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Genetic engineering on microorganism: the ecological and bioethical implications

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ABSTRACT

With the increasing global population, the idea of Genetic Engineering on microorganism has greatly been embraced by man to improve on his well-being. However, the increasing use of the genetically modified products calls for general concern. There exist so many schools of thoughts on the ethical and ecological implications of this technique and its products. This paper describes the historical evolution of genetic engineering, the reason and process by which genetically modified microorganism are produced and their application in chemical, agro-alimentary industries, medicine, agriculture, the environment and research. It further describes the bioethical implications and the risk posed by genetically modified microorganisms on the environment and human health. As a means to search for solution against the problems raised, the paper explains how risk could be assessed, monitored and managed taking into consideration all the ethical values of man and his environment so as to minimize harm.

Keywords: Genetic Engineering, Genetically Modified Microorganism, Bioethics, Environment, Risk, Health.

1. Introduction

For thousands of years, man has purposely manipulated the evolution of other organisms; farmers have used selective breeding to improve their livestock and crops. As a result, we have cows that produce more milk, hens that lay more eggs, sheep with better wool, and disease-resistant plants with higher productivity. To widen his imagination, man has furthered his quest for knowledge through biological manipulation and technology to develop Genetically Modified Organisms (GMO).

With the increasing global population, the idea of Genetic Engineering (GE) has greatly been embraced by man to improve on his well-being. Its application spans a broad array of domains such as agro-alimentary, chemical and pharmaceutical industries, agriculture, and even in environmental protection [1]. This has been through the use of Genetically Modified microorganisms (GMM) particularly bacteria and fungi due to their small size and ease of manipulation. Though products of GMM have largely been accepted and consumed by the population, their utilization remains questionable as regards the role and implication in the ecosystem. This has raised ethical concerns relating to dignity, respect for person, consequences and justice of their utilization and acceptability.

In order to clearly grasp the extent to which GMM are important to man, their ethical and ecological implications, it is necessary, to define them and explain the context in which they are used, specify the possible risks associated with their environment, the ethical questions surrounding them, and finally suggest possible ways to solve and manage any resultant problem.

2. History of Genetic Engineering

As early as 1865, the idea of genetics was raised by Mendel while monitoring the inheritance pattern of organisms from one generation to another [2]. It took about 35 years for other researchers to grasp its significance until the 1900s where there was a steady progress in understanding the genetic make-up of all living things ranging from microorganism to humans. In 1920, a major step in human control over genetic traits was taken when Muller and Stadler discovered that radiation can induce mutations in animals and plants.

Later in 1930 and 1949s, several new methods of chromosome and gene manipulation were discovered, such as the use of colchicine to achieve a doubling in chromosome number and other techniques to induce gene mutations using chemicals such as nitrogen mustard and ethyl methane sulphonate [3]. This was closely followed by the discovery of double helix structure of DNA (deoxyribonucleic acid), the chemical substance of heredity, by James Watson and Francis Crick in 1953. Since then, there was an explosive progress in the field of genetics.

In the mid-1970s, the public of the Western world was astonished to learn that scientists had recently invented ways to move pieces of genetic material, the very blueprint of life, from one species to another [3]). The earliest of such discoveries was the transfer of a gene for antibiotic resistance from certain bacteria species to *Escherichia coli* by researcher at Stanford University in 1975 [4]. This introduced the era of genetic engineering so-called "genetic revolution" which extended from bacteria to plants, mammals and ultimately human cells [3, 4]. Supporters and opponents of genetic engineering were just as divided about the basic ethics or morality of the technology as they were about its practical implications. This first wave of concern died down during the 1980s as genetically modified microorganisms were released into the environment and no disasters occurred [3]. Guidelines were later established by the American National Institute of Health to control possible hazardous effects of GMOs [4]. On the contrary, these guidelines were progressively weakened in subsequent years, despite substantial records of abuses, accidental releases and other "minor" scandals. For example, a researcher at Montana State University introduced the Dutch elm disease into a new area while testing the toxicity of genetically modified bacteria on fungi [4].

As the twenty-first century begins, genetic engineering has taken over the traditional biotechnology industry so completely that many people now use the terms genetic engineering and biotechnology interchangeably. This raises the question "is the world safe using genetically engineered products?"

