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DEVELOPMENT OF BIOTECHNOLOGY: THE LEGAL CHALLENGES

Nik Ahmad Kamal Bin Nik Mahmod*

INTRODUCTION

The advent of biotechnology has brought into fore various ethical and legal issues that have caused tremendous amounts of excitement and interest in the world. Issue like human cloning has not only caused furor among various professions especially clerics and legal experts, but has boiled up into debates that seriously touched upon the right of scientists to carry on with research in that area. At the other end of the scale, biotechnology research on foods, plants and animals has been widely applauded for its therapeutic values as well as its potentials to solve the long-standing problem of food shortages in the third world.

In Malaysia, the promulgation of necessary legislation to deal with the development of biotechnology has been very slow.[1] In addressing the issues of the required legal framework for Malaysia, pertinent controversies on biotechnology products will be discussed together with their possible ethical and legal drawbacks. In addition to this, the paper will attempt to present an overview of the needs for Malaysia to legislate on various matters pertaining to biotechnology products and activities.

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* Associate Professor, Ahmad Ibrahim Kulliyyah of Laws, International Islamic University Malaysia. The original paper was presented at the International Conference on Biotechnology: The Islamic Perspectives, held from 9th to 10th through 10 September 2003, Kuching, Sarawak organized and sponsored by the Institute of Islamic Understanding Malaysia.

1 The most recent is a Bill on the Protection of New Plant Varieties Bill. It is meant to recognize and protect the contribution made by farmers, local communities and indigenous people in the discovery of plant varieties which is expected to lead to investment on breeding of such new varieties. It is in line with Malaysia's obligation under TRIPs. Among others, the Bill outlines the procedures and conditions for the registration of these plant varieties. The star, Friday 5 September 2003, p. 12.

The Concept Of Biotechnology

The Oxford English Dictionary gives two definitions of biotechnology: "The branch of technology concerned with the development and exploitation of machines in relation to the various needs of human beings"; "The branch of technology concerned with modern forms of industrial production utilizing living organisms, especially micro-organisms, and their biological processes".[2]

In the scientific process, biotechnology is the alteration of molecules, genes and cells- the basic building blocks of life- to develop useful products, processes or services such as new medicines and therapies, cloning, genetically foods and enhanced crops.[3] In the widest sense, biotechnology can be viewed as the application of a scientific understanding of biological and biochemical processes to a broad range of medical, industrial, agricultural and environmental settings. It involves the manipulation of molecules, genes and cells-the basic building blocks of life- in order to achieve a desired result.[4] In short, the term "biotechnology" refers to laboratory manipulation of genes and the use of living organisms or their products to change their use to improve or cure human health and the human environment.[5]

The Required Legal Framework

As far as Malaysia is concerned, the lack of legislation that deals with biotechnology processes and products is probably because of the lack of knowledge and understanding on the effects of biotechnology experimentation and its products to the people, its environment and to the country as a whole. Furthermore, the adverse implications of biotechnology processes and its products

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2 Oxford English Dictionary, 2nd Edition.

3 http: //www.biotechinfo. i.e./content/content. asp? section visited on 11 November 2003. In the United States, "usage of the word biotechnology has come to mean all parts of an industry that knowledge create, develop, and market a variety of products through the willful manipulation, on a molecular level, of life forms or utilization of knowledge pertaining to livingsystems".Http://biotechterms.org/sourcebook/saveidretrieve.php3?id=230

4 Ibid.

5 Peters, Pamela, Biotechnology: A Guide to Genetic Engineering, Wm.C.Brown Publishers, Inc., 1993.

have not been fully realized and therefore the urgency to have a clear legal framework for Malaysia to deal with it is not there. The other problem is the struggle to find standard guidelines and benchmark to draft such laws given the fact that the rest of the world is still groping to lay down their own comprehensive legislation. It is also an undeniable fact that the legal fraternity is still struggling to understand the complexities and the highly technical and scientific nature of biotechnology innovations.

Nonetheless, the government is aware of the potential of biotechnology research that the Ministry of Science, Technology and Environment (MOSTE) has developed a comprehensive National Biotechnology Program. This includes a strategic plan with a concrete mission and vision to ensure that the program will be developed to the benefit of Malaysia for now and the future where jobs are created, economic growth sustained and that the health of humans and the environment is protected.[6] The ethical considerations are not neglected with the formation of the Committee on Biotechnology and Biodiversity Policy. This Committee is assisted by a Technical Committee chaired by the Secretary General of MOSTE.

