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A CASE STUDY OF BIOENGINEERING IN AMERICA: PROFITS, RISKS AND STANDARDS OF VALUE IN THE COMMERCIALIZATION OF MONSANTO COMPANY'S NEWLEAF POTATO

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ABSTRACT

Last year, approximately 45 million acres of American farmland were planted with crops that had been genetically engineered to either produce their own pesticides, or withstand herbicides. The long and short-term effects of this biotechnology on humans and the environment, are being studied, but remain unknown. Leading the way in the field of bioengineered crops is the Missouri-based Monsanto Company. Monsanto believes that current agricultural practices are inconsistent with sustainable development. The NewLeaf potato is one of three products Monsanto has created to feed the growing world population. The genetically engineered crop produces, in every cell of the plant, a pesticide that kills its most common predators.

This paper offers a case study of the development, regulation, and commercialization of Monsanto's bioengineered potato. It is an interdisciplinary approach that focuses on the economic, environmental, and the ethical facets of how the product was created, and how it has been brought to market. The paper will bring to light the inherent benefits, risks, and the standards of value used in assessing this contemporary implementation of biotechnology.

I. INTRODUCTION

Each year since 1996, increasing numbers of acres of US farmland have been planted with potatoes, corn, and cotton, some of which have been genetically engineered to repel some types of insects. Since there are currently no regulations mandating labels for genetically engineered plants and vegetables in the United States, you may already have unknowingly eaten one of the food products resulting from these crops. These transgenic crops include a gene from the naturally occurring soil bacterium *Bacillus thuringiensis*, or Bt, which makes a toxin repellent to some insects. Proponents of the technology claim it will lead to higher crop yields, lower use of pesticides, and generally benefit a rapidly growing world population. However, opponents warn that the bioengineered crops introduce unknown environmental risks.

The uncertainty surrounding this emerging technology creates an urgent need for a balanced examination of the development, regulation, and use of genetically engineered crops. This paper provides an analysis of the environmental, economic, and ethical facets inherent in this controversy. The paper uses a case study approach to examine the development, regulation and commercialization of one particular transgenic crop, Monsanto Company's NewLeaf Potato. The NewLeaf potato is one of three products Monsanto has created to feed the growing world population. The genetically engineered crop produces, in every cell of the plant, a pesticide that kills its most common predators.

Monsanto claims that the NewLeaf Potato will result in greater yields and lower use of pesticides. Will Monsanto's new strategy provide a path leading to sustainable development as the firm claims, or will the uncertainties inherent in this technology subject us to serious environmental hazards? In addition, what is the source of value in weighing whether this technology will truly be an ally to sustainable development or will instead imperil future generations? The case study approach highlights concerns which might be addressed in future implementations of genetic engineering.

In the next section the development of Monsanto's NewLeaf Potato is outlined in the form of a case study. Next, an economic framework is developed to assess potential benefits and costs of the new technology. This is followed in section IV by an examination of the environmental impact of transgenic crops. The ethical implications of the manner in which this product was developed, commercialized and regulated are addressed in section V followed by concluding remarks, recommendations and concerns.

II. THE COMMERCIALIZATION OF MONSANTO'S NEWLEAF POTATO: A CASE STUDY

After initial field-testing was begun in 1990, the "NewLeaf Potato" was being grown commercially as early as 1995.[1] What makes this potato different from every other variety on the market is the addition of genetic material from the bacterium *Bacillus thuringiensis,* or Bt. Bt is a naturally occurring substance that produces a protein which is toxic to certain insects, particularly in their larval stage. There are thousands of strains of Bt, each of which targets specific insects. The variety focused on by Monsanto in this case is *Bt tenebrionis.* This strain proves fatal to the Colorado potato beetle, which is the scourge of potato farmers. By splicing the Bt gene into the potato itself, the entire potato plant, from leaf tip to tuber, contains the bacteria in every cell. Any beetle that feeds on the plant will ingest the bacteria, and will die. This development, according to Monsanto, will reduces the need to spray the plants with multiple applications of insecticides, reducing both costs and environmental risks. The company reported that those farmers "who grew NewLeaf potatoes reported eliminating from one to five insecticide sprays for control of this pest. These growers were able to reduce total insecticide

