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BIOTECHNOLOGY POLICIES AND PROGRAMMES IN DEVELOPING COUNTRIES: Survey and analysis

A Study Prepared for UNIDO by the

Council on International and Public Affairs*

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NOTE

Tables referred to in the text will be found following the footnotes at the end of the chapter in which they are cited.

PREFACE

This study has been prepared for the Industrial Technology Development Division of the United Nations Industrial Development Organisation (UNIDO) in Vienna. It brings together information on the emerging experience of several developing countries in their efforts to strengthen their national capacity in biotechnology and to harness the potential benefit of that technology for their peoples. There are, of course, a number of other developing countries which have embarked on national programmes in biotechnology so that the countries included in this study are only part of that larger universe. We have, however, included those countries that have mounted the most substantial effort thus far to build their capacity in biotechnology.

A preliminary draft version of this study was prepared by David Dembo, Ward Morehouse, and Lucinda Wykle and circulated for comment. It draws on earlier work of the Biotechnology Research Group, a joint undertaking of the Council on International and Public Affairs and the International Center for Law in Development.

That preliminary version has been substantially revised and augmented through interviews with senior scientists and government officials in the countries covered by the study as well as through critiques of individual country chapters by individuals knowledgeable about biotechnology policies and programmes through their own direct experience.

We should like to acknowledge with grateful thanks the following for their assistance in preparing this revised and expanded version of the earlier draft report: Dr. Oscar Burrone of Instituto de Investigaciones Bioquimicas, Clarence Dias of the International Center for Law in Development, Dr. Sergio L.M. Salles Filho of Universidade Estadual de Campinas, Calestous Juma of the African Institute for Technology, Rodolfo Quintero, one of Mexico's leading scientists who has played a key role in shaping programmes for biotechnology in his own country and internationally, and Professor Richard Suttmeier of Hamilton College, USA. We are also grateful to several senior scientists and government officials in the countries covered by this study for giving us an opportunity to interview them, either recently in connection with the study or on earlier occasions.

Needless to say, the views expressed in this report are entirely our own and not necessarily those of the persons who have assisted us in preparation of the study or UNIDO as the agency sponsoring the study.

David Dembo
Ward Morehouse
Lucinda Wykle
Council on International and Public Affairs

New York
December 1989

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ACRONYMS USED IN THIS STUDY

Chapter

II. BRAZIL

CEBIQ - Centre for Biotechnology and Chemistry
CEBTEC - Centro de Biotechnologica Agricola (Part of ESALQ)
CENARGEN - National Research Center for Genetic Resources. Located in Brasilia. Established in 1974 by EMBRAPA.
CNP_q - National Council of the Development of Science and Technology
EMBRAPA - Empresa Brasiliera de Pequisa Agropecuaria
ESALQ - Escuela Superior de Agricultura Luis de Queiroz. Located in Piracicaba. One of the leading agricultural research centres.
FAO - United Nations Food and Agriculture Organization
FINEP - Financier of Studies and Projects
IAC - Campinas Agronomy Institute
IARC - International Agricultural Research Centers
INPI - National Institute of Industrial Property
IPT - Institute of Technological Research
PADCT - Programa de Apoio ao Desenvolvimento Cientifico e Tecnologico
PRONAB - Programa Nacional Biotecnologia de Brasil. Established under CNP_q in 1981.
USAID - United States Agency for International Development

III. INDIA

CCMB - Centre for Cellular and Molecular Biology
CSIR - Council of Scientific and Industrial Research
ICGEB - International Centre for Genetic Engineering and Biotechnology
NII - National Institute of Immunology
NRDC - National Research Development Corporation of India

IV. CHINA

SCST or SSTC - State Commission of Science and Technology
SRIFFI - Scientific Research Institute of Food and Fermentation Industry

V. MEXICO

CIBOSA - Biochemical Industrial Center
CINVESTAV - Advanced Research Center of Mexico Polytechnic
CONACYT - National Research Council of Science and Technology
FERMEX - Fermentaciones Mexicanos (Japanese-Mexican joint venture)
FOMEX, FOMIN, FONEI and FONEP - National Financing Agencies
IPN - National Polytechnical Institute
UNAM - National Autonomous University of Mexico

VI. THAILAND

ASEAN - Association of South East Asian Nations

VI. THAILAND (continued)

BOSTID - Board on Science and Technology for International Development
NCGEB - National Center for Genetic Engineering and Biotechnology. Created in 1983 by the Ministry of Science, Technology and Energy.
STDB - Science and Technology Development Board
TIAC - Technical Information Center
TISTR - Thailand Institute of Scientific and Technological Research

VII. ARGENTINA

CIIADO - Integrated Artificial Insemination Centre of the West
CONICET - National Council for Scientific and Technical Research
CIS - Research Committee of Buenos Aires
DPT Vaccine - Diptheria vaccine
GEB - Genetic Engineering and Biotechnology
HIV - Virus which causes AIDS (Acquired Immune Deficiency Syndrome)
ICGEB - International Centre for Genetic Engineering and Biotechnology
INTA - National Agricultural Research Centre
INTI - National Institute of Industrial Technology
SUBCYT - Science and Technology Secretariat. Coordinating body for the national programme on biotechnology.

VIII. CUBA

CENIC - National Center for Scientific Research
CIB - Center for Biological Research
CIGB - Center for Genetic Engineering and Biotechnology
ICIDA - Cuban Institute for Research on Sugarcane By-Products
NACSEX - North American Cuban Scientific Exchange

IX. NIGERIA

CGRB - National Centre of Genetic Resources and Biotechnology
FIIRO - Federal Institute of Industrial Research
IAR - Institute for Agricultural Research
IITA - International Institute for Tropical Agriculture
NIMR - National Institute for Medical Research
OAU-STRC - Organization of African Unity's Scientific and Technical Research Commission.

CHAPTER I

INTRODUCTION

This study is part of a series of technical publications issued by UNIDO that review technological developments, their potential, their implications for industrial development, and the policy approaches being followed or to be adopted by developing countries. The present study focuses on the field of genetic engineering and biotechnology.

The main body of the study deals with eight selected developing countries. For each country, policies in biotechnology are examined, followed by programmes in the public and private sector being undertaken to implement these policies. Policies and programmes are then reviewed in relation to global trends in biotechnology and in terms of their effectiveness in achieving declared policy goals.

The final two chapters in the study discuss the international context for building capacity in biotechnology in developing countries and the lessons for other developing countries in the experience of the eight countries included in the study. In these chapters, different policy and programme approaches are compared and assessed in terms of their potential usefulness for strategy formulation in other developing countries.

It is important to emphasise that a number of other developing countries, in addition to the eight selected for this study, have initiated significant efforts to strengthen their capacity in biotechnology. The countries included in this study are, therefore, only part of that larger universe. However, the eight countries covered in the study include those that have undertaken the most substantial efforts thus far to build their capacity in biotechnology.

CHAPTER II

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN BRAZIL

I. Policies for Genetic Engineering and Biotechnology

Biotechnology policy in Brazil is contained within the broader definitions of scientific and technology policy and sectoral policies (industry, agriculture, public health, etc.). The first concepts of a biotechnology policy were developed in 1975 under the jurisdiction of the National Council of the Development of Science and Technology (CNPq) as the Integrated Program in Genetics. The purpose of the Program was to systematise information and coordinate action in genetics at the national level, without being interpreted as a "preoccupation with new technologies" (i.e., biotechnology), but as part of scientific and technology development in general. At the end of the 1970s, CNP_q and the Financier of Studies and Projects (FINEP) were moving more in the direction of new technologies and implemented the Integrated Program of Genetic Engineering, focused primarily on the development of human resources. The spread of the "preoccupation" with biotechnology in the beginning of the 1980s led to the establishment of the Programa Nacional Biotecnologia de Brasil (PRONAB) under CNPq in 1981. PRONAB was created to try to integrate and coordinate the diverse institutions and funds involved in biotechnology in the areas of energy (Alcohol Program), agribreeding and health, with special emphasis on capacity in genetic engineering.1/

PRONAB provides a mechanism for consultation among scientists, engineers, industrialists, and government officials in the National Council for Scientific and Technological Development. The objective is to create the necessary infrastructure for biotechnology research and technological development in Brazil by strengthening university, business, and government links. Its main focus is on obtaining funds for training scientists, increasing the competence of Brazilian scientists and developing facilities for research.2/ CNPq and FINEP are responsible for the coordination and elaboration of PRONAB. Therefore, the primary program and strategy for the development of biotechnology in Brazil is at the national level.3/

On a general level, Brazil's scientific and technological strategy seeks to promote activities in R&D through a policy of revitalisation of the physical and human infrastructure. In reality, the distinctive element of the governmental strategy in the area of science and technology is recognising the necessity of applying results obtained in the laboratory to economic and social objectives. Another relevant strategy is development of priority sectors of the economy, aimed at improving national autonomy.4/ This involves two points of action: to modernise and diversify for greater international competitiveness, and to promote autonomy in segments of social importance that are ignored. An example of this is the high priority given to the public health field - particularly vaccines and diagnostic kits and to primary production of food. Another relevant strategy adopted by Brazil in relation to biotechnology development is import substitution. The industrial sector of Brazil has the capacity to compete on an equal footing with industries of more industrialised countries through increases in productivity and in the quality of the products of the nation's industries. For this, a government policy has been proposed to promote the development and transfer of the most recent technological innovations to industrial uses.5/ An example of this is the chemical-pharmaceutical industry, but this is more the exception than the rule within the more general context of modernisation and improved technological capacity.

There are two basic opinions on the motivation behind the promotion of biotechnology in Brazil. The primary view is that it was the initiative of some technicians at CNPq and FINEP in the late 1970s and early 1980s which was translated into the Program of Genetic Engineering and PRONAB. The second opinion is that the importance of science and technology was recognised at the national level for confronting the economic crisis. This long-term perspective incorporated the need for technological progress in diverse sectors of the economy to add strength to the overall economy in Brazil.

In the Fall of 1986, a three-year programme for $100 million (in U.S. dollars) for development of biotechnology was established which involves 20 important products for Brazil's national self-sufficiency.

Brazil obtained $210 million in funding for development, approximately $70 million from the World Bank and $140 million from the Brazilian government, approximately 55 per cent of which will go to research in biotechnology, chemistry, and industrial technology. The total designated for biotechnology is US $92.3 million.6/

Policy acts specifically for biotechnology, apart from scientific and technology policy in general, were actually implemented with the creation of the Program of Support for Scientific and Technology Development (PADCT), generated by CNPq and FINEP in 1984. This programme of five years duration was organised in conjunction with the World Bank, and provides a sub-programme of biotechnology with a strong bias toward the development of processes and products for application in the productive sector, especially in health, agribreeding, and energy (the same as PRONAB), which will be designated US $92.3 million. PADCT began to function in 1985, but nevertheless is a major dispensor of resources explicitly for biotechnology.7/

The market for biotechnology is expected to reach US $440 million by 1990. The immediate goal is to coordinate biotechnology research, and to provide scientific and commercial support.8/

Foreign collaboration includes foreign direct investment firms in Brazil, as well as joint projects with other Latin American and developing countries such as Indonesia. Foreign biotechnology firms in Brazil include Bristol Laboratories, Pfizer, Novo Industri do Brasil, and National Distillers (for a more complete listing of both national and foreign biotechnology companies in Brazil see Table I).9/

A Brazilian-Argentine Biotechnology Centre opened in the Spring of 1987 to study waste treatment, alternative forms of energy (e.g., the use of sugarcane waste to produce energy or biomass), animal feed, and pharmaceuticals.10/ It will form the Binational School of Biotechnology, which is similar to the Brazilian-Argentinian School of Information. The Centre is also involved in the production of enzymes and antibodies.11/

In addition, Brazilian and Indonesian scientists have worked together on discovering a possible acid-tolerant, nitrogen-fixing bacterium for sugarcane.12/

Little research is actually carried out by private industry, although there are research centres and centres in universities. Firms conducting advanced biotechnology research include Biobras in Montes Claros, Leivas Leite at Pelotas, Biomatrix, Bioplanta, and Valee. Many companies complain that there is not enough government funding or support for their research efforts.13/

Biotechnology in Brazil is most advanced in agriculture. Agricultural objectives for Brazilian biotechnology focus on improving production through the use of tissue culture and genetic engineering, developing nitrogen fixation micro-organisms adopted to different conditions, increasing photosynthetic efficiency, improving biological pest control, and increasing animal husbandry productivity. Crops and basic foods given priority include sugarcane, beans and milk. Basic food research is being conducted by EMBRAPA. Plant tissue culture research is being carried out at several centres including CENA, Planalsucar's Research Centres, and IAC (Campinas Agronomy Institute).14/ Tissue culture research is carried out in the centres of EMBRAPA, and also ESALQ/USP, UNICAMP, and the University of Vicosa, among others.15/

Agriculture and food products and processes which are being developed from biotechnology include pesticides and fungicides, nitrogen fixation, tissue cultures of vegetation, milk products, beverages, fermentation (yeasts), additives, glucose and fructose. The five principal products with potential commercial value are beer and distillation processes, cheese and other lactose products, organic acids (mainly citric), and antibiotics.16/

The first biological insecticide plant in Latin America opened near Sao Paulo, Brazil in 1987, but had not yet begun operation due to lack of necessary funding. It is focusing on developing a natural insecticide against caterpillars which destroy sugarcane Caterpillars are soaked in a virus which attacks them. A liquid is taken from the soaking and changed into powder form. The powder will be mixed with water and used on plantations to kill new caterpillars, replacing chemical pesticides. A single spraying is supposed to protect an entire crop.17/ A Brazilian entomologist discovered a virus within the cassava hornworm which when sprayed onto a cassava crop killed 90 per cent of the hornworms. Hornworms damage as much as half of the cassava crop in southern Brazil.18/

In the energy sector, the main emphasis is on the Brazilian National Alcohol Program, the largest alternative energy programme in the world. This programme provides three per cent of the nation's Gross Domestic Product. This area appears to be the most commercially promising for biotechnology in Brazil. Techniques used for this programme involve plant cell and tissue culture, including plant cloning techniques for sugarcane with greater tolerance to herbicides. There is also work being conducted on nitrogen fixation for sugarcane which may reduce fertiliser costs if successful.19/ A research scientist at Brazil's research centre, EMBRAPA (Empresa Brasiliera de Pesquisa Agropecuaria), said that 20 strains of suspected nitrogen-fixing bacterium had been isolated in the roots and stems of several varieties of sugarcane, and they are working with a Belgian team to identify them. Research is also being conducted for finding new or improved micro-organisms for converting starchy and cellulosic materials to sugars for ethanol production.20/ Brazil's ethanol project, in addition to giving Brazil practical experience in and facilities for technology, provides a viable energy alternative.21/ Fermentation techniques are also being perfected, and fermentation time has been significantly reduced (now being done within just a few hours). Research related projects also examine enzyme processes for producing biomass.22/

In the health and pharmaceutical sector, Brazil is involved in the production of polypeptides, vaccines (primarily for Chagas disease, leishmaniosis, malaria, hepatitis, hoof-and-mouth disease, and African swine disease), monoclonal anti-bodies, enzymes, and diagnostic kits (especially for Chagas disease and hepatitis).23/

Research supplies are able to enter the country duty-free through special import facilities located in the Butantan Institute, operated under the authority of the National Research Council. The supply centre is setting up a million dollar inventory available to the entire Brazilian scientific community.24/

Brazil does not currently recognise patents for food, medical drugs, or living organisms. There are also no specific laws governing safety regulations or recombinant DNA. Licenses are issued for products for medical use.25/

In Brazil, three fundamental conditions must be met for a patent. The product or process must constitute a novelty, it must contribute to the industrial, economic, and social development of the nation, and it must not harm the public well-being in material or spiritual terms.

Aside from these conditions of the Brazilian Code of Industrial Property on the absolute novelty and industrial utilisation, there are several exceptions to the law which should be noted. First, products or processes must not violate the law (moral, health, or public safety), religious cultures, or sentiments of respect and veneration. Substances, materials, or products (except respective processes of manufacturing that are patentable) obtained by chemical methods are excluded. Foods, medications, and pharmaceutical-chemical products, including their respective processes of manufacturing, are not patentable. Mixtures and metal alloys that do not possess intrinsic and specific qualities, and are defined qualitatively and quantitatively are also not patentable. A mere combination of processes or methods which are already known, or simple changes in form, dimension, or material do not constitute new technological results. Micro-organisms are excluded, as are other inventions for determined ends. Surgical and therapeutic techniques are not patentable, but equipment and machines are exceptions. Systems, programmes, plans, computation, and theoretical conceptions are excluded.26/

To summarise, in accordance with Brazilian legislation, they do not concede privileges for substances, materials, mixtures, food products, pharmaceutical chemicals, medicines, any species, as well as respective processes of acquisition or modification, nor uses or related uses of inventions for a determined end.27/

In Brazil, the main organ responsible for the execution of the policies of industrial property is the National Institute of Industrial Property (INPI). It controls and regulates the importation of technology, supports national innovation and the diffusion of technological information.

The patent debate in Brazil revolves around two basic arguments. On one side, it is alleged by the Assocciation of Biotechnology Enterprises in Brazil with an interest in modern biotechnology, that the concession of patents is essential to Brazil's national technological development since it guarantees protection of the activities of those responsible for the evolution of the national technological capacity. On the other hand, patenting innovative processes favors those who already have the capacity, that is the industrialised countries. Thus, it is thought that allowing patents in these advanced technologies would inhibit local technological progress.28/ Brazilian enterprises engaged in biotechnology are of the general opinion that the absence of intellectual property rights impedes investment in biotechnology because they are denied a period of exclusive exploration and recuperation of their investment.29/

An examination of the requests of patents already deposited in Brazil from 1980-85 in the area of new biotechnology demonstrates that the overwhelming majority are made by enterprises of industrialised countries (for example, the United States made up 58 per cent of the total deposited requests by 1987).30/

II. Programmes in the Public and Private Sector

A few regional and local biotechnology centres are developing in Brazil with good university connections and infrastructure.31/

There are several government agencies and programmes. They include FINEP (Financier of Studies and Projects), CNPq, Programa de Apoio ao Desenvolvimento Cientifico e Tecnologico (PADCT), and others.32/ In 1985, the Special Secretariat for Biotechnology (SEB) was set up under the Ministry of Science and Technology (MCT).

The creation of SEB was patterned after the example of the Special Secretariat of Information (SEI), which has the central role in conducting Brazilian information policy. However, the structure and political authority of SEB in government spheres will not be sufficient, and are nowhere near that attained by SEI for various reasons (see Section III). SEB officially has the status of the main organ responsible for biotechnology policy at the national level, to promote disclosure, and to oversee the execution of diverse programmes of institutions connected to MCT, federal organisations, and scientific and technological institutes. SEB does not do this because it does not have the authority, but filled a niche of influence, developed the idea of promoting the integration of institutions that are involved in biotechnology R&D, linking them with the productive sector. In this respect, it has stimulated the formation of Integrated Centers of Biotechnology (CIBs), a project which was designated about US $90 million from 1987-89.33/

FINEP, formerly under the jurisdiction of the Ministry of Science and Technology (MCT), is presently under the Secretariat of Science and Technology linked to the President of the Republic. It is an agency for increasing study, research, projects and programmes related to the socio-economic, scientific, and technological development of the country. Its beneficiaries are universities, public and private enterprises, engineering firms, etc. FINEP is responsible for the National Fund of Scientific and Technological Development. It is the financing agent of PADCT, and it is responsible for scientific research and technological development for information, biotechnology, fine chemicals, and new materials.34/

A new biotechnology centre in Rio de Janeiro was created in 1987 called Bio-Rio with the purpose of strengthening university-industrial ties. It is being constructed on the campus of the Federal University of Rio de Janeiro, with an initial investment of US $24 million. It is to be used as a coordinating mechanism in the linkage of R&D to the productive sector. It is also designated to foster international cooperation in priority areas of biotechnology. For example, Bio-Rio will set up joint ventures and promote training. Bio-Rio's coordinator estimated that up to US $300 million per year could be generated by the project by 1990. Business firms seeking Bio-Rio's services must be national or have Brazilian controlling share of stock. Bio-Rio renders research services to companies in exchange for investment, initially to be about $10 million.35/

The Brazilian Biotechnology Association (ABRABI) has 36 members, and it is estimated that there are more than 60 biotechnology companies in Brazil. Some sources have remarked that these are usually initiated in response to short-term needs rather than a long-term integrated plan. The example cited is the Proalcohol programme, which arose in response to high oil prices in the 1970s, and the need to relieve an increasing debt burden.36/ Other sources have disagreed with this view, however.37/

There are approximately 30 research centres, both public and private, in Brazil. Sixteen of these are working with plant biotechnology. Fifteen have tissue culture labs. However, few are able to apply modern genetic engineering techniques (such as recombinant DNA) to crop plants. There is the National Research Center for Genetic Resources (CENARGEN) in Brasilia. CENARGEN was established by EMBRAPA, the Brazilian Agricultural Research Enterprise, in 1974 to coordinate research in plant and animal germplasm. The National Research Programme for Biotechnology was formed by EMBRAPA under the coordination of CENARGEN.38/ EMBRAPA will have a Centre of Genetic Engineering independent of the national programme. The Centre of Biotechnology of Rio Grande do Sul has the genetic engineering capability to produce animal vaccines. Also, the Centre of Genetic Engineering of UNICAMP works with DNAr.

CENARGEN's main functions and responsibilities are within the agricultural sector, the most advanced area of biotechnology in Brazil. One function includes germplasm introduction and collection. The objective is to supply the Cooperative Agricultural Research System (SCPA) with new genetic material, especially in the area of breeding.

CENARGEN works in collaboration with other institutions in Brazil and other countries in botanical exploration and germplasm collection. One purpose of this is to provide a medium to long-term seed storage system for the conservation of different species. CENARGEN also supplies research laboratories with plants and genetic material.

CENARGEN is engaged in germplasm exchanges with many foreign institutions in countries with whom Brazil has diplomatic relations, as well as international organizations such as the International Agricultural Research Centers (IARCs) and the United Nations Food and Agriculture Organisation (FAO).

Genetic engineering began at EMBRAPA in 1981. The objectives included the identification, isolation, characterization, and cloning of microbial and plant genes to be manipulated for the genetic improvement of plants. Cellular and molecular biology techniques will be used to improve protein quality, produc- tivity, resistance to disease, insects, and harsh environmental conditions through gene transfer. Documentation and information for genetic resources are maintained in data bases by CENARGEN and EMBRAPA.39/

CENARGEN is hindered by a lack of government funding and Ph.D. level personnel. However, more than $5 million has already been invested in CENARGEN's Genetic Resources and Biotechnology programme. International funding comes from the World Bank, and the Inter-American Development Bank. Funding is also received from the United States Agriculture Department (USDA), the UN Food and Agriculture Organisation, and domestic sources such as the Ministry of Agriculture.40/

CENARGEN is engaged in a number of joint projects with universities, government agencies, and international organisations such as the United States Agency for International Development (USAID).

Presently there are ten Ph.Ds, eight MSc, and seven BSc researchers in Molecular Biology, Biochemistry, Plant Physiology, etc. at CENARGEN. There are an additional 18 personnel on grants at the Ph.D., MSc, and undergraduate levels.

