink, *Preliminary Data Touch Off Genetic Food Fight*, 283 SCI. 1094 (1999) [hereinafter Enserink, *Preliminary Data*]; Martin Enserink, *The Lancet Scolded Over Pusztai Paper*, 286 SCI. 656 (1999). *But see* Peta Firth, *Leaving a Bad Taste*, 280 SCI. AM. 34 (1999).

34 *See* Enserink, *Preliminary Data*, *supra* note 33.

35 *Id.* at 1094-95.

36 *See* Joy Bergelson et al., *Promiscuity in Transgenic Plants*, 395 NATURE 25 (1998), *available at* http://www.arabidopsis.org/madison98/abshtml/321.html. [hereinafter Bergelson].

37 Richard Caplan & Ellen Hickey, *Weird Science: The Brave New World of Genetic Eng'g* 4, *at* http://www.pirg.org/ge/press/weirdscience (last visited Feb. 12, 2001) [hereinafter *Weird Science*].

38 *Id.*

39 BREWSTER KNEEN, FARMAGEDDON: FOOD AND THE CULTURE OF BIOTECHNOLOGY, 206 (New Society Publishers 1999).

plants are truly experiments in the sense that results can be predicted but never guaranteed. The amount that is known about genes is far outweighed by the information that is not known. Though scientific study has always been about exploring the unknown, the amount of unpredictability in genetically engineered food raises serious questions about how much risk is too much, and who should bear the burden of this risk. Food made with genetically engineered ingredients is not labeled in the United States, so for now, American consumers are forced to accept the consequences of genetically engineered foods—whatever they may be.

b. Antibiotic Resistance

When scientists isolate and transfer a desired foreign gene into a recipient cell, they add another foreign element, known as a "marker gene," to help them track the success of the genetic transfer.[40] The marker gene used most often is a bacterial gene for antibiotic resistance.[41] The antibiotic resistance gene is appealing because scientists can expose the recipient cell to an antibiotic after the genetic transfer and if the cell survives, they can assume that the antibiotic resistance gene, accompanied by the desired foreign gene, successfully entered the recipient cell.

Unfortunately, the use of the marker gene does not come without risk. The antibiotic resistance trait engineered into the plants could be transferred to bacteria and aggravate the growing problem of resistance to various antibiotics in humans and animals. As animals and humans eat genetically engineered foods, they are exposing the bacteria in their mouths and intestines to the resistance genes. DNA can be transferred to bacteria,[42] and the widespread exposure of bacteria to resistance genes could be catastrophic for the control of disease.[43] Even those who minimize the threat of antibiotic resistance transfer recommend against using antibiotic resistant genes in genetically modified foods for antibiotics that are still useful.[44]

c. Allergens

Another human health risk presented by the use of genetically

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[40] *See Weird Science*, *supra* note 37, at 3; ORGANIC CONSUMERS ASSOCIATION FACT SHEET, *supra* note 3, at 2; TEITEL & WILSON, *supra* note 11, at 38.

[41] *See Weird Science*, *supra* note 37, at 3.

[42] *See id.*

[43] *See* TEITEL AND WILSON, *supra* note 11, at 53.

[44] *See* Yoshida, *supra* note 15, at 203.

modified ingredients in foods is uncontrolled exposure to allergens. Eight percent of children in the United States suffer from food allergies, with symptoms ranging from mild unpleasantness to sudden death.[45] Usually, individuals with known food allergies can monitor the ingredients in the foods they eat to avoid exposure to the problematic substance.

Experiments have shown that genetically engineered food can take on the allergenic properties of transferred foreign genetic material.[46] In 1996, Pioneer Hi-Bred, in an attempt to improve the nutritional quality of soybeans, developed genetically modified soybeans that contained a foreign protein taken from a brazil nut.[47] The fact that allergies to brazil nuts are relatively common and can be fatal prompted researchers to check the allergenicity of the genetically modified soybean.[48] Even though animal tests of the genetically modified soybeans had turned up negative,[49] the Nebraska researchers found that individuals allergic to brazil nuts would also be allergic to the genetically modified soybeans.[50]

The issue of genetically engineered food compounds the concerns raised by the brazil nut research in two ways. First, genetically engineered foods are not labeled. This is problematic for individuals with allergies because it removes their ability to avoid foods that could harm them. Though an individual with an allergy to certain types of fish can take care to avoid fish in all its forms, they have no weapons against a tomato genetically engineered with a fish gene. Second, genetic engineers splice and combine all different types of genes into food, creating the possibility of new and unexpected food allergies. It would be impossible to predict how individuals would react to genetic material from products and organisms not normally eaten as food.

d. Risks from the use of Viral Promoters

Another major health risk created by the development and sale of genetically engineered food and crops is the potential side effect

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45 *See* ORGANIC CONSUMERS ASS'N FACT SHEET, *supra* note 3, at 2.