The main consideration of a legal framework to regulate biotechnology activities is its adverse effect to human being and the environment. In this respect, debates are still rife on the desirability of certain biotechnology activities such as human cloning. In this perspective, the legislature will have to take a stand on whether certain biotechnology activities and products are acceptable or not.

Biotechnology activities are mainly derived from genetic engineering. Therefore, the decision to regulate biotechnology activities will have to center around the regulation of genetic engineering. The process of genetic engineering is simply the manipulations of DNA (deoxyribonucleic acid) that contain genes. Scientists are capable of crossbreeding and transferring genes using methods such as direct injection of cells with DNA or to

6 Dato' Seri Law Heng Deng, " Ethics In The Biotechnology Century", in Abu Bakar Abdul Majeed (ed.), Bioethics-Ethics in the biotechnology century, IKIM, 2002, 1 at 3.

insert the DNA into specifically modified bacteria or viruses that carry it into cells they infect.[7] In short, it involves removing the "bad" genes by cut and paste method or performing gene therapy. The product of this process is called either transgenic plants or transgenic animals. Genetic engineering is used in the production of pharmaceuticals, gene therapy, and the development of transgenic plants and animals. This capability is the main method used in human cloning. In the move to regulate biotechnology activities and its products, Malaysian Parliament may have to assess the ethical, legal and social issues of these activities. Various approaches can be taken and among them is to look into the jurisprudential justification of legislative design.

The 'utilitarian' approach to law rests on the principle of public good and public happiness that minimizes pain and unhappiness. Jeremy Bentham, a British Jurist believed in the philosophy of utilitarianism. He said man by nature follows pleasure and discards pain. Utilitarianism means that everything should be viewed with a view to utility which a thing offers.[8] Bentham's theory of utilitarianism was based on the assumption that mankind has the same definition of pain and happiness. This is unfortunate as standard of happiness is infinitely variable.[9]

Hyakuda Sakamoto rightly put that gene manipulation technology should be applied in order to maximize human welfare and happiness while minimizing pain and unhappiness.[10] Then again, he argued, what is pain and what is happiness? He analogizes the ideas of protecting the environment with the goal of maximizing human happiness. He said that there are two types of ideas of protecting the environment. One is to protect nature in order to preserve the best environment for human being and the

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7 Glenda D.Webber, "Regulation of Genetically Engineered Organisms and Products", Project BIO, Iowa State University, 1996.

8 Hari Chand, Modern Jurisprudence, International Law Book Series, 1994, p.67.

9 See Ernest Albee, A History of English Utilitarianism, at 270 citied in Hari Chand, ibid.

10 Hyakuda Sakamoto, "The Human Genome and the Human Control of Natural Control of Natural Evolution: Genetics- Past, Present and Future" , supra, note 6, p.9.

future generations. The other is to protect nature for its own sake. He argued that there is doubt whether to preserve the environment for the sake of human beings and the future generations is essentially part of "Fundamental Human Rights". He said:

> *The antagonism between the two reasons for "protecting nature" may cast doubt on the concept of fundamental human rights" with regard to whether it is within the scope of our "fundamental human rights to change (improve or destroy) nature in order to ensure human survival or enhance our happiness.*[11]

The learned writer contended that this very reason is the logical basis for the objection to gene therapy, cloning and gene manipulation, by means of recombinant DNA.[12] He suggested a new approach in dealing with ethical, legal and social issue of genetic engineering: human genome should be preserved because such preservation is a harmonious activity of holistic nature, and not because it is part of fundamental human rights.[13] Harmonious holism, he said is based for instance, on East Asian values of giving priority to total and social well "orderedness" than on individual interests or individual rights and dignity.[14]

The other approach is regulating genetic engineering based on the principle of "altruism". According to Walter Schweidler, "altruism" can be defined in two ways, the utilitarian way or the Universalist way.[15] By utilitarian model, "altruism" encompasses the doing of the best thing for as many persons in need of help as possible. Schweidler further added that:

> *According to the classical utilitarian principle that to act morally means to maximize pleasure and minimize suffering for the largest amount of persons affected by one's action. In view of this principle, biotechnology altruism consists in the fight against suffering, and how many and which patients are going to profit from that*

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11 Ibid, note 10, p.10.
12 Ibid, note 10, p. 10.
13 Supra, note 10, p.13.
14 See further pp. 13-14, supra, note 10.
15 Walter Schweidler, "Global Bioethics Invitiatives-From a European Prespective", supra, note 7, at 13.