3. What is genetic engineering?

It has been very difficult for people to clearly differentiate between genetic engineering and biotechnology as they are usually used interchangeably. Genetic engineering (GE) as defined by the American dictionary of history in encyclopedia is the deliberate manipulation of an organism's genetic makeup to achieve a planned and desired result [5]. GE is therefore considered as an extension of traditional biotechnology defined as the use of living organism or their parts to provide goods and services thereby improving the well-being of humans [6]. The development of recombinant DNA (rDNA) technology has revolutionized biotechnology from traditional biotechnology whose origin can be traced back to the use of yeast for baking bread and fermentation of alcohol to modern biotechnology using genetically modified organisms in agriculture, industries and medicine [7]. Nowadays GE is often termed modern biotechnology.

4. Producing Genetically Modified Microorganism

Just as DNA is the core of genetic studies, rDNA; DNA that has been genetically altered through a process called gene cloning, is the focus point of genetic engineering. In gene cloning also known as recombinant DNA technology, a DNA molecule is cut in half lengthwise and joined with a strand from another organism or perhaps even another species to form a recombinant DNA molecule. The DNA is cut into shorter fragments through the use of restriction enzymes and the ends of the fragments are usually produced such that they have affinity to complementary ends of other DNA fragments and will seek those out of the target DNA. Some restriction enzymes generate blunt ends, cutting across both strands of DNA while others generate a staggered cut, producing "sticky ends." These ends anneal by hydrogen bonding to similar ends on another DNA segment cut with the same restriction enzyme. The ends of these complementary DNA molecules are held tightly together by DNA ligase. The most used DNA carrier molecules are plasmids but also viral DNA molecule can also be used. Plasmids are small, circular, self-replicating, extrachromosomal pieces of DNA that occur naturally. A plasmid can encode a protein that offers its host a selective advantage. For example, a plasmid that encodes an antibiotic allows its host bacterium to thwart competing microbes. Alternately, a bacterium might possess a plasmid that encodes antibiotic resistance. Plasmids are readily isolated from bacterial cells and can be altered in vitro by inserting or deleting specific sequences of DNA. Because they can be used to create clones of genes, plasmids are called cloning vectors. The rDNA molecule is then incorporated into microorganisms such as bacteria and fungi or even cells of higher organisms.

Gene transfer (transformation) can be done by transfection which is the introduction of nucleic acids into cells by non-viral methods. It involves the use of calcium phosphate, DEAE-dextran or other substances. Also, it can be done by physical methods such as electroporation which disrupts cellular membranes of organism using electrical pulse, direct microinjection into cell and biolistic particle disruption into cells using gene guns. The transformed cells are selected in culture by screening for gene markers such as antibiotic resistance, ß-galactosidase, choramphenicol acetyl transferase, luciferase etc. acting as gene reporters.

In gene cloning, the gene transfer can be homologous, i.e. it comes from the same species, or heterologous, from another species or genus. An example of a heterologous gene transfer is the cloning a *Bacillus thuringiensis* gene that encodes an insecticide in *Pseudomonas* [8]. A heterologous gene can also come from an animal or plant cell (e.g. cloning the gene encoding human insulin in *Escherichia coli*).

5. Reasons for genetic modification of microorganism

Generally, traditional biotechnology made use of microorganisms such as yeast in baking, and lactobacilli in the production of dairy products. Biotechnologists were faced with so many challenges using the wild microbial flora. These wild microbial floras were usually unstable and not consistent in their ability to produce the desired product. It became very difficult for biotechnologists to obtain a homogenous product within a long period of time and therefore was unable to manage the quality of their products. The microbes sometimes were unable to survive in the fermenters. The conditions within the fermenters inhibited or alter the normal functioning of the microbes and their survival. Also, the final products were even toxic to the microbes (feedback repression). Industries in this domain were usually faced with low productivity probably due to the low growth rate of these microbes. This low growth rate of the microbes made the cost of production expensive.

All these difficulties faced greatly affected the output of this industries financially and economically. There became need for stable microbes which could resistant fermentation conditions and enhance production.

With the discovery of genetic engineering, biotechnologist found out these microorganisms could be genetically modified such that they would resists fermentation conditions. For example, cloning a gene which encodes for thermo-resistance gene to survive the high temperature in fermenters. Genetic engineering could also produce clones of a particular microorganism which is stable with similar properties and could multiply rapidly. With all this advantages, genetically modified microbes had an urge over wild flora and were rapidly adopted in biotechnological purposes.

