

GENETICALLY MODIFIED FOODS AND PUBLIC HEALTH DEBATE: DESIGNING PROGRAMS TO MITIGATE RISKS

MOYE BONGYU

University of Dschang, Cameroon

GLORIA BILLINGSLEY

Walden University

MUSTAFA YOUNIS

EMEKA NWAGWU

Jackson State University

ABSTRACT

Human health is determined by both natural and artificial factors, amongst which what people consume is a critical variable. There is no consensus about the likely effects of the Genetically Modified foods/organisms (GMOs), but the fact remains that their effects on health are risky and highly unpredictable especially with the globalization tendency. The purpose of this study is to examine how the GMOs risks to public health can be reduced by policymakers enhancing public confidence in the GM foods. The Precaution Adoption Model (PAPM) has been selected to tackle this health problem. This model has been described and evaluation strategies analyzed on the basis of which success can be determined.

BACKGROUND AND INTRODUCTION

Human health is determined by both natural and artificial factors, amongst which what people consume is a critical variable. The proliferation of genetically modified (GM) food in the marketplace has resulted in heated public debate, scientific discussion and media coverage about their safety. Formerly, the use of selective breeding was commonplace but this was a sluggish and unreliable

method. Genetic engineering now allows scientists to insert specific genes into a plant or an animal without having to go through the trial and error process of selective breeding (Hoswtuffworks, 2004). Scientist first discovered the technique of genetic modification in the 1970s (Mitchell and Lee, 1998). GMOs were first introduced for commercial production in 1996 and since then their use has increased rapidly and by 2002 GE crops were planted in 145 million acres worldwide (McCullum, 2003).

GM foods are variously known as genetically engineered (GE) foods, genetically modified organisms (GMOs), genetically altered foods and “biotech foods.” GMOs are a special set of technologies that alter the genetic make up of living organisms as animals, plants or bacteria (Whitman, 2000; Heaf, 1999; Bren, 2003). GE is the process of taking genes from one strain of a plant, animal, or virus and inserting them into another, with the goal of reproducing characteristics of the original species in the receiving species (ASAP, 2004). The process of combining genes from different organisms is known as recombinant DNA technology, and the resulting organism is said to be “genetically modified”, “genetically engineered,” or “Transgenic.” (Genome, 2004). It means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (FAO, 2001). The Convention on Biological Diversity has defined biotechnology as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.” (MCCullum et al, 2003:319).

The standard approach to deal with the risks of the GMOs is called the “precautionary principle” that would consider the biotech produce unsafe until proven otherwise (Watts 2000). From this standpoint foods should not be put in the market until it is proven beyond reasonable doubt that they are safe (EBSCO, 2004). The Precaution

Adoption Model (PAPM) which involves the adoption of new precaution or the abandonment of a risky behavior that requires deliberate action (DiClemente, 2002) will be used to design a program to tackle this controversial health issue.

GMOS DEBATE

Scientists, food producers, consumers and public interest groups, governments and policy-makers are polarized on this issue. On the one hand, the GMO businesses and some scientists argue that the GMOs are the only way out against starvation in the 21st century. Because GMOs are cheaper, pest and drought resistant, herbicide tolerant, disease resistant, cold resistant and more nutritive (Whitman, 2000; Karen, 2001; DaSilva, 2002; Bren, 2003) they can ensure large-scale production to meet the skyrocketing demands. Transgenic soybeans, rice, sweet potato corn, cotton and canola are said to be herbicide and insecticide resistant. On the horizon are bananas that produce human vaccines against infectious diseases such as hepatitis B; fish that mature more quickly; fruit and nut trees that yield years earlier and plants that produce new plastics with unique properties (Genome, 2004).

On the other hand, environmental activists, religious organizations, public interest groups, professional organizations, some government officials and scientists have raised concern about the potential environmental hazards and safety of the GMOs. Unintended health impacts from GMOs are related to allergens, antibiotic resistance, decreased proteins and toxins. The concerns are that they might contain allergenic substances due to the introduction of new genes into the crops or animals. Many children in the U.S and Europe have developed life-threatening allergies to peanuts and other foods. It is also that the process involves the use of antibiotic-resistance

genes that can lead to the production of antibiotic-resistant bacterial strains that are resistant to available antibiotics. Another worry is that the GMOs may be less nutritious, and might contain lower amounts of phytoestrogens, which protect against heart disease and cancer (Bakshi, 2003; Whitman, 2000; EBSCO, 2004; Smith, 2003). Besides, while genetic engineering allows scientists to create eggs with less cholesterol, or meat with less fat, such advances may also pose risks to the environment and human health (Wright, 2002).

