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Title: Ethical Considerations of Transgenic Biotechnology as a Tool to Address Global Food Insecurity: Implementation and Regulation in Developing Countries

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Transgenic biotechnology holds enormous potential as a tool to address global food insecurity. Transgenic food crops have been shown to increase food availability and food system security by incorporating disease, pesticide and drought resistance. Production costs of transgenic crops are lower due to the reduced need for costly pesticides and manual tillage, leaving more disposable income for farmers to buy food. Biofortified and nutritionally enriched transgenic crops may be able to reduce vitamin and micronutrient deficiencies. Despite the many promising applications of transgenic food crops in developing countries, many governments have raised major objections to the utilization of transgenic food production and have resisted transgenic crop adoption. The majority of these objections appear to be rooted in societal values, economics related to trade, and ethical principles, not biophysical science. My analysis of the current regulatory system suggests that ethical considerations regarding transgenic food crops are best addressed as part of local regulations rather than incorporated in global trade restrictions. I argue that while there is no silver bullet for solving world hunger, the utilization and responsible regulation of biotechnology could meaningfully contribute its reduction.

Key words: Transgenic biotechnology, food security, world hunger

Ethical Considerations of Transgenic Biotechnology as a Tool to Address Global Food Insecurity: Implementation and Regulation in Developing Countries

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I understand that my thesis will become part of the collection of Oregon State University, University Honors College. My signature below authorizes release of my thesis to any reader upon request. I also affirm that the work represented in this thesis is my own work.

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PROLOGUE

I was first introduced to biotechnology as a high school student in AP biology. Fantastical stories of fluorescing plants, Franken-salmon and big, scary biotech corporations willing to beat down any farmer in their paths sparked an interest that would follow me through my career as an undergraduate in biology at Oregon State University. I got in touch with Dr. Steve Strauss, a distinguished professor in the College of Forestry who has championed much research in the area of forestry biotechnology and soon my initial interest transformed into a University Honor's College and International Degree thesis. It quickly became evident, in my research for writing my undergraduate thesis, through biology coursework and in doing research with transgenic poplar plants in Dr. Strauss' laboratory, that policy and regulation of genetically modified organisms were some of the biggest inhibitors of biotechnological progress. The controversy surrounding biotechnology, including safety concerns, questions about labeling and ethical and socioeconomic considerations, was endless. If one thing was clear, it was that people are passionate about their food. From coined phrases identifying "frankenfoods" to bioterrorist attacks on genetically modified crops, controversy and opposition has plagued the GMO past and continues to greatly influence its future. Despite resistance to GM food, it has been widely adopted and continues to impact the agricultural landscape, including in developing nations that have adopted it. A great need for effective policies and regulations has presented itself at the local, state, national and global levels of government. After graduation, I plan on attending law school and continuing my work in the field of biotechnology as an intellectual property or patent attorney. It is also my goal to work on regulations and policies that will bring biotechnology to developing nations as one response to food insecurity. In my heart, I am all about feeding hungry people.

CHAPTER 1 INTRODUCTION

1.1 The Global Food Situation

In the most recent Statistical Yearbook on Food and Agriculture published by the United Nations, (UN) 867 million people were reported as chronically undernourished.[1] This means that 1 in 8 people around the globe are calorie-deficient because they are not getting enough food or because the food that they are consuming does not provide enough nourishment. Eradicating extreme global hunger and poverty is one the major goals of the UN Millennium Development Project.[2] Access to food is a basic human right that is currently under violation in many parts of the world. Both governmental and non-governmental organizations have dedicated humanitarian efforts to address global food insecurity.

As a global community, we can respond through the development of technology as well as through policies regarding agricultural production. Although some argue that there is more than enough food being produced to feed the world population and the problem lies in food distribution, the political and economic overhaul that would be needed for redistribution would be an enormous challenge even in well developed, socialized countries. Furthermore, the world population is expected to reach 9 billion by 2050 and it has been suggested that to feed an additional 2 billion people, food production will have to be doubled by 2050.[3] Thus the potential of biotechnology should be considered in addressing food insecurity.

The four aspects of food security include: access to food, utilization of food, food availability, and food system stability. The rapidly changing socio-economic and environmental conditions such as those caused by population growth, increased resource consumption, and climate changes are likely to affect every

[1] "FAO Statistical Yearbook" FAO, 2013
[2] Ruane and Sonnino, 2011
[3] Braun, 2010

aspect of food security, especially in developing nations. Transgenic biotechnology, which has already been employed in a number of developing and developed nations, may improve food security by providing pest, herbicide, and disease resistance, tolerance to drought and flooding, and biofortification. Its full implementation in developing countries, however, has been strongly resisted by countries that have adopted an approach to transgenic regulation modeled upon that of the EU. In addition, these countries often fear that trade with the EU and aligned countries would be negatively impacted by market perception or actual GMO admixture.

1.2 What is Biotechnology?

There are a very wide range of biotechnologies, from traditional plant breeding to culturing of cells in artificial media to genomic sequencing. This thesis focuses on transgenic biotechnology, or the asexual modification or insertion of DNA into a host genome. As a result, novel phenotypes arise that can change the amount and type of protein, the building block of life that is produced in an organism. Transgenic biotechnology is just one type of biotechnology and the only type of broad concern.

What sets all the forms of transgenic biotechnology from other kinds of biotechnology is the use of *in vitro*, chemical isolation, modification, and asexual insertion of DNA (i.e., recombinant DNA technology). Target sequences are identified with an associated use, isolated using restriction enzymes, amplified using PCR, separated using gel electrophoresis and cloned into a construct that can be delivered to the host genome asexually. Delivery methods can include using a vector such as Agrobacterium or using an injection system such as a gene gun. Antibiotic resistance is often cloned into constructs while the organism is grown on an antibiotic to select for successful transgenic events. Site-specific mutagenesis is used to try and direct where the target gene will be inserted into a host genome, but there remains a lack of control over where genes are inserted in most ongoing research and application. Mutagenesis mechanisms commonly include zinc finger nucleases, but there is a growing list of options. There are also synthetic means of creating and recombining nucleic acid to produce phenotypic changes.

The changes produced with transgenic biotechnology can range from virtually undetectable in plants that produce their own insecticide toxin to major phenotypic changes such as in the case of transgenic salmon that grow twice as fast as their natural hatched counterparts under intensive aquaculture conditions.

1.3 The History

In a strict sense, biotechnology has been around since the dawn of the domestication of plants and animals. Humans have produced hundreds of breeds of dogs, tomatoes many times larger than their native relatives, and sweet yellow ears of corn that look nothing like the brown, bitter maize originally found in Central America – and all using conventional or pre-conventional breeding techniques. This artificial selection of desirable traits has resulted in new varieties of plants and animals, many of which are poorly fit to survive in their natural habitat without cultivation. Even before Mendelian genetics were fully understood, people knew, in an informal sense, how to use phenotypic variation and heredity to select for desired traits. This is known as artificial selection and it is one form of biotechnology.

As the understanding of genetics grew, so did the potential for biotechnology. Artificial selection, requiring many generations of crossing the selected individuals, relies on naturally occurring variation as well as new mutations to arise organically which is untargeted and often difficult to predict. It is also limited to selecting traits from within breeding species. Transgenic biotechnology, on the other hand, allows for the sharing of genes across species that cannot interbreed and the creation of new kinds of genes. Since transgenic biotechnology requires knowledge of where and how a gene is expressed in a genome, it can be highly targeted and fairly accurately predicted. GM methods sidestep the wait time needed for new mutations to arise naturally and become a prominent target of selection. Recombination among genetic variations further expands the diversity provided by new and existing mutated genes and thus of associated phenotypes.

The first published use of recombinant nucleic acid (DNA and RNA) technology is credited to Nobel Laureate Paul Berg, who in 1972 successfully inserted an *E. coli* operon and lambda phage genes into the genome of the SV40 virus found in monkeys.[4] A year later, the first GMO was produced when Stanley Cohen and Annie Chang successfully conferred antibiotic resistance to the plasmid of *E. coli*.[5] Later, in 1977, Marc Van Montagu and Jozef Schell discovered the horizontal gene transfer ability of Agrobacteruim and its potential as a gene delivery mechanism in plants.[6] Occurring naturally, Agrobacterium infects plants using a DNA-transferring plasmid (T-plasmid) that produces tumors. The virulent T-plasmid can be disarmed of its tumor inducing genes, and genetically engineered to insert novel genes into the genome of plants.

