Global Concerns and Issues in Biotechnology

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INTRODUCTION

The impact of modern biotechnology is becoming increasingly evident, as the substantial investments over the past two decades in research and development in modern biotechnology are now resulting in a wide range of new products, processes, and services, which contribute to improvements in human health, agricultural production, and environmental conservation. This is evidenced by the fact that total sales of new biotechnology products in the United States alone in 1995 were about US$10 billion. These are estimated to grow at 12% annually over the next decade (Ernst and Young, 1996).

Biotechnology is not an industry in itself, but a set of enabling technologies, arising from modern biology, that are being applied to research and product development in several existing industries, notably in pharmaceuticals and agriculture and in environmental conservation.

Biotechnology consists of a gradient of technologies, ranging from the long-established and widely used techniques of traditional biotechnology to the novel techniques of modern biotechnology that enable the genetic manipulation of living organisms, provide modern immunology with a basis for new diagnostics and vaccines, and allow new cell and tissue-culture techniques for the production of biological products (Persley, 1990).

GLOBAL CONCERNS

Four key global concerns need to be addressed by the applications of modern biotechnology.

1) Food production

The World Food Summit in Rome in Nov. 1996 highlighted the need for substantially increased food production, especially in developing countries. The Summit's Action Plan agreed with the intention of the global community to halve the number of people who are undernourished over the next decade, from 800 million to 400 million. This action will require a two-pronged approach based on both the need to continually increase food production just to keep pace with population growth and the need to increase the incomes of the urban and rural poor so that they are able to purchase food and fuel for their families.

2) Poverty reduction

A dynamic agricultural sector is the engine of growth for many countries and is based on the sale of surplus food by farm families and by the sale of commodities for export. The increasing importance of high-value export commodities offers new opportunities for developing countries. For example, the expanding exports of high-value horticultural crops, such as vegetables, fruits, and flowers, has significantly increased the incomes of many smallholder cooperatives in Kenya. Chile and Colombia also have benefited from similar high-value horticultural exports.

3) Disease control

There is increasing global concern as to the need to control infectious diseases affecting humans and animals. Some diseases are long-standing but seemingly intractable problems, such as sleeping sickness, measles, and malaria. Others, such as AIDS and Ebola virus, are newly discovered threats.

4) Environmental conservation

There is global concern as to the need for environmentally sustainable development. This concern is based on the concept that it should be possible to increase the standard of living of the world's population without unnecessarily depleting the world's finite natural resources and further degrading the environment. This requires increasing productivity from existing agricultural land, so as to avoid bringing more wilderness areas into farming. These areas are a rich source of biodiversity, and often only marginally suitable for agriculture. Yet pressure for new land for farming is a continuing threat to environmental conservation.

ISSUES IN BIOTECHNOLOGY

Modern biotechnology can contribute to the resolution of the global issues of hunger, poverty, disease, and environmental degradation, but three key issues will affect its successful applications to these problems over the next decade.

1) New technology development

After several years of skepticism, modern biotechnology is starting to have significant economic impact on agricultural productivity through improved productivity, enhanced products, and reduced input costs. At least 15 novel ag-biotech products are on the market with initial sales of US$380 million in 1996 and an expected market growth of 20% annually over the next decade. The products are mainly genetically engineered crop varieties with novel traits, new diagnostics for plant and animal diseases, and several new biopesticides. Novel vaccines against major animal diseases are in late stages of development (Ernst and Young, 1996).

In 1997, it was estimated that about 1.5 million acres of transgenic crop varieties were grown in the United States. These crops include maize, cotton, and potatoes with insect resistance; soybeans with herbicide resistance; and tomatoes with extended shelf life. Other novel products that are close to market are canola able to produce lauric oils, which would make it a direct competitor with coconut and palm kernel oils, and several biopesticides able to attack fungal diseases and insect pests.

Most of these novel products in agriculture are coming from new biotechnology firms in the United States or multinational seed and chemical companies. There has been significant consolidation in the ag-biotechnology business over the past few years, as many of the new biotechnology firms with commercially viable technologies have either merged, been acquired, or entered into strategic alliances with major firms to enable the development and distribution of the new technologies. The products of the new technologies in agriculture will be distributed mainly through the seed of new crop varieties. Hence, the alliances established between new biotechnology firms and seed companies, often with their own plant breeding programs, are starting to have commercial returns.

