

THE BIOETHICS BEHIND ORGANIC AND GENETICALLY MODIFIED FOOD

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ABSTRACT

Over the years, there has been research done on many foods and their link with our health. This is one of the reasons why the demand for safe, high-quality and healthy foods are greater than before. People get paranoid when they hear stories about certain foods being linked to a cancer or health disease. There are also people who also question the safety of organic foods.

Some skeptics are asking whether there is any real difference between organic and non-organic foods. To guarantee something as being organic, certain standards have been put in place by the various organizations. These standards must be met by food - be it plant produce, meat or poultry - labeled as "organic". Organically grown foods, therefore, that are sold in stores and groceries should have organic Seal.

Of course, we can't always be too sure if people really are following that strictly implemented rule. So you may be wondering in what other ways we can determine organic food safety. We already know that organically grown foods are those grown without pesticides, artificial fertilizers, insecticides and other synthetic chemicals. But even organic farmers have admitted to using some fertilizers and herbicides sparingly. They use these chemicals as their second line of defense.

As consumers, we actually have the right to inspect, investigate even, the foods we put on our table. If we are pro organic, it wouldn't hurt to delve deeper as far as the source of these organic foods go. Some other factors which determine organic food safety are the following: 1) if the food is grown in soil whose humus content is increased through the addition of organic materials, 2) if the mineral content of the soil

where the food is grown was increased through the aid of natural mineral fertilizers.

Hence, this article addresses the bioethical issues in organic food and tries to address the issues pertaining to the genetically modified food. Emphasis will be given to the genetically modified food, as the world are debating the decision what facts are important to include to support their particular view point on the genetically modified foods.

INTRODUCTION

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

Food safety, quality and security are rising concerns both nationally and internationally. The hegemony of multinational agribusiness corporations promoting non-sustainable agriculture practices erodes both cultural and biological diversity; promotes cruel and environmentally damaging concentrated animal feeds operations supported by wholesale use of antibiotics, anabolic steroids, lives vaccines, pesticides and other drugs; and the planting of patented, genetically engineered/modified (GM) and hybrid crop varieties coupled with toxic agrichemical pesticides and fertilizers.

The validity of these concerns will be documented from a holistic veterinary, public and environmental

health perspective. The bioethical basis for the adoption of bio-regionally appropriate, sustainable, traditional, innovative, community supported and supporting, humane, socially just, and organically certified farming practices and marketing cooperatives will be detailed. In the face of climate change, rising oil and food prices, dwindling to conventional petrochemical based agribusiness is one of humanity's most urgent priorities.

The price of success in maintaining and promoting human population growth with decreased mortality rates and arguably longer life expectancies means more hungry mouths to feed and potential disease outbreaks to fend off. In more affluent and consumptive socioeconomic sectors around the world the diseases of affluence like obesity-diabetes/metabolic syndrome and cancer are part of the price of success. But the ever more impoverished and landless survivors of averted epidemics and famines, and the more affluent but disenchanting, together make the kindling of inter-tribal conflicts, war and acts of terrorism inevitable.

Uncoupled from any family planning and concerted population control, effective resource management and conservation, pollution control, sustainable agricultural practices and economics local and global, poverty, sickness and famine will be the legacy of human condition, passed on with increasing virulence from one generation to the next. Look at our history since the beginning of the industrial revolution, the age of reason, and the epoch of colonial imperialism, once nationalistic, now corporate and transnational. The fear - based progress and the success of the modern age envisioned by the military industrial technocracy generations ago, to essentially find ways to profit in the name of fighting famine and pestilence, two of our primal fears, by selling more drugs to save more people for what? And by selling more toxic chemicals to produce more food - for why, but mainly to fatten the cattle of the rich as Gandhi observed, now mean that there are ever more mouths to feed and souls to suffer.