The Asilomar Conference on Recombinant DNA molecules was organized by Paul Berg in 1975 to address the biohazards of recombinant products to workers in laboratories, the general public, animals and plants.[7] The participants of the conference recognized the potential risks presented with the introduction of transgenic organisms into the environment and took it upon themselves to create guidelines to minimize these risks. At the time, there was no legislation in the US prompting them to create recommendations for the research and containment of transgenic organisms. One of the major outcomes of the conference was a paradigm for dealing with the regulation of new scientific discoveries. The conclusions from the conference guided subsequent research and stimulated public debate about the social, regulatory and environmental issues surround recombinant DNA technologies.

Of the transformed crops, the most common modification is for herbicide resistance. "Roundup Ready" soy beans were first commercialized in 1996 by Monsanto, followed by alfalfa, corn, cotton, canola, and

[4] Berg, 1972
[5] Chang and Cohen, 1973
[6] Van Montagu and Schell, 1977
[7] Berg, 1975

sugarbeets.[8] The Roundup technology provides crops with herbicidal glyphosate resistance that is not present in conventional varieties and weeds. The herbicide Roundup can therefore be applied to Roundup Ready crops to control weeds and reduce tillage without damaging the actively growing plants.

Insect resistance is the other most common form of GMO crops. Crops carrying the *Bacillus thuringiensis* (Bt) Cry protein are resistant to the European corn borer. It causes an estimated 1 billion dollars annually in damage and pest control costs in North America alone.[9] When ingested by the corn borer and related species, the Bt cry protein is broken down into smaller proteins by enzymes the alkaline gut. The smaller proteins then attach to receptors on the lining of the intestine that damage the cell walls, eventually killing the insect. The Bt cry protein can only be digested in alkaline conditions, and binds to specific receptors not present beyond the target insects, so is considered highly safe for humans and other animals, especially those with acidic gut environments.[10] Other GM traits found in commercialized food crops include virus resistance, enhanced nutrition, tolerance to environmental stressors, and edible vaccine production. These traits have been shown to increase food production in quantity and quality while decreasing production costs and environmental damages.

The first GMO to be approved by the FDA as safe for human consumption and the environment was the Flavr- Savr tomato in 1992.[11] The Flavr-Savr tomato was genetically modified by reducing the expression of the polygalacturonase (PG) enzyme to suppress the breakdown of naturally occurring pectin. Inhibiting the breakdown of pectin results in pro-longed ripening periods and maintains the flavor and color of the tomato. The Flavr-Savr tomato was intended to prolong shelf life while maintaining desired flavor and

[8] "Roundup Ready System," *Monsanto,* May 2014, http://www.monsanto.com/weedmanagement/pages/roundup-ready-system.aspx
[9] "Bt Corn," *Syngenta,* May 2014, http://www.syngenta.com/global/corporate/en/products-and-innovation/research-and-development/biotechnology/Pages/biotechnology-bt-corn.aspx
[10] "Bt Corn," *Syngenta,* May 2014, http://www.syngenta.com/global/corporate/en/products-and-innovation/research-and-development/biotechnology/Pages/biotechnology-bt-corn.aspx
[11] Wohlers, 2013

color. After review, the FDA concluded that "The intended effect of the altered RNA of the new PG [polygalacturonase] gene that suppresses the breakdown of pectin in Flavr-Savr tomatoes does not raise safety questions. Pectin is a part of many fruits and is a generally recognized as safe (GRAS) substance"[12] The precedent set by the Flavr-Savr Tomato by the FDA and its conclusion about GRAS, significantly influenced the legalization of subsequent GMO foods and food products in the US.

The first release of genetically modified organisms into the environment occurred during field trials of ice-minus bacteria commercially known as Frostban. Ice-minus bacteria are genetically modified varieties of *Pseudomonas syringae* that lack a coat protein. The protein facilitates the formation of ice crystals on the outer bacterial cell wall. Plants treated with the ice-minus bacteria incurred less frost damage. A California company, Advanced Genetic Sciences (AGS), fell under harsh scrutiny in 1986 when it allegedly began field trials in without the approval of the Environmental Protection Agency (EPA) or the House of Representatives subcommittee on genetic research concluded.[13]It was later found that the field trial was in fact contained and they were eventually granted permission to go ahead with true field trials after years of resistance from the protesters led by anti-GMO activist and environmentalist group leader Jeremy Rifkin[14]. BBC News quoted Rifkin saying, "When I first heard that a company in Berkley was planning to release these bacteria Frostban in my community, I literally felt a knife go into me. Here once again, for a buck, science, technology and corporations were going to invade my body with new bacteria that hadn't existed on the planet before. It had already been invaded by smog, by radiation, by toxic chemicals in my food, and I just wasn't going to take it anymore."[15]When approval was finally granted, the fields were attacked by the first GM crop ecovandals. The Ice-minus bacteria were never used commercially for undisclosed reasons from AGS, but the controversy generated from the Ice-minus bacteria field trials and their release into the environment set the stage for future GM crop controversies.

[12]Wohlers, 2013
[13] Palca, 1986
[14] "GM Crops: A bitter harvest?" BBC News, 2002, http://news.bbc.co.uk/2/hi/science/nature/2045286.stm
[15] "GM Crops: A bitter harvest?" BBC News, 2002, http://news.bbc.co.uk/2/hi/science/nature/2045286.stm

1.4 A diversity of concerns over transgenic biotechnology

There are a myriad of concerns over the use of transgenic biotechnology in the environment and food, some based in science and some in religious or ethical systems. As is the case with any induced change in gene expression, whether from GM or not, modified plants could produce new or extant proteins in amounts that have some toxicity for humans or other organisms. . It is for this reason that all foods produced from GM crops are subjected to food safety tests that check for toxicity and potential allergens. In addition to concerns about food safety, environmental impacts need to be assessed when releasing a GM plant into the environment. Included are studies of whether gene flow will have unacceptable effects, and in some cases on whether it is possible to mitigate it. There also exists a wide array of irrational anxiety and distrust rooted in unsound scientific evidence or misconceptions about what a Genetically Modified Organism (GM0) really is. For some, the process of "playing God" by altering otherwise "natural" genetics is inherently wrong and risky. How can we know what the consequences of intervening with nature will bring? How different is transgenic risk from the aggressive modifications undertaken daily, all over the work? Undoubtedly the use of transgenic technology presents a list of valid concerns, but it is critical for debaters to come to the table with a solid understanding of what transgenic biotechnology is and is not so that the most meaningful questions are answered with the most accurate information.

It is estimated that 60-70% of processed foods in America are made using ingredients derived from GMO crops.[16] The US is the largest producer of GM crops in the world.[17] Of its largest GM crops, 85% of corn, 91% of soybeans, and 88% of cotton are genetically modified.[18] The first wave of GM crops was limited

[16] *P. Byrne, "Labeling of genetically engineered foods," Fact Sheet No. 9.371. Food and Nutrition Series, September 2010 (Fort Collins: Colorado State University Extension), http:// www.ext.colostate.edu/pubs/foodnut/09371.pdf*
[17] Davison, 2010
[18] *Center for Food Safety, About Genetically Engineered Foods, 2013 (Washington, DC), http://www.centerforfoodsafety.org/issues/311/ge-foods/about-ge-foods*

to plants that carried resistance to insects and herbicides for agricultural benefits. Now licensing for a GM variety of salmon that grows twice as fast as native varieties is being reviewed by the FDA as the first GM animal to be approved for human consumption.[19] GM crops are also being developed to improve nutritional value and resilience to environmental stressors. GM crops have resulted in higher yields, lower production costs, less pesticide use and more nutritious foods. Although some countries including the US, Brazil, Canada and Argentina have readily adopted the use of GM crops, other countries and several non-governmental organizations (NGOs) have maintained their reservations. The widespread adoption of GM crops presents benefits, but also risks that need to be addressed through regulation. Some of these risks include the potential for allergens and gene flow that may impact weed control and populations of wild relative. Global imports and exports of GM crops render the GM controversy a global issue. The global risks associated with GMOs in the food supply need to be addressed through global regulation, or at least harmonized regulation. In addition to biophysical concerns that are cited in the GM debate, there are a number of non-biophysical concerns that need to be addressed such as socioeconomic and ethical considerations.

