Biotechnology and Development: Threats and Promises for the 21st Century

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I Introduction

This paper has been written as a contribution to the current policy debate about the status of biotechnology for international development. As we move into the 21st century it has become clear that biotechnology is certain to play a key role in economic and social development throughout the world. Already its impact on agriculture, health and the environment has been noted widely in the relevant literature but this is nothing compared to the widely held expectation that this generic technology will revolutionise these and other sectors in the coming decades. However, biotechnology is also a two-edged sword in that its capacity to modify and alter the course of nature raises many questions of ethics and risk. Unless these are resolved its economic potential is certain to be compromised. And for developing countries in particular, therefore, such issues of risk perception and management have great significance.

This paper sets out to clarify the complex issues involved in this debate. Section II sets out briefly the science and technology (S/T) policy agenda for Third World development before giving a short stylised history of biotechnology. It shows how what was at one time a well-recognised set of craft techniques for the traditional manufacture of food and drink (going back millennia in time) has become (over the past thirty years or so) a major science-based technology. Summary data on investment trends and institutional developments are presented. Section III takes the discussion up to the present in more detail by setting out the current issues as they affect two sectors, agriculture and health. Here, while there are many promises, biotechnology is under threat as a result of a series of well-publicised events associated with environmental impacts. Section IV turns to related questions of risk and summarises how these are dealt with in the literature. In particular it contrasts conventional formal risk analysis (based on probability theory) with the more recent idea of the *"Precautionary Principle"*, which has come into play as a result of the evolutionary nature of modern environmental impacts, and its popularisation following the UNCED Earth Summit of 1992. Using examples from Europe and the Third World it will explore these debates in the light of the recently signed Biodiversity Protocol signed in Cartagena, Colombia last year. Finally Section V will cover what this analysis means for appropriate public policy agendas in developing countries.

II Biotechnology and Development

(i) Science, Technology and Development

The role of science and technology (S/T) in development has been through nearly half a century of debate and discussion. The end of the Second World War heralded a period of international optimism that combined the recognition of economic inequality with a determination that international action could reduce it substantially. And while the organisations created at the time (such as the United Nations and the big financial bodies like the International Monetary Fund and the World Bank) probably had peace and stability as their primary focus [1][1], an important secondary element was the harnessing of S/T to economic growth and development. By the mid 1950s it was known that technological factors were probably the single most significant factor explaining rates of economic growth but how that related to investments in S/T was not at all clear.

The early debates on this centred on the disjunction between modernisation and autarchic agendas. Initially the former held sway and many developing countries

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[1] See Chapter 1 for a discussion of this point.

invested heavily in a public S/T infrastructure. This was made up of universities, research institutions and related bodies whose role it would be to "modernise" and enhance economic production. However, technology development did not follow this model but began instead to rely much more on foreign direct investment and technology transfer. Partly as a result, the tone of the 1970s became much more radical (in the old political sense) [2], technology being seen as a tool of exploitative economic relations on the part of corporations having their roots in the industrialised countries of Europe, North America and East Asia.[2] However, more recently still the agenda has become much more complex and in a sense less narrowly political. Arguably this has a lot to do with rapid changes in globalisation on the part of international capital and technology. But clearly it has also been affected by the fact that some (formerly underdeveloped) economic systems have been able to benefit substantially from the import of foreign technology. The issue is now recognised as one of understanding in more detail the macroeconomic context and policy regimes that are beneficial in this regard. Science and technology can be a positive resource provided this context is suitable. The difficult question is to determine for each economic system what determines that suitability.

Combined with this is the issue of how to deal with large and unproductive public R&D systems. As mentioned above, during the years following de-colonisation many Third World countries invested heavily in organisations whose function was to conduct R&D of relevance to economic development. The belief was that in some sense "investment" in public science would create possibilities for more rapid rates of innovation than would obtain from the interplay of market forces. We now know that such expectations were never likely to be realised, that their underlying assumptions were hopelessly oversimplified and that in fact relations between "science" and economic production are very complex indeed. Meanwhile, however, huge infrastructures have been created whose economic impacts are certainly sub-optimal and in extreme cases probably negative. Enormous sums of public money are tied up in unproductive assets including "human capital", the key resource for a dynamic economic system. At the same time economic production routinely accesses new technology from other sources (usually from productive enterprises in the industrialised world) [3].

Nowhere is this clearer than with respect to the major new technologies that are starting to play a significant role in economic change. Especially in areas like computers, new materials, telecommunications and biotechnology, so frequent and complex are the discoveries involved that it has become vitally necessary to keep abreast of their rapid evolution since they impinge on practically all areas of economic production. This paper concentrates on only one of these, biotechnology, though it should be recognised that at a general level some of the issues and debates may also be relevant to others as well. Already biotechnology is used extensively in agriculture, agri-business, pharmaceuticals and environmental management. And it shows promise of being able to deal with some of the major food security and health problems currently experienced by many of the poorer developing countries. At the same time it is, in its recent guise, a radically new technology whose adoption carries with it certain risks. How to manage biotechnology to ensure maximum social benefit at minimal risk is therefore high on the policy agenda of all countries, especially those in the poorer parts of the Third World. The remainder of the paper explores how this issue might be managed on the part of relevant public policy analysts.

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[2] See Chapters 7 & 8.

(ii) Biotechnology

According to Sharp [4] biotechnology is the "application of biological organisms, systems and processes to manufacturing or service industries". She goes on to point out that in this sense "biotechnology has been around since the New Stone Age when humankind first learned the art of cross breeding plants and animals, and of using yeast to leaven bread and ferment alcohol".[3] This so-called *first generation* biotechnology was superseded around the turn of the 20th century by more systematic (*second generation*) efforts to use science to screen and categorise microorganisms that might have useful applications (penicillin being a good example). Throughout the first half of the 20th century biochemists and microbiologists strove to produce useful products but over this period Sharp shows how developments in hydrocarbon chemistry switched to the petrochemical sector and it was here that most innovations took place.

