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Biotechnology & Genetic Engineering: Certain Issues For Law And Policy

To Begin With

As with any science, the excitement of pursuit of knowledge and a better understanding of life could have been the basis of the growth and evolution of biotechnology. Growing in leaps and bounds, throughout its process of evolution, and more so now than ever before, it has presented a challenge in terms of what is the dividing line between the growth of a scientific discipline and the implications of its commercialisation for society at large, and what the ecological implications of such technology are. I cannot find a better way to express it than in the words of Dorothy Nelkin "that biotechnology raises many of the same problems as nuclear power; the hazards are invisible and there remains uncertainty about the health effects of low level long-term exposure" (Nelkin, 1993).

And yet, there are some very significant benefits from such technology–not only from the point of view of understanding the world around us better, but from the point of view of application of that understanding for the benefit of human life and health. At the same time, biotechnology, as with any other technology, is a major source of public power in modern society, and raises important concerns regarding rights of use, control and participation in its use. Discussions about technology, its capacity, what it can and cannot do, what it should and should not do, are the reverse side of the coin to debates on the capacity, ability and entitlements of the humans affected by it. (Feenberg, 1995). Kloppenburg examines this in the case of agricultural biodiversity by questioning whether access to advanced breeding lines and other elite germplasm developed by commercial seed firms in the industrialised nations will actually benefit the bulk of third world producers. Such access might simply reinforce processes of social differentiation among peasant producers, facilitate global elaboration of factor markets, accelerate environmental degradation, and deepen technological dependence among nations (Kloppenberg, 1988).

This paper does not seek to make any judgments as regards the growth of biotechnology. Nor does it attempt to cover all the myriad range of issues surrounding the subject. What it does seek to do is to present some of the issues arising in the area of biotechnology in agriculture, and leave them as some points to ponder over.

Some illustrations

The case of Roundup

Monsanto's Roundup herbicide has as its active ingredient glyphosphate, a broad-spectrum herbicide that has the effect of destroying any crop it falls on. It has been argued that glyphosphate has the effect of binding tightly to the soil particles which are exposed to it. This characteristic, it is stated, goes to ensure that it is not dispersed much from the area it is sprayed on, and hence it has minimal 'side effects'. There are contentions for and against such a proposition. However, in practice, farmers normally use it before the crops emerge, and use other herbicides at the later stages of crop growth. The patent that Monsanto holds over Roundup expires in the year 2000. Monsanto has been creating a market niche for genetically engineered crops that can withstand Roundup. Most popular among these are the Roundup Ready (RR) soybeans.

A pre-condition for purchasing the RR soybean is the signing of a contract (the Grower´s Contract) which lays down certain constraints on the farmers, including inter alia that the soybeans can be sowed only for one season, and cannot be saved from the harvest for purposes of resale, replanting, or research; the contract allows only the Roundup formula of glyphosphate to be used on the crop. The contract envisages an enforcement mechanism by stipulating that the farmers entering into such contracts are obliged to allow Monsanto representatives to inspect; and the penalties for violation of any of the obligations are high (GRAIN, 1997).

One of the arguments in support of the RR Soybean has been that it would decrease herbicide use. However, according to the United States Department of Agriculture (USDA), expanded plantings of the Roundup Ready soybeans in the USA increased the use of glyphosphate on soybeans by 72%. The USDA also reports a 29% increase in overall herbicide use on soybeans. Use of RR soybean varieties has also been thought of as one of the reasons for the outbreak of the soybean Sudden Death Syndrome in some of the states in the USA, since the RR soybean varieties have little resistance to the disease (GRAIN, 1997).

The case of Bt

Bacillus Thrunginiensis (Bt) is a naturally occurring soil bacterium, fatal to certain insects that had been used by organic gardeners as a traditional pesticide. Non-genetically engineered natural Bt has been used widely by farmers in sprays to kill agricultural pests when needed. It has been hailed as a perfect pesticide because it can specifically target certain pests without having a detrimental effect on mammals, birds or most non-target insect species and microplants. Bt sprays leave no poisonous residue on crops or trees and are readily degraded by sunlight and the environment within a week after application.

