Ethics in Biotechnology

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Abstract

The most modern techniques in biotechnology owe their existence to the discovery of DNA cloning and the genetic manipulation of organisms. However Biotechnology is not new science In fact, many applications represent old practices with new methodologies. Human have been used organisms for their benefit in many processes for several thousand years. Therefore, one way of thinking about biotechnology is to consider two categories of activities: those that are traditional and familiar and those that are relatively new. Study of ethical and social concern in these categories makes this clear that there are many unanswered questions in this fields that requires caution regarding to public using of this technologies.

Genetic manipulation (GM) especially cloning is a wonderful advancement in technology and knowledge. However, Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and

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implantation into a woman's body would be at this time an irresponsible, unethical, and unprofessional act. The environmental safety aspects of GM crops vary considerably according to local conditions. Different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods.

Keywords: biotechnology, cloning, GM organisms, genetic manipulation, ethics

Introduction

Biotechnology is most briefly defined as the art of utilizing living organisms and their products for the production of food, drink, medicine or for other benefits to the human race, or other animal species. Technically speaking, humans have been using biotechnology since they discovered farming, with the planting of seeds to control plant growth and crop production. Animal breeding is also a form of biotechnology. More recently, cross-pollination of plants and crossbreeding of animals were macro-biological techniques in biotechnology, used to enhance product quality and/or meet specific requirements or standards. The discovery of microorganisms and the subsequent burst of knowledge related to the causes of infectious diseases, antibiotics and immunizations could probably be counted among man's most significant, life-altering discoveries.

However, the most modern techniques in biotechnology owe their existence to the discovery of DNA cloning and the genetic manipulation of organisms is exciting modern day's techniques.

Biotechnology is not new science In fact, many applications represent old practices with new methodologies. Human have been used organisms for their benefit in many processes for several thousand years. Historical accounts have shown that Chinese, Greeks, Romans, Babylonians and Egyptians among many others have been involved in biotechnology since nearly 2000 B.C. Therefore, one way of thinking about biotechnology is to consider two categories of activities: those that are traditional and familiar and those that are relatively new. Within each category can be found technologies that are genetic-that involve modifications of traits passed down from one generation to the next-and technologies that are not. In addition, there are interesting issues connected with a number of biotechnologies such as old and new.

A. Traditional and old Biotechnologies

A prime example of traditional genetic biotechnologies is selective breeding of plants and animals. The rudiments of selecting plants and animals with desirable traits and breeding them under controlled conditions probably go back to the dawn of civilization, but the expansion of knowledge about genetics and biology in this century has developed selective breeding into a powerful and sophisticated technology. New molecular approaches like marker-assisted breeding (which enhances traditional breeding through knowledge of which cultivars or breeds carry which trait) promise to enhance these approaches even further.

Traditional breeding technologies have been immensely successful, and indeed are largely responsible for the high yields associated with contemporary agriculture. These technologies should not be considered passé or out of date. For multi gene traits like intrinsic yield and drought resistance, they surpass genetic engineering. This is because selective breeding operates on whole organisms -complete sets of coordinated genes- while genetic engineering is restricted to three or four gene transfers with little control over where the new genes are inserted. For the most important agronomic traits, traditional breeding remains the technology of choice.

Other traditional nongenetic biotechnologies include the fermentation of microorganisms to produce wine, beer, and cheese. Industry also uses microorganisms to produce various products such as enzymes for use in laundry detergents. In an effort to find microorganisms that produce large amounts of enzymes, scientists sometimes treat a batch of organisms with radiation or chemicals to produce randomly genetic alternations. The process, called mutagenesis, produces numerous genetic changes in the bacteria, among which might be a few that produces more of the desired product.

B. Biotechnology Today

Biotechnology does not mean hunting and gathering animals and plants for food. However domesticating animals like sheep and cattle for use as livestock is a classic example of biotechnology. Our early ancestors also took the advantage of microorganisms and used fermentation to make breads, cheeses and yogurts. Different biotechnological advances can be found in nearly all sectors of industry today. There are, of course, the obvious medical, pharmaceutical and food industries.

Advances in biotechnology are being used to determine cause and effect of various diseases and are used in the production of drugs. The production of foods is enhanced by biotechnological advances that improve crop yields, introduce *in-situ* insect resistance and provide new ways of food preservation. Technological advances also include biodegradable packaging and built-in bio-indicators of food contamination. In the environmental sector, biotech has played a role in remediation of contaminated land, water and air, pest control, treatment of industrial effluents and emissions, and acid mine drainage.