6. Applications of Genetically Modified Microorganism

Since the mid-20th century, GMMs have been widely used to produce numerous molecules required by the pharmaceutical, agro-alimentary and chemical industries. Producing these molecules involves culturing the microorganism responsible for producing the required molecule in a fermenter containing a suitable nutritive medium under defined conditions. This operation is generally performed in a confined atmosphere and, in theory, does not cause microorganisms to be released into the environment.

There exist several domains in which GMM are used and have generally been classified into five categories as described by [9] from the Laboratory of Microbiology and Food Hygiene in Rennes, France;

a. Chemical industries; producing bioactive molecules
b. Agro-alimentary; producing fermented foods
c. The environment; various uses in agriculture, for pollution control, etc.
d. Medicine; producing microbes and substances for therapeutic purposes (e.g. live vaccines, pharmaceuticals)
e. Research; gaining fundamental knowledge

a. Chemical industry for producing bioactive molecules

In the chemical industry, GMMs have been used to produce many molecules such as enzymes, organic acids and biofuels produced by these microorganisms. Majority of these products serve as reagents for other industries. Certain enzymes produced are used in agro-alimentary industries to digest food products and catalyze the synthesis of other products such as alcohol or organic acid in brewery industries. Other products of the chemical industries act as final products for consumption by man or its environment. These include alcohol, amino acids, vitamins or fuel used by automobiles.

b. Agro-alimentary for producing fermented foods

A vast number of fermented foodstuffs we consume have genetically been modified. In the western world particularly the U.S.A., most foodstuffs such as Bread, wine, cheese, butter, crème fraiche, yoghurts, kefir, fermented meats (dry-cured sausage, salami) and fermented vegetables (sauerkraut, olives) are produced by the action of an extremely varied microbial flora. Some of these fermented foods can either be produced from a complex and little known microbial flora that may be categorised as wild flora found in raw materials and the environment. This includes some unpasteurized cheeses, beers and sourdough bread. Others are made from industrial starter cultures of simpler composition and identified flora usually been manipulated genetically (industrial floral) and may include many cheeses made from pasteurized milk. Lastly, other fermented foodstuffs contain both complex wild flora and industrial flora. The organoleptic component of genetically modified foodstuff serves an additional advantage of genetically modified microbial flora over the wild flora.

c. Environmental protection in pollution control and Agriculture

Microorganisms extensively exploit their environment in search for food and protection to enhance their survival. In return, they generate substances useful to man and eliminate other substance not needed by man. Microorganisms come into play in many pollution control processes, the most common of which is sewage treatment, a process that involves highly complex wild flora. Methods for controlling pollution of more specific compounds (hydrocarbons, slurry, various pesticides, etc.) have also been developed and involve selected flora, which is less complex (in terms of diversity). However, the action of this flora is far from optimal and therefore requires genetic improvement. Numerous GMMs with properties that are compatible with the process (resistance to the substrate to be biodegraded, good establishment in the environment, etc.) have been developed.

In the agricultural sector, microbial strains are used to enhance the growth of plants and crop protection by enriching the soils with valuable nutrients. In the same way as above, it has been necessary to develop genetically recombinant strains to optimise these processes. Strains of *Sinorhizobium meliloti* that have been genetically improved to enable nitrogen fixation by the plant have been used since 1997 to seed legume crops [9]. Similarly, pesticides using other genetically improved species (*Agrobacterium radiobacter*) are used in soils.

d. Medicine - producing microbes and substances for therapeutic purposes

In the pharmaceutical industry, many molecules (such as antibiotics or vitamin B12) are produced by microorganisms which synthesize them naturally. There are also numerous molecules whose gene has been cloned in microorganisms (e.g. human insulin, growth hormone, Hepatitis B vaccine). All these molecules have been marketed for many years and are part of developed countries' daily therapeutic arsenal (recombinant insulin has been produced since 1983) [10].Owing to their ability to survive or pass through human and animal mucosa, microorganisms can be used to treat or prevent certain diseases. For example, a strain of *Lactobacillus jensenii* has been modified to secrete the CD4 protein used by the HIV virus in the vaginal mucosa to penetrate lymphocytes. This secreted protein also traps viruses [11].