Recent studies in the United States estimate that 57% of all organic farmers use foliar Bt sprays frequently, occasionally, or as a pest control method of last resort (as cited in Plaint, 1999). Because of the effectiveness and safety of foliar Bt compared to the pesticides it displaces, Bt is a very significant pesticide.

Biotechnology has taken the potential of Bt a step further by the production of genetically engineered Bt plants, the logic being that if a plant itself has inherent characteristics of being a Bt pesticide, it would lead to a decrease in the use of any other pesticide. The controversy surrounding such Bt plants, however, is that the widespread use of such plants has proven ecological consequences that cannot be ignored. Such use provides a biological advantage to Bt-resistant insects over and above the normal vulnerable insects in the population and results much faster in the growth of Bt resistant insects. The International Rice Research Institute (IRRI) has been producing Bt rice and itself openly admits to the Bt resistance problem in a pamphlet: "As in the case with all insecticides, insect pests will eventually develop resistance to Bt toxins. It is not possible to predict how long Bt rice will remain effective, but the development of pest resistance to Bt toxins can be slowed by careful design of Bt rice plants and use of appropriate strategies for the deployment of these plants" (GRAIN, 1998).

In essence, the commercialization of the traditional Bt biopesticide is being criticized, as the widespread and unplanned use of the pesticide only provides greater scope for the insects to develop resistance to the Bt toxins and thereby destroys any possibility of using this biopesticide in a traditional sustainable manner.

Some interesting facts relating to the genetically engineered Bt plants as explained in a plaint filed in March 1999 at the District Court of Columbia, USA, merit serious consideration. The plaint has been filed against the U.S. Environment Protection Agency (EPA) by a number of individual organic farmers and non-governmental organisations seeking redressal against the registration of genetically engineered Bt plants permitted by the EPA. The plaint states that such plants present certain new and unprecedented adverse environmental impacts not associated with the use of natural, foliar Bt sprays. These impacts include, inter alia, the widespread creation of multiple insects resistant to foliar Bt sprays, direct harm to non-target plants and beneficial insect populations by exposure to new, unique forms of Bt toxins, and the dispersal of the genetically engineered Bt traits into non-genetically engineered crops and weeds (Plaint, 1999).

The plaint points out that in general, plant pests are susceptible to the use of Bt as a biopesticide because the pests contain genes that confer susceptibility to specific toxins produced by Bt. However, dissemination of genetically engineered Bt plants will lead to selective evolutionary pressure which will cause pests targeted by Bt to lose "susceptibility" genes, that is "resistance" genes rather than "susceptibility" genes will predominate in the population. This will lead to the development of Bt resistance to multiple Bt toxins in major pests within a relatively short period of time (between 2 to 10 years), as evidenced in documented studies of such resistance in the European Corn Borers and the Colorado potato beetle. As a result, Bt foliar sprays will be rendered ineffective and thus be lost as a pest control option for organic and conventional farmers. This will have significant economic impact upon numerous small organic farming operations. Additionally, the loss of Bt will force many farmers to return to using traditional, synthetic insecticides. To further substantiate this, the plaint also draws attention to numerous government-sponsored reports which have found that resistance-management plans are needed to slow the development of Bt resistance occurring because of the commercial use of genetically engineered Bt plants (Plaint, 1999).

Terminator and Traitor Technologies

Terminator technology uses a genetic engineering approach to prevent the unwanted germination of plant seeds. It essentially ensures sterility of the plant at the end of the first season, thereby forcing farmers to return to the commercial seed market each time they wish to grow the plant.

The proponents of the technology insist on its benefits, inter alia, (1) it will stimulate plant breeding for minority crops and marginal lands; (2) that it will encourage the owners of valuable proprietary traits to commercialise them knowing they can’t be stolen or re-used; (3) that it will encourage the use of higher-quality, cleaner seed; (4) that it will end late-season "sprouting" that reduces crop value.