The era of modern (*third generation*) biotechnology began in the early 1970s as a result of two major breakthroughs in molecular biology. The first was the discovery that a gene from one organism could be isolated and inserted into the genome of another. This meant that desirable characteristics could at least in principle, be introduced into a microorganism that had never had it previously. The second breakthrough was the discovery of techniques for fusing and multiplying cells (hybridomas). Taken together the impact was potentially revolutionary. Henceforth it would be possible to reprogramme microorganisms to act as small factories for the production of a wide variety of useful products. Sharp [4] points out that already by the early 1980s therapeutic proteins such as insulin, human growth hormone and Factor VIII (to treat haemophilia) were being manufactured on an industrial scale and biotechnology applications to agriculture were beginning to be appreciated also. In the same paper she presents a stylised account of biotechnology development through the centuries. It gives a clear description of the complexity of an evolutionary technology that started from empirical roots but has now matured into a science-based technology operating across many trajectories and products. Special note should be made of its systemic nature whereby constituent techniques and processes cut across trajectories and expand production possibilities. We shall return to this aspect below.

Investment in scientific research and new information technologies contributed significantly to these developments. It is noteworthy that in the early stages, motivations and interests of scientists and scientific institutions (as opposed to industrial or economic demands) drove research and development (R&D) activities leading to the establishment of the biotechnology industry. Indeed developments in molecular biology rDNA and biotechnology had stimulated the entry of pharmaceutical and chemical companies into the field in the late 1970s. Chemical companies began to invest in biotechnology in 1977 when they realised that biotechnology could be used to create new products for agriculture. By 1980 a number of multinational companies had made initial commitments to biotechnology and by 1983 things had changed drastically. Large chemical and pharmaceutical companies began to make heavy investments in biotechnology. This trend was accompanied by a rapid transition from Mendelian to molecular genetic applications in agriculture, medicine and industry.[4]

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[3] See p 218. It is difficult to understand why she has omitted agriculture from this definition since her subsequent reference to plant breeding is a clear inclusion of agriculture.
[4] Ibid. pp. 195-197

The 1990s have seen dramatic advances in our understanding of how biological organisms function at the molecular level, as well as in our ability to analyse, understand, and manipulate DNA molecules. The entire process has been accelerated by the Human Genome project, which has invested substantial public and private resources into the development of new technologies to work with human genes. The same technologies are directly applicable to other organisms, including plants and animals. This has given rise to the scientific discipline of *genomics*, which has contributed to powerful new approaches to identify the functions of genes and their application in agriculture and medicine. These new discoveries and their commercial application have helped to promote the biotechnology industry mainly in North America and Europe. Indeed several large corporations in Europe and the United States of America have made major investments to adapt these technologies to the production of improved plant varieties of agricultural importance for large-scale commercial agriculture [5].

In 1999 over 70 genetically modified (transgenic) varieties of crops were registered for commercial cultivation worldwide. These include new varieties of cotton, potato, pumpkin, tobacco, tomato and clove. More than 15,000 field trials have been undertaken globally. New genetic modifications of more than 100 plant species are growing in laboratories, greenhouses, or in the field, providing farmers with new agronomic traits, particularly herbicide tolerance and pest resistance that enable them to grow these crops more easily and profitably. In 1999 the global area under genetically improved crops was 40 million hectares mainly of corn (maize), soya bean, cotton, canola (rappelled) and potatoes. Eighty five percent of this area is in North America (USA and Canada) and the remaining fifteen percent in developing countries notably Argentina, China, Mexico and South Africa [6].

Over the past ten years or so third generation biotechnology has become a growth sector in the industrialised countries of Europe, North America and Japan. Here the US in particular is clearly the world leader. In 1998 there were nearly 1300 specialist biotechnology companies employing some 153,000 people directly while sales of biotechnology products reached$13.4 billion (an increase of 17% over the 1997 figure. In addition the US has a strong research base with companies spending some $10 billion in 1998. Again in 1998 Monsanto alone allocated some $1.2 billion for biotechnology research while in the same year Novartis announced the establishment of its *Agricultural Discovery Institute* (for genomic studies) at a cost of $600 million. In the public sector similar sorts of investments are being made. Thus the National Institutes of Health allocated $15.6 billion in 1999 for basic bioscience research while the US Departments of Agriculture and Energy spend annually a further $2 billion [6].

(iii) Biotechnology and Developing Countries

How has biotechnology impinged on the Third World? Here both the threats and promises are considerable. For example, on the one hand biotechnology promises the capacity to improve radically rates of growth of food production and of other primary commodities such as cash crops for export. On the other, there are dangers that new synthetic substitutes derived from biotechnology can drive traditional export products out of the market. Already companies based in the North can produce products like pyrethrum and artificial sweeteners without any recourse at all to traditional products and the chances are that this capacity will grow considerably over the coming decades. Similarly with the use of modern techniques of tissue culture. Wambugu et al. [7] shows how tissue culture has been used to promote the production of disease-free bananas in

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East Africa. The potential benefits for many subsistence farmers are likely to be considerable. On a more industrial scale tissue culture is now being used to promote the production of export led high value horticulture crops such as cut flowers. On the other hand, concerns have been expressed in recent years regarding the way international seed corporations have begun to dominate agricultural production in many developing countries, for example through using genetically engineered seeds in a proprietary fashion.

Particularly important here for developing countries is the status of agricultural biotechnology. Here the scale and scope of private sector investment has been growing drastically over the years. In 1985 of the total $900 million spent in agricultural biotechnology R and D by the public and private sectors, $550 million equivalent to almost two-thirds of total expenditures, was spent by the private sector. In 1990 estimates indicated that global R&D expenditure in biotechnology by the private sector was $2.7 billion, slightly more than twice the $1.3 billion by the public sector. More recent data on investment, and R&D expenditure show that there has been a drastic increase in the decade 1985 to 1995. It is estimated that investments by the private sector will grow at 12% per year to reach $34 billion by the year 2006 [6]. The development of biotechnology applications is capital intensive, requiring substantial long-term investments, which often can be mobilised only by the private sector. Significant investment of the private sector in biotechnology clearly demonstrates the need for the public sector to forge linkages with the private industry in biotechnology R and D to access resources of the private sector.

