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KEY ISSUES IN BIOTECHNOLOGY



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PREFACE

This paper reviews several key issues surrounding modern gene technology and its application in the areas of crop agriculture and medicine, and presents the potential benefits and challenges associated with them. It concludes with the major implications for policy makers.

This paper has been prepared by the UNCTAD secretariat in accordance with the work programme of the Division on Investment, Technology and Enterprise Development, and as part of the analysis of the relationship between science and technology and development, and the implications from that for policy formulation and international cooperation in technological capacity-building. In particular, it addresses and provides balanced information on biotechnology, with particular attention to genetically modified crops, health and intellectual property rights.

This paper was reviewed by Professors Richard Braun, Norman Clark, Calestous Juma and Bernd Michael Rode.

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KEY ISSUES IN BIOTECHNOLOGY

INTRODUCTION

Biotechnology is a collective term for a group of technologies that use biological matter or processes to generate new and useful products and processes. As such, it ranges in complexity and maturity from ancient brewing and bread-making techniques to genetic modification through hybridization and interbreeding of plants and animals, as well as the manipulation of individual genes in humans, animals, plants and micro-organisms.

Biotechnology is a key technology for the new millennium. It has an immense range of applications in agriculture, medicine, food processing, environmental protection, mining, and even nanoelectronics. On the other hand, the potential for altering the genetic structure and characteristics of living organisms, including humans, plants and animals, has resulted in many concerns about safety and ethical implications of the new technologies. So far, most of the safety issues have emerged from agricultural biotechnology, but some cutting-edge developments in medical biotechnology are now presenting the major ethical concerns.

I. GENETICALLY MODIFIED CROPS AND FOOD

The basic argument put forward in favour of genetically modified (GM) crops is that they 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 opened up opportunities for increasing crop yields, reducing crop losses to insects, disease and post-harvest storage problems, and enhancing 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.

Traditionally, new varieties of specific crops have been bred by mutation and 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 of 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 in most cases 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.

A. Environmental impacts of genetically modified 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 destabilization of some 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 from those from field tests. So far, despite the fact that millions of acres of *Bt* crops have been 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. In-depth research on specific ecosystems could provide answers to these questions.

B. Genetically modified 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 GM 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.

C. Who benefits from genetically modified food and crops?

Pro-biotechnology scientists and firms have pointed out that GM 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 per cent safe. Potential risks must be weighed against potential benefits and compared with risks and benefits of traditional agriculture. Such risk-benefit analyses should 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 yields benefits for commercial farmers and private sector firms. For farmers, insect-resistant and herbicide-tolerant crops produce somewhat higher yields and lower costs in respect of chemical inputs, tractor fuel and labour. Profits accrue to the firms that developed the seeds. As a result, revenues at national level are boosted. Furthermore, potential environmental risks might be offset against the environmental benefits of reduced agrochemical use and more efficient land use. But for

consumers, these early GM crops, food products derived from them, and the perceived benefits are not evident.

D. “Terminator technology” and farmer-saved seed

For developing countries, the potential benefits for farmers may be inequitably distributed both at 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 publicized 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 commercialized, but research and development on other GURTS is ongoing in many organizations. The use of “terminator technology” may, on the other hand, provide an in-built safety system to stop the inadvertent hybridization of genetically modified varieties with unmodified species (plants, crops, etc.) growing in nearby areas.

Opponents claim that this technology would increase poverty amongst the poorest farmers in developing countries, 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 based on GURTs. 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 or disappear 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 historical and cultural motives for exchanging and replanting saved seed, and therefore any technologies that effectively prevent this would not be acceptable.

E. Genetically modified crops and food security

A very important challenge for developing countries that hope to use 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 them 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

metabolized 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.

II. BIOTECHNOLOGY AND HEALTH

Despite much international attention given to GM 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, 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.

A. Drugs, vaccines and diagnostics

The first biotechnology product approved for human health care was synthetic human insulin, which came onto the market in the United States in 1982. Since then, more than 170 biotechnology-related drugs and vaccines have been approved by the United States 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 2000 are medicines to treat pneumococcal diseases in children, diabetes, cancer and haemophilia.

DNA technology is expected to revolutionize 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. Conventional vaccines are made from either live, weakened pathogens (disease-causing agents) or killed pathogens. Vaccines produced using live pathogens confer greater and longer-lasting immunity than those using killed pathogens, but may carry some risk of causing the full-blown disease to develop. Applying individual proteins as antigens in sub-unit vaccines is made possible by recombinant DNA technology.

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 safety of those based on killed pathogens. Several preventive 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 with producing weakened live organisms. Second, DNA vaccines are more stable at normal temperatures. Refrigeration costs can take up to 80 per cent 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, owing to the developments taking place on DNA arrays, which are also known as DNA chips, and microarrays. Microarrays 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. Microarray technology is also expected to greatly increase the efficiency of drug discovery, although no drugs have as yet been developed using the technology.

B. 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, including sickle cell anaemia and cystic fibrosis, are now thought to be caused by a single mutant gene. 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, accessible by scientists for analysis and application. Future benefits will undoubtedly include improved drug and vaccine development.

This increased ability to understand genetic variability in humans may lead to health care benefits to individuals who are genetically susceptible to certain diseases. Genetic screening and analysis, for example, makes it possible for tailor-made treatment (see Pharmacogenomics below) or offers opportunities for lifestyle changes. However, there are very real concerns that the availability of individuals' genetic information to organizations outside of the medical profession, including insurance companies or their employers, may lead to privacy invasion, genetic discrimination and other forms of misuse.