The concern of the traditional farmers is, however, that these arguments display a lack of understanding of agriculture in many third world economies, where there already is a tremendous diversity in seed varieties evolved and evolving through research and use in the practical day to day lives of many communities. Such innovation cannot be undermined and thwarted by characteristics introduced to control the very nature of life, and create dependency by forcing the farmer to return to the seed market every year. It may be simple to argue that there is no coercion to purchase seeds with such technology, and that it is a free choice. That would be a naïve argument ignoring the force of corporate power and market

strategy. The state as a regulator and policy maker would therefore have to make some very clear choices.

Traitor technology is essentially technology that disables natural plant functions, which can be activated only by exposure to a chemical. Novartis, which holds a patent on this technology, is reported to have explained this as: "inactivation of endogenous regulation" so that "genes which are natively regulated can be regulated exclusively by the application to the plant of a chemical regulator" (RAFI, March 1999). Among the genes that Novartis can control in this manner are patented SAR (systemic acquired resistance) genes that are critical to a plant's ability to fight off infections from many viruses and bacteria. The implications of this technology would be to force the farmer to approach the company not only for the seed, but also for the chemical activator. The impact of the chemical on sustainability of the soil, its fertility, are questions that remain unanswered. The 'benefits' of such technology for the farmer are difficult to imagine. The traitor technology is the clear manifestation of the undesirable extent of biotechnology development. This vests the corporate with the complete power over the very existence of a plant, the seeds of which a farmer has already bought.

Some Thoughts

a) Commercialization of genetically modified plants poses serious environmental risks. Further it is widely acknowledged that certain risks associated with these plants are not known. At the same time, the temptation associated with use of such plants is immense, given the promise of increased productivity and lesser use of pesticides. The corporate marketing strategy involved in the process plays an important role as well, as against the lack of an informed debate concerning the long-term implications of use of such plants. In developing countries like India, the presence of a large agriculture-dependent economy, the majority of the members of which are not literate, adds the factor of misinformation and lack of well-informed use of such plants.

There is, therefore, an immense responsibility on the regulatory authority dealing with clearances and permission for such plants. The precautionary approach has emerged as an important concept in international environmental law as a manner of addressing unpredictable ecological implications. The essence of the precautionary approach is embodied in Principle 15 of the Rio Declaration (UN Doc. A/CONF.151/5) as well as in the Preamble to the Convention on Biological Diversity (UN Doc.A/CONF.151/26), both concluded at the Earth Summit in 1992 which, in essence, provide that where there are threats of serious or irreversible damage, or threat of significant reduction or loss of biodiversity, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environment degradation and avoid or minimise such threats.

The effect of this principle would essentially be that assessment of the potential impacts of a genetically modified plant must be carried out before, and not after permission is given to commercialise such a plant. However, even the success of such an approach would be limited, since it is unlikely that ecosystem dynamics will be well enough understood at any time in the near future for this aspect of environmental impact to be confidently predicted. The impact on endangered species is one of special concern, but one that is not adequately addressed by the law.

Laws dealing with biotechnology normally adopt a risk assessment approach; however, the difference of opinion invariably surrounds the thresholds of risk and degree of uncertainty allowed in such approaches. Further, the resistance- management strategies as proposed by

the law or the regulatory authority are often either inadequate or are found lacking in terms of implementation. For instance, in the case of the Bt plants, there is agreement in that the approach to be adopted is to grow Bt toxin-free plants alongside the genetically engineered variety, and that refuge areas would enable the toxin-free varieties to survive and contribute their genes to the next generation. However, this has not always accompanied cultivation of Bt crops.

b) A further aspect for consideration is the lack of any mandatory labeling of any genetically modified plant and its products, in order to draw the essential distinction between such a plant and an ordinary one. This is not a necessary prerequisite in law today. For instance, there is no mandatory pesticide labeling of any crop grown from Bt plants. Similarly, in the case of the Roundup Ready soybeans, there is no requirement to label the genetically engineered crops. This has implications in that consumers are not given a chance to make an informed choice.