fight is determined by the circumstances of the action, that is, its place and time.[16]

From the Universalist point of view, Schweidler said, bioethical "altruism" is not grounded in our task to fightagainst suffering but in the natural desire of every human being to have a life free from illness and suffereing.[17] He admitted that the definitions given by both schools appear to be academic, but it is decisive for any ethical approach to the problems of global bioethics. The utilitarian approach seems to be problematic as one need to divide between pain and pleasure and the fine balance between the two may not be achievable.[18] Schweidler prefers the Universalist approach as it is capable of dealing with issues of bioethics brought about by the development of biotechnology. He gave an interesting example:

If maximizing pleasure and minimizing pain were the ethical basis of medical action then the capacities of organ transplantation would hardly raise significant ethical problems. The question whether the person from whom the desperately needed organ are taken is dead or not would not be decisive; the only question would be which one whom it is taken from, would profit more from it in respect to his or her balance of pleasure and pain.[19]

The Islamic laws approach is rested upon the verse in *Surah Al Maidah* (4:119) with the meaning to the effect that:

Verily of the servants I shall most certainly take my due share, and shall lead them astray and fill them with vain desires. And I shall command them and they will change God's creation.

Nonetheless, there is no consensus on the issue of total ban on genetic engineering. If genetic engineering is a form of knowledge, it will be valid so long as it is not contrary to the *Quran* and the *Sunnah*. Parveen Jamal and Hamzah Salleh submitted that beneficial aspects of (in the form of safe and environment friendly

16 Ibid, p. 19.
17 Supra, note 15, p.20.
18 See further his illustration on this point. Ibid.
19 Supra, note 15, p.26.

biotechnology) are in no way against them. [20]In 1998, a conference held in Kuwait with the theme, "Genetics, Genetic Engineering, the Human Genes and Genetic Treatment- An Islamic Perspective" has supported genetic fingerprinting, genetic counseling, and genetic diagnosis because they are in the interest of man.[21] The Kuwait Conference has also agreed that cloning and use of germ cells (stem cells) obtained from premature human fetuses are highly objectionable. Thus, all kinds of cloning and germ cell based research should be prohibited. It has also to be noted that genetic materials used in research must be obtained from *halal* means.[22]

These are basic jurisprudential principles for the regulators in Malaysia to consider in the course of their efforts to draft the relevant legislation to handle activities and products of biotechnology. On the other hand, legislation may take the approach of having a great faith in technology and holds on a belief that biotechnology research in general is an unmitigated good.[23] Or, legislature can approach the matter with caution with a belief that the legal system (the courts) is able to prevent harm before the harm gets out of control. This has been the traditional approach of legislation; the other alternative is to oppose to technology advancement altogether and to legislate against any form of technology development to be harmful to human being and the environment. And, the middle course is to recognize the substantial benefits and at the same time to closely watch its development especially its real threat of harm and the limited ability of the legal system to control that harm. The last approach seems sensible in the light of the present advancement of bio-technology. In the wider perspectives, existing laws in various countries as well as international conventions may be used as the terms of reference.

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20 Parveen Jamal and Hamzah Salleh, "Problems in Biotechnology Research" ,(2002) 1 IIUM Engineering Journal, 33 at 36.

21 Ibid, p.37.

22 Supra, note 20, p. 37.

23 See E. Richard Gold, "Hope, Fear, and Genetics: Judicial Responses to Biotechnology",http://www.ornl.gov/TechResources/HumariGenome/publicat/judicature/article7.html

Human Cloning

The decision to ban reproductive human cloning is rested on the argument that human cloning violates human dignity and also violates an individual's right to unique genetic identify. Cloning simply means producing a genetically identical duplicate of an organism and it involves the exact replication of the donor genes. Therefore, the genetic make-up of the child is no longer considered unique.[24] Furthermore, cloning of human being is against human rights to exist naturally and reproduce asexually.[25] Other ethical and legal issues about human cloning are: the issue of legal parentage of cloned person. The legal relationship between the clone and the duplicate; the issue of registration of birth of clone person; the issue of discrimination that arises after the cloned person has been brought into life in the light of initial legal difficulties to give recognition to him/her.