e. Research gaining fundamental knowledge

Another no less important use of GMMs is in research laboratories, as they enable us to better understand how microorganisms function. Numerous genes belonging to a wide variety of microbial species have therefore been cloned and have given rise to thousands of GMM strains used as research material by researchers. In Europe today, genetically modified microorganisms are mainly used to produce molecules in fermenters. In this case, the microorganisms are in fact maintained in a confined atmosphere which theoretically prevents their release into the natural environment. They are used to produce the molecules used in the pharmaceutical, agro-alimentary and chemical industries.

7. Bioethical implication of Genetically Modified Microorganism

The use of GE and its products is related to so many ethical issues. To explain their bioethics implications, it is necessary to outline the basic principles of ethics. Ethics basically rely on four fundamental principles; respect for person, beneficence, non-maleficence and justice [12].

- **Respect for person** states that we should love the life given to us (self-love) implying that each person should enjoy autonomy (self-rule), be capable to decide and make choices, have respect for individuals, the community and local culture. Also the dignity of people should be taken into consideration.
- **Beneficence** takes into consideration the physical, mental, and social well-being of individuals and benefits of any activity undertaken by man. It supports the development of science and medicine, and its provision to those who suffer, because we should continue to make life better. Beneficence is based on the belief that all people have an intrinsic motivation to love doing good instead of harm, expressed as compassion.
- **Non-maleficence** which means do no harm dictates that we should be reasonably cautious about premature use of a technology and any activity before potential risks are understood.
- **Justice** implies that individuals should have equal opportunity; there should have even distribution to benefits and equal exposure to risk. In cases of venerable groups, special concern and protection should assign.

These four principles set the bases for bioethics. Bioethics considers ethical issues raised in medicine and biology and especially those raised by humans in the society and the environment using biotechnology [13]. The ethical issues of genetic engineering and its products are discussed with regards to the fundamental ethical principles.

a) Religious values (Respect of person)

Religion defines life as a creation of GOD Almighty; only 'Him' is the giver and taker life. This implies that man is his creation and therefore should not manipulate his creation. Arguments based upon life's sacredness suggest that altering life forms violates the will of a creator [14]. Some religious critics perceive genetic engineering as "playing God" and object to it on the grounds that life is sacred and ought not to be altered by human intention [15]. Such religions defy their worshipers from consuming genetically modified products. The failure to label genetically engineered foods means that persons who follow religious dietary restrictions will be unable to ensure compliance with their beliefs.

Some people object to any tinkering with the genetic codes of humans, or even of any life form and argue that it is against the ethical principle of respect of person. Other objectors argue from secular principles, such as the outspoken and ardent Jeremy Rifkin, who claims that it violates the inherent "dignity" of humans and other life-forms to alter their DNA under any circumstances [16]. Religious objections assume the existence of some creator whose will is defied by genetic engineering, and secular objections assume that life in its "natural" state, unaltered by human intention, is inviolable because of its inherent dignity [17].

Man has the right to make a choice on what he has to consume. What counts as an acceptable level of risk, or an acceptable resource for food consumption, is in the final instance a matter of personal choice. A principle of free and informed consumer choice seems to bespeak the necessity of labeling, both in cases where perceptions tend to exaggerate risks and where they typically underestimate risks. Objectors of genetic engineering do not really accept to consume genetically modified products and therefore it is the responsibility of the administration or government to clearly notify the community products that are genetically modified. Today, in most of our markets the value of choice has been violated. Marketers sell for the goal of making profit not taken into consideration the desire of their consumers. There is debate among different nations, and also among different experts, about the need to label food that is derived from GMOs.

b. Benefits

The principles of beneficence clear states that any activity undertaken by man for his use or the environmental must be beneficial to him, his community as well as the environment. Genetic engineering has been very instrumental in improving human well-being and supplied us with products that alleviate illness, clean up the environment, and increase crop yields, among other practical benefits to humanity and the ecosystem. The socioeconomic benefits are not neglected. Most countries with this advance technology have fully been empowered with riches creating economic and political stability. This is well elaborated above on the applications of GMM.