applications between 33 percent and 42 percent on their NewLeaf fields compared with their unimproved fields."[2] (It should be noted that this new transgenic crop does not completely eliminate the need for insecticide applications. Monsanto still recommends up to eight different pesticides to combat aphids, and two for wireworms.) In 1998, Monsanto offered farmers the option of planting "NewLeaf Plus" potatoes, which had an added resistance to potato leafroll virus. Naturemark, the Monsanto subsidiary responsible for the NewLeaf potato, promises that "NewLeaf potatoes are the fist step toward complete biological insect control."[3]

In 1993, Monsanto began the process of getting the necessary approval to market the NewLeaf potato from three federal agencies, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the US Department of Agriculture's Animal and Plant Health Inspection Service (USDA – APHIS). In that year, Monsanto applied to the EPA for registration of the *Bt tenebrionis* protein in potatoes. In 1994, the FDA Food Advisory Committee (FAC) reported a finding of no outstanding food safety issues with regard to NewLeaf potatoes (consistent with the FDA's 1992 policy). In March, 1995, the EPA approved a limited registration of the *Bt* engineered potatoes (along with an identical approval for *Bt* corn and cotton). In that same month, the USDA – APHIS announced that it would no longer regulate Monsanto's Russet Burbank potato lines, having determined that they did not represent a plant risk. In May of 1995, the EPA approved full commercialization of the *Bt* potatoes, registered by Monsanto's subsidiary NatureMark under the name NewLeaf. The EPA's rationale was that "Because the insecticide is natural and nontoxic to animals, it does not pose a risk to public health or the environment"[4]. In May of the following year, the USDA (APHIS) announced it would no longer regulate Superior and Atlantic Potato lines.

This year 45 million acres of US farmland were planted with genetically engineered crops and next year the number will likely be significantly higher. Consumers are unable to choose whether or not to purchase products resulting from such crops because there are no labeling protocols in effect at this time. The potential environmental impacts are largely unknown. This point was underscored by a recently released laboratory study by Cornell University scientists. The scientists found that when the larvae of monarch butterflies ate pollen from corn, genetically engineered to include Bt, nearly half died and others suffered stunted growth.[5]

III. ECONOMIC ANALYSIS OF THE NEWLEAF POTATO

The analysis of the commercialization of this emerging technology proceeds from an examination of economic aspects. In this section an economic framework is developed to analyze the private and social benefits and costs

involved in the introduction of the NewLeaf Potato. While the framework examines the specific costs and benefits associated with this particular crop, the analysis could easily be generalized to evaluate other agricultural products of genetic engineering. The commercialization of the NewLeaf Potato raises two fundamental questions. First, what is the economic impact on society of the introduction of this potato? Second, what role, if any, should the government play in the oversight and/or regulation of this particular crop and the burgeoning life sciences industry?

The Economic Impact of the New Leaf Potato

When performing an economic analysis of a new project or product all incremental costs and benefits are assessed[6]. From the firm's perspective, all private incremental costs and benefits are identified. The firm then estimates the present value of the costs and benefits[7]. The firm will undertake projects for which the present value of benefits exceeds the present value of costs. Analysis from a public policy perspective should incorporate both private and social incremental costs and benefits.

In order to evaluate the costs and benefits of the NewLeaf Potato it is necessary to identify all parties affected by the crop. The analysis will focus on Monsanto's private costs and benefits; the impact on the market for potatoes; and the social benefits and costs.

The Economic Impact of the New Leaf Potato on Monsanto

Clearly Monsanto expects the net benefits of the NewLeaf Potato to exceed the costs.[8] Potential benefits to the firm include increased market share, increased profits, and enhanced competitive advantage. The firm's competitive advantage versus the industry may be strengthened through its strategic move into the high growth life sciences industry and through "first mover" advantages. Patents on bioengineered crops may provide a sustainable advantage. Further, the firm may enhance public perception by spinning the new product as a corporate attempt to move the world toward sustainable development.