Moral debates in bioethics continue to surround the field of biotechnology. The public response to issues such as the value of genetically modified organisms (GMOs), versus the risks involved in their release into the environment, more-or-less quenched the enthusiasm of the bioremediation industry for GMO research, in the early 1980's. Genetically modified foods (GMFs) continue to be produced, but with more and more governments clamping down on production and distribution and answering calls by the public demanding strict testing and labeling procedures.

Exciting new developments are being made in bio-fuel research, at a time when fossil fuel prices as sharply increasing. However, the question of whether a diminishing supply can meet the ever-increasing demand is under debate by those who do not believe the fossil fuel crisis is imminent. If they are correct, there is still some question of whether the cost of biofuel research and development is worth the effort.

Finally, there are the highly publicized and emotional debates surrounding the use of human embryos and stem cells for genetic research. Although the benefits of such research are obvious to most, the cost to human rights, morality and religious integrity are too high for some.

C. Broad Spectrum of Biotechnological Applications

Today the known applications for biotechnology can be seen as a broad spectrum. Biotechnology is generally divided into following sub fields – blue, red, white or grey and green biotechnology.

1. Blue Biotechnology

It applies to marine or aquatic applications such as restoring and preserving various aquatic species, such as blue crabs in the Chesapeake Bay. A second example is land-based marine aquaculture that is based on methods for large-scale hatching and growth of marine fishes in a completely self-contained recirculating environment.

2. Red Biotechnology

Red biotechnology deals with genetically altered microorganisms that are used for producing products like insulin and vaccine for medical use. It is through red biotechnology based research that antibiotics for different infections have been developed and vaccines for boosting the immune system against disease and to detect and treat any genetic disorders and disease have been produced. Red biotechnology also helps in reproductive technologies like in vitro fertilization, DNA profiling, forensics and in technologies of transplantations.

3. White (Grey) Biotechnology

It involves the creation of useful chemicals for the industrial sector through organisms like moulds or yeast. This form of biotechnology is also referred to as grey biotechnology. It is with the help of white biotechnology that the environment is helped in the control of pest animals and plants. Biotechnology has helped in cleaning up oil spills, protecting endangered species by storing DNA samples to be used for future research and to help remove any excess nutrients there may be in the soil and water. Research in biotechnology also aims at leaching metals from the soil to provide for clean mining, in the detection of landmines and in the cleaning of arsenic and other metal contamination. An important example of bioremediation is microbe that is utilized to clean up toxic to hazardous industrial wastes in the environments, such as PCBs.

4. Green Biotechnology

Green biotechnology, also known as agricultural biotechnology, deals with applications related to agriculture such as production of disease resistant or UV resistant plants. Green biotechnology involves the manipulation of plants and animals to produce species that are more environments friendly and productive. Development of varieties of wheat that are disease resistant by crossbreeding different types of wheat is an example of green biotechnology.

5. Multicolored Biotechnology

Biotechnology is often multidisciplinary, and so many applications may be classified in more than one ‘color’ category. For example, the production of biodiesel from agricultural or waste materials could be considered both white green, or white and blue biotechnology.

D. Ethics and Bioethics

Scientific research into human genetics has been a continuing a source o intriguing, and at times formidable, ethical issues. The recent world wide interest in a project to map and ultimately sequence the estimated three billion base pairs of the genome has generated controversy over the effect such knowledge might have on us, as well as about the wisdom of investing so much research funding. The question is largely a matter of science policy rather than ethics. As an investment of scarce resources, the genome initiative may not be the wisest at this time. However, even so, it is not the wisest way to spend research resources; it would not make it unethical. The confusion may lie in the profligate manner in which epithet such as unethical or immoral are used to tarnish a person or enterprise we do not like.

It is difficult to define ethics comprehensively. In general, the ethics is the branch of philosophy concerned with how we should decide what is morally wrong or right. Sometimes the Words ‘ethics and morals are used interchangeably. Ethics, though, is a specific discipline that tries to probe the reasoning behind our moral life particularly by critically examining and analyzing the thinking that is or could be used to justify our moral choices and actions in particular situations. A precise definition of ethics may be difficult to find, but there is considerable agreement on the meaning of bioethics.

Bioethics is simply an application of moral principles in the Biological Sciences that are applied in the different research fields especially in medicine, health care and the life sciences; a systematic discipline that applies moral philosophy to healthcare practices. Bioethics is broad in its interests, it embraces clinical, organizational and community levels of ethical issues. From its earliest stirrings, bioethics has paid considerable attention to ethical issues related to new scientific techniques such as Human Genome Project (HGP), cloning, and Genetically Modified Organisms (GMOs).

