

Current Trends of Genetically Modified Organisms and Foods and their Future Perspectives: An Overview

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Abstract

The ratio of the population of human being and the quantity of the edible components are reciprocally proportionate. The quantity of the food components is reduced due to different reasons namely, environmental conditions, inaccessibility of the water for farming, inferior income of farmers etc. to make out with all these situations and produce the food in the quantity, which must be available for all the human being is becoming hard day by day. Thus, the rising trends of the biotechnological engineering has come forward to solve these issues with the tools of genetic engineering, titled as GMO (genetically modified organisms). The GMO became a worth asset in the modern world. Although this technique has some hidden difficulties but to meet up the situation this is the best possible resolution at present. In this overview authors stipulated a future perspective for the GM organisms concomitant with enlisting certain concerning challenges. This review will provide new insights into the prospect of GMO and their progression to attain the mile stone.

Keywords: Environmental hazards, GMO, GMO crops, Human health, Hunger elimination, Patenting of GMO, Pitfall of GMO.

I. Introduction

It is a general view that humans have always tailored the genome of both plants and animals. This invasive process, which has existed for thousands of years, several times through mistakes and failures, was primarily carried out through the crossing of organisms with enviable features. This was accomplished with the intention of generating and producing new plants and animals that would ultimately benefit humans, in terms of offering better quality food, more opportunities for people to move and transport products, greater returns to work, resistance to diseases, etc. Though, generating genetically modified organisms does not carry on without conflicts. One part of the equation has shown concern with objections made by debaters of genetically modified organisms to the manipulation of life, as disparate to defenders who argue that it is fundamentally an extension of conventional plant cultivation and animal breeding techniques. There are also conflicts regarding the risks to the environment and human health from employing genetically modified organisms. Concerns about the risks to the environment and human health from genetically modified products have been the issue of much debate that has led to the progress of regulatory platform for the assessment of genetically modified crops. However, the absence of a globally accepted has the impact of slowing down technological progress with negative results for areas of the world, which could benefit from novel technologies. Thus, whilst genetically modified crops can provide maximum advantages in food safety and in adapting crops to accessible climate variation, the absence of reforms, as well as the deficiency of harmonization of the frameworks and set of laws about the genetic transformations results in all those anticipated advantages of employing genetically modified crops being suspended. Nonetheless, it is understandable that the evolution of genetically modified products is not going to end. For that rationale, studies on the effect of genetic transformation on medical technologies, agricultural production, commodity prices, and land utilization and on the environment in common, should therefore prolong. The work along these notions and objectives can be well compiled under following heads:

Probable risks of employing genetically modified products

The application of genetic modification allows genetic material to be transferred from any species into plants or other organisms. The introduction of a gene into different cells can result in different outcomes, and the overall pattern of gene expression can be altered by the introduction of a single gene. The sequence of the gene and its role in the donor organism may have a relatively well-characterized function in the organism from which it is isolated. However, this apparent “precision” in the understanding of a gene does not mean that the

consequences of the transfer are known or can be predicted [1]. Copies of a gene may be integrated, additional fragments inserted, and gene sequences rearranged and deleted—which may result in lack of operation of the genes instability or interference with other gene functions possibly cause some potential risks [1]. Therefore, there could be a number of predictable and unpredictable risks related to release of GMOs in the open environment. The report prepared by the Law Centre of IUCN, the World Conservation Union (2004), enlists numerous environmental risks likely to occur by the use of GMOs in the field. These major risks are as follows.