The price of success in maintaining unhealthy concentrations of animals for human consumption and for other commercial purposes, made possible by the use of vaccines, antibiotics and other drugs has meant more resistant and harmful pathogens more and more being harmful to humans the so called zoonotic diseases. When computer along with the environmental impact of extensive livestock herding and grazing. CAFOs are the number one contributor to climate change; and a leader of the pack in ground

and surface water pollution and topsoil waste. Corporate profits notwithstanding, the misguided altruism of philanthropic agencies and individuals playing into the FDA system, giving \$ billions in drugs, food aid, and seed and livestock varieties unsuited for sustainable farming, is a major impediment to real progress in the human condition that is inseparable from environmental health and quality, and from the protection and restoration of both cultural and biological diversity.

ORGANIC IS SUPERIOR

Studies comparing the nutrient content of organic versus conventionally grown crops report significantly lower levels of potentially toxic aluminium, mercury and lead in the organically grown, that also had higher levels of many essential trace minerals and other nutrients, notably boron, calcium, chromium, copper, iodine, iron, lithium, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, silicon, sodium, sulfur, vanadium, and zinc. Also more vitamin C, bioflavonoids and other antioxidants, and less nitrate. Produce from animals fed organically grown feed are more nutritious than from CAFO raised animals fed manufactured food-and beverage industry byproducts and synthetic supplements and drugs. Organic beef has more healthful Omega 3 fatty acid content; organic chicken has more Vitamin E, Omega 3 and beta carotene, as has organic milk, that has also more antioxidants, lutein and zeaxanthin. Like holistic medicine, organic farming is systemically integrated within the physical parameters of general systems theory and quantum mechanics as they relate to dynamic living ecosystems, with the overlays of ethics, esthetics, and metaphysics. As 2008 President of the Pennsylvania Sustainable Agriculture Association's annual conference, dairy farmer Kim Seeley advised in his opening address, that we must all "Obey Nature's laws first before we accept man's laws."

Advances in the science and bioethics of alternative human and veterinary medicine and organic agriculture that are based on this new paradigm hold much promise and should be supported by the corporate sector as well as by the consumer-populace and governments around the world.

Since goals enjoy priority over the tools used to achieve them, they also determine the basic values of the tools. Organic agriculture's tools are pre-eminently those which are efficient in the use of resources, sustainable and safe. The organic farming community and genetically modified food must

determine its meaning of the notoriously slippery term "efficiency." Economists have faulted the "efficiency" of organic farming and genetically modified food based on a notion of pecuniary efficiency which often ignores such incredibly important resources as clean air and water. Pecuniary efficiency is the ratio of the money required to produce a product to the amount of money gained in selling it. A more appropriate ratio is the amount of valued and limited natural resources (including human labor) consumed in the production of food to the amount of human life, health, delight and well-being produced by the entire production process. In this ratio human labor, namely the opportunity and delight of peoples to be involved in the growth of their own food or to earn a wage doing it, may be as much a valued outcome as an input.

Organic is Efficient: Or can be. Because much of organic farming is still in innovative or experimental form, it may be terribly inefficient, especially in the use of the farmer's personal time and energy. Studies in innovation have demonstrated repeatedly that efficiency is attained only in the more mature stages of a productive process or organization. Conceptually, however, it is clear that to the extent that resources used in organic farming are renewable and actually renewed, it achieves an efficiency which so troubles economists that they suspect it of claiming immunity from the laws of thermodynamics. Academic economists who measure efficiencies of productive processes often arbitrarily ignore (or designate as "externalities") input costs such as damage to the environment or to the health of the laborers. They also can discount such output values as superior quality (e.g. superior taste and nutrition), community benefits (food security, employment) and long term values such as the retention and enrichment of a body of knowledge about a productive process to be passed to the next generation (e.g. the locally appropriate art of organic farming itself).

Organic is Sustainable: Here we refer to the sustainability of the tools used in organic farming, including the labor of the farmer and his/her helpers. The renewability of resources in the present promises a perpetual renewability, absent any plausible argument to the contrary. In general the prudent use of non-renewable resources is not a direct contradiction to sustainability in organic farming since the pace of innovation in developing renewable resources is more likely to match the exhaustion of non-renewable resources if that pace of exhaustion is slow. And organic farming has the greatest potential to slow that pace. Organic farming does not have to

violate the second law of thermodynamics.