1. Human Genome Project (HGP)

The aim of the HGP is to provide scientists with powerful new tools to help them clear the research hurdles that now keep them from understanding the molecular essence of other tragic and devastating illnesses. Gene mutations probably play a role in many of today's most common diseases, such as heart disease, diabetes, immune system disorders, and birth defects. These diseases are believed to result from complex interactions between genes and environmental factors. When genes for diseases have been identified, scientists can study how specific environmental factors, such as food, drugs, or pollutants interact with those genes. Any project regarding this Human Genome (HG) means to identify the full set of genetic instructions contained inside our cells and to read the complete text written in the language of the hereditary chemical DNA (deoxyribonucleic acid). As part of this project, biologists, chemists, engineers, computer scientists, mathematicians, and other scientists could able to work together to plot out several types of biological maps that will enable researchers to find their way through the labyrinth of molecules that define the physical traits of a human being. Packed tightly into nearly every one of the several trillion/billion body cells is a complete copy of the human "genome" – all the genes that make up the master blueprint for building a man or woman. One hundred thousand or so genes impound inside the nucleus of each cell are parceled among the 46 sausage-shaped genetic structures known as chromosomes. New maps developed through the Human Genome Project will enable researchers to pinpoint specific genes on our chromosomes. The most detailed map will allow scientists to translate the genetic instructions encoded in the estimated 3 billion base pairs of nucleotide bases that make up human DNA. The development of gene-splicing techniques over the past 20 years has given scientists remarkable opportunities to understand the molecular basis how a cell functions, not only in disease, but in everyday activities as well using these techniques, scientists have mapped out the genetic molecules, or genes, that control many life processes in common microorganisms. Human Genome Project is normally take 10-25 years to complete and consists of two major components. The first - creating maps of the 23 pairs of chromosomes - should be completed in the first 5 to 10 years. The second component is sequencing the DNA contained in all the chromosomes will probably require the full 15 years. The advantages and disadvantages are as follows:

Advantages:

- Human Genome Project research will help solve one of the greatest mysteries of life:
- Fertilized Eggs: One fertilized egg is known to give rise to so many different specialized cells, such as those making up muscles, brain, heart, eyes, skin, blood, and so on.
- Health Disorders: Most inherited diseases are rare, but taken together; the more than 3000 disorders known to result from single altered genes rob millions of healthy and productive lives.
- Gene Structure: Having a gene in hand allows scientists to study its structure and characterize the molecular alterations, or mutations that result in disease.
- Location of gene: Progress in understanding the causes of cancer, for example, has taken a leap forward by the recent discovery of cancer genes. Once a gene is located on a chromosome and its DNA sequence worked out, scientists can then determine which protein the gene is responsible for making and find out what it does in the body.

Disadvantages:

- Although DNA sequencing technology has advanced rapidly over the past few years, it is still too slow
- It is costly to use for sequencing even the amount of DNA contained in a single human chromosome.
- It is a long-term process.

Ethical Issues of the Human Genome Project

Human Genome Project emphasized sequencing the entire human genome. This goal, however, is controversial because of the high cost and because many critics believe that sequencing of huge amount of non-coding DNA should have low priority in a time of limited funds for research. Only about 5 percent of the genome contains sequences that their coding regions are most likely to contain information valuable to the medical and biological communities. Some biologists still argue that there is little point in sequencing the other 95 percent. A major criticism of the HGP is similar to that raised against other mega-science projects such as the space station or the superconducting supercollider: This big science vs. little science argument maintains that funding such large-scale projects takes scarce resources from researchers who may study certain areas of particular interest more efficiently. Some critics suggest that the ability to diagnose a genetic disorder before any treatment is available does more harm than good because it creates anxiety and frustration. Indeed, geneticists have isolated several disease-causing gene mutations and have studied them in detail without developing a treatment. For example, the mutation in the beta-globins' gene that results in sickle cell disease was identified in 1956, but there is no treatment yet. Because of the genetic variation between individuals, there never will be one definitive human sequence. The lack of a definitive sequence creates uncertainty about the appropriate definition of "normal," which in turn makes the discussion of public policy issues difficult.

2. Cloning

The scientists of the world define cloning in different ways. To use a specific definition, the American Medical Association (AMA) defined cloning as "the production of genetically identical organisms via somatic cell nuclear transfer. 'Somatic cell nuclear transfer' refers to the process which the nucleus of a somatic cell of an existing organism is transferred into an oocyte from which the nucleus has been removed" (Council on Ethical and Judicial Affairs).