46 *See* Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688 (1996).

47 *SEE* TEITEL & WILSON, *supra* note 11, at 35. *See also* INST. OF SCI., TECH., AND PUB. POLICY, GENETIC ENG'G: A CAUTIONARY APPROACH, http://www.istpp.org/genetic_engineering.htm#foods (Feb. 13, 2001) [hereinafter A CAUTIONARY APPROACH].

48 *See* Spitzer, *supra* note 1, at 5.

49 *See* ORGANIC CONSUMERS ASS'N FACT SHEET, *supra* note 3, at 2.

50 *See* TEITEL & WILSON, *supra* note 11, at 35.

associated with the use of viral promoters. Viral promoters are used in the genetic engineering process to help activate the foreign genes once they are inserted into the recipient plant.[51] In a naturally occurring plant, the plant's genes have promoters that control when a particular gene is activated and for how long. This ensures that a gene begins working at the appropriate time during the plant's development and producing its product at the appropriate level.[52]

When genetic engineers insert foreign genes into a plant, they must also include a promoter to tell the gene to begin producing its protein. Virtually all genetically engineered crop plants contain a viral promoter from a plant virus known as the cauliflower mosaic virus.[53] The cauliflower mosaic virus is used as a promoter because, as a virus, it has the capability to infect a plant cell and direct the workings of that cell. The cauliflower mosaic virus is an especially powerful promoter, capable of forcing the hyper-expression of the foreign gene at two or three times that of the organism's own genes.[54]

The use of these strong viral promoters is a cause for concern. The viral promoters present safety risks because they can promote expression not only of the inserted foreign gene but also of other genes within the plant.[55] This could lead to unpredictable results in the recipient plant. In addition, research on the cauliflower mosaic virus has shown that it is highly likely to be involved in horizontal gene transfer, that is, the movement of genes between species.[56] As the cauliflower mosaic virus moves between species it will continue to do its job—promoting the hyper-expression of genes. According to one study, the consequence of such inappropriate over-expression of genes may be cancer.[57] Questions have also been raised about the possibility of these promoters coming into contact with other viruses and creating entirely new strains of viruses.[58]

Research on cauliflower mosaic virus and other viral promoters is still in its infancy, but the questions already raised in relation to its

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51 NATURAL LAW PARTY, RISKS ASSOCIATED WITH THE USE OF THE CAULIFLOWER MOSAIC VIRUS PROMOTER IN TRANSGENIC CROPS 1, *at* http://www.btinternet.com/~nlpwessex/Documents/camv.htm (last visited Jan. 10, 2001).

52 Hansen, *supra* note 14, at 7.

53 *See id.*

54 *See id.*

55 *See id.*

56 *See* Mae-Wan Ho, *Cauliflower Mosaic Viral Promoter—A recipe for Disaster?* 4 MICROBIAL ECO. HEALTH & DISEASE (forthcoming 2001), *available at* http://www.i-sis.org/camvrecdis.shtml.

57 *See id.*

58 *See id.*

safety and regulation are cause for concern.

2. *Risks to Environmental Health*

a. *Genetic Pollution*

One of the main risks to the environment stems from the fact that genetically engineered crops are unpredictable living things living in the even more unpredictable natural world. In the laboratory, scientists can control the conditions under which genetically engineered crops are grown, regulating what comes into contact with the plants in addition to all aspects of their environment. In the field however, the genetically engineered plants come into contact with all sorts of other living organisms, including weeds, other plants, insects, people, birds, and various other wildlife. In addition, there can be strong winds, heavy rains, excessive sunlight, and a whole range of other environmental conditions that affect and are affected by the genetically modified plant. There is no way to predict the results and effects of these interactions with the foreign genetic material. Once the genetically modified plants are released into the environment, scientists no longer have any control over them, and as they reproduce, migrate, and mutate, they raise several issues of concern.

First, genetically modified plants produce pollen that may also contain the foreign genetic material inserted into them. The pollen can be picked up by insects, birds, wind, or rain and carried into neighboring fields or wild areas. If the neighboring farmer happens to be farming organically, the genetically modified pollen could do catastrophic damage to the farmer's entire crop. This happened to organic corn chip maker Terra Prima, who lost $87,000 when its European exports tested positive for GE ingredients.[59] Although requiring buffer zones between genetically engineered crops and natural crops is a step in the right direction, many farmers are not following the regulations, and even with full compliance, it would be impossible to entirely eliminate the risk of contamination by genetically engineered pollen.[60]

The DNA from genetically modified plants can also transfer to wild relatives, creating hybrid populations over which scientists have no control. As discussed above, the genetically engineered mustard plants reported in *Nature* in 1998 were twenty times more likely to

[59] Spitzer, *supra* note 1, at 6.

