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Article · January 2015

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Journal of Biology, Agriculture and Healthcare
ISSN 2224-3208 (Paper) ISSN 2225-093X (Online)
Vol.5, No.11, 2015

Ethical Issues of Biotechnology, Possible Risks and Their Management

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Abstract
Biotechnology comprises on various techniques that exploit the application of biological organisms, systems or processes for the benefit of human being. It has helped the medical science by developing new diagnostic tools and kits to diagnose the diseases. Industrially it has created a thriving business in enzymes, antibody and promises newer and less expensive products. Biotechnology has improved the agricultural production, by developing varieties having resistance against biotech and abiotech stresses. Production of diseases free plants with improved nutritional value has proven the role of biotechnology in agriculture sector. Theses biotechnological techniques also have been criticized by various religious scholars, scientist and economists. Present review has elaborated the various techniques and their related ethical, social and economical factors so that we may know about the possible benefits and related risks, before using applying these techniques in any field of biotechnology.
Keywords: Biotechnology, Ethical issues, Social issues, Economic factors

Introduction

The term Biotechnology may be defined as the application of engineering principles on biological sciences to form new products from raw materials of biological origin, for example, vaccines or food, Or the use of living organisms and their products to modify or improve human life and environment health (Verma *et al* 2011). Cheese was probably the first direct products of biotechnology, because it was prepared by adding rennet to sour milk, which is possible only by exposing milk to microbes. Yeast is thought as the oldest microorganisms that have been exploited by humans for their benefit. Yeast has been widely used to make bread, vinegar production, and other fermentation products (Verma *et al.,* 2011). In the mid-eighties and early-nineties it became possible to transform plants and animals. However recognizable modern manifestation in biotechnology began in early1960s (Daar, 2011). Today, biotechnology has wide-ranging applications, from agriculture to cloning of living organisms and altering life forms. Genetics and biotechnology offer a door to a new era in the history of mankind. Insulin, used to treat diabetics, and as a blood clot-reducing enzyme for heart attack victims is now produced easily and cheaply as a result of biotechnology. Biotechnology has great potential to improve the quality of human life by improving their health by providing them more nutritious food with improved environmental conditions. It can ensure sustainable development by improving agricultural productivity.

1-Bioethics

The term bioethics is typically used to study the controversial ethical issues emerging from new situations and possibilities brought about by advances in biology and medicine. It is also moral discernment as it relates to medical policy, practice, and research. Biotechnology is playing an important role for the improvement of human life. However due to extensive and absurd use of natural resources deterioration to social and natural environment has also been occurred. The ethical evaluation of biotechnological interventions rests first upon a good understanding of the science behind these interventions, and second upon balancing the risks and benefits such interventions pose. In addition, the power of new molecular techniques to manipulate life, insert the genes of one species into the genes of another species, and otherwise redirect living organisms both in captivity and in the wild to specific human purposes, raises questions about the proper role of humans in their environment and in the alteration of living organisms.

Bioethics is not local affairs that can be solved by a local society, inspite they are global issues whos effects will be universal. An ethical system that is exclusive or discriminatory in any other way is ipso facto, morally damaged. In general, there is nothing wrong with technology, as such. In itself, it is ethically neutral, neither right nor wrong. It is an important non-moral value, connected with human skills and achievements. But, the uses to which any technology is put, is a moral issue. For example, developing, let's say, an infectious contraceptive is a technological affair, it is a local and localizable affair, even a personal/individual affair, but the 'exploding population' amongst which such a putative contraceptive is released or unleashed, is an ethical matter

(Tangwa, 2004). Current approaches in bioethics largely overlook the multicultural social environment within which most contemporary ethical issues unfold. In multicultural settings, patients and their families bring many different cultural models of morality, health, illness, healing, and kinship to clinical encounters. Religious convictions and cultural norms play significant roles in the framing of moral issues. At present, mainstream bioethics fails to attend to the particular moral worlds of patients and their family members (Turner, 2003)