[19] Wohlers, 2013

CHAPTER 2 METHODS

2.1 Methods

The findings and conclusions in this paper are based on secondary research. The bulk of research was conducted through the Oregon State University online library databases, Google scholar, and article referrals from experts in ethics and biotechnology. Each article that was used to support one of two major conclusions reached in this thesis; significant articles were incorporated as evidence to support a two part hypothesis. First, that GM crops hold the potential to reduce food insecurity in developing countries, and second, that GM crops should be implemented to improve food security with responsible regulation. Subsequent recommendations for the regulation of biotechnology were also given.

The findings of this paper focus on the major international regulatory frameworks and political organizations dealing with biotechnology including the US, EU, WTO, Cartagena Protocol and NGOs such as Greenpeace and the Nuffield Council on Bioethics with respect to developing nations. The potential of biotechnology as a tool to reduce food insecurity in developing nations was identified and supported using the specific examples of Golden Rice in Asia, Bt cotton in India, Africa and virus resistant papaya. Regulatory agencies, their policies, and how they differ between nations was examined to determine how to best regulate biotechnology in developing nations should it be widely adopted. In forming a conclusion, human health, environmental protection and non-biophysical risks were addressed in determining if biotechnology should be implemented to reduce food insecurity in developing nations and if so, how it should be regulated.

CHAPTER 3 FINDINGS

3.1 Regulation of Biotechnology in the US

Despite its novel characteristics, there are no new laws specific to transgenic crops; biotechnology is regulated by the same government agencies that regulate conventional agriculture. In the US, the regulation of biotechnology is divided between the Environmental Protection Agency, (EPA) the Food and Drug Administration (FDA), and United States Department of Agriculture (USDA). Depending on the characteristics, biotechnology projects may fall into the jurisdiction of one or more of these agencies. This is known as "The Coordinated Framework for Regulation of Biotechnology" which was set up in 1986 and based on the pre-existing public health and environmental policies[20]. It was designed by the Reagan Administration's Office of Science and Technology and Policy (OSTP) to ensure that biotechnology products were safe for the environment and human health.[21]Biotechnology research conducted in laboratories and greenhouses is regulated under the National Institute of Health (NIH) out of its Office for Biotechnology Activities (OBA).

The EPA regulates the sale, distribution and use of pesticides regardless of how they are developed and produced. Of the commercial GM crops grown in the US, one of the most widely adopted GM crops carry insect resistance. These GMOs are referred to as Plant Incorporated Protectants (PIPs). Because they act to prevent, destroy or control pests, PIPs fall into the realm of pesticides. PIPs are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) which examines pesticides to ensure that they are not dangerous to the environment or human health.[22] Roundup Ready crops are an example of an herbicide-resistant crop, although the plant itself is not regulated by EPA because it is not producing its

[20] "How the Federal Government Regulates Biotech Plants," *USDA*, 2013, http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=biotech-plants.xml
[21] "Coordinated Framework for Regulation of Biotechnology," *USDA Office of Science and Technology Policy,* 1986,
[22] "How the Federal Government Regulates Biotech Plants," *USDA*, 2013, http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=biotech-plants.xml

own herbicide. Rather, the new use of Roundup with the GM crop is regulated by EPA. Bt corn is an example of a PIP because the plant actually produces its own insecticide and is therefore considered a pesticide and subject to regulation by the EPA.

The USDA regulates biotechnology under the Animal and Plant Health Inspection Service (APHIS) which was implemented to protect agriculture from potential pests and disease. The USDA does not regulate all GM crops, but only those created using pathogen vectors and containing pathogen-derived DNA sequences. One of the main goals of APHIS is to prevent adverse effects on crop health or endangered species from the release of transgenic genes into the environment via cross breeding with natural or feral populations. Products and organisms developed with the use of pathogen vectors and recombinant DNA are considered potential pest and disease risks. USDA-APHIS names these "regulated articles"[23] and mandates special procedures for the handling, confinement and disposal of such products. Developers can apply for a petition to deregulate GMOs based on a number of biosafety assessments including the potential for plant pest risk; disease and pest susceptibilities; the expression of gene products, new enzymes, or changes to plant metabolism; weediness and impact on sexually compatible plants; agricultural or cultivation practices; effects on non-target organisms; and the potential for gene transfer to other types of organisms.[24] Research field trials fall under the jurisdiction of USDA-APHIS. The USDA also regulates very large field test of PIP plants along with the EPA.

Laboratory and greenhouse research is not regulated by USDA-APHIS as the experimental GMOs are grown in biosecure environments that do not present the same risks of genetic contamination as do field trials. Instead, laboratory and greenhouse research is regulated by the National Institute of Health (NIH) under the Office of Biotechnology Activities (OBA). The HIH/OBA is administered under the US

[23] "How the Federal Government Regulates Biotech Plants," *USDA*, 2013, http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=biotech-plants.xml
[24] "How the Federal Government Regulates Biotech Plants," *USDA*, 2013, http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=biotech-plants.xml

Department of Health and Human Services. Under the NIH guidelines, recombinant and synthetic nucleic acids are defined as:

"(i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above."[25]

The purpose of the NIH guidelines is to detail the appropriate development and handling of recombinant and synthetic nucleic acids. The goal is to protect human health and prevent genetic contamination. Experiments involving recombinant and synthetic nucleic acids that require NIH approval must be reviewed and approved by the NIH or other federal agencies with jurisdiction in order to receiving NIH funding. Federal agencies including the EPA, FDA and USDA may issue research approval in which case the NIH may not require additional review. Institutional Biosafety Committees (IBAs) work under the NIH at the local level to review research involving recombinant and synthetic nucleic acids. Private investigators and investors may also endorse additional research oversights. Institutions receiving NIH funding must comply with all NIH guidelines in all research areas to receive any NIH funding within the institution. Experiments may be de-regulated if they qualify under one of the NIH exceptions. According to the NIH guidelines, "those that do not present a significant risk to health or the environment"[26] as determined by the director of the NIH may be exempt from the guidelines.

The FDA assesses bioengineered foods, as it does for all products intended for human consumption, through specific food safety standards. The FDA holds food manufacturers accountable for the safety of their products under the Federal Food, Drug, and Cosmetic Act of 1938. In 1992, the FDA released its

[25] NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Section I-B
[26] NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Section III-F-8

"Statement of Policy: Foods Derived from New Plant Varieties."[27] The 1992 policy applies to all new plant varieties including those produced using genetic modification and engineering. Under the Federal Food, Drug and Cosmetic Act, the 1992 policy also applies to animal feedstuff. Within the 1992 policy, the FDA concluded that "bioengineered foods do not differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."[28] That is to say that foods produced with genetic engineering are substantially equivalent to their conventionally produced counterparts when considering the method of improvement alone. The food safety standards that apply to conventionally produced plants should therefore apply to GMO products. All food products that are "generally regarded as safe" (GRAS) by the FDA do not require special labeling. The FDA only requires the labeling, and only for the chemical changes of nutritional relevance not of the use of recombinant DNA technology, when they differ significantly in composition, nutritional value or safety from conventional counterparts. It is on account of the 1992 policy that US regulation of GMOs is said to be product-based, though both EPA and USDA do employ process triggers, as discussed above.