[60] *Farmers Unclear About Biotech Rules*, N.Y. TIMES, Feb. 1, 2001, *available at* http://www.nytimes.com/2001/02/01health01ap-biotech.html.

outcross to wild relatives than the non-genetically modified mustard plants.[61] If this holds true for other species and in other circumstances, the spread of genetically engineered plants could be even more difficult to regulate. If the genetically engineered traits of herbicide tolerance and pest resistance spread into wild populations, it could result in the creation of super-tolerant plants and pests. These super-bugs and super-plants will require stronger and more toxic chemicals to control and eliminate them.[62] All of these environmental harms are serious, and yet the genetically engineered food experiment continues with very little signs of concern coming from the industry or the regulatory authorities.

b. Threats to Wildlife, Insects and Soil Organisms

Genetically engineered plants contain the genetically engineered trait in every single cell. In the majority of cases, this trait is herbicide tolerance or pesticide resistance.[63] Whereas normally these highly toxic chemicals are sprayed on the outside of the plant or in the plant's environment, with genetic engineering the toxins are ubiquitous. The human health risks of the internalized toxins are currently unknown,[64] but evidence of environmental risk is growing.

The genetically engineered pollen that has the potential to create the genetic pollution described above has also been shown to kill beneficial insects. Specifically, pollen with the genetically engineered *B.t.* pesticide has been shown to kill Monarch butterflies.[65] In addition, evidence exists that *B.t.* crops may also be harmful to bees[66] and lacewings.[67] Furthermore, soil organisms may be affected as the living roots and root hairs of the crops express the toxic chemicals. This is another environmental harm that cannot be eliminated from the genetic engineering process. These threats to beneficial insects and likely to other wildlife as well should be taken into consideration when deciding whether genetic engineering is worth the risk.

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61 Bergelson, *supra* note 36.

62 ORGANIC CONSUMERS ASS'N FACT SHEET, *supra* note 3, at 5.

63 GREENPEACE FAQ, *supra* note 4.

64 *See* U.S. NAT'L ACAD. SCI. REPORT ON BIOTECH FOODS 72, 129 (2000) (discussing the toxicity of genetically engineered plants and foods); Spitzer, *supra* note 1, at 5.

65 J.E. Losey et al., *Transgenic Pollen Harms Monarch Larvae* 399 NATURE 214 (1999).

66 Spitzer, *supra* note 1 (quoting *Cotton used in medicine poses threat: genetically altered cotton may not be safe*, BANGKOK POST, Nov. 17, 1997).

67 *See id.* (quoting A. Hilbeck et al., *Effects of transgenic BT corn fed prey on mortality and dev. time of immature Chrysoperla carnea*, 27 ENVTL. ENTOMOLOGY, 480, 480-96 (1998)).

3. Issues in Food Security

In addition to questions about human and environmental health and safety, the genetic engineering of the food supply also presents unique issues and risks to food security. In the simplest terms, a small number of corporations are taking legal and physical control over the world's food supply, thereby decreasing biodiversity while working within systems of food ownership at the genetic level. The issues of patents on living organisms, ag-biotech monopolies, and the creation of monocultures all raise serious questions about the soundness of genetically engineering the world's food supply.

a. Patents

Corporations like Monsanto are able to genetically engineer a particular seed with a foreign trait and then patent that seed.[68] The Monsanto Corporation can then dictate the terms of use of their patented product. Some corporations holding patents on seeds and crops have required farmers to sign legal documents compelling them to grow only that company's seed, use only that company's chemicals, and pay "technology fees" for the genetically engineered seeds in addition to the cost of the seeds themselves.[69] The availability of patent protection for these products increases the interest of investors, as patents help to ensure profits as long as farmers agree to plant the genetically engineered crops and consumers agree to buy the food. The role of patents in genetically engineered food and crops raise many issues that cannot possibly be addressed here, but are important nonetheless.

b. Monopolies

Food security is further threatened by the fact that a smaller and smaller number of huge corporations are taking control of the ownership of the food supply. For example, last year, a single company, Empresas La Moderna, owned twenty five percent of the world seed market.[70] Companies and divisions like Aventis CropScience, Dow Agro Science and Monsanto, all with millions of dollars invested in ag-biotechnology, have taken control of the

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[68] Calgene, the corporation that produced the FLAVR SAVR tomato, received a patent for its tomato in 1990. TEITEL & WILSON, *supra* note 11, at 41. Since then US patent law has protected virtually all genetically engineered food. Patents on living organisms were made legally possible in the United States by a 1980 Supreme Court decision. *See* Diamond v. Chakrabarty 447 U.S. 303 (1980).