Environmental Hazards

There is strong fact that genetically modified plants appear to interrelate with their environment [1, 2]. Within the past four decades, research has been increasingly drawn toward understanding whether there is a link between the changing human-nature relationship and its impact on people's health. However, to examine whether there is a link requires research of its breadth and underlying mechanisms from an interdisciplinary approach. This article begins by reviewing the debates concerning the human–nature relationship, which are then critiqued and redefined from an interdisciplinary perspective. The concept and chronological history of “health” is then explored, based on the World Health Organization's definition. Combining these concepts, the human-nature relationship and its impact on human's health are then explored through a developing conceptual model. It is argued that using an interdisciplinary perspective can facilitate a deeper understanding of the complexities involved for attaining optimal health at the human–environmental interface. This reflects that genes introduced into genetically modified plants may be moved to other plants or even to other organisms in the ecosystem [3-5]. The potential of genetically modified plants to meet the requirements of growing population is not being recognized at present. This is a consequence of concerns raised by the public and the critics about their applications and release into the environment. These include effect on human health and environment, biosafety, world trade monopolies, trustworthiness of public institutions, integrity of regulatory agencies, loss of individual choice, and ethics as well as skepticism about the real potential of the genetically modified plants, and so on. Such concerns are enormous and prevalent even today. However, it should be acknowledged that most of them are not specific for genetically modified plants, and the public should not forget that the conventionally bred plants consumed by them are also associated with similar risks where no information about the gene(s) transfer is available. Moreover, most of the concerns are hypothetical and lack scientific background. Gene transfer between plants, specifically among interconnected plants, results in genetic contamination and is carried out by the transport of pollen [6,7]. The potential of genetically modified (GM) crops to transfer foreign genes through pollen to related plant species has been cited as an environmental concern. Until more is known concerning the environmental impact of novel genes on indigenous crops and weeds, practical and regulatory considerations will likely require the adoption of gene-containment approaches for future generations of GM crops. Most molecular approaches with potential for controlling gene flow among crops and weeds have thus far focused on maternal inheritance, male sterility, and seed sterility. Several other containment strategies may also prove useful in restricting gene flow, including apomixis (vegetative propagation and asexual seed formation), cleistogamy (self-fertilization without opening of the flower), genome incompatibility, chemical induction/deletion of transgenes, fruit-specific excision of transgenes, and transgenic mitigation (transgenes that compromise fitness in the hybrid). As yet, however, no strategy has proved broadly applicable to all crop species, and a combination of approaches may prove most effective for engineering the next generation of GM crops [7]. Because natural wild plant varieties are probably to have a competitive disadvantage against genetically modified crops, they may not be able to survive, causing in the reduction or disappearance of wild varieties [8,9]. Biotechnology is providing us with a wide range of options for how we can use agricultural and commercial forestry lands. The cultivation of genetically modified (GM) crops on millions of *hectares* of lands and their injection into our food chain is a huge global genetic experiment involving all living beings. Considering the fast pace of new advances in production of genetically modified crops, consumers, farmers and policymakers worldwide are challenged to reach a consensus on a clear vision for the future of world food supply. The current food biotechnology debate illustrates the serious conflict between two groups: 1) Agri-biotech investors and their affiliated scientists who consider agricultural biotechnology as a solution to food shortage, the scarcity of environmental resources and weeds and pests infestations; and 2) independent scientists, environmentalists, farmers and consumers who warn that genetically modified food introduces new risks to food security, the environment and human health such as loss of biodiversity; the emergence of super weeds and super pests; the increase of antibiotic resistance, food allergies and other unintended effects. This article reviews major viewpoints which are currently debated in the food biotechnology sector in the world. It also lays the ground-work for deep debate on benefits and risks of Biotech-crops for human health, ecosystems and biodiversity. In this context, although some regulations exist, there is a need for continuous vigilance for all countries involved in producing genetically engineered food to follow the international scientific bio-safety testing guidelines containing reliable pre-release experiments and post-release track of transgenic plants to protect public health and avoid future environmental harm [9]. Mutating biodiversity worldwide will lead to increased resistance of several species of weeds, others to dominate and others to decline or disappear, therefore, generating a complete and general deregulation in ecosystems [10,11]. Farmland

biodiversity is an important characteristic when assessing sustainability of agricultural practices and is of major international concern. Scientific data indicate that agricultural intensification and pesticide use are among the main drivers of biodiversity loss. The analysed data and experiences do not support statements that herbicide-resistant crops provide consistently better yields than conventional crops or reduce herbicide amounts [11]. They rather show that the adoption of herbicide-resistant crops impacts agronomy, agricultural practice, and weed management and contributes to biodiversity loss in several ways: (i) many studies show that glyphosate-based herbicides, which were commonly regarded as less harmful, are toxic to a range of aquatic organisms and adversely affect the soil and intestinal microflora and plant disease resistance; the increased use of 2,4-D or dicamba, linked to new herbicide-resistant crops, causes special concerns. (ii) The adoption of herbicide-resistant crops has reduced crop rotation and favoured weed management that is solely based on the use of herbicides. (iii) Continuous herbicide resistance cropping and the intensive use of glyphosate over the last 20 years have led to the appearance of at least 34 glyphosate-resistant weed species worldwide. Although recommended for many years, farmers did not counter resistance development in weeds by integrated weed management, but continued to rely on herbicides as sole measure [11]. Despite occurrence of widespread resistance in weeds to other herbicides, industry rather develops transgenic crops with additional herbicide resistance genes. (iv) Agricultural management based on broad-spectrum herbicides as in herbicide-resistant crops further decreases diversity and abundance of wild plants and impacts arthropod fauna and other farmland animals. Taken together, adverse impacts of herbicide-resistant crops on biodiversity, when widely adopted, should be expected and are indeed very hard to avoid. For that reason, and in order to comply with international agreements to protect and enhance biodiversity, agriculture needs to focus on practices that are more environmentally friendly, including an overall reduction in pesticide use. (Pesticides are used for agricultural as well non-agricultural purposes [11]. It is a common belief in scientific circles that research needs to be prolonged to assess the risks and benefits of crops more precisely and sufficiently.