2-Socio-economic issues

Biotechnology is more than just a scientific issue. Scientific community assuring us that biotechnology is harmless, and promises marvelous advantages to humankind, even that it may be the key to our survival in an ever-changing world. On the other hand there exist a diverse array of arguments about the right of man to interfere in nature or God's process and the dangers to the environment, the food chain and ultimately our own health. Such issues are largely related to cultural backgrounds and levels of public perception and awareness. It is therefore necessary that decisions on the use of new technologies should respect socio-economic realities. Public understanding of biotechnology as a science and technology is important because the products of biotechnology and consequent benefits and risks are ultimately going to affect everyone. Biotechnology holds great promise as a tool to preserve and enhance environmental quality. Years of plant breeding show that genetics is the most cost-effective, environmentally safe way to address problems that reduce yields. But without public understanding, acceptance, and support, the role that biotechnology could play in solving environmental and food production problems could be stymied. Biotechnology is offered as a solution to human problems, and often, to problems caused by humans. Yet biotechnology may create as many problems as it solves. Some environmentalists and other critics have pointed out that perhaps we would be better off learning to live in harmony with nature, rather than attempting to make nature conform to our specific needs. Biotechnology promises to play an increasingly powerful role in the further taming and manipulation of our natural and unnatural worlds. In part due to the technological imperative, our destruction of the environment is a result of the very impetus which drives the biotechnological interventions to ameliorate it. Biologists and biotechnologists must take a broader view of their practice than the instant goals they seek to address. Potential benefits of biotechnology to mankind have led to multi-billion dollar per year investments involving new companies and many existing enterprises. (Hodgson, 1987)

3-Cultural issues

Before its practical reality biotechnology was the science of imaginations. Biotechnology is quietly different in reality from the literary and science novel fantasies of popular culture. The ethics of biotechnology entails both a reflection on the immediate consequences of its use, and on the underlying social and cultural conditions of which it is a part. The eugenics movement that occupied serious and well-respected scientists and politicians in Europe and America earlier in this century testifies to the ways in which the application of science can go morally wrong. It is, therefore, not surprising that as the biological sciences and biotechnology have enjoyed remarkable success during the past 30 years, public awareness and discomfort, particularly with genetic engineering, have increased. All technology modifies our relationship to our environment, to our work, and to ourselves, but biotechnology strikes much closer to home, enabling us to modify life itself. These considerations raise the question of the scientists' responsibility in the application of the knowledge and techniques they have produced. Historically, biotechnology has grown out of the simple search for biological knowledge. As biologists sought to penetrate to the molecular core of living processes, they invented tools to assist them in that process. As in the case of PCR---a method for making many copies of specific DNA sequences for analysis---and many other biotechnologies, biologists have put to use the very processes of life itself in their study of life, borrowing the molecular machinery of life to analyze living processes. But as with all scientific endeavors, the tools by which science investigates the world often yield tools by which we may transform the world. While science is often pursued for its own sake and the simple pleasure of understanding the world, the combination of the tools of knowledge with practical ends cannot be ignored when considering the moral value of the enterprise. Investigation of the structure of the atom led inexorably to the application of this knowledge in the building of atomic weapons. It is a legitimate and by no means resolved moral question to ask what the moral responsibility of the scientific community is in guiding the use of the fruits of its intellectual labors.

4-Environmental issues

Biotechnology has been proven better for the improvement of our environmental health. Biological pesticides are being used more efficiently which has also reduced the chemical pesticides. Genetically engineered plants have also reduced the need of fertilizers thus minimized the pesticide pollution to rivers and costal water resources. One of the first modifications through genetic engineering in microorganisms was done in bacteria that have the ability to digest oil spilled in the oceans. Bioremediation and, in general, the improvement of the environment have been the primary aims of a great deal of biotechnological research. In the marine context, much of the

scientific work being done is aimed at ameliorating the effects on food species and marine ecosystems of overdevelopment, pollution, and loss of breeding habitats. While biotechnological methods promise a variety of important social and environmental benefits, public response, especially to the release of genetically modified species into the environment, has been mixed. Though not always based on a sound understanding of the science and technologies involved, the public is wary of genetically altered foods and concerned about the inability to control biological agents once they are released into the environment. The benefits of a particular biotechnological intervention in the environment typically accrue directly to the sponsor, often a commercial interest. However, the harms that may result from such interventions typically do not remain confined to those interests or the individuals responsible for introducing them, but instead may propagate throughout the environment and affect the general public. A gene that protects a food crop from certain pests benefits the farmer and the seed company directly, but should that gene cross into a noxious species, it may well create problems for the general public.