[69] TEITEL AND WILSON, *supra* note 11, at 76.

[70] *See id.* at 42.

agricultural biotech market. These gigantic monopolies threaten to squeeze out the voices of farmers and consumers in the debate about genetically engineered food and will clearly use all their power to protect their financial interests in the technology. Relying on a handful of self-interested corporations to make important and far-reaching decisions about agriculture and food cannot possibly result in equitable policies, because genetic engineering threatens even the small organic farmer with risks of genetic drift and genetic pollution.

c. Monocultures

One final issue in food security is the encouragement of monocultures, which is a by-product of the current ag-biotech system. The large ag-biotech companies invest money in research until they have created a promising strain of a particular crop. They then patent that strain, replicate it, and mass-produce it. Farmers can buy the genetically engineered seed and plant endless rows of genetically identical crops, all containing the foreign gene. History and science show that plants need diversity to survive, one devastating example of that fact was the 1845 Irish Potato Famine. The creation of monocultures by ag-biotech companies, leaves no room for natural diversity. If a genetically engineered crop is susceptible to a new virus, the whole crop will be destroyed since there will be very little chance that some of the crop may have a particular mutation to protect it from the virus.

These three threats to food security offer warnings to consumers. Agriculture is moving in a new direction—following the path of profits and genetic reductionism—in an attempt to provide corporations with complete control of the food system. Even if the safety of genetically engineered food were to be proven at some point, these issues in food security must still be considered and addressed.

This overview of the risks to human and environmental health and safety posed by the genetic engineering of food and crops suggests several points. First, consumers and advocacy organizations working on this issue have valid concerns that are supported by evidence. Second, the genetic engineering of food and crops is a transformative technology that affects many different sectors of society. It raises complex issues for farmers, consumers, food producers, food packagers, parents, stockholders, legislators, and others. The questions it raises and risks it presents will not be remedied with a quick and easy solution; any solution will require considering the perspectives of all interested parties as well as considering their rights and responsibilities. Finally, and most importantly, the opponents of genetically engineered food and crops raise concerns about potentially serious human and environmental health threats. Many of the concerns are based on the fact that the science creates unknown and unknowable results. With the current level of understanding in the field of genetics, it may be impossible to predict the outcome of the genetic engineering experiment. The question must then be asked: when does the risk created by the unknowns become unacceptable? The evidence, as it currently exists, suggests that perhaps we have surpassed the level of acceptable risk.

B. The Industry Responds

In response to the claims raised by the opponents of GE food and crops, the proponents raise their own issues, mostly focused on discussions about the potential benefits of the technology. Very briefly, this section will consider three common claims by industry.[71] Though these three points may sound reasonable on the surface, a quick look at the evidence suggests that even the supposed benefits of GE technology are not certain.

1. GE is a Natural Extension of Traditional Breeding Methods

The claim that genetic engineering is a natural extension of traditional breeding methods arises in nearly any debate or discussion about genetically engineered food and crops. Proponents argue that farmers and scientists have been selectively breeding plants to have certain specific traits and characteristics for hundreds of years and that genetic engineering just allows that natural method to be taken to the next level. The argument implies that opponents of genetic engineering are being driven by unfounded fear and ignorance.

This argument is clearly hollow and misleading. Every one of the points addressed above provide examples of the difference between the genetic engineering of crops and food and traditional breeding methods. The presence of marker genes and powerful promoters, the insertion of genes from other species and even kingdoms into plants that could never occur in nature, and even the technology

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[71] *See* A CAUTIONARY APPROACH, *supra* note 47. ("According to its developers, the technology of genetic engineering was created to improve food production, reduce the use of pesticides and herbicides, and increase yields to feed our growing world. ... Supporters assert that genetic engineering is a natural extension of traditional crossbreeding...").

itself all provide evidence that genetic engineering is not the same as traditional breeding. Traditional breeding methods take advantage of selective breeding techniques to cross-pollinate plants to produce hybrids and different characteristics. The selective sexual and asexual reproduction used by traditional breeding methods maintains some level of shared evolutionary history.[72] This evolutionary history allows traditional breeding practices to make changes in nature, while maintaining natural species boundaries that help protect against random unpredictability. Genetic engineering represents a radical departure from this practice.[73] This radical departure creates the new risks and concerns discussed above, which are not by-products of traditional breeding practices.