Also foodborne diseases are widespread and increasing public health problem. The WHO defines foodborne illnesses as diseases either toxic or infectious in nature, caused by the agents that enter the body through the ingestion of food. In industrialized countries, 30 per cent of people have had food related illness. In the U.S. for example, there are 76 million cases of foodborne illness each year, resulting in 325, 000 admissions to hospital and 5000 deaths. In Europe and Central Asia, 130 million people are affected each year by foodborne illness (Karen, 2001). Furthermore with the complexity of food production chain there are greater opportunities for contamination and the growth of pathogens, and many foodborne diseases that were contained within a small community are now taking global dimensions (Karen, 2001). Further, advanced countries have monopolized the GMO technology through strict patents and licensing agreements leading to marginalization of developing countries (Bakshi, 2003; McCullum et al, 2003).

The environmental impacts of introduced GMOs can be either ecological or genetic and may include: unintended effects on the dynamics of the population in the receiving environment as a result of impacts on non-target species, which may occur directly, or indirectly by changes in land use or farming practices; unintended effects on biogeochemistry, especially through impacts on soil

microbial populations that regulate the flow of nitrogen, phosphorus and essential elements; and the transfer of inserted genetic material to other domesticated or native populations, generally known as gene flow, through pollination, mixed mating, dispersal or microbial transfer (FAO, 2001).

PROBLEM STATEMENT

The confusing array of claims, counterclaims, scientific disagreement and misinterpretation of research that is present in the media has led to considerable confusion and suspicion of the populace (Whitman, 2000). The bovine spongiform encephalopathy (BSE) or what is commonly known as “mad cow disease” experience has led to more deterioration of the weight the masses give to assurances from politicians, scientists and food industry. In the US, consumers have been largely untroubled by the issue, and the divergence of opinion has created a trade issue between governments (AgBiotechNet, 2004).

Ultimately, the controversy surrounding GMOs comes down to whether they are adequately tested for safety. Given that the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) have had to call for the removal of previously approved pesticides from the market, some consumers are understandably concerned about the GMO safety. In addition, GMOs like all new technologies are instruments that can be used for good or bad in the same way that they can either be democratically managed to the benefit of the most needy or skewed to the advantage of specific groups that hold the vital political, economic and technological power.

There is no consensus about the likely effects of the GMO foods, but the fact remains that the effects on health are risky and highly unpredictable. The demands for deregulation have therefore increased concerns about the

safety of GM foods. When scientists move genes between organisms it is difficult to predict how the introduced genes will interact with existing ones or what possible effects on human or the environment will be (Mitchell and Lee, 1998; Pusztai, 2001)

Countries producing GMOs must therefore have clear and responsive regulatory policies and authoritative bodies to ensure that scientific risk analysis is carried out and that all possible safety measures are taken through testing before the release of biotechnology products, and afterward through close monitoring. More importantly, the human rights adequate food and democratic participation in debate and eventual decisions concerning the new technologies must be respected, as must the right to informed decision (FAO, 2001). The purpose of this study is to examine how programs can be established to reduce the GMOs risks to public health thus enhancing public confidence in the GM foods.