5-Legal issues

Legal issues are being arises in the use of biotechnological techniques. Particularly modern techniques such as stem cell technology, gene therapy, and human genome project have generated many issues in the society and there is need to resolve them for the satisfaction of the person who is receiving treatment or getting benefit from these techniques. But due to lack of motivation, in developing countries like Pakistan governments have not yet established the necessary legislation, institutions or infrastructures to protect vulnerable persons and to address bioethical issues. As a result, people are not interested in bioethics issues since measures are not taken to create awareness on the field in the country. More over it has been assumed by the people that bioethics is a field of Western discipline or field of study that deals with issues on High-Tech and addresses directly issues arising from or related to the use of High-Tech, health related issues and practice in the West and modern medicine which does not needed by developing countries. In western countries laws have been formulated that regulates the biotechnological products. In U.S.A the Plant pest act is used to regulate the genetically engineered plants under the supervision of U.S. Department of Agriculture (USDA). The Environmental Protection Agency (EPA) regulates the release of genetically engineered microbes into the environment under Section 5 of the Toxic Substances Control Act, Microbial Products of Biotechnology. Under this act, the EPA must operate under the risk-benefit approach and is required to meet a substantial burden of proof before it can even request data on a particular organism or before it can regulate or prohibit the production and release of microorganisms. This patchwork of Federal regulatory authorities covering biotechnology is confusing and inefficient. The public interest would be better served by a single office or agency responsible for evaluating the variety of biotechnological interventions and their impact on the environment. A possible impediment to biotechnology development in the United States is the current litigious climate. The concepts of a risk-free society and cradle-to-grave security have created "glitches" in the legal system that allows a single individual to halt important scientific projects. For example, Rifkin (1983) has successfully used the courts to stop genetic engineering projects by invoking the need for environmental impact statements. Recently, a highly promising vaccine against swine pseudo-rabies was recalled because it involved a deletion of genetic material from the virus. It is interesting that less precise genetic alterations and deletions made with the old technology are acceptable for vaccine development, even though they are not well understood. It is clear that lawyers, judges, and the public will react out of fear and ignorance if they do not understand the processes involved.

6-Religious issues

Scientists and technologists are able to play real games with God/Nature, manipulating the building blocks of living things at will. It is a dangerous game, its purported anticipated benefits notwithstanding, in which they are being encouraged, aided and abated, supported and funded by powerful industries and corporations, for motives of profit (Tangwa 2004). The newly developed molecular techniques of gene identification, genetic engineering, and artificial reproductive procedures represent a quantum leap in our ability to manipulate life itself, a domain long held by culture and religion to be the province of a divine agency. Religious scholars have criticized the use of biological techniques to expose the privacy and dignity of human being. Some religions have taken the issue of stem cell technology very serious. As according to them research on embryonic stem cell is like to kill the human. Similarly the criticism of religious scholars on human genome project was very severe. It is often argued by religious people that biotechnological interventions are not natural, or that they go against some divine or natural order of things. But human beings are also natural---natural products of evolution. Our technological development is no less natural than the mud wasp's construction of a nest. Thus, it might be concluded that genetic engineering is a natural phenomenon, akin to the "genetic engineering" that takes place in nature every time a gene crosses over on chromosomes, a gene mutates, or a bacterial plasmid migrates from one species to another. There is an important difference between "natural evolutionary processes" and "natural genetic engineering." Natural evolutionary processes do not make a choice, they do not deliberate with the intention of

achieving an end. What distinguishes natural evolutionary processes is that they are not goal directed, whereas human actions are always goal directed. To argue that genetic engineering is simply an extension of natural evolutionary processes does not morally justify the practice. With this line of reasoning, any biotechnological intervention could be justified as simply a natural process. But clearly not every intervention is good. It can only be determined to be good based upon a moral deliberation that takes into account its risks and benefits and the appropriateness of intervening in the first place.