2. *Genetic Engineering is Actually Good for Humans and the Environment*

Another common claim is that genetic engineering of crops is actually good for humans and the environment, because it allows farmers to spray less of the toxic chemicals required to foil pests and weeds. The majority of genetically engineered crops are modified to be either herbicide tolerant or to produce their own pesticides.[74] Opponents argue that if a plant produces its own pesticide, then farmers don't have to spray pesticides on the plants, which reduces the presence of harmful toxic pesticides in the environment. Again, though this argument appears strong, these benefits are not as clear-cut as they may appear on the surface.

Plants that are genetically engineered for pesticide resistance may still need the application of pesticides. Even when farmers plant crops that produce their own *B.t.*, for example, they will still need to spray their fields to control other insects resistant to *B.t.*[75] Moreover, plants that are resistant to herbicides allow farmers to spray even more chemicals on the plants since they are not concerned about the chemicals killing their crop as they would with non-genetically engineered varieties.[76] These facts, combined with the risks listed above as well as the fact that the widespread use of genetically

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[72] *See Weird Science*, *supra* note 36, at 4.

[73] *See* COUNCIL FOR RESPONSIBLE GENETICS, FAQ ABOUT GE FOOD, *at* http://www.gene-watch.org/programs/FAQ-Food.html (last modified Summer 2000).

[74] *See* GREENPEACE FAQ, *supra* note 4.

[75] *See* Coghlan & Fox, *supra* note 23.

[76] A CAUTIONARY APPROACH, *supra* note 47. ("Some scientists estimate that not only will herbicide use triple as a result of herbicide resistant crops, but will ultimately give rise to herbicide resistant weeds as well.").

engineered *B.t.* crops is threatening the organic farming industry, reveals that the use of genetics to control weeds and pests in this situation may not be as beneficial as touted.

3. Genetic Engineering Will End World Hunger

One final argument made by proponents of genetic engineering to note is that genetic engineering of food and crops will end world hunger and allow scientists to make good food even better. This resulted from negative publicity in Europe which forced the biotech industry to work on its image. As with the publicity surrounding the first Green Revolution in the 1970's, the biotech industry found comfort in presenting itself as a beneficial and life-saving presence. News from the biotech industry has recently focused on the production of rice fortified with vitamin A, the so-called "Golden Rice." The industry claims that golden rice will reduce diseases and deaths in developing countries associated with a lack of vitamin A in the diet, and its production has been used to try to prove the acceptability of genetic engineering.[77]

Though providing more food and more nutritious food are both noble benefits, even these benefits have raised hackles among the opponents of genetically engineered food, with good reason. First, problems of world-wide hunger are not due to lack of food. Experts accept as an established fact that enough food exists to feed the world population, and that issues of hunger are due to access, distribution, and sustainability of practices. Hunger is a huge social problem, prevalent not just in developing countries but throughout the industrialized world. The quick-fix claim of the biotech industry is hard to challenge since it is a worthwhile goal, but the reality of the situation makes it clear that genetically engineering crops will not cure the world of hunger. According to Dr. Mellon of the Union of Concerned Scientists, "There are 10 simple steps we could take right now to feed a billion hungry people, from building roads, to distributing iron tablets, to encouraging people to grow gourds in their back yards."[78]

In the same vein, the creation of fortified foods through the use of genetic engineering technology is another example of a quick techno-fix to a larger, more complex problem. Opponents of genetic engineering have questioned the effectiveness of the technology

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[77] *See* Michela Wrong, *Field of Dreams*, FIN. TIMES, Feb. 25, 2000, *available at* http://www.genepeace.ch/new/fields_of_dreams.htm.

[78] *Id.*

associated with the production of the Golden Rice, proving that products fortified with vitamin A through GE will not end vitamin A deficiencies.[79] Deficiency of a single micro-nutrient like vitamin A seldom occurs in isolation but is one aspect of a larger context of deprivation and multiple nutrient deficiencies.[80] In addition, the same issues of distribution and access remain with genetically engineered rice as with non-GE rice—the obstacles of access and distribution must still be overcome to get the rice to those who need it. The use of this technology in this manner provides good publicity for the industry, but it may not be able to fulfill its promises. Both of these arguments present a narrow and limiting view of a very major social problem.[81]

These are just three of the main arguments used in favor of the agricultural-biotechnology industry. Though they present a good face, each has serious flaws in reasoning and perspective that reduce the credibility of the arguments.

The arguments outlined in this section provide a glimpse of the picture behind the controversy surrounding genetically engineered food and crops. Opponents are worried about the safety of the products for humans and the environment, while proponents see potential benefits and profits as well as unjustifiable worries. Part of the problem is clearly the current limit of scientific knowledge. Both sides of the controversy can find scientific evidence that supports their view and seems to refute that of their opponents. The full results of this experiment with the food supply cannot be predicted, so the real question becomes how much risk is too much and who gets to draw that line. In these situations, when industry presents consumers with products that may not be safe, consumers can usually look to government regulatory agencies to protect their health and safety, but in this situation, even the government is having difficulty setting limits for this new technology.