Currently, the FDA does not require labeling of GMO-containing food products as is the standard for all products that are "Generally Regarded as Safe" (GRAS). Only foods that differ significantly in nutritional content, contain known allergens or produce toxins above acceptable limits require labeling in the US.[29] In 2001, the FDA put forth guidelines for voluntary labeling of food products, applying to both GM and non-GM food.[30] Within the guidelines, the FDA suggests that manufacturers may wish to label their products to highlight the use or non-use of genetic modification, but that such labels should not be

[27] Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, *FDA,* January 2001
[28] Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, *FDA*, January 2001
[29] *P. Byrne, "Labeling of genetically engineered foods," Fact Sheet No. 9.371. Food and Nutrition Series, September 2010 (Fort Collins: Colorado State University Extension), http:// www.ext.colostate.edu/pubs/foodnut/09371.pdf*
[30] *P. Byrne, "Labeling of genetically engineered foods," Fact Sheet No. 9.371. Food and Nutrition Series, September 2010 (Fort Collins: Colorado State University Extension), http:// www.ext.colostate.edu/pubs/foodnut/09371.pdf*

misbranded. The FDA recommendations caution manufactures against using labels such as “GMO free” or “GM free” because modification is a broad concept and most all food crops have been modified in one way or another. The FDA also trusts that the certified organic labels are sufficient for advertising that a particular food has been produced without the ingredients containing GMOs. Part of the USDA organic certification standard requires that organic foods are not grown with intentional use of GMOs. It does not, however, guarantee that organic foods contain zero levels of GMO content.

Despite the FDA’s conclusion that GMOs are “generally regarded as safe” and do not require special labeling, there are proposals for labeling at the federal, state and local level. Proponents of labeling argue that consumers have a fundamental right to know what is in their food. Some consumers want to avoid GMO-containing foods for religious or ethical reasons having nothing to do with food and environmental safety. Others simply do not trust the science behind the food and environmental safety checks and wish to avoid foods they feel are dangerous. There are also those who feel that the widespread incorporation of GMOs into the food system will have negative and unforeseen consequences in the future that can only be combated by consumers boycotting GM products. Opponents of labeling counter argue that labeling will imply food safety warnings that are not based in sound science and may cause undue concern. They claim that if GM foods exhibit allergenic or substantially different nutritional qualities, that the FDA already requires labeling. Most anti-labeling arguments come back to the extra cost that would be felt by all consumers. They argue that labeling GM food will not result in consumer choice, but rather aversion to buying and eventually by not stocking GMO-containing products as was witnessed in Europe. Moreover, they argue that organic food already offers the choice to avoid GMOs in food.

In addition to personal preference, there are a number of logistical concerns that are associated with GMO labeling. First, a working definition of what constituents a GMO would need to be agreed upon. Generally, organisms are said to be genetically engineered if they contain a gene that was artificially inserted into their genome, but there are some definitions that extend to organisms that have developed

unnatural traits through artificial selection. Additionally, regulators would have to decide if certification should be content or process based. Content-based regulation would require a threshold of GMO content to be established while a processed based approach, like that of the organic certification process, would rely on inputs to be certifiable or not (and might also have a threshold associated with that process contribution). There are existing thresholds in countries that already require labeling that could serve as templates, but it would be necessary for the FDA to establish its own threshold. There is no international level of GMO content that has been deemed non-GMO containing, so the same trade issues that face US exports of GM food now would follow the agricultural industry into a future with labeling. Non-GMO labeled foods in one country could be illegal in other countries in the absence of a universal threshold. The FDA would also need to address whether or not animals fed GM feedstuff could be certified as non-GMO containing. If labeling were to become mandatory, food processing plants would have to rebuild infrastructure to accommodate GM and non-GM foods to ensure that mixing does not occur beyond the set thresholds. Stringent thresholds can make compliance difficult, costly, and economically risky.

3.2 Regulation of Biotechnology in the European Union

In the European Union (EU) GMOs are regulated by the European Food Safety Authority (EFSA) that reports to the European Commission. (EC) Unlike the US and its more or less "product-based" approach, the EU operates under a strict "process-based" approach to regulating GMOs. The EC has adopted the "Precautionary Principle" stating that, "Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."[31] Due to controversy surrounding the interpretation the precautionary principle, the EC later released the "Communication from the Commission on the Precautionary Principle." The Communication specified

[31] "Consolidated Version of the Treaty on the Functioning of the European Union," *Official Journal of the European Union,* Article 191, 2010

that "Whether or not to invoke the Precautionary Principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection"[32] The precautionary principle places the burden of proof that a product is safe for human health and the environment on the producer. GMOs are considered potentially hazardous and continue to be considered so until "proven" otherwise. According to the Communication, in the absence of scientific "certainty" legislators are not legally entitled to authorize the use of GMOs.

Authorized GMOs must pass a stringent safety check by the EFSA and then be approved by the EC before they become legal in the EU. Once legalized, the GMO products must be labeled if any component contains more than 0.9% GMO presence, and there is zero tolerance for GMOs that are not approved.[33] GMOs are considered "new foods being made by a new process"[34] and thus must undergo a case-by-case scientific evaluation of food and environmental impacts by the EFSA. The process of approval can take over 2 years and cost producers so much that only large international biotechnology companies can afford to jump through its hoops.[35]While some may applaud the EU for its iron grip on the legalization of GM crops, many others have accused the European Commission of using unscientific justifications for the prohibition of certain crops as a result of pressure from anti-GMO NGOs.

For foods that pass the EFSA food safety check and are granted approval by the EC, labeling is mandatory above the 0.9% threshold mark. Originally intended to provide freedom of food choice for the consumer, labeling was included in the EC policy on biotechnology. However, the freedom of choice is

[32] "Communication from the Commission on the Precautionary Principle," *Commission of the European Communities*, 2000
[33] Davison, 2010
[34] Davison, 2010
[35] Davison, 2010

only available in a small number of member countries that include Czech Republic, Estonia, the Netherlands and Spain. Most retailers in the remaining member countries refuse to sell GMO products.[36] The decision on the part of a retailer to keep GMO products off the shelves is likely due to pressure and threats of boycotts from NGOs that would damage brands, and in some cases the illusion that foods in need of labeling are potentially unsafe. Since most GMO products are imported from US, Canada, Argentina and Brazil, labeling can result in a price premium for the non-GMO food producers.[37] Thus, GMO producers must bear the costs of labeling and the costs of poor public perceptions on the shelves.

The slow and costly regulatory process of the EC has resulted in the approval of far fewer imported GMO products than are being commercially grown and distributed word-wide, and almost no GMO crops grown at all. This is problematic for a governing body that relies heavily on GM crop imports to feed its population. As the enforcer of the most stringent GMO regulatory system, the EU has struggled to reconcile its dependence on GM crops with the policies of the major GMO cultivators. As a result, international disputes have arisen and forced the global regulators such as the WTO and Cartagena Protocol to address international GMO policy and regulation. Currently, very few African countries have legalized GM crops for fear that adoption of GM crops would negatively affect trade with the EU.

3.3 The potential of biotechnology

Impoverished places such as sub-Saharan Africa and parts of Asia could greatly benefit from the implementation of pest-resistant, biofortified, and disease-resistant crops.

Pest resistant crops could reduce damages due to insects and weeds while decreasing the production cost of chemical herbicides and manual weeding, thus providing more disposable income to farmers. A study on Bt cotton in India examined the how growing and Bt cotton on small farms affected farmers economic

[36] Davison, 2010
[37] Davison, 2010

access to food. The economic effects of Bt cotton on small farmers is of particular importance because about half of all undernourished people world-wide are small farmers and about half of the global GM crop area in planted in developing countries.[38] The results showed a 5% mean calorie increase in consumption in Bt adopting households over non-adapting households.[39] The types of calories being consumed were shown to be higher in protein, indicating that Bt cotton adoption also resulted in access to more nutritious food. It was estimated that the proportion of food-insecure households would drop by 15-20% if all non-adapters were to grow Bt cotton.[40]The results suggested that the adoption of Bt cotton among small farmers in India had positive economic and nutritive effects for farm families.