c) Commercialization of genetically modified crops could pose a threat for crop diversity. Traditional varieties of crops cultivated by farmers across the world are rich sources of genetic diversity. Not all these varieties have been mapped and documented. However, with the introduction of genetically modified crops the fear is that these may lead to a proliferation of monocultures that would have severe implications for biological diversity, and following from the same, disappearance of specific traits such as resistance to diseases. The Union of Concerned Scientists, a non profit international organisation based in the USA, in their report of 1993 state that crop genetic diversity is already diminishing at a stunning rate, as farmers around the world are persuaded to abandon the numerous landraces of the past in favor of a relatively few modern crop varieties, and further that expensive transgenic plants, which will generally have to create large markets to recoup research costs, will exacerbate that trend (The Union of Concerned Scientists, 1993).

d) It would not be far-fetched to state that biotechnology has militaristic implications that need to be addressed. The technologies, equipment and material in relation to biological agents are invariably known to have dual uses. As pointed out by one commentator, the most common cheating scenario places the facilities of a weapons programme amidst a nation's biotechnology industry. Continuous monitoring of a country's dual use capabilities therefore lies at the core of an effective regime to ensure that use of biological agents is not used as a pretext for developing biological weapons.

e) Intellectual property rights (IPRs) over biotechnological 'inventions' is another area of controversy. The principles of the EU Directive on Legal Protection of Biotechnological Inventions state that the advantages of protecting biotechnology and genetic engineering include the development of less polluting and more economical methods of cultivation and improvements in combating major epidemics, endemic diseases and hunger in the world.

Plant Breeders´ Rights is another form of IPR that gives a monopolistic right over marketing a certain variety of seed for a period of time. The rationale for PBRs is to provide an incentive for commercial breeders.

The problem with IPRs is with the fact that: (1) It regards nature and eco-systems as raw materials that can be 'innovated' upon and have monopoly rights attained over them; (2) there are ethical objections to the patenting of life itself; (3) there are ecological considerations relating to the fact that monopoly rights over life forms may lead to the disappearance of biological diversity; and that genetic manipulation, unless very strictly regulated, could result in severe ecological disruption; (4) privatisation and granting IPRs over elements of diversity

would eventually vitiate the concept of ‘sustainable use’.; (5) granting IPRs over genetically modified varieties would have serious implications for the rights of farming communities all over the world, which have over a period of many years of consistent observation, skill and effort, developed invaluable knowledge and along with it a storehouse of invaluable varieties of seeds. IPRs, by interfering with their informal method of innovation and selection, conflict with this.

f) The other major problem with biotechnology is that it often relies on the appropriation of knowledge, innovations and practices of local and indigenous communities throughout the world. For instance, the multitude properties and uses of the Neem tree *(Azadirachta indica)* have been known to people in India for centuries. Patents have been obtained now by W.R.Grace on the insecticidal, human non-toxic and biodegradable properties of the Neem– all of which have been known and used by Indians. This and many other instances, termed as ‘biopiracy’, have generated some very serious debates on the notion of "innovation", of ‘’new and inventive steps", that form the basis for any patent. The fact that the knowledge of local and indigenous communities may not have arisen in a ‘modern scientific laboratory’, but has its own rational, scientific basis, is a fact that has not concerned the notion of biotechnology and of IPRs over biotechnology. The fact that modern scientific ‘innovation’ often runs piggy-back on knowledge of local and indigenous communities has never caused any serious debate until recently.

The Convention on Biological Diversity concluded at the Earth Summit in 1992 specifically recognizes the need to recognize and protect the knowledge, innovations and practices of local and indigenous communities. Countries are in the process of formulating their laws for regulating access to genetic resources, and ensuring the return of benefits for the same.

g) The other significant aspect for concern is the need for biosafety guidelines. Nations today normally have authorities designated to evaluate proposals for the use of biotechnology; the degree of capabilities, of transparency, and of public participation in decision-making, however, differs.

Biosafety Protocol under the Convention on Biological Diversity

At the international level, the debate regarding regulation for transboundary movements of genetically modified organisms has been going on for some time now. This has been one of the most contentious issues at the meetings of the Conference of Parties to the Convention on Biological Diversity.