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[79] *See* Craig Holdrege & Steve Talbott, *Golden Genes and World Hunger: Let them Eat Transgenic Rice?*, 108 NETFUTURE (July 6, 2000), *at* www.oreilly.com/people/staff/stevet/netfuture/2000/jul0600_108.html#2.

[80] GENETIC RES. ACTION INT'L, ENG'G SOLUTIONS TO MALNUTRITION, *at* http://www.grain.org/publications/reports/malnutrition.htm (Mar. 2000).

[81] There are many interesting commentaries on the Golden Rice issue in addition to the mainstream reports on the potential benefits of the technology. These commentaries also illustrate some of the complexities of the corporatization of agriculture and the role of patents which are relevant and interesting. *See generally id.*; *Golden Rice and the Trojan Trade Reps: A Case Study in the Pub. Sector's Mismanagement of Intellectual Prop.*, RAFI COMMUNIQUE (Sept./Oct. 2000), *at* http://www.rafi.org.

IV. THE REGULATORY STRUCTURE IN THE UNITED STATES

The development and widespread use of genetic engineering in agriculture presents a situation in which the unpredictability of the science, coupled with inconclusive scientific evidence, puts everyone at a disadvantage. Genetic engineering is a technology that has transformed, and will continue to transform, the relationships between and among humans and the natural world. For the most part, it is impossible to even begin to predict the full implications of the power to successfully (or unsuccessfully, as the case may be) tinker with the genetic make-up of living organisms. When transformative technologies are introduced into society, there will be a lag time between their introduction and their proper control and regulation. People, organizations, and agencies need time to understand the technology and comprehend its full range of possible effects before knowing how to regulate it most effectively to support its benefits and minimize its harmful effects. At this stage in the development of genetically engineered food and crops, the government has not made an effort to appropriately regulate the technology. Instead, it has merely taken existing laws and stretched them beyond their original intents in an attempt to regulate this new technology. The result is that the public is not adequately protected from the potential risks to human and environmental health and safety.

A. The Current Regulatory Structure

Genetically engineered food and crops are regulated through a patchwork of laws spanning three governmental agencies—the Food and Drug Administration ("FDA"), the Environmental Protection Agency ("EPA"), and the United States Department of Agriculture ("USDA").[82] A brief look at how these agencies have divvied up regulatory control of genetic engineering in agriculture illustrates both the continuing complexity of this issue and the inadequacy of the current regulatory structure. Though this discussion is far from comprehensive, even this brief overview reveals many of the flaws of the current system.

1. The Food and Drug Administration and GE Food

Food products containing genetically modified ingredients fall

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[82] Bette Hileman, *Biotech Regulation Under Attack*, CHEMICAL AND ENG'G NEWS, May 22, 2000, at 28 [hereinafter Hileman].

under the regulatory umbrella of the Food and Drug Administration. The FDA has primary responsibility for regulating food additives and new foods other than meat products under the authority of the Federal Food, Drug, and Cosmetic Act ("FDCA").[83] The FDCA gives the FDA the power to remove unsafe foods from the marketplace and make producers legally responsible for the safety of the foods they market. The FDA can also require pre-market approval of food additives, unless they are generally recognized as safe. The FDA can exercise these powers over "adulterated" food, which is defined as food that contains an added substance unless either: a) the FDA has approved the safety of the substance by issuing a specific food additive regulation, or b) the substance is generally recognized as safe.[84] Under these regulations, the FDA is able to protect consumers by requiring manufacturers to provide scientific evidence to support the safety of adulterated food.

In 1992, the FDA decided that the majority of genetically engineered food (foods derived from new plant varieties produced by genetic engineering) would not be regulated as adulterated food.[85] Consequently, manufacturers are not required to earn FDA approval for foods produced with genetically engineered ingredients, except under special circumstances when food safety questions exist sufficient to warrant formal pre-market review.[86] Instead, the FDA established an advisory process, whereby manufacturers consult with the agency about the human health risks of their products.[87] Until recently, this consultation process was voluntary.[88] Therefore, although the FDA could require safety testing of all genetically engineered food, they choose not to. In fact, the regulations of 1992 specifically exempt these experimental foods from the FDA's power to regulate food additives even though, as is clear from the

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[83] Pub. L. No. 75-717, 52 Stat.1040 (1938) (codified as amended at 21 U.S.C. §§ 301-93 (1994)).

[84] *See Food and Drug Admin. Pub. Hearing on Genetically Engineered Foods* 3 (Nov. 30, 1999) (statement of Rebecca Goldburg, Env'l Defense Fund) *at* http://www.edf.org/pubs/Filings/FDAhearing1199.htm [hereinafter, Goldburg statement]; Glenda D. Webber, *Regulation of Genetically Engineered Organisms and Products* 4, *at* http://www.aphis.usda.gov. [hereinafter Webber].