In view of serious possible effects of human cloning; many countries have considered reproductive human cloning as being a direct threat to human dignity and integrity, and have decided to ban any form of it.[26] Even though the United States had announced the ban of human cloning, no federal law has been enacted to ban human cloning. The United Kingdom has gone further on the issue of human cloning under the Human Fertilization and Embryology Act 1990.[27] Human cloning is said to fall within the scope of the Act whereby section 3(1) provides that no person shall:

> ....*bring about the creation of an embryo, except in pursuance of a license.*

As stated above, there is no law that governs human cloning in Malaysia. The Human Tissues Act 1974 (Act 130) regulates the removal of body parts for purposes of organ donation. The main aim of the Act is to control and regulate the removal of body parts from the deceased person rather than regulate any type of clinical or reproductive methods.[28]

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24 Majdah Zawawi, "Human Cloning: Ethical and Legal Perspectives", supra, note 7, p.130

25 Ibid.

26 Ibid, note 24, p.131.

27 For further overview of the Act, please refer to Majdah Zawawi, ibid, note 24 „ pp.132-134.s

28 Ibid, note 24, p.134.

In the case where Malaysia decides to regulate human cloning under an Act of Parliament, the United Kingdom Act seems to be of possible reference. After all, many British statutes are taken in log, stock and barrel into Malaysia. International Conventions such as the Council of Europe's Convention on Human Rights and Biomedicine 1998 expressly prohibits reproductive human cloning.[29] Ironically, not all members of the European Union have ratified the Convention.

The United Nations has promulgated the Universal Declaration on the Human Genome and Human Rights, which also makes the protection of human dignity the central governing principle. Article 11 states:

> *Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.*

Another guide can be taken from the Declaration of Helsinki on biomedical researches involving human beings. It however does not prohibit human cloning but it provides general guidelines for medical practitioners involved in biomedical research activities involving human subjects.[30]

It is argued that therapeutic cloning should be allowed as it is a means to cure diseases or a technique that could extend means to acquiring new data for the sciences of embryology.[31] The potential medical benefits, it is said, of genetic engineering are too great for us to let nebulous fears of the future drive policy.[32] On the other hand it is argued that cloning involves the sacrifice of fetuses and this is not acceptable morally and ethically.

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29 Protocol of the Convention, Article 1 provides: "Any intervention seeking to create a human being genetically identical to another human being whether living or dead, is prohibited".

30 Supra, note 24, p.136. In the direction of regulating human cloning, it appears that the government is drafting a bill on Reproductive Human Cloning. It is uncertain whether the proposed law will also cover therapeutic cloning.

31 http:// home.hawaii.rr.com/johns/ethics.htm visited on 30 December 2004.

32 http://hotwired. Wired. Com/ synapse/braitennis/97/37/left l.html visited on 30 December 2004.

Reproductive Technologies.

Assisted Reproductive Technologies (ART) is specialized infertility treatments which entail consummation of conception without conventional sexual intercourse.[33] It simply means making babies without having actual sexual intercourse. The procedures include:

i) Artificial insemination by husband.
ii) Artificial insemination by donor.
iii) Gamete inter-fallopian transfer.
iv) In vitro fertilization.
v) Surrogacy.

Artificial insemination by husband (AIH) is acceptable but artificial insemination by donor will raise religious and ethical concerns. Genetically, the sperm donor is the father. What role does the husband play? He may be legally the father of the child, but what is his status morally and ethically?

While in-vitro fertilization serves to help a woman to bear a child and thereby "cure" her of her infertility, what is the status of unused fertilized embryo? If it is destroyed, would that be legal or would that amount to destroying a human life? What if an unmarried woman underwent the process through a donor's sperm? What would be the status of the child? What if in the course of monitoring the development of the fertilized ovum, abnormalities are found, and the doctor decided to terminate the pregnancy? Would that be allowed under the law on abortion?

The issue of a woman bearing the child of another woman has become a thorny legal issue. It gives rise to number of religious and ethical concerns [34] as well as impending legal questions such as:

Tampering with normal process of creation
Woman 'leasing' their womb for monetary benefits
Tempting married woman to resort to this method to relieve them from the agony of pregnancy.

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33 See generally Abul Fadl Mohsin Ebrahim, "Religio-Ethics and Assisted Reproductive Technologies" supra, note 7, p.93.

34 Ibid, p. 101-102

Surrogate mother claiming legal rights to the child
Issue of blood ties.

These are essential ethical, legal and social issues that require stringent measures to be taken by the relevant legislatures. Even though these are not 'recent' issues, the delay in resolving them may further complicate the matter.