It is to enable the Third World to deal sensibly with such issues that many commentators have advocated building up biotechnology capacity in the developing countries themselves. At one level the argument is straightforward. So strategic is biotechnology nowadays that no country can afford to neglect it. However, at a deeper level the issue is by no means clear-cut since it begs the question "what is biotechnology capacity?" Essegbey and Stokes [8] show that capacity goes well beyond "laboratories plus scientists". Indeed in most African countries there is no real shortage of suitably trained scientific manpower in the life sciences (though there are equipment and related laboratory constraints). What seems to be mainly missing, however, in many cases are the entrepreneurial capabilities, supportive institutions and associated networks needed to translate raw scientific knowledge into economic production. It is this systemic competence that determines "biotechnology capacity" and that appears in very short supply. Clark and Juma [9] explore this point in some detail arguing that strategic links with carefully chosen types of production is probably a necessary ingredient in building such capacity. And there is an important role for government in helping to create and nurture such links. Essegbey and Stokes [8] conclude that Ghana has probably reached the stage at which the application of tissue culture techniques is feasible. But it is an open question as to whether real biotechnology "capacity" is yet present.

III Current Issues.

A. Agricultural Biotechnology

Biotechnology has begun to affect agriculture in the following ways. Firstly it can provide at least a partial solution to the problem of feeding the world's growing population. Even with improved food distribution and access, this cannot be achieved without dramatic increases in crop production. Converting more land for agricultural use is environmentally unsustainable. Genetic engineering has also opened up opportunities to

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increase crop yields, reduce crop losses to insects, disease and post-harvest storage problems, and enhance the nutritional value of some crops. In addition, crops are now being developed to resist abiotic stresses, such as drought and soil salinity. This will allow increased crop production on marginal land, and therefore bring possible benefits to poorer rural areas. Finally biotechnology can contribute significantly to "agri-business", for example by helping to make foodstuffs more attractive to consumers and otherwise contributing to the globalised food industry.

(i) Genetically- Modified Crops And Food

Genetically modified (GM) crops are produced as follows. Traditionally, new varieties of specific crops have been bred by cross-pollination of two strains, usually of the same species, in order to transfer desirable traits from each into the new variety. These traits might include higher yield, greater resistance to certain pests or diseases, slower ripening or better tolerance to drought or soil stresses. Genetic engineering allows the selective transfer of one or more genes that code for desired traits from one variety to another, which means that it is a faster and more accurate method of breeding new varieties. It also allows the transfer of genes between species, which cannot be achieved by traditional breeding. For example, some of the first commercial releases of GM crops were modified with a gene from a bacterium, *Bacillus thuringiensis* (*Bt*), which codes for a toxin against some crop pests. *Bt* insecticide sprays have been in use for several decades, and are approved for organic farming. However, introducing the *Bt* toxin gene directly into a plant genome raised many concerns about the genetic engineering of crops, and food products derived from them.

(ii) Environmental Impacts of GM crops

One of the major concerns about introducing GM crop varieties is the uncertain impact on the environment. One of the potential problems is that the novel gene might be unintentionally transferred by pollination to other plants, including weeds and also wild relatives of the crop species. Scientific research has shown that this is technically possible, but the potential long-term impacts this might have are still unclear. There are fears that such transfers could lead to the development of resistant 'super-weeds', loss of genetic diversity within crop species, and possibly even the destabilisation of entire ecosystems. This last concern also emerges from the specific application of *Bt*, where the genetic modification results in toxin being produced directly by the crop. Environmentalists argue that the toxin might unintentionally be taken up by non-targeted organisms, which might destroy populations of benign insect species. Much research has been done on the possible impact of *Bt*-engineered crops on the Monarch Butterfly, with inconclusive results. Laboratory results have differed significantly with those from field tests. So far, despite millions of acres of Bt crops being planted over the past few years, there is little empirical evidence that the populations of non-target organisms are decreasing in nearby areas. However, it is clear that some of the feared impacts are likely to be ecosystem-specific. As a result, field trial results in one country or ecosystem may not provide conclusive evidence of environmental safety for other countries or ecosystems. Greater understanding of how specific ecosystems work is needed.

(iii) GM food and human health

Concerns have also been expressed about the risks to human health of food products derived from genetically modified crops. This is particularly the case where novel genes have been transferred to crops from organisms that are not normally used in food or

animal feed products. Many who oppose genetic engineering suggest that this might lead to the introduction of previously unknown allergens into the food chain. Controversy was sparked when a gene from a Brazil nut was successfully transferred into a variety of soya, which was being developed for animal feed. It was confirmed that the allergenic properties of the Brazil nut were expressed in the soya. However, the counter-argument was that this case demonstrated the effectiveness of scientific testing for safety. The allergen was specifically tested for during the development process, and as a result of the positive results the product was never developed for commercial use. Scientists further argue that the structure and characteristics of known allergens are well documented, and that testing for possible new allergens is therefore relatively easy.

Another fear about food safety is the possible production of toxic compounds resulting from genetic modification. Many scientists argue, however, that by introducing one, or a very few, well-defined genes into a crop, toxicity testing is actually easier for genetically modified crops. In traditional breeding, entire genomes, or parts of chromosomes are transferred, and this often requires a lengthy breeding process to remove undesirable genes from the variety being developed. The last major concern for food safety is the use of antibiotic resistance genes as 'markers' in the genetic transformation process. Some of the antibiotics used for this purpose are still used to treat human illnesses, and there is concern that resistance to the antibiotics could be transferred to humans and animals through food and feed products. However, no evidence of this has so far emerged, and scientists have now developed techniques to remove these 'marker' genes before crops are developed for commercial use.

(iv) Who benefits from GM food and crops?