[85] *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22984 (May 29, 1992).

[86] A specific safety question would be raised if the genetically engineered food contained genes from a known allergen, like a peanut protein. *Id.; see, e.g., id.* at 22986-88. *See also* Goldburg statement, *supra* note 84; Webber, *supra* note 84.

[87] *See* Hileman, *supra* note 82, at 28.

[88] *See id. See also* Philip Brasher, *FDA Issues New Biotech Foods Rules*, The Associated Press (Jan. 17, 2001), *at* http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm.

discussions above, genetic engineering is used to *add* some foreign element to the plant. Manufacturers are consequently free to use genetically engineered products in food and need not guarantee the safety of the foods they market.

In addition, the FDA has not used its power under the FDCA to require labeling of all genetically engineered foods. Producers of food are required to describe the product by its common name and to reveal all important facts associated with claims made or suggested on the label, but currently, the fact that a food product contains genetically engineered ingredients has not been determined to meet the labeling standard.[89]

The FDA believes that genetically engineered foods are "substantially equivalent" to non-GE foods and therefore does not give them special scrutiny.[90] Opponents of genetically engineered food, who recognize the threats to human and environmental health discussed in the previous section, and those familiar with the basic technology of genetic engineering, can see that, in fact, genetically engineered foods are different. By tinkering with the genetic material of plants and attempting to control traits and characteristics with unpredictable science, scientists have created new risks and concerns with genetically engineered foods. These new risks require closer regulation than non-adulterated foods.

2. The Environmental Protection Agency

The Environmental Protection Agency also plays a role in the regulatory structure of genetically modified crops and food. The EPA regulates pesticides according to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), under which they are responsible for regulating the distribution, sale, use and testing of pesticides to protect humans and the environment .[91] Genetic engineering is often used to insert genes for pesticide resistance into plants, and the EPA is responsible for regulating the pesticides produced by these genetically engineered plants.[92] As part of the patchwork of regulation of genetically engineered food and crops, the EPA regulates the pesticide, but not the plant. For example, in the case of corn genetically engineered to produce *B.t.*, the EPA

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89 *See* Webber, *supra* note 84, at 2.

90 *See* Hileman, *supra* note 82, at 29.

91 *See id.* at 28.

92 *See* Rep. Dennis J. Kucinich, *Genetically Engineered Food*, Kucinich Action Center, http://www.house.gov/kucinich/action/gef_statement.htm [hereinafter Kucinich] (last visited Feb. 13, 2001).

regulates the *B.t.* toxin, but the USDA regulates the actual genetically engineered corn.[93] The EPA does not subject plants that are engineered with traits other than pesticide resistance, such as herbicide tolerance, to environmental review.[94]

Under FIFRA and other EPA regulations, developers of plants genetically engineered to produce pesticides must submit raw health and safety test data to the EPA. The test data is publicly available during a thirty-day notice and comment period before the crop is approved.[95] Though this system does force developers to provide some safety data (which is more than is required by the FDA), the EPA has not done a comprehensive environmental review of the health and safety implications of genetically engineered *B.t.* crops.[96] As higher acreages of genetically engineered crops are being planted across the United States, the risks to environmental health are going unmonitored. The long-term effects of releasing genetically modified plants into the wild environment should be evaluated.

3. *The United States Department of Agriculture*

The final part of the United States' regulatory web is the Department of Agriculture. The USDA regulates genetically engineered plant products under the Federal Plant Pest Act, which is administered by the Animal and Plant Health Inspection Service ("APHIS").[97] APHIS administers a permit system whereby companies, academic institutions or scientists who want to move or field test genetically engineered plants must obtain the proper permits. APHIS must also complete an environmental assessment of the possible environmental impacts of the field test under the National Environmental Policy Act ("NEPA"). Once the genetically engineered crop is ready for commercial sale, the developers must petition the USDA for an exemption from the Plant Pest Act. Developers receive permits certifying that the genetically engineered plant is not a pest, and therefore is not in need of further regulation.[98]

As with the other governmental agencies, the USDA seems to

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[93] *See id.*

[94] *See id.*

[95] *See* Hileman, *supra* note 82.

[96] *See* Kucinich, *supra* note 92, at 6.

[97] *See* Glenda D. Webber, *Regulation of Genetically Engineered Organisms and Products*, Biotechnology Info. Series, *at* http://www.aphis.usda.gov/bbep/bp/overview/html (last visited Mar. 21, 2001).