Researchers work in close collaboration with the University of Brasilia. There is a formal exchange of scientists and technology with Plant Genetic Systems-Ghent and the University of Ghent-Belgium, as well as formal collaborations with the University of Florida and the University of California-Davis.41/

The Center for Biotechnology and Chemistry (CEBIQ), part of the Foundation for Industrial Technology, was formed with the supervision of the Secretariat of Biotechnology of the Ministry of Science and Technology.

The Center is mainly concerned with R&D in biological, chemical, and enzymatic processes. The Center undertakes a range of contract work with industries, as well as collaborative work with international and domestic institutions or universities.

Center staff is involved in promoting biotechnology courses, and developing research opportunities for students in its laboratories.42/

In Sao Paulo, there are two major biotechnology centres. One is the Instituto Butantan, a non-profit institute located in and maintained by the state of Sao Paulo. It is involved in biomedical research and the production of sera and vaccines for public health. Instituto Butantan works closely with the University of Sao Paulo, and has some ties to the Institute of Technological Research (IPT), sharing facilities and recruiting scientific expertise. Instituto Butantan, along with the Brazilian Ministry of Health, created the Center of Biology.43/ IPT is an important centre of technological research in general in Brazil, with a priority area in biotechnology. IPT has a good reputation for research on fermentation and enzymatic processes, and the development of deterioration-resistant materials (i.e., textiles, inks, leather).44/

The Brazilian campaign for self-sufficiency in immuno-biologicals required the increase in the production of sera and vaccines, an important priority at Instituto Butantan. The most important priority has been the production of anti-venoms (especially of snakes), products which cannot be imported from another country. This became crucial after the closing of a commercial facility engaged in the process. This is the first time the Institute developed its own technology and production engineering. In 1987-88, its facilities were to have been expanded to include production of bacterial vaccines, and plants for tetanus, diphtheria and pertussis. The Institute's priorities over the next five years include the development of technology in sera, tetanus, pertussis- diphtheria, rabies, monoclonals, human proteins, and genetic engineering (for human vaccination). The Institute believes that by developing these domestically, the cost of buying these technologies can be avoided, and foreign dependence can be reduced.45/

Instituto Butantan is a candidate for affiliation in the United Nations International Centre for Genetic Engineering and Biotechnology which would serve as a source of expertise, technology, and manpower training.

The Institute has 1,400 employees, of which approximately 300 have bachelor or higher level degrees. The Institute has library and computer facilities.

Funding for the Butantan Institute is provided by the Ministry of Health, which in 1987 issued a grant of about $800,000. The Institute's total budget for 1987 was about $4 million, plus an additional $10 million in capital for buildings and equipment invested by the Ministry of Health. The Ministry of Science supplied a $300,000 grant. The majority of the Institute's $4 million budget was provided by the state of Sao Paulo, and part from the production of sera and vaccines.46/

The major centre of agricultural research in Brazil is EMBRAPA, which has more than 40 centres, involved in all cultures (except sugarcane and coffee) and all regions of the country. The Escuela Superior de Agricultura Luis de Queiroz (ESALQ) in Priaciaba, through the Centro de Biotechnologica Agricola (CEBTEC), is without a doubt one of the principal centres of the country, especially in tissue culture. In ESALQ, CEBTEC has done extensive research on plant biotechnology and micro-propagation. CEBTEC is a technical-scientific organ of the Foundation of Agrarian Studies Luiz de Queiroz (FEALQ) within ESALQ. It was created in 1981 and develops projects in vegetable and animal biotechnology, and alcohol fermentation. It receives a large part of the resources of the private sector and of international organisations. ESALQ's genetic research on eucalyptus trees is world renowned. Genetically improved eucalyptus trees have attained a much higher level of productivity than those produced by traditional methods.

The University of Campinas (UNICAMP) has set up a multidisciplinary biotechnology research centre with an initial investment of US $7 million. It is involved mainly with molecular biology, genetic engineering, and biochemistry of natural products (for example, enzymes, pharmaceuticals, and pesticides of microbiological origin). Agricultural and pharmaceutical products are its priorities. UNICAMP is involved in a collaborative sugarcane project with Mexico, Cuba, Argentina, Peru, and Chile. Once established, the centre began to seek private financial support. At Rio de Janeiro State Federal University, research is being conducted on genetic alterations of fish for fleshier, less bony fish through chromosomic changes.47/

Other states which support biotechnology include Parana, Bahia, and Brasilia DF.48/ Various programs of biotechnology have also emerged in Rio Grande do Sul, Sao Paulo, Minas Gerais, Santa Catarina, and more recently, Rio de Janeiro. Rio de Janeiro was involved in the creation of Integrated Centers of Biotechnology (CIBs) of SEB. Only the programmes of Rio Grande do Sul and Rio de Janeiro transcend the sphere of public policy, and have some consolidated perspective. The others may be short-lived, faced with the impossibility of political communication and mobilisation of funds for financing projects.49/

In the private sector, Souza Cruz is one of the largest private companies to invest in biotechnology in Brazil, with an investment (as of mid-1988) of $12 million. Bioplanta is a subsidiary of Souza Cruz, formed as a joint venture between British-America Tobacco (via Souza Cruz) - 55 per cent - and Native Plants, Inc. - 45 per cent. Souza Cruz anticipates global importance for plant biotechnology by the end of the century, and wants a share of the market (Souza Cruz maintains 100 per cent of the capital in Bioplanta).50/ Bioplanta's principal research is on eucalyptus trees. It is working to improve their density and resistance to viruses and pests by micropropagation. The company is also engaged in the study of improving the productivity of black pepper since Brazil currently exports $130 million worth per year, and expansion of the market could be aided by micro-propagation and *in vitro* tissue cultivation of black pepper. In addition, Bioplanta is a world leader in research on Mycorhiza fungus, which can provide more growth and greater economy in fertilisation, particularly phosphorous fertilisation.51/ Bioplanta also produces disease resistant varieties of seed and diagnostic kits for plant disease.52/

For a more complete listing of public and private institutions (domestic and international), see Table II.

III. Review of the Success of Brazilian Policies and Programmes

Obstacles which Brazil faces to development in the area of biotechnology include a lack of human resources, training, and infrastructure. In addition, the lack of finances, the isolation of the major R&D centres with poor communication between them, difficulty in obtaining and maintaining equipment, and weak links between the major actors (government, industry, and universities) add to the problem. Domestic firms often find it too difficult to compete with foreign firms in Brazil, and industry tends to import technology from abroad, rather than developing its own.53/

Other obstacles are related to the lack of communication between different agencies responsible for the promotion, coordination, and execution of a policy with coherent objectives. The excessive bureaucratisation in the definition of priorities, approval of projects, and the application of resources has been a further hindrance.54/

The National Biotechnology Program. PRONAB has been criticised for being too general in its objectives, and for excluding major actors in the decision-making process (for example, the Brazilian Public Corporation for Agricultural Research, or EMBRAPA). Other criticisms include a lack of long-range planning, and ambiguous budget plans.55/ The establishment of PRONAB has had few effective results thus far. This is not to say that the Program is dead, but that its authority has been greatly reduced in relation to what was expected. Prioritising the development of human resources has been at the expense of technological development and communication between public research and the productive sector. PRONAB has increased the dispersion of resources for biotechnology, which is a result of the absence of priorities. In short, PRONAB is hardly an historical landmark that brings to light the importance of biotechnology in the context of a "new wave of innovations."56/

According to such critiques, the programme does not represent a qualitative leap in relation to programmes already in existence in the range of work of CNPq, FINEP, the Secretariat of Industrial Technology (STI), and other governmental organisations. The programme places little emphasis on industrial absorption of research, centering mainly on the formation of human resources. The dispersion of resources is arranged according to the function of the absence of a political definition concerning areas and priority sectors for biotechnology development in base industries.57/

PADCT's results, although more tangible than those of PRONAB, still leave much to be desired. There is a communication problem when it comes to decision- making on urgent requests between the promotion and coordination agencies, technical groups, and accessory committees. There is excessive bureaucratisation in the definition of priorities, approval of projects, and application of resources. PADCT has not managed to overcome its academic bias, but is nevertheless a major director of R&D. For reasons described, PADCT has not managed to use up even 50 per cent of the provided resources. Despite all these problems, PADCT was and still is the principal initiative at the national level in the development of biotechnology.58/

The Special Secretariat of Biotechnology (SEB) was established and is developing in absence of more relevant functions as a result of not having defined powers, by not having centralised those activities already in existence at CNPq and FINEP, and by not depending on sufficient financial resources to conduct a process already devoid of support for the development of biotechnology in Brazil.59/

Today the public institutional configuration for biotechnology in Brazil is not centralised by any organisation in particular. CNPq, FINEP, SEB, and CAPES are continuing the agenda in a disjointed fashion for the most part. This dislocation worsened in the last year of existence of MCT (no longer exists) and subsequently led to the creation of the Secretariat of Science and Technology, which in turn is linked to the President of the Republic. This is still not completely institutionalised.

Brazil's ethanol or alcohol fuel industry, Petrobras, has been criticised, and has been critical itself of the alcohol programme. The state-owned company is apparently operating at a loss by selling the alcohol, and the programme for using alcohol as automotive fuel has been characterised as economically inefficient. The cost of the fuel is high, and alcohol is 25 per cent less efficient than petrol. From January to May of 1988 alone, Petrobras lost $200 million due to alcohol sales. In addition, the huge sugarcane fields could also be used to grow food for the people or export commodities like soya beans. Sugarcane, being a monoculture crop, also debilitates the soil. In the longer run, the alcohol fuel programme may be viable as other energy sources are depleted, and as the fuel efficiency and production efficiency of sugarcane improves.60/

In the health and pharmaceutical sector, Brazil has had little success in developing new products, and relies more on imports and joint ventures with major transnational corporations.61/

Foreign biotechnology firms in Brazil tend to fare better than domestic firms which often find it too difficult to compete with foreign companies due to lack of funds and human resources, the isolation of the major R&D centres with poor communication between them, difficulty in obtaining and maintaining equipment, and weak links in the infrastructure (between industry, government, and universities), as well as a dependence on foreign technology. Thus, industry tends to import technology from abroad, copying techniques rather than developing its own. This is particularly true for the health and pharmaceutical sector.62/

Two companies trying to displace foreign companies in the agricultural sector are Biomatrix (national company) and Bioplanta (subsidiary of Cia Souza Cruz in a joint venture with British-American Tobacco), which are to sell virus-free strawberries and potatoes to Brazilian farmers.63/

Most Brazilian work in biotechnology relies on traditional methods, and so is focused on traditional biotechnology research. Traditional research includes industrial processes that manipulate whole microorganisms and plants, enzymology, classic genetic improvements, plant selection and fermentation. A few institutes are moving into modern biotechnology, based on recent advances in genetics, molecular biology, cell/tissue culture, and so on, but a stronger scientific foundation is needed.

IV. Brazilian Policies and Programmes in Relation to Global Trends

Brazil stands out among developing countries in terms of biotechnology capability. However, Brazil is traditionally dependent on foreign technology and joint ventures for more advanced technological processes. The industrial sector is fairly underdeveloped, and Brazilian industry tends to avoid funding risky projects, and relies on processes and products already in existence. Personnel trained in advanced biotechnology techniques are also limited.64/

Brazil is most advanced in agriculture and fermentation technology in the field of biotechnology, but is more dependent on foreign technology in the health and pharmaceutical sector.65/

In Argentina and Brazil, several universities conduct programmes relating to vaccines and diagnostic kits in the livestock sector, but there is little activity in the development of growth hormones or genetic manipulation.66/

In 1965, EMBRAPA began to identify and reproduce native strains of soybeans for the production of inoculants in order to substitute them for nitrogen fertilizers which made up 75 per cent of production costs. Soybean crops in Brazil presently rely solely on rhizobium inoculants and do not use nitrogen fertilizers. There are seven factories which produce significant amounts of these inoculants in Brazil, but there are problems due to contamination or lack of proper fermentation equipment.67/

Tissue culture, as previously mentioned, is used by two firms in Brazil, EMBRAPA, and a few other organisations. Brazil had ten culture collections, more than any other Latin American country, at the end of March 1988.68/

Brazil is also involved in pesticide production, and has a large market for them. However, Brazil still depends mostly on imports for this. In comparison to other Latin American countries, Brazil's pesticide production is much more advanced.69/

In enzyme production, 80 per cent of the world market is supplied by just three firms. Therefore, prospects of entering enzyme production is severely limited in Latin America, with only Brazil and Argentina having much chance of doing so.70/ Novo Industri just began operating in the State of Parana this year. There are other smaller national firms which occupy about 20 per cent of the market which will not survive the entrance of Novo.71/

Foreign companies in Brazil account for 83 per cent of total pharmaceutical sales in the country. In addition, national production of medicines depends on the import of drugs and raw materials (usually from TNCs). 68 per cent of drugs used in production are imported. The pharmaceutical market in Brazil is seventh in the world market with a consumption of U.S. $2 billion, and is expected to grow.

Sera and vaccines are important areas in biotechnology for developing countries, including Brazil, as infectious and parasitic diseases are one of the major causes of death. This is not true for industrialised countries, so the same emphasis is not placed on this segment of biotechnology in industrialised countries. Brazil has the longest tradition of Latin American countries in this field and rather well-developed technology. The Butantan Institute, founded in 1900, is very active in this area. However, all vaccines are produced by traditional synthetic methods.72/

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TABLE I

National and Foreign Biotechnology Companies in Brazil

APV do Brasil Industria e Comercio Ltda. (Sao Bernado do Camoa)
- Subsidiary of APV Co. Ltd. (U.K.)

* Acatec (Sao Paulo)

Aquacultura S.A.

* Acoplast Industria e Comercio Ltda (Guarulhos)

* Aggrogem Biotecnologia Agricola

* Aracruz Celulose S.A. (Rio de Janeiro, Aracruz)

* Agropecuaria Tres Ilhas

Bayer do Brasil S.A. (Sao Paulo)
- Subsidiary of Bayer AG (FRG)

Bio Fill

Biocon do Brasil Industrial Ltda. (Rio de Janeiro)
- Subsidiary of Biocon Ltd. (Ireland)

Biolab Merieux (Rio de Janeiro)
- Subsidiary of BioMerieux SA (France)

* Biomatic Aparalhos Cientificos Ltda. (Porto Alegre)

Biomatrix (Rio de Janeiro)

* Bioplanta (Campinas, Sao Paulo)
- Subsidiary of Cia. Souza Cruz

* Bioquimica do Brasil S.A. (Montes Claros)

Biotest S.A.

Brazil-Henkel S.A. Industrias Quimicas (Sao Paulo)
- Subsidiary of Heinkel KG (FRG)

* Bristol Babcock Instruments do Brasil S.A. (Sao Paulo)

Cabisa-Castelo Bioquimicas S.A.

* Central de Tratamento de Efluentes Liquidos S.A. (Camacari, Bahia)

* Cialgas (Taboao da Serra, Sao Paulo)

CODETEC (Sao Paulo)

*Codistil (Piracicaba, Sao Paulo)

Companhia Florestal Monte Dourado (Sao Paulo)

* Companhia Suzano de Papel e Celulose (Sao Paulo)

* Copersucar (Sao Paulo)

Cultilab-Materiales para Cultura de Celulas

Degremont-Saneamento e Tratamento de Aquas Ltda. (Sao Paulo)
 - Subsidiary of Degremont (France)

* Dorr Oliver Brasil Ltda. (Diadema, Sao Paulo)

Dow Corning do Brasil Ltda. (Sao Paulo)
 - Subsidiary of Dow Corning (USA)

* Embrabio (Andar, Sao Paulo)

Engenho Novo (Rio de Janeiro)

* Fermasa Maquinas e Equipamentos S.A. (Rio de Janeiro)

Filsan-Equipamentos e Sistemas S.A.

Hewlett-Packard do Brasil Industria e Comercio Ltda. (Barueri, Sao Paulo)
 - Subsidiary of Hewlett-Packard (USA)

Immoval (Sao Paulo)

* Instrumentos Cientificos CG Ltda. (Sao Paulo)

* Interc[illegible] (Rio de Janeiro)

IPT

* Jaakko Poyry Engenharia Ltda. (Sao Paulo)

Laboratorio Gross S.A.

Laboratorios Wellcome S.A. (Cotia, Sao Paulo)
 - Subsidiary of Wellcome Foundation (U.K.)

Laboratorio Sintofarma (Sao Paulo)

Leivas Leite S.A. (Rio Grande do Sul)

* Macro Energetica S.A. (Recife, Pernambuco)

* Microbiologica (Rio de Janeiro)

Niro Atomizer Industria e Comercio Ltda. (Diadema, Sao Paulo)
- Subsidiary of Niro Atomizer AS (Denmark)

Novo Industrido Brazil Industria e Comercio Ltda. (Sao Paulo)
- Subsidiary of Novo Industri AS (Denmark)

Perkin-Elmer Industria e Comercio Ltda. (Sao Paulo)
- Subsidiary of Perkin Elmer Corp. (USA)

Pharmacia Biotechnology International AB (Sao Paulo)
- Subsidiary of Pharmacia Biotechnology AB (Sweden)

* Promon Engenharia S.A. (Sao Paulo)

Quimbrasil (Sao Paulo)

* Quimis Aparelhos Cientificos Ltda. (Diadema, Sao Paulo)

* Riacent (Sao Paulo)

* Rio Lab Productos e Equipamentos para Laboratorios Ltda. (Rio de Janeiro)

Sanofi

SBS (Sao Paulo)

* Setal Instalacoes Industrias SA (Rio de Janeiro)

Shell Brasil S.A. (Petroleo) (Rio de Janeiro)
- Subsidiary of Shell (U.K.)

* Snamprojetos Engenharia S.A. (Sao Paulo)

Stauffer Productos Quimicos Ltda. (Sao Paulo)
- Subsidiary of Stauffer Chemicals Co. (USA)

Union Carbide do Brasil Ltda. (Sao Paulo)
- Subsidiary of Union Carbide Corp (USA)

Vallee (Minas Gerais)

Varian Industria e Comercio Ltda. (Sao Paulo)
- Subsidiary of Varian Associates, Inc. (USA)

Zanini S.A. Equipamentos (Sertaozinho, Sao Paulo)

*) Indicates a national company

Sources: Coombs, J., The Biotechnology Directory 1986: Products, Companies, Research and Organizations (New York: Stockton Press, 1986), pp. 119-122; and Sergio Luiz Monteiro Salles Filho of the Universidade Estadual de Campinas.

TABLE II

Biotechnology Related Institutions

Butanta Institute (Sao Paulo)

Caxias do Sul University, Institute of Biotechnology (Caxias do Sul)

Ceara Federal University, Centre for Non-Conventional Energy (Ceara)

Conselho Nacional de Desenvolvimento Cientifico Tecnologico (CNPq) (Brasilia)

Empresa Brasileira de Pesquisa Agropecuaria (EMBRAPA) (Brasilia)

Energy Company of Sao Paulo (CESP) (Sao Paulo)

Financiadora de Estudos e Projetos (FINEP) (Rio de Janeiro)

Fundacao de Amaporo a Pesquisa do Estado de Sao Paulo (FAPESP) (Sao Paulo)

Fundacao Banco do Brasil (formerly FIPEC) (Brasilia)

Instituto Brasileiro de Informacao em Ciencia e Tecnologia
(Rio de Janeiro)

Instituto Nacional de Controle de Qualidade em Saude (INCQS)
(Rio de Janeiro)

Minas Gerais Federal University, Department of Microbiology (Minas Gerais)

Ministry of Agriculture (Brasilia)

Ministry of Industry and Commerce (Brasilia)

Ministry of Industry and Commerce, Patent Office (Rio de Janeiro)

Ministry of Trade and Industry (Rio de Janeiro)

National Centre for Genetic Resources (CENARGEN) (Brasilia)

National Institute of Technology, Centre of Industrial Technology (FTI)
(Sao Paulo)

Oswaldo Cruz Foundation (Rio de Janeiro)

Paraiba Federal University, Centre for Agricultural Science (Areia, Paraiba)

Pernambuco Federal University (Recife, Pernambuco)

Piracicaba School of Agriculture, Department of Genetics
(Piracicaba, Sao Paulo)

Promocao de Pesquisa Cientifico e Tecnologia do Estado de Sao Paulo
(PROMOCET) (Sao Paulo)

Source: Coombs, J., The Biotechnology Directory 1986: Products, Companies, Research and Organizations (New York: Stockton Press, 1986), pp. 119-122.

CHAPTER III

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN INDIA

I. Policies for Genetic Engineering and Biotechnology

The principal agency for formulating and implementing government policies toward biotechnology in India is the Department of Biotechnology in the Ministry of Science and Technology of the central government. The mission of the Department has been set forth in the official notification establishing the Department in these 13 points:

1) To evolve integrated plans and programmes in Biotechnology.

2) Identifying specific programmes of Research and Development and Manufacturing in biologicals and biotechnology and oversee the initiation and pursuit of related research and manufacturing activities.

3) Identify, set up and support centres of excellence for Research and Development in biotechnology and ensure proper dovetailing of these activities for activising the national priorities and objectives.

4) Act as a screening, advising and approving agent of the Government with regard to import and transfer of new technologies for the manufacture of biological and biotechnological products and their intermediates.

5) Evolve safety guidelines for biotechnology Research and Development and manufacturing in India.

6) To act as the central agency for the import of genetically manipulated materials, cultures, cells, specimens, tissues and biotech products including DNA and RNA of any type or size and for promoting their production in the country.

7) Serve as the interministerial and intragency nodal point for all specific international, bilateral and multilateral Research and Development collaboration and agreement in the area of biotechnology and as the nodal point for all technology transfers in the area of biotechnology.

8) Manufacture and applications of cell-based vaccines.

9) To evolve programmes of manpower development in the area of biotechnology where there are gaps in competence.

10) Serve as an administrative and implementing department of agencies, commissions, boards, etc. specifically formed by the Government for fulfilling the national objectives in biotechnology and also to serve as the nodal point for the collection and dissemination of information relating to biotechnology.

11) Work relating to the setting up of the International Centre for Genetic Engineering and Biotechnology.

12) Serve as the authorised department of the Government in respect of legislative and Parliamentary requirements in all areas mentioned under Allocation of Business for the Department.

13) National Institute of Immunology (NII) New Delhi.1/

The Department of Biotechnology was set up in February 1986. However, its origins go back at least as far as 1982 when the government established the National Biotechnology Board. That Board was replaced by a separate department four years later in recognition of the need for a focal point within the central government for planning, promotion, and coordination of biotechnology programmes.