Potential costs include operating costs related to developing, testing, producing, distributing and marketing the NewLeaf Potato. Other opportunity costs would include any lost sales of the firm's pesticides. In addition the firm may incur costs related to the increased risk inherent in these products, compared to the firm's traditional products. Since this industry is riskier than a firm's traditional operations, capital costs[9] may rise. Further, the firm may incur additional costs related to potential product liability. Finally Monsanto has incurred lobbying costs in its efforts to persuade the government that there is no need for regulation.

The Economic Impact of the NewLeaf Potato on the Agricultural Market for Potatoes:

Next we consider the impact of this product on the agricultural market. Potential benefits include higher yields and lower production costs to farmers. The lower production costs may be achieved since the NewLeaf Potato will require fewer pesticide applications. Some consumers may prefer potatoes treated with less pesticide and there may be resulting health effects. Also, in the future, this technology may yield potatoes with increased nutritional benefit.

Costs to those in the agricultural market include purchasing costs of the potatoes as well as potential liability. The environmental risks of the product are uncertain and the farmer may be liable in a legal sense. Further, the farmer will face the potential of damage to other crops on the farm. In addition, some customers may become reluctant to consume foods which are the product of genetic engineering. Finally, the farmer may become dependent on Monsanto since Monsanto is the sole provider of the NewLeaf Potato. This dependence may result because the farmer will be purchasing a critical input from a monopolistic supplier.

The Economic Impact of the NewLeaf Potato on Society

Finally we consider potential benefits and costs to society. Potential benefits include lower food prices, health benefits arising from lower use of pesticide, and environmental benefits due to lower use of pesticide and reduced fuel use (since no fuel is needed to produce, distribute or apply pesticides related to the Colorado potato beetle). Further, the crop may lead to enhanced US competitiveness if the industry continues to grow and prosper and is centered in the US. This may lead to significant employment opportunities in the life sciences industry. Finally, the NewLeaf Potato may indeed represent a first step toward sustainability. Concerns about feeding the growing world population suggest that significant improvements in crop acreage yields will be necessary over the next 30 years.

Potential social costs include the risk of negative environmental impact in the US and elsewhere (this is detailed in the environmental section). There are also risks related to antitrust issues. Since Monsanto is the sole provider of this potato, prices would be expected to be higher than in a more competitive market. Other costs include transactions, oversight and regulatory costs incurred by government and stakeholder groups.

The Role of the Government in Oversight and Regulation of the Life Sciences Industry

While the competitive market system is generally recognized by economists as an efficient way to allocate society's scarce resources, there are well-recognized situations where a free market outcome leads to suboptimal results. In these situations of "market failure", government intervention can improve the outcome, from a social standpoint. One well recognized example of

market failure exists when there are costs and benefits that accrue to parties other than the buyers and sellers during the production or consumption of a product or service. This is referred to as an *externality or spillover* since there are costs and/or benefits which spill over to individuals external to the market transaction.

The failure of the market to include *environmental* costs and benefits in production and consumption decisions has long been recognized as an example of a market failure that creates a basis for government intervention. Environmental protection is a collective good and therefore is difficult to value and regulate. Since it is available to all, whether or not they pay for it, free riders benefit by opting not to pay the costs associated with "producing" environmental protection[10]. Since pollution and/or environmental degradation costs are often external, the costs are not borne by the producer or consumer. When externalities are present, the preferences expressed in the marketplace will not be a complete measure of a good's value to society. As a result, the market overproduces those goods that generate external costs, and underproduces goods that generate external benefits. Therefore resources will generally not be allocated in a socially optimal manner. The failure of the market to include environmental costs in production and consumption decisions encourages environmental damage and therefore creates a basis for government intervention.