c. Drawbacks and limitations

Though genetic engineering has been beneficial to humans, it however has some negative impact on man and the ecosystem. The used of GMP may affect human health causing diseases, disrupt the ecological balance exterminating certain species, cause drug and herbicides resistance and lower the genetic and ecological diversity. Certain diseases have as well been created be researchers trying to manipulate microorganism. This was the case of Dutch elm disease into a new area while testing genetically modified bacteria in fungi [4]. This violates the ethical rule of non-maleficence by doing harm. However, the acceptability of genetically modified products is judged based on the cost-benefit analysis, whether the benefits over weigh the harm [18]. The possible negative impact of genetic engineering is explained in details below on risk of GMM.

d. Justice and equity

Genetic engineering is a technique master minded by the western world. This part of the world dominates the political, socioeconomic and developmental decision undertaken by world governing bodies. The implication of justice and equity in implementing this technique and the consumption of its product demands for a rational distribution of the risk and benefits. Apart from direct benefits or harms that may result from genetic engineering, which we have already considered, there is also the problem of how genetic engineering may affect the distribution of social goods as well as political rights. Such issues are often referred to as problems of distributive justice. Question on whether certain vulnerable factors such as poverty are subjected to the use of GMM, are there bias in designating guidelines for the production of GMM and their products are usually posed. Judgments from such perspectives clear shows that justice or equity is marginalized due to the fact that the goal of genetic engineering to improve on the well-being of humans has been

shifted to wealth, politics and economic values of the nations.
In general the ethical implication of genetic engineering is subjective to an individual's desire and priority after making a cost-benefit analysis. A study in China showed that people would accept genetic engineering for health related issued rather than in enhancing modification on food products [19].

8. Risk posed by Genetically Modified Microorganism
Genetic manipulation of microorganisms produces variants with altered physiology state. In order to survive and disseminate in their environment, they need to adapt to the prevailing conditions. The danger posed by these genetically modified organisms is therefore related both to their dispersal into the environment and to their potential for adaptation to a new environment [17]. The environment, health or socioeconomic sectors are possible areas of potential risk of the GMM.

a. Ecological disruption
Microorganism within the ecosystem exists as numerous diverse species living within particular ecological niches. Genetic manipulation of microorganisms may lead to the emergence of more adapted forms which may better adapted to a new environment, may colonise it, thus greatly disrupting the ecological balance, whether microbial, plant or animal. Such a problem is genuinely conceivable and was apparent even before the arrival of GMMs. Some cases are already known in which microorganisms have found themselves in a new ecological niche as a result of (generally accidental) human intervention. They have subsequently colonise this niche, disrupting it to a great extent. A well-known example of this involves the toxigenic unicellular alga *Chrysochromulina polylepis* which, because of human activity (the release of nitrogenous substances into the sea), invaded part of the North Sea and the English Channel, leading to significant health problems as it produces toxins which are pathogenic for humans [20].

b. Spread of resistance
Majority on microorganism are parasites harbored by other organisms. Their relation can sometimes be symbiotic; both beneficial to each other. On the other hand, some can be harmful, causing disease in plants, animals and humans. In plants, herbicides are usually used against microbes causing plant diseases. In humans drugs such as antibiotics are used especially in viral, bacteria and fungi diseased. GMM may develop to variant types which can no longer be controlled and hence leads to drug or herbicide resistance. Opponents of the technology predict several disastrous scenarios; two concerns that exacerbate the challenges of using GMO technology for agriculture are: (i) hybridization between transgenic microorganism and their feral counterparts will create new invasive species capable of asphyxiating natural ecosystems; and (ii) evolution of insect resistance against transgenic insecticidal crops will foster ultra-resistant super-pests. For example, the diamondback moth (*Plutella xylostella*) has developed resistance against *Bacillus thuringiensis* sprays [7].

c. Reduced ecological diversity
The ecosystem is a very diverse with numerous microbial species. This diversity plays a very important role in managing the ecosystem. The Adoption of GMMs may reduce the genetic diversity as well as ecological diversity of microbial flora. GMM may be more adapted to the environment and compete out the local strain within their genetic variant [21].