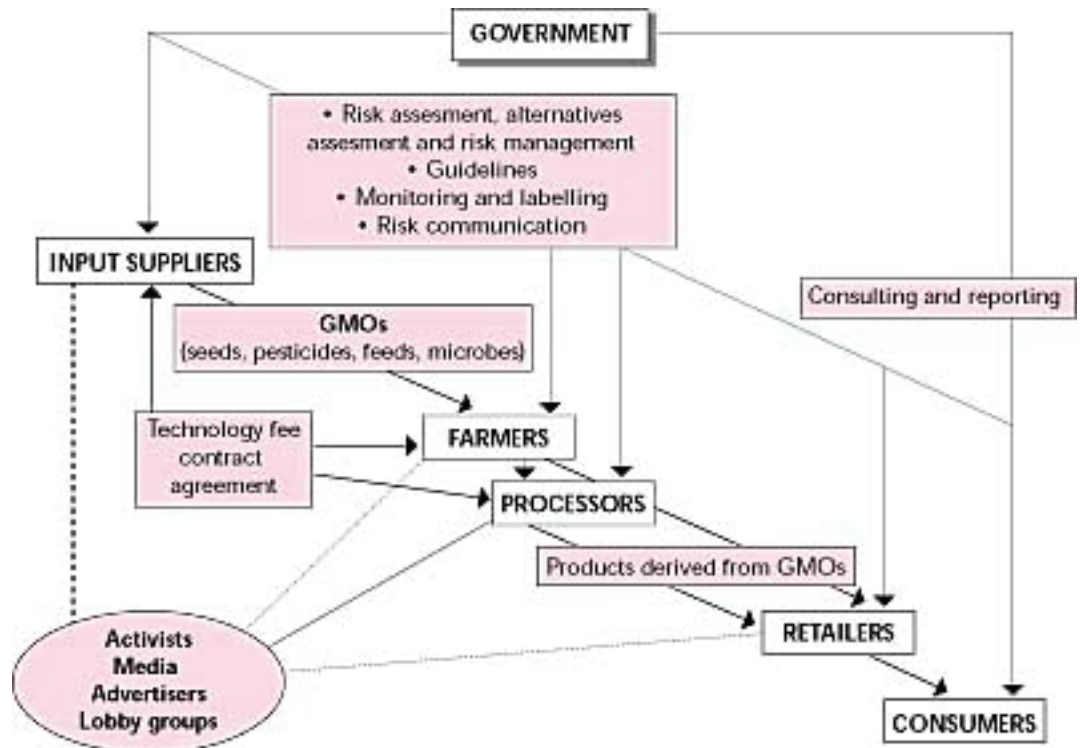
PROGRAM NEED AND DESIGN

Applying the Precaution Adoption Model (PAPM) GMOs risks are macro health problems, consequently; the type of protection is passive. In passive protection individuals are not required to make a behavioral change, this is instituted through policy, laws, or some other means. Unlike active participation that deals with micro level health problems and an individual behavioral change is needed to protect against the health risk (Issel, 2004).

GMOs in Food Chain

The agricultural production and distribution system can be thought of as a supply chain: 1) goods flow from producers (farmers) through processors and retailers to reach the consumer; 2) advertisers, activists, lobbyists and the media seek to influence choices made by people at each

stage of the supply chain; 3) government regulatory bodies assess the risks, set rules and monitor compliance; 4) producers of food, fish, fiber and forest products purchase inputs such as seeds, planting materials, agrochemicals, fertilizers, feed, fermentation promoters and machinery; 5) GMOs reach the public through markets(FAO, 2001). Below is a pictorial depiction of the food chain with various stakeholders playing specific roles:



Source: Adapted from Economic Impacts of Genetically Modified Foods on the Agric Sector: A Synthesis (FAO 2001)

Among the actors, at the macro level are the government agencies that are supposed to play the regulatory role. The government has always been accorded the role of regulating the activities of the private sector in order to avoid abuses.

Regulations

Historically, industry has proven unreliable at self-compliance to existing safety regulations. In the United States there are different agencies responsible for the regulation of different aspects of the GMOs: the Environmental protection Agency (EPA), the Food and Drug Administration (FDA) and the Department of Agriculture (USDA). The EPA conducts risk assessment studies on activities that could potentially cause harm to human health and the environment. The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives the FDA authority to regulate foods for humans and animals, including foods derived from bio-engineered plants (Morgan 2003). Under the Act, companies have a legal obligation to ensure that any food they sell meets the safety standards of the law. If a food does not meet the safety standards, the FDA has authority to take it off the market (Bren 2003). The USDA has many internal divisions that share the responsibility for assessing GM foods. Among these are: Animal Health and Plant Inspection Service (APHIS) which conducts 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. Simply put, the EPA evaluates GM plants for environmental safety, the USAD evaluates whether the plant is safe to grow, and the FDA evaluates whether the plant is safe to eat (Whitman, 2000).

The FDA does not mandate pre-market safety tests. However, it does review companies' voluntary GE/GM

toxicology, nutrition, and allergenicity testing results. A special FDA review is required only if the GM crop: produces unexpected genetic effects; has significantly higher levels of toxicants than present in other edible varieties of the same species; has significantly altered levels of important nutrients; contains new substances that differ significantly in composition from such substances currently found in food; contains proteins that cause an allergic response; and contains marker genes that could produce antibiotic resistance on people (ASAP, 2004). One doubts how this can be feasible and effective when the GMO companies determine the above factors.

At the international level, Codex Alimentarius, an international organization created by the WHO and the Food and Agriculture Organization of the United Nations, is the highest body on food standards. It sets global food safety reference standards, has also intensified international discussions on food safety. The United Nations has started to issue regular food safety awareness bulletins and has been engaged in more activities about food safety (Mitchell, 1998). Codex Alimentarius Commission addressed the risks to public health associated to the consumption of foods derived from biotechnology by establishing a Task Force (the Ad Hoc Intergovernmental Task Force of Foods Derived from Biotechnology) in 1999 to deal with this issue (WHO, 2004). But in spite of the national and international efforts, the problem has not been solved, consequently the need for more effective interventions.

Justification of Need

The global debate on how to regulate the GE foods encompasses a multitude of issues: 1) food safety risks, 2) environmental risks, 3) who participates in risk analysis and risk decision-making, and 5) labeling and the consumers' rights to know what they consume

(McCullum, 2003). All of these issues are the determinants and the contributing or mitigating factors of the health risks of GMOs.