Organic is Safe: This is the safety of its tools in their impact on workers, the environment and all living beings who share in it. Clearly its rejection of toxic chemicals and a careful use of organic fertilizers demonstrate organic farming's potential of being ideally safe.

THE SEVEN BIOETHICAL PRINCIPLES OF HUMANE, ORGANIC, SUSTAINABLE AGRICULTURE

1. Humane sustainable organic agriculture (HOSA) entails the production of domestic animal protein and fiber on the economically prudent basis of an ecologically sound animal husbandry and the wise and appropriate use of natural resources. Such husbandry aims to enhance or at least protect the natural biodiversity of indigenous wild plant and animal species, and does not result in environmental degradation and pollution.
2. HOSA is socially just, respecting human rights and interests, especially those of indigenous peoples and native, peasant, and family-farm cultures and traditions, since the preservation of cultural diversity has inherent value just as does the preservation and enhancement of natural biodiversity.
3. HOSA recognizes the connections between farm worker health and safety, consumer health and farm animal health and well-being. It respects the right of consumers of animal protein to wholesome and healthful produce derived from animals whose basic physiological, behavioral, and social needs and requirements, which are integral to their overall health and well-being, are fully satisfied by the methods of husbandry that are practiced. The use of veterinary drugs to maintain animal health and productivity is minimized by the adoption of humane animal husbandry practices, which in turn lowers consumer health risks. Productivity is linked with optimal animal welfare, which in turn is linked with the optimal carrying capacity of the environment and availability of renewable natural resources.
4. HOSA is bioregionally appropriate, if not autonomous, linking livestock and poultry production with ecologically sound, organic crop and forage production systems and/or environmentally sound rangeland management.
5. HOSA does not engage in the import or export

of any agricultural commodities, especially meat, wool, hides and animal feedstuffs, that have been produced at the expense of natural biodiversity and nonrenewable resources, and which undermine the rights and interests of local farmers and other indigenous people who practice sustainable, ecologically sound and socially just agriculture.

6. HOSA philosophically, is based upon the aphorism that we do not inherit the land, we borrow it from our children; it is ours only in sacred trust. This means, therefore, that HOSA entails respect and reverence for all life, its philosophy being Creation- or Earth-centered. It therefore embraces concern for the rights and interests of people, animals, and the environment. By so doing, it reconciles conflicting claims and concerns with the absolute right of all life to a whole and healthy environment and to equal and fair consideration.
7. HOSA provides the foundation for a community of hope and of a planetary democracy, whereby world peace, justice, and the integrity of Creation may be better assured. It leads to the recovery of culture, agri-culture being the cultivation of the land and the production of food based on a hallowing covenant that commits us to the sacred obligation of caring for the Earth by farming with less harm and eating with conscience.

BEWARE OF THE FDA'S 'LIFE SCIENCE'

Industrial agribusiness' indifference and corpus of denial of toward the suffering of intensively raised farm animals parallels the indifference toward all the harmful agrichemical pesticides and fertilizers that are now in our rain, food, drinking water, mothers' milk, and even amniotic fluids, and that have turned the countryside into a toxic chemical wasteland.

The infamy and hegemony of the multinational, oligopolistic corporations like Monsanto, Novartis, and Syngenta, that have named their business the 'Life Science' industry, pushing these agricultural inputs from seed and equipment to chemical fertilizers and pesticides onto developing countries, after decimating the once sustainable network of small farming and food processing operations in the Americas and Europe, and much of the rest of the industrial, 'developed' world, are a matter of public and historic record. This multinational industry essentially 'out-sources' agricultural production of commodity crops that it imports to the U.S. on the cheap from countries where poverty and corruption

often rampant, and where agricultural chemicals banned in the U.S. are widely used.