The Human Genome Project will lay the foundation for proteomics research, which will be undertaken primarily by the Human Proteome Organization.¹ Proteomics research will focus on the

proteins encoded by the genes (one gene may encode, through alternative splicing, up to 35,000 proteins) which are responsible for the more sophisticated processes in living organisms.

C. Pharmacogenomics

Pharmacogenomics is concerned with individual response to drugs based on genetic make-up. Finding the most suitable drug and dosage for a specific patient is currently 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 metabolization of the drug, and any adverse side effects, is largely determined by genetic inheritance. Understanding these processes through genetic analysis of individual patients is likely to lead 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 metabolize 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. Pharmacogenomics is a very recent, but fast-moving area of research, which is likely to revolutionize health care. Genetic analysis of individuals, and ready access to a wide range of drug options, will of course be prerequisites for taking advantage of the opportunities offered.

D. 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 patients' 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 concerns, for example, over 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 "localized" basis, without affecting the patient's basic genetic "blueprint". The first such therapy was approved in 1990 to treat a four-year-old child suffering from severe combined immune deficiency. Some of the child'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 gene therapy is likely to become very important for the treatment of diseases caused by single mutant genes.

III. GOVERNING BIOTECHNOLOGY: POLICY CHALLENGES

A. Building capacity for developing and managing biotechnology

This paper has highlighted some of the potential risks and benefits of GM crops, the use of DNA for vaccines and diagnostic tests and the mapping of the human genome. Application of biotechnology to meet the needs of developing countries requires the creation of an infrastructure for the transfer of relevant technologies, development of institutions with the capacity to adopt and develop the know-how required for successful application of biotechnology. This includes building capacity to understand their own ecosystems and to select, acquire, manage and further develop those biotechnologies that are most appropriate to national needs. Clearly, such efforts require investing in science and technology education and research. Given the scarcity of public resources in developing countries, various innovative avenues, including public-private partnerships, South-South cooperation and the use of information technology networks, should be explored. However, the starting point in building capacity is a needs assessment, which would lead to both a national strategy and the efficient allocation of scarce resources to meet those needs.

B. Biosafety and bioethics: capacity for risk assessment

Biosafety is concerned with the potentially adverse impacts of biotechnology on human, animal and plant health, and the environment. Biotechnology also gives rise to socio-economic and ethical concerns, some of which have been described here. Physical risk and uncertainty are technical issues, and policies and regulatory regimes intended to manage these risks will depend largely on scientific capacity, including human expertise and well-equipped laboratories. This capacity simply does not exist in many developing countries at present. The types of biotechnologies mentioned here are characterized by a great deal of scientific uncertainty. The Cartagena Protocol on Biosafety, the first international agreement specifically negotiated to deal with products of genetic engineering, is based on applying the Precautionary Principle to risk assessment of genetically modified organisms. This Principle holds that an absence or lack of scientific proof of risk should not be taken as conclusive evidence of the safety of any given organism and requires risk/benefit analysis. This gives some degree of reassurance to developing countries that are as yet unable to undertake comprehensive risk assessments. However, in the application of the Precautionary Principle, it must be argued that no technology is completely risk-free, and that the Precautionary Principle could be open to misuse as a trade barrier and as a barrier against further development of biotechnology. This suggests that there is a need to address concerns about the consistency of particular measures between the provisions of the Agreement on the Trade-related Aspects of Intellectual Property Rights and the provisions of the Convention on Biological Diversity.

C. Building awareness of biotechnology

Some of the applications of biotechnology described earlier have potentially serious implications for socio-economic welfare, and ethical and moral well-being. If biotechnology is to be used to provide benefits to a country's population, then political support, as well as public awareness and acceptance of

new technologies are essential. There is a wide range of potential applications, and decisions have to be made concerning the choice of technologies, according to national needs. The public has a constructive role to play in helping to make these choices, but in most countries, including industrialized countries, public awareness and knowledge about biotechnology are insufficient for ordinary people to have an effective and qualified voice in biotechnology development. Building public awareness and disseminating qualified and balanced information about biotechnology is a critical issue in most countries.

D. Accessing biotechnology: intellectual property rights

Many of the new products and processes associated with biotechnology have been developed in the private sector, and this has led to concerns that proprietary rights to these technologies might mean that many developing countries will be unable to access them. Another issue is that it is felt by many that ownership rights of genes and other living matter, as intellectual property, is not morally acceptable. Furthermore, the patenting of gene sequences and biotechnology techniques with broad applications means that developing countries in particular may be excluded from affordable access to technologies that they urgently need. Against this, innovating organizations argue that without the limited monopoly rights to profit from their new products and processes that are conferred by intellectual property rights (IPRs), there is no incentive to invest in research and development. Moreover, some argue that where IPRs cannot be adequately protected, this will act as a barrier to technology transfer. In fact, very little systematic evidence has been collected in respect of the role of IPR regimes in encouraging or constraining the transfer of technology. Related to this, it is worth noting that biotechnology is knowledge-intensive, and much of the knowledge needed to develop and manage biotechnology is already in the public domain. Finding ways to access, assess and select appropriate knowledge from this freely available global pool is perhaps a more significant problem for developing countries. Developing countries should make efforts in this direction through modern means of information technology.

NOTE

- ¹ Members of the Human Proteome Organization include Celera Genomics, Scripps Research Institute, Harvard University, University of Southern Denmark, Yamaguchi University of Japan and Roche Pharmaceutical Co. These members were scheduled to meet in April 2001 in Virginia, United States, to work out their tasks and plans.

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