Pro-biotechnology scientists and firms have pointed out that genetically modified food products have now been on the market for several years, without a single reported case of adverse effects on human health. Against this, it has been argued that possible long-term impacts would not become clear for some years. Potential environmental impacts will be particularly difficult to predict, monitor and manage. As scientists readily admit, no technology is ever 100 percent safe. Potential risks must be weighed against potential benefits. Such risk-benefit analyses will be done at different levels: at a national level, by governments and regulatory agencies; at production level, by farmers and firms; and at the individual level, by consumers. The first group of GM crops introduced mostly yielded benefits for commercial farmers and private sector firms. For farmers, insect resistant and herbicide tolerant crops produce higher yields and lower costs in respect of chemical inputs. Profits accrue to the firms who developed the seeds. As a result, revenues at national level are boosted. Further, potential environmental risks might be offset against the environmental benefits of reduced agrochemical use and more efficient land usage. But for consumers, these early GM crops, and food products derived from them, the perceived benefits were not evident.

(iv) 'Terminator Technology' and Farmed Saved Seed

For developing countries the potential benefits for farmers may be inequitably distributed both a global and national levels. Large commercial farmers who can afford GM seed will profit from increased yields, but a significant increase in production on a wide scale will lead to a reduction in the unit price of the crop. For small farmers, continued production with conventionally bred varieties is then likely to result in a loss of income. An associated problem, which has been identified by many people, is the potential future application of Genetic Use Restriction Technologies (GURTs), often dubbed 'Terminator

Technology', that would prevent farmers from reusing saved seed. The first GURT to become widely publicised was a technique that involved genetic modification of a crop to kill off its own seed before germination. Its first expected application was to protect seed that had already been genetically modified for a desirable trait, thereby providing technical protection for the seed company's legal Intellectual Property Rights. Under intense public pressure, the firm developing the technology announced that it would not be commercialised, but research and development on other GURTs is on going in many organisations. One argument in its favour is that its use would prevent the accidental spillovers on to other germplasm in adjacent locations, thereby improving biosafety. People who hold this view argue that there are other mechanisms to assist the poor small farmer in developing countries [10]. The development and use of GURTs should not therefore be banned on poverty grounds such as this.

Opponents claim that this technology would increase poverty amongst the poorest developing country farmers, who rely on the use of saved seed. Against this, it might be argued that this group of farmers could not in any case afford the original cost of the seed for crops and crops varieties that GURTs would be used for. This, in fact, might be seen as the *real* problem for small scale and subsistence farmers, whose lack of access to credit is often the reason why new seed is not bought each season. In fact, this inequitable situation already exists in respect of many hybrid crop varieties, which give relatively high yields, but where the original cost of seed is high, and the beneficial characteristics of the hybrid diminish with replanting of saved seed. Another of the GURT technologies under development would have a similar impact. This involves modification that would not prevent the use of saved seed, but would effectively remove the desirable trait for second and subsequent plantings. However, it has also been noted that in many cases there are historic and cultural motives for exchanging and replanting saved seed, and therefore any technologies that effectively prevent this will not be acceptable.

(v) GM crops and food security

A very important challenge for developing countries that hope to utilise biotechnology to address food security objectives is that the new GM crops may not be appropriate to their most urgent needs. Biotechnology firms are unlikely to address these needs unless they are commercially profitable, and this leaves a large gap for the public sector to fill. Bearing in mind that research costs are usually very high, new forms of public-private sector partnerships need to be sought in order that the benefits of biotechnology reach those who need it most. One promising new initiative has been the development of 'Golden' rice, which has been modified to enhance its production of beta-carotene, which is metabolised into Vitamin A. This new variety has the potential to address the huge problem of Vitamin A deficiency in developing countries, which causes partial or total blindness in around half a million children each year. However, in the long term, there is a need for developing countries to build capacity to address their most urgent concerns. This includes building capacity to understand their own ecosystems, undertake risk assessments, and utilising and adapting existing technologies to priority applications. This applies not only to crop agriculture, but also to animal and human health, and the protection of biodiversity.

B. HEALTH BIOTECHNOLOGY

Despite so much international attention on genetically modified crops and food products, genetic engineering in health has been the main focus for modern biotechnology for the past several decades. Today, the greater part of global research and development in

biotechnology, and the most cutting-edge applications of gene technology are related to health. A variety of biotechnological techniques are used in modern drug development and medical treatment. In some cases, for example, gene therapy, genetic engineering is the basis for both the process and the product. In others, gene technology is used simply as one tool in the development of new products such as pharmaceuticals.

(i) Drug, Vaccines and Diagnostics

The first biotechnology product approved for human healthcare was synthetic human insulin, which came onto the USA market in 1982. Since then, more than 170 biotechnology-related drugs and vaccines have been approved by the USA's Food and Drug Administration, of which 113 are currently on the market. Another 350 biotechnology medicines, together targeting over 200 diseases, are in the later stages of development. Amongst those approved during the year 2000 are medicines to treat pneumococcal diseases in children, diabetes, cancer and haemophilia. DNA technology is expected to revolutionise vaccine development in the future. DNA vaccines have only recently started the testing process, but are expected to eventually replace other methods of vaccine production. To state it simply, conventional vaccines are made from either live, weakened pathogen (disease causing agent) or a killed pathogen. Vaccines produced using live pathogens confer greater and longer-lasting immunity than those using killed pathogens, but carry some risk of causing the full-blown disease to develop.

DNA vaccines contain only those genes of the pathogen, which produce the antigen and not those used by the pathogen to reproduce itself in host cells. Therefore, DNA vaccines are expected to combine the effectiveness of live vaccines with the comparative safer of those based on killed pathogens. Several preventative and therapeutic vaccines for HIV are currently in early trials. DNA vaccines are likely to be more extensively available to developing countries than conventionally produced vaccines. First, the cost of DNA is low compared to producing weakened live organisms. Second, DNA vaccines are more stable at normal temperatures. Refrigeration costs can take up to 80% of a vaccination programme's budget where conventional vaccines are used in tropical countries. However, there are still some uncertainties about the potential for vaccine DNA to 'invade' the host's genome and possibly trigger genes relating to tumour development. There is therefore a great deal of caution surrounding the development of DNA vaccines at this time.