In other words, cloning is the method of produce a baby that has the same genes as its parent. Simply take an egg and remove its nucleus, which contains the DNA/genes. Then take the DNA from an adult cell and insert it into the egg, either by fusing the adult cell with the nucleated egg, or by a sophisticated nuclear transfer. Further more stimulate the reconstructed egg electrically or chemically and try to make it start to divide and become an embryo. Then use the same process to implant the egg into a surrogate mother that would use with artificial insemination. However, many groups defined cloning is the production of tissues and organs through growing cells or tissues in cultures along with the actual producing of embryos to be born with the use of stem cells. When an egg is fertilized and it begins to divide, the cells are all the same. As the cells divide, certain cells differentiate and become the stem cells that produce certain tissue and then organs.

Potential Medical Benefits:

- The possibility that through cloning technology we will learn to renew activity of damaged cells by growing new cells and replacing them.
- The capability to create humans with identical genetic makeup to act as organ donors for each other, i.e., kidney and bone marrow transplants.
- The benefit of studying cell differentiation at the same time that cloning is studied and developed.
- Sterile couples will be able to have offspring will have either the mother's or father's genetic pattern.

- **Potential Harms and Disadvantages**
- The possibility of compromising individualities.
- Loss of genetic variation.
- A "black market" of fetuses may arise from desirable donors that will want to be able to clone themselves, i.e., movie stars, athletes, and others.
- Technology is not patented yet. It has a low fertility rate. In cloning Dolly, 277 eggs were used, 30 started to divide, nine induced pregnancy, and only one survived.
- The clone would be a human being and deserve all the rights and privileges that a non-cloned human has. A clone should not be a second-class citizen.
- Unknown psychosocial harms with impacts on the family and society.
- Producing clones for research or using their parts is unethical. It would be against the code of ethics of a doctor to harm a clone (i.e., use it for an organ transplant).

Ethical Issues in Human Cloning

The successful cloning of an adult sheep, announced in Scotland, is one of the most dramatic recent examples of a scientific discovery becoming an issue to discuss among the scientists and theologians, physicians and legal experts, talk-radio hosts and editorial writers. They have been busily responding to the news, some calming fears, and other raising alarms about the prospect of cloning a human being.

We just simply do not know the harms that will come from cloning. Cloning would lead to the loss of individuality because one's genetic predispositions and conditions would be known. However, the human clones could differ greatly in personality and even grow up with different conditions than the cloned. This could be a great stress to the clone and possibly even the loss of ability to choose for itself and arise following concerning possible problems with mutations and clones. Since the somatic cell from which clones originate likely will have acquired mutations. Although these mutations might not be apparent at the time of cloning, genetics problems could become exacerbated in future generations.

The cloning can possibly change the gene pool from how we now know it. Most likely, it would not be a good change. Technology as we presently know it will not effectively support the cloning of humans. The success rate was quite low when cloning Dolly. Only one of the 277 tries succeeded. The same problems of the difficulty of having the fertilized egg implant parallels with that in vitro fertilization. Technology has not yet been able to provide an answer to some of the areas of cloning.

Some opponents of cloning believe that such individuals would be wronged in morally significant ways. For example, a child might be constantly compared to the adult from whom he was cloned, and thereby burdened with oppressive expectations. Even worse, the parents might actually limit the child's opportunities for growth and development: a child cloned from a basketball player, for instance, might be denied any educational opportunities that were not in line with a career in basketball. Finally, regardless of his parents' conduct or attitudes, a child might be burdened by the thought that he is a copy and not an "original". The child's sense of self-worth or individuality or dignity, so some have argued, would thus be difficult to sustain. There is also the fear that some would want to clone people to create large armies of the same soldier or even produce large amounts of workers. This would also lead to the creation of a second and lower class for clones. In other words, the power to create humans is only to be used in a marriage between husband and wife.

There is a natural sentiment that is offended by the mental picture of identical babies being produced in some biological factory." Which raises the question: once people learn that this picture is mere science fiction, does the offense that cloning presents to "natural sentiment" attenuate, or even disappear? Some argued that the critics' fears -- or at least, those fears that merit consideration in formulating public policy -- dissolve once genetic determinism is refuted. People might continue to express concerns about the interests and rights of human clones, about the social and moral consequences of the cloning process, and about the possible motivations for creating children in this way.