The Department has reformulated the 13 points enumerated above in the official statement of its mission in the following eight major tasks:

1) To evolve integrated plans and programmes in biotechnology;

2) To identify specific R&D programmes in biotechnology and biotechnology-related manufacturing;

3) Establishment of infrastructural support at the national level:

4) To act as an agent of the Government for import of new recombinant DNA based biotechnological processes, products and technology;

5) To evolve bio-safety guidelines for laboratory research, production application;

6) To initiate scientific and technical efforts related to biotechnology;

7) Programmes of manpower development in the areas of biotechnology; and

8) Establishment of International Centre for Genetic Engineering and Biotechnology.2/

The objectives for developing India's capacity in biotechnology can best be understood within the context of the country's overall technology policy. In January 1983 the government of India issued a formal technology policy statement, the basic goals of which are "the development of indigenous technology and efficient absorption and adaption of imported technology appropriate to national priorities and resources."3/ These two goals are further articulated in the following 11 aims:

1) attain technological competence and self-reliance to reduce vulnerability, particularly in strategic and critical areas, making the maximum use of indigenous resources;

2) provide the maximum gainful and satisfying employment to all strata of society, with emphasis on the employment of women and weaker sections of society;

3) use traditional skills and capabilities, making them commercially competitive;

4) ensure the correct mix between mass production technologies and production technologies and production by the masses;

5) ensure maximum development with minimum capital outlay;

6) identify obsolescence of technology in use and arrange for modernization of both equipment and technology;

7) develop technologies which are internationally competitive, particularly those with export potential;

8) improve production speedily through greater efficiency and fuller utilization of existing capabilities, and enhance the quality and reliability of performance and output;

9) reduce demands on energy, particularly energy from non-renewable sources;

10) ensure harmony with the environment, preserve the ecological balance and improve the quality of the habitat; and

11) recycle waste material and make full utilization of by-products.4/

To fulfill these broadly based aims, the National Biotechnology Board prepared at the beginning of the present decade a long-term plan in biotechnology for India. That plan lists ten "national objectives":

1) Self sufficiency in food, clothing and housing.

2) Adequate health and hygiene.

3) Provision of adequate energy and transportation.

4) Protection of environment including soil and forest conservation.

5) Improvements to the health, productivity and breeding of cattle and other animals.

6) Proper water and soil management.

7) Modern education and communication.

8) Gainful employment.

9) Appropriate industrial growth.

10) International balance of trade.5/

The long-term plan for biotechnology identified seven major sectors of activity, and within each of those sectors, one or more priorities. These are listed in Table 1.

Principal policy components of the public sector in biotechnology are reflected in the major areas of activity of the Department of Biotechnology. These include manpower development, infrastructural facilities, R&D programmes, international R&D collaboration and major science and technology "mission" projects (e.g., embryo transfer technology, development and production of immuno- diagnostics and vaccines). A more detailed examination of these various activities is given in the next section of this chapter on programmes in the public and private sector.6/

The Department of Biotechnology plays an important role in coordination of research, development, and other activities related to biotechnology. One of the principal means for such coordination is through advisory committees and task forces. The major advisory body is the Scientific Advisory Committee to the Department of Biotechnology, which is composed of ten members, including the Secretary of the Department of Biotechnology as Chairman. Four other key scientific officials are ex-officio members - namely, the Directors-General of the Indian Council of Agricultural Research, Indian Council of Medical Research, and Council of Scientific and Industrial Research, as well as the Chairman of the University Grants Commission. The five remaining members are senior scientists from academic institutions, public sector research centres, and industry.7/

Task forces of the Scientific Advisory Committee have been organized on a number of different subjects, including the following:

Information System in Biotechnology
Microbial and Industrial Biotechnology
Plant Molecular Biology and Agricultural Biotechnology
Biochemical Engineering Process Optimisation and Bioconversion
Medical Biotechnology
Aquaculture and Marine Biotechnology
Integrated Manpower Planning
Production of Biomass Using Tissue Culture Technology (fuel, fodder, timber and commercial and industrial woods)
Large-Scale Use of Biotechnology
Infrastructural Facilities
Veterinary Biotechnology
Biological Control of Pests and Disease

Two other key committees are the Standing Advisory Committee for Biotechnology (SAC-Overseas), which consists of scientists of Indian origin at academic and research institutions in North America and Europe, and the Recombinant DNA Advisory Committee.8/

The last-named committee is primarily concerned with safety regulations for recombinant DNA research in India. A report was issued by the committee in the early 1980s containing safety regulations and proposals for guidelines for recombinant DNA research. These guidelines include specifications for institutional biosafety committees, physical containment levels, and other safety precautions. According to the report of the Recombinant DNA Advisory Committee on Safety Regulations for India, the hazard classification followed by the U.S. Center for Disease Control was in most cases "considered appropriate" and "exchanger" classification based on information provided in the U.S. National Institutes of Health guidelines helps to determine whether specific experiments are exempt (e.g., when the experiment involves organisms in the same "exchanger" sublist).9/

Another critical policy area in the development of biotechnology in India concerns R&D incentives for industries and industrial property rights. The government provides a variety of such incentives for research and development generally (including but not limited to biotechnology). Examples include:

Exemption from having to obtain an industrial license for import of capital goods being used for R&D.
Exemption from customs duty for all scientific and technical instruments for use in educational research institutions.
Various fiscal incentives such as the deductibility from income tax of expenditures for in-house R&D and for payments to support research at universities and non-profit research institutions by companies.10/

There are also a number of incentives for commercialisation of indigenous technology. These include preferential treatment in industrial licensing, exemption from the normal government industrial licensing provisions, special investment allowances, and soft loan, risk capital, and other special arrangements for companies using indigenous technology available through government industrial financing institutions such as the Industrial Development Bank of India and the Industrial Finance Corporation of India. Another facility seeking to encourage the commercialisation of indigenous research is the National Research Development Corporation of India, a public sector company attached to the Department of Science and Technology. NRDC conducts a number of schemes toward this end such as financing the scale-up of research through pilot plant and demonstration units, equity investment in companies starting up with know- how licensed through NRDC, and the export of indigenous technologies.11/

Industrial property rights in India are defined in the Indian Patents Act of 1970, which came into force in 1972. This Act sought to address some of the distortions which have arisen in many developing countries with patent laws essentially the same or very similar to those in industrialised countries. A typical result of such arrangements is that most of the patents granted in the developing country are held by foreigners, mainly companies from industrialised countries, who take out patents not to utilise them but to prevent others from doing so. In an effort to confront this problem, India in its 1970 Patent Act, abolished patents on chemical compounds and drug formulations, reduced the term for process patents for drugs, food, and medicines to five-seven years (compared to a term of 14 years for other patents), and made patents liable to be revokedfor non-use under certain circumstances. Other features of the Act included a provision for licensing of all chemical, food, drug, and medicine patents and a maximum royalty of four per cent. New varieties of plants were specifically held to be non-patentable. In more recent years, there has been some discussion of the possibility of changing some of these provisions, including recognition of plant breeders' rights.12/

Indian patent laws protect only technological processes for producing food, medicine and chemicals, not the products themselves. Indian patent laws provide protection for about five to seven years as opposed to the 20 in the United States. India, like Brazil and other developing countries, has resisted stricter patent legislation on the basis that products which improve health or save lives should not be controlled by such laws. The United States has previously retaliated against countries like Brazil and Thailand for refusing to strengthen patents on American pharmaceutical products by levying a 100 per cent duty on some of their imports. India faces similar retaliatory measures. This could disrupt about 300 scientific projects between India and the U.S. ranging from the development of antimalaria vaccines and the study of leprosy, to the study of marine alloys. These projects involve over 250 Indian scientists.13/

II. Programmes in the Public and Private Sectors

At this relatively early stage in the development of biotechnology in India, most activity is taking place in the public sector. (Although the origins of scientific work related to biotechnology go back many years, indeed decades, a concerted and coordinated national effort to build capacity in biotechnology got underway with the creation in 1982 of the National Biotechnology Board.) As ofApril 1989, the major programmatic elements of the public sector effort undertaken and coordinated by the Department of Biotechnology include the following components:

Manpower development programme
National facility for animal tissue and cell culture collection
Genetic engineering unit
National animal house facility
Biotechnology information system
Pilot plant facilities using tissue culture technology
Oral polio vaccine unit
Viral vaccine project
Vaccine action programme
Oil palm demonstration project
Embryo transfer technology
Aquaculture
Development and production of immunological-diagnostic kits
Immunological approaches to fertility control
Assessment of applications for industrial license and foreign collaboration in biotechnology
Biotechnology product plan
International bilateral cooperation
International centre for genetic engineering and biotechnology
Guidelines for recombinant DNA research 14/

In envisaging the scope and character of the work of the Department of Biotechnology, it is important to understand that its primary function is coordination of effort with existing institutions for training and research and government science and technology agencies. In performing this coordination role, it fulfills four functions - priority setting, planning, monitoring, and implementation. It gets involved in direct implementation of activities only as a last resort when no other suitable alternative is available.15/

In manpower development, the Department of Biotechnology has supported post- graduate and post-doctoral programmes in biotechnology in 13 institutions in the country. These institutions include some of India's leading universities and research institutes, such as the Jawaharlal Nehru University in New Delhi, Poona University in Pune, Indian Institutes of Technology in Delhi, Kharagpur, and Bombay, and the Indian Agricultural

Research Institute and India Institute of Medical Sciences, both in New Delhi. These programmes for the most part provide training at the masters degree level. However, the Indian Institute of Sciences in Bangalore has instituted a Post-Doctoral Research Training Programme in Biotechnology and Life Sciences. The number of students admitted each year ranges from three to 20, and the duration of the programme of study is, in most cases, two years.16/

Other manpower development programmes include short-term training courses in biotechnology, the Biotechnology Associateship Scheme, the Visiting Scientist Programme, and a training scheme for technicians. The Biotechnology Associateship Scheme provides support to Indian nationals conducting advanced research or undergoing specialized training in both India and overseas, with emphasis on the latter. Through the end of the 1987-88 financial year (March 31, 1988), 35 associateships have been awarded (31 overseas and four within India) and another batch of 17 scientists (12 long-term and 5 short-term) have been selected for awards to begin in the following year. Another 25 associateships were awarded in 1988-89. The Visiting Scientist Programme supports Indian scientists from abroad who undertake research in institutions in India for periods of three to six months.17/

Another major area of emphasis in the work of the Department of Biotechnology is the creation and support of infrastructural facilities for teaching, research, and industrial activities. Table 2 indicates what facilities have thus far been created.

Another major infrastructural facility is the Biotechnology Information System. It includes an "Apex Centre" at the Department of Biotechnology and nine "Distributed Information Centres" in the following fields at the institutions indicated:

1) Genetic engineering:

i) Indian Institute of Science, Bangalore;
ii) Madurai Kamaraj University, Madurai;
iii) Bose Institute, Calcutta;
iv) Jawaharlal Nehru University, New Delhi.

2) Animal cell culture and virology:

v) Poona University, Pune

3) Plant tissue culture, photosynthesis and plant molecular biology:

vi) Location to be identified.

4) Oncogenes, reproduction physiology, cell transformation, nucleic acid and protein sequences:

vii) Centre for Cellular and Molecular Biology, Hyderabad.

5) Immunology:

viii) National Institute of Immunology, New Delhi.

6) Enzyme engineering, immobilized biocatalysts, microbial fermentation and bioprocess engineering:

ix) Institute of Microbial Technology, Chandigarh.

The Biotechnology Information System also has on-line connections, through a computer centre in Paris, with a number of data banks elsewhere in the world.18/

R&D programmes supported by the Department cover a wide range of subjects and involve three major projects - propagation of bamboo by tissue culture, formulation of larvicides against malaria (Biocide-S) and bio-leeching of low-grade copper ore. Recently approved projects include a Centre for Research and Training in liposome technology in the Department of Biochemistry at Delhi University, gene cloning of synthetic human insulin, propagation of bamboo through tissue culture and development of improved strains of methane producing bateria and mosquito larval bio-insecticide.19/

Biochemicals and reagents are critical supplies for the conduct of research in biotechnology. In order that these supplies will be readily available to research institutions in India, the Department of Biotechnology has established a programme for indigenous production of biochemicals such as restriction enzymes and reagents for DNA synthesis at the Centre for Biochemicals on the Delhi University campus. This same centre operates a centralised facility for the import and supply of fine biochemicals to research institutions throughout the country.20/

Two other important programmes of the Department involve S&T (Mission Mode) projects and Technology Missions. These initiatives seek to apply the results of research. Among projects under these two programmes are Embryo Transfer Technology (for cows and buffalo), Production of Immunodiagnostics, Immunological Approaches to Fertility Control, the Technology Mission on Vaccination and Immunisation (for low-income sections of the population), and the Technology Mission on Oil Seeds. Also seeking to promote the application of biotechnology research are various activities by the Department to promote biotechnology industry such as a tour of biotechnology facilities in the USA by a group of Indian industrialists.21/

The Department of Biotechnology is also responsible for international collaboration which involves cooperative activities with a number of other countries, including the USA and the USSR. Discussions have been held and visits exchanged with several other countries, including China, Czechoslovakia, Indonesia, Italy, Germany, and the Netherlands. New Delhi is also the site of one of the two components of the International Centre for Genetic Engineering and Biotechnology being established under the auspices of UNIDO. The Delhi facility has started to function with the appointment of several researchers.22/ Construction has begun for permanent quarters for ICGEB on a plot of 25 acres in the Jawaharlal Nehru University campus.

The Department has administrative responsibility for the National Institute of Immunology in New Delhi. The Institute carries on a research programme in areas related to immuno-contraception, development of vaccines against communicable diseases, immuno-diagnostic kits, and cattle herd improvement through embryo transfer technology.23/

Financial allocations from the government of India for support of technology have increased steadily during the decade of the 1980s. In 1988-89, recurring or the "non-Plan" budget estimate was a little more than $1 million while the "Plan" budget estimate was for $25 million. In 1989-90, the budget estimate for "non- Plan" estimate increased very slightly while the "Plan" budget estimate grew to approximately $34 million.24/

Most of the work in biotechnology in India today is conducted in the public sector and supported by the government. However, there is growing interest outside of the government in both the non-profit and industrial sectors. Thus, the Centre for Advancement of Biotechnology was established as a non-profit voluntary scientific research organisation in the city of Bangalore in 1987. And the Swedish pharmaceutical company, A.B. Astra, has joined forces with the Indian Institute of Science, also in Bangalore, to establish a centre for basic research in genetic engineering and biotechnology. The centre's Director is Professor J. Ramachandran, who was previously Director of the Protein Chemistry Division of Genentech, Inc. in the USA. There is also some work being conducted on biotechnology at the R&D facility of Hindustan Lever, Ltd., a subsidiary of Unilever, and various public sector companies producing drugs and related products.25/ Other transnationals which are establishing R&D facilities in biotechnology in India include Pharmacia and Hoechst, with proposals from other transnational pharmaceutical companies under consideration.

Other R&D initiatives in the industrial sector involving Indian companies, with or without foreign collaboration, include Southern Petrochemicals Ltd. in Madras, United Breweries in Bangalore, and the pharmaceutical company, Rambaxy in Delhi. All of this activity in R&D is beginning to be reflected in commercial production. In 1988, for example, the Department received 40 applications from the Ministry of Industry for review for industrial licenses and/or foreign collaboration. Of these, 22 were for the latter.26/

Some biotechnology-based products are actually on the market in India. One of the first is a diagnostic kit for filaria being manufactured by Cadbury. Another significant breakthrough involves commercialisation of a biotechnology-based service - DNA "fingerprinting" - which is now available through the Centre for Cellular and Molecular Biology, a government-supported research laboratory in Hyderabad. With only a handful of private companies throughout the world offering such services, CCMB hopes that its low-cost facility will attract orders from overseas, as well as meeting needs within the country.27/

III. Review of Policies and Programmes in Relation to Global Trends

There are several important global trends in biotechnology that are significant for the development of biotechnology in India.28/ One of the most important is the increasing privatisation of technological knowledge and the growing role of transnational corporations in enlarging and applying that knowledge in commercially marketed products. This trend is reflected in India in the several TNCs that have either set up or are exploring the creation of R&D units in the country. It is also reflected in the promotional activities of the Department of Biotechnology in seeking to establish foreign collaborations in biotechnology for Indian companies. Foreign companies are attracted to India, among other reasons, because of considerably lower research costs and the substantial pool of trained scientific and technical personnel. This trend is viewed with apprehension by some Indian scientists as the following comment indicates:

> ASTRA's entry two years ago was vehemently opposed by the Council of Scientific and Industrial Research (CSIR) which warned that it would amount to killing indigenous drug research by draining the local talent. Critics say that invasion by foreign subsidiaries is nothing but a new form of technological colonisation of India. "They use our best brains on our soil to produce drugs that will ultimately be sold to us" lamented one scientist. "It is a strange situation where our own scientists are used to fight our own pharmaceutical industries" followed another. This reminds one of the cotton research laboratories in India to supply quality raw material to British textile industry in the colonial era.29/

Yet another global trend of significance to the further development of bio-technology in India is the attraction of highly qualified personnel to major centres of research and development which typically provide substantially higher compensation and much better research facilities. This phenomenon, commonly called the brain drain, exists both internationally and internally in India's case. India's response to the international brain drain is found in such schemes described above as the Visiting Scientist Programme, Overseas Associateship Scheme, and the North American Advisory Committee, all designed to increase links with advanced centres of research in the industrialised countries and to attract back to India, for short periods or permanently, Indian scientists working abroad. But there is also a potentially serious problem of internal brain drain with the establishment of TNC R&D units within the country. This is likely to have particularly adverse consequences for the application of biotechnology in agriculture:

> It has been feared that the talent may be weaned away from traditional agriculture in the field of biotechnology. We cannot expect basic bio-chemists to be attracted to applied research in agriculture and veterinary research because of the lucrative offers in medicine and pharmaceutical industry.
>
> Already, the scarcity of plant breeders is being felt in the agricultural university I come from because of two reasons: cuts in funds in traditional plant breeding research and secondly, exciting research opportunities in the field of biotechnology. Many of the positions have been left unfilled because trained graduate students leave for other lucrative offers in commercial sectors. The ones who stay will be lost to biotechnology.30/

Research priorities in biotechnology at the global level are a reflection of the privatised character of biotechnology R&D and the domination of marketing and production by transnational corporations. Priority attention is given, all other things being equal, to products for which there is the strongest market demand. A good illustration is Genentech's anti-blood clot medicine, TPA, which helps to save lives of heart attack victims and costs $2,000 for a single dose. Thus, the general orientation for biotechnology, at least where it involves more advanced techniques of genetic engineering, has been on human health, with secondary attention to agriculture and animal husbandry, food processing, and energy, although there certainly is some attention given to these other sectors as well.

These kinds of international trends, nonetheless, pose a difficult problem for a country advancing rapidly in biotechnology like India. Take, for example, the project to map the human genome, a hugely expensive and time-consuming undertaking. In the United States, where some elements in the biotechnology community are urging the U.S. government to undertake such a project, cost estimates are in the billions of dollars over a 10 to 15 year period. However, the Director of the Centre for Cellular and Molecular Biology believes that India has "all the capabilities" to do this work at a mere fraction (he estimates $200 million) of what it would cost in the United States. While genome mapping is not a high priority with the Department of Biotechnology, the CCMB Director has urged the Indian Prime Minister to provide support for such an undertaking on the grounds that the more advanced industrialised countries may not share their results with the rest of the world, or will make access difficult and expensive.31/

This, broadly speaking, is also the situation in India. Substantial attention has been given to human health in the programmes and activities of the government's programmes administered primarily through the Department of Biotechnology, although, of course, there is also some work being done in the fields of animal husbandry, agriculture, and energy. This orientation toward human health is even more pronounced in the private sector with the development of R&D units in India under the auspices of or in collaboration with transnational pharmaceutical companies.32/ However, the Secretary of the Department of Biotechnology emphasises that his Department, recognising this global trend, has sought to strike a better balance in its own work, which includes a number of initiatives such as those mentioned above, especially in animal husbandry and agriculture.33/

There is occasional debate at the international level, within the UN system and among agencies and institutions involved in Third World development, about whether or not biotechnology can be given a "pro-poor" thrust that will make it possible to avoid some of the adverse distributional consequences of the Green Revolution in developing countries. There is very little evidence of such an orientation within the industrialised countries themselves. Those with more substantial incomes are certainly much more likely to be able to take advantage of the benefits of biotechnology first. That situation is probably also generally the case with India's programmes in biotechnology - with the notable and important exception of some of the work being done on vaccines for endemic diseases which, if the cost of manufacturing the vaccines on a large scale can be brought down low enough and vigorous measures of dissemination adopted, would bring an immediate and direct social benefit to tens of millions of poor people in India.

One major global trend apparently is not likely to affect India very much, at least thus far. This is the phenomenon of product or crop displacement - i.e., use of biotechnology makes it possible to grow or manufacture (through "factory farming" techniques) in industrialised countries natural products such as medicinal plants, fragrances, or flavors previously imported from developing countries. Recent estimates have placed the loss to developing countries collectively from such displacement at approximately $10 billion annually. The only product likely to be displaced through these techniques exported in significant quantities from India is saffron, for which no monetary calculation of export value is immediately available but it is assumed to be quite modest, certainly as a factor in India's total exports.34/

IV. Review of Policies and Programmes in Relation to Their Goals

The first thing to be said about the relationship of policies and programmes in biotechnology to their goals is that it is much too early to tell how effective they have been. While the antecedents of the work being done today in biotechnology in India go back many years, a concerted effort to fashion and implement a national policy in biotechnology began only in the early part of the present decade. It is in the very nature of investments, whether public or private, in such aspects of advanced technology development as manpower and infrastructure that they take a long time to yield significant results.

India, to be sure, does have a number of advantages which should augur well for its programmes and policies in biotechnology achieving, in time, the goals of these policies and programmes, at least in some signficant measure. These advantages include relatively abundant trained manpower, substantial infrastructure for advanced scientific research and technological development, substantially lower research costs, certainly than are found in the industrialised countries, and government recognition of the potential importance of biotechnology at the highest political levels.35/

A recent analysis of the outlook for biotechnology internationally and within India put the case for a strong and vigorous national effort in these terms:

(a) Its stage of scientific development today is the highest amongst all the developing countries of the world. Every item of consumer goods that one buys in India is today made in India, and the range and variety is large, and the quality often good. It exports more than 150 categories of goods including highly sophisticated finished products made entirely in India.

(b) Although the quality is not always high, it has a large number of persons trained as biologists in a number of disciplines in institutions spread over the length and breadth of the country.

(c) In the past three years, the Government of India, the various scientific agencies in the country, and the Prime Minister, have recognized the importance of investment in biology and have given basic research in biology and development of biotechnology top priority.

(d) India has a strong organized public sector as well as a private sector, both with tradition of scientific entrepreneurship.

(e) India has strong professional societies in the area of biology.

(f) The country has a wide variety of animals and plants, and is thus rich in biological natural resources.

(g) It has sun-shine almost throughout the year in most places.

(h) Its biologists are aware of what is happening elsewhere so that the country is in a position to learn lessons from other's successes and failures.

(i) Biotechnology is labour-intensive and labour is cheap in India.

It is, therefore, not only India's prerogative but also obligation to show the way to other developing nations in regard to large-scale development of modern biology and biotechnology.36/

But notwithstanding these advantages and the relatively short time period in which to show significant results, some analysts and critics of India's programmes in biotechnology believe there are important problems. One of these problem areas is the continuing drain of scientific talent away from India at the international level and away from the public sector to the private sector within India.