The economic analysis of the NewLeaf Potato presented above suggests that there are both potential positive and negative externalities associated with this new technology. Potential positive externalities include environmental benefits arising from the reduced use of pesticides and fuel, the possibility of enhanced U.S. competitiveness and the potential for achieving progress toward sustainable development. Potential negative externalities arise from the potential for environmental harm. This implies that the social outcome may be improved by government intervention, perhaps in the form of independent testing, oversight, labeling requirements and regulation of the NewLeaf Potato and other transgenic crops. The benefit of such intervention is dependent on the crop's environmental impact. This is discussed in detail below.

IV. ENVIRONMENTAL ANALYSIS OF THE NEWLEAF POTATO

Monsanto Company's transformation from a chemical company to a life sciences company has been heralded by the firm as a move toward sustainable development. Indeed the firm's call for movement toward sustainable agriculture is implicit in all its press releases on this topic. The company is saying, in effect, that by increasing crop yields and reducing dependence on pesticides, which has both an economic and an environmental price tag, sustainable agricultural systems worldwide will benefit. In fact this may be a rather simplistic interpretation of "sustainable" development. By definition sustainable practices are those in which there exists a balance between input and output. In other words, "Sustainability is a concept that can be summarized by saying that each generation should pass on to the next a set of undiminished environmental assets, by meeting the needs of the present without compromising the future. Sustainable development is development that maintains an appropriate balance with nature."[11] Agriculture that would be under

this model relies on healthy soil, rotation of crops, integrated pest management and crop diversity. If the crop yield is heavily reliant on ever increasing input of fertilizers to offset nutrient loss in the soil and if the soil itself is degraded by overuse and erosion (a common phenomenon in monocultural systems) then a reduction in pesticide usage does not translate to a sustainable practice.

On the surface, and certainly according to Monsanto's public relations experts, it would seem that the NewLeaf potato might herald the beginning of the end of the use of dangerous chemical pesticides. Nature's own formulae are being tapped to control pests on a genetic level. *Bacillus thuringiensis* is not regarded as a threat to humans, and organic farmers commonly use it to control beetle infestations. As mentioned above, some (but not all) sprayings of deadly pesticides can be eliminated. Crop damages decrease and yields per acre increase, leading Monsanto to claim that they are helping in the struggle to develop sustainable agricultural models. Biotechnology in the last few decades of the twentieth century has given rise to an incredible world of genetically engineered possibilities. In agriculture and plant technology, the ability to transfer genetic material from totally unrelated species into plant tissues has raised some profound questions and implications. From an ecological perspective, it is impossible not to wonder whether this ability will lead to some radical solutions to current problems on a worldwide basis, or whether the solutions will themselves become worldwide problems.

Potential For Ecological Damage

There are, however, many considerations that have not been adequately addressed by Monsanto or the federal government. These issues include insect resistance to *Bt*, the possibility of transgenic crops becoming weeds, the likelihood of transgenic crops cross-pollinating with wild relatives, and the relative safety of ingesting *Bt* in food products. Each of these questions requires careful analysis and discussion in order to fully understand the implications.

Organic farmers have used *Bt* for years to protect their crops from insects. It is applied as a spray, and it deteriorates in a few days. However, *Bt* is used sparingly, and usually not as a first line of defense. No adequate studies have been conducted to determine if the new *Bt* potatoes will so overwhelm the balance that the targeted insects will develop a resistance. The preliminary results, though, have not been promising. Nature always seems to find a way to re-establish a balance. As greater numbers of beetles feed on the new transgenic crops, some will begin to develop enough resistance to *Bt* to survive. Such overexposure to the toxin will undoubtedly result in an increasing population of beetles which pass on this resistance tendency to their offspring. Even Monsanto acknowledges that this will occur, although their timeframe is drastically different from that posed by critics (30 years vs. 5 years)[12]. There is increasing evidence that *Bt* tolerance in targeted insects has already made a foothold in other *Bt* genetically engineered plants[13]. Monsanto has suggested the use of "buffer zones" as a means of limiting the likelihood of the development of tolerance. Each crop area would be surrounded by a zone in which no *Bt* crops are grown. In theory, these zones would harbor insects which