At the fourth Conference of Parties to the CBD, a decision was adopted to the effect that the Biosafety Protocol should be finalised and adopted by early 1999. However, this has not been possible because some countries are of the opinion that biotechnology is the technology for the future and that over-regulating it would endanger competitiveness in the world market. A group of six grain- exporting countries (the Miami group), supported by the Biotechnology Industry Organisation have maintained highly inflexible positions on most of the contentious issues of the Protocol.

On the other hand, Scandinavian countries have been insisting on a precautionary approach. The concerns of many developing countries is that the protocol should provide adequate safety measures, and a system of accountability and redress for harm resulting from transboundary movement of LMOs (living modified organisms), as well as increased capacity to deal with biosafety issues.

The decision of the Conference of Parties to the CBD that initiated the development of the protocol defines the scope of the proposed protocol in a manner as to cover transboundary movement of LMOs resulting from modern biotechnology *that may have adverse effects on the conservation and sustainable use of biological diversity.*

The terms of the draft of the biosafety protocol contain similar terms; however, the thresholds for determining how and in what manner *adverse effects on the conservation and sustainable use of biodiversity* will be determined, is not dealt with. A further contentious issue is whether the Protocol should include only LMOs or also *products thereof.*

The Protocol provides that agreements or arrangements entered into by Parties must be consistent with the objectives of the Protocol, and not result in a lower level of protection than that provided for by the Protocol, and that parties must inform the Biosafety Clearing-House of any agreements or arrangements they have entered into before or after the Protocol's coming into force, and the Protocol's provisions will not affect transboundary movements taking place pursuant to these.

The Protocol recommends a procedure for Advance Informed Agreement (AIA) between the parties to the Protocol, prior to the transfer of biotechnology and/or LMOs. However, there is difference of opinion whether the AIA procedure would be applicable for all LMOs or whether low-risk LMOs should be exempted from AIA.

At the Cartegena meeting, several developed countries said that only LMOs destined for deliberate release into the environment should be subject to AIA procedures, and LMOs intended for human or animal consumption did not pose a significant threat to biodiversity and could be dealt with in other provisions. Some delegates emphasized that countries had the right to take stricter measures. Many developing countries said that all LMOs should be subject to AIA procedures as any LMO, irrespective of intended use, could be accidentally released during transfer and handling. Many developing countries have also objected to the proposal of developed countries suggesting potential differentiation in risk levels between LMOs intended for deliberate release and those intended for food, feed and processing, supporting instead the subjection of all LMOs to the AIA procedures.

A study of the meetings for the Biosafety Protocol reflects starkly on how political positions affect decisions about the environment and the power of the biotechnology industry in influencing those positions.

In Conclusion

The question confronting the regulation of biotechnology development is, on what grounds and on what principles should regulation draw the line and set up a framework for biotechnology. How can a framework be established that would effectively regulate and control the events that would be and have already been unleashed by a technology that purports to benefit humanity as no other, but at the same time has the inherent capacity to provide humanity with its worst nightmare–the vesting of food and other natural resources in the hands of a few–putting the alteration of natural life processes to an extent that life itself can be controlled in the hands of a few, for when attempts are made to control plant life, in effect attempts are made to control the entire food chain. It should not be forgotten that life as we know it all evolved somewhere at some time on this planet from a single cell that obtained the ability to convert sunlight into life-sustaining energy. Major alterations in evolution have occurred through minor, insignificant changes–a single cell able to replicate being one such

change. Biotechnology now seeks to control these very forces of not only sustenance but also evolution and must, consequently, be regulated. Some examples of technology changing and regulating our lives without our realisating it are present in daily modern life: electricity discovered and regulated just over a century ago, the computer–not even a century old, flying machines–again not even a century old–now make visions of interplanetary exploration itself possible, and these are not even as integral to our existence as food itself.

I would like to conclude with the thoughts of A.N.Whitehead who stated: "Duty arises from your potential control over the course of events. Where attainable knowledge could have changed the issue, ignorance has the guilt of vice."

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