Thus modern biotechnology is well on the way to having a significant impact on agriculture, especially in North America, and increasingly in other OECD countries, especially the major agricultural exporting countries. The research and development (R&D) programs of the past decade are showing that it is possible to develop new transgenic crop varieties with improved pest and disease resistance that require less pesticide use, fruits and vegetables with extended shelf life, and oil crops with specified oil content. Genetic mapping techniques are being used routinely in some cereal breeding programs to substantially reduce the time and cost of developing a new crop variety.

The emerging technologies that will become increasingly important are the greater use of genome mapping in plant and livestock breeding, especially to identify specific genes that convey desirable characteristics; improved

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transgenic plants with more specific promoters to enable improved control of genes inserted in target plants; the combination of biotechnology with information technology to develop decision support systems for farmers, applicable to practices such as integrated pest management; and novel vaccines against human and animal diseases.

In the pharmaceutical industry, progress has been even more rapid. There are 34 biotechnology therapeutics/vaccines approved by the Food and Drug Administration in the United States. Product sales in 1995 were valued at US$7 billion. There are also 284 potential new pharmaceuticals in clinical trials in the United States, 40% of which are for cancer treatments and 10% for AIDS/HIV treatment. Biotechnology is now an integral part of new drug development, and it is estimated that 85% of all new pharmaceuticals will be produced using biotechnology by the year 2000 (Ernst and Young, 1996).

The size of the markets now being captured by biotechnology-based products reflects the substantial R&D investments, especially by the private sector. In 1995, the annual R&D expenditure in biotechnology in the United States alone was about US$10 billion, of which 80% was for human health care and 20% for agriculture. To give an indication of the scale of R&D investments, a new biotechnology firm such as Chiron invested US$166 million on R&D in 1995, while a major pharmaceutical company such as Merck had an R&D budget of US$1.23 billion in 1995 (Ernst and Young, 1996).

The **global challenge** is that the early commercial applications of biotechnology are almost all emerging in North America, and there is relatively little R&D investment addressing the problems of food production, human and animal health, and environmental conservation throughout the developing world.

The Consultative Group on International Agricultural Research (CGIAR) currently invests about US$25 million annually in biotechnology. This amount includes about US$10 million invested by the International Livestock Research Institute (ILRI) in animal biotechnology and about US$15 million spread over the several other international agricultural research centers dealing with biotechnology applications to the major tropical food crops (CGIAR, 1996).

There is significant under-investment by the international development community in the potential of agricultural biotechnology in developing countries. Indeed the CGIAR's total biotechnology investments are less than those of a small biotechnology firm in the United States or a national research organization in a small country such as Australia. An urgent need exists for much more creative partnerships among national governments of all countries, the national and multinational private sector, and the international development community, if the necessary level of investment is to be made in biotechnology to address the urgent needs of food production, human and animal health, and environmental conservation on a global scale.

2) Intellectual property management

The significant investments in modern biotechnology by the private sector are being driven by the fact that many of the new products and processes are protectable by patents and other forms of intellectual property. Thus a company is able to capture many of the benefits of its investments in biotechnology, in contrast to previous public-good research in biology, from which an individual company could not benefit directly from the intellectual property involved. This means that the powerful new discoveries in modern biology and genetics are able to be developed into products for commercial purposes.

The second significant development is that in the negotiations of the Uruguay Round of the General Agreement of Tariffs and Trade (GATT), the signatories agreed to set minimum standards for trade-related intellectual property (TRIPs). Thus, all nations who are signatories to the GATT agreement have agreed to instigate an internationally accepted form of intellectual property management over the next decade.

The third significant development is the fact that public sector R&D institutions, especially those in industrial countries, are also addressing the requirement to best manage the intellectual property they develop and the need to generate income to at least partially fund their research programs. This reflects government policies to ensure that there is a return on investments of public funds in R&D, in that intellectual property generated from inventions can be used to negotiate access to other proprietary technologies, for continuing product development and availability to the community.