would be less likely to develop a resistance. A resistant insect would be less likely to find another resistant insect with which to mate, and the resistant gene would be less likely to be transferred. However, the problems with this system are many. No one knows whether the buffer system would in fact work, or even how large they would need to be. As it stands, the idea is simply a suggestion, not a requirement. In reality, most farmers do not have the available land to let sit as a buffer zone. So it would seem that this particular "solution" would not effectively deal with the problem, which unfortunately will not disappear. Once tolerance to the toxin has been established, some new form of pest control must be developed. Meanwhile, organic farmers will have lost a valuable alternative to artificial pesticides.

A crop which proliferates within the confines of the pre-determined growing region is a success. But what happens when that crop has been engineered to out-compete those species which impose limits on it? Whenever a species gains an advantage in its habitat, it will expand to fill every available niche within that habitat. By giving a particular plant species a genetic "edge" on the competition, the likelihood increases that the plant species will begin to grow out of control. Whenever a plant is growing where we don't want it to, or growing beyond our ability to regulate it, that plant takes on the characteristics of a weed. While this has not happened on any fields planted with NewLeaf potatoes, there have been other precedents in nature, and the issue bears some consideration.

What happens in a field of genetically altered crops when the natural system of pollination occurs? Pollen from a transgenic potato could be carried to a wild relative, transferring the new genetic traits into the wild plant. Since the particular trait in question, insect resistance, is one which confers an advantage in the plant, it could well take hold and become an integral part of the hybrid plant. Potato growers in the U.S. may not have much to fear in this regard, since most evidence suggests that there are few, if any, wild relatives of domesticated potatoes here. However, as transgenic potatoes are introduced in other regions of the world, specifically South America, the concern grows considerably. Potatoes originated in South America, and given the hundreds of varieties that exist in that region, the possibility of gene flow from one species to another becomes very likely. The cascading effects on the ecosystems become difficult to predict and potentially very damaging.

Regulations And Food Safety

The question of the safety of bioengineered foods is one of the most hotly debated topics in this field. In the case of the NewLeaf potato, the safety issue has become mired in a political quagmire. Technology has clearly outpaced the regulatory system, and the federal government is still trying to decide which agency will have the ultimate control over the decision-making. In 1986, the three agencies involved in the regulatory process, the EPA, the FDA, and the USDA, devised a coordinated framework for the regulation of genetically modified organisms. The framework laid out an oversight structure, the administration of which would be based on existing laws. Basically, once

certain issues like confidentiality of trade secrets were worked out, the agencies have tried to work concurrently and with a measure of cooperation. In 1992, the Food and Drug Administration issued a policy regarding the labeling of bioengineered foods. Under the authority granted to the FDA by the Federal Food, Drug, and Cosmetic Act (FFDCA), the agency must oversee any substance added to a food to determine of it is safe. However, once the safety of the substance is established, the Act simply requires that the labeling be truthful and not misleading. "The Act does not require disclosure in labeling of information solely on the basis of consumers' desire to know."[14] In the case of the New Leaf potato, the FDA doesn't consider the Bt protein to be an additive. Rather, the FDA sees it as a pesticide (indeed, Bt is a registered pesticide, according to the Environmental Protection Agency). As a pesticide, it is no longer the responsibility of the FDA. By law, the FDA cannot require the listing of pesticides on labels. However, the EPA argues that since the food itself is safe, and since Bt has not been show to cause any adverse effects on lab mice in short term tests, the combination of food and pesticide does not pose a health risk. (Bt, according to the FDA, falls into the category of GRAS, or "generally regarded as safe".) Critics are quick to point out that long term studies have yet to be done, and that Bt, when used as a spray, carries a warning about coming in direct contact with the substance. Monsanto, meanwhile, refers all such questions back to the FDA, the agency they claim is responsible for monitoring the safety of any food substance. The FDA, however, maintains that the ultimate responsibility lies with the company. "The Act (FFDCA) places a legal duty on developers to ensure that the foods they present to consumers are safe and comply with all legal requirements."[15]