Some consumers and advocacy groups urge mandatory labeling that discloses the use of genetic engineering. Others advocate more stringent testing of these products before marketing. Still others want a ban on all genetically engineered foods (Bren, 2003)

In January 2003, the nonprofit Center for Science in the Public Interest (CSPI) released a report concluding that the FDA's safety review process for the regulation of GMOs needs to be strengthened in order to improve public confidence about their safety. CSPI recommended that Congress should provide the FDA with legal authority for mandatory review of the safety and approval of GE crops, including the authority to require any data it deems necessary to conduct a thorough food safety assessment. The CSPI also recommended that the FDA 1) develop detailed safety standards and testing guidelines, 2) require developers to submit complete details about their testing methods and the actual data from the safety tests 3) establish an approval process that is transparent and provides the public with an opportunity to comment on the submissions, 4) perform and make available to the public detailed assessments of commercialized GE foods, 5) reassess the safety of commercialized GE foods if new safety concerns are recognized or new tests become available, and 6) ask developers of current GE foods to provide additional data to give greater assurance of safety. Finally, when the FDA lacks authority to implement any of the recommendations, Congress should pass legislation (McCullum, 2003).

In response to the upswelling of public concern, the FDA held three open meetings in Chicago, Washington, D.C., and Oakland, to solicit public opinions and begin the process of establishing a new regulatory procedure for

government approval of GMOs. In Japan, the Ministry of Health and Welfare announced that the testing of GM foods would be mandatory as of April 2001. Some states in Brazil have banned GM foods entirely, and the Brazilian Institute for the Defense of Customers, in collaboration with Greenpeace, has filed suit to prevent importation of GM crops (Whitman, 2000). But the World Trade Organization has stopped countries from banning modified food, even when there have been referenda or mass protests and petitions. And the US government has threatened trade war measures against Europe over import restrictions (Mitchell and Lee, 1998)

Companies as well as, public institutions, including USDA all have GMO research programs. But most of the research is oriented towards market search, corporate objectives and the objectives of the funding groups. It is not unusual for organizations to interpret scientific data to suit their needs or selectively promote studies that further their political positions. For example, the National Research Council recently came under fire for the 2000 research paper on GMOs when it was learned that an individual associated with the study left the Council to become the executive director for the Biotechnological Industry Organization (ASAP, 2004). As a matter of fact, less emphasis is given the safety issues. As the health issue needs a preventive intervention, the Precautionary Adoption Process Model (PAPM) seems to be the most apt to solve this problem.

PAPM THEORETICAL FRAMEWORK

It should be re-iterated that the adoption of a precaution or the abandonment of a risky behavior requires deliberate action (DiClemente, 2002). This model can be applied at the macro level to see how the institutions adopt decisions or policies to deal with health issues. At the core

of this theory is the cost-benefit decision-making perspective, which assumes that policymakers weigh the expected benefits against the costs and adopt the precaution if the balance appears favorable (Weinstein, 1988).

PAPM identifies seven stages along the full path from ignorance to action (DiClemente, 2002). At some initial point in time people are unaware of the health issue (Stage 1). The consumers who are not aware of the risks of GMOs, as is generally the case in the developing countries fall within this group of people at this stage. When people first learn about this issue, they are no longer unaware, but they are not necessarily engaged by it either (Stage 2). This implies those who are aware of the probable risks of the GMOs but remain indifferent or passive about that. People who reach the decision making stage (stage 3) have become engaged by the issue and are considering their response. In the case of the GMOs, these are those who are actively involved about the GMOs and are fighting for or against legislation or other preventive measures to be taken. These include the GMO corporations, consumer activists groups, FDA, scientists groups, foundations and so on. This decision process can result in one of two options. If the decision is to take no action, the precaution adoption process ends there (Stage 4). But if, people decide to adopt precaution (stage 5), the next step is to initiate behavior (stage 6). As regards the GMOs this will imply the adoption of precautionary measures and their implementation. Finally, if appropriate, the behavior has to be maintained over time (stage 7). This implies constant monitoring to ensure that the measures taken to avoid the health risks are being followed (Weinstein and Rothman, 1998).

The precautionary model has been fashionable in dealing with risky health situations. According to the UN Environmental program, “when an activity raises threats of harm to human health or the environment, precautionary

measures should be taken even if some cause and effect relationships are not fully established”(UN, 2001). The four components necessary to achieve its implementation include: 1) taking preventive action in the face of uncertainty; 2) shifting the burden of proof to the proponents of the activity; 3) exploring wide range of alternatives to possible harmful actions, and 4) increasing public participation in decision-making (Kriebel 2001). As noted by Applegate, “properly construed, this principle defines a process for taking environment and health protective actions, while the dangers of not taking such actions remain uncertain...It seeks to anticipate the risks of new and existing technologies so as to avoid or minimize them” (McCullum et al, 2003).