Risks to Human Health

There may be allergenic effects - mostly in people who are predisposed to allergies - or other adverse effects on human health [12; Figure 1]. Biotechnology offers a variety of potential benefits and risks. It has enhanced food production by making plants less vulnerable to drought, frost, insects, and viruses and by enabling plants to compete more effectively against weeds for soil nutrients. In a few cases, it has also improved the quality and nutrition of foods by altering their composition. However, the use of biotechnology has also raised concerns about its potential risks to the environment and people. For example, some people fear that common plant pests could develop resistance to the introduced pesticides in GM crops that were supposed to combat them. Genetic engineering provides a means to introduce genes into plants via mechanisms that are different in some respects from classical breeding. A number of commercialized, genetically engineered (GE) varieties, most notably canola, cotton, maize and soybean, were created using this technology, and at present the traits introduced are herbicide and/or pest tolerance. Gene technology enables the increase of production in plants, as well as the rise of resistance to pests, viruses, frost, etc. Gene transfer is used to modify the physical and chemical composition and nutritional value of food [12]. Gene transfer in animals will play a part in boundless possibilities of improving qualitative and quantitative traits. The yield, carcass composition and meat characteristics are the use of nutritive substances? Not sure what is being said here? and resistance to diseases can be improved. On the other hand, negative effects of gene technology on animals, human, and environment should be considered. An overview is the compilation of various studies that present both positive and negative impacts of genetically modified food on human health [12]. Experimental studies in animals have shown weight gain, changes in the pancreas and kidneys, toxic effects to the immune system, changes in blood biochemistry among other effects [13, 14; Figure 1]. Moreover, the lack of large-scale long-term epidemiological studies, which lead to safe conclusions about the allergenic effects of genetically modified plants, makes researchers doubtful about the use of genetically modified products. This is due to the introduction of a gene that expresses a non-allergenic protein, and does not mean to produce a product without allergenic action. Besides, allergies from genetically modified products may be more intense and dangerous, as the allergenic potential of these foods is stronger than that of traditional plants [15,16].

Resistance to Antibiotics

It should be noted from the beginning that the use of antibiotic-resistant genes has stopped in most mutated products. The main issue now lies in the widespread use of antibiotics in feed which, as a natural outcome, end up in the human body through taking in the dairy products and meat, and ultimately create resistant germs in the human digestive system [17,18; Figure 1]. Due to the increased demand of animal protein in developing countries, intensive farming is instigated, which results in antibiotic residues in animal-derived products, and eventually, antibiotic resistance. Antibiotic resistance is of great public health concern because the antibiotic-resistant bacteria associated with the animals may be pathogenic to humans, easily transmitted to humans via food chains, and widely disseminated in the environment via animal wastes [17,18]. These may cause complicated, untreatable, and prolonged infections in humans, leading to higher healthcare cost and sometimes death. In the

said countries, antibiotic resistance is so complex and difficult, due to irrational use of antibiotics both in the clinical and agriculture settings, low socioeconomic status, poor sanitation and hygienic status, as well as that zoonotic bacterial pathogens are not regularly cultured, and their resistance to commonly used antibiotics are scarcely investigated (poor surveillance systems) [18]. The challenges that follow are of local, national, regional, and international dimensions, as there are no geographic boundaries to impede the spread of antibiotic resistance. In addition, the information assembled in this study through a thorough review of published findings, emphasized the presence of antibiotics in animal-derived products and the phenomenon of multidrug resistance in environmental samples. This therefore calls for strengthening of regulations that direct antibiotic manufacture, distribution, dispensing, and prescription, hence fostering antibiotic stewardship. Joint collaboration across the world with international bodies is needed to assist the developing countries to implement good surveillance of antibiotic use and antibiotic resistance [18; Figure 1]. Nevertheless, more research and studies are required to determine the distinctions between transgenic plants from conventional plants and whether genetically modified plants present additional risks to the consumer public [19,20].