Yet it seems clear that some of these concerns, at least, are based on false beliefs about genetic influence and the nature of the individuals that would be produced through cloning. Consider, for instance, the fear that a clone would not be an "individual" but merely a "carbon copy" of someone else -- an automaton of the sort familiar from science fiction. As many scientists have pointed out, a clone would not in fact be an identical *copy*, but more like a delayed identical *twin*. In addition, just as identical twins are two separate people-biologically, psychologically, morally and legally, though not genetically - so, too, a clone would be a separate person from her non-contemporaneous twin. To think otherwise is to embrace a belief in genetic determinism - the view that genes determine everything about us, and that environmental factors or the random events in human development are insignificant. We must also remember that children are often born in the midst of all sorts of hopes and expectations; the idea that there is a special burden associated with the thought "There is someone who is genetically just like me" is necessarily speculative. Moreover, given the falsity of genetic determinism, any conclusions a child might draw from observing the person from whom he was cloned would be uncertain at best. His knowledge of his future would differ only in degree from what many children already know once they begin to learn parts of their family's (medical) history. Some of us knew that we would be bald, or to what diseases we might be susceptible. To be sure, the cloned individual might know more about what he or she could become. However, because our knowledge of the effect of environment on development is so incomplete, the clone would certainly be in for some surprises. Even if we were convinced that clones are likely to suffer particular burdens that would not be enough to show that it is wrong to create them. The child of a poor family can be expected to suffer specific hardships and burdens, but we do not thereby conclude that such children should not be born. Despite the hardships, poor children can experience parental love and many of the joys of being alive: the deprivations of poverty, however painful, are not decisive. More generally, no one's life is entirely free of some difficulties or burdens. In order for these considerations to have decisive weight, we have to be able to say that life does not offer any compensating benefits. Concerns expressed about the welfare of human clones do not appear to justify such a bleak assessment. Most such children can be expected to have lives well worth living; many of the imagined harms are no worse than those faced by children that have been acceptably produced by more conventional means. If there is something deeply objectionable about cloning, it is more likely to be found by examining implications of the cloning process itself, or the reasons people might have for availing themselves of it.

Human cloning falls conceptually between two other technologies. At one end, we have the assisted reproductive technologies, such as in vitro fertilization, whose primary purpose is to enable couples to produce a child with whom they have a biological connection. At the other end we have the emerging technologies of genetic engineering - specifically, gene transplantation technologies - whose primary purpose is to produce a child that has certain traits. Many proponents of cloning see it as part of the first technology: cloning is just another way of providing a couple with a biological child they might otherwise be unable to have. Since this goal and these other technologies are acceptable, cloning should be acceptable as well. On the other hand, many opponents of cloning see it as part of the second technology: even though cloning is transplantation of an entire nucleus and not of specific genes, it is nevertheless an attempt to produce a child with certain traits. The deep misgivings we may have about the genetic manipulation of offspring should apply to cloning as well.

To see what can be learned from such a comparative approach, let us consider a central argument that has been made against cloning - that it undermines the structure of the family by making identities and lineages unclear. On the one hand, the relationship between an adult and the child cloned from her could be described as that between a parent and offspring. Indeed, some commentators have called cloning "asexual reproduction," which clearly suggests that cloning is a way of generating descendants. The clone, on this view, has only one biological parent. On the other hand, from the point of view of genetics, the clone is a sibling, so that cloning is more accurately described as "delayed twinning" rather than as asexual reproduction. The clone, on this view, has two biological parents, not one - they are the same parents as those of the person from whom that individual was cloned.

Cloning thus results in ambiguities. Is the clone an offspring or a sibling? Does the clone have one biological parent or two? The moral significance of these ambiguities lies in the fact that in many societies, including our own, lineage identifies responsibilities. Typically, the parent, not the sibling, is responsible for the child. However, if no one is unambiguously the parent, so the worry might go, who is responsible for the clone? Insofar as social identity is based on biological ties, will not this identity be blurred or confounded? A surrogate mother may be required to relinquish all parental claims to the child she bears. In these cases, the social and legal determination of "who is the parent" may appear to proceed in defiance of profound biological facts, and to subvert attachments that we as a society are ordinarily committed to upholding. Thus, while the *aim* of assisted reproductive technologies is to allow people to produce or raise a child to whom they are biologically connected, such technologies may also involve the creation of social ties that are permitted to override biological ones. To some critics, admittedly, this difference will not seem terribly important. Some objects to cloning on the grounds that children created through this technology would be "designed as a product" rather than "welcomed as a gift." The fact that the design process would be more selective and nuanced in the case of genetic engineering would have no moral significance from this perspective.

3. Environmental and Ecological Risks on GMOs and GM Food

Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called “modern biotechnology” or “gene technology”, sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between non-related species to either the producer or consumer of these foods. This is meant to translate into a product with a lower price, greater benefit (in terms of durability or nutritional value) or both. Initially GM seed developers wanted their products to be accepted by producers so have concentrated on innovations that farmers (and the food industry more generally) would appreciate. The initial objective for developing plants based on GM organisms was to improve crop protection. The GM crops currently on the market are mainly aimed at an increased level of crop protection through the introduction of resistance against plant diseases caused by insects or viruses or through increased tolerance towards herbicides. *Insect resistance* is achieved by incorporating into the food plant the gene for toxin production from the bacterium *Bacillus thuringiensis* (BT). This toxin is currently used as a conventional insecticide in agriculture and is safe for human consumption. GM crops that permanently produce this toxin have been shown to require lower quantities of insecticides in specific situations, e.g. where pest pressure is high. *Virus resistance* is achieved through the introduction of a gene from certain viruses that cause disease in plants. Virus resistance makes plants less susceptible to diseases caused by such viruses, resulting in higher crop yields.