The precautionary principle has been criticized for being overly vague. Critics also argue that the current regulatory processes are already precautionary and this principle is not scientifically sound because it advocates making decisions without adequate scientific justification. Worse still, if it were implemented, the precautionary principle would stifle innovation by requiring proof of safety before new technologies could be introduced (Kriebel et al, 2001). Taking all into consideration, a group of scientists have argued that the precautionary principle is not only good science, it is also good economics at least for four reasons: 1) precautionary action benefit workers, 2) precautionary action does not impose damaging cost on the industry, 3) precautionary policies can stimulate technological innovation, and 4) economic logic supports timely action to avoid substantial health and environmental costs (McCullum et al, 2003)

Target Population

The GMOs have global presence. All Consumers of GMOs worldwide are the target of this study. The poor and the uninformed consumers are the most vulnerable because

they do not know the health risks they incur by eating these types of foods. The consumers who are disorganized and generally ill informed have to be protected against the aggressive and rich GMO companies that can use every means possible to ensure that they maximize their profits. Much care is not therefore taken to protect the powerless consumers against unsafe food that can be detrimental to their health. It is hoped that the proposed intervention programs will protect the citizens from these health risks.

Goals, Objective and Strategies

There should be pre-release testing (especially when limited to laboratories or computer models), mandatory pre-market approval and in addition and when necessary accompanied by post- release monitoring. In the form of a logic model, the program goals can be articulated with the specific means of achieving these goals. The ultimate goal of the program is to prevent the consumers from falling prey to the risks of GMOs such as allergic substances, antibiotic resistance genes and cancer. The strategies to accomplish this goal include risk analysis, community participation, labeling and the equivalence approach.

Risk Analysis

Due to the relationships that exist between safety of GMOs and the implications on consumers' health, FAO continues to stress the importance of accurate risk management and effective risk communication. Regulatory agencies formulate their standards according to science-based assessment of risks. Many consider that decision-making based on science is the only objective way to set policy in a world of diverse opinions, values and interests (FAO, 2001). Risk analysis is a process consisting of three components: risk assessment, risk management, and risk communication.

Risk Assessment is a scientifically based process consisting of the following steps: 1) hazard identification,

2) hazard characterization; 3) exposure assessment; and 4) risk characterization. Hazards, and the chance of those hazards occurring, are thereby studied and models constructed to predict risk. Risk in the context of safety includes two elements: 1) hazard, an intrinsic factor that indicates the damage if the event occurs; and 2) the probability or chance that the event will occur (FAO, 2001)

According to a CODEX report, risk management is the process of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the protection of consumers' health and for the promotion of fair trade practices as well as, if necessary, selecting appropriate prevention and control options (CODEX, 1999).

Risk communication is the interactive exchange of information and opinions among assessors, risk managers, consumers, industry, the academic community and other interested parties through out the risk analysis (FAO, 2001). The results communicated have to be in simple and various types of languages for the consumers to understand. The informants are therefore expected to be gender, age and culturally competent.

Involvement of Stakeholders

The consumers, the target population should take part in all levels of the program design. Mindful of its delicate nature, a participatory approach for the risk analysis and decision making of health issues is highly recommended. This has been commonplace in countries like Denmark, Norway, the United Kingdom and Japan, but very limited in the United States. The right to democratic participation addresses the need for justice and equity, which are of major concern in the context of GMO related decisions. Widely communicated, accurate and objective assessments of the benefits and risks associated with the use of genetic technologies should involve all stakeholders.

Principles of justice may include gender equality, need, accountability, liability, and fair democratic procedures (FAO, 2001). Consumers need to be more involved in local, national and international debates and policy guidance of GMOS. Presently the available fora for discussions are few and elitist which leads to lack of accountability.

There is the need for more opportunities enabling the exchange of information among scientists, corporate representatives, policy-makers and the public at large. This has to include the members of the advisory committees set up for the formulation of laws, regulations and policies that would help to ensure that their perspectives were fairly represented. Routine and integral national and international forums have to be created to enable the citizens' to voice their views on analyzing of the GMO issues and making of public decisions. The states have to protect the citizens' capacity to participate, especially when other participants are more powerful, assertive and aggressive (FAO, 2001). This implies the provision of public resources to ensure that those forums take place in a spirit of fairness and justice.

In line with the systems approach, probable risks of the GMOs should be analyzed with thorough knowledge of the economic, political and social contexts.