[98] *See* Hileman, *supra* note 82, at 28.

begin with the assumption that genetically modified plants, ready for commercial sale are not worthy of special attention. Even with a NEPA assessment, the USDA could certify a genetically modified plant that harms the environment as long as it also produces benefits.[99]

This jumble of laws makes up the current regulatory framework for ensuring environmental and human health and safety. Though such a system might be adequate for a non-transformative, predictable technology, it is inadequate in light of the risks and concerns raised by the widespread cultivation and consumption of genetically engineered crops and food. Federal agencies are not demanding safety testing—instead, the agencies seem to be assuming that these products pose no risk and thus do not require close regulation. All of these laws and regulations have been applied ad hoc to the new technology, and consequently, the laws cannot possibly address the full range of genetic engineering's possible effects. It is clear that the interests of the corporations and the producers have been put ahead of the safety concerns of consumers.

The most appalling aspect of the regulatory structure is that the agencies involved have the legal power to take more of an interest in the regulation of genetically engineered food and crops but have made conscious decisions not to. For example, the FDA under FDCA could, using logical reasoning, say that foods that have genes added to them through genetic engineering are foods with additives, subject to the adulterated food regulations. This would place the burden on industry to provide scientific evidence of the safety of the substances added to genetically engineered foods. This standard would treat genetically engineered foods to the same regulation as other foods with additives instead of exempting them, which is the current FDA practice.

In addition, the level of scientific understanding in this field is low. Unpredictable results and effects are part of the genetic engineering process. In light of these facts, the regulatory structure should provide a cautious approach to the environmental release and human consumption of genetically engineered products. If at some future point industry is able to prove the safety of these products, then the current lax attitude of the regulators may be justified. Until that time, genetically engineered food and crops should be regulated and evaluated under standards reflective of their true nature as potentially hazardous experiments. The current system does not go

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99 *See id.*

far enough to protect consumers from the possible risks of the technology.

V. WHAT SHOULD BE DONE?

The preceding sections of this article illustrate the challenging position in which we now find ourselves. As a society, we are faced with a new technology that provides humans with some level of genetic control over plants and animals. It is impossible to predict what the full impacts of this technology will be. However, evidence exists to suggest that the radical procedures used to transfer DNA between and among species and even kingdoms are cause for concern. Opponents of genetic engineering have found warning signs of danger to the environment and human health in experiments with genetically engineered food and crops. These concerns are not being addressed by industry, which continues to state, despite evidence to the contrary, that these new techniques are not different than traditional breeding methods and that no new risks are being created. In addition, industry responds to concerns by saying that no definitive evidence exists proving that these products are not safe, shifting the burden of proving safety to the consumer. On top of all this is the inadequate regulatory structure, which fails to require safety testing and works under the assumption that there is no cause for concern. As a result, the genetic engineering debate has become more than an intellectual exercise, it has become a crisis situation.

At a minimum, the scientific evidence about the safety and risks of genetically engineered foods are inconclusive. Even so, the government and the industry are not proceeding with caution. Instead, the genetically engineered food experiment is being pushed more and more aggressively. This is a mistake. There is much to be lost if this experiment fails and little to be gained if it succeeds. In such a situation, care must be taken to ensure that even in a worst-case scenario, harm will be minimized.

The fact is that someone needs to carry the burden of proving the safety of these technologies. Inconclusive scientific evidence and controversial risks and benefits do not excuse this responsibility. This burden should not fall on consumers but should be firmly with the industry and the government. It is the industry that is creating the risks and reaping the financial benefits, and therefore, it is the industry that should satisfy the demands of the consumers. In addition, until such time as the industry proves that their products are safe, consumers should not be made unknowing guinea pigs in the experiment. There should be a moratorium on the sale of genetically engineered food and crops until the questions raised by the technology are satisfactorily answered. As this article has shown, consumers' concerns about the consumption of genetically engineered food and the release of genetically engineered crops into the environment are based in fact, not fear or ignorance. A moratorium would effectively remove the risks associated with genetic engineering in agriculture and allow the technology to develop only once consumer safety is made a priority.

VI. CONCLUSION

So, why all the fuss about genetically engineered foods? For-profit companies, making decisions based on profit margins and available markets, are tampering with the food supply in unknowable and unpredictable ways. These tampered products are not differentiated on supermarket shelves so consumers have no say in whether they participate in this experiment or not. Evidence exists to suggest that these products may have serious implications—for the environment and for human health. To top it all off, the usual mechanisms for protecting consumers—namely governmental regulations and advocacy organizations—have not had the chance to develop appropriate measures for evaluating this new technology. Until such time as the legal, regulatory, and ethical structures are put in place to more adequately deal with the implications of genetically engineered food, these risks should be borne not by consumers but by industry.