Animal Cloning:

Unlike human cloning, animal cloning has not been relatively subject to much controversy compared to human cloning. The birth of Dolly, the first cloned sheep has created more interest and research. Since then scientists had cloned mice and monkey. Animal cloning has its own ethical implications. It may be accepted to prevent extinction of certain species of animals like the Panda. There is also issue where transgenic animals are designed to help researchers diagnose and treat human diseases. There is also issue of xenotransplantation or transgenic transplantation for the benefit of human being. Nonetheless, there are setbacks such as deformed or dead embryos or those survived suffered from incurable diseases. If these animals are destroyed, the question of animal cruelty will arise. As far as Malaysia is concerned, the law is uncertain. If it involves endangered animals, The Wild Life Act 1972 protects such animals from abuse.[35] Under the Canadian Council on Animal Care (CCAC), guidelines are given for the use of animals in biotechnology research whereby animals should be properly treated. However, Islamic and Catholic view points about animal cloning is the same as human cloning as it is an interference in the domain of God.

Other Products of Genetic Engineering

Besides crossbreeding and selection, today's scientists are capable of transferring genes that determine many desirable traits from one plant or animal to another. The transfer of DNA is done by various methods, such as direct injection of cells with DNA or literally shooting cells with DNA-covered particles from a special gun. Another widely used method is to insert the DNA into specially modified bacteria or viruses that carry it into cells they infect. A plant or animal modified by genetic engineering to

35 Schedules 2,4 and 5 list down the protected animals.

contain DNA from an external source is called transgenic. These methods are used in the production of pharmaceuticals, gene therapy, and the development of transgenic plants and animals.

The Human Genome project leads to the ability to know some diseases in advance. This will allow the research to cure them. Methods like gene therapy or the use of drugs to cure these defects may not be suitable and have adverse effects to the body. Genetic research also leads to the possibility of removing bad genes from body of child in the womb. This may also include research to cure genes that causes aging. Manipulation of an early embryo which has consequences for the characteristics possessed by the child that is subsequently born. It can be either positively desirable or it may have negative effects. Gene splicing is another method where sibling of one's choice can be produced. Like human cloning, manipulation of genes may raise ethical and legal issues that need to be addressed by the regulators. Among the legal issues involved are:

- *The use of confidential information pertaining to individual information on gene mapping and DNA sequencing without the consent of the owner.*[36]
- *The ability to predict diseases may lead to gene manipulation and the selection of perfect babies that may lead to unlawful termination of pregnancy of less-than-perfect ones.*[37]
- *The issue of unconstitutional discrimination under Article 8 of the Malaysian Federal Constitution of 1957 against those whose genes has been found to be defective such as in employment.*[38]
- *Cell-lines and DNA samples are kept in special repository for research purposes. Such repository raises issued of privacy, safeguarding of genetic information and*

36 Law of privacy may also be involved here.

37 See M. Nizam Isa, "Ethical Issues of Human Genome Project", supra, note 7, p. 85. Unlawful termination of pregnancy may amount to illegal abortion under the Malaysian Penal Code.

38 The US has introduced a Bill in the Congress to combat genetic discrimination in health insurance and emploument.

genetic versus the benefits of drug discovery and curing of diseases.[39]

It is clear that genomic research and its products need to carefully regulated or otherwise it may violate fundamental human rights recognized by the Constitution.

Gene Therapy

Gene therapies will prevent, cure or more effectively treat many diseases that previously were unavoidable, incurable, or untreatable, or that responded to treatment only incompletely were was accompanied by numerous side effects. Some of the legal problems raised are as follows.[40]

- The cost is very high and the law will have to deal with issues of the scope of health insurance coverage unless the policies specifically exclude gene therapies.
- The law will have to regulate on safety and efficacy of gene therapies especially when it raises issues such as appropriateness of experimenting on children and fetuses, and in the case of germ-line therapies, on human embryos.
- Dispute over intellectual property rights of research products between researchers and sponsors.
- Issue of professional negligence where standard of care for health care professionals will have to be determined as well as the general standard of care for persons who handle the processes of gene therapies.
- The extent of parental consent in law; whether there is a legal limit to the authority of parents to manipulate the genetic characteristics of their children to improve their performance academically or in extra-curricular activities.

Similar to legal issues raised in cloning and gene manipulations, gene therapies raised pertinent legal problems that

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39 Supra, note 37, p.88.

40 Maxwell J. Mehlman, "The Human Genome Project and the Courts: Gene Therapy and Beyond", http://www.ornl.gov/TechResources/Human_Genome/publicat/judicature/article6.html

need to be addressed by the legislatures as well as all the members of the legal fraternity.