Labeling of GM Foods

Labeling is a public policy technique that ensures consumers education and the right to know about what they are consuming. Many European countries, Japan, Australia, New Zealand, South Korea and China, already require GE products to be labeled (ASAP, 2004). The FDA reluctantly in 2001 proposed simply voluntary labeling of the GE foods. The arguments are that labeling is misleading, first because there is cross-pollination between GE and non-GE foods and secondly, it creates a misconception that the non-GE foods are of superior

quality (McCullum et al, 2003). The food labels have to be designed to clearly convey accurate information about the product in simple language for everyone to understand. The greatest challenge to labeling therefore is, how to educate and inform the public without damaging the public trust and causing harm or fear of GM foods (Whitman, 2000). Any significant differences between bio-engineered food and its conventional counterpart have to be disclosed in the labeling. These would include differences in nutritional properties, the presence of an allergen that consumers will not expect in the food, or any property that would require different handling, storage, cooking or preservation (Bren, 2003). Of recent the “Biotech Label Law” has been introduced in the European Union, that mandates labeling food products and animal feed containing more than 0.9 per cent of GMOs. Such laws create a more educated consumer who has the opportunity to turn to healthier alternatives such as olive oil and make informed decisions after considering the inherent risks of certain foods (News Medical, 2004).

Substantial Equivalent Approach

One approach that is used in assessing risks of GMOs is derived from substantial equivalence which considers whether the GM food is as safe as its traditional counterpart, where such counterpart exists. Such an assessment requires an integrated and stepwise, case-by-case approach focusing on: identity, source and composition; toxicity, effects of processing and cooking; the transformation process, the DNA itself and protein expression products of the introduced DNA; effects on function; potential toxicity, potential allergenicity and possible secondary effect and potential dietary impact of the GM food. If the GMO-derived food is judged to be substantially equivalent to its conventional counterpart,

then it is considered to be safe as the counterpart. If not, then, further tests are conducted (FAO, 2001).

The GM food should be submitted to rigorous testing for untoward effects before it is released to the public (Beaver, 1999) through toxicology/nutritional and chemical analysis and methods such as mRNA fingerprinting, proteomics and secondary metabolite profiling. These novel methods are needed to screen for harmful consequences on health and to pinpoint the risks before the food enters the chain (Pusztai, 2001).

In addition to its own scientists who evaluate safety data, the FDA looks for outside experts such as the National Academy of Science (NAS), for advice on food safety assessments. In response to the public concern about the long-term effects of consuming GM foods, the FDA, USDA and EPA requested assistance from the NAS. The NAS has currently been conducting studies on the potential unintended health effects of the genetically engineered foods. More than 50 biotech foods have been evaluated by the FDA and found to be as safe as conventional food, including: canola oil, corn, cottonseed oil, papaya, soybeans, potatoes, squash, sweet beets, sweet corn and tomatoes (Bren 2003). But there is no guarantee that the producers will not change their methods.

IMPLEMENTATION BARRIERS

One use of the PAPM is to help identify barriers that inhibit preventive action (DiClemente, 2002). In America for instance, anti-statism has been prevalent and government regulation has been seen as an intrusion to individual rights and freedoms. More so, many people lack confidence in government agencies and believe that the government always works for businesses. This fear was accentuated by the Tuskegee affair where people were used as guinea pigs.

More so, governments have always succumbed to the economic interests. The result is that adopting programs, making policies and putting them into practice become driven by economic interests. (Heaf, 2004). Biotechnology is big business and enormous potential profits are at stake. Monsanto's shareholders have seen a four fold increase in their shares since 1994, and were unhappy when the company reported profits of only 294 million dollars on sales of 7.5 billion dollars (Mitchell and Lee, 1998). Thus this company as well as others can use their financial power to avoid any regulatory policies. Companies like Monsanto, Dupont and Novartis spend billions on the research and production of GM foods. The Rowett Research institute, like many scientific establishments, has become increasingly dependent on the financial support of these companies because of government cuts. The intense competition for markets and to realize profits on investments undermines the possibility of planning in cooperative and systematic way (Mitchell and Lee, 1998). Another dangerous situation for prevention is the trend for the domination of the GMO market by few multinational corporations.

Consumers do not all have the access to information and resources to make informed decisions about the GMOs. Most people especially in the developing countries lack education and consequently cannot effectively participate in the GMO debates and cannot take advantage of the policies adopted. Experts have the ethical obligation to present information in the way that can be understood by laypersons. There should therefore be the education of the general public in genetic technologies and principles.

In addition there exist problems of having trained personnel, equipment and financial resources to deal with this health issue. The personnel working for the regulatory agencies have to be well paid and modern equipments have to be put at their disposal so that they can be better able to

analyze the probable risks of the GM foods. If not there is the risk that they will fall prey to the pressures of the GMO companies that as aforementioned have enormous resources.

