
Biotechnology Regulatory, Safety And Ethics

ABSTRACT

Biotechnology consists of various techniques that helps in improving and providing better life to human beings. Biotechnology has provided several biomedical tools and techniques, to diagnose and cure diseases. Even biotechnology set a new parameters in industrial, agricultural, and biomedical fields. With the help of biotechnology several new enzymes, antibodies and vaccines are founded, which have promised less expensive products and cost effective treatments for many hazardous diseases by replacing highly expensive treatments and drugs. Along with it biotechnology has improved agriculture on large scale like it has gifted us plants with improved immunity, nutritional value and high yield which in either ways is beneficial for humans. But recent incline in the development and use of genetically modified products resulted in debate in all over the world. As each coin has two faces similiar in the case of biotechnological products, even it has a negative aspects. It is difficult to predict difficulties, benefits, risks and ethics related to biotechnological products, along with few regulatory aspects. Changes and technological revolutions are important because they bring required changes to the world, it just requiries careful consideration of safety, and ethics related to new products because with it we can reduce risks and ethics in future. And ethical considration is also important because in some cases biotechnological products may ended with some unanticipated results which may be criticized by several groups of society and even by few scientists. In present we have several examples of products and biotechnological techniques that have had faced criticism, like BT crops, GM organisms and few food industrial products due to their negative impacts on living organism were criticised and even were banned to use. That's why ethical examine of biotechnological products is important before using and launching them in market, because by not doing so we can risk several lifes, our futur generation and even we can put our planet in danger. It is medatory to analyse potential and benefits of biotechnological products, along with its drawbacks and ethical issues.

INTRODUCTION

Biotechnology has a wide range of definitions, however; the term "biotechnology" is about using biological systems, organisms, plants, and techniques for the benefits of people. While biotechnology is bounded to scientific, and technological knowledge, some where it also shares boundaries with ethics. The enhancement and regulation of biotechnology has given birth to several discussions from different sectors, as law, political, religious, economic and social. Biotechnology has diverse roles to play in various sectors, as biotechnology is included in formation of curd, beer and vine fermentation, formation of natural cooking gas by bacteria, bread and even pizza formation. Advancement in biotechnology has uplifted industrial and agricultural sectors on huge parameters with the help of special techniques Recombinant DNA, gene therapy, enzyme engineering, stem cell and cloning. These techniques have accelerated scientific research, it is mainly a breeding techniques which have been used in genetic engineering of living cells, animals, plants and human being from past few decades, which have tiggered the ethical issues and concerns in the creation of genetically modified organism as tomatoes, soya, wheat, and rice, animal cloning as transgenic cows, horses and sheep (dolly) and most importantly human embryo cloning have been facing ethics.

Some masses have view that by doing so we are challenging or nature. However, by RDNA hundreds of vaccines, drugs, enzymes and proteins are formed un-naturally, as insulin, vaccine for malaria and polio are few example of RDNA technology. Most importantly biotechnology has changed the vision towards agriculture by giving us GM organisms and plants, as BT cotton, BT wheat, BT rice, sugarcane and many other are good examples of revolution in green biotechnology. BT crops have high yield, they are drought resistance, pest and herbicide tolerance, and even they have more nutritional values than un-modified crops. In 1996 first genetically modified crop was introduced in US market and even was adopted by farmers on larger scale and as a result great success was achieved by increased yield and many other desirable characters. In spite, of all it, biotechnology has been a burning topic of debate since from its beginning in early 1970s for its safety and ethics. However, ethics are as important as its positive outcomes and benefits because, introducing these in environment may lead to instability, safety risks, ethical aspect. So, for the safety purpose these crops have a specific selection procedure. Ethical and safety concern was firstly mentioned by a molecular biologists on certain research to the Asilomar Conference in 1974, in a scientific gathering by United States governments. As a results, of this conference, guidelines for RDNA were made and published by National Institutes of health (NIH) Recombinant DNA Adviosry Committee (RAC), to provide guideline how the experiments should be conducted to hinder unpredicted products from genetically modification experiments or organisms. It is important to consider these rules for safety and ethics, because at some stages the role of ethics may not be visible.