Public Concern About Foods And Food Plants As Products Of Genetic Engineering

The Third National Agricultural Policy (1998-2010) touched upon the need to enhance food security as one of its specific objectives. One of its strategies and policy thrusts is on Agri-biotechnology and specialty natural products. Among others, it states that:

> The economic foundation for the development of agri-biotechnology and specialty natural products industries will be strengthened. Government support and commitment for a strong R&D and HRD programs will be intensified to build a pool of world-class researches and technical personnel. The current incentive framework will be continued to accelerate establishment and development of these industries. This includes provision of new and additional funding for research facilities and the setting up of more incubation centres. More conservation activities will be undertaken to preserve and manage biological diversity and legislation introduced to regulate access to genetic resources.[41]

Clearly, the will is there and no reinventing is needed as far as the Ministry of Agriculture of Malaysia is concerned. The only issue is whether the present law is sufficient to regulate the development of agri-biotechnology that the Ministry is striving for.

Genetically modified foods such as maize, soyabean, and cotton seeds are the results of genetic engineering and they are known as LMO and GMO (Living Organisms and Genetically Modified Organisms). Also transgenic plants that can tolerate herbicides, resist insects or viruses, or produce modified fruit or flowers are being grown and tested. The question is, how safe are they? Consumers need answers about scientific development, characteristics, cost, and safety of genetically engineered foods so they can make their own decisions about their use. This does not apply to local foods production but includes also imported food. In Malaysia, there appears to be no comprehensive statute that

41 http://agrolink.moa.mydpn3/dpn/summary./html

regulates genetically modified foods. In that light, Malaysia should take into account practices in advanced countries like the United States of America (USA).[42]

In the USA, genetically engineered foods are regulated by the United States Department of Agriculture (USDA) through one of its divisions called the Animal and Plant Health Inspection Service (APHIS). APHIS administers the Federal Plant Act (FPPA). APHIS regulates interstate movement, importation, and field testing of "organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests".[43] APHIS regulations provide a list of the organisms regarded as plant pests so applicants know if their product is subject to APHIS regulations. Organisms not in the list will still be subject to the regulations if there is reason to believe that the resulting organism is or will be a plant pest. Scientist who wants to conduct a field test or move any plant pest must obtain the permit from APHIS.

Genetically engineered foods and its regulations[44] are controlled by the Foods and Drugs Authority (FDA) which has the primary responsibility to regulate food additives and new foods, except meat and poultry products that are regulated by the USDA.[45] The FDA has a very broad authority under the Federal Food, Drug and Cosmetic Act (FFDCA) to regulate the introduction of new foods, whether they were conventionally produced or developed by genetic engineering. FDA has two kinds of authority to regulate the safety of foods; namely; to remove unsafe and wholesomeness of the foods they market. Secondly, giving pre-market approval to food additives, unless they are generally recognized as safe.

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42 Glenda D.Wedder, "Regulation of Genetically Engineered Organisms and Products", Project BIO, Iowa State University, 1996.

43 Ibid.

44 Supra, note 42.

45 However, genetically engineered animal growth hormones bST and pST are under FDA regulation because the agency is required to determine the safety and effectiveness of animal drugs. Ibid.

The following guidelines are provided by FDA on genetically engineered foods:[46]

a) Unexpected effects-products unexpected genetic effects.
b) Known toxicants- has significantly higher levels of toxicants than present in other edible varieties of the same species.
c) Nutrients-significantly alters levels of important nutrients.
d) New substances-differ significantly in composition from such substances currently found in food.
e) Allergenicity-contains proteins that cause an allergic response.
f) Antibiotic Resistance Selectable markers-contain marker genes that theoretically may reduce therapeutic effects of elinically useful antibiotics.
g) Plants Development to Make Specially Nonfood Substances-plants developed to make substances like pharmaceuticals or polymers that will also be used for food.
h) Issue Specific to Animal Feeds-significant changes in nutrients or toxicants.

These are comprehensive guidelines and these should serve to assist in ensuring that these products are safe to human beings. The other guidelines can be derived from International Convention.