Two key broad areas of modern biotechnology are now used in disease diagnosis. The first is cell fusion, which involves the production of self-replicating antibodies – Monoclonal Antibodies - for a specific antigen, or disease agent. Monoclonal antibody diagnostic tests have been on the market for several years and are now one of the most profitable areas of commercial biotechnology. These diagnostic tests are actually quite inexpensive to produce, and this presents opportunities for some developing countries to enter the international biotechnology market, and also develop diagnostics for diseases of particular local relevance where these do not yet exist.

The second area of biotechnology used for diagnostics is DNA technology. DNA probes, which use isolated segments of DNA to 'attract' complementary gene sequences from pathogens, are already on the market. They are relatively cheap to produce, and are usually more stable in transit and in tropical climates, than conventional diagnostics. DNA diagnostics are likely to grow into a major product area in the future, due to the developments taking place on DNA arrays, which are also known as DNA chips, and micro arrays. Micro arrays allow the detection and analysis of thousands of genes in a

single small sample, giving the power of many DNA probes in one small array. Micro array technology is also expected to greatly increase the efficiency of drug discovery, though no drugs have as yet been developed using the technology.

(ii) The Human Genome Project

The Human Genome Project is an international research initiative, started in 1990, which aims to 'decode' the human genome. An almost complete map of the genome has already been produced, and sequencing is now expected to be complete by 2003, two years ahead of schedule. It is now estimated that the human genome has around 30,000 genes. Many common genetic disorders are caused by defects in several genes. However, around 4,000 other disorders are now thought to be caused by a single mutant gene, including sickle cell anaemia, and cystic fibrosis. The Human Genome Project has identified many of these mutant genes. In fact, on average during the past two years, a new disease gene has been identified every day. It will take many more years to fully understand how all of the genes in the human genome work, but already the new knowledge generated by the Project has led to many developments in medicine. Furthermore, this new knowledge is in the public domain, and therefore freely available to scientists who are able to access it, and have the ability to analyse and use it. Future benefits will undoubtedly include improved drug and vaccine development.

However, there are societal implications from this increasing ability to understand genetic variability in humans. Genetic screening and analysis of individuals may potentially lead to healthcare benefits to those individuals, for example, through tailor-made treatment (see Pharmocogenomics, below) or opportunities to make lifestyle changes where the individual is genetically susceptible to certain diseases. But there are very real concerns that an individual's genetic information may become available to organisations outside the medical profession, including insurance companies and employers. There are therefore concerns about loss of privacy, and genetic discrimination.

(iii) Pharmocogenomics

Pharmocogenomics is concerned with individual response to drugs based on genetic makeup. Finding the most suitable drug, and dosage, for a specific patient is done on a trial-and-error basis. Dosage is calculated according to the weight and age of the patient. Actual patient response, including processing and metabolisation of the drug, and any adverse side effects, is largely determined by their genetic inheritance. Understanding these processes through genetic analysis of individual patients is likely to lead, in the future, to more effective treatment and improved drug development. Treatments could be tailor-made for the patient, resulting in faster recovery, more cost-effective use of drugs, and a decrease in adverse reactions to some drugs. In drug development, it will become possible for new drugs to be targeted at specific groups that are able to metabolise them effectively and without serious side effects. This will mean fewer failed drugs trials, and less wastage of costly research and development where a particular drug is suited only to a niche market. Pharmocogenomics is a very recent, but fast-moving area of research, which is likely to revolutionise health care in industrialised countries in future years. However, questions must be raised about the feasibility and time scale for the benefits to reach most developing countries. Genetic analysis of individuals, and ready access to a wide range of drug options, will of course be prerequisites for take advantage of the opportunities offered.

(iv) Gene Therapy

Gene therapy involves the genetic engineering of a patient's genetic code to remove or replace a mutant gene that is causing disease. There are two broad types of gene therapy that are possible. Germ-line, or stem cell, gene therapy involves altering a patient's DNA in their stem (reproductive) cells. The modification to their genetic 'blueprint' is permanent, and hereditary. This type of gene therapy is complex, and is considered too risky to undertake until the underlying biology is better understood. It also raises many ethical problems, for example, the potential misuse of the therapy to create 'designer' babies. At the moment, germ-line gene therapy is banned in many countries. The second type of therapy is somatic gene therapy. This involves engineering cells on a 'localised' basis, without affecting the patient's basic genetic 'blueprint'. The first such therapy was approved in 1990, to treat a four year old child who suffers from Severe Combined Immune Deficiency. Some of the girl's white blood cells were extracted, genetically engineered in the laboratory, and infused back into her bloodstream. This successfully strengthened her immune system. Gene therapy techniques for cystic fibrosis have also been approved, and candidate techniques for the treatment of Parkinson's Disease, Alzheimer's Disease, and some cancers are under development. Somatic cell gene therapy is likely to become very important for the treatment of diseases caused by single mutant genes.

IV Risk and Uncertainty

(i) The Issue

From Section III therefore, it can readily be seen that while modern biotechnology has great welfare potential is subject to significant concerns of ethics, morality and risk. This was recognised at a relatively early stage in Article 8 (g) of the Convention for Biological Diversity (CBD), which enjoins all signatories to:

> Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health[5]

As Essegbey and Stokes [8] point out the risks are of two main types: "those associated with the contained use of biotechnological processes and intermediate products in laboratories; and potential risks and uncertainty of the impacts of biotechnological products when released into the wider environment".[6] However, while the former have been reasonably well catered for in most countries in terms of regulatory guidelines, the situation is not so clear-cut for the latter category. In the USA and Europe, risk assessment has been done on a step-by-step, case-by-case basis [12] and has co-evolved with technology development, governance structures and management expertise. However, in many parts of the Third World the "international diffusion of biotechnologies is progressing at far greater speed than their original development, leading to fears that developing countries are, or soon will be, exposed to biotechnology

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[5] See Glowka et al [11] p. 45.