The main aim of this report is to provide some vision to ethical concerns, safety and regulations in biotechnology. This report focuses on agriculture. Basically, ethics involve consideration on merits and demerits of any application and technology and their effect to environment, existing species, organisms and most importantly on humans, along with it economic, social and religious disputes with the development of technology are also considered by ethics and safety. It is important to understand difference between ethics, law and moral values. We cannot replace ethics with morality. As in India 2001, the unauthorized cultivation of BT cotton was unethical, as well as illegal. In one of the article by the New York Times, it was reveled that several European countries have either adopted GMO crops or either they are deciding in future. However, it was reported by US General Accounting Office that U.S. facing restrictions in GM crop market (Environmental News Network, June 27, 2001). Even genetically modified crops have to face criticism, even than from mid-1990s, a rapid adoption of 4 major crops were reported, corn, soybean, canola and cotton in several countries, US is one of them with significant interest in bio engineered crops. Furthermore, these crops were opposed by some of the Non-governmental organizations (NGOs) such as Friends of earth, Greenpeace and many more, in the pressure from these companies genetically engineered products were banned and removed from US market, as Gerber (baby food), Frito Lay (snacks), IAMs (pet food) and many more. After that few bills were introduced by Congress, into the US House of Representative and Senate (Boxer, S. 2080), in which it was compulsory to label if food contain GMOs. In US a brand named Taco Bell used a variety of BT corn, which was not yet approved for human use in the US Environmental Protection Agency (EPA). It was issue of debate because this crop has allergic concerns and this crop was called off by the US from retailers and the countries where it was exported. From thousand of reports and studies by several bodies, risks of dealing with genetic crops and their ethical issues regarding with health/ environment, some of them are as, many of the surveys mentioned that GMOs have toxic elements and harmful proteins which causes allergies and reducing human immunity and even causing cancer.

Secondly they have detrimental effects of non modified crop species and environment. For instance, Ice-minus (*Pseudomonas syringae*) is pathogenic bacteria present in plants, which is used in many researches. And made a bacterial solution for spraying, according to the ethics release of pathogenic bacteria in environment is unjustifiable, its release could risk human health, they argue that it could imbalance the ecological cycle. We have great risk for the loss of biodiversity because GM crops are likely to threat to existing species by outgrowing or eliminating local/native flora, followed by several other issues, such as spread of herbicide tolerance from GMOs to non-modified crops and weed species, and most importantly human pathogens may become resistant to several medicines, vaccines, drugs and antibiotics, which may end in worst condition for health sector. We can not ignore the risk and future impact of biotechnology on mankind. To avoid future problems related to genetically modified organism and plants government bodies and scientists made few rules for the selections of GMOs with the help of selectable and non-selectable markers to reduce detrimental impacts. There are even rules for the safety of customer and consumers, NGOs and other human rights advocates says, that consumer have right to know, whether the food they are buying and using is genetically modified or not, and if it is then what may be the consequences of using bio-engineered food. For example, in 1996, a protein from Brazil nut have been introducing into canola and soybeans. Allergic reactions were reported by FDA and as a resultant product was banned in 1999 from further development and human use. Most importantly, these all procedure of genetic engineering requires huge amount of funds and time, this is one of the reason, why few economist criticize biotechnological products.

ETHICAL CONSIDERATION IN AGRICULTURAL BIOTECHNOLOGY

This report is about ethics issues and safety in agricultural field, especially genetically modified crops. There is a broad range of concerns, because when a biotechnological crop is out in the nature it may impact the soil where it is grown, native ecology, humans who are in contact with these crops either they consume it, they wear the clothes made from it, or either they inhale the pollens of these crops in any way, BT crops may show their consequences in future generation. Some of potential issues involved in cultivation and use of GM crops:

Presence of harmful and allergenic proteins in food

There are several examples of genetically modified crops which shown allergies to the consumer. It may be the result of overproduction of some of innate compounds which are resulting in high level of toxic substance in transgenic products. Several experiments and tests are required to control the production of toxic level in GM crops which are not required for human diet. For instance, clothes made from BT cotton have allergic reactions and rashes to users. In general, genes in parental plant are not allergic but when they are used in transgenic plants, they become highly allergenic. In 1996 CP4 EPSPS enzyme was used in soyabean for herbicide tolerance but this toxic enzymes does not shows any impact on human being because this enzyme get digested rapidly and ending with out harm or allergy. Soil changes due to BT crops were also reported, crop remaining are the source of carbon and other toxic elements in the soil which are responsible for changes in microbial modifications in soil. Cry protein produced by one of the BT crop have negative effects on wwoodlice, earthworms, mites, protozoa and many other soil species. These crops are responsible for changes in geography, temperature, soil type and variety of native plants.

There are several rules and techniques to reduce these ethical issues and ensure safety of users of BT crops. These crops are even a reason for modifications in humans. Kanamycin, a marker gene, inactivates the antibiotics but we don't have any definite example of it in humans but due to public concern, Kanamycin use was prohibited. Some of the governmental and non-governmental bodies ensure that GM crops we are going to use are not allergenic. The World Health Organisation (WHO) and Food and Agricultural Organisation (FAO) made a procedure to check the allergic impact of GM crops.