> The greatest opportunity for the country in biotechnology lies in reversal of brain drain. A large number of Indian scientists working in the United States and other Western countries are at the forefront of many areas of biotechnology. The Indian government should devise ways and means to attract them back.37/

Another concern is with what some perceive to be the relatively weak links of R&D with the productive sectors of the Indian economy. It is generally thought that, among areas of advanced technology, the link between research and production is closest in biotechnology. Recognition of this circumstance led some of the early discussions about the shape of India's national effort in biotechnology to favor public sector corporations concerned with linking R&D production and marketing of products in each of half a dozen major priority areas for research and development. But this feature was not included in the National Biotechnology Board when it was created, nor is it a part of the structure of the successor entity to the Board - namely, the Department of Biotechnology.38/

Some critical observers of India's effort in biotechnology believe that the link between research and production is the most significant shortcoming in this effort. The question of whether the half a dozen public sector corporations that were part of the original long-term plan in biotechnology should now be established has been raised from time to time in the Scientific Advisory Committee to the Department of Biotechnology, but thus far, there has been no action by the government. That policy makers are aware of the problem of linking research and production, however, is reflected in the establishment of a public sector company, Risk Capital and Technology Finance Corporation, Ltd., which apparently will be backing several biotechnology-based new ventures.39/

Concern has also been expressed about the import of technology. The issue for those who share this concern is not with import as such but rather with what they see as failure to build strong indigenous capability while absorbing imported technology. Turn-key projects in biotechnology - for example, in the field of vaccine production - may provide for the transfer of relevant technology but not its absorption and internalisation by the Indian partner.40/

Yet another area of concern is with research priorities. One perspective is reflected in the following observations, which focus on the relative neglect of agriculture:

> Like in the Western countries, the Indian biotechnology programmes appear to be dominated by health and medicinal related research. But it is in agriculture where most of the potential for the country lies. Research in agriculture is also made more important because of lack of research in the West on tropical plants. The Department of Agricultural Research being outside the Ministry of Science and Technology where DBT is located may perhaps be responsible for relatively low priority given to biotechnology in agricultural research. There is, therefore, need for galvanising ICAR into biotechnology research and its greater coordination with DBT.41/

It should be noted again that the Secretary of the Department of Biotech- nology contends that, at least within the programmes conducted by his department, there is a better balance between agriculture and human health. Without making any calculation of relevant level of effort but simply by categorising these initiatives by their application to either human health or to agriculture, it can be said that the principal R&D projects mounted or supported by the Department of Biotechnology (i.e., its "Technology Missions" and its "S&T 'Mission Mode' projects") are almost evenly divided between human health (six) and agriculture and animal husbandry (seven).42/

Another view of what this particular critic believes would have been a national effort in biotechnology more responsive to India's more urgent economic and social needs is found in the following passage which enumerates key characteristics of that effort:

> First of all, it must expressly exclude all experiments with cloning of mammals, or involving the production of toxins. Secondly, it must give a high priority to developing food crop seeds that can withstand drought, resist pests and grow on soils which are deficient in micro-nutrients. Thirdly, it should seek to produce genetic varieties which maximise the food crop's ability to use sunlight and minimise the requirement of chemical fertiliser. Fourthly, the programme should aim at developing cheap vaccines for major diseases such as malaria. And finally, it should promote research to upgrade the stock of high-yielding milch cattle at a low cost. In all this, the programme must not allow the results of its research to become private or patented property. And the policy should expressly discourage or ban patented products, especially the use of packaged biological kits imported for farm use here, whose precise contents are unknown.43/

There is concern that, with its relatively limited resources, the Department of Biotechnology has spread itself too thin - with the result that the level of effort in many instances is "subcritical". Another concern is with the "coordinating" role of the department which all to often, in this view, leads to a lack of accountability. In other words, the department may provide financial support for specific activities to another agency or institution outside its direct administrative control, but because it does not exercise administrative control, its ability to assure that the funds it provides are used in fact, and not just in form, to accomplish the purpose for which the financial support was provided.44/

In terms of operational capability, such critics contend, the Department of Biotechnology consists of the National Institute of Immunology, which it inherited from the Department of Science and Technology under whose auspices it was originally established, and more recently, two public sector undertakings for vaccine production, both heavily dependent on foreign know-how. Whatever progress is occurring within India is taking place in institutions and other facilities that in most cases existed already and in any event are following their own independent paths of development.45/

Whether there are any lessons in the Indian experience thus far for other developing countries is not clear. Not only is the time period for assessing India's policies and programmes in biotechnology relatively short, but India is hardly a typical developing country. Its sheer size, coupled with its substantial efforts over the past four decades to build up its national capacity in science and technology, puts it in a category by itself - or at most with one or two other developing countries. While no doubt some of the concerns expressed here would be applicable to other countries, those countries would also experience quite different concerns.

NOTES

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Table 1

Sectoral Priorities in Biotechnology

Health

i) Prophylactic
ii) Therapeutic
iii) Diagnostic
iv) Hygiene
v) Population control

Industry

i) Fermentation (antibiotics, organic acids)
ii) Biofuels
iii) Food and feed
iv) Metallurgy and mining
v) Oil recovery

Agriculture

i) Soil fertility
ii) Bio-fertilizers
iii) New varieties
iv) N_2 fixation
v) Quick propagation through tissue culture
vi) Improvements to animal health and productivity

Energy

i) Biomass
ii) Energy plantation
iii) Biofuels and bioreactors

Environment

i) Conservation of forests and afforestation
ii) Pollution control
iii) Waste recycling

Communication and Informatics

i) Computer based information collection and dissemination

Education and Training

i) University level education
ii) Specialised training programme

Source: National Biotechnology Board, Department of Science and Technology, Government of India, Biotechnology: Long Term Plan for India, New Delhi: The Board, reprint 1983.

Table 2

Infrastructural Facilities in Biotechnology

	Name	Agency
1)	Microbial Culture Collection	Institute of Microbial Technology. Chandigarh
2)	Blue Green Algae	Indian Agricultural Research Institute. New Delhi
3)	Plant Tissue Culture Collection	National Bureau of Plant Genetic Resources. Indian Agricultural Research Institute. New Delhi
4)	Animal House Facility	Central Drug Research Institute. Lucknow; National Institute of Nutrition. Hyderabad; and Indian Institute of Science. Bangalore
5)	Animal Cell Line and Tissue Culture	Poona University. Pune
6)	Oligonucleotide Synthesis	Indian Institute of Science. Bangalore; Centre for Biochemicals. Delhi; and Centre for Cellular and Molecular Biology. Hyderabad
7)	Biochemical Engineering and Pilot Plant	Institute of Microbial Technology. Chandigarh
8)	Bio-Informatics	i) Genetic engineering: - Indian Institute of Science, Bangalore - Madurai Kamaraj University. Madurai - Bose Institute. Calcutta - Jawaharlal Nehru University. New Delhi ii) Animal cell culture and virology: - Poona University. Pune iii) Plant tissue culture. photosynthesis. and molecular biology: - To be identified

iv) Oncogenes, reproduction physiology, cell transformation, nucleic acid and protein sequences:

- Centre for Cellular and Molecular Biology, Hyderabad

v) Immunology:

- National Institute of Immunology, New Delhi

vi) Enzyme engineering, immobilized biocatalysts, microbial fermentation and bioprocess engineering:

- Institute of Microbial Technology, Chandigarh

Source: Department of Biotechnology, Ministry of Science and Technology, Government of India, Programmes in Biotechnology, New Delhi: The Department, January 1988.

CHAPTER IV

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN CHINA

I. Policies for Genetic Engineering and Biotechnology

China has a long history in the use of traditional biotechnology, but has been involved in modern biotechnology since about 1975 after successfully cloning and expressing foreign DNA in E. coli. In 1980, a development programme for biotechnology was outlined by the State Commission of Science and Technology (SCST). 1/ The Chinese government has recognised the importance biotechnology may have in solving problems related to population (over one billion), food, health care, energy, and the environment, and as a result has made it a national priority.

China's main policy goals in the area of biotechnology are to improve and innovate equipment and technology, to reduce imports of biotechnology products, and to strengthen basic research in hopes of making the transfer of results from the laboratory to industry more feasible.2/

The main policies of the Chinese government have been to improve the coordination of research. Links between universities and industry, and between research institutes themselves have been surprisingly disjointed considering the majority are state-owned and operated. China has made efforts to strengthen the knowledge base through increased funding, to encourage private enterprise and entrepreneurship (to a degree), to promote better linkages between universities and industries, to enact laws and regulations regarding patents in order to encourage foreign investment, to promote international exchanges and cooperation (including joint research and joint ventures), and to adopt a more open policy to the world economy, particularly by encouraging the coastal areas to become more export-oriented.3/

The long-range policy of the Chinese government is to promote products or processes which may be marketable by the turn of the century. This is to be achieved through the modernization of the traditional biotechnology industry, and the development of some new biotechnology sectors. Due to financial constraints, China must focus on a few specific areas of research in which it has strengths.4/

In addition to China's decision to open up more to the rest of the world, the country has also begun to offer preferential treatment to foreign investment and foreign technology imports. The Chinese government has established high-tech development zones and industrial parks where preferential treatment is also extended to wholly foreign-owned firms. The two biotechnology research bases established in Guangdong and Beijing provide examples of this national programme for biotechnology promotion. The government has also granted more freedom in decision-making, as well as operating privately-owned firms to scientists and engineers. This is a segment of China's national economic management reforms.5/

Long-term national priorities for specific areas of development are new varieties of high-yield, quality, disease-resistant plants and animals; new medicines and vaccines; food processing, protein and chemical engineering.6/

Short-term national policy goals are geared to reaching the marketplace by the early 1990s. More than half of the budget for science and technology development in the Seventh Five-Year Plan will go to support gene and cell engineering for development of new products and processes for agriculture, pharmaceuticals, environmental protection, etc. Forty-five per cent of the budget for biotechnology R&D will be for the development of fermentation and enzyme engineering, and transferring the results to the productive sector.7/

As part of the policy to promote inter-disciplinary and inter-institutional cooperation, "open laboratories" have been set up in which most of the research staff is made up of visiting fellows from different universities, production sectors, and even foreign countries. Some of the open laboratories include the Laboratory of Molecular Biology, the Research Institute of Microbiology (virus, enzymology, genetics, microorganisms), the Experimental Marine Biology Laboratory, and the Beijing Laboratory for Structural Chemistry of Unstable and Stable Species.8/

The main policy and programme coordinating agency for biotechnology in China is the National Center for Biotechnology Development in Beijing. It was established in 1983 under the State Science and Technology Commission. It consists of six functioning institutions of the Beijing Research Base to which it provides assistance in the form of funds, international cooperation and exchanges. The Center is responsible for coordinating the programmes of the six institutions as well. The mandates of the Center include formulating national policies for biotechnology R&D. It was set up to help coordinate, monitor, and evaluate major national research projects. The Center is also responsible for helping to finance major projects, and to provide the necessary equipment for them. The Center promotes university-industrial links and the transfer of R&D from laboratory to industry and commercialisation. The National Center for Biotechnology Development provides financial and technical assistance for biotechnology research. The Center is engaged in personnel training, the transfer of technology and information to industry, and is charged with establishing pilot plants and experiment bases.9/

In fulfillment of its mandate, the Center is investing US $25 million to set up a modern biotechnology experiment base in Beijing and Guangdong. The research base in Beijing will focus on genetic engineering (gene isolation, recombination, expression, etc.), cell engineering (monoclonal antibodies, cellfusion for new animal and plant varieties, etc.), enzyme engineering, fermentation technology (amino acids, antibodies, etc.), and reactor engineering research. Guangdong, in the province of Guangzhou, was chosen as one of the two sites for a research base because of the abundance of biological resources and its close proximity to Hong Kong which allows greater access to the outside world.10/

The six institutions affiliated with the National Center for Biotechnology Development are the Institute of Microbiology, the Laboratory of Molecular Biology of the Chinese Academy of Agricultural Sciences, the Scientific Research Institute of Food and Fermentation Industry (SAIFFI), the Institute of Virology, Tsinghua University, and the Institute of Biophysics.11/ A Scientific Advisory Committee has been set up to assist the Center by the Chinese government. The Committee consists of 28 members.12/

Until recently nearly all biotechnology R&D was in government hands. Most of the funding still comes from government sources. However, only a few years ago the government initiated new policies for setting up private research and development units, especially for serving rural enterprises. Since 1987 the number of private research units and companies has doubled, now numbering over 11,000.13/ Many are spin-offs from state-owned institutions. In order to encourage entrepreneurship, tax incentives have been provided to these high-tech firms, and funding is available not just from private sectors but state-owned banks and institutions are made available as well. This has also meant that it is necessary for the government to establish corporate laws, fiscal and monetary policies, licensing and regulatory codes on technology transfer and foreign direct investment. Incentives have also been provided to professors and researchers to serve as consultants to enterprises.14/

There has been a marked improvement in the availability of foreign high technology equipment in recent years for modern molecular biology research in China. This includes the Fudan University Genetics Department and the Academy Institutes in Shanghai. Though equipment is not readily available as in the U.S., some of the newer research facilities are almost on par with U.S. laboratories. Though equipment is not much of a problem, information is. Thus, a great deal of research is unnecessarily duplicated. The government's commitment to biotechnology has succeeded in improving China's laboratories and level of sophistication of equipment.15/

China is in the process of building new scientific research facilities. In Shanghai there are three new bioresearch centres. One is the new molecular biology building affiliated with the Chineses Academy of Science (CAS) Institute of Biochemistry. Another is the Life Sciences Institute, also on the CAS Shanghai campus The Life Sciences Institute is to be supported from Chinese sources (possibly the biotechnology programme), and will focus on neurobiology, a subject that has received little attention in the past. The third new institution is to be located on the Fudan University campus, to be called the Thomas Hunt Morgan Institute of Genetics (most of the funding is from a U.S. foundation in Washington, D.C.). It will focus in part on developmental genetics, also a neglected area in the past.16/

The restructuring of China's R&D system is still in the early stages. Many large state-owned enterprises with poor R&D capability are merging together to combine their strengths and minimise their weaknesses. Others have sought foreign partnerships to modernise.17/

The main policy goals adopted by China have thus included an increased openness to world markets, an effort to create a more favorable environment for technology transfer and foreign investment, and a new strategy to encourage exports in China's coastal areas where biotechnology research is most advanced.18/

By the end of 1987, as part of China's open policy, 9,973 foreign-funded projects had been approved, of which 4,300 have begun operation (largely in the coastal areas). In 1987 alone, 2,233 foreign-funded projects were approved.19/

International exchanges and cooperative projects have been enacted, some under the sponsorship of the United Nations and other international organizations, and some for foreign visiting fellows to open laboratories. China is also engaged in several joint ventures. For example, in 1985, a subsidiary of Phillips Petroleum of the U.S. and the China Huangui Chemical Engineering Company signed an agreement to build a joint single-cell protein plant. Also in 1985, China and Japan signed a five-year R&D agreement between Nippon Zeon Company Ltd. and China's Biotechnology Development Center for R&D in animal cell culture aimed at developing pharmaceuticals and fragrances.20/ In 1986, a symposium and an international exhibition on biotechnology was held in China. Some 37 companies from around the world attended the exhibition. There has also been an increased exchange of information with countries advanced in related science and technology.21/

In regard to information and library services, China publishes a journal entitled the "Chinese Journal of Biotechnology" which reports on Chinese achievements in the field, and is available in English through the Chinese Academy of Sciences in Beijing. A gene library for rice was begun in 1982. There is a library of virology with over 10,000 books, journals, etc. (half of which are imported) at the Institute of Virology.22/ There does not appear to be one central source for information, however. As a result, it is not uncommon for research to be duplicated.

A new patent law was enacted in China in 1985 covering inventions related to microorganisms. As of April 1985, a deposit of the organism is required at a Chinese repository for those seeking a Chinese patent. When a foreign inventor applies for a Chinese patent, they must go to a patent agency designated by the government. Product patents are not recognised, but patents may be granted for manufacturing and production processes. Foods, drinks, drugs, plant and animal varieties, etc., cannot be patented. The first patent law was approved in China in 1984 to protect the interests of Westerners in joint ventures to encourage investment.23/ The Technology Contract Law was enacted in 1987 mainly due to the increasing number of domestic technology transfer and R&D contract disputes. Several regulations and laws regarding international technology transfer and foreign investment have also been enacted.24/

U.S. pharmaceutical companies doing business in China have complained that sales have been severely limited because products were copied by Chinese factories - a result of inadequate patent protection. Export control problems have also been a constraining factor in the development of ties between the U.S. and China in commercial biotechnology. Cooperative projects have been slow in developing due to conflicts over issues of intellectual property rights.25/

II. Programmes in the Public and Private Sector

The Chinese government has initiated two programmes in support of its biotechnology policies and goals. One is the "Spark Program", which is a programme for lending technical and financial support to the rural economy in hopes that its results would spread to other rural regions. The programme includes setting up demonstration plants and training of the local labor force. The particular focus of the programme is on agriculture, such as tissue culture technology, microbial pesticides, domestic animal embryo transplantation, and hormones to speed animal growth.26/.

The "Torch Program" is another major government-sponsored programme which offers technical and financial support to industrial enterprises to promote commercialisation of R&D results. The State Science and Technology

Commission (SSTC) is the chief agency responsible for the implementation of the "Spark" and "Torch" programmes. The "Torch Program" was implemented in the second half of 1989, with biotechnology at the top of the list of high tech development priorities. The objectives are "to mobilise China's scientists and engineers" to develop and market high technology products (aimed at both domestic and international markets), and gradually build up an industry based on new and emerging technologies. This includes restructuring the R&D system to provide more flexibility to laboratories. The training of scientists and engineers is another priority of the "Torch Program". The programme has ambitious goals for establishing a large number of high-tech enterprises, and technology parks and districts, which will require an enormous amount of funding and training of specialists.27/

The National Research Center for Science and Technology Development under the SSTC is responsible for technology assessment, formulating national biotechnology policy, and evaluating the results. The Advisory Committee gives advice on setting priority R&D areas, as well as reviews research proposals and undertakes some of the key projects. Members of ad hoc panels and committees from universities and research institutes also act as advisory bodies to the government.28/

An estimated 4,000-5,000 science and technology personnel are engaged in biotechnology-related research in China.29/

In agriculture, tissue culture technique has been used for many years. More than 20 haploid crop plants have been created, of which wheat, corn, rubber, and citrus are ranked first in the world. Many new rice varieties are in large-scale field tests. A simple biotechnique for introducing exogenous DNA into plants after self-pollination has been applied to cotton and rice in China for several years. Disease resistant genes have also been successfully transformed. Basically, biotechnology in agriculture blends some new biotechnology techniques with traditional plant breeding.30/ The "Spark Program" has focused on dissemination of tissue culture technology, developing new breeds of fresh-water fish, microbial pesticides, animal embryo transplantation, diagnostic agents for animals, and hormones for animal growth.31/

In the health care field, antibiotics have been produced in China for the last 30 years, and its animal production is the largest in the world. China is also one of the largest producers of Vitamin C, much of it for export. A fermentation process for Vitamin C developed in the 1970s in China was transferred to a transnational corporation a few years ago.32/

About 27 million people in China suffer from B-hepatitis, and cancer is the number two killer in the country. Therefore, R&D has focused on interferon and B-hepatitis vaccine for several years. Both have since entered the pilot plant stage, and are preparing for large-scale production. In addition, some monoclonal antibody disgnostic agents have entered the marketplace.33/

On the industrial side, there are approximately 40 factories which produce at least 60 enzyme preparations. Immobilized enzymes are now used in the production of penicillin, and high fructose syrup is now on the market. Enzyme engineering is one of the top priorities in China's biotechnology field.34/

Biogas containing methane is produced using industrial or farm waste. and distributed through a pipeline to rural areas. Microbial leaching of ores such as copper and uranium has been used on a small scale.35/

Some of the most advanced programmes in biotechnology in China exist in the six institutions affiliated with the National Center for Biotechnology Development. For example, the Institute of Microbiology, established in 1954, is engaged in fermentation technology (amino acids, organic acids, antibiotics and enzymes), vaccine production, study of anti-virus genes from plant sources, monoclonal antibody research, microbial research, and biotechnological treatment of industrial waste water. The Institute has the largest culture collection in China, and has a pilot plant which contracts out to industries (especially for penicillin, detergents, and downstream technology). The Institute's genetic engineering department was established in 1976.36/

The Laboratory of Molecular Biology of the Chinese Academy of Agricultural Sciences was established in 1984 for agricultural research. The Laboratory's biotechnology projects include genetic engineering of a vaccine to treat diarrhea in young animals, genetic engineering of the delta-endotoxin gene of Bacillus, recombinant DNA and gene expression in insects, nitrogen fixation, gene cloning, and the establishment of a gene library of certain plant species.37/

The Scientific Research Institute of Food and Fermentation Industry under the Ministry of Light Industry was established in 1957. The Institute has a staff of close to 300, and is largely involved in fermentation and enzyme technology. It is also involved in gene cloning, production of single cell protein, and amino acids.38/

The Institute of Virology of the Chinese Academy of Preventive Medical Sciences was established in 1956. Its research programmes include the expression of hepatitis B virus surface antigen in mammalian cells, preparation of recombinant human interferons, the cloning and expression of hepatitis A virus VP_1 gene, the development of a disgnostic kit for hepatitis B virus infection, a recombinant influenza virus vaccine, monoclonal antibodies, and other vaccines, etc. The Institute has an extensive library, publishes the Chinese Journal of Virology, maintains a virus strain collection centre, and has a subsidiary Chinese Research Center for the AIDS virus.39/

The Department of Biological Science at Tsinghua University was established in 1983. Research focuses on the study of liposomes as vectors of plant genes and as drugs for antihepatitis and antileptospiresis, cell electrofusion, isolation and preparation of rennin, neutral protease, etc., and improved production technology for ascorbic acid by fermentation.40/

The Institute of Biophysics of Academic Sinica was established in 1958. The Institute is involved in nucleic acids, yeasts, enzymology, cancer and cell biology, isolation, cloning and expression of a silk protein gene, foreign DNA expression in plant cells, genetic engineering of celluloses, protein engineering, and animal and plant chromosome genetic engineering.41/

III. Evaluation of Policies and Programmes in Relation to Global Trends

China's enormous market potential has made it very attractive to transnational corporations involved in biotechnology. Joint ventures and foreign investment in China began to increase in the early-to-mid-1980s, along with the global trend toward growing domination of large transnational corporations in the biotechnology field.