The poster child of biofortification in developing nations is Golden Rice. Golden Rice has been genetically modified to produce beta carotene, a Vitamin A precursor, in its endosperm, giving it a dark yellow color. Vitamin A deficiency is a condition affecting millions that can result in blindness, chronic health problems and even death. Rice is a staple food in about half of the world's population, lending itself well as a potential delivery method for Vitamin A to populations that need it most. A large proportion of Vitamin A deficient mothers and children live in rice-consuming populations. According to WHO, an estimated 127 million preschool children are affected by vitamin A deficiency, with 250 000–500 000 becoming blind every year, half of whom die within 12 months of losing their sight.[41] While its adoption has been opposed by Greenpeace and the organization's claims that Golden Rice is not effective, organizations such as the Bill and Melinda Gates Foundation and the International Rice Institute are working to realize its full potential in areas where it is needed most. Helen Keller International is a NGO that is independently evaluating Golden Rice. If shown to reduce Vitamin A deficiency in Vitamin A deficient populations and approved by national regulators, it holds the potential to be a major tool to prevent blindness and child mortality.

[38] Kouser and Qaim, 2013
[39] Kouser and Qaim, 2013
[40] Kouser and Qaim, 2013
[41] "Database of vitamin A deficiency," *WHO*, 2014, http://www.who.int/vmnis/vitamina/data/en/index.html

The story of the GM papaya in Hawaii is an example of how GM crops can be used to address disease outbreaks. The ringspot virus is a virulent papaya pathogen that is problematic worldwide and threatened to completely destroy the Hawaiian papaya industry in the 1990's. At the time of the viral outbreak in 1992, there was no effective treatment for the ringspot virus and within five years the production of Hawaiian papaya was cut in half.[42] In anticipation of an outbreak in Hawaii, scientists developed ringspot virus resistant papaya variety using GM technologies. Within the first year that the ringspot virus resistant papaya was released, 98% of Hawaiian papaya farmers registered to receive the transgenic seed, a testament to the effectiveness of the GM papaya against the deadly ringspot virus.[43] Papaya, like Golden Rice, is a source of Vitamin A and primarily produced in the developing world.[44] The ringspot virus continues to threaten papaya crops worldwide. Developing nations could greatly benefit from the adoption of ringspot resistant papaya much in the same way that the papaya industry was saved in Hawaii. Resilience to disease or pest outbreaks would be especially important in countries that rely on one specific crop for export income, such as coffee or citrus exporters. However, such countries are also highly vulnerable to trade disruptions if their trading partners do not accept GMO derived products—making decisions about technology adoption very difficult.

3.4 The Cartagena Protocol and WTO

While there is urgent need for cohesive international regulation of GMOs, implementation of such regulations has presented major challenges to biosafety policy. The Cartagena Protocol on Biosafety (CPB) has been instrumental in influencing the current international regulatory structure, but the absence of major agricultural producers of GM crops, such as the United States and Australia, as participating

[42] Gonsalves et al., 2007
[43] Gonsalves et al., 2007
[44] Gonsalves et al., 2007

parties—and its failure to effectively integrate with existing regulatory groups like the World Trade Organization (WTO)--have greatly weakened the Protocol and its credibility.

As an extension to the Convention on Biological Diversity (CBD), the CPB functions as an international treaty that regulates the safe transportation and use of Living Modified Organisms (LMOs) across national borders in a world that is increasingly dependent on modern biotechnology. As of May 2012, there have been 160 parties that have signed onto the Protocol with the mission:

> "To strengthen global, regional & national action and capacity in ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements."[45]

The CPB focuses on two procedures for introducing LMOs either as food sources or new additions to the environment. The first of these procedures, or the Advanced Informed Agreement (AIA), requires adequate notification by countries seeking to import a LMO to a new region and acceptance by the receiving party based on the risk assessment guidelines outlined by the CPB. The second procedure dealing with the LMOs intended for direct use as food or feed employs the precautionary approach to assess whether or not a LMO will pose significant risks to the environment or public health. Under the precautionary approach, parties may refuse the import of LMOs in the case of insufficient scientific evidence to prove their safety in both the environment and for public health.[46] These regulations aim to ensure that LMOs are safely imported and exported between countries, but proper evaluation of biosafety is essential in enforcing such regulations.

In October of 2010, The Nagoya—Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety "completed" the CPB. The Supplementary Protocol is expected to

[45] "The Cartagena Protocol on Biosafety," *Conventional on Biological Diversity*, 2012
[46] "The Cartagena Protocol on Biosafety," *Conventional on Biological Diversity*, 2012

"strengthen the Cartagena Protocol's objective to provide for the safe transfer, handling and use of LMOs that may have adverse effects on biodiversity by compensating for, and preventing, damage to the environment."[47] Since the Supplementary Protocol places the burden of proof that a LMO has resulted in adverse effects to the biodiversity of a particular party, countries are limited in their abilities to assess and measure the damage done. The CPB utilizes a risk assessment and management program to prevent the trade of potentially harmful LMOs to plant, animal and human health as well as taking into consideration the potential socio-economic losses associated with a particular LMO as tools of evaluation.

Biotechnology undoubtedly holds major potential for reducing food shortages with crops that are faster growing, more resistance to pests and biofortified, but there remains a degree of uncertainty regarding the environmental and health effects that such advancements could have in store. There are varying perspectives and strong beliefs surrounding the GMO debate around the world that has made a global consensus regarding the import and export of GMOs nearly impossible. The appears to be significant tension between the guidelines put forth by the WTO and those proposed by the CPB, but a closer evaluation of both regulatory organizations reveals that a holistic approach by both could lead to mutual reinforcement. The major source of conflict deals with each organization's interpretation of the precautionary approach. While the CPB recognizes the lack of scientific certainty as legitimate grounds for refusing the import of a GM crop, the WTO requires sound scientific evidence that there are adverse effects on the environment or public health. However, it is plausible that "the provisions in the Cartagena Protocol in fact enrich the SPS Agreement by adding details that help operationalize the precautionary principle in the context of LMOs, giving real meaning to the preamble recognition that the trade and environment agreements should be mutually supportive."[48] The relationship between the CPB and WTO is a developing one that will need attention as it grows into the future.

[47] Komen, 2012
[48] Gayathri and Kurup, 2009

The CPB charges party members with the responsibility of developing domestic frameworks of biotechnology regulation that often results in gaps and deficiencies in implementation. High proportions of countries without the necessary means of implementing biosafety policies threaten to prevent the realization of CPB objectives.[49] Additionally, the major producers of GM crops that have not signed onto the CPB including Canada, Argentina, Australia, Russia, and the United States detract from the legitimacy and effectiveness of the CPB.

3.5 Patents and the seed supply

Before the days of agricultural biotechnology and use of hybridized seed, farmer relied on saving and sharing seed to plant crops each year. The ability to genetically engineer seeds changed the game dramatically. Advances in biotechnology presented farmers with a revolutionary opportunity to purchase GM seeds with desired characteristics such as herbicide and insecticide resistance that could substantially increase yield or profit. However, buying into the GM crop market meant farmers could not save seeds and must return to the biotech companies each year to buy their patented seed. Patents awarded to the biotech companies afforded them the right to require farmers to buy their seed each year or ensure that no patented product was found in their yield for sale. Contracts on sold seed reinforced this further and even more strongly. Intellectual property rights (IPRs) are widely accepted as an integral component in the advancement of agricultural biotechnology. IPRs promote innovation.

IPRs, as they apply to agricultural biotechnology, aim to promote the research and development of new and beneficial technologies by making innovations available to the public without the risk economic loss associated with publishing the information freely. Two of the most crucial means of protecting agricultural innovations include plant variety rights (PVR) and plant patents, and utility patents.[50] These mechanisms ensure that innovators have legal rights to their novel biotechnology with the insurance of

[49] Komen, 2012
[50] Das, 2011

financial compensation should those rights be violated. Plant variety rights have played a major role in the development of conventional plant breeding while the more recent patents on biological technologies have been awarded to protect intellectual property associated with transgenic processes.[51]

The Trade-Related Aspects of Intellectual Property Rights (TRIPS), by which all WTO members must abide, is most comprehensive agreement regarding intellectual property rights. Under TRIPS, material must be novel, not naturally occurring in nature and usable. IPR systems vary greatly between countries with the developed, technology producers favoring strong intellectual property protection and less-developed technology consumers preferring weaker patent protection so that they can afford the technologies produced by the developed countries.[52] Not surprisingly, big biotech companies have been a major driving force behind the establishment of stringent IP laws that protect their innovations.