The question of responsibility, then becomes a multifaceted one. Who will be held accountable if a new, pesticide resistant strain of Colorado potato beetle develops because of overexposure to Bt? Will Monsanto be able to address the possibility of transgenic potatoes hybridizing with wild or other domesticated varieties in other parts of the world? If a health risk to humans becomes apparent, will Monsanto be liable, or will the federal government be held responsible? Should the government require all genetically engineered foods to be labeled as such, or are they safe until proven otherwise?

V. ETHICAL EVALUATION

It has been demonstrated above, in attempting to assess the economic value and impact of the NewLeaf Potato, a discussion of environmental realities is necessary. This clarifies questions of accountability for unknown environmental risks, and questions about regulation protocols. To fully understand these types of issues, an examination of the ethical implications of this particular process of commercialization offers an opportunity for insight into the affirmations and errency of how this process unfolded.

Ethics, as a philosophical endeavor, is a rational inquiry into moral behavior. Although in the history of philosophy since the 1900's there have been a growing number of thinkers who have become critical of technology. This

section of the paper addresses the inherent ethical questions that this product raises.

Normative Ethical Standards of Value

Applied ethics, perhaps considered foreign to commercial endeavors, is an aide to a thorough evaluation of the value to society of a technology like the NewLeaf potato. While traditional quantitative value is number based, qualitative value assesses the impact on the quality of participant's lives. The qualitative values of an ethical inquiry incorporate benefits and costs of emerging technologies which may be difficult or impossible to quantify.

The traditional ethical approach to a case study like this is casuistry, or relying on a paradigm case. Taken from the use of precedents in law, this approach is usually helpful in offering a standard of behavior that a case can be measured against. It is difficult to use casuistry with the case of the commercialization of the NewLeaf. This technology is emerging, and, as shown above, the risks to the ecosystem are unknown. It is this problem of unknown costs that makes this case unique. There have been products before which affect the environment, but never before have genetically altered products been introduced into the agricultural environment on this scale. Current examples, like augmented production of milk in cows, parallel the NewLeaf, but such cases themselves cannot act as a precedent since the facts of these cases are still coming to light, and the technologies used are radically different.[16]

It is the application of normative ethical theories, rather than casuistry, which offers insight into the ethical dimensions of *this* process of commercialization. If one looks at a consequences based ethic, one in which the final outcome of a particular course of action is used as measure, then it can only be said that if harmful outcomes present themselves it usually becomes a legal matter of accountability since the damage has been done (assuming that accountability can assigned to a particular source). If the final outcome is positive, or in other words no harm comes to individuals or communities by this course of action, then Monsanto's endeavor to capitalize on this technology can be considered to be ethically satisfactory. That is to say, "No harm, no foul."

The use of a deontological ethical standard is a clear affirmation of Monsanto's course of action. This is to say that when the standard of measure is duty, then Monsanto has a duty to its shareholders to maximize profit. Even if unknown risks materialize, Monsanto will be ethically justified in saying it was attempting to develop market share in the emerging life sciences, as they ought to have. Monsanto will claim that this product was brought to market in accordance with current regulations, and that to fail to bring the product to market in light of environmental uncertainties would have been a violation of the responsibility the firm has to produce maximum return on shareholder investment.

It is another issue whether or not regulatory agencies, whose duty it is to make sure that products are safe before they are offered to consumers, might be criticized on ethical grounds. It would depend on the presence of harm, and, perhaps more importantly, on proof of negligence on the agency's part. If this did come to pass, the agencies could be said to be unethical in so far as their duty is concerned.

The other predominant normative ethical standards, teleological or ends oriented ethic, and a rights based ethic, however show various moral concerns related to this case of genetic engineering that need further exploration.