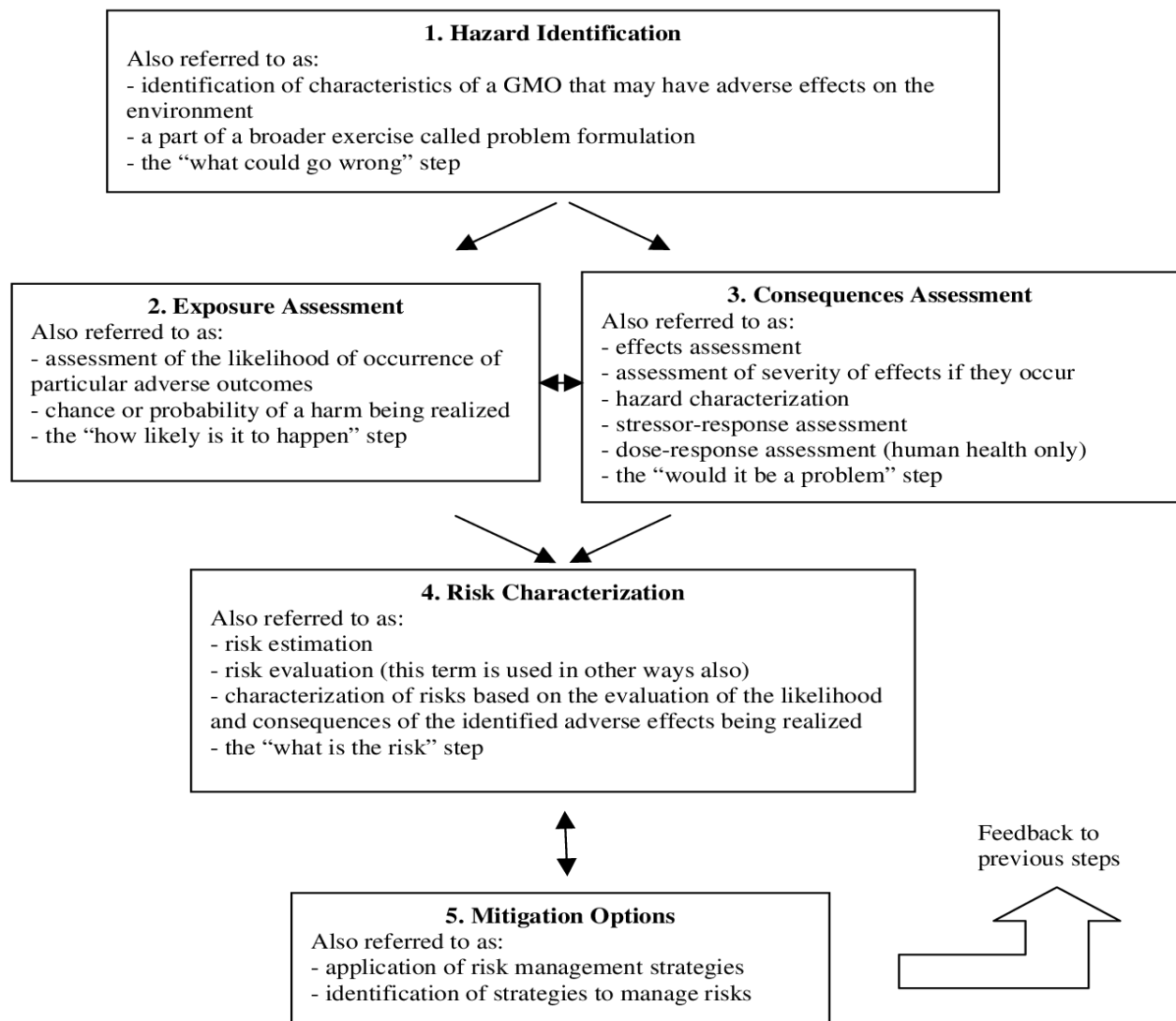


Figure 1: The top down conceptualization for designing the risk assessment process in genetically modified organism. (<https://www.semanticscholar.org/paper/Conceptualizing-risk-assessment-methodology-for-Hill/82f8005c3f6787b669ab3ba9efe7998ced4365aa/figure/0>)

Benefits of using genetically modified products

Hunger Elimination

One of the arguments set forth by advocates of genetically modified products is to remove world hunger, a perception that has encountered various reactions [21- 23]. Commercial potential of biotechnology is immense since the scope of its activity covers the entire spectrum of human life. The most potent biotechnological approach is the transfer of specifically constructed gene assemblies through various techniques [23]. However, this

deliberate modification and the resulting entities thereof have become the bone of contention all over the world. Benefits aside, genetically modified organisms (GMOs) have always been considered a threat to environment and human health. In view of this, it has been considered necessary by biosafety regulations of individual countries to test the feasibility of GMOs in contained and controlled environments for any potential risks they may pose. This paper describes the various aspects of risk, its assessment, and management which are imperative in decision making regarding the safe use of GMOs. Efficient efforts are necessary for implementation of regulations. Importance of the risk assessment, management, and precautionary approach in environmental agreements and activism is also discussed [23]. A series of extensive and long-term research has shown that the benefits of growing genetically modified crops in the fight against global food shortages and hunger have been noteworthy. The steady augmentation in the global population has led researchers to focus on the advantages of developing genetically modified products, rather than the potential risks they present each time [24, 25]. Besides, biofortification through plant breeding is a sustainable approach to improve the nutritional profile of food crops. The majority of the world's population depends on staple food crops; however, most are low in key micronutrients. Biofortification to improve the nutritional profile of pulse crops has increased importance in many breeding programs in the past decade [25]. The key micronutrients targeted have been iron, zinc, selenium, iodine, carotenoids, and folates. In recent years, several biofortified pulse crops including common beans and lentils have been released by HarvestPlus with global partners in developing countries, which has helped in overcoming micronutrient deficiency in the target population. Recently, an overview has focused on recent research advances and future strategies for the biofortification of pulse crops [25].