Impact on environment and native species

Genetically modified crops that are insecticide or herbicide resistant to check the rate of agricultural pests and weeds, also have a detrimental effect on native or existing crops and organisms. These crops even harm or kill the non-pests. Which result in ecological shift and even most of pests develop immunity against these crops. For instance, a lacewing larva which fed on a variety of transgenic corn (Cry 1 Ab) was reported with an inclined rate of mortality in comparison to the larva feeding on non-modified corn crop. Some of the weeds when they come in contact with BT crops develop mutation in them and cover large area. Pollen drift from these crops causes a problem they contaminate non-modified crops.

Incline in weediness of crop plant

It is one of the debate topics, but it is somewhere right, that release of GM crops in environment may cause agricultural weeds and farmers may have to face huge problems in checking and controlling this agricultural weeds. Crops which have weed-like characters, when they are genetically modified and transformed into GM crop may invade and grow on such a large scale like weeds. For example, crops like *Oryza*, *Brassica napus*, *Mendicago sativa* have weed-like characters, and their weed-like growth may be controlled by using some mixture of ingredients.

Pests resistance

Cultivation and use of BT crops with pests and disease resistance on such a large scale have been resulting in resistance of pests against chemicals. The target pests *Helicoverpa armigera* and *Helicoverpa zea* are less affected by Cry 1Ab and Cry 1Ac in BT corn and cotton. These pests are evolving by mutation in them becoming nearly resistant to these genes. In addition, the diamond-back moth is a pest of Brassica crop in all over the world. It was the first pest reported with resistance to BT toxins, used to check their growth rate. So resistance to pathogenic protein by pests will arise problems in coming future of transgenic crop.

Effects on Biodiversity

Instant use of genetically modified crops is resulting in biodiversity decline. Pollens from GM crops can contaminate other non-GM crops and as a result local and native varieties will disappear from planet. In Mexico farmers are not allowed to grow genetically modified maize crop but, however; Mexican import maize on large scale for using them in food. That's why in a study, 870 maize plants in 125 fields in 18 different locations were studied and not in a single seed out of 153,746 have had genetically modified DNA. Use of conventional soy is replaced by GM soy crop which is glyphosphate-tolerant and it is harmful for environment. In Argentina and the United States a glyphosphate weed was appeared because in these countries the use of

glyphosate- tolerant soy was very common. As a result, cultivation of genetically modified soy dropped in Argentina from 21% in 2004 to 1% only in 2013.

- To handle the problems related to use of genetically transformed crops two basic safety concerns are :
- To tackle the problem of DNA transfer by pollen and seed, male sterile plants can be used because they don't produce pollens. And by this way pollen shift can be reduced and may also hinder seed dispersal.
- To avoid the entry of pathogenic molecules in food chain by using non food crops in as GM crops, like tobacco. Or use of fluorescent markers to monitor expression of linked genes.

Regulation and Public concern: GM crops

Genetically modified crops have been facing problems for commercialization along with the market restrictions. Despite of the benefits of this new technique there is a pressure on regulation and legislation of GM crops. For good use of GM crops or animals, adequate biosafety system along with proper guidelines, appropriate review, feedback from farmers and consumers are required. Many countries have made a regulatory system to ensure effective and safe evolution of GM crops. Many are working to make a proper legislative frame for environmental and commercial release of transgenic crops, because genetically modified crops may raise social, religious, ethical, political, economic, scientific and technological. FDA announced that labeling of transgenic products or food is must, by doing so public will be able to identify between genetically modified and non- modified stuff and it would be their choice to use either of them. By proper labeling public will come to know about the compositions of products and the allergies or other reaction from these genetically modified products. By labeling people will have information about risks and benefits of using them with truthful knowledge, and non misleading information.

Conclusion

From several decades biotechnology has been used as a technique or a tool to benefit mankind by producing new characters in agricultural plants and animals. Revolution in technology have gifted us new techniques for the formation of transgenic crop, genetically modified plants, vaccines, drugs, and many other products. Public have diverse opinion related to genetically modified crops, it was designed to improve agricultural, industrial, and medicinal sectors. Main objective of GM crops to benefit farmers with high yield, cost effective farming and crops with good self lives. However, other masses share view about the safety of GM crops. It have been made compulsory to label GM products to make it separate from non- modified crops, to ensure safety and ethics related to it, because these GM crops may contain allergen and different composition or nutritional contents, which may result in allergies or some adverse reaction to the consumers. By advanced regulation system we can reduce risks and ethics related to biotechnology. To conclude, proper assessment of all aspect of genetically modified crops and its effects on present and future generation can benefit living organisms.

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