Concerns about the Goals of Biotechnology

The first concern is whether the telos, or end sought, of Monsanto is sustainable development or profit. While the firm has touted its belief in the goal of sustainable development it seems that the true corporate end is profit. That, in-and-of-itself is not a bad thing at all, but it is not ethical for the company to claim it is one when it is really another. For example, while the firm has recently decided not to pursue the so-called "terminator" gene at this point, due to public pressure, Monsanto did intend to incorporate it into transgenic crops. When put to the question of whether or not that technology could lead to unpredicted sterility in other crops, Monsanto's reply was to something to the effect of "well you can always buy more seeds ..."[17]

Monsanto may be willing to risk environmental costs, not for developing new methods toward sustainable development, which could be negatively impacted by some of these technologies[18] , but for the profits that come from a strong percentage of the agricultural markets. There is nothing wrong ethically with the goal or end for Monsanto to be profitable, but to put forth a goal that is more appealing, when in fact it might not be the case in the long run, is putting a "spin" on the issue, and might be considered misleading. The confusion about the goals of Monsanto can foster an implicit sense of mistrust, and could affect consumer confidence in its research and products.

Individuals might have more trust in Monsanto's products if the firm did not claim its end to be something (sustainable development) that is only a means to another end (profit). This teleological ambiguity is not wholly unethical, but is worthy of questioning. A teleological normative ethic as a standard of measure will not work without a clear end. So Monsanto cannot be held to an end-based ethic, because it is unclear which end it is seeking.

Participation in the Process of Commercialization

Perhaps the most intriguing standard of ethical measure for the commercialization of this product would be a rights-based ethic. The interplay between the interests of Monsanto and society come to the forefront when this standard is implemented. Monsanto has the right to voluntarily develop and commercialize products (as stated earlier, it can be said to be their duty to shareholders to do this, in so far as it is profitable). Individuals and

communities have the right to voluntarily purchase and consume products with an expectation of safety. The key term here is "voluntarily."

The NewLeaf potato came to market amid confusion of regulatory agency policies. Questions about the lack of information regarding environmental impact and the firm's lobbying to pass regulatory requirements (especially when it comes to "labeling") have been raised. From a rights-based ethical standpoint the individual has no voluntary say whether or not he consumes this product. One cannot choose this potato over another because without genetic testing a NewLeaf potato is indistinguishable from an "old leaf' potato. On that point alone the process is unethical, for the right to an informed choice has been circumnavigated.

Whether or not Monsanto has the liberty to gamble with the environment is also in question. There are unknown risks that introducing transgenic crops into the ecosystem create, but the opportunity for individuals to participate (either though independent testing, or lobbying by citizen action groups) in the weighing of the risks comes only after the technology has been brought to market. This process unfolded without public awareness or participation. The bent toward self-regulation by federal agencies is a common trend in biotechnology. There is a sense of urgency for communities around the world to be wary of a rush to development in the life sciences. As bioethics scholar Thomas Shannon responded when asked about self-regulation and the implementation of technologies, "the dice have already been rolled for you.[19]"

The ethical issues raised by a normative standard based on rights, are the issues most in need of further examination. The lack of opportunity for participation by individuals and communities is the clearest ethical dilemma inherent in this case. Monsanto is not the cause of this, nor should it be. The essential significance of the ethical evaluation of this particular process of commercialization is that a community should be aware of the risks and be able to participate in the evaluation of value based on those risks. It is not enough to say it is profitable, and that the unknown risks remain unseen. It is these issues of trust and liberty that fall under the heading of qualitative standards of value. Further, how is value assessed when all research is conducted by firms profiting from commercialization of the technology? If, in someway, our rights are diminished by the lack of autonomy in the process of the commercialization of the NewLeaf potato, how will our rights fare as this process intensifies with other products?