The biotech industry has exploded over the past couple of decades making it a major global business. As of 2009, the global biotech market was valued at $5.5 billion dollars a year.[53] With such an enormous investment, comes the need for an insurance policy. Companies need to be assured that their investment in the research and development of biotechnologies will be rewarded in the market. As a result, patents have proliferated and ownership of these patents has become concentrated in a small number of companies.[54] The gains of private industry in the biotech seed market have been enormous. However, many of the major patents on GM crop production methods have run out or will soon. Although new methods are constantly being developed and patented, it is likely that farmers will be able to use the old GM crops without fear of patent infringement. Nonetheless, as the technology improves, and as genes are

[51] Stein, 2012
[52] Friedman, 2009
[53] Strauss, 2009
[54] Strauss, 2009

stacked to provide greater yield benefits,[55] the benefits of purchase of seed from biotech seed companies is likely to continue.

The rights of farmers, while originally excluded from protocols such as the Convention on Biological Diversity, became included after they spurred much public debate. As outlined by Subhamoy Das in his article on agriculture, biotechnology and intellectual property rights, "The original intent of farmers' rights was to recognize farmers and members of indigenous rural or traditional communities for their role in creating, domesticating, and building sources of agricultural varieties and diversity for food and agriculture."[56] Unfortunately there are no strong legal means of protecting these rights as there are with the protection of IPRs.

Traditionally, it was within the rights of farmers to save and resell seed from year to year. Seeds were considered a part of a collective heritage and widely shared among farmers. After the Supreme Court decision on the Diamond vs.Chakrabarty case in 1980, seeds were on their way to being commodified and privatized. Since then, most major GM crops have been bought up by a few big companies, such as Monsanto, that have the resources to protect their GM seeds with patents[57], leaving farmers with the decision to buy the GM seeds each year or risk missing out on the advantages associated with using biotechnology by planting conventionally produced crops. It is worth noting that conventionally bred varieties are also increasingly patented, so this is not just a GMO issue. IP law in the US has laid the foundation for international IP systems such as TRIPS.

One solution to the balancing the rights of private industry and farmers in the field of agricultural biotechnology that has been presented is the idea of a public-private partnership. It has been suggested

[55] Fernandez-Cornejo et. al., 2014
[56] Das, 2011
[57] Stein, 2012

that, “Any system of IPR protection must take into account the needs of the community as well as the services provided to the commercial or highly productive sector, including limitations that may be imposed on a farmer's ability and rights to replant saved seed.”[58] Innovative biotechnology need to be accessible to farmers, but also worth the investment of private companies. A private-public partnership works to achieve a balance between public needs and private interests.

The current IP system, as outlined in this thesis, was championed by private US biotech industry. It was designed for developed countries to protect the IPRs of private companies which are protected under the US constitution to promote innovation. At times, it fails to protect farmers from accidental patent infringement. Even if they are found innocent after a trial, the court fees may tempt farmers to settle with big biotech companies to avoid additional cost and stress. For this reason, some have suggested incorporating an intent clause. The challenge, however, lies in the difficulty of proving intent. Advances in biotechnology hold enormous potential with private industry benefitting from financial gains and the public sector gaining tools to help reduce global food insecurity. A system under which both private interests and public needs are equally addressed and protected is essential for the continued promotion of innovation and research in agricultural biotechnology.

3.6 The NGO phenomenon and Greenpeace

Non-governmental organizations (NGOs) have played a surprising role in the public’s perception of biotechnology. Efforts range from education to full-blown terrorist attacks on GM crops and field trials. These organizations work to heighten anxiety about what might go wrong with GMOs in the food and environment and despite having very little basis in scientific fact, their attack campaigns have been largely successful. NGOs such as Greenpeace have garnished major media attention and are often the loudest, if not the only, voice on GMOs that the public hears.

[58] Das, 2011

Greenpeace is the self-proclaimed largest independent direct-action environmental organization in the world. It is a non-governmental organization (NGO) that lobbies for a number of environmental issues, not the least of which are human health and environmental concerns over the employment of GMOs in the world food supply. Greenpeace is vehemently anti-GMO. Greenpeace is active worldwide, but it has significant influence in EU members and aligned countries. The US has not been sympathetic of claims made by Greenpeace. In the April of 2000, the EPA rejected a petition by Greenpeace to revoke Bt crop licensing.[59] However, Greenpeace has wielded greater influence in other countries. In September of 2013, Greenpeace successfully halted field trials of Bt eggplant in the Philippines.[60] Greenpeace is also thought to be one of the main political actors influencing the EU's precautionary approach. Critics have accused Greenpeace of using unsound scientific claims and going as far as committing acts of bioterrorism.

3.7 Certified Organic

Greenpeace is not the only major organization to oppose GMOs. The organic industry is at risk for genetic contamination that could result from gene flow between GM and organic crops. Many countries have adopted certification standards for organic foods. To be certified organic, products must adhere to the organic production standards set forth by the country they are sold in.

In the US, the certified organic standards are maintained by the USDA. It is an inputs-based agricultural system that forbids the use of most synthetic materials including pesticides, antibiotics and biotechnology. The organic industry is committed to preserving ideals such as preserving natural resources and biodiversity, supporting animal health and welfare, and adhering to the organic standards mentioned previously. Organic farmers must undergo an annual inspection when they must prove that they have taken the appropriate steps to become certified organic. However, organic is not synonymous with GMO

[59] Dove, 2000
[60] Laursen, 2013

free because farmers must only prove that they did not use GM technologies. No test is done to test for GMO presence that could have resulted from accidental genetic contamination.

3.8 Bill and Melinda Gates Foundation

The Bill and Melinda Gates Foundation is a non-profit organization that is dedicated to a number of humanitarian causes. Their focus areas include research and development, access and market systems, agricultural policies, strategic partnerships and advocacy, and livestock. The Gates foundation has embraced biotechnology as one approach to addressing hunger and poverty among small-scale farmers. They believe that helping farmers increase yields involves a comprehensive approach that includes the planting of crops that are more resistant to disease, drought and flooding. The goal is "to reduce hunger and poverty for millions of farming families in Sub-Saharan Africa and South Asia by increasing agricultural productivity in a sustainable way."[61] Currently, the Gates Foundation is one of the organizations working to evaluate and employ Golden Rice with the partnership of the International Rice Research Institute (IRRI).

They also have invested in research on various drought-resistant crops, as well as many other types of biofortification. Agricultural development is one of the Bill and Melinda Gates Foundation's largest initiatives with more than $2 billion donated as of May 2014.[62] The Foundation works to listen to farmers, increase farm productivity, encourage sustainable agriculture, and create impactful partnerships.

3.9 Nuffield Council on Bioethics

Religious, political, and philosophical reflections have a long history with agriculture and the environment. Agricultural ethics is defined as systematic thinking about the values and norms associated

[61] "Agricultural Development Strategy Overview," *Bill and Melinda Gates Foundation*, 2014, http://www.gatesfoundation.org/What-We-Do/Global-Development/Agricultural-Development
[62] "Agricultural Development Strategy Overview," *Bill and Melinda Gates Foundation*, 2014, http://www.gatesfoundation.org/What-We-Do/Global-Development/Agricultural-Development

with the food system.[63] Agricultural ethics explains how ethical concepts and tools can address issue areas in the food system. Ethics more generally addresses the question of "What makes actions right or wrong?" There are various approaches to answering this question. Some refer to institutional rules such as those laid out by a country's legislation. There are many examples, however, of an action being legal and ethical such as in the case of occasional psychological abuse on one's spouse. Others turn to cultural origins of morality. Customs and cultures vary around the world and there is a sense that morally permissible actions are universal. Religion also has close ties to people's ethical systems, but again, religions can vary from culture to culture. Religion has also been used as grounds for unethical behavior in history as in the story of the crusaders. Even science has been used to explain ethics, but science tends to address what "is" and not what "ought to be." The Council on Agricultural Science and Technology set up a task force on Agricultural Ethics that identified a major goal of agricultural ethics as developing "clear, non-contradictory, comprehensive, and universal standards for judging right and wrong actions and policies."[64] Greater understanding about the standards that should be used to judge what is right and wrong can be achieved through analysis and argument on various ethical issues. The Nuffield Council on Bioethics is one such mode of analysis.