Article 19 of the Biodiversity Convention states that:

> *member states shall maintain means to regulate, manage or control the risk associated with the use or release of LMOs resulting from biotechnology which are likely to have adverse environmental effects that could impair the conservation and sustainable use of biological diversity.*

This resulted in the promulgation of Biosafety protocol, but it only deals with movements of LMOs only. It does not include products containing LMOs. The problem lies on consumers' confidence on such product as they will not consume products that they do not want to consume. This brings about a question on the

46 Supra, note 42.

right to information. Consumers should be given the choice on whether to buy food products that are genetically engineered or otherwise. Thus, the issue of labeling comes into play and the need to ensure that consumers are fully informed about the products. Regulating genetically engineered food should also include the requirement of labeling them. So far, FDA has required genetically engineered foods to be labeled as such. The FFDCA requires producers of food products to describe the product by its common name and to reveal all important facts associated with claims made or suggested on the label. Some FDA authorities believe that these products would have to be kept separate during all phases of production, storage, processing and distribution.

Current FDA policy does recognize that in certain situations consumers should be advised through labeling, such as when the genes for proteins to which some people are allergic are transferred from one species to another. FDA also could require labeling if the nutritional content of the food is changed. Oranges are an important source of vitamin C.A genetically engineered orange that had a significantly lower vitamin C level would have to be labeled.

The Malaysian Ministry of Health has announced that the amendment to the Foods Act 1985 that came into effect recently covers products labeling, wording of the nutrient content, its comparison and functions, and advertisement.[47] All food products will now have to carry their specific nutritional information to protect consumers from misleading information. The amendment also prohibits manufactures to carry information claiming that their products can cure or protect them from diseases and ailments. It is, however, uncertain whether the new amendment would cover genetically engineered foods.

Genetically Modified Food Plants

Statutes that regulates the use of pesticide authorizes the enforcement authority to set tolerances level in or on food crops. In Malaysia, the Department of Agricultural is authorized under the Pesticides Act to do so. The USA Environment Protection Agency (EPA) functions under two acts, the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) and

47 The Star, 7 September 2003, p. 1.

the FFDCA.FIFRA makes EPA responsible for regulating the distribution, sale, use, and testing of pesticides in order to protect humans and the environment as well as setting the desired tolerance level on pesticide on crop after harvesting.[48]

Genetically engineered food plants have the capability to resist pests. For example, the gene of Bacillus thuringiensis, commonly known as Bt, a bacterium that occurs naturally in the soil produces proteins that are lethal to certain insects with alkaline digestive tracts. Genetic engineering makes it possible to locate the gene that produces Bt proteins lethal to insects and transfer the gene into crop plants. Corn that resists European corn borers and potatoes that resist the Colorado potato beetle are two examples of food crops that are being developed through Bt technology. The protein that is toxic to some insects causes no harm to animals with acidic digestives tracts, such as humans.[49]

The US FDA's role is to regulate food plants that produce pesticides. Guidelines on food plants that produce pesticides are as follows:

1) The pesticide is not derived from a known food source. Bt is an example of this type of pesticide since it is derived from bacteria.
2) The pesticide is derived from and introduced into a known food source, but the way humans are exposed to it in their diets changes. Perhaps the food now contains more of the pesticide than it did before. May be a widely consumed food, like potatoes, is modified to produce a pesticidal substance that it did not have before. Another possibility is that a pesticide normally expressed in the inedible parts of a plant now is in the parts that are eaten or perhaps a pesticide derived from a food plant that is eaten raw.
3) The pesticide has a different structure, function or composition than its counterpart that already occurs in food. For example, the structure of a protein pesticide that already occurs in food could be altered significantly.

Intellectual Property Rights under TRIPs and the Convention on Biological Diversity (CBD)

48 Glenda D. Webber, supra, note 42.
49 Ibid.

The right of inventor to benefit from his inventions is recognized today. In biotechnology fields, such rights also accrue. The WTO's sanctioned Trade Related Intellectual Property Rights (TRIPs) recognizes that:

> The protection and enforcement and enforcement of Intellectual Property Rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantages of producers and users of technological knowledge. [50]

On this basis, it is argued that biotechnology invention should as well be protected. They confer the inventor of new process and /or product exclusive monopoly rights for the minimum period of 20 years. The right includes the exclusivity in making, using, offering for sale, selling or importing the invented product. However, TRIPs agreement allows members to exclude some inventions from patentability such as inventions contrary to morality, diagnostics, therapeutic and surgical methods for the treatment of humans or animals, plants and animals and essentially biological processes for the production of plants or animals are some of the areas where patents can be denied. At the same time inventions relating to micro-organisms, non-biological and microbiological processes should be granted patents. It is also mandated that for plant varieties in case it is excluded from patentability, must provide for an effective sui generis system of protection. Sui generis means that parties are free to devise a protection system that is an alternative to the TRIPs patent system such as Plant Variety Protection (PVP) and Plant Breeders' Rights (PBR) already in place in some countries.[51]