7-Possible Risks and Benefits of Biotechnology

An essential element in the ethical evaluation of biotechnology is the analysis of the possible harms and their likelihood of occurring, weighing these risks against the probable benefits. Since biotechnology encompasses a wide variety of biological methods and techniques in a wide variety of circumstances, the analysis of the risks and benefits will be highly contextual, depending upon the peculiarities of each specific application. For instance, the use of genetically engineered bacteria to produce insulin in a commercial laboratory is quite different from the release of genetically engineered bacteria into the natural environment. Conditions can be controlled in the laboratory and, with appropriate safety measures, the modified bacteria can be prevented from escaping. But the release of a genetically engineered species into the environment poses additional risks depending on the viability of the organism, the nature of its genetic modification, and the purpose for which it is introduced. This discussion will be confined to the principles that may apply to the ethical evaluation of biotechnology in general, recognizing that the ethical evaluation of each particular intervention will depend upon its specific circumstances. Adequate assessment of the risks of releasing a genetically modified species into the environment entails a thorough knowledge of the ecology of the environment and how the modified species will interact with other species. Proposals for the introduction of genetically modified species into the environment have been criticized on the grounds that there is insufficient ecological knowledge and that, in general, the science of predictive ecology is underfunded and poorly understood. Even in individual species, it is difficult to predict the health effects of inserting foreign DNA into an organism or otherwise modifying the expression of genes it already contains. A number of deleterious pleiotropic effects have been shown to occur in genetically modified species. In fact, the only way to determine these effects is through experiments upon individual organisms, a fact not lost upon animal welfare advocates. The ultimate safety of transgenic organisms can only be evaluated through careful study of their release into the environment, with the consequent risk that we will discover a cascade of harmful effects on the environment only after it is too late to stop the spread of the organism. The ecology of environments is highly complex and relational. Individual species can play a variety of roles within an environment and the effects of a change in a species can be highly unpredictable. The problem is not simply inadequate knowledge but rather the complexity of ecological systems. Complex systems, in general, may be highly nonlinear, meaning that there may be little or no correlation between incremental changes in a system and how it behaves. In mathematical models of complex systems, the effects of changes in a system are, in principle, unpredictable. The only way to discover these effects is to observe how the system behaves upon the introduction of a specific change.

Since adequate risk assessment depends upon prediction and quantification of risk, the effects of the introduction of new or modified species into an ecosystem may not be adequately quantifiable or manageable, making each such introduction truly experimental. The lessons learned from the endangered species program are valuable in this context. Biologists have learned that in order to save a species, it is necessary to save its habitat. We might postulate a biotechnology corollary to this principle: Altering a species may alter its habitat, even if you do not know exactly how.

The complexity of ecological systems makes it very difficult to identify specific causes of environmental change, and since one may not be able to anticipate specific changes, it is possible that scientific observation will fail to detect them. Without the development of a much richer general science of ecology, and specific ecological studies of the environments into which biotechnology is introduced, adequate risk assessment may be impossible. It follows, then, that in the absence of adequate ecological study before biotechnological interventions take place, and in the absence of a commitment to long-term study after they have been introduced, the ethical evaluation of risks and benefits is incomplete. Proceeding on the basis of inadequate study may be unethical. One especially troubling risk of the introduction of genetically engineered species into the environment is the possibility that the modified genes will cross to other species. This problem is most characteristic of plants and microbes, especially bacteria. It is also possible that genetically modified viruses may target unexpected species, spreading either deleterious or beneficial genes in unexpected ways. A related risk is the short generation time and potentially rapid evolution of microbes. If a genetically altered microbe persists in the environment, it is possible that it may evolve in unforeseen ways, producing unforeseen effects. Controlling the spread of genetically engineered species in the environment is also difficult, especially in the marine context where individual organisms can be quickly spread to vast areas by ocean currents. In addition to the unpredictability associated with introducing new or modified species into the environment, harmful effects may

be irremediable. Once a genetic modification has hopped to another species, there is little that biologists can do to effectively contain the spread of the gene. Once disrupted in this fashion, the ecological balance may be irrevocably altered, to the detriment of the ecosystem and its associated benefits to humans. One promising method for protecting marine environments against the adverse consequences of introducing genetically modified species of fish has been to limit the reproductive capabilities of the fish. In this way, adverse ecological impacts may be reversed by discontinuing the release of the modified species.