The Nuffield Council on Bioethics is an independent body established by the Nuffield Foundation and co-funded by the Wellcome Trust and the UK's Medical Research Council.[65]The council has produced two reports on the GM crops. The first was published in 1999 and titled *Genetically Modified Crops: the Ethical and Social Issues* and the second was published in 2004 and titled *The Use of Genetically Modified Crops in Developing Countries.*[66]The 2004 report found that 777 million people in developing countries, including one third of the population of sub-Saharan Africa, are undernourished and predicted

[63] "Agricultural Ethics," *Council for Agricultural Science and Technology*, 2008
[64] "Agricultural Ethics," *Council for Agricultural Science and Technology*, 2008
[65] Weale, 2010
[66] Weale, 2010

that population growth would substantially raise food requirements in the next 20 years.[67] It identified GM crops as one option for increasing agricultural production in light of worsening crop growth conditions. The precautionary approach was critiqued for preventing technological innovation.

"We conclude that an appropriate interpretation is a more flexible precautionary approach. By this we mean that the risks arising from the use of GM crops need to be compared with the risks of other possible courses of action, and of 'doing nothing'. Introduction of a GM crop may pose fewer risks than exist with the current agricultural system. For example, a GM crop could reduce the amount of pesticides used. The risks of 'doing nothing' may often be as great, or greater than the risks of action."[68]

The report identified insect/pest resistance, disease resistance, resilience to environmental stressors, herbicide tolerance, improved nutritional value, and biopharmaceuticals as possible benefits of GM crops in developing countries. It also examined the potential risks of GM crops. It was concluded that "The current evidence from safety assessments of GM crops does not suggest any significant risks to people who eat them," and that the risks of gene flow should be considered on a case by case basis, stating that, "We are not persuaded that possible negative results of gene flow in some areas are sufficient to rule out the planting of GM crops elsewhere in developing countries. There are also a number of ways of preventing and controlling gene flow."[69] The concern over the corporatization of the food supply was also addressed and it was recommended that "additional resources should be committed by the UK government and the EC to fund a major expansion of GM-related research relevant to the needs of small-scale farmers in developing countries."[70]

[67] "GM crops in developing countries" *Nuffield Council on Bioethics,* 2004
[68] "GM crops in developing countries" *Nuffield Council on Bioethics,* 2004
[69] "GM crops in developing countries" *Nuffield Council on Bioethics,* 2004
[70] "GM crops in developing countries" *Nuffield Council on Bioethics,* 2004

A number of frequently asked questions about GM crops in developing nations were presented and answered: 1) Are GM crops really necessary given that food distribution, not production is the issue? 2) How can GM crops solve world health problems? 3) Will GM crops only be available to large-scale farmers and how will they affect trade? 4) How can traditional agricultural practices be respected and maintained? 5) How is sustainable agriculture achieved? First, the report argues that food redistribution would be nearly impossible and therefore it is important to examine the contributions that GM crops could provide. Secondly, Golden Rice is cited as an example of a GM crop that could help address world health problems. Thirdly, it is argued that producers of non-GM crops could face financial disadvantages in the world market due to lower yields and higher production costs. Fourthly, it is recommended that farmers in developing countries be included in decision making to ensure that local customs, such as that of saving seed, are respected. Finally, the report states that the best method of practicing sustainable agriculture is an integrated approach using more than one agricultural strategy.

The final chapter of the report focuses on the policy, trade, and regulation of GM crops in developing countries. It is suggested that regulation of GM crops in developing countries considers the successes and failures of the various regulatory systems of the developed world while including local communities in the decision making process. On evaluating risk, the report recommended a "centralized and evidence-based safety assessment at the national or regional level." And that "Environmental and health risks should be assessed on a case by case basis."[71] The report urges the EU to consider the effects that its stringent regulation has on farmers in developing countries and for agreements between policy makers and the seed industry to be agreed upon to prevent the exploitation of farmers purchasing GM seed.

There were two main conclusions generated from the reports; first, that GM crops should be analyzed on an unbiased case-by-case basis using a benefit to risk assessment, and second, that in the case that the

[71] "GM crops in developing countries" *Nuffield Council on Bioethics,* 2004

benefits of using GM crops outweighed the risks in a developing country, there was a moral imperative to make such crops available to developing countries.

An important question that flows from these conclusions is whether or not GM technologies can actually benefit developing countries. The potential benefits have already been identified and include pesticide resistance, resistance to abiotic stressors, disease resistance and biofortification. Although in the developed world, food production has kept up with food demand in large part due to the efforts of the Green Revolution, Africa and parts of Asia did not experience a gain in agricultural productivity.[72] The Council argued that the food supply and agricultural incomes could be increased by increasing agricultural productivity using GM technologies. It may be true that there is enough food produced to feed the world population, but as the 2004 reports states, "Given the limits of redistribution, we consider that there is duty to explore the possible contributions which GM crops can make in relation to reducing world hunger, malnutrition, unemployment and poverty."[73] However, the report is also clear that transgenic technologies cannot, on their own, solve world hunger. Proper regulation and fair application of property rights have to be established if the benefits of GM crops are to be manifest.

[72] Weale, 2010
[73] "GM crops in developing countries" *Nuffield Council on Bioethics,* 2004

CHAPTER 4 ANALYSIS

4.1 Is it possible for genetically modified crops to reduce food insecurity?

Food security encompasses access to food, utilization of food, food availability, and food system stability. Access to food refers to the economic means necessary for buying or growing food. Utilization of food refers to its utility to the body, which is its ability to nourish. Food availably is the gross production of food before distribution and food system stability refers to robustness in the face of changing environments. GM crops have the potential to improve food availability by increasing gross food production. They can improve access to food by reducing production costs, increasing yields and therefore leaving more money for farmers to spend on buying food. GM crops can also improve food utility and nutritional value through biofortification and help stabilize the food system by offering robust varieties that are drought and flood tolerant. Two potential benefits of adopting GM crops in developing nations stand above the rest; the ability to improve food utility and nutritional value through biofortification and by offering robustness in the face of changing environments.

GM crops carrying traits like pest and disease resistance have been shown to increase the yield of various crops by reducing the damage from insects, weeds, and drought. GM technologies can make crops more robust to biotic and a biotic stressors resulting in a higher yielding and more stable food supply. Resistance to other environmental stressors like disease can also be combated with transgenic disease resistance. In some cases, crops may fail due to disease pandemics that can be stopped only by transgenically introducing genetic resistance. This was the case with papaya in Hawaii. Higher yielding food crops translate to more food availability and greater food system stability.

Food could be better utilized with the use of biofortification. Fortifying GM crops involves increasing or introducing micronutrients such as zinc and iron in the parts of plants that are consumed. Providing essential nutrients in staple crops like rice could reduce or eliminate the need for supplements. Currently,

providing supplements to malnourished people is a costly and inefficient method of delivery. It is possible to incorporate vaccines into foods that can be produced, stored at low cost, and administered locally; these await suitable medical system adoption and controls. The ability to grow nutritionally enhanced crops in places of low food security could increase the utility of what food is available.

Since about 50% of all undernourished people worldwide are rural farmers in developing countries[74], increasing their access to food is critical in reducing food scarcity. By influencing the socioeconomic situations of small-scale farmers, GM crops may be able to extend famer's economic access to food. By lowering production costs through less tillage and pesticide use, and increasing crop yields, the margin of revenue would be extended. Most of GM crops are not grown for direct food use[75], but increased yields and decreased production costs of GM crops grown exclusively for exportation would still result in a financial gain to the farmer that could then be used to buy or plant food supplies.