Herbicide tolerance is achieved through the introduction of a gene from a bacterium conveying resistance to some herbicides.

In situations where weed pressure is high, the use of such crops has resulted in a reduction in the quantity of the herbicides used. Generally, consumers consider that traditional foods (that have often been eaten for thousands of years) are safe. When new foods are developed by natural methods, some of the existing characteristics of foods can be altered, in either a positive or a negative way National food authorities may be called upon to examine traditional foods, but this is not always the case. Indeed, new plants developed through traditional breeding techniques may not be evaluated rigorously using risk assessment techniques. With GM foods, most national authorities consider that specific assessments are necessary. Specific systems have been set up for the rigorous evaluation of GM organisms and GM foods relative to both human health and the environment. Similar evaluations are generally not performed for traditional foods. Hence, there is a significant difference in the evaluation process prior to marketing for these two groups of food.

While theoretical discussions have covered a broad range of aspects, the three main issues debated are tendencies to provoke allergic reaction (allergenicity), gene transfer and outcrossing. Gene transfer from GM foods to cells of the body or to bacteria in the gastrointestinal tract would cause concern if the transferred genetic material adversely affects human health. This would be particularly relevant if antibiotic resistance genes, used in creating GMOs, were to be transferred. The movement of genes from GM plants into conventional crops or related species in the wild (referred to as "outcrossing"), as well as the mixing of crops derived from conventional seeds with those grown using GM crops, may have an indirect effect on food safety and food security. Several developed countries including USA and UK have adopted strategies to reduce mixing, including a clear separation of the fields within which GM crops and conventional crops are grown. Feasibility and methods for post-marketing monitoring of GM food products, for the continued surveillance of the safety of GM food products, are under discussion.

There is growing concern about environmental issues, which must be welcome by all who are concerned about environmental ethics and justice to current and future generations. Nevertheless, any biotechnology that is in conflict with the moral issue and sustainability principle will be called "unethical". Biotechnology has potential for ecological improvement, if applications are targeted with that objective. The ecological alarming make people concern about the introduction of new organisms into the environment, including GMOs. Ecological studies are needed, and monitoring of releases of GMOs, to gain data to allow prediction of the ecological impact of such introductions. We should support program that are designed to provide methods to monitor the release and survival of GMOs. It appeals to our sense of values based on human utility. There is a further way to argue for the protection of nature and the environment, and it is a more worthy paradigm. It is that nature has value for itself because it is there. We should not damage other species, unless it is absolutely necessary for the survival of human beings (not the luxury of human life).Nature has life, thus it has some value. Another paradigm for looking at the world is a religious view, that God made the world so the world has value. Moreover, we are stewards of the planet, not owners. This paradigm can make people live in a better way than if they look at the world only with the paradigm of human benefit. There needs to be examination of the view of nature that different people have, so that we can find what the commonly acceptable limits to modification of nature, plant and animal varieties, and human beings are. In the modern world any new science can easily spread, so researchers are accountable to all peoples of the world. Field releases of GMOs are regulated in all countries of the world, officially, as they should be. The procedures vary, as does the public satisfaction with such procedures. They are also subject to political climate, and bureaucratic regulations conflict with industry and with the principle of beneficence, whereas inadequate regulations risky and harmful.

Ethical Issues in GMOs and GMF

The reasons cited for the unacceptability of genetic manipulation of organisms and food can be grouped into two major categories***:***

- Fear of unknown
- Unknown health concerns

Fear of Unknown

In general, most of the Bioethicists always predicted that all organisms were connected with the unknown nature or danger of the results of genetic manipulation. Some people saw this in terms of a disaster, while others have less dramatic concerns. There is also fear associated with unknown research fields, which is true of any area. We could subdivide this concern into health and ecological concerns.

Unknown health concerns

Many Bioethicists may see these techniques as unacceptable, regardless of the state of technology and regulation. The questions about food also illustrate this concern. In developed countries like Japan, Canada, Australia 12-16% of the public who were concerned about concerning products made from GMOs, said that such foodstuffs or medicines would be unnatural. While in public survey in Britain, 70% agreed that "natural vitamins are better for us than laboratory-made ones" only 18% disagreed. In fact, rationally we can say such foods are just as natural as foods made from any modern crop or animal breed.