A major, global venture of this agribusiness industry has been to develop varieties of high-yield hybrid seeds, and more recently, genetically engineered seeds that are resistant to herbicides, produce their own pesticides, nutrient supplements for livestock, (like lysine that factory farmed pigs need a lot of), and even pharmaceutical drugs, created not to feed the hungry world, but for patent-protected, new and profitable commodities. During the 1980's these monopoly players---the petrochemical, pharmaceutical and life science conglomerates---rushed to buy up all independent seed companies and their seed stocks. Patented, high yield hybrid varieties are few in number, widely planted, and genetically uniform. The uniformity means genetic vulnerability to disease (same for the patented hybrid strains of commercially farmed animals). It is these highly inbred, hybrid varieties that are now being genetically engineered, and spreading world wide at the ever quickening pace of global monopoly.

The seed stocks of conventional and heirloom varieties are not being planted, are deteriorating in storage, and when planted are likely to be come contaminated by the pollen of genetically engineered crops from neighboring fields and counties. This accelerating decline in the genetic diversity of our major food, feed and fiber (and biomass and green manure) crops, coupled with the genetic disruption of plant genomes that the genetic engineering process can cause (see below) call for a total moratorium on any further plantings of GM seeds. As referenced below, there are enough documented research studies to negate the government-industry response to such a moratorium and community-linked GM-FREE Zones that would say that there is no scientific evidence of harm to animals or to human consumers, and that GM seeds are 'substantially equivalent' to conventional varieties.

The socially and politically disruptive and devastating human suffering soon to come, according to some agronomists, including Nobel laureate Norman Borlaug (whose crop 'improvement' genetic research has arguably caused more harm than good in the hands of agribusiness oligopolies) is from the Ug99 strain of black stem rust fungus on the world's wheat crop. This world wheat crop has so little genetic diversity now that there are few varieties and cultivars with any genetic resistance to this devastating disease that could mean global famine. Putting all our eggs in the same basket is never a wise investment.

This industry has convinced legislators that genetically engineered crops are safe, and 'substantially equivalent' to conventional varieties of food and animal feed crops. But the scientific evidence, and documented animal safety tests, point in the opposite direction. The US government even attempted to have genetically engineered seeds and foods included under the National Organic Standards. Genetically engineered crops of corn, soy and canola that are herbicide resistant, and corn that produces its own insecticidal poison called Bt, get into the human food chain, and are put into livestock feed and pet foods with the government's blessing: And quite probably to the demise of the honey bee and a large agricultural sector of bee-pollination dependent orchard and field crops.

Herbicide resistant crops actually absorb the herbicide that is repeatedly sprayed to kill competing weeds which we and the animals subsequently consume, along with whatever endogenous pesticides they have been genetically engineered to produce and have been treated with from seed to shelf.

As for the documented, peer-reviewed, published studies generally mandated by good judgment before the government's approving any novel food, such as a genetically engineered one, there were virtually none made public before and after the Life Science Industry developed and patented new GM foods and animal feeds and put them on the market. In spite of world wide public opposition, GM crops and seeds have respectively come to dominate and contaminate both conventional and organic food and industrial commodity crop markets. Arguably the worse case scenario of non-sustainable industrial agriculture is the U.S. government's commodity crop support program that subsidizes corn and soybean production--crops, now predominantly GM, that result in serious soil erosion and water pollution from agrichemicals-- at an estimated \$ 12.2 billion. Such subsidies are a disincentive to farmers to adopt more ecologically sound farming practices.

This industry, rising from its agribusiness commodity-crop, pet food, petrochemical fertilizer and pharmaceutical roots, became a star of investor hope in the World Trade Organization's new world order, and with free trade blessings. But its promises of better seeds and crops through genetic engineering that will benefit all, in spite of a now almost global domination, has caused far more harm to many than any good. The indirect and unforeseen costs far outweigh the short term benefits, which more and more governments and businesses are beginning to

realize. The Life Science industry employs scientists to defend GM crops and the genetic engineering and cloning of farm animals, like oil companies employed scientists to say that global warming/climate change was a myth. They gave billions to Universities, setting up Chairs, Departments, Fellowships and lucrative consultative and patent sharing agreements, along with the US Chamber of Commerce. One of the first government employed scientist to blow the whistle on the health risks and unproven safety of GM foods was immediately fired. He worked for the same British government laboratory that collaborated with China to develop genetically engineered wheat.