[6] Op. cit. p 35.

related risks which they do not yet have the capacity to manage."[7] The question then is how should they plan to cope with this dilemma in the best interests of development.

(ii) Risk Analysis

To understand the problems involved in risk analysis in relation to biotechnology it is necessary to take a step back in time. Science has always understood that technological and economic interventions are subject to risks. But such risks were seen as computable in the sense that values could be assigned to them. Decision-makers would then combine standard estimates of contributions to welfare with such risk values before making final policy recommendations. For example, the decision to introduce an innovation in crop production in a region would depend first of all on projected net benefits, which would be determined, say, through social cost-benefit analysis (SCBA). SCBA typically values expected outputs and inputs to projects and computes a resultant "rate of return" to the relevant capital investments. But these estimates would then be adjusted to allow for factors preventing the expected costs and benefits being realised. The techniques used would vary but ultimately would rest on probability theory—that is by computing the likelihood of sub-optimal performance based on past events of a similar nature.[8] The adjusted projected net benefits would be computed and the decision to go ahead with the intervention would then proceed according to some wider set of decision criteria (for example whether or not the adjusted rate of return to the investment exceeded some numerical percentage like the current social discount rate used by the national planning agency[9]).

Of course it was always realised that such numerical forecasts would be imperfect. To take this into account a "safety" factor was often also added to allow for the possibility of "non-computable" risks. For example in the building of a new bridge, it would be accepted that despite over a century of bridge-building knowledge on the part of civil engineers, things could still go wrong. And therefore so-called "fail safe" factors would be included to allow for this. But (and this is the important point) ultimately the system in question was always seen to be computable in principle. It existed as an objective entity in reality, however hard it was to formulate it numerically in practice. As Thompson [14] has put it, the view is based on an acceptance of 18th Century Natural Law and the utilitarian ethics that followed from the Enlightenment. It is useful at this stage in the argument to distinguish between two criticisms of this view.[10] The first is a systems criticism. The second one is an ethical one.

On the first it is essential to realise that much of modern experimental science is based on the view that the system under investigation is relatively stable. This then allows it to be subject to experiment and characterisation in the sense that its parameters are computable. Once we know these, we can predict with some certainty how it will behave in future periods. If you like we can assign probability values to future behaviour based

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[7] Ibid. p. 6.

[8] Thus formally a distinction is made between "risk" and "uncertainty". In the latter whereas future states of nature are known there is not enough prior knowledge available to determine an exact set of probabilities. In such cases these would be estimated with aid of by "experts", those who were trusted to know the state-of-the-art and could make judgements with authority. This type of technique is sometimes called a Bayesian technique after the scientist who first suggested this statistical approach. See [13] for a discussion of the use of Bayesian formulae in relation to Third World science policy decisions.

[9] Alternatively where investment funds were limited only the high value projects would be sanctioned

[10] See [14] page 24, for a reference to John Stuart Mill in this context.

upon how the system has behaved in past periods. On the other hand if the system in question is evolving in terms of its underlying structure, then such a procedure is flawed simply because its parameters are no longer stable. Indeed its parametric instability increases in proportion to its rate of evolution. This need not be too much a problem in bridge building (bridges, and their immediate environments, are relatively stable systems) but is certain to be a serious problem in a field such as biotechnology subject to very rapid technical change. Here assigning probability values to, say, the impact of a GMO becomes impossible simply because the future "states of nature" are unknown. We live genuinely in a state of ignorance about the future system in question.[11]

The second criticism is equally fundamental. For even if formal risk analysis could show that an intervention is likely to be relatively harmless there may still be important issues associated with values and ethics. Thompson, for example, shows how in the context of the GM controversy consumers became "deeply resentful of a marketing approach that denied them the opportunity to give or withhold consent. Even consumers who thought of themselves as potentially benefiting from GM foods nevertheless insisted upon the right to decide for themselves whether to eat it or not."[12] Tait [10] shows how throughout the 1990's there arose increased resistance among many sections of European public opinion to the use of biotechnology to modify crop production. Some of this may have been "irrational" in the formal scientific sense but by no means all. The impact of "mad cow" disease in the UK did great damage to public trust of government regulation. It also called in question the relative inability of science to provide a coherent impartial judgement of such issues. Nor did the early attitude of industry help. Tait and Chataway [17] for example, show how "Monsanto's response to European calls for a more precautionary approach to regulation was to mount a campaign of opposition"[13], including a refusal to countenance "product labelling" as mechanism that might allay public concerns. And though much of the agro-biotechnology industry has now come to realise that a more inclusive strategy is probably necessary to deal with such issues, a great deal of damage has been done to their corporate interests.

To re-cap, the application of formal risk analysis to biotechnology issues is twofold. Firstly it runs foul of the speed at which biotechnology is moving. And so has difficulty in making judgements that stand up to strict scientific scrutiny. Even the application of fail-safe devices does not deal properly with the problem, not least because all too frequently scientists have been less that candid about the validity of their methods. Secondly, however, there are important ethical objections about the very nature of biotechnology interventions, and these concern the rights of the public to agree or not with them whatever may be the objective risks involved. Here many environmental groups have emerged in recent years to argue vigorously against the application of the biosciences to many aspects of economic production. And, as we shall see below, they are doing so to great effect not only in Europe but also in many Third World countries.

(iii) New Approaches

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[11] Again more rigorously, a distinction should be made between "uncertainty" and "ignorance". In the former future states of nature are known. In the latter they are not, in which case the assigning of objective probabilities becomes impossible. In the case of biotechnology change the level of ignorance is certain to be considerable. We are grateful to Mick Common for pointing out this distinction to us. Clark and Juma [15] explore these issues in respect of technology more generally. See Chapters 1 and 9.