Squibb (U.S.) Pharmaceutical Company was one of the first TNCs to enter into a joint venture with the Chinese in 1983. Squibb formed Sino-American Shanghai Squibb with their Chinese counterparts. Squibb agreed to trade skills and training for access to the Chinese market. The agreement also included that bulk materials manufactured under Squibb's own patents would be produced in Squibb's U.S. plants, and shipped to the Sino-American plant in order to maintain control of its patented products.42/

Other major joint ventures include Biogen (Geneva), one of the largest biotechnology companies, which signed an agreement with the Chinese pharmaceutical firm, Shaanxi Pharmaceutical Bureau in Xian, in 1984. Biogen was permitted to produce and market its genetically engineered gamma interferon. In turn the company agreed to train Chinese scientists and supply Chinese hospitals.43/ Biotech (U.S.), Promega (U.S.), Genetic Diagnostics Corporation (U.S.), and Nippon Zeon (Tokyo) are also engaged in joint ventures with China in biotechnology.44/

In the pharmaceutical sector, antibodies against polio virus, hepatitis B, Epstein-Barr virus, malaria, and others have been obtained. Certain problems persist, however, which hinder commercialisation; such as establishing standard techniques, and stable, sensitive, simple diagnostic procedures to be able to mass produce monoclonal antibodies.45/ China's antibiotic industry is a highly integrated system which leads the world in terms of total annual output with the production of more than 80 antibiotics. However, the assortment of antibiotics is very obsolete. For example, tetracycline and streptomycin, which have been severely restricted or prohibited in the West, still account for about 75 per cent of China's antibiotics. Penicillin and cephalosporin, popular in advanced countries, only account for about two per cent of China's antibiotics. The number of new antibiotics discovered which may be accredited to China only amounts to one out of 7,000 worldwide.46/

Plant genetic engineering is still in the early stages in China, though plant tissue culture techniques have a solid foundation. The work in wheat, corn, rubber, poplar and citrus haploid plants ranks with the best in the world. Some problems in this field include how to transfer these achievements to the industrial scale. In addition, techniques for cell screening, lack of efficiently designed bioreactors for large-scale plant cell culture, and maintaining stock materials with stable genetic traits are all obstacles in transferring results from the laboratory to industry.47/

In the area of industrial enzymes, China produces 20 to 30 kinds for food, beverages, pharmaceuticals, and the textile industry, but downstream processing is very backward in some factories. In addition, no enzyme preparation has been able to meet the food regulation criteria.48/

Biotechnology requires multidisciplinary research between science, technology, engineering, and management and marketing. China has poor linkages among them.49/

In comparison to R&D in advanced countries, China still has a long way to go to close the gap. There is a shortage and scattered distribution of personnel. The technological level is low and outdated, and a lack of modern equipment and processes creates a bottleneck for commercialising products. Due to a lack of coordination, there is often a repetition of research projects. There is a weakness in basic research, with a marked inability to transfer research results to the production sector. Better linkages are therefore needed between universities and industries. There is also a need for China to modernise its biotechnology industry.

Some new biotechnology products have reached the marketplace, though in limited quantity. They include monoclonal antibody diagnostics, high fructose syrup, single-cell protein, microbial pesticides, new enzyme preparations, and some virus-free meristem culture.50/

By following in the tracks of foreign research, upstream technology is much stronger than downstream processing, and for those firms engaged in more sophisticated production engineering, foreign partnership is usually required.51/

China has very favorable natural conditions for the development of biotechnology, and has a strong foundation in some areas of life sciences. However, it cannot expect to compete on all fronts with developed countries due to limited financial resources and trained personnel.52/ Therefore, China must concentrate on a limited number of goals in order to make breakthroughs in selected areas of strength. The main goal is to follow the development of technology abroad, while enhancing basic research at home. The main purpose is to serve the needs of over one billion people for food, health care, energy, and environmental protection.

IV. Review of Policies and Programmes in Relation to Their Goals

China has been involved in "new" biotechnology since approximately 1975, yet progress in the field has been relatively slow. Reasons for this include weak basic research in molecular biology, the need to import a number of enzymes and chemicals, relying on foreign technology, and the need for greater exchange of information with the outside world.53/

During the last few years there has been considerable progress in China's use of recombinant DNA techniques. For example, the cloning of the surface antigens of the hepatitis B virus, the genetically engineered human alpha-interferon gene has been expressed in E. coli, and the penicillin acylase gene has been cloned and expressed. These successes demonstrate that Chinese scientists have grasped rDNA techniques, and that there is a capable, if small, contingent of scientists working with biotechnologies in China.54/

Weaknesses include inadequate pilot plant and manufacturing facilities, dependence on foreign technology as most projects are experiments already performed by foreign scientists, a weakness in b[illegible] and applied research, and the necessity of importing a number of products [illegible] research.55/

An important issue for China is the training of specialists. Many universities are staffed by teachers educated in the 1950s, a period influenced by flawed scientific theories, and are often not engaged in research which would keep them more up to date. Another major issue is that many students educated abroad fail to return (only 10-50 per cent return) due to a lack of opportunities to conduct their own research programmes. Incentives such as research grants awarded upon return should be provided to reverse this "brain drain".56/

Basic research is grossly underfunded and undersupported relative to applied research in China. The major source of funding comes in fact from "reallocating" resources for applied biotechnology research to basic research. This, however, places scientists in a precarious situation, and should regulation of funding be increased it could stifle what little basic research there is. In spite of this, some interesting and innovative research projects have been pursued that are not merely imitations of research in the West, or of other projects being carried out elsewhere in China.

NOTES

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CHAPTER V

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN MEXICO

I. Policies for Genetic Engineering and Biotechnology

Biotechnology is an attractive avenue of development for Mexico given that it has many of the natural resources to take advantage of it, and the potential of its applications to food and agriculture. In addition, biotechnology is a field in which new technological advances may be combined with traditional agricultural practices. Mexico has a fairly long and successful history in traditional biotechnologies from the production of beer, liquor, and cheese.1/ Mexico produces more biotechnology-related products obtained by traditional methods, not including genetic engineering, than any other Latin American country (see attached tables).2/ Mexico's industrial and scientific infrastructure is, according to some, fairly well established for biotechnology, with the exception of large-scale or expensive initial investment.3/

The most important areas of research are in health, food, and agriculture. In the agricultural sector, Mexico is using plant tissue culture techniques to apply to various fruits, potatoes, corn, and sugar cane, but only at the laboratory/research level. Tissue culture is used at the industrial level only for the production of flowers.4/ Mexico has had some experience in the production of agave henequero for tequila, but commercialisation has not yet been achieved. The production of single-cell protein for feed has been examined as Mexico must import vast amounts of protein for feed. Since Mexico produces a large amount of petroleum and organic residues from the sugar industry, it would be feasible and economical. Three options have been examined by Mexico in this respect. One is the production of single-cell protein from methanol in petroleum for which they may attempt to acquire ICI's patent. This was ruled out because of the rise in price of petroleum and the fall in soybean import costs. Another option is that Mexico may attempt to acquire the process developed by the Cuban sugar industry.5/ The Sugar Workers Corporation decided to finance a pilot-plant project for producing yeast from molasses, based on technology developed by CINVESTAV (the strain and some fermentation processes were obtained from Cuba in a collaborative project).6/ A third option is the use of sugar cane for biogas which has been studied at the pilot plant level by CINVESTAV (the Advanced Research Center of Mexico Polytechnic). The cultivation of yucca for the production of single-cell protein has also been considered, but yucca is very low in protein content and would have to first be enriched, which would make investment costs unfeasible.7/

Mexico's policy goals for biotechnology development include personnel training, better linkages between government, academia, and industry, and improved regulations to attract foreign investment and protect Mexican national interests as well.8/ The new Mexican government (1989) has decided that now new companies can be 100 per cent foreign-owned. Biotechnology is on the priority list for foreign investment, and also for international technical cooperation.9/

Mexico has traditionally pursued a policy of import substitution for industrialisation. Mexico remains, however, dependent on imports and has a low export capacity.10/ Furthermore, about 60 per cent of Mexico's export earnings go toward financing its enormous debt.11/ Since 1982, Mexico's policies were changed somewhat with some trade liberalisation policies going into effect, and a new industrial promotion strategy for more efficient, competitive, export-oriented products.12/ The Mexican policies related to liberalisation of the economy have been enlarged by the new government, so today there is little market protection for specific products.13/ More specific goals for priority areas for biotechnology development in Mexico include food and feed development, biological fertilizers, bioinsecticides, improvement of plant and animal species, pollution limitation, production of biogas and enzymes, vaccines, antibiotics, and mineral leaching (see attached tables).14/

Mexico produces the most important antibiotics on the market.15/ Most antibiotics are obtained by fermentation. In Mexico, local production of semisynthetic penicillins is carried out by traditional methods which are at an economical and environmental disadvantage to the new enzyme biotechnological processes.16/ Currently there are three producers of semisynthetic penicillins, and all of them use the enzymatic method.17/ Regional vitamin production is low and carried out by traditional methods. In Mexico, the only company producing vitamins by fermentation (Vitamin B_{12}) withdrew from the market in 1981 because of problems with the use and availability of efficient strains.18/ According to other sources, however, vitamin B_{12} may never have been produced in Mexico, but imported as a raw material and the fermentation process completed elsewhere.19/ The National Autonomous University in Mexico (UNAM) is conducting a project for producing Vitamin B_{12} by fermentation.20/

In the area of human resources development, bachelor and master degrees in biochemical engineering are available in 20 institutions. Two of these have Ph.D. programmes and there are eight masters programmes.21/ Most post-graduate programmes cover general areas of biotechnology such as enzymatic and fermentation technology, genetics, and genetic engineering. Only two focus on plant biotechnology. The two most important institutions of higher learning in Mexico are the National Autonomous University of Mexico (UNAM), and the National Polytechnical Institute (IAN) with small, but first-rate teams of young scientists, by world standards.22/ According to the National Research System figures, there were 200 researchers in biotechnology in 1989.23/

During the last 15 years, the public sector expenditure for the procurement of scientific and technological material has made up only between 0.6 and 1.5 per cent of Mexico's Gross National Product (GNP).24/ In 1989, the figure was around 0.7. The private sector spends only five per cent of total investment in biotechnology. This figure includes national and foreign companies.25/

The majority of biotechnology research is in the public sector, the universities, research institutes, or federally-owned technological institutes. Therefore, one goal of the Mexican government is to get the private sector more involved in biotechnology research and improve the linkages between the public and private sectors. Linkages between industry and research have yet to be established. The Mexican government has acted as a partner with several companies and transnational corporations (TNCs) in the past, but its participation in this respect has diminished.26/ There are a few national companies engaged in biotechnology-related research.

In the food sector, there are approximately four companies which produce yeast, one of which was built with French investment.27/ One company, FERMEX, which produces amino acids, was built with Japanese technology as well as capital. FERMEX is 51 per cent owned by the Japanese and 49 per cent owned by the Mexican government. It only produces lysine and glutamic acid (leucine production is used in its internal process). Most probably it will cease production of glutamic acid to become one of the largest producers of lysine in the world.28/ Sosa Texcoco, a government-owned company, produces algae spirulina.

In the health sector, seven human vaccines are produced by a government laboratory. There are several companies involved in traditional diagnostic systems. CIBIOSA, a Japanese joint venture, covers the domestic market for penicillin. Transnational corporations involved in producing antibiotics by fermentation processes in Mexico include Pfizer, Fermic, Upjohn, Abbott and Cyanamid.

In the chemical and industrial fields, Quimica-Mexicana produces citric acid. Pfizer and Enmex have fermentation plants where enzymes are produced. Industrial waste-water treatment, one of Mexico's largest problems, is being addressed by several companies who have built water purification systems. Production of biogas and bioleaching of copper are also taking place in the private sector.

In agriculture, the most important vaccines for livestock are produced by both public and private companies. There are seven companies that produce inoculants.29/

Though the initiative in biotechnology is usually in the public sector, joint ventures, both public and private, are often used as a means of acquiring technology. Another goal for Mexico is to acquire foreign technology which may be adapted to Mexico's specific requirements. For example, the company FERMEX acquired foreign technology from Japan to suit Mexico's need for several amino acids, and CIBIOSA (Biochemical Industrial Center) did the same in the production of penicillin.30/ At the same time, the Japanese companies are partners in these companies.

The National Research Council of Science and Technology (CONACYT) is the main financing and coordinating agency for biotechnology in Mexico, though biotechnology is only one of the areas covered by the agency. There is no other agency specifically established for coordinating a national biotechnology programme.31/ In 1989, CONACYT financed a minimum of 200 research projects per year, and some additional 200 are funded by other grant agencies. For 1990, it plans to invest around $400,000 in research.32/ CONACYT also provides a special scholarship programme for biotechnology. Study abroad scholarships for biotechnology comprise approximately 15 per cent of CONACYT's total scholarships for study abroad.33/

The patent and trademark law in Mexico dates back to 1976, and was recently reformed. According to Mexican law in the past, neither plant nor animal varieties, nor biotechnological processes could be patented. In addition, food, drinks, fertilizers, herbicides, fungicides, general medicines, and so forth could not be patented. However, a certificate of invention is available to cover biotechnology processes and products. By

1997, however, biotechnology processes for pharmochemical and agrochemical products, genetic processes for plants and animals, and biotechnology products will be patentable.34/

There are various state and private agencies which provide financial assistance for R&D. There are grants from CONACYT, and funds from international organisations such as UNIDO. A minor amount of funding is generated by the biotechnology development sector itself. Other sources of funding include FOMIN, FONEP, FONEI, and FOMEX, all national agencies. There is also a programme of financing for pre-exportation manufacturers which focuses on helping Mexican business people to foster the importation of needed services and products. No estimate is available on the amount of funds for biotechnology. There are, however, no fiscal or credit incentives to encourage the development of multinational ties between TNCs and national companies, so linkages there are tenuous.35/

II. Programmes in the Public and Private Sector

There are various public programmes to support science and technology, and to promote linkages between universities and industry. They include the Shared Risk Program of CONACYT, the Program of Financial Support for Technological Development of the Bank of Mexico, and the Venture Capital Program of the National Industrial Development Fund.36/

The Shared Risk Program is to help foster the linkage of the industrial and research sectors. This programme funds projects from 25 per cent to 75 per cent, depending on the project's social and economic impact. The Program of Financial Support for Technological Development, sponsored by the Bank of Mexico, is the fund for industrial equipment which helps support all the stages needed to introduce technology development in the marketplace.37/

There are 20 consolidated research groups, and 11 pilot plants for biotechnology. Eight of the major research institutes include the Research Center of Genetic Engineering and Biotechnology of the National Autonomous University of Mexico (UNAM).38/ The Research Center consists of about 36 researchers, and concentrates on the health and food sectors. It has a pilot plant for fermentation, with an investment of $3 million.39/

The Research Center of Nitrogen Fixation at UNAM has about 25 researchers in genetics, molecular biology of plants, and nitrogen fixation, with a global investment of about $4.5 million.

The Institute of Cellular Physiology at UNAM includes 29 researchers in bioenergetics, metabolic regulation, and neuroscience.

The Institute of Biomedical Research at UNAM has a fermentation pilot plant, a department of immunology, and a department of biotechnology.

The Center for Research and Advanced Studies at IPN has 27 researchers and 69 graduate students. Research is concentrated on molecular biology in relation to biomedicine. The Department of Biotechnology and Bioengineering at the Center for Research and Advanced Studies has 16 research laboratories. Research focuses on food technology, enzyme technology, and environmental problems. The department has 26 researchers and a fermentation pilot plant.

The Modern Plant Biology Unit at the IPN Center for Research and Advanced Studies consists of 27 researchers, largely engaged in the genetic engineering of plants to improve selected varieties, increase yields and disease resistance.

The Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT) is another major research facility. CIMMYT is one of the network of international agricultural research centres (IARCs) supported by national and multilateral funding agencies and foundations such as the World Bank and the Ford Foundation. Because of its international status, the focus of its research work is broader than Mexico, but it has had a major impact on Mexican agriculture in recent decades.40/

Mexico is engaged in the production of seeds and vegetables largely by traditional methods. Some new enterprises work on the micropropagation of plants, and in the commercialisation of embryo transplants.41/

In Latin America, Mexico is a major producer of three amino acids: L-lysine, L-leucine, and glutamic acid. The three are produced by fermentation. They are produced in the quasi-public sector (FERMEX, for example) where the government took the initiative of establishing a joint venture for amino acids. The major producer is Fermentaciones Mexicanos (FERMEX) of which the state owns 60 per cent, and two Japanese companies (Kyowa Hakko and Sumitomo) own the remaining 40 per cent. Mexico is now the largest producer of L-lysine, and supplies 100 per cent of the domestic market.42/

The Center for Technological Innovation of the National University of Mexico (UNAM) has played an important role in patenting monoclonal antibodies for the diagnosis of amebiasis. Other diagnostic systems include DNA hybridisation probes.43/

Mexico is developing enzymes for industrial purposes such as lactase and penicillin-amidase, and is working on the production of biogas and bioleaching systems for copper and improved oil uptake.44/

The large Mexican companies are already investing in biotechnology projects, bringing technology from outside the country. Most are investing in waste-water treatment, agro-chemicals and food-feed additives. So far, only one company is doing a project using a recombinant bacteria. Enzymologa bought the technology from Suntory to produce phenylalanine to manufacture aspartame. Its operation is scheduled to begin this year (1990).

There have been at least two field trial tests of transgenic plants (tomatoes) in Mexico, and the government has set up a group to study regulation of biotechnology in Mexico.45/

III. Review of Policies and Programmes in Relation to Global Trends

By international standards, Mexico has a mature and fairly efficient traditional biotechnology industry which provides a good foundation for modern biotechnology. A fairly promising intrastructure exists, but it is fragmented, and there is a lack of structural support at the national level for equipment, capital goods, industrial services, and coordination. Financial resources are limited as well.46/

Private industries in Mexico tend to share two common characteristics. One is that they have a strong dependence on foreign technology, and the other is the limited extent of their use of modern biotechnology.47/

Biotechnology is a sector in which the gap between Mexico and more industrialised countries is quite large. Therefore, Mexico is trying to promote specific projects in which they are already competitive, or can become so in a fairly short period of time.48/

Today, Mexico's trade protection policies have been criticised by various transnational corporations and industrialised countries as hindering technology transfer, particularly in the development of the pharmaceutical industry.49/ For example, Mexico's Pharmaceutical Decree of 1984 brought a strong reaction from U.S. pharmaceutical companies when they were asked to put the generic names in a prominent place on their products as well as their trade names.50/

Within Latin America, Brazil, Argentina, and Mexico have made some important advances in the field of biotechnology which were significant in local and relative terms. Only Brazil stands out among these countries as a possible competitor of Mexico on the international level, especially with respect to its alcohol-petroleum substitution programmes.51/

However, the situation is very different with respect to competition from industrialised countries. Here Mexico's fledgling biotechnology effort is quite vulnerable. The situation is greatly compounded by the heavy international indebtedness of the country, which makes it much more difficult to pursue independent policies that are questioned by the major foreign and international agencies and institutions holding Mexico's debt.

A good illustration is the Mexican position with respect to patent protection for plant and animal varieties, microorganisms, and the technological processes on which these are based. In recent years, intense pressure has been brought to bear on the Mexican government to bring its patent policies and regulations into greater conformity with those prevailing in the major industrialised countries. The result of this pressure is that by the middle of the 1990s, Mexico's position with respect to providing patent protection for what has historically been in the public domain will be in substantial conformity with existing practices in industrialised countries.52/

Because of Mexico's proximity to the United States, it suffers with particular severity from a problem that affects in greater or lesser measure other developing countries which have made a substantial commitment to strengthening their own capacity in biotechnology. This is the problem of "brain drain." It is very difficult to keep talented Mexican scientists and engineers working in Mexico when there are numerous opportunities and much more generous levels of compensation and usually with far superior research facilities so close by.53/

Another area of vulnerability is access to vital equipment and supplies. Most of these come from Mexican sources. A Mexican biotechnology company official estimates that 90 per cent of its raw materials are Mexican in origin. However, the remaining ten per cent do come from outside - principally the United States - and are absolutely vital to maintaining production volumes and product quality and to keeping costs manageable.54/

The company with which this official is associated, for example, has had difficulty from time to time not with biotechnological raw materials but with equipment suppliers, especially of scientific instruments. Recently it wanted to acquire the latest version of a particular item of equipment which it sought to acquire from the Mexican subsidiary of a large United States scientific equipment manufacturer. Eventually it did succeed in obtaining the equipment it desired but only after considerable additional effort. In other words, this was not treated as a routine transaction, as it almost certainly would have been if the Mexican biotechnology company had been U.S.-based.55/

Several international agencies are conducting studies of how biotechnology should be developed for application in Mexico and the Latin American region. Among those organisations which have conducted studies are FAO, UNDP, the World Bank, UNIDO, and PAHO. It is assumed that the international community (banks, companies, etc.) wish to invest in biotechnology in Mexico and are searching for the most profitable sectors, which will probably be agriculture and agroindustry.56/

IV. Review of Policies and Programmes in Relation to Their Goals

Among developing countries, Mexico has made significant progress in recent years in strengthening its national capacity in biotechnology. Nonetheless, serious problems remain to be overcome.

Thus, Mexico's programmes and policies are not as well defined as they might be. It is also lacking some of the necessary industrial infrastructure. Communication between the scientific and the industrial sector is very limited. Therefore, it is difficult to transfer results from the laboratory to the market. This is exacerbated by deficiencies in Mexico's pilot plant programmes. Mexico is quite dependent on foreign technology and on joint ventures with transnational companies. In fact, the Mexican biotechnology industry has developed with essentially no indigenous biotechnology. However, the multinational ties between TNCs and national companies on which Mexico depends are weak, one reason being that there is still no substantial incentive programme to strengthen these ties.57/

Drug manufacturing companies are required to spend four per cent of their gross sales of intermediate products on R&D as of 1984.58/ The new economic policies are trying to promote exports, and not trade protection and import substitution. In the pharmaceutical sector, for example, Mexico now manufactures more than 60 per cent of new active substances which were previously imported and more than 90 per cent of the finished product (medicines).59/

The pharmaceutical industry is where Mexico has been losing ground on an international scale. In Mexico, the industry is fully developed in traditional manufacturing methods, but not in new technology. This is due in part to a lack of resources, and dependence on foreign technology and products (both intermediate and final). Mexican patent policies, designed to protect domestic R&D efforts, are considered to provide insufficient protection for foreign investment and transfer of technology, although this situation is changing with recent changes in Mexican patent policies mentioned above.60/ Research costs are very high, investment incentives are lacking, links between research and industry are very weak, and the development of the infrastructure is uneven and disjointed.61/

The government needs to formulate an integrated national strategy in biotechnology which will provide more effective coordination for different sectoral policies and programmes. One critical element in formulating such a strategy will be to identify and concentrate resources on a limited number of major national priorities. Mexico's resources in biotechnology, both human and material, are not inconsiderable, at least in relation to other developing countries. However, they are deployed over a wide range of activities, with the result that the level of effort in any one area tends to be sub-critical.62/

Along with proliferation of activity, Mexico's effort in biotechnology is characterised by a wide gap between policy and performance. A major cause of that gap is inadequate commitment of resources to programmes in biotechnology, reflecting the extremely difficult financial situation in the country during the decade of the 1980s.