Alarming facts about genetically engineered foods

- " Animals have become seriously ill or died from Genetically Engineered (GE) foods
- " Hazardous genes from GE foods that you eat can become inserted into your own genes
- " An unexpected poison killed 37 persons eating a food supplement produced by GE bacteria. This disaster was not coincidental:
- " Top researchers confirm that genetic engineering is inherently unsafe and unpredictable. It may therefore generate unexpected harmful substances in GE food
- " Numerous studies have demonstrated that GE causes "non-target effects" in addition to the specific "desired effect". These effects are little understood, completely unpredictable and may be hazardous to the individual and the environment. This underscores the fundamental unsafety of genetic engineering.
- " The present procedure for assessing the safety of GE foods is not designed to detect unexpected substances
- " Therefore, harmful substances may appear in GE food approved as food
- " Still, GE foods are sold in most food stores in the US and in many other countries
- " In the US and Canada, they are not even labeled

Urgency

1. Family managed farming, organic and conventional, is in crisis in many areas because policy makers and the general public do not know what values would be lost if industrial agriculture swept the field of all family operations. Until recently organic agriculture has been almost exclusively family-sized operations. Many of the values located in organic farming will have an extremely difficult

time surviving in an industrial context. How to protect those values as organic operations scale up to sizes needed to supply public demand will be at most hit-and-miss without explicit agreement on those values and the guiding principles which preserve them. These are the real "soul" of organic farming.

2. When industrial firms co-opt the technical recipe which entitles their market product to organic certification, the neglect of a whole range of other values is almost, but not necessarily, certain. Public policy makers cannot be expected to know why this loss of the soul of organic farming is even important if its supporters have not formed a single voice and basic message to express it. The industrial operations are likely to continue the degree of commitment to environmental, labor, farm family, rural community, farm animal welfare values which has been traditional to their corporate culture. And successful family operations, in scaling up, will be strongly tempted to ape the corporate culture rather than to preserve that of their own tradition.
3. The industrial segment hoping to profit by new genetic technologies find the market for foods derived from genetically modified organisms (GMOs) threatened by the success of the principle of free choice in foods represented by the "organic section" in the grocery store. The GMO community has launched an open attack on the value of family farming. It needs to be defended explicitly.
4. If public policy makers can be guided by an

explicit, broadly supported consensus on the values and ethics of organic farming, so can the individual members of the organic farming community. It is extremely animating, encouraging, unifying and rededicating to review the rock-bottom values of a specific vocation, especially one which is arduous, innovative, under attack, and economically risky. A really solid answer to "Why am I doing this?" is a great thing.

Some of the issues concern to Indian BT Cotton and Brinjal

Some of the promoters has favoured Bt Brinjal which is having a much debate in India now a days as the promoter are saying that it will be beneficial to small farmers because it is insect resistant, increases yields, is more cost effective and will have minimal environmental impact. On the other hand, concerns about Bt Brinjal relate to its possible adverse impact on human health and bio-safety, livelihoods and biodiversity.

Some consultations are planned at seven locations in the country but some are looking for development and regulation process has caused a raging debate in the country on the relevance and need for a t brinjal. This debate has revolved and evolved around issues of its safety to human health, environment, farmers' seed rights, consumer choice etc. industry promoters as well as public and private sector scientist consider Bt Brinjal a breakthrough in agricultural research and development in India. On the other hand opponents including scientists, civil society groups, farmers unions and even some political parties argue that the risks far exceed the benefits.

Arguments made in favour of Bt Brinjal	Arguments made against Bt brinjal
Pest Management and environmental impacts	
<ul style="list-style-type: none"> • Brinjal cultivation involves usage of huge amount of pesticide. 60% of plant protection cost is for controlling fruits and shoot borer • Small and marginal farmers use 25-80 sprays of pesticides in Brinjal cultivation • In spite of the extensive use of chemical pesticides, the pest is difficult to control by the application of pesticides as the larvae are often hidden in the fruit and do not come in contact with the insecticides. Further the application of pesticides has to be critically timed by farmers in such a way so as to kill the larvae before they bore into shoots and fruits. • None of the botanical pesticides are expected to 	<ul style="list-style-type: none"> • Effective non-pesticide pest management and integrated pest management exists and is being practiced • The question of internal destruction of pests in dangerous to the health of the consumer. The integrated pest management systems, in combination with good farming practices, are the only healthy solution to good crops. A healthy farm ecosystem is the key to pest management. This includes selection of good seeds, appropriate irrigation systems and improving soil quality • The experiences with a few other GM crops released in India and other parts of the world especially Bt cotton