Much of the intellectual property, patents, and knowledge and investment in the effective use of agricultural biotechnology at present lie with a small number of firms worldwide. Successful access and freedom to operate with the core enabling technologies by other parties to evaluate their applicability to orphan commodities and global concerns will require critical negotiations and knowledge of the available resources, including genetic resources and intellectual property.

3) Regulatory systems

The third issue that will affect the successful application of biotechnology to address global concerns is the development of safe and effective regulatory systems to guide the applications of biotechnology and public acceptance of the new biotechnologies.

In the pharmaceutical industry, the regulatory procedures for pharmaceuticals developed using recombinant DNA technology are essentially the same as those used for chemical drug development and conventional vaccines. These procedures, although often lengthy and expensive, are based essentially on the product developed and its behavior in clinical trials and not on the process by which it was developed. There are now several hundred novel products in clinical trials worldwide as potential treatments for various human health problems.

In agriculture, the development of acceptable regulatory arrangements has been more controversial, largely due to the perceived threats to the environment from genetically modified organisms. The approaches taken by various countries differ. For example, the United States, Australia, and Japan have developed regulatory systems based largely on assessing the familiarity of the product and its characteristics and using existing legislation governing the regulation of new agricultural products to the greatest extent possible.

The regulatory systems developed within the European Union place more emphasis on the process by which the product was created and are backed by legislation in individual countries, largely to address the concerns of the environmental community.

A great deal of work has been done by many countries throughout Asia, Africa, Latin America, and the Middle East to develop appropriate regulatory systems and to develop internationally acceptable regulatory systems suitable to the social and economic needs of particular countries. Various bilateral and international agencies, including ISNAR, OECD, the Rockefeller Foundation, the United Nations Agencies (FAO, UNEP, and UNIDO), and the World Bank have been active in this field. Several developing countries now have in place or are developing regulatory systems suited to their needs and enabling them to address their problems in food production (Doyle and Persley, 1996).

There has been a protracted international debate to develop a harmonized regulatory system for agricultural biotechnology. Some of these discussions are taking place under the auspices of the Convention on Biological Diversity. In view of the over-arching use of biotechnology, the Commission on Sustainable Development is also well placed to set the issue of safe use of biotechnology in the context of sustainable development in its widest sense.

The key points in the development of a regulatory system to enable the safe use of biotechnology are that the system should be based on scientific principles; it should take account of community concerns as to the risks perceived in any new technologies; and it should be sufficiently flexible to adapt and learn from new knowledge as it accumulates (Doyle and Persley, 1996).

CONCLUSION

After a decade of discussing the *promise* of modern biotechnology, its effectiveness in delivering new pharmaceuticals to treat human and animal diseases and new agricultural technologies to increase agricultural productivity and protect the environment has been proven. Modern biotechnology will be the main source of new technologies for human health care and the improvement in food production and environmental conservation over the next decade. The present applications in agriculture are limited to the major temperate

export commodities and the high-value horticultural crops. There is significant under-investment by developing countries and by the international development community in biotechnology. Indeed the CGIAR's total biotechnology investments of about US$25 million per year are less than those of a small biotechnology company in the United States. There is an urgent need that national governments, development agencies, and the private sector invest in the development and applications of modern biotechnology to meet the global concerns of hunger, disease, poverty, and environmental degradation. This will require many more creative partnerships and a greater sharing of knowledge and concerns among public R&D agencies, national and multinational companies, and the international development community, if the necessary levels of scientific, human, and financial resources are to be directed at the urgent needs of food production, human and animal health, and environmental conservation on a global scale.

These new partnerships in biotechnology will require

1) Clear identification of problems that could be addressed by the application of modern biotechnology,

2) Scientific capability;

3) National and international financial resources;

4) Management of intellectual property; and

5) Internationally acceptable regulatory systems that are suitable to the social and economic needs of particular countries.

It is instructive to recall that there has been little public outcry in industrial countries when new biotechnology-based treatments for cancer or AIDS are evaluated through clinical trials, given that the patients consider that the prospect of a possible successful cure outweighs any perceived risk inherent in a new technology. One might imagine that there are also people living in other countries in hunger, sickness, and poverty, who, if given the option, may similarly weigh the benefits and risks associated with new biotechnologies, if it offered them the glimpse of a better life, free of hunger, disease, and poverty. This is the challenge of modern biotechnology.

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