Economic Benefits

Genetic modification in plants was first recorded 10,000 years ago in Southwest Asia where humans first bred plants through artificial selection and selective breeding. Since then, advancements in agriculture science and technology have brought about the current GM crop revolution. GM crops are promising to mitigate current and future problems in commercial agriculture, with proven case studies in Indian cotton and Australian canola. However, controversial studies along with current problems linked to insect resistance and potential health risks have jeopardised its standing with the public and policymakers, even leading to full and partial bans in certain countries. Nevertheless, the current growth rate of the GM seed market at 9.83–10% CAGR along with promising research avenues in biofortification, precise DNA integration and stress tolerance have forecast it to bring productivity and prosperity to commercial agriculture [26-28]. A number of studies reveal the economic benefits of using genetically modified products. During 1996 to 2011, farmers' income worldwide enhanced by \$92 million from the use of genetically modified crops. Part of the revenue is due to the more efficient treatment of weeds and insects, while another part is because of lower overall production costs. The maximum economic benefits have been achieved in the US, Argentina, China and India, meanwhile, production costs have fallen sharply [26]. At this point, nevertheless, there are contradictory reports [27,28].

Insect Resistance

Bacillus thuringiensis (or BT) is a Gram-positive, soil-dwelling bacterium, generally used as a biological pesticide. During sporulation, many BT strains give rise to crystal proteins (proteinaceous inclusions), called δ -endotoxins, which have insecticidal action. This has led to their application as insecticides, and more recently, to genetically modified crops employing BT genes, such as BT corn. The principal target of these plants is to fight against the European Corn Borer insect that is accountable for the destruction of maize crops with a loss of up to one billion dollars a year [27].

Nematode Resistance

Parasitic nematodes are accountable for much of the crop losses. They attack numerous distinct plants by destroying the root system. Nematodes, which are essentially a worm species, survive in the soil in very difficult conditions for many years. Chemical control of nematodes is prohibited because there is a high environmental risk [29]. Nevertheless, root-knot nematodes are microscopic round worms, which cause severe agricultural losses. Their attacks affect the productivity by reducing the amount and the caliber of the fruits. Chemical control is widely used, but biological control appears to be a better solution, mainly using microorganisms to reduce the quantity of pests infecting crops. Biological control is developing gradually, and with time, more products are being marketed worldwide. They can be formulated with bacteria, viruses or with filamentous fungi, which can destroy and feed on phytoparasitic nematodes. To be used by the farmers, biopesticides must be legalized by the states, which has led to the establishment of a legal framework for their use, devised by various governmental organizations [30]. The only natural way to deal with this is through crop rotation (the practice of growing a series of dissimilar or different types of crops in the same area in sequenced seasons), but this is often not possible due to the high financial cost [29,30]. Thus, the introduction of genes from nematode-resistant plants seems to be the only way to deal with the problem [31].

Resistance to Herbicide Round Up

It is common ground that the use of herbicides and pesticides in general creates serious problems for the environment and, as a result, for human health. It is known that in areas where wheat is cultivated, that is, where the use of herbicides is increased, the number of child births is distinctly decreasing, complications in childbirth occur, and children are born with critical health problems principally related to mental retardation and autism spectrum [32]. An overview encompasses the physiological and yield constraints of herbicide applications with special reference to wheat productivity. Post-independence lagging of Indian agriculture to feed its population led to haphazard use of chemical pesticides, and consequently it has to be decided, which deteriorated the productivity pay-off specifically of wheat and rice. Past few decades witnessed the potential application of certain phytohormones in augmenting abiotic stress to get rid of yield gap and productivity constraints [33]. Genetically transformed products enable farmers to employ a smaller amount of herbicides. Genetically modified soy beans give rise to an enzyme resistant to the action of the herbicide. The herbicide Round Up destroys the action of a plant enzyme, thereby destructing the plant. Genetically transformed plants, however, generate a glyphosate-insensitive form of this enzyme, enabling it resistant and not affected by the action of the herbicide [34- 36]. Claims have been made recently that glyphosate-resistant (GR) crops sometimes have mineral deficiencies and increased plant disease [37]. This review evaluates the literature that is germane to these claims. Conclusions are: (1) although there is conflicting literature on the effects of glyphosate on mineral nutrition on GR crops, most of the literature indicates that mineral nutrition in GR crops is not affected by either the GR trait or by application of glyphosate; (2) most of the available data support the view that neither the GR transgenes nor glyphosate use in GR crops increases crop disease; and (3) yield data on GR crops do not support the hypotheses that there are substantive mineral nutrition or disease problems that are specific to GR crops [37]. Researchers are having conflicts on the impacts on human health and animals [38].

Cold Resistance

A significant advantage of genetically modified plants is the creation of varieties, which are resistant to cold temperatures that would normally lead to the plant freezing and destroying the plant, consequently losing production. Since the mid-2010s, due to fast global change in climate and plants cannot adapt to rapid temperature variations, scientists have changed their mindset to transgenic plants to address the problem [39].