Reduced effectiveness of pesticides just as some populations of mosquitoes developed resistance to the now-banned pesticide DDT; many people are concerned that insects will become resistant to B.T. or other crops that have been genetically-modified to produce their own pesticides.

Gene transfer to non-target species Another concern is that crop plants engineered for herbicide tolerance and weeds will cross-breed, resulting in the transfer of the herbicide resistance genes from the crops into the weeds. These "superweeds" would then be herbicide tolerant as well. Other introduced genes may cross over into non-modified crops planted next to GM crops. The possibility of interbreeding is shown by the defense of farmers against lawsuits filed by Monsanto. The company has filed patent infringement lawsuits against farmers who may have harvested GM crops. Monsanto claims that the farmers obtained Monsanto-licensed GM seeds from an unknown source and did not pay royalties to Monsanto. The farmers claim that their unmodified crops were cross-pollinated from someone else's GM crops planted a field or two away. More investigation is needed to resolve this issue.

There are several possible solutions to the three problems mentioned above. Genes are exchanged between plants via pollen. Two ways to ensure that non-target species will not receive introduced genes from GM plants are to create GM plants that are male sterile (do not produce pollen) or to modify the GM plant so that the pollen does not contain the introduced gene. Cross-pollination would not occur, and if harmless insects such as monarch caterpillars were to eat pollen from GM plants, the caterpillars would survive.

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

HUMAN HEALTH RISKS

Allergenicity Many children have developed life-threatening allergies to peanuts and other foods.

There is a possibility that introducing a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals. A proposal to incorporate a gene from Brazil nuts into soybeans was abandoned because of the fear of causing unexpected allergic reactions. Extensive testing of GM foods may be required to avoid the possibility of harm to consumers with food allergies. Labeling of GM foods and food products will acquire new importance, which will be discussed later.

Unknown effects on human health there is a growing concern that introducing foreign genes into food plants may have an unexpected and negative impact on human health. A recent article published in *Lancet* examined the effects of GM potatoes on the digestive tract in rats. This study claimed that there were appreciable differences in the intestines of rats fed GM potatoes and rats fed unmodified potatoes. Yet critics say that this paper, like the monarch butterfly data, is flawed and does not hold up to scientific scrutiny. Moreover, the gene introduced into the potatoes was a snowdrop flower lectin, a substance known to be toxic to mammals. The scientists who created this variety of potato chose to use the lectin gene simply to test the methodology, and these potatoes were never intended for human or animal consumption.

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

ECONOMIC CONCERNS

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

Patent enforcement may also be difficult, as the contention of the farmers that they involuntarily grew Monsanto-engineered strains when their crops were cross-pollinated shows. One way to combat possible patent infringement is to introduce a "suicide gene" into GM plants. These plants would be viable for only

one growing season and would produce sterile seeds that do not germinate. Farmers would need to buy a fresh supply of seeds each year. However, this would be financially disastrous for farmers in third world countries who cannot afford to buy seed each year and traditionally set aside a portion of their harvest to plant in the next growing season. In an open letter to the public, Monsanto has pledged to abandon all research using this suicide gene technology.

REGULATION AND THE GOVERNMENT'S ROLE IN THIS PROCESS?

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

In Japan, the Ministry of Health and Welfare has announced that health testing of GM foods will be mandatory as of April 2001. Currently, testing of GM foods is voluntary. Japanese supermarkets are offering both GM foods and unmodified foods, and customers are beginning to show a strong preference for unmodified fruits and vegetables.