4.2 Should genetically modified crops be adopted to improve food security?

Having come to the first conclusion that GM crops hold enormous potential for reducing food insecurity by increasing crop yields, decreasing production costs, increasing farmers' incomes, and improving the quality of food, it becomes important to address the question, "What are the consequences of GM implementation?" There are human health and environmental risks that need to be assessed when novel toxins or other molecules are introduced into the food supply. Non-biophysical risks should also be taken into account when analyzing the pros and cons of using GM crops as means to reduce food insecurity. Socioeconomic and ethical concerns need to be considered and, if they cause strong social disruption, may trump the technical advantages discussed above.

[74] Kouser and Qaim, 2013
[75] Kouser and Qaim, 2013

The debate over whether or not biotechnology, as a family of processes, is safe for humans and the environment is a relatively old and uninteresting argument. Biotechnology has, in numerous forms, been utilized in food production since the dawn of domestic agriculture with little to no pushback. What tends to be more controversial about biotechnology is the more recent employment of transgenic technology. It makes it possible to introduce entirely new genes and specifically alter the levels of gene expression in a genome. Similar to conventional breeding, the resulting proteins expression levels can be unpredictable from insertion event to event, requiring that many are examined to choose safe and adapted genotypes. As is the case with plants produced from traditional breeding methods, there is also a risk that variety will cross-pollinate, at some level with native and organic species.

Such gene flow is ubiquitous in agricultural systems. The Coordinated Framework in the US is built upon the assumption that the GM method per se is no more risky than conventional breeding and should be subject to the same safety standards as conventionally produced food. Both conventional and GM foods undergo mandatory safety checks. Although it is theoretically possible to create a variety of plant that exhibits allergenic or toxic properties that were not present in conventional varieties, the regulatory framework of the US and other countries would prevent such a food from ever entering the food supply without clear labeling to this effect. Mitigating gene flow is a prominent concern of many researchers, and while some crops could be rendered at least partially sterile to avoid this problem, for most this is impossible or socially unacceptable. New solutions to reduce genetic comingling continue to be addressed in the laboratory, but the main solutions reside in where plants are put in the environment, and the establishment of legal tolerances and thresholds for admixture. Although gene flow between GM and non-GM plants has occurred, there have been no adverse effects on human health or the environment observed to date. As a result of the global export and import of GM crops, gene flow regularly crosses national borders in food shipments, and has caused market and trade disruptions worth many millions of dollars.

Formally, GMOs are regulated without regard to ethical concerns or socioeconomic impacts in the USA. However, in practice regulatory decisions are often influenced greatly by political considerations. Although no major religions have chosen to eschew GMO technology, there are some moral and religious objections to the use of GM crops in the food supply. Some people fear that consuming foods produced with transgenic technology may infringe on their moral and religious convictions. For these people, the process of producing food by means other than natural sexual reproduction is inherently wrong. They believe that it is wrong to "play God" by altering genomes outside the natural methods of sexual recombination. For others that have dietary restrictions such for religious or moral reasons, transgenic technology makes it possible to insert genes from prohibited food into food that is permissible to eat. In such cases regulatory agencies may want to consider special labeling as they would for GM food products that exhibit allergenic properties. While extra labeling costs may deter developing countries from planting GM crops with the need for labeling, there are no current crops for which this would be necessary. As is the case with labeling for vegan or Kosher, the burden of labeling could also be placed on those with particular dietary preferences. Buying organic would be a one such way of avoiding foods produced using GM technologies.

Cross-pollination and breeding between GM and non-GM crops is expected based on standard agricultural experience, but with GMOs is a special concern Regulators in the USA do not account for mixing of GM and non-GM crops in food processing facilities or during farming; those are left to the market to manage if GMO content is a concern. In other countries, such as those of the EU, GM and non-GM processing facilities are regulated to reduce mixing. Adverse effects from gene flow are primarily felt by farmers cultivating non-GM crops. Organic farmers could lose some of their markets if testing discovered a detectable level of GMO presence their food products. However, the organic certification process is based on inputs and current certified organic foods are not tested for GMO presence in the US by certifiers. In contrast, the EU does test for levels of GMO presence and thus genetic contamination occurring in the US could adversely affect trade with the EU and aligned countries. In the

US, the burden of keeping GM crops out of non-GM crops is placed on non-GM crop farmers as is generally the case with all specialty products. For exported crops in developing countries to be economically advantageous (when GM technology is employed for those crops in the country), steps would need to be taken to prevent or minimize gene flow that could negatively impact trade with the EU and other countries that have stringent limits on GMO presence.

Although process-based labeling of GMO products is not currently mandatory in the US, there has been a strong demand for labeling to provide more choice for consumers. Labeling of GM products has not been instituted because it would reflect non-scientific views in a very costly process to GM crop producers. For consumers that wish to purchase non-GM food and for producers that wish to advertise non-GM food, there the FDA has published voluntary guidelines for labeling. In the EU mandatory labeling has resulted in widespread aversion to GMO-containing products forcing marketplaces to remove all GMO-containing products from their shelves. Consumers should have the right to choose, but labeling in the EU has inadvertently resulted in less consumer choice because GM food products are not available on the shelves. GM producers in developing countries would need to be reasonably guaranteed a market place for their crops. Mandatory labeling of GM foods could actually reduce consumer choice.

Human health and environmental risks associated with the implementation of biotechnology in developing nations could fairly easily be minimized as it is now in both the US and EU regulatory systems. The science suggests that the benefits of utilizing biotechnology as a means to reduce food insecurity would far outweigh the risks. From a scientific standpoint, it can be concluded that biotechnology should be implemented in developing nations to address food insecurity. Non-scientific considerations may or may not support the same conclusion. Proper regulation would need to be put in place to ensure that moral and religious objections to GM foods are respected, consumers are provided with rightful choices, steps to minimize gene flow are taken, and protection offered to farmers from being exploited by large agribusinesses.

4.3 How should biotechnology be regulated in developing nations?

The human health and environmental risks associated with GM crops remain unchanged across national borders. It seems fitting, therefore, that food safety and environmental impact pertaining to biotechnology is addressed at the international level. Guidelines like those provided in the Cartagena Protocol must be taken seriously by GM producers and trade partners that are signatories to the Convention on Biololgical Diversity, or trade with countries that are. If the Cartagena Protocol is not ratified or respected by the major producers of GM crops, then it will not function effectively enough to guide international biotechnology policy and a new international regulatory framework would need to be created. It may take relaxing the interpretation of the Cartagena Protocol to encourage all the major GM crop producers to sign. It would be necessary for all GM crop producing countries and other international regulatory agencies such as the WTO to function compatibly with the protocol much in the same way that federal and state powers interact within the US. This would ensure that poor food and environmental safety policy on one country's part would not negatively impact another. International oversight could also help alleviate trade tensions while allowing individual countries to address non-scientific concerns.

As is, the regulatory and legal framework for addressing biotechnology in the US and EU should not be forced upon developing countries by trade sanctions or less formal demonstrations of preferences for non-GM foods. Developing countries should have the financial and legal freedom to pursue GM technologies. For example, if Africa wants to adopt drought-resistant corn for domestic use, it should be able to do so without fear of the repercussions that such an action would have on its biggest importer, the EU, due to low levels of adventitious presence.

4.4 Conclusion

It is important to recognize that there is no silver bullet for solving world hunger. However, the utilization and responsible regulation of biotechnology could meaningfully contribute to the solution. Having reviewed the potential benefits and risks of GM crops and associated political systems, I have come to three main conclusions:

First; GM crops have to potential to improve food security by providing resistance to pests, herbicides, and disease, biofortifying staple crops, providing tolerance to drought and flooding, and improving the socioeconomic status of farmers by increasing yields and lowering production costs.

Second; GM crops should be implemented in developing countries as a tool to improve food security because, in many cases, the benefits outweigh the risks. Therefore, there is a moral imperative that these technologies are available to farmers in developing countries as one tool to improve food security.

Third; In regard to biophysical risks, transgenic biotechnology should be regulated internationally while addressing socioeconomic and ethical concerns at the national level. Responsible regulation should ensure that moral and religious objections to GM foods are respected, open trade is promoted, consumers are provided with meaningful choices, steps to mitigate gene flow are taken when essential for coexistence of GM and non-GM systems, and that protection is offered to farmers from being exploited by neocolonial powers and large agribusinesses.

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