Heat Resistance

In the near future, progressive global warming (as scientists at least claim) will have disastrous outcomes for plants, especially in areas where water shortages are already occurring. Creation of modified genes (Sh2 and Bt2) can aid plants to resist high temperatures [40, 41; Figure 2].

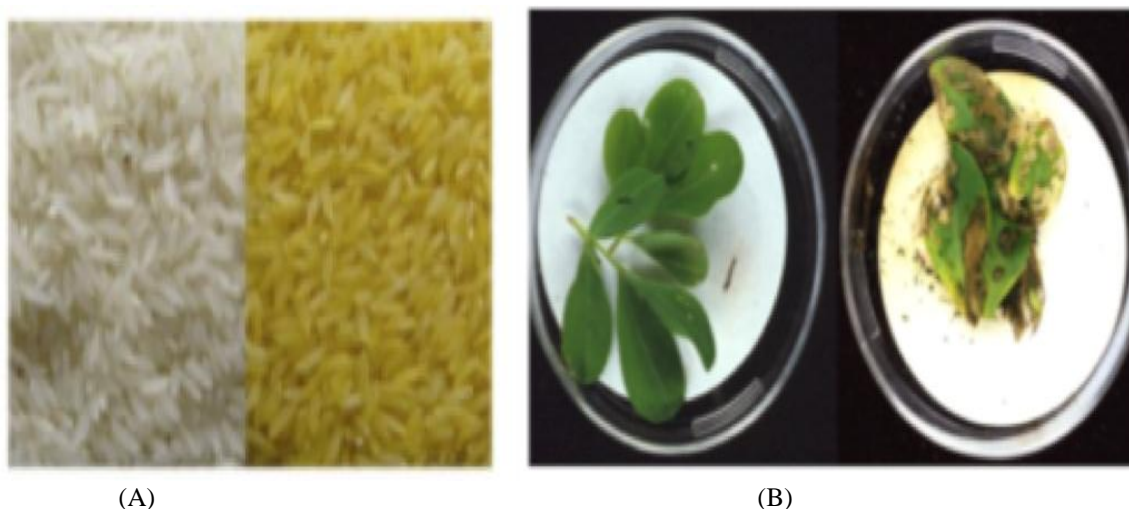


Figure. 2 Genetic modification in the crops. (A) The genetic modifications in the rice crop make it more resistant against the insects and pests. (B) The genetic modification in the plant tissue culture shows the stable growth and ability to fight against the pests.

Basic concepts related to genetically modified products

The Notion of Substantial Equivalence

The concept of substantial equivalence has been introduced in the debate on genetically modified products to ensure that these foods are safe [37]. Genetic modification is a special set of gene technology that alters the genetic machinery of such living organisms as animals, plants or microorganisms. Combining genes from different organisms is known as recombinant DNA technology and the resulting organism is said to be

‘Genetically modified (GM)’, ‘Genetically engineered’ or ‘Transgenic’ [37]. The principal transgenic crops grown commercially in field are herbicide and insecticide resistant soybeans, corn, cotton and canola. Other crops grown commercially and/or field-tested are sweet potato resistant to a virus that could destroy most of the African harvest, rice with increased iron and vitamins that may alleviate chronic malnutrition in Asian countries and a variety of plants that are able to survive weather extremes [37]. There 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. Technologies for genetically modifying foods offer dramatic promise for meeting some areas of greatest challenge for the 21st century. Like all new technologies, they also pose some risks, both known and unknown. Controversies and public concern surrounding GM foods and crops commonly focus on human and environmental safety, labelling and consumer choice, intellectual property rights, ethics, food security, poverty reduction and environmental conservation. With this new technology on gene manipulation what are the risks of “tampering with Mother Nature”? What effects will this have on the environment?, what are the health concerns that consumers should be aware of? and is recombinant technology really beneficial? This review will also address some major concerns about the safety, environmental and ecological risks and health hazards involved with GM foods and recombinant technology [42]. The principle of substantial equivalence holds that if the genetically modified product contains substantially equivalent ingredients present in the conventional product, then no further safety rules are desired. In this way the principle of substantial equivalence is a tool of evaluating genetically modified products and finding negative factors (such as allergens due to the presence of new proteins) [37, 41,43]

The Precautionary Principle

According to the preventive principle, any novel genetically modified product should not be made available to consumers unless there is first-hand evidence that the product is safe or if there are critical conflicts and conflicting opinions of researchers on the safety of the product in question [44, 45]. One of the priorities to address food security is to increase the access of farmers to biotechnology, through the application of scientific advances, such as genetically modified organisms and food (GMF) . However, the spread of (mis)information about their safety strengthens the clamor for mandatory GMF labeling [45]. A relevant overview of food labeling policies, has been noticed to consider the principles suggested by the Codex Alimentarius Commission, and analyzes the consequences for the world food security of the Brazilian labeling policies compared to developed countries [45]. It also discusses the discriminatory application of GMF mandatory labeling in the absence of any scientific evidence as it has the potential of causing social harm and jeopardizes research, production, and distribution of food and consumers' right to information [45]. Certain researchers, however, have argued that the preventive principle can act as a disincentive to the evolution of science and society, as it may stop or delay any novel technology that is capable of solving environmental or economic issues [46]. It should be noticeable, however, that criticisms have been raised about the utility and the manner the preventive principle works [47].