d. Health related issues
Most microbes used in food, chemical industrials are generally nonpathogenic. However, genetic manipulation of these microorganisms may lead to the development of virulent form which may be pathogenic causing diseases to humans, plants and animals. Also, genetic manipulation of pathogenic strains to less virulent forms in the development of vaccines against certain diseases may develop to more virulent forms. This is the case of tuberculosis vaccine where US researchers created a variant which was much more virulent than the native strain, by trying to inhibit the activity of a virulence gene in *Mycobacterium tuberculosis* [22]. The issue is even more crucial when it comes to the development of biological weapons: in this case, the primary objective is the creation of new pathogens against which an army or an enemy country is not able to defend itself. A US team thus recently modified the smallpox virus so that it would bypass the immune defenses in humans due to vaccination or be resistant to available drugs. Another area of research involved the modification of the cowpox virus so that it might cross species barriers and infect other species, such as humans. One of the viruses developed demonstrated an increased pathogenicity [23]. Such GMOs threaten to escape the control of scientists and to have unpredictable consequences on animal and human species.

e. Socioeconomic risk
The uncertainties of environmental and health impacts of GMMs are intertwined with economic and social uncertainties. Public concern about genetically modified food relates to the potential environmental and health related risks involved as well as economic risks [7, 21]. Genetic modifications of food have primarily been motivated from the production side, in order to increase yield, rather than from a consumer demand and health perspective [24]. This refers to this as "technology-push" rather than "demand-pull". Negative impact of this technique and its products will affect the economic values of the industries and nations [25].

9. Environmental risk assessment
As stated above, GMM are associated with potential risk on human's health and their environment. To minimize the health and environmental problems associated with GMM, the risk needs to be assessed so as to be properly managed. Environmental Risk Assessment (ERA) is therefore an important aspect to be taken into consideration when using GMM in biotechnological processes. So many countries have put in strict regulations concerning a thorough Risk Assessment (RA) before releasing these products into the environment or introducing them to the market [15]. This assessment regulation is generally stricter in certain genetically modified products than others depending on factors such as the product type, their use and the type of microorganism being used. There are arguments on whether to harmonize existing regulations to the point that similar cases are treated similarly, regardless of how the genetic modification has come about. Treating like cases alike is actually one of the most central principles in ethics across various ethical theories [15]. The basic features of general risk assessment of GMMs are understandably different from those associated with chemicals. GMMs are living organisms and therefore, unlike chemicals that may become diluted, GMMs have the potential to disperse to new habitats, colonize those sites, and multiply. Their novel activities, including the production of metabolic products, enzymes and toxins will occur as long as the GMMs remain metabolically active. Once established, living organisms cannot be

recalled [26]. A common description of risk as described by Beauregard and collaborator is the probability of harm and its consequence or mathematical presented as:

Risk = probability x consequence = likelihood of event x (negative) impact of event

This form of risk above states that by managing the two constituents of risk probability and consequence we are able to influence the risk. When scientists look at risk they are calculating three basic questions:

Question 1: what can go wrong (or the possibility of harm)?
Question 2: how likely is that to happen (or the probability of harm)?
Question 3: what are the consequences if it happens (or the severity of harm)?
However, to get a balance between a potential risk and a potential benefit, usually a fourth question is been asked?
Question 4: what are the consequences if we do NOT allow these GM products?

Risk assessment of genetically modified microorganism is usually done using either of the two ways: step by step or case by case.
According to the **step-by-step** approach, testing of a GMM should start under contained conditions and proceeds with stepwise release into the environment, according to the gathered knowledge concerning biosafety issues [27]. Releases are progressing from small scale trials with strict containment measures to avoid spread of the GMO to larger scale trials with fewer control and containment measures until sufficient data have been collected to conclude on the environmental safety of a GMM. This sequential environmental release of a GMM into its receiving environment is crucial to identify potential adverse effects as soon as possible and to be able to stop the release into the environment if risks are considered unacceptable or not manageable by risk management measures.

In the case by case approach, each specific characteristics of the GMM is considered individually and assessed. Each of the following characteristics needs to be assessed before release into the market or environment. They include;

- The potential lifespan (e.g. annual or perennial crops and trees)
- The modified or introduced traits (herbicide-tolerance, drug resistance, altered composition parameters, etc.)
- The intended use of the GMO (import and processing only or cultivation)
- The range of relevant environmental conditions where the GMO is expected to be released.