The Convention on Biological Diversity (CBD) where Malaysia is a signatory offers significant conservation on biodiversity. 'Conservation' is defined as preventing from loss and wastage, destruction as well as degradation. 'Biodiversity' is the variability among living organisms from all sources, including

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50 Article 7

51 Rajesh Vellakkat, "Biotechnology Laws in India: An Introduction:, http://www.patfiling .com/article show.asp?articleID=104.

terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part.[52]

Article 15 of CBD recognizes sovereign rights of states on their natural resources and also recognize their rights to determine access to other states to them on a mutually agreed basis. However, it is up to the states to take measures with the aim of sharing in fair and equitable manner results of researches, benefits arising from commercial and other research. Therefore, genetic materials should only be taken out of the country with consent. Article 16 provides for the transfer of technology on inventions made by the use of genetic materials acquired from the source country. Nonetheless, this has not been a free flow of reciprocity as there are lack of political wills in the states, issues of brain drain and lack of expertise of food productions, it helps in the creation of therapeutics and pharmaceuticals materials, and also in gene splicing and laboratory creation of human organs.[53]

It is said that the Convention on Biological Diversity (CBD) and Trade Related Intellectual Property Rights (TRIPs) are inconsistent with each other as CBD is for conservation of natural resources where it grants ownership to the country where it situate, and allows their movements only on informed consent.[54] TRIPs, on the other hand, protects the right of inventors and those who have patented any plant or animal or any products related to or containing them, no matter how the genetic materials were procured and the patenting will affect the rights of indigenous people.[55] For instance, the patenting of *neem* tree and *basmati* rice are examples of the ability of scientists from development countries to exploit the traditional products from the third world. Malaysia, a country with hundreds of plant species with therapeutic potentials should be protected from similar exploits by scientists from developed countries. One good example is the

52 Parveen Jamal and A.H. Ansari, "Future Directions in Conservation of Biological Diversity and Biotechnology Researches: An Interdisciplinary Approach", Indian Journal of International Law, vol.40, no.2, 2000,137 at 139.

53 Ibid.

54 Supra, note 52, p.10.

55 Ibid.

bintangor tree of Sarawak that has a potential to cure HIV/AIDS. should also be protected.[56]

The Geographical Indications Act 2000 has the objectiv of facilitating the registration of plants and animals found in tl country. The purpose is to protect plants or animals found in a particular region, and that include provisions for protecting them from being patented in other countries. [57] Nonetheless, there is doubt whether the Act can be effectively enforced outside jurisdiction in a case where a species is smuggled out of the country and researched upon and a new discovery is made for that purpose followed by a patent being registered in that country.

Other status seem to provide some kind of protections for the purpose of biological conservation in Malaysia.[58] The Wild Life Act 1972 provides for the protection of endangered animals that includes the creation of wild life habitat like the natural parks and sanctuaries.[59] The National Forestry Act 1984 provides that permit is required for the purposes of research, recreation and education and training. Such permit does not extend to the appropriation of forest produce. This includes also the collection of samples for whatever reason. The Native Plants Protection Act 1934 regulates the conservation of native plants. The Fisheries Act 1985 protects aquatic animals and plants through the establishment of marine parks and reserves. Nonetheless, regulations concerning prospecting of genetic resources are still inadequate even though the statutes referred above do provide bit and pieces of regulations. But, these Acts drafted years ago, do not provide for the new elements of prior informed consent and sharing of benefits. The difficult task is to regulate the appropriation or misappropriation of our biological diversity in view of the fact that these resources are yet to be identified fully in Malaysia.[60]

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56 Ibid.

57 Ibid.

58 See Ida Madieha Azmi, "Intellectual Property Aspects of Biological Resources – The Malaysian Perspective" , Michael Blakeney (ed.) Perspectives on Intellectual Property aspects of Ethnobiology, Volume 6, Sweet & Maxwell, 1999, p.141.

59 ibid, p.150.

60 Supra, note 52, p.151.

CONCLUSION

Biotechnology is here to stay. As fast as law changes, it is also true that technology also advances by leaps and bounds It is a question whether the law can catch up with the pace with which the technology changes. A wait and see attitude may be a fair move but unknown to them. Laboratories and scientific centers have opened up the Pandora boxes and only time can see whether it can be contained. What is needed in Malaysia is pro-activity of the legislature in dealing with these challenges. New law is definitely needed.