[12] See op. cit. p. 25. Thompson also makes reference to Durant, Bauer and Gaskell [16].

[13] See p. 6.

In order to deal meaningfully with the risks associated with modern biotechnology, therefore, a range of new approaches has been suggested and it is useful at this stage to summarise what these might be. Central to these is the notion of the Precautionary Principle, which began to emerge as an important conceptual organiser in the build up to the UNCED Earth Summit in the early 1990's. Hence Common [18] quotes Principle 15 of the Rio Declaration as follows:

> In order to protect the environment the precautionary principle shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[14]

The Precautionary Principle is thus essentially a general injunction to decision-makers to postpone action where the environment is at risk but as Common [18] points out "it does not offer much in the way of guidance as to how the problem should be dealt with. To say that a lack of certainty should not inhibit measures to protect the environment from serious and irreversible damage does not indicate what should be done and how it should be done. Nor does the principle suggest how one might set about answering such questions."[15] Common goes on to discuss some recent proposed mechanisms designed to operationalise the Precautionary Principle like the adoption of a *Safe Minimum Standard* or the posting of *Environmental Performance Bonds*[16] for project interventions. However, in both cases these are controversial and have been subject to criticisms even for well-defined projects. In the case of radical biotechnological change it is difficult to see how a specific decision tool of such types could play a useful role.

Nevertheless it is clear that in many countries the Precautionary Principle is having practical influence. Tait [10] for example, shows how many European countries have now begun to take a much more cautious approach to biotechnology policy, especially with regard to the advent of GM crops. Her view is that the time has come to take the precautionary principle much more seriously than has been the case in the past. But this cannot be done through the simple application of the old risk-based formulae for the simple reason that we are now dealing with future events and our perceptions of such events and their implications. Here we are in a world of great uncertainty and ignorance, where views are influenced by economic, social, ethical and ideological interests, and therefore where decision-making has to be consensual if it is to be successful. Indeed one of the major problems faced by industry, science and government is that for many years each of these "estates" has refused to see the issue in this light and has therefore lost credibility in the eyes of ordinary people. Tait calls for a constructive dialogue among all interested parties so as to clarify the issues and reach a social consensus on all the underlying problems. This does not mean abandoning science. Rather it implies the need to recognise the limitations of science in a field that is developing very fast indeed.

But how should this be done? The first step is to recognise who the interest groups are and what factors influence their views. Tait identifies the following:

- Environmental pressure groups (ENGO's)

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[14] See p. 213
[15] Ibid. p. 214.
[16] See also Perrings [19]

- Consumer organisations (CNGO'S)
- Multinational companies (MNC'S)
- Small scale industry (SME'S)
- Farmers and farmer organisations (FO'S)
- The public research system (and the scientists that work in it).
- Government ministries and secretariats.

Each of these interest groups generally view issues of biotechnology risk quite differently even where the presenting evidence appears to be very similar. But their views are neither static nor homogeneous. For example "unlike their American counterparts, several European companies would have been prepared at an early stage to accept labelling of food products arising from GM crops, avoiding one of the stimuli which has had an important impact on European public opinion."[17] Again Paarlberg [20] shows how agricultural and scientific ministries are usually much more promotional to biotechnology that are environmental ministries. And the views of European CNGO's have certainly changed from a neutral position to a much more hostile position over the 1990's as trust in regulatory authority has dissipated (Tait [10]).

In a recent IFPRI publication Paarlberg [20] has analysed policies towards GM crops in four developing countries, Brazil, China, India and Kenya. Of these only China has been positive about granting permission for planting to go ahead. In each of the other countries international pressures from ENGO's, CNGO's and donors are working to discourage such developments despite the fact that government agencies in all three countries are much more positive towards GM crops. In China's case, however, NGO pressure groups are simply not allowed to function. Interestingly enough Paarlberg concludes that the existence of IPR regimes is not by any means the main determinant of MNC behaviour in any of the countries. Monsanto, for example, has been offering to share GM sweet potato technology with Kenyan scientists for nearly a decade but has been prohibited on biosafety grounds. In China MNC's have been quite happy to enter into collaboration agreements despite widespread and blatant IPR piracy. Conversely, a relatively strong IPR regime in Brazil has not in itself been enough to get a GM revolution going in that country (Paarlberg [20])[18]. Stokes [21] has come to similar conclusions in her study of Zimbabwean biotechnology policy.

A related issue concerns international trade. Because trade in GM crops, for example, is subject also to the WTO agreement, in effect signing up to the WTO has constrained countries' abilities to prevent imports of GM crops on grounds of risk and safety. Because of the importance of this issue the WTO has set up a Committee on Trade and Environment to deal with associated disputes. As Tait and Bruce [22] point out, however, the current WTO position is that such trade restrictions should be based on current internationally agreed food safety regulations and that if national standards are higher than these current *Codex* standards, "the additional safeguards must be based on scientific evidence and grounded in risk assessment."[19]   In other words the WTO

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[17] See Tait [10], p. 184.

[18] See page 30.

[19] See p. 105. These standards refer to the *Codex Alimentarius* established in the 1960s by the FAO and WHO Tait and Bruce show that the Codex contains more than 200 standards for foodstuffs and in 1998 membership of the Codex Commission comprised 163 countries representing 97% of the world population. They also refer to the Codex web site--- www.fao.org./docrep/w9114e/

position does not recognise the wider view of risks associated with biotechnology development as outlined above.

V Public Policy for Biotechnology

How then should Third World governments proceed with respect to biosafety issues given the promises and threats of modern biotechnology? We suggest that an important necessary condition is the building up capacity to understand biotechnology in all its aspects so that whatever regulatory/promotional regimes countries put in place are as fully informed as possible. And it is here that such countries are bound to confront a much more basic issue of S/T policy—the inability of traditional governance structures to fully understand the details of possible technology developments and hence to construct effective plans and policies to promote them safely. For while there are usually well-trained scientists within national laboratory systems who are well able to understand the detailed nature of biotechnology they are often not well connected into decision-making structures at government level. At the same time the degree of "connectivity" between relevant S/T organisations is often not very good either. What this means in practice is that since "innovation systems" are not well developed, mechanisms for relevant governance are hampered by lack of knowledge.