EVALUATION STRATEGIES

Selected GM traits have to be evaluated against the principle of social, economic and ecological sustainability, including the potential of modern agricultural technology to enhance global food security (McCullum, 2003). The GMOs will also be evaluated in the broader political, social and economic contexts of the world today because the gravity of the risk will depend on the prevailing situation.

Evaluation Method

The summative evaluation, specifically of the program impact will be used. Program impact is assessed by the ability of an intervention to produce the intended outcomes and to verify the cause-effect relationships between the intervention inputs and program outcomes (Timmerick, 2002; Kettner et al, 1999). The process evaluation often associated with the summative evaluation, can be used to access the administrative activities of the regulatory agencies especially the involvement of the stakeholders and the objectivity of information given and the seriousness of preventive measures.

Finally, the outcome evaluation will be used to assess the final results of program activities- the consequences of the program management. The fundamental questions here are: What are the changes seen in the risk factors? What measurable changes can be identified? (Timmerick, 2002). This implies asking the question whether there have been any changes in the risk factors of the GMOs. As a corollary, the impact evaluation will focus on comparing the GMO program outcomes with

an estimate of what would have happened in the absence of the program.

As regards the evaluation design, the projected trend line versus post-program comparisons and the comparisons between jurisdictions with or without programs can be used. In the first case the estimates of the preprogram trends of GMO risks are compared with what actually happened in the society after the intervention programs were implemented. The difference between the projections based on the pre-program trends and the actual post-program data can be attributed to the program (Dye 2000). This design can effectively measure the impact of the intervening programs for GMO safety, but there is the problem of collecting data over a long period of time and determining the non-spuriousness of the relationships.

From another perspective, there can be a comparison of countries where intervening efforts have been made to mitigate the MGO risks and those where lesser efforts have been put into place. For example, in recent times there have been more efforts within the European Union to ensure the safety of GMO foods than in the USA. If the probable GMO risks diminish within the countries of the European Union, then one can rationally conclude that this might be due to the programs impacts.

This evaluation should be linked to the feedback process by the systems model. This approach relies on the on four processes: inputs, process, outputs and feedback (Timmerick, 2002). Feedback is ongoing and implies return to each of the aspects of the reduction of the GMO risks program to ensure that everything is working as previewed. Post market monitoring can be necessary to ensure that the GMO businesses are not violating the rules of the game and in the case of any violations the business owners have to be taken to the courts of law for sanctions that may range from the payment of damages to closure.

Success Determination

From the community perspective, the intervention of diverse stakeholders especially the consumers in the GMO debates and the transparency of these debates can be seen as an indication of success. If the consumers are more informed about the GMOs so that they can make informed decisions and have more confidence in these foods this will be seen as success.

The government agencies would have recorded some success if they can establish verification procedures, establish documentation and record keeping and monitoring systems (Morgan, 2003). There will be more to their credit if they can withstand the pressure from the GMO businesses whose ultimate goal is to maximize profits.

Finally, if the GMOs can restore the confidence of the consumers so that there will be an increase in the demand of their products, consequently increase in profits, then that will be fine. In a nutshell, what is needed is the cooperation of the stakeholders for the benefit of all (win-win situation). In this situation there will be the reconciliation of profit needs of the GMOs, and the food and safety needs of the consumers.

Data to be collected

Community-level interventions require the use of community level data (Issel 2004), which should be from diverse sources. Primary data will be collected through interviews, surveys, community forums and focus groups (of the GMO businesses, government agencies, activists and consumers). By getting information from both the advocates and proponents of the GM foods, it will be easy to reach at objective conclusions.

Information will be needed about the number of GM foods, the number and frequency of the debates about the GM foods, the number of labeled GM foods and the number of people with related health problems. Data

should also be collected and analyzed on the various violations of the safety standards and the sanctions imputed by the authorities.

CONCLUSION

GMOs are not as bad as their detractors think, they are not as good as their advocates believe either. There is nothing inherently evil or Frankenstein-like about the genetically modified foods. Technologies for GM foods offer dramatic promise for meeting some areas of greatest challenge for the 21st century. But like all new technologies, they also pose some risks both known and unknown (Genome, 2004). It is difficult however to make informed decisions about GMOs when there is little information about their safety (Pusztai, 2001). Regulatory policies and programs are needed to ensure that modern biotechnology is in line with the principles of social, economic and ecological sustainability and ethics. In the future, with galloping population growth and diminishing productivity, the GMOs will be inevitable, and the problem should be at the level of controlling them so as to avoid health risks.