E. Ethical Criteria for Biotechnological Research

The following criteria might be useful in determining whether biotechnological research is ethical.

- What is the benefit? To whom? Is it life saving? Human benefit is greater than monetary benefit.
- Do no harm to humans. What is an acceptable level of risk? Follow ethical codes on free and informed consent for human experimentation.
- Do not cause pain. Protect animal rights as much as possible, use less sentient/conscious to animals for research, and develop non-animal alternatives.
- Independent open decision-making on safety questions, consider ethical and social impact.

- Inform and educate the public and scientists about all dimensions of the projects, scientific, social, economic and ethical, using third party media.
- Do no harm to the environment. Use the technology that is most environmentally sustainable over the long-term.
- Minimize consumption, may need to introduce environmental quotas to do this according to just distribution of global assets and introduce maximum levels for individual production of pollution.
- Protect biodiversity. Protect endangered species. Allow farmers affordable or free access to breeding stock, and encourage planting of diverse crops.
- Justice to all people, and future generations. Share benefits and risks.
- Bioethics still needs to be developed in order to approach this abstract area of thinking.
- Scientists as well as the public perceive limits to what are acceptable, or "ethical", biotechnology, and further research is needed to determine what these limits are.

Possible Major Laws and Principles in Biotechnology

Biotechnology can provide useful tools for combating disease, hunger and environmental contamination, but it should not be viewed as a universal remedy or as miraculous. For example, life-saving medicines may have serious side effects, and, while our expanding knowledge of genetics can help create the next generation of medicines, it can also raise important ethical issues. Following major general laws and principles can be used to impose in Government Law and regulations throughout the world.

1. Realization and Approbation of Biotechnology and apply it for the Benefit of Human Being

The resolution of bioethical issues requires broad public discourse. The Government of any country can acknowledge their responsibility to consider the interests and ideas of all segments of society and to be sensitive to cultural and religious differences. Biotechnologists will pursue applications of biotechnology that promise to save lives or improve the quality of life. Biologists, technologists and economists will seek dialogue with patients, ethicists, religious leaders, health care providers, environmentalists, consumers, legislators, and other groups who share an interest in bioethical issues.

2. Awareness of Biotechnology and its Benefits and Implications towards the Public

The public and the elected representatives of the National Biotechnology Directorate of each country need greater knowledge and a better understanding about biotechnology and its applications. The relevant authorities should have better understanding and interactions among themselves. All the Research Universities, Biotech Research Institutes and Biotech Industry will disseminate their research findings for the benefit of the researchers and bioethicists.

3. Privacy in Genetic Information

Individually identifiable medical information must be treated confidentially and safeguarded from misuse. We should oppose the use of medical information to promote intolerance, discriminate against or to stigmatize people.

4. Priority Areas Focus for New Products to Safe Guard Health

Priority should be given to the potential areas of health and environmental protection in the developed countries. The procedure can be the model of other developed countries e.g. United States, UK, Canada, biotech products are extensively regulated by federal agencies such as the Food and Drug Administration, the Environmental Protection Agency and the Department of Agriculture. As such, Malaysia also supports science-based regulation by government agencies to safeguard health, ensure safety and protect the environment.

5. Respect and Treat the Laboratory Animals Humanely

Laboratory animals are essential to research on new therapies and cures. The concern researchers should test new treatments on laboratory animals to assess product safety before administering them to humans. Student can develop "transgenic" animals -- those with genes from another species, usually humans -- to test treatments for life-threatening diseases. The National Biotech Directorate will follow rigorously all government regulations and professional standards in the Malaysia, such as the Animal Welfare Act and the federal guidelines for animal care and use promulgated by the National Institutes of Health in USA and UK.

6. Awareness on Ethical and Social issues regarding Genetic Research

The treatment on genetic disorders by altering the genes of human sperm or eggs until the medical, ethical and social issues that will arise from this kind of therapy have been more broadly discussed and clarified. Also, we support continuation of the voluntary moratorium on the potential cloning of entire human beings, with the understanding that research should continue on the cloning of genes and cells to benefit humankind.

7. Ethical Standards

At present the developing countries will abide by the ethical standards of the authorized developed countries such as American Medical Association and UK Medical Association, where appropriate, other health care professional societies to ensure that the products are appropriately prescribed, dispensed and used.

8. Promote Sustainable Agriculture with Environmental Benefits

Farmers must produce increasing amounts of food per acre to feed a growing global population. As because there are significant advantages to increasing the yield of crops the biotechnologists will strive to make this possible while reducing the amount of external supplements (fertilizers, pesticides, etc.) necessary.