In turn this then allows different interest groups to exploit a confused situation to try to achieve advantage for this or that position, regardless of the objective situation. Paarlberg, for example, shows how the NGO sector in India has been able to stir up popular feeling against GM technology by playing on fears about the activities of international corporations. And this is despite the fact that in some cases the adoption of GM technology could have beneficial consequences. For example, India's cotton factors are "plagued by bollworms that have become resistant to chemical sprays. Insecticidal Bt cotton presents an alternative method to control bollworms, yet efforts by Monsanto/Mahyco since 1997 to gain biosafety approval-------have repeatedly been slowed by NGO protests. By filing law suits---and by sponsoring physical attacks against field trials, anti-GM activist groups in India have transformed the biosafety approval process into a highly politicised—and at times paralysed--- policy struggle".[20] Thus an activity with clear development and environmental benefits has been stopped by pressure groups that ostensibly are working in the best interests of the environment and development. Nor are the battles confined to the NGO sector, for in Brazil disagreements between environmental and science ministries have clearly played an important role in slowing down biotechnology development, while in Kenya biosafety legislation has been heavily influence by donors whose views may not have been totally disinterested.[21]

We would therefore recommend that countries take an approach similar to that recommended by Tait [10]. *First* of all national governments should recognise explicitly they are dealing with an extremely complex issue for which there are no simple solutions. Certainly they should not assume that they can issue directives from on high and wait for these issues to be obeyed uncritically. *Secondly* they should begin to encourage dialogue between and among all relevant stakeholders with the aim of clarifying the true nature of the issues and minimising degrees of misunderstanding and confusion. One good example of how this might be done is a recent attempt in Ghana to raise biotechnology awareness through the use of a "stakeholder conference". In this case a donor-funded project brought together as many interest groups representatives

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[20] Op. cit. p. 19

[21] Ibid. pp. 15 and 12.

as possible with a view to setting priorities for biotechnology development in Ghana over the medium term.[22] Led by a policy research organ from a key ministry the project team then went on to conduct research into how well such stated priorities are being met in practice, through an analysis of secondary literature and interviews with individual stakeholder groups. Finally a smaller feedback workshop was arranged at which results were discussed and disseminated. At the same time a newsletter was produced and disseminated as widely as possible so that all groups could feel they were part of this dialogue and could benefit from the resultant exchange of views. It is not difficult to see how the appropriate use of the Internet could enhance and promote such initiatives.

Thirdly, countries need to do more to build up relevant S/T capacities amongst civil servants. As Paarlberg points out biosafety administrators are prone to err on the side of undue caution if they know that they will be subject to NGO and media criticism. This has certainly been the case in Kenya where the drafting of policies has proceeded much faster than the capacity to administer the resulting decisions. Indeed donors have an important role to play here since they are apparently much readier to fund the drafting of biosafety policies that the building up of necessary implementation capacity. Indeed it is interesting to note that of all countries in the Paarlberg study, it is arguably the one that has done most to build up an independent (of donors) biotechnology capacity (China) that has done most to promote the sensible use of GM crops for development. *Fourthly*, developing countries need to do more at Higher Education level to provide their scientists with an understanding of the social and economic contexts within which biotechnology is likely to develop. So fundamental is this technology to practically every avenue in modern life, that training the current generation of students solely in narrow areas of relevant disciplines (like molecular genetics, for example), is certain to produce graduates that have great difficulty in providing the necessary advice to policy makers.

All this is not say that progress is not being made. The intense dialogue surrounding the drafting of the Biosafety Protocol to the Biodiversity Convention (signed finally in Cartagena in January 2000) shows that countries can certainly get their act together when it comes to international policy. In this case the big debate took place between two major blocs; the so-called *Miami* group of countries (Argentina, Australia, Canada, Chile, Uruguay and the USA) and the *Like-minded* group of developing countries and NGOs. The former group felt they had most to lose in terms of trade and were much less willing to agree to a restrictive protocol than the latter group. It was able to "water down labelling requirements and succeed in that the protocol applies only to LMOs so that no segregation is required for non-living GM organisms"[23]. However, the very fact that the Like-minded group were unsuccessful here may well reflect their weaker capacity to argue what must have been a complex case at that event.

VI Concluding Comments

This paper has been written as a contribution to current debates about biotechnology policy in and for Third World countries. Inevitably it has set out the issue in relatively simple terms and readers are encouraged to consult the cited texts and other sources for more detailed discussion of the issues. However, not only is biotechnology now evolving very rapidly, it is almost certainly going to play a fundamental role in future development policies in both developed and developing countries. It promises immense gains in food security, environmental protection, agriculture, health and industrial production. But it

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[22] See Essegbey et al. [23] The donor in this case was the UK bilateral agency DFID.

[23] Tait and Bruce Op. cit. p. 107.

also interferes with living processes in ways, and to degrees that have never occurred before in human history. We simply do not know what the impacts will be, how widely spread and with what effects. Moreover the advent of third generation biotechnology has raised ethical issues that are deeply felt by people and organisations at all levels. All the more reason, therefore, to approach associated public policy analysis with as much dispassion and objectivity as possible. Our suggestion is that decision-making in this sphere should not rest solely upon narrow instruments of decision-making as conventionally understood. Instead governments must establish new initiatives, capabilities and institutions that can have a profound effect on legitimacy at a much more fundamental level. Only when this is done will biotechnology in Third World have the role and status it deserves.

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Abstract

This paper sets out to clarify the complex issues of risk perception and management in connection with biotechnology and Third World development. It summarises the main threats and promises associated with the technology before explaining why traditional approaches to risk are flawed from both a scientific and an ethical standpoint. It ends by making suggestions about how the precautionary principle may be made an operational tool for governments interested in ensuring that biotechnology leads to sustainable development.