REFERENCES

- AgbiotechNet. Safety of Genetically modified Foods.<http://www.agbiotechnet.com>
- Agroecology/Sustainable Agriculture P (ASAP). 2002. GMOs: Looking at both Sides of the Controversy.<http://www.aces.uiuc.edu>

- Applegate, J.2001. "The Prometheus Principle the Precautionary Principle to harmonize the Regulation of Genetically Modified Organisms." *Indiana Journal of Global Legal Studies*.9, 207-264
- Bakshi, Anita. 2003. "Potential Adverse Health effects of genetically modified Crops." *Journal of Toxicology & Environmental Health*, Vol. 6, Issue 3.
- Bren, Linda. 2003. Genetic Engineering: The Future of Foods? *FDA Consumer*, Vol 37, Issue 6.
- DaSilva, Edgar J. 2002. GMOs and Development. *Journal of Biotechnology*
- DiClemente, Ralph J.; Crosby, Richard A.; and Kegler, Michelle C. eds. 2002. *Emerging Theories in Health Promotion Practice and Research: Strategies for improving Public Health*. San Francisco: Jossey Bass
- Dye, Thomas R. 2002. *Understanding Public Policy*. 10th ed. New Jersey: Upper Saddle River.
- EBSCO.2004. Our Genetically modified Future. *National Health Review*, Issue 84
- FAO. Genetically Modified Organisms, Consumers, Food Safety and the Environment. 2001.<http://www.fao.org>
- Genome. What are Genetically Modified Foods? Human Genome Project Information. <http://www.ornl.gov>

Heaf, David J. 2004. Genetically modified foods: Crisis or opportunity? Conflicting Pre-Scientific World Views, Ethical Action in Freedom and the Form of Society. <http://www.heaf.freeuk.com>

Howstuffworks.What are Genetically modified Foods?
<http://home.howstuffworks.com>

Issel, Michele L. 2004. Health Program Planning and Evaluation: A Systematic Approach for Community Health.Boston: Jones and Bartlett Publishers.

Karen, Birchard. 2001. "Europe Tackles Consumers fears Over Food Safety." Lancet, Vol 357, Issue 9264.

Kettner, Peter M; Moroney, Robert M.; and martin, Lawrence L. 1999. Designing and Managing Programs: An Effectiveness-based Approach. New Delphi: Sage Publications.

Kriebel, Dickner D. 2001. "Reenergizing Public Health Through Precaution." American Journal of Public Health. 91, 1351-1365

Kriebel, Dickner D.; Epstein R. 2001. "The Precautionary Principle in Environmental Science." Environmental Health Perspectives, 874-876.

MuCullum, Christine; Benbrook, Charles; Knowles, Lori; Roberts, Susan and Schryver, Tamara. 2003. "Application of Modern Biotechnology to Food and Agriculture: Food Systems Perspective." Journal of Nutrition Education Behavior. 35, 319-332.

Organic Consumers Association. New Studies Set Off Alarms on Health Hazards of GMOs. <http://organicconsumers.org>.

Pusztai, Arpad. 2001. "Genetically modified Foods: Are they a Risk to Human/Animal Health?" American Institute of biological sciences

Mitchelle, Paul and Lee, Keith. 1998. Concern Grows Over Genetically Modified Food. World Socialist Web (wsws.org).

Smith, Jeffery M. 2003. "Genetically Modified Foods Have Serious Health Risks: The Science behind the Anti-biotech Movement." Conscious Choice

Social Issues Research Center. 2004. Genetically Modified foods. St. Clements, Oxford, United Kingdom.

Timmreck, Thomas C. 2002. Planning, Program Development, and Evaluation: A handbook for Health Promotion, Aging, and Health Services. Boston: Jones and Bartlett Publishers.

United Nations Environmental Program. 2001. Stockholm Convention on Persistent Organic pollutants, May 22.

Watts, Jonathan. 2000. Targets now set by the G8 group to reduce "Diseases of poverty" Lancet, Vol 356, Issue 9227.

Weinstein, Neil D. 1998. "The Precaution Adoption Process." Health Psychology. 7(4), 355-386)

- Weinstein, Neil D. and Rothman, Alexander J. 1998. "Stage Theories of Health Behavior: Conceptual and Methodological Issues." *Health Psychology*. Vol. 17, No. 3, 290-299.
- Whitman, Deborah B. 2000. "Genetically modified Foods: Harmful or Helpful?" *Cambridge Health Abstracts*.
- World health Organization (WHO). 2004. WHO/Europe Seminar: Release of GMOs in the Environment: Is it a health hazard? Rome, Italy, 7-9 September 2000.
- Wright, Catherine. 2002. "Health Risk Identified for Genetically Engineered Meat." *Nation's Health*, Vol 32, Issue 8