8- How to manage risks

There are two ways in which risks can be managed. They are reflected in the differing approaches to biotechnology taken by Americans and Europeans.

a- **Risk-Benefit Approach**

This approach is based on the probability that what is more than harm. it is a process that is intended to support the decision maker by providing an in-depth analysis of the problem, thereby enabling the decision maker to take a more informed decision. (Walker et al., 2005). We can then make our decision about using the item in accordance with the results. This is a risk-benefit approach, and it comes naturally for Americans. In United States commercial interests are favored over environmental concerns until it can be confirmed that a particular prasctice is unsafe for humans. A notable exception to the risk-benefit approach is the Food and Drug Administration's (FDA) process for granting approval for medical drugs and devices.

b- **Precautionary Approach**

This approach is more commonly favored by Europeans, which dictates that no product is acceptable until it has been proven safe scientifically. This approach prevents the patients from unseen problems as the product or practice has already been demonstrated before it is admitted to that person.

One of the basic problems with assessing the risks of biotechnological interventions is that it may be very difficult to establish the exact cause of a particular harmful effect in the environment. Several solutions have been offered for this problem, including the use of unique genetic markers to label genetic modifications of organisms. Should the release of such organisms into the environment cause problems, the modified genes can be traced back to the specific project responsible for their release. The Institute of Virology at Cambridge University has demonstrated that such genetic markers can indeed be used to track modified genes. The use of these markers for genetically engineered organisms would promote accountability and provide an added incentive to ensure the safety of genetically modified organisms prior to release. An additional inducement to minimize risks can be created by amending the legal liability incurred by the release of genetically modified organisms. For instance, the European Parliament's Committee on the Environment, Public Health and Consumer Protection recommended that the release of genetically modified organisms into the natural environment should be conducted under strict' liability, "whereby any individual or organization claiming for damages caused by another party does not have to prove that the other party acted negligently in order to claim damages, but merely to show that the damage was caused by the actions, activities or products of the other party. Commercial interests involved in the release of genetically engineered organisms into the natural environment would, thereby, have a strong financial incentive to minimize the risks of their intervention. The Committee also recommended that the release of genetically engineered species be conducted only if appropriate insurance coverage has been provided by the sponsor prior to the release.

Ethical deliberation requires impartiality, that is, disinterestedness on the part of those who judge. Thus, scientific grants are awarded through blind peer review so as not to be biased by personal relationships. But the use of biotechnology may affect us all. One of the problems with the peer review mechanism is that the practice of science itself predisposes practitioners to particular values. If the question is strictly scientific, then peer review can provide impartial assessment, but if the question concerns the place of scientific values in public policy or ethical deliberation, then scientific peer review is inherently biased. Because of the uncertainties of the risks of many biotechnological applications and the impacts of these risks to both human and ecological interests, the ethical evaluation of biotechnological applications requires a very different kind of process than our present regulatory system provides. Our system relies heavily upon scientific expertise and a general predisposition to minimize regulation and promote trade. Questions regarding the application of biotechnology in the environment require far greater public participation and, in general, greater impartiality.

Conclusion

By using the techniques developed by biotechnology researchers can scientist can alter the life cycle of species by inserting a gene of wholly unrelated species and enhance disease/ stress resistance in that specie. The techniques like development of DNA vaccines and genetically altered bacteria and other transformations of life through biotechnology have been pursued for the sake of the social benefits which biotechnologists promises. Cheaper and more effective medicines are possible when produced through biological rather than chemical means. But appropriate balance of environmental and health concerns against economic benefits is essential for

the use of biotechnological applications. People should be given awareness about both the benefits and risks of a product. They also be aware that whether the benefits justify the risks, who reaps the benefits and who bears the risks. If the risks and benefits are disproportionately distributed to different groups, the practice may be unjust which may effect the community.

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