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TABLE 1

PRINCIPAL PLANT BIOTECHNOLOGY RESEARCH INSTITUTIONS
AND THEIR AREAS OF WORK

1989

Institution	Areas of PB Research Mp	BF	GP	GI	PSM	BR	Main Obectives of Research	Main Species
CIB	x				x		Preservation and exploitation of arid zone species. Tolerance to saline stress.	Turnera diffusa Oregan Radish Cow pea
CICY	x			x	x	x	Biosynthesis of alkaloids. Biochemistry and physiology of cultured cells. Cloning of high yielding plants Selection of somaclonal varia- nts for disease reistance.	Agaves Catharanthus roseus Datura inoxia Agroindustrial crops
CIIDIR	x						Large scale production of rootstocks and elite trees.	Apple Prunus spp. Pistachio Woody species
CIMMYT				x			Embryo culture for wide crosses	Maize Wheat
CINVESTAV-DF					x		Biosynthesis of flavouring, pharmaceutial compounds and pesticides by in vitro cultured cells.	Capsicum Tagetes erecta Vanilla Trigonella
CINVESTAV-I	x			x		x	Genetic engineering for the production of food crops resistant to virus, bacterial and fungal diseases and insects and with higher protein quality.	Rice Tomato Bean Maize Amaranth Capsicum
CP-Chapingo	x			x			Selection of somaclonal variants for stress and dis- ease resistance Cloning of novel genotypes and elite materials.	Pinus Maize Rice Coconut Amaranth Tomato
INIFAP	x	x		x			Culture of haploids and embryo rescue for genetic improvement Production of virus free material.	Sugar cane Coconut Yuca Rice Citrus

Cont. Table 1

IPN-ENCB					x	x	Somatic embryogenesis production of colorants and pharmaceuticals by *in vitro* cultured cells.	Alfalfa Beetroot Cacao Celery
UAAAN				x			*In vitro* selection for fungal resistance	Maize
UACH-Ch	x	x		x			Selection of somaclonal variants. Cloning of novel genotypes and elite materials Production of disease free material	Vanilla Pineapple Ornamentals Potato Eucaliptus Others
UNAM-CIFN						x	Molecular biology of nitrogen metabolism and fixation.	Beans
UNAM-ENEP	x		x				Preservation of endangered species.	Orchids *Lophophora williamsii* Chamaedora palm
UNAM-FQ						x	Basic research on the biochemistry of *in vitro* cultured cells.	Maiz Amaranth
UNAM-IB			x		x		Preservation of endangered species. Biosynthesis of food additives by *in vitro* cultured cell.	Orchids Onions Garlic Others

Mp - Micropropagation DF - Disease free material GP - Germplasm preservation
GI - Genetic improvement PSM - Production of secundary metabolites BR - Basic Research

CIB: Centro de Investigaciones Biológicas de Baja California A. C.
CICY: Centro de Investigación Científica de Yucatán A. C.
CIIDIR: Centro Interdisciplinario de Investigación para el Desarrollo Integral de la Comunidad. Unidad Durango, Instituto Politecnico Nacional.
CIMMYT: Centro Internacional de Mejoramiento de Maiz y Trigo, A. C.
CINVESTAV-I: Centro de Investigaciones y Estudios Avanzados del IPN. Unidad Irapuato.
CINVESTAV-M: Centro de Investigaciones y Estudios Avanzados del IPN. Mexico.
CP-Chapingo: Colegio de Postgraduados, Chapingo.
INIFAP: Instituto Nacional de Investigaciones Forestales, Agrícolas y Pecuarias, Estaciónes en Nuevo Leon. Tabasco, Toluca y Zacatepec, Secretaría de Agricultura y Recursos Hidráulicos.
IPN-ENCP: Escuela Nacional de Ciencias Biológicas, Instituto Nacional Politécnico.
UAAAN: Universidad Autónoma Agraria Antonio Narro, Saltillo, Coah.
UACH: Universidad Autónoma de Chapingo.
UNAM: Universidad Nacional Autónoma de México.
UNAM-CIFN: Centro de Investigaciones sobre Fijación del Nitrógeno.
UNAM-ENEP: Escuela Nacional de Estudios Profesionales, Unidades en Iztacala y Zaragoza.
UNAM-FQ: Departamento de Bioquímica, División de Estudios de Posgrado.
UNAM-IB: Instituto de Biología.

TABLE 2

PUBLIC RESEARCH INSTITUTIONS
WITH R & D CONTRACTS IN
PLANT BIOTECHNOLOGY

1989

RESEARCH INSTITUTION*	ON-GOING CONTRACTS WITH COMPANIES		TECHNOLOGIES TRANSFERRED
	Number	Area	
CICY	1	In vitrc selection of disease resistance traits	2: 1) yield increase 2) seed quality improvement
CINVESTAV, IRAPUATO	2	Genetic engineering for virus and insect resistance in food crops	
COLEGIO DE POSTGRADUADOS	1	Micropropagation of elite woody species	
UNIVERSIDAD AUTONOMA DE CHAPINGO			1: Micropropagation of Coffee varieties resistant to orange rust
UNAM: INSTITUTO DE BIOLOGIA	1	Biosynthesis of food additives	

* Institutions are arranged by alphabetical order.

TABLE 3

PRINCIPAL MEXICAN FIRMS WITH PLANT TISSUE CULTURE LABORATORY

FIRM (private/public)	LOCALITY	SPECIES	TOTAL ANNUAL PRODUCTION OF MICROPROPAGATED PLANTS	INVESTMENT IN TISSUE CULTURE LAB (US DLLS)	NUMBER OF EMPLOYEES IN LAB	MARKET % NATIONAL	MARKET % INTERNATIONAL	PLANS FOR IN-HOUSE RESEARCH	LINKS WITH PUBLIC RESEARCH CENTRES	FUTURE PLANS
Biogenetica Mexicana, S.A. de C.V. (private)	Offices in Mexico D.F. Greenhouses and lab in Tepotzotlan	Gerbera Gypsophyla Dieffenbachia Caladium Spatiphyllum	100,000	90,000 (1984)	4	100		No	No	Invest $520,000 US in a lab and greenhouses in Michoacan to produce ornamentals for export market
El Rancho La Joya (Nursery) (private)	Offices and lab in Atlixco, Puebla	Orchids	100,000	100,000 (1985)	2	20	80	No	No	Micropropagate other species such as roses for export market
Invernamex (Nursery) (private)	Office and lab Tepotzotlan State of Mexico	Gerbera Gypsophyla Strawberry Raspberry Blackberry	600,000	400,000 (1989)	8	100		Yes	Universidad Autonoma de Chapingo	Go into export market
Viveros "El Morro" (Nursery) (private)	Mexico D.F. Greenhouses and plantations in Guerrero, Oaxaca, Michoacan and Morelos	Spatiphyllum Singonium	300,000	400,000 (1988)	?			No	No	
FIRA (Bank of Mexico) (public)	Tezoyuca, Morelos	African violet, gerbera Chrisanthemum Strawberry	100,000	45,000 (1988)	?	100		YES	Universidad Autnoma de Chapingo	Transfer micropropagation methodologies to small producers

SOURCE: SURVEY, OCTOBER, 1989.

NOTE: 8 other tissue culture laboratories have been reported (FIRA, 1989) but some are no longer functioning and the others are extremely small.

CHAPTER VI

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN THAILAND

I. Policies for Genetic Engineering and Biotechnology

The major factors behind the interest in biotechnology in Thailand appear to be the marketing and export potential of biotechnology products, the potential for the replacement of costly import items, revenue, and availability of raw materials.1/ Thailand's technological policies include manpower development, R&D improvement, promotion of technology transfer, and promotion of its use in the private sector.2/

There are three broad trends in Thailand which will affect biotechnology development in Thailand. First, there is pressure on Thailand to introduce patent laws, particularly in the area of pharmaceuticals. This has been met with strong resistance from Thailand to such laws. Second, the nature of restructuring agriculture has led to the "grabbing" of land for corporate farming, of which biotechnology has been a key element. Third is the effort to make Thailand the next focus for development in Asia as a newly industrialised country (NIC).3/ Another factor which deserves mentioning is Thailand's foreign debt which requires Thailand to focus on serving world market demands rather than the needs of local people. However, the dependence on foreign, and specifically transnational corporations, technology often conflicts with the export-oriented focus of the national economy.4/

As agriculture is the mainstay of the Thai economy, the importance of biotechnology in Thailand lies mainly in the areas of animal husbandry and sugar production, but may not be that valuable for use in reforestation (a major issue in Thailand).5/

The main policy formulation and coordinating agency for biotechnology in Thailand is the National Center for Genetic Engineering and Biotechnology (NCGEB), created in 1983 by the Ministry of Science, Technology, and Energy. The primary institutions affiliated with the agency are Chulalongkorn University, Mahidol University, Kasetsart University, King Mongkut's Institute of Technology, Chiang Mai University, Khon Kaen University, Prince of Songkhla University, Srinakharinwirot University, and the Thailand Institute of Scientific and Technology Research.6/ Another major support agency for biotechnology R&D is the Science and Technology Board.7/

Thailand's and NCGEB's policy goals with respect to biotechnology are to promote university and industrial links, to coordinate government and international support to biotechnology institutions, to transfer R&D in the laboratory to industry, and to improve small and medium-scale bioindustry.8/

Thailand's major goals for the future entail the promotion of biotechnology products for export, the promotion of local products competing with imports, the improvement of mechanisms for acquiring foreign technology, and the support of R&D and manpower training.9/ In order to achieve these goals, Thailand will have to have improved financing in the field, improved links between the public and private sectors, a broader, better-trained manpower supply, and improved laws and regulations governing patents, genetic resource conservation, and safety issues.

NCGEB is directly engaged in the funding of research projects, the promotion of transfer of technology and information to industry, and the development and construction of pilot plants.10/ NCGEB also provides research fellowships for post-graduates, sponsors workshops and seminars on genetic engineering and biotechnology, and provides technical and information services.11/ For example, in cooperation with the Thailand Institute of Scientific and Technological Research (TISTR), NCGEB maintains culture collections and acts as a clearinghouse for some microorganisms for researchers.12/

NCGEB cooperates with institutes in the U.S., U.K., Australia, Netherlands, Japan, and other ASEAN countries. With the U.S., the Science and Technology Development Board of Thailand interacts with academic and commercial contacts in the U.S. in addition to collaborative programs with NCGEB. For example, USAID helped NCGEB to form the national network for plant tissue culture technology.13/

Thailand has a program for the development of enzyme technology with the United Kingdom. The U.K. also offers collaborative research projects and fellowships to Thai students.

In Australia there is a program to promote joint commercial ventures with industries in both countries.

The Netherlands has provided plant genetic engineers for lectures and workshops at NCGEB affiliated laboratories.

Japan has assisted in establishing R&D training and facilities at a National Agro-industrial Biotechnology Center. Other ASEAN countries have collaborative projects, largely concerning food, in particular with Australia.14/

NCGEB gives support to affiliates in setting up laboratories for R&D based on manpower and the potentials of the planned research. NCGEB publishes "Biotechnology Business News" bi-monthly. NCGEB compiles information on biotechnology, and its information unit maintains a collection of reference books and leading journals. On-line information services are available to all projects supported by NCGEB.14/

The main features of present policies on biotechnology in Thailand include investment promotion, industrial protection, export promotion, and promotion of small-medium industries.16/

With respect to the monitoring and regulatory system for the biotechnology industry in Thailand, public services are available, including information and quality control.

The Science and Technology Development Board (STDB) is the agency responsible for administering projects and increasing interaction between the research and business sectors. Its main functions are to strengthen S&T institutional framework, administer an R&D funding support programme, and review S&T policy and practice. STDB's funding of $49 million comes from grants and loans provided by USAID and the Royal Thai Government.17/

A Technical Information Center (TIAC) is being established for the R&D and business communities as a modern information facility. It will draw upon universities, government research laboratories, and private consulting firms.18/

BOSTID, the Board on Science and Technology for International Development, is part of the National Research Council (an arm of the U.S. National Academy of Sciences). BOSTID works with counterparts in developing countries such as Thailand to provide technical advice on R&D and industrial development. BOSTID contributed to the development of STDB in Thailand, and is helping to establish information and service centres as well.19/

II. Programmes in the Public and Private Sector

The majority of Thailand's programmes fall within the agricultural sector. At Chiang Mai University, there is a project for improving yeast strains for the production of food yeast. Embryo transfer technology is being used in dairy cattle at Kasetsart University, as well as the production of disease-free potato seeds on a commercial scale, and the development of micro-organisms for compost production. Biotechnology is also used in the development of flowering and ornamental plants. Steroid immunisation is being used at Chulalongkorn University to enhance fertility in the swamp buffalo, and scientists are also engaged in N_2 fixation bacteria research for rice, and Shiitake mushroom cultivation. Mahidol University is involved in strain selection and cultivation of terrestrial snails for export and the production of mosquito larvicide and field trials of mosquito control using spore-forming bacteria. The utilization of vesicular-arbuscular myccorrhiza and its combined effect with nitrogen-fixing bacteria in legumes, and the improvement of N_2 fixing blue-green algae for use as a biofertiliser to improve rice yields is being examined at TISTR. The use of low-cost cassava for non-toxic, natural colorings for food, drinks, and pharmaceuticals is being researched at Kasetsart University. A red fungus was discovered capable of producing red pigments from cassava in liquid culture.20/

In the health and pharmaceutical sector, Thailand is engaged in the production of glucoamylase and pure glucose at Chulalongkorn University, and citric acid production in submerged cultures at Kasetsart. The molecular cloning of Herpes Simplex Virus Type 2 DNA is being investigated at Mahidol University.21/

In the industrial sector, the treatment and utilization of tapioca starch waste water is being addressed at King Mongkut's Institute of Technology. The coversion of solid waste to methane gas by anaerobic digestion is being studied at Chulalongkorn University.22/

As is evident from the above listing of programmes, the majority of research and development is being carried out in universities rather than the private, industrial sector.

In the area of institution building and human resource development, NCGEB contributes by providing information training, university-industry links, and some scholarships to students, although presently there are less than 500 persons directly engaged in biotechnology, and there is a severe shortage of Ph.D.s in the field.23/

Various sectors which are being promoted in an effort to displace imported products are largely agriculturally-related. Some areas include pure glucose (for pharmaceutical purposes), disease-free potato seeds on a commercial scale (200 tons are currently imported annually), N_2-fixation for rice to reduce fertilizer dependence, and local production of the Shiitake mushroom of which large numbers are imported and local production previously occurred at the expense of a precious variety of oak tree.24/

Efforts to strengthen Thailand's biotechnology infrastructure include the preparation of genetic engineering materials for researchers at Mahidol University, as well as the research and development of cell technology for production and supply of cell cultures at Mahidol. A culture collection is also being established at TISTR. Other efforts include a microbiological research centre at Mahidol and an "in vitro" germ plasm collection and plant exchange at Kasetsart.25/

Possible areas of concentration for the future are in biopesticides, biofertilizers, food colors and flavors, diagnostics, antibiotics, and vaccines. Future technologies employed (now existing only as R&D in university laboratories) will include genetic engineering, nucleic acid probes, monoclonal antibodies, and enzyme production. These areas will all be influenced by advances in the more industrialised countries.26/

III. Review of Policies and Programmes in Relation to Global Trends

The infrastructure for biotechnology in Thailand is relatively strong compared to other areas of science and technology. Research in biomedical and agricultural sciences is fairly strong, while bioprocess engineering is still fairly weak.27/

Thailand's biotechnology capability remains largely below average relative to leading firms in industrialised countries. In a survey of 40 firms spanning eight biotechnology sectors in Thailand, aquaculture was rated the highest in Thailand, slightly above the average on an international level. Feed, seed, and dairy industries followed at a level below the average for firms in industrialised countries, but higher than most local firms. Plant tissue culture, fermentation, and health-related biotechnology firms were rated the lowest with capabilities well below the world average. These particular industries are, however, the most advanced in utilising biotechnology, so it will be most difficult for Thailand to compete on an international scale in these areas.28/

The larger firms in Thailand tend to fare better than the smaller ones, as do those which are foreign-based (subsidiaries) or part of joint ventures, since it is easier to acquire and rely upon foreign technology. Those firms which are export-oriented tend to be more innovative as they must be able to compete on an international level. Also, those firms with R&D on-site rather than elsewhere also did better.29/

Thailand still lacks the means and the policies to encourage biotechnology industries to improve their technological development capability, so innovative capacity remains low. Thailand has thus fared better in unsophisticated technologies where they may rely on local capability such as in aquaculture and flower production. Slightly more than half of the close to 40 firms surveyed fell into such a category. The majority of firms engaged in production of organic acids, alcohol, and pharmaceuticals obtain technology from foreign sources.30/

Thailand's strengths in biotechnology may be attributed more to resource(raw material) availability than to technological know-how. Overall, technological capabilities in Thailand in this field remain low by international standards, and the lack of innovation must be addressed if it is to be successful on an international level in the future.31/

IV. Review of the Success of Thailand's Policies and Programmes in Relation to its Goals

Overall, Thailand's national policies in the area of biotechnology, according to some of its own scientists, are inadequate and ambiguous. Thailand's technological policies need to be substantially improved. One of the main problems with these policies is the absence of the means for their implementation, complicated by a high degree of dependence on transnational corporations.

Doctoral level education is very limited, contributing to the problem of developing technology locally. Other causes for the lack of innovation include inadequate skilled manpower, insufficient equipment, poor R&D capability, lack of funds, and the absence of a technological policy at the firm level. Some have said independent government-certified testing agencies to help speed up the product approval process would also provide greater incentive to innovation.32/

The ability to acquire technology is hindered by a lack of infrastructure, barriers to technology transfer, lack of manpower, deficiencies in information services (especially small, government-dependent firms), weak university-industrial ties, deteriorating information services, and a need for foreign specialists to teach new technology.33/

One study points out the need for improved laws and regulations governing the patent system, biosafety issues, and the use and conservation of genetic resources.34/ This is a major point of contention between the U.S. and Thailand, as improved patent laws would naturally benefit U.S. corporations seeking markets there, particularly in the area of pharmaceuticals.35/

Efforts are being made to improve the infrastructure and human resources for biotechnology in Thailand, and numerous collaborative biotechnology programmes exist between Thailand and other countries. Increased contact with scientists in other countries, improved internal linkages between universities and industry should expedite the transfer and absorption of technology in the biotechnology field for Thailand.

NOTES

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CHAPTER VII

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN ARGENTINA

I. Policies for Genetic Engineering and Biotechnology

The Secretariat for Science and Technology (SECYT) is the principal body responsible for science policy in Argentina. CONICET, the National Council for Scientific and Technical Research, falls under the authority of SECYT and is the most important national executive institution for all areas of the sciences through ad hoc commissions. Also under SECYT are the executive structures set up to deal with specific areas considered national priorities, including the National Programs. The National Program on Biotechnology (PNB) is one of these. The PNB established priority areas for research and development and grants subsidies for specific biotechnology projects. Both CONICET and PNB are financing agencies open to all laboratories of the country, independent of their emphasis, including provincial centres, the National Agricultural Research Center (INTA), the National Institute of Industrial Technology (INTI), universities, etc.

In addition, there are other institutes developing activities in biotechnology such as the universities, INTA and INTI, that have budgets of their own to finance such activities in addition to applying to CONICET and PNB for funds. These latter institutes are not financing agencies open to the scientific system in general.

The major policy goals which depend on biotechnology development in Argentina are the achievement of domestic self-sufficiency in areas of heavy reliance on imports (such as potato seed), the development of markets for locally-developed products, the use of agricultural wastes, the ability to learn more balanced enzyme technology, and the use of biotechnology as a basis for future industrial growth, particularly in pharmaceuticals. It must be noted that since 1984, PNB has emphasised all relations between biochemistry of plants and genetic engineering of plants.

More specific goals of the Argentine biotechnology effort are genetic improvement of plants, nitrogen fixation, both for humans and animals, and vaccine diagnostic bits. The main emphasis is on the agricultural and health sectors.1/

In order to achieve these goals, Argentina hopes to receive training through the Regional Program in large-scale production of cell cultures, bacteria and viruses.2/ Argentina is also involved in a program with Brazil (Argentine/Brazilian Center on Biotechnology). Through such cooperation, Argentina seeks to strengthen four basic areas of research. These include large-scale production of measles vaccines, large-scale production of DPT vaccine and hepatitis B vaccine, and production of viruses for developing diagnostic methods for hepatitis B and HIV. Only the DPT vaccine is in an advanced stage of development at this point, through the programme (CABBIO) with Brazil, although there are two laboratories working on development of diagnostics for hepatitis B.

The institutions that participate in the Regional Program on Biotechnology are: Roffo Hospital of the University of Buenos Aires, in a project on the mass production of monoclonal antibodies; INGEBI and the Department of Biochemistry of the University of La Plata, in a project on the development of diagnostics for vegetable diseases; the Institute for Diagnosis and Research on Chagas' Disease of the University of Litoral, INGEBI and the Institute of Biochemical Research, in a project on the development of diagnostics for Tripanosomiasis and Leishmaniasis. All of these participate through their own laboratories that are already involved in these projects.

Argentina, through PNB, is affiliated with the International Center for Genetic Engineering and Biotechnology (ICGEB). PNB guarantees the participation in ICGEB of all laboratories involved in biotechnology.

The Biochemical Research Institute of the Campomar Foundation has the most complete library in the country in biochemistry, molecular biology and biotechnology. Also, INTA has a well-provisioned scientific and technical library, as well as IBM computer facilities.7/ In Buenos Aires, there are more than 20 complete and up-to-date libraries in biology, biochemistry, chemistry, etc.4/

Funding for science and technology comes partly from the budgets of the various institutes. However, most of the funding comes from CONICET or PNB. Argentina has among the highest appropriations for science and technology in Latin America. Research and development appropriations, as of 1985, accounted for approximately 0.7 per cent of the Gross Domestic Product. A total of $500 million was designated for science and technology. CONICET, the National Science and Technology Council, administered $140 million, but this goes to all sciences for equipment and researchers and technicians (some 7,000 people). The National Biotechnology Program has a $1 million budget which was administered by the Department of Science and Technology, plus $2 million which went to the Argentine-Brazilian Biotechnology Agreement (CABBIO).5/ Since then, the budgets have been noticably reduced. CABBIO had a budget of $500,000 in 1988.

There is a Technology Transfer Directorate within CONICET, but incentives to transfer technology from research centres to the productive sector are only now being established.6/ Previously, full-time researchers were prohibited from entering into consultancies. They now may, for up to 20 per cent of their time. In three years, some 200 contracts have been entered into between scientific institutes and businesses.

As of 1984, Argentina offered no Ph.D.s in agricultural science. In fact, the only Ph.D. level programme at that time was in chemical engineering, which began only in 1980.7/ Argentina does offer interdisciplinary training and research in its universities. The Buenos Aires University has a curriculum in biotechnology. In addition, the Scientific Research Commission, SUBCYT, and CONICET have similar curriculums. Several courses are also organized annually by research institutes.8/ Several bilateral and multilateral cooperation treaties and training programmes are in operation. The National Scientific and Technical Research Council will grant fellowships for foreign graduate students, especially from other Latin American countries.9/ Argentina has a reasonably well-trained scientific community in the basic sciences related to genetic engineering and biotechnology. However, many were dismissed under the military regime or have emigrated elsewhere.10/

Patent protection is granted for DNA expression vectors, modified plasmid, or procedures for producing microorganisms. Argentina is the only Latin American country which provides for the deposit of microorganisms. With the exception of Chile, Argentina is the only Latin American country which provides specific protection for plant species. No Latin American countries are signatories to the Union for the Protection of New Varieties of Plants.11/ Argentina did adhere to the Paris Convention for the Protection of Industrial Property, revised in 1967, but did not sign the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedures of 1977. Adherence to the latter is being considered by the Technical Advisory Committee of the National GEB programme.