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

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

In Europe, anti-GM food protestors have been especially active. In the last few years Europe has experienced two major food scares: bovine spongiform encephalopathy (mad cow disease) in Great Britain and dioxin-tainted foods originating from Belgium. These food scares have undermined consumer confidence about the European food supply, and citizens are disinclined to trust government information about GM foods. In response to the public

outcry, Europe now requires mandatory food labeling of GM foods in stores, and the European Commission (EC) has established a 1% threshold for contamination of unmodified foods with GM food products⁴⁰.

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

The EPA conducts risk assessment studies on pesticides that could potentially cause harm to human health and the environment, and establishes tolerance and residue levels for pesticides. There are strict limits on the amount of pesticides that may be applied to crops during growth and production, as well as the amount that remains in the food after processing. Growers using pesticides must have a license for each pesticide and must follow the directions on the label to accord with the EPA's safety standards. Government inspectors may periodically visit farms and conduct investigations to ensure compliance. Violation of government regulations may result in steep fines, loss of license and even jail sentences. As an example the EPA regulatory approach, consider B.t. corn. The EPA has not established limits on residue levels in B.t. corn because the B.t. in the corn is not sprayed as a chemical pesticide but is a gene that is integrated into the genetic material of the corn itself. Growers must have a license from

the EPA for B.t corn, and the EPA has issued a letter for the 2000 growing season requiring farmers to plant 20% unmodified corn, and up to 50% unmodified corn in regions where cotton is also cultivated⁴¹. This planting strategy may help prevent insects from developing resistance to the B.t. pesticides as well as provide a refuge for non-target insects such as Monarch butterflies.

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

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

allow for this type of intervention.

HOW ARE GM FOODS LABELED?

Labeling of GM foods and food products is also a contentious issue. On the whole, agribusiness industries believe that labeling should be voluntary and influenced by the demands of the free market. If consumers show preference for labeled foods over non-labeled foods, then industry will have the incentive to regulate itself or risk alienating the customer. Consumer interest groups, on the other hand, are demanding mandatory labeling. People have the right to know what they are eating, argue the interest groups, and historically industry has proven itself to be unreliable at self-compliance with existing safety regulations. The FDA's current position on food labeling is governed by the Food, Drug and Cosmetic Act which is only concerned with food additives, not whole foods or food products that are considered "GRAS" - generally recognized as safe. The FDA contends that GM foods are substantially equivalent to non-GM foods, and therefore not subject to more stringent labeling. If all GM foods and food products are to be labeled, Congress must enact sweeping changes in the existing food labeling policy. There are many questions that must be answered if labeling of GM foods becomes mandatory. First, are consumers willing to absorb the cost of such an initiative? If the food production industry is required to label GM foods, factories will need to construct two separate processing streams and monitor the production lines accordingly. Farmers must be able to keep GM crops and non-GM crops from mixing during planting, harvesting and shipping. It is almost assured that industry will pass along these additional costs to consumers in the form of higher prices. Secondly, what are the acceptable limits of GM contamination in non-GM products? The EC has determined that 1% is an acceptable limit of cross-contamination, yet many consumer interest groups argue that only 0% is acceptable. Some companies such as Gerber baby foods⁴² and Frito-Lay⁴³ have pledged to avoid use of GM foods in any of their products. But who is going to monitor these companies for compliance and what is the penalty if they fail? Once again, the FDA does not have the resources to carry out testing to ensure compliance. What is the level of detectability of GM food cross-contamination? Scientists agree that current technology is unable to detect minute quantities of contamination, so ensuring 0% contamination using existing methodologies is not guaranteed. Yet researchers disagree on what level of contamination

really is detectable, especially in highly processed food products such as vegetable oils or breakfast cereals where the vegetables used to make these products have been pooled from many different sources. A 1% threshold may already be below current levels of detectability.

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

In January 2000, an international trade agreement for labeling GM foods was established^{44, 45}. More than 130 countries, including the US, the world's largest producer of GM foods, signed the agreement. The policy states that exporters must be required to label all GM foods and that importing countries have the right to judge for themselves the potential risks and reject GM foods, if they so choose. This new agreement may spur the U.S. government to resolve the domestic food labeling dilemma more rapidly.

CONCLUSION

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

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