The Safeguard Clause

The safeguard clause permits Member States of the European Union to avert the circulation and sale of genetically modified products likely to be harmful to citizens [48, 49]. Genetically modified organisms (GMOs) have been available for commercial purchase since the 1990s, allowing producers to increase crop yields through bioengineering that creates herbicide-resistant and insect-resistant varieties. However, consumer knowledge about GMOs has not increased at the same rate as the adoption of GMO crops [49]. Consumers worldwide are displaying limited understanding, misconceptions, and even unfamiliarity with GMO food products. Many consumers report that they receive information about GMO food products from the media, Internet, and other news sources. These sources may be less reliable than scientific experts whom consumers trust more to present the facts [48]. Although many in the United States support mandatory GMO labeling (similar to current European standards), consumer awareness of current GMO labeling is low. A distinction must also be made between GMO familiarity and scientific understanding, because those who are more familiar with it tend to be more resistant to bioengineering, whereas those with higher scientific knowledge scores tend to have less negative attitudes toward GMOs [49]. This brings to question the relation between scientific literacy, sources of information, and overall consumer know GMO foods.

The Cartagena Protocol

The intention of this document is to guard the world's biodiversity by instituting rigorous rules on the transfer of genetically modified products from one country to another [23,50].

Labeling of Genetically Modified Products

The appearance of genetically modified products has led to the requirement for labeling of these products [49,51]. Genetically modified foods should have a special label reflecting that they contain genetically modified ingredients. Nevertheless, as simple as it sounds, the issue of genetically modified products labeling is

particularly complex and difficult, as there are significant questions about how labeling to be done [9, 52; Table 1]. For example, it has been argued that products containing either modified protein or foreign DNA should bear a special label. However, there are genetically modified products that do not contain modified protein or foreign DNA, thus there is the debate whether these foods, although modified, need special labeling or not. [5, 9, 37; Table 1].

Table 1. Procedure of labeling the product and their description manufactured using the GMO concept. Currently conceptualized in Brazil.

Legislation	Requirements
Decree n° 4.680/2003	Both industrialized and <i>in natura</i> foodstuff which contain more than one percent of GMOs should be labeled. The label must include the name of the gene donor species. If a food is animal material and the animal was fed GMO feed, it must also be labeled.
Ordinance n° 2.658/2003	Prescribes the use of the letter "T" in the center of a yellow triangle with black outline as a GM symbol in the label.
Interministerial Normative Instruction n° 1/2004	Establishes the Technical Regulation on Food Labeling and Food Ingredients that contain or are produced from GMOs.
Law n° 11.105/2005 (also known as Biosafety Law)	States that information about GM nature must be included on the label of foods and food ingredients intended for human or animal consumption, but does not specify how this should be done.
Decree n° 5.591/2005	Regulates the Biosafety Law, does not specify GMO labeling procedures and merely reproduces the text of the law (Article 91).
Decree n° 6.041/2007	Establishes a Biotechnology Development Policy and creates the National Biotechnology Committee. One of the guidelines of the policy is the creation of regulation of conformity assessment, including labeling.

Ethical Concerns

The central ethical issue concerning with the cultivation of genetically modified plants is that the generation of these crops is fundamentally an interference with the natural flow of life [23, 53]. Genetically modified (or GM) plants have attracted a large amount of media attention in recent years and continue to do so [54]. Despite this, the general public remains largely unaware of what a GM plant actually is or what advantages and disadvantages the technology has to offer, particularly with regard to the range of applications for which they can be used. From the first generation of GM crops, two main areas of concern have emerged, namely risk to the environment and risk to human health. As GM plants are gradually being introduced into the European Union there is likely to be increasing public concern regarding potential health issues. Although it is now commonplace for the press to adopt 'health campaigns', the information they publish is often unreliable and unrepresentative of the available scientific evidence. It is considered to be important that the medical profession should be aware of the state of the art, and, as they are often the first port of call for a concerned patient, be in a position to provide an informed opinion [54]. The ethical dilemma appears as to how to find the middle ground in the use of genetically transformed products, given that different countries have different perceptions of the significance of risk, with many countries banning the use of genetically modified products, while companies producing these products pay attention to profits, and do not consider the issues that may or may not arise. The problem here focuses on the high degree of unpredictability about the impact of using genetically modified organisms, while the arrangements proposed are usually shaped by financial and political interventions [37, 55]. Consumer attitude is also of particular importance, as consumers are buying and paying their vote of approval at the same time. Consumers are divided into two categories, the consumers who favor the genetically modified organisms and those who oppose them. Consumers' views are influenced by the information they are offered each time, the existing regulations, the confidence they have in the government in regulating the issues that arise, and what they are prepared to pay [37, 55].