Argentina has restrictions for the introduction and transportation of exotic or pathogenic microorganisms. No guidelines have been established so far for recombinant DNA, but there is a consensus among the scientific community to follow the guidelines of the U.S. National Institutes of Health.12/

II. Programmes in the Public and Private Sector

The most developed areas of genetic engineering and biotechnology in Argentina, as in Brazil, are the livestock and human health sectors. Argentinian scientists have programmes for developing vaccines for foot and mouth disease prepared by genetic engineering techniques, diagnostic kits for animal viruses, and production of animal pathogenic microorganisms for use in vaccines for improved animal health.13/ Programmes to develop vaccines through genetic engineering for aphthous have been unsuccessful - there are, however, seven companies that produce the vaccines through traditional methods.

In the private sector, several countries are engaged in the production of selected cattle embryos, including Munary Asociados, La Promavera, La Catalona, and IRABSA. A number of companies have experience in artificial insemination. Among them is Integrated Artificial Insemination Center of the West (CIIADO), a nationally-owned company which provides artificial insemination, sexing, semen conservation, and embryo freezing services.14/

The private sector is active in using tissue culture for propagation of potatoes, developed through state aid.15/ Private companies are also using tissue culture to produce fruits and other vegetables.

Argentina has some history of producing enzymes of plants or animals by extractive methods, such as pancreation, chemotripsin, and natural renin. Production of microbial enzymes began only in the early 1980s through a joint venture between Miles (a U.S. firm) and Arcor (a local food industry firm).

Together they established the Milar company, which with the Miles license, imports improved strains from its laboratories. Milar produces microbial enzymes for the food sector. Sales in 1986 were valued at $2.8 million, and exports at $365,000. However, imports of enzymes increased due to the growing demand for glucose isomerase, a product needed for the production of fructose, which happens to be produced by Arcor.16/

Argentina is the only Latin American country which produces isoglucose or fructose. Five plants, including one of Arcor's, have been set up for this purpose Two are sugar firms, and the remaining two are maize-producing and processing firms. Since Argentina produces sugar, the government has fixed production quotas for fructose. The production of fructose may have several effects. One is the establishment of a large market for locally-developed enzymes. Other effects may be the incentive to use agricultural wastes from fermentation processes, the ability to learn enzyme mobilisation technology in more advanced phases.17/

Several agencies of the federal government are trying to promote biotechnology as a basis for future industrial growth. These include the public health ministry, which views biotechnology as a way for Argentina to enter into the pharmaceutical industry. Many international companies manufacture drugs in Argentina, but 45 per cent of the market is produced locally. Yet research in this area is practically nonexistent. In 1984, the cost of developing a new drug was about $40 million, but the largest pharmaceutical company in Argentina only grossed about $60 million per year.18/

The pharmaceutical sector in Argentina is characterised by a smaller presence of TNCs, enabling local firms with traditions in the sector to move into biotechnology. The private sector has sought a niche in markets which have not yet been adequately covered. For example, the diagnostic reagents market using biotechnology in Argentina is estimated at $20 million, and vaccines at $35 million. The Poly-Chaco firm of Argentina is involved in diagnostic reagents, and has been successful in expanding the market for diagnostic reagents for Chagas' disease from 100,000 to seven million tests annually, covering both the Brazilian and Argentine markets. They also work on hepatitis B diagnosis.19/ Other areas of diagnostics are also being investigated by companies such as S.A. de Rosario.

An Argentinian pharmaceutical company, Sidus, created a new company - Biosidus, S.A. - in 1985. Its purpose is to prepare medical and biological substances through biotechnological methods. Its initial project was the production of alpha and gamma human interferon, and the company is beginning laboratory tests for use in human beings. Interferon production at Biosidus is carried out by both traditional leucocyte culture methods and the subsequent production and secretion of interferon from a virus or infectious agent, as well as by recombinant DNA engineering. In the long term, Biosidus plans to develop DNA probes for detecting viruses responsible for sexually transmitted diseases, respiratory viruses, and infant diarrhea. Biosidus is also beginning work in the area of vaccines, particularly hepatitis B vaccine.20/ Another local company has been producing bovine and porcine insulin for human use for three years - since Eli Lilly closed its plant in Buenos Aires.

In the industrial sector, INTI is conducting a project for the production of pulialano, a fine chemical used for substituting plastic containers in the food and cosmetic industries.21/ However, INTI's project in biotechnology does not appear to be moving forward.

Another programme is the Research Committee of Buenos Aires (CIC), which is supposed to promote research. CIS's mandate states that it must spend 60 per cent of its funds in research of local importance. Five areas were chosen, including natural resources, food technology, clinical research, energy, and building technology.22/

III. Evaluation of Policies and Programmes in Terms of Global Trends

The military regime which seized power in 1976 left a lasting mark on the country's economy and its relationship with the international scientific community. The most important problem which plagues Argentine biotechnology is its unstable economy. In addition, Argentina suffers from similar problems in the development of biotechnology as many of its Latin American neighbors.23/ Local industry tends to be risk-averse when it comes to investing in long-term research or R&D not leading to immediate tangible results. Industry in Argentina uses foreign technology almost exclusively, and there is very little industry-supported research in the country.24/

The National Institute of Agricultural Technology (INTA) is an example of Argentina's foreign dependence for biotechnology. The role of INTA has traditionally been to adapt foreign innovations to Argentina's needs. INTA has developed links to universities and other institutes funded by CONICET. Problems which are unique to Argentina are demanding that indigenous technologies and solutions be developed.25/

In the past, foreign research has been carried out in Argentina. As regulations in industrialised countries have tightened and become more specified, companies and institutes have turned to developing countries not just for potential markets, but to test products and processes. One particular instance of rabies vaccine testing in 1986 created an outrage among the Argentinian scientific community, as testing was conducted without prior knowledge by the Argentine government. The testing was conducted by the Wistar Institute (U.S.), on an experimental farm of the Pan American Health Organization in Argentina.26/ Argentina, like most developing countries, has no specific regulations for the research, production or release into the environment of genetically engineered microorganisms. However, there are two laws prohibiting the introduction into the country of exotic microorganisms.27/ The Argentinian scandal prompted scientists at a meeting in Paris in 1988 to draw up guidelines to ensure that researchers from one country do not exploit lax laws in another country by conducting experiments abroad that would be severely restricted or prohibited at home.28/

IV. Evaluation of the Success of Argentine Policies and Programmes

The main reason for the development of an inadequate scientific base in Argentina compared to its potential is problems with funding - both the amounts available and the continuity of funds. The inadequacy of salaries has been responsible for a "brain drain" to other, more industrialised countries.

INTA and INTI face similar problems as other Argentine research organisations. These include large numbers of small, fragmented laboratories (INTI has about 40), a large percentage of the budget goes to salaries (65 per cent for INTI), and isolation from basic scientific research. INTI laboratories are well-equipped by Argentine standards, and it has approximately 500 scientists, but its operating funds are limited. INTI activities now mainly consist of providing technical services to the industries.29/

Information and library collections severely deteriorated under the military regime. A large number of foreign books and journals need to be purchased to update university collections, and to satisfy the severe shortage of scientific material.30/

Argentina's potato industry is a success story as part of the goal for achieving domestic self-sufficiency. Five firms devoted to the micropropagation of potatoes achieved self-sufficiency in five years. In 1980, Argentina imported approximately US $4 million of potato seed. By 1985, less than US $1,000 was imported.31/

Argentinian science in general, as well as biotechnology in particular, has suffered from two basic adversities in the past. One is Argentina's political instability, which brought persecution to the academic and scientific community (especially at the hands of the military). The other is Argentina's shaky economy. There is also a shortage of equipment and foreign journals. There is also an absence of needed training programmes. Argentina is experiencing a "brain drain" as many of its best and brightest are leaving for the United States and Europe.32/

In addition, the open door policy of the universities is permitting too many unqualified students into the university system.33/ Furthermore, the universities are mainly engaged in teaching, and research is seldom geared to practical applications, as is the case in most Latin American universities.34/

Biotechnology in Argentina is viewed mainly as a method of competing at lower costs, especially in vaccines, biologicals, and diagnostics. Much of the local "innovation" in pharmaceuticals, for example, is merely developing new combinations of drugs, some with as many as five different active ingredients. In fact, the drug regulation system almost broke down entirely under the military government.35/

Argentina's best hope is to properly train a new generation of scientists, and coordinate efforts of individual research institutes and universities. However, Argentina's economic problems will continue to cast a shadow of uncertainty on the future of Argentine biotechnology development, regardless of how well coordinated and administered a programme they may have.

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CHAPTER VIII

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN CUBA

I. Policies for Genetic Engineering and Biotechnology

In the 1980s, biotechnology became a priority in Cuba in an attempt to solve some of its economic needs. This is evident from the fact that the science budget has almost doubled in recent years. It is somewhat surprising given the economic problems and the possible shortage of basic research expertise that the new emphasis has been placed on central research planning. Apparently Fidel Castro and some scientists share the belief that bioscience could be Cuba's economic salvation.1/ Historically, biotechnology got its start in Cuba with the development of interferon in 1982, under the express order of Fidel Castro.2/

The major institutions in Cuba involved in biotechnology include the Center for Genetic Engineering and Biotechnology (CIGB), the National Center for Scientific Research, the Immunoassay Center, and the Center for Biological Research (CIB). CIGB has more than 300 researchers, and is more than 70,000 m^2 in size. A similar facility constructed in the U.S. might cost $50-60 million (for land, buildings, and equipment). Cuba is starting a new branch of CIGB in another city in Cuba, but its emphasis will be on agriculture and animal products.3/ Three of these institutions are participants in the Regional Program for the Development of Biotechnology for Health in Latin America. These are the Center for Genetic Engineering and Biotechnology, the National Center for Scientific Research, and the Immunoassay Center. The objectives of their participation in the Regional Program are to expand their diagnostic capability, to increase the production of reagents, and to meet quality and packaging standards for transportation and storage in Third World countries. Activities of the institutions include development of diagnostic methods using monoclonal antibodies for hepatitis B, production of hepatitis B vaccine using recombinant DNA, production of a meningitis B vaccine, development of a diagnostic technique for AIDS, and production of inputs needed for recombinant DNA technology.4/

The Cuban government does not have a set national plan for biotechnology, but a government agency known as the "Biological Front" was created in the 1980s in an effort to link all institutions engaged in biotechnology so that they could meet to discuss their agenda.5/

Cuba contributes about $1.66 million to the $11.3 million budget of the Regional Program for the Development of Biotechnology Applied to Health in Latin America. Brazil and Argentina are the largest contributors with over $5 million and $3 million respectively.6/

Cuba was one of the candidates for hosting the International Centre for Genetic Engineering and Biotechnology (ICGEB) set up by UNIDO, but later withdrew its offer to facilitate agreement. Cuba then decided to build its own facility.7/ Cuba has invested well over $50 million - some observers suggest as much as $100 million - in the new Centro de Ingenieria Genetica y Biotecnologica (CIGB), the main physical facility for which was constructed in

1986. It is the largest in Latin America, with facilities similar to some of the best in the world. CIGB focuses mainly on the health sector; its activities are further described in paragraph 10 below.8/

Much of Cuba's scientific staff was trained at the National Center for Scientific Research (CENIC). Research at CENIC concentrates on public health, drug synthesis, some environmental science, and corrosion research. New biotechnology methods are employed where possible. Research at CENIC has been placed under much tighter control by the National Academy of Sciences, a division of the central government. The Academy assigns priority areas of research, with feedback from laboratories. Approval for suggested research must be obtained from superiors. Areas assigned priority tend to be those with foreseeable results.9/

CENIC is an older and much larger institution than the Center for Biological Research (CIB). CIB was founded in 1981, primarily to supply Cuban doctors with interferon for testing against cancer and viral diseases.10/ CIB fomented the development of genetic engineering in Cuba through the successful cloning, expressing, and producing of alpha and gamma interferons by recombinant methods.11/ CIB is a government (public) institution with an annual budget of about US $500,000, and a scientific staff of around 25 (as of 1985). The Center is well equipped with modern devices such as ultracentrifuges, autoclaves, ultrasound equipment, etc. CIB has a library with subscriptions to at least 96 journals in the field of immunology, genetic engineering, and biotechnology.12/

CIB's proximity to the scientific and teaching institutions such as the Tropical Medicine Institute, the National Center for Scientific Research and the School of Medicine promotes better communication between them, and they are better able to share facilities. There are also some important biology libraries in the area.

The future agenda of CIB's activities includes the production of interferons, production of monoclonal antibodies for diagnostic and therapeutic purposes, research in vaccines, etc. CIB is also involved in the training of personnel from other institutions in Cuba, as well as abroad. Financing will continue to come mainly from the government, as well as from international sources.13/ The Center for Biological Research was chosen as an affiliated centre to ICGEB.14/

Lines of research at CIGB include proteins and hormones, vaccines and diagnostics, energy and biomass, plants and fertilizers, cloning, expression, and cell genetics. For a product listing as of January 1989, see Table [illegible].15/

A good educational system has contributed substantially to Cuba's biotechnology capability. Many researchers were trained in the Soviet Union, as well as Britain, France, and Mexico, and even a small number in the United States. Most, however, are trained in Cuba. There are informal collaborations with U.S. scientists, particularly through NACSEX (North America Cuban Scientific Exchange).16/

International collaborations also include exchanges with Finland, the USSR, Sweden, Spain, Belgium, Switzerland, and some Eastern European countries.17/

The role of the private sector in biotechnology in Cuba is almost non-existent as most programmes, institutions, and universities are government operated. This also affects the existence of patents. Since the institutions are government-owned, there is little domestic need regarding patent legislation. On an international level, the absence of patent laws and regulations may discourage trade and investment in Cuba. A need may develop for the protection of Cuba's own products and processes if they begin to market them internationally.

In Cuba, many new products or processes are for domestic use, but some are for export to provide technical and medical assistance to the Third World.18/ Presently Cuba spends a large amount of money on insulin imports, with a demand as large as Mexico's. Therefore, a facility for insulin is planned. Cuba does place strong emphasis on health care, and they have stressed pharmaceuticals and human health in their biotechnology research. In the case of insulin, for example, Cuba claims that those who are in need of it receive it from the government.19/ Further evidence of the importance given health care in Cuba are the infant mortality and life expectancy figures which rival those of the United States.20/

Overall, Cuba's goals are directed at short-term results rather than basic research. They are looking for fairly quick results with applications not too far in the future. The "Biotechnology Front", a high-level policy-making body, was established in 1981 to speed up this focused research by providing new laboratories with direct government support.21/ Specifically, Cuba's policies and goals are largely concerned with the pharmaceutical sector and the production of interferon, and the agricultural sector with visions of improving sugar cane technology, the most important crop in Cuba.

II. Programmes in the Public and Private Sector

Cuba has over 40,000 researchers and scientific staff. Research spending in 1986 was $165 million (more than one per cent of the national budget). Programmes include animal vaccines, interferon, biomass conversion, and high-protein food additives.22/ Special emphasis, as indicated by a majority of Cuba's programmes, is placed on the health sector.

In the agricultural sector, Cuba recently cloned the gene of the micro-organism which causes red water fever in cattle, a major problem in Latin America (and sometimes affects the U.S.). Studies are being conducted on whether it may be viable as a vaccine.23/ Plant biotechnology is also a national priority, and a major area of research at CENIC, largely on sugar cane.24/

Cuba produces about eight million tons of sugar per year, most of which is exported to the USSR. Sugar cane is the most important crop in Cuba, and various biotechnology methods are being used to improve it and use it more efficiently. One method used is somaclonal variation to produce new varieties, where the hormones of plants are genetically manipulated so they will exhibit new genetic properties.25/ Somaclonal variation has produced five varieties which are resistant to eye spot disease.26/ Varieties which are highly productive are combined with those which have greater disease-resistance, and vice-versa. Field tests were being conducted by 1986 on sugar cane modified by somaclonal variation. CENIC uses micropropagation to distribute the varieties. In this way many plants can be produced from the tissue of a single plant grown in a flask.27/ By-products of sugar cane are being developed for use as yeast for animal feed and human food supplements, particle board for furniture, and drugs to treat asthma. Much of this research is carried out by the Cuban Institute for Research on Sugarcane By-Products (ICIDA) in Havana.28/ Cuba produces more than 120,000 tons of yeast per year for feeding purposes. There are plans to set up a production facility for penicillin. They already have a good laboratory for human vaccine production.29/ Scientists at the University of Havana are examining wax from sugar cane for its possible use in drug and fine chemical production.30/ Wax from sugar cane is currently used to coat citrus fruit, and as a base for cosmetics. This wax, discovered by Dr. Jorge Martinez at the University of Havana, contains large amounts of phytoesterols which can be fermented with bacteria to produce intermediaries for steroidal drugs. Researchers are also interested in producing contraceptives and asthma medications.31/

Other agricultural research concentrates on improving the amino acid composition of yeast for animal feed, ways of using waste from sugar refining (biogas), and characterisation of active substances in plants.32/ Human health is considered the top priority for biotechnology in Cuba. The government has prided itself on its ability to provide free health care to its population.

In the health and pharmaceutical area, Cuba is now the world's second largest producer of human-derived interferon (due to an extensive blood donor system). MediCuba is the state-owned pharmaceutical firm which is to market several forms of interferon on an international level.33/ Cuba is trying to use interferon cloning and protein harvesting technology as a model in hopes that other products will follow. Interleukin-2 was cloned by 1986.34/

The Center for Biological Research (CIB) initially concentrated on interferon, but has since diversified. CIB has laboratories for in vitro gene manipulation, DNA sequencing, enzyme purification oligonucleotide and peptide synthesis, monoclonal antibodies, and a computer facility.35/ CIB is also engaged in vaccine development, fermentation and cell culture, energy and biomass utilisation, food production, genetics, and plant biotechnology.36/ About half of its operation is now dedicated to the production of human interferon. CIB was intended to serve as a model for other areas of research, and for developing skills in DNA splicing, gene synthesis, etc. The Center's most important achievements include the regular production of human leucocyte interferon for clinical use, production of beta interferon for research, the cloning and expression of the alpha-2 interferon gene and the beta interferon gene in E. Coli, the development of the ELISA system, and the production of several restriction enzymes for genetic engineering.37/

In 1987, Cuba announced plans to market an ultra-microelisa system designed for use in mass diagnostic programmes, with as much as 90 per cent savings on the cost of reagents with other automated systems. The system screens for a variety of antibodies. The first practical application was screening for alpha-fetal protein, and planned uses for congenital hyperthyroidism, AIDS, and hepatitis B virus. Currently, ten pediatric hospitals have the complete system in Cuba. The domestic need was expected to be met in 1988, and it was planned to put the system on the world market by that time as well.38/

Also in 1987, scientists at the Meningococcal Research Center in Havana developed a possible vaccine against Group B meningococci. Clinical trials were conducted involving over 200,000 people at high risk. Epidemiologically, it is considered to be the most serious health problem in the country. The disease can be fatal in as few as five hours after symptoms appear, and strikes about 1,000 Cubans per year.39/

The development of monoclonal antibodies for human health care is a top priority. The study of atherosclerosis, now the major cause of death among Cubans, is geared to isolating a monoclonal antibody against the apoliprotein-B receptor to study predisposition to the disease.40/

An area of novel research is the vaccine against clostridium hemalyticum, the toxin gene of which has been cloned and expressed.41/

III. Review of Policies and Programmes in Relation to Global Trends

Some of Cuba's technological achievements, such as the cloning and expression of alpha-2 interferon, are very impressive given their degree of isolation and the complete economic blockade by the U.S. Cuba's scientists are well-trained, even by international standards.42/ Despite Cuba's isolation from U.S. technology, Cuba has made considerable progress in the biotechnology field. As a result of the U.S. trade embargo and limited contact with Western and U.S. scientists, Cuba has been forced into developing its own procedures, certain equipment, and products in many cases, which are otherwise unavailable. Except Cuba and Trinidad/Tobago, Caribbean countries do not have the human resources or facilities for biotechnology, and lack the policies for its promotion and development.43/

Cuba has used its biotechnology efforts to promote its participation in many groups of international cooperation such as FAO, WHO, UNIDO, UNESCO, etc. Biotechnology has thus been a tool to demonstrate the development of Cuba. At the same time, because Cuba has invested so much in biotechnology, especially for a developing country, it has been able to obtain in most of the international biotechnology programmes, large amounts of money to support its research activities.

In Latin America, and probably in the Third World, Cuba has established itself as the centre for biotechnology conferences, organising large seminars every two years with attendance of more than 4,000 researchers from all over the world.

Biotechnology is heralded as one of Cuba's most impressive achievements, particularly in the area of human health. However, when they started negotiations to export their products, they found they had little experience in commercialisation. For this reason, they have established a company (managed more on capitalist principles) to promote their products outside of Cuba. This has met with little success thus far. This, combined with the fact that Cuban products for human health may not find large export markets in most Third World countries, biotechnology may have been oversold as a development factor for Cuba. One of the reasons they are having difficulties in exporting their products is because in the research phase they have not followed all the schemes and procedures established in industrialised countries. Cuba has argued that their products are fine, that they have used them in Cuba and Eastern Europe, but so far, at least in Latin America, their products have not been accepted. Only the meningitis B vaccine has been sold to Brazil on a large scale (10 million doses at $10 per dose).

It is interesting to note that when Cuba speaks about biotechnology, it generally does not mention the more traditional products such as yeast or alcohol, even though it has several research groups and institutes working on those areas.44/

As in many other areas of its national life, Cuba's work in biotechnology is greatly complicated by its proximity to and relationships with the United States. While individual U.S. scientists have established contact with counterparts in Cuba and there is some modest movement in either direction, there are also serious obstacles. There is little difficulty for U.S. scientists to go to Cuba, but Cuban scientists frequently experience difficulty in getting visas from the U.S. government.45/

Cuba has received significant assistance, both financially and in training and transfer of technology, from the Soviet Union. This support certainly has enhanced Cuba's work in biotechnology. Nonetheless, basic progress has been achieved primarily through Cuba's own efforts.

Cuba's relative isolation, while it clearly has posed problems for its work in biotechnology, may also have been a blessing in disguise. As indicated, it has been compelled to move forward in much greater measure on its own. This has meant developing its own procedures and in some cases equipment for research. The U.S. trade embargo and the absence of industrialised country-based transnational companies from the Cuban market has meant that it has not been subjected to the same kind of competition, often on very unequal terms, that have faced institutions and companies in, for example, Mexico. Overall, it has been relatively less affected by global trends in biotechnology than most other developing countries which have made a significant commitment to strengthening their national capacity in biotechnology.

IV. Review of Policies and Programmes in Relation to Their Goals

Cuban policies and goals for biotecnolo[illegible]ve been structured by the government to emphasise the development of pr[illegible]s as quickly as possible. Cuba's programmes on human health and agricul[illegible] in particular, production of interferons and improvement of the sugar ca[illegible] crop, have been quite successful, certainly in comparison to what ha[illegible] been elsewhere in the world.