Risk assessment is usually accompanied by biosafety guidelines which covers all research work involved in the field test/trial of GMO. Such guide lines are meant to address certain underline questions. For example the Thailand biosafety Guidelines [28] in Genetic Engineering and Biotechnology addresses the following objectives;

- To confirm the observations made during laboratory work, and the results from tests conducted at the laboratory level.
- To gather accurate information/data on the stability, transmission/heredity and expression of transgenes under field conditions.
- To assess the viability (e.g. survival, propagation, competitive ability) of genetically manipulated organisms under field conditions.
- To assess the adaptive or evolutionary potential of genetically manipulated organisms under changing environmental conditions.

10. Risk monitoring
After risk assessment, only acceptable genetically modified products are introduced into the market or the environment. However, in a course of time, certain environmental changes can possibly have an impact on the safety of the product. There is need to constantly monitor the quality of this product to ensure their safety. Risk monitoring is thus a post marketing risk assessment measure. The aim of GMM monitoring is to detect potential adverse effects of GMMs and their use on human health and the environment and if necessary, to facilitate early and appropriate mitigation action.
The first step in GMM monitoring is to identify potential adverse effects of the GMM in the environment. A main tool for the identification of adverse effects is the formulation of cause effect hypotheses derived from the ERA, biosafety research results as well as from existing knowledge of ecology and ecosystem theory. The monitoring should be able to address the most relevant effects of the respective GMM and its use.
The next step is to prioritise the identified effects and to select the relevant indicators, parameters or monitoring objects that are appropriate to address these effects or relevant protection targets. In monitoring, step by step as well as case by case approaches should be applied in order to be able to identify all possible effects of the genetically modified products.

11. Risk management
After risk assessment and monitoring, identified adverse effects needs to be managed thoroughly. The term “risk management” refers to the process of weighing alternatives and making decisions (policies) about risk [27]. Risk managers must consider the costs and benefits of competing alternatives, including the status quo (i.e., decide not to act). Broadly speaking, Risk managers can make four types of decisions: First, they can avoid the risk. Second, risk managers can reduce risks as the ERA did. Third, they can transfer risks onto other institutions or sectors of society, which agribusiness often do through insurance policies that mitigate the losses they may incur from lawsuits pertaining to any harms caused by genetically modified crops. Finally, risk managers can choose to accept the level of risk determined through risk assessment processes, as often happens when genetically modified products are approved for release into the environment [7].
A variety of decision makers act as risk managers in the diverse patchwork of GMM policy. The decisions to be made about GMMs can be thought of in four broad stages.

- The first stage is the research and development phase of GMOs. Here decision makers face questions about whether GMOs should be created, how much money should be spent on which activities, and how the safety of lab works can be secured.
- The second stage concerns decisions regarding release of GMOs into the environment. Risk managers at this stage must consider the potential risks and benefits for humans and the environment.
- The third stage involves questions about whether and how GM-containing products and GMOs should be traded and

brought to the market. Of special importance here are the trade rules established by the World Trade Organization and the conflicting international treaties made under the rubric of the U.N. Cartagena Protocol on Biosafety.

- Finally, risk management decisions must be made about the processing and consumption of GM-containing products.

In risk management, both the scientist and the policy marker need to work in close collaboration. In real life observation this is not truly the case. Scientists and policy makers have different goals, attitudes toward information, languages, perception of time, and career paths. Important issues affecting their working together include lack of mutual trust and respect, different views on the production and use of evidence, different accountabilities, and whether there should be a link between science and policy [29].

12. Conclusion

Ever since genetic engineering was discovery in 1970s, the world has fully been under the era of gene revolution. Genetically modified microorganisms are widely exploited in so many domains; from agriculture, medicine, industries to the environment. Their products are of great importance to man and its environment. However, their undesirable effects and ethical implications still remains a major worry to many minds whether they should be accepted or not. The acceptance of genetic engineering or it products is subjective to an individual's desire and priority after making a cost-benefits analysis. Precautionary measures such as risk assessment, monitoring and management have been put in place by policy makers to ensure the safety of genetically modified microorganisms and their products. The effectiveness of these measures will depend on the close collaboration between scientist and policy makers in working together. Never the less, we encourage scientist in the field of genetic engineering to work with the goal of improving on the well-being of humans taking into consideration all the ethical values of man so as minimize harm.

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