Ethics and the Environment

Environmental ethics plays a pivotal role in discussions concerning biotechnology and genetic engineering, as many of the arguments presented against genetic engineering have to do with whether it is morally right to genetically modify organisms and the environment, as this may have serious environmental impacts. This shift is evident even in product ads, where companies say environmental protection is a priority for them [56, 57].

Animal Ethics and Intellectual Property Rights

Distinctively in reference to animals, modern ethical and intellectual property rights hold that animals including humans, have rights and that these rights should not be violated at any cost [58, 59]. Animals require to be treated as living organisms and not as commodities or human services. Introducing genes into animals and

carrying out experiments can lead to drastic changes in the physiology and behavior of the animal. The results may not be desirable, and in some cases, they may even be disastrous [60].

Genetically Modified (Patenting Living) Organisms

The creation of new organisms inevitably leads to the need to register them and allocate their ownership. But even in the case of registration of a novel product, the 'owner' of the new organism must ensure that the genetic transformation does not cause undesirable effects to the environment and humans, as he will be responsible for any problems that may arise [61, 62]. Further, it is a basic ground that humans have always changed the genome of both plants and animals [63]. This invading process, which has existed for thousands of years, many times through mistakes and failures, was originally carried out through the crossing of organisms with desirable features [64]. This was accomplished with the aim of creating and producing new plants and animals that would benefit humans, that is, they would offer better quality food, more opportunities for people to move and transport products, greater returns to work, resistance to diseases, etc. Nevertheless, creating genetically modified organisms does not proceed without conflicts. One part of the equation concerns objections made by disputants of genetically modified organisms to the manipulation of life, as opposed to defenders who argue that it is essentially an extension of traditional plant cultivation and animal breeding techniques. There are also conflicts regarding the risks to the environment and human health from using genetically modified organisms [65]. Concerns about the risks to the environment and human health from genetically modified products have been the subject of much debate, which has led to the development of regulatory frameworks for the evaluation of genetically modified crops. However, the absence of a globally accepted framework has the effect of slowing down technological development with negative consequences for areas of the world that could benefit from new technologies [65,66]. So, whilst genetically modified crops can provide maximum advantages in food safety and in adapting crops to existing climate change, the lack of improvements, as well as the absence of adjustment of the structure and regulations about the genetic transformations outputs in all those anticipated benefits of employing genetically modified crops being suspended. However, it is obvious that the evolution of genetically modified products is not going to end [65,66; Table 2]. For that cause, research on the influence of genetic modification on medical technologies, agricultural production, commodity prices, land use and on the environment in general, should therefore carry on in future as well [67].

Table 2. Comparative analysis of Agriculture Biotechnology invention and their Patent Protection.

Inventions	Brazil	USA	European Union
	Legislation	Legislation	Legislation
process to obtain a transgenic plant	Industrial Property Law (Law no. 9.279/96)	Title 35 United State Code (Utility Patent)	Directive 98/44/EC ¹
transgenic plants	Plant Variety Protection Law (Law no. 9.456/97)	Title 35 United State Code (Utility Patent)	Directive 98/44/EC ²
plant variety sexually reproduced	Plant Variety Protection Law (Law no. 9.456/97)	Title 7 United State Code (Plant Variety Protection Act)	Community Plant Variety Right – CVPR
plant variety asexually reproduced	Plant Variety Protection Law (Law no. 9.456/97)	Title 35 United State Code (chapter 15 – Plant Protection Act)	Community Plant Variety Right – CVPR

¹Besides the Directive 98/44/EC, the European Union has also the European Patent Convention and Implementing Regulation to enforce patent protection. ²“2. Inventions that concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.” (Article 4(2) of Directive 98/44/EC).

II. Conclusions

Recently there has been extended technological progression in creating genetically modified organisms. undoubtedly in the future there will be a continuum likely to be influenced by both scientific improvement and public affectation towards genetically modified organisms. Creating genetically modified organisms, nevertheless, does not continue without conflicts; there are certain controversialists of genetically modified organisms who perceive their production as a manipulation of life, as well as conflicts regarding the hazard to the environment as well as human health. Even though, it is apparent that the evolution of genetically modified crops is not going to end. Research on the consequence of genetically modified crops towards agricultural production, commodity prices, land use and the environment in general should thence continue. Besides, taken together the present compilation and the earlier report [68], it is necessary to communicate the consumer in view of

understanding the role of modern technology in crops and agricultural production, and particularly to understand the importance of genetic transformations. In whatsoever case, there should be intransigent and enforceable regulations for the application of genetically modified organisms, an assessment of the latent risks of genetically modified crops and apprehensible references to the consequences of genetic modification, on the environment as well as on human wellness.

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