While Cuba has received some outside assistance, major credit for its achievements in biotechnology should be given to its strong educational programme in the basic sciences. Centralised research planning and the emphasis on quick results and immediate applications of biotechnology detract from advances in research. On the other hand, an institution like CENIC has been described as something of a haven for the basic researcher although every researcher has to obtain the permission of a superior to do anything new. Independent peer review is also lacking, which creates an atmosphere open to those who promise fast results, even though their methods and ideas may not be always be scientifically sound.

Overall, Cuba's national policies and programmes are well-integrated, with a good infrastructure for carrying out policy goals. Greater access to markets and scientific research in other countries would certainly help to accelerate Cuba's progress in biotechnology, and this may come as the international political situation changes.

But Cuba's work in biotechnology - and in particular, its flagship centre, CIGB, face a larger problem in the long run, if not the short term. The Cuban government has made a very substantial investment of resources, human and material, in CIGB. The government clearly made such a large commitment because it expected significant returns from that investment. Sooner or later, CIGB will be called to account on the government's investment. External observers knowledgeable about and sympathetic to Cuba's work in biotechnology think that, notwithstanding all that CIGB has already accomplished, it has yet to produce returns to Cuban society commensurate with the investment already made in it.46/

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31. Miller, *op. cit.*, p. 24.
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33. Fox and Miller, *op. cit.*, p. 68.
34. Beardsley, *op. cit.*, p. 8.
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42. Beardsley, *op. cit.*, p. 8.
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PRODUCT LISTING
January 1989

PHARMACEUTICAL PRODUCTS

Human leukocyte alfa interferon

Human recombinant alfa-2b interferon

Human natural gamma interferon

Human transfer factor

Human recombinant EGF

Antimeningococcal BC vaccine

MONOCLONAL ANTIBODIES (MAb)

CB-HSV2.1: Detection of Herpes Simplex 2 Virus

CB-CL.1: Detection of Chlamydia trachomatis

CB-CMV.1: Detection of Cytomegalovirus

CB-CEA.1: Detection/purification of CEA

IA/CB-LDL.1 & A/CB-LDL.2: Detection of ApoB lipoproteins

CB-R.1 & CB-R.2: Detection of Rotavirus

CB-IFNA2.1: Purification of Hu-r IFN alfa-2b

CB-IFNA2.2 & CB-IFNA2.3: Study of Hu-r IFN alfa-2b

CB-IFNG.10: Detection of Hu-r gamma IFN

CB-EGF.1 & CB-EGF.2: Quantification of Hu-r EGF

CB-TSH.1: Detection of Human TSH

CB-IgE.1: Detection of Human Immunoglobulin E

CB-IL2.1 & CB-IL2.2: Study and purification of recombinant Human Interleukin-2

CB-Bt.1: Detection of the 230 kd toxic protein of Bacillus thuringiensis var. Krustaki

CB-tPA.1. Detection of Human tPA

IOR-T1: Against human T cells

IOR-T3: Against human T cells

IOR-T4: Against helper T lymphocytes

IOR-T6: Against human thymocytes

IOR-T7: Against human fetal thymocytes

IOR-T8: Against T lymphocyte suppressors

IOR-T11: Against E Rosette receptor

IOR-L3: Against human leukocytes

IOR-M1: MAb against monocytes and macrophages

IOR-B1: MAb against human B cells

DIAGNOSTIC KITS

ROTACIB-I: Immunoenzymatic set for Rotavirus detection in feces

HERPESCIB: Herpes Simplex antigen detection by immuno-fluorescence

RECVIH: Diagnostic system for the detection of antibodies against recombinant antigenic components of HIV (184 tests)

BIOLOGICAL REAGENTS

Lentil Lectin

Beta Galactosidase

Murine epidermal growth factor (EGF)

Bovine Serum Albumin (BSA) nuclease-free

Immunogold staining reagent

RESTRICTION ENDONUCLEASES

Alu I	BamH I	Bgl I	Bgl II
Cla I	EcoR I	EcoR V	Hinc II
Hind III	Hpa I	Hpa II	Kpn I
Nco I	Pst I	Sal I	Sma I
Taq I	Xba I	Xho I	Xho II
Sau96 I	Sau3A I	Hae III	

MODIFICATION ENZYMES

T4 DNA Ligase

DNA Polymerase I Large Fragment (Klenow)

Exonuclease III

Polynucleotide Kinase

M-MuLV Reverse Transcriptase

DNA MOLECULAR WEIGHT MARKERS

pBR-322 DNA - Alu I digest

Lambda Phage DNA - EcoR I digest

Lambda Phage DNA - Hind III digest

PRIMERS

M13 Sequencing Primer 15MER

M13 Sequencing Primer (-20)17MER

M13 Sequencing Primer (-40)17MER

M13 Sequencing Primer (-47)24MER

M13 Reverse Sequencing Primer 16MER

M13 Hybridization Probe Primer 16MER

pb Pst I Site Primer

pb Sal I Site Primer

pb Hind III Site Primer (counter-clockwise)

pb EcoR I Site Primer (clockwise)

pb Pst I Site Primer

pb Sal I Site Primer

pb EcoR I Site Primer (counter-clockwise)

pb Hind III Site Primer (clockwise)

pb BamH I Site Primer (counter-clockwise)

pb BamH I Site Primer (clockwise)

Lambda gt-11 Primer (forward) 24MER

Lambda gt-11 Primer (reverse) 24MER

Lambda gt-11 Primer (forward) 15MER

NON PHOSPHORYLATED LINKERS

Alu I	BamH I	BamH I	BamH I
Bcl I	Bgl II	Cla I	Cla I, Taq I
Cla I	EcoR I	EcoR I	EcoR I
Hae III	Hha I	Hind III	Hind III
Hind III	Hpa I	Hpa II	Hpa II, Msp I
Kpn I	Nco I	Pst I	Sal I, Taq I
Sph I	Sst I, Sac I, Alu I		Tha I
Xba I	Xba I	Xho I, Taq I, Ava I	
BamH I	Bgl II	Pvu I	Sal I
Sal I	Sma I	Sma I	Xba I
Xho I	Xho I		

ADAPTORS

BamH I, Sma I	BamH I, Pst I
EcoR I, [illegible]	EcoR I, Sma I
EcoR I, Pst I	Hind III, Pst I
Hpa II, Taq I, Sma I	

OLIGONUCLEOTIDE CUSTOM SYNTHESIS

PLASMIDS

pSP6-4 and pSP6-5

pUC-18 and pUC-19

pBR-322

PHAGES

M13mp 18 and M13mp 19

CHAPTER IX

POLICIES AND PROGRAMMES FOR BIOTECHNOLOGY IN NIGERIA

I. Policies for Genetic Engineering and Biotechnology

Biotechnology is still in its initial stage in Nigeria. There have been some biotechnology research efforts in food science, textiles, pulp, paper, and pharmaceuticals. It was only in 1987 that a National Centre of Genetic Resources and Biotechnology (CGRB) was established in Ibadan. This indicates an awareness on the part of the Nigerian government of the importance of biotechnology in the country's development. Through government efforts, problems regarding adequate funding and equipment, and a shortage of qualified personnel in the field are being addressed.1/

One of the major research institutes in Nigeria is the National Institute for Medical Research (NIMR), created in 1976. Its main task is biomedical research of the numerous health problems of Nigeria. It is one of some 24 research institutions under the Federal Ministry of Education, Science and Technology. The Institute's activities are fully financed by the federal government of Nigeria, except for some foreign grants. NIMR is the Nigerian National Affiliated Centre to ICGEB (the International Centre for Genetic Engineering and Biotechnology).2/

NIMR works with the universities and teaching hospitals to train biomedical scientists.3/ The Institute has a direct relationship with seven other centres throughout Nigeria. These include the University of Benin with laboratories for human genetic research and fermentation technology, the University of Nigeria, Nsukha with a laboratory for plant tissue culture techniques, the National Veterinary Research Institute for animal vaccine production, the National Animal Production Research Institute at Ahmeder Bello University for animal breeding, the University of Ibadan for genetic and hemoglobin research, and the University of Lagos for molecular biology and host-parasite relationship.4/

The Institute's research programmes focus on communicable diseases, environmental and community health, metabolic diseases, clinical science research, traditional medicine, and genetic engineering and biotechnology.5/

In 1985 there were only 19 scientists at NIMR plus technical and other staff. Equipment at NIMR includes ultracentrifuges, gamma counters, deep freezers, gel electrophoress apparatus, etc. There is a library at NIMR, as well as several at other universities.6/

There are two international research institutes in Nigeria for biotechnology. They are the International Institute for Tropical Agriculture (IITA), and the West African Sorghum Programme, which have been particularly active in improved crop variety. One of the major areas of research at IITA is to increase the genetic diversity for plant breeding. Some success in this has been achieved in rice, cowpeas, yams, and soya beans. The institution has performed well because it has received adequate funding, and it has highly qualified personnel in biotechnology.7/ IITA was set up some 21 years ago as the first major link in Africa of a network of research institutes in developing countries. IITA is sponsored by the World Bank, Food and Agriculture Organization, and the UN Development Programme. IITA works with national research centres, research institutes in developed countries, and

African farmers.8/ Located at IITA is probably the most sophisticated plant engineering laboratory in Africa which has developed higher-yield, faster growing, more disease-resistant varieties of several crops.9/

At present there is no established policy on biotechnology research, just fragmented efforts by individual research institutes. Efforts are being made to set up the infrastructure for laboratory facilities, and to train qualified personnel for biotechnology.10/

Nigeria's national goals and priorities for genetic engineering and biotechnology in the human health sector are vaccine production against endemic diseases, early diagnosis of inherited diseases such as sickle cell anemia, the classification of pathogens and their epidemiology, knowledge of drugs and biologically active substances, and biological control of important vectors through gene manipulation, and the preservation of biological diversity.

In the agricultural sector, Nigeria seeks to intensify production. Five priority areas are given: host-parasite interaction in plants, gene manipulation of plant cells for nitrogen fixation, host-parasite relations in animals, gene selection for desirable traits in animals, and vaccine production against animal diseases.11/ Nigeria is also pressing for national self-sufficiency in wheat, but needs new techniques in order to accomplish this goal.12/

In the industrial sector, the main priorities are in enzyme production, fermentation technology, production of preservatives and oils, and biological waste treatment.13/

As part of its national policy, Nigeria is urging domestic producers to shift from exporting raw materials such as cocoa, to processed goods.14/ Nigeria is also encouraging the substitution of local products for imports. For example, in 1984 all local breweries were issued an ultimatum that gave them until 1985 to find local substitutes for imports needed in production. Before the deadline, most breweries were able to find local grain sources for at least one lager beer. But soon after the government was ousted, imports started again.15/

The Ministry of Science and Technology has set up a national committee on genetic engineering and biotechnology in order to improve links and communication between the scattered microbiologists, geneticists, and other scientists in the country.16/

A new, more favorable foreign investment climate has been established as another national priority in Nigeria. Many of the old, corruption-ridden import licensing structures and the commodity price controls were eliminated. The exchange rate structure underwent considerable adjustment (through the market mechanism). Now instead of the multiple approval system for investment, investors can get approval with a single application within one month. It is possible for foreign ownership up to 80 per cent equity, and as much as 100 per cent tax free.17/

Private sector firms either must or prefer to keep R&D expenses low, therefore research is carried out almost exclusively in research institutes and universities. However, public research seems to lack focus, and activity in the universities is low, largely due to inadequate funding. Not until 1984 did funding increase somewhat as local R&D began to receive some attention. This led to a "technology policy" for Nigeria with special attention given to the brewing industry.18/

Funding for individual projects may only be obtained at the institute level. The government completely funds university research too. The Ministry of Education administers funding and makes policies for Nigerian universities. The largest allocation in 1988 went to the Nigerian Institute for Oil Palm Research, followed by the National Cereals Research Institute, the Institute for Agricultural Research, and the National Veterinary Research Institute. These were among the largest recipients of government funding in 1988, and therefore they give a good indication of government priorities for research. The total amount of funding was N92.6 million, or around US$18.5 million.19/

The pattern of funding breaks down into approximately 30 per cent for agriculture, 15 per cent for the food industries, 10 per cent for health, and 45 per cent for other research. This estimate is based on the amount of existing research infrastructure in research institutes, universities, etc.20/ However, only about 0.1 per cent of the GNP goes to science and technology. The resources come mainly from the government, and some from the private sector. The private sector is dominated by TNCs.21/

The National Office of Industrial Property is supposed to regulate the imports of technology into Nigeria, but they have little to do with biotechnology as of yet.22/

Nigeria's patent and investment policies can significantly influence R&D in the area of biotechnology. The government offers direct (tax credits or cost sharing) and indirect subsidies to industry investing in R&D. Indirect subsidies include exclusive patent rights to firms or individuals to develop and market a product without any competition for a certain length of time. 23/

II. Programmes in the Public and Private Sector

In the agricultural sector, research efforts are focused on crop production, single cell protein technology for animal and human food supplements, livestock and animal health, forestry, fisheries, and crop storage. The major achievement is in the production of seeds for higher-yield, disease-resistant crops. The research institutes involved are IITA, the Institute for Agricultural Research (IAR), the Cocoa Research Institute of Nigeria, the Nigerian Institute for Palm Oil Research, the Institute of Agricultural Research and Training, Lake Chad Research Institute, the National Root Crop Research Institute, and the Nigerian Universities. Only cross-breeding takes place in these institutes, with the exception of IITA, which has just begun genetic resources and tissue culture research. Genetic engineering techniques are not used at present. There is no biotechnology research activity in crop storage.24/

A UNDP project in Nigeria is a nursery near Ibadan where women farmers graft the roots of Cleopatra mandarin orange into a commercial variety of orange to improve the quality and quantity of fruits produced by the trees.25/

The International Institute of Tropical Agriculture (IITA) and the National Root Crop Research Institute at Umudike have been able, through hybridisation, to develop high-yield maize, rice, and cassava seedlings. However, except for one or two big farmers, these developments are not being used.26/ Part of the problem may be that small farmers are unaware of the developments, or find it difficult to acquire the products.

Other areas of research at IITA include the maize-streak virus, which they solved by developing resistant varieties of maize, and making it available to the small farmer. IITA has also introduced a natural enemy of the cassava mealy bug, and is researching Black Sigatoka disease, which threatens plantain production. IITA also developed the "alley farming" system which utilizes leguminous trees which fix nitrogen at the roots, acting as a natural fertilizer.27/

Single cell protein production is another area in which research is being conducted, largely as a feed supplement for poultry and livestock, with possible applications as a food supplement for humans. Some advantages include reduced dependence on imports if the project proves to be an economically feasible one. However, single cell protein production requires very capital-intensive fermentation technology. In addition, there are concerns about the safety of its use (high levels of RNA contained in the "food supplement" may cause kidney stones and gout), nutritive value, cost and flavor.28/

Research is also being conducted in animal husbandry and animal health, such as new breeds of cattle for beef and milk, and production of bacterial and viral vaccines. The research institutes engaged in this area are the National Animal Production and Research Institute, the National Veterinary Research Institute, and the Nigerian universities. Some of the vaccines are being produced by transnational corporations in Nigeria, notably Pfizer and Dizengoff.

Food processing is an area in which there have been some major R&D achievements, such as in wine production from local fruits, beer and bread at the Federal Institute of Industrial Research (FIIRO). In addition, there is some private biotechnology research in this area, as well as universities. FIIRO has made considerable efforts to transfer its findings to the public.29/

About ten of the 24 government research institutes are involved in biotechnology-related research, largely in agriculture and food processing. Genetic engineering is being appli d to deriving improved varieties of yams, improving the shelf-life of palm wines, and to developing strains of wheat, which are more suited to the climate.30/

Little headway has been made in research involving biotechnol gy in the pharmaceutical sector. The establishment of a national research centre for pharmaceuticals took place only in 1987. Its main purpose is to examine the potential of Nigeria's natural resources for dr and pharmaceutical raw materials. There have been a variety of vaccines produced at the National Institute for Medical Research.27/

The NIMR has a works programme geared to the advancement of the prevention, diagnosi, and effective treatment of diseases prevalent in the country through bi lical research. Studies are conducted on the malaria parasite, hepatitis B vaccine, development using gene manipulation, and bordetella pertussis in hopes of developing a more potent and less toxic vaccine. Hybridoma, tissue culture, and fermentation technologies are employed at NIMR. Communicable diseases, environmental and community health, non-infective metabolic disease, microbial genetics for the production of vaccines, and genetic engineering and biotechnology are the priority areas of the Medical Institute.32/

In 1989, a Nigerian scientist (virologist) at the Lagos University Teaching Hospital, Dr. Clement Anyiwo, in collaboration with 12 British scientists developed a new and more efficient method of testing for the AIDS virus. The process utilizes human leukocyte antigens, the substances responsible for inducing immunity in the body. Dr. Anyiwo said the new method could be used to determine the different stages of AIDS, something not possible until now. The test is more efficient than others, but very expensive. It cannot be developed in Nigeria at this time due to an absence of materials and experts, except perhaps at the University of Nigeria at Ibadan. The method has already been accepted in Britain and France.33/

To demonstrate the importance of developing the pharmaceutical and health care sector in Nigeria, especially one using modern biotechnology and genetic engineering techniques, there was a severe outbreak in March 1989 of spinal meningitis which killed hundreds in the northern part of the country. The state currently had only 300,000 doses of vaccines in stock, but needed at least one million to contain the outbreak.34/

Another need in Nigeria lies in the preservation of its species diversity. To this end, a conference was hosted at IITA which the United Nations Environment Programme helped to organise in 1989. The conference brought together African national scientists and world experts to review and make recommendations for future genetic resources of yam, maize, plantain, and other crops. IITA has an ultra-modern gene bank which was designed for tropical conditions. It has over 400,000 specimens of a variety of tropical crops for use by breeders, national research centres, and other international organisations. In addition, it was decided by the conference that the organisation of African Unity's Scientific and Technical Research Commission (OAU-STRC) would be actively involved in the training of African technologists in genetic engineering and biotechnology.35/

III. Review of Policies and Programmes in Relation to Global Trends

A biotechnology policy in Nigeria has only begun to take shape, and it is doubtful that Nigeria will be able to develop its biotechnology programme alone. By comparison to other developing countries, there is a relatively high skill level in biotechnology research in Nigeria, with over 50 per cent of all of Africa's scientific and technical manpower. And the quantity and types of research institutes in Nigeria indicate government recognition of the importance of biotechnology. However, by global standards, personnel for genetic engineering and biotechnology are inadequately trained and inexperienced, and funding for training is generally lacking.36/

Most laboratories, research institutes, and universities are poorly equipped for biotechnology research, and scientific equipment, machines, and materials have to largely be imported. Only IITA has the proper facilities.

This was the purpose of establishing the Center for Genetic Resources and Biotechnology, though at present it has few of the resources to carry out its mandates.37/

The areas where biotechnology is most needed in Nigeria are controlled by transnational corporations. The technologies employed are mostly foreign, though Nigerians have some expertise. Local firms lack the resources to invest in high technology research, and foreign companies carry out most of their research in their home countries. Innovative research can only be carried out with government support.38/

In the health sector, due to a weak infrastructure, dependence on foreign products and technology will probably continue for a long time. Whereas in agriculture, research results may lead to higher productivity and the ability to displace some imported products.39/ For example, enhanced food production could have spin-off effects on downstream industries such as breweries. Increased crop resistance to disease could reduce the amount of chemicals imported for disease control. The drug industry could be vastly improved as it is an especially underdeveloped sector. Most drugs are imported, and thousands still die from common tropical diseases.40/

IV. Review of Policies and Programmes in Relation to Their Goals

As stated earlier, a Nigerian biotechnology policy has not yet been established, and research is only in its nascent stage, though efforts are being made to set up the infrastructure.

Biotechnology development in Nigeria has been hindered by limited government and private funding, and a lack of investment by transnational corporations. Nigeria tends to import finished products rather than produce them from local materials. It was not until 1976 that the government attempted to promote a policy of import substitution when oil revenues fell. This was fairly successful in certain sectors, such as the breweries, until the government was overthrown. However, in most sectors no major efforts were made to fund the research on import substitutes, either by public or private sources.41/

The frequent changes in government has had a negative impact on the development of biotechnology and R&D in general.42/

There is a strong need for trained personnel at the doctorate level, as well as educated technicians and staff. Even if some training is received abroad through international cooperation, there is a fear that scientists will not return to work in Nigeria.43/

There are other problems in the Nigerian educational system as well. The universities have lowered their admission standards, thus the number of students being admitted to the universities is too high, and the quality of the applicants has been lowered.44/

The government has been fairly successful in its goal to create an atmosphere to encourage foreign investment, though investors have been somewhat slow in responding.45/

The main policy areas which need to be addressed are manpower training, strengthening of the infrastructure for biotechnology, access to international information, an enhanced role for the private sector, and the supply of equipment and research materials.46/

The major problem confronting biotechnology in Nigeria is inadequate funding. This is a serious obstacle to Nigeria's policy of self-sufficiency, since intensive research cannot be carried out without finances for training and new facilities. For this reason it is necessary to mobilise the private sector to make a financial investment in biotechnology.47/

There is also a lack of coordination between research and production. Nigeria is attempting to close the gap between research and development, and has taken steps to try to bring researchers and industrialists together. For example, a consultative committee made up of researchers, industrialists, bankers, and some science and technology ministry officials was formed. In addition, research institutes, with the aid of more investment from the private sector in mass-production, could do more to close the gap.48/

The infrastructure in Nigeria is weak, and the technological level low. Nigeria's national electrical supply system is unreliable, a necessity for biotechnology. However, institutes such as IITA are able to function and are relatively strong in biotechnology, albeit at high costs.49/

Biotechnology is a necessity for Nigeria for many reasons, but in particular for food supply and improved human health. There is a need to shift to scientific agriculture as research on seedlings and their multiplication is so vital. At present most Nigerian farmers are unaware of some of the agricultural research breakthroughs on enhancing the genetic quality and yield of certain grains and seedlings. Therefore, only a few are planting the new species. One farmer said that although he was aware of an improved variety of cassava, it was difficult for him to acquire it.50/ Therefore, the government needs to improve dissemination of information to the farmers, and ensure supply of new varieties to them.

Due to the competition for scarce resources, and the emphasis on programmes which address matters of life or death, research priorities will be assigned on the basis of how they affect these areas. Biotechnology for agriculture could help meet the need for productivity by using cell tissue culture, nitgrogen fixation, and embryo transfer (for increased cattle productivity). In the area of human health, biotechnology can offer vaccines and the use of monoclonal antibodies for disease control.51/ All of these efforts seek to improve the quality of life for Nigeria in a region where there are primary concerns of survival.

Nigeria, along with the majority of the African region, is far from using or developing advanced genetic engineering and biotechnology techniques compared with developed countries. Unlike developing countries such as Brazil, which is now in a position to be concerned with competing on an international level in biotechnology, Nigeria's capabilities are limited to focusing on immediate and basic