VI. CONCLUSION

The introduction and commercialization of transgenic crops provides both benefits and potentially significant costs. The costs and benefits of this emerging technology accrue to society at large as well as to those involved in the agricultural markets. Benefits include the environmental benefits resulting from lower use of pesticides and fuel as well as potentially lower food costs and the future possibility of more nutritious food products. Monsanto and other firms may profit from this industry's growth and this may provide additional

economic benefits to the country. The most significant potential cost is the unknown environmental impact of this technology. Other costs include the possible dependence of farmers on a single or a few suppliers of seed, potential negative health impacts[20], and costs related to regulation and oversight. How these costs and benefits are to be weighed and how regulation of this industry should proceed are important questions which have not been adequately addressed.

The interdisciplinary analysis of this emerging technology revealed the following concerns:

1. **the current inability to adequately assess environmental impact** - A great deal of research will be required before the potential costs can be adequately estimated. The recent study by Cornell University scientists which found a detrimental impact on Monarch butterflies from consumption of the pollen from Bt corn provides a warning of just how little is currently known. Failure to research adequately before proceeding may lead to some type of environmental disaster.
2. **the sufficiency of current regulatory requirements** – Is current regulation of this technology adequate given the unknown environmental impact? It appears that the current regulatory framework should be redesigned to better accommodate emerging technologies.
3. **the absence of consumer information** - There is very little information available to consumers. Given the unknown impact of this technology and the dearth of research, labeling and/or consumer information should be mandated so that consumers can choose whether or not they eat the output of such crops.
4. **the representation of corporate and federal ends** - Are firms like Monsanto adequately and accurately specifying goals? What should be the end of the federal government and regulatory agencies?
5. **the relevant standard of value** - Who will decide how to assess and weigh the relevant costs and benefits and what standards will be used?

It is recommended that these issues be addressed in a timely fashion due to the rapid growth in the development and commercialization of transgenic crops. Ideally, an interdisciplinary framework could be developed to address the environmental, economic, ethical, sociological and political implications of this quickly emerging technology.

ENDNOTES

[1] Refer to the Monsanto website at http://www.monsanto.com/ag/articles/irmhist.html

[2] As stated on the firm's website on 4/23/99 at http://www.monsanto.com/ag/articles/envrus.html

[3] As stated on the firm's website on 4/11/99 at http://www.naturemark.com/pages/April96_05.html

[4] From the agency's website on 5/12/99 at http://www.nal.usda.gov/bic/federal_biotech/news/epa.potato.595.html

[5] see New York Times 5-21-99 and Wall Street Journal page B2 5-20-99.

[6] *Incremental analysis* implies focusing on "new" costs and benefits attributed to the project/product which would not be realized under the status quo.

[7] These cash flows are discounted at a rate which incorporates the firm's cost of capital and the riskiness of the project under consideration.

[8] Were this not the case, the firm would not have introduced the product.

[9] the costs of raising new debt and equity capital.

[10] These costs represent pollution prevention and pollution clean up costs.

[11] Nottingham (1998) page 161.

[12] See Pollan 1998.

[13] From the Sierra Club's website on 4/5/99 at http://tamalpais.sierraclub.org/sierra/199701/jfprios3html also from http://www.ucusa.org/agriculture/gen.risks.environment.html

[14] From the FDA's website on 4/23/99 at http://vm.cfsan.fda.gov/~lrd/

[15] ibid.

[16]Susan Gilbert, "Synthetic Hormones in Milk Raises New Concerns," New York Times, 19 January, 1999, p. 12(F).

[17] Barnaby J. Feder, "Plant Sterility Research Inflames Debate on Biotechnology's Role in Farming," New York Times, 19 April, 1999, p, 13(F)

[18] As stated in the environmental section, the use of the BT toxin to such the degree as it is in the New Leaf, Monsanto is risking making that toxin ineffective.

[19] The author questioned Dr. Shannon on February 9, 1999.

[20] The impact of food products resulting from transgenic crops may affect human health. It is impossible to assess the impact at this point. [20] see New York Times 5-21-99 and Wall Street Journal page B2 5-20-99.

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