9. Utilization of Bioremediation to Clean up Hazardous Waste

Develop the method for using biotechnology to harness the power of naturally occurring organisms to degrade contaminants at hazardous waste sites. The research will strive to optimize the cost efficiencies and environmental advantages associated with using biotechnology while protecting human health and the environment. These could include the development and implement more environmentally safe and cost-effective means of treating hazardous waste streams in industrial processes.

10. Conservation of Biological Diversity

The genetic variation of animals, plants and other organisms is a valuable natural resource. The environment is constantly changing, and without an adequate store of genetic diversity, organisms will not be able to adapt. Genetic diversity decreases, however, every time a species, breed or crop variety becomes extinct. The governments along with other research organizations could develop a data base catalog to conserve these precious resources.

11. Avoid Biotechnology for Bioterrorism

Biotechnologists should strongly support the Biological Weapons Convention, a treaty signed by the United States and many other nations banning development and use of biological weapons.

F. Biotechnology in Islamic Perspectives

The doubt rising now a days against the biotechnical solutions to the problem of infertility, invitro fertilization and genomes-genetic engineering aspects (Cloning) - whether they are justified or not. Now a days question arises whether they tamper with the Sunan (Ways) of the Almighty Allah? It is true that such technologies may be abused. However, we should look at the positive aspect of such technology, just as a Knife has its numerous benefits if used correctly and can prove disastrous if misused. Now a technology to resolve infertility cannot be condemned outright as being against the Sunan of Almighty Allah since infertility, should be viewed as defect or disease. It seems that cloning would not fall under the category of trying to resolve the problem of infertility. It should be used for the satisfaction of one's own personal ego – to have clone of one. Reproductive cloning is too dangerous, and raises far too many ethical and social questions. Producing children in that manner would be threaten the very institution of marriage, and in view of that would be an illegal venture under Islamic law.

Research is also going on regarding the environmental cues, genes and structures that direct cell differentiation into whole organs composed of different tissue types. Because of somatic cell nuclear transfer cloning, the tissues and organs would be genetically identical to the patient and, therefore, would not be rejected. This application of cloning technology is often referred to as therapeutic cloning, or somatic cell nuclear transfer (SCNT). God has commanded that the sacred powers of procreation are to be employed only between man and woman, lawfully wedded as husband and wife". Cloning only involves one parent, therefore it is not following God's plan in which a man's sperm and a woman's egg are needed to create life. So cloning of a person is definitely against almighty's law. Undifferentiated cells that are genetically identical to the patient have remarkable therapeutic potential.

Given the proper environments, these cells could develop into new tissues that could replace diseased tissues and cure diseases such as diabetes, Parkinson's, Alzheimer's and various types of cancer and heart disease. This avenue of study could produce replacement skin, cartilage and bone tissue for burn victims and nerve tissue for those with spinal cord or brain injuries. The remarkable potential of cellular cloning is to cure diseases and restore function to diseased tissues. Therefore, Muslim Scientists can support the application of cloning for only therapeutic cases but not other purposes.

G. Conclusion and Recommendation

Genetic manipulation especially cloning is a wonderful advancement in technology and knowledge. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's body would be at this time be an irresponsible, unethical, and unprofessional act. Federal and state legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. The federal government of all the countries and all interested and concerned parties encourage widespread and continuing deliberation on these issues. In order to further understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been addressed. Federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics, and on other developments in the biomedical sciences, especially where these affect important cultural practices, values, and beliefs. Government and scientists should try to develop other ways beside the natural way to bring life into this world. It would be advantageous to science and medicine to clone tissues and organs.

While the environmental risks assessments of genetically modified organisms, (GMOs) should cover both the GMO concerned and the potential receiving environment. The assessment process should include evaluation of the characteristics of the GMO and its effect and stability in the environment, combined with ecological characteristics of the environment in which the introduction will take place. The environmental safety aspects of GM crops vary considerably according to local conditions. The investigations should focus on the potentially detrimental effect on beneficial insects or a faster induction of resistant insects; the potential generation of new plant pathogens; the potential detrimental consequences for plant biodiversity and wildlife, and a decreased use of the important practice of crop rotation in certain local situations; and the movement of herbicide resistance genes to other plants.

Different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods. GM foods are currently available on the international market have passed risk assessments and are not likely to present risks for human health. An improved and harmonized framework for the risk assessment of GM foods should be taken in general.

Need to examine the potential negative effects on human health of the consumption of food produced through genetic modification, also at the global level. Such evaluations must be holistic and all-inclusive focusing on human health and environmental effects. It is hoped that the assessment report could form the basis for a future initiative towards a more systematic, coordinated, multi-organizational and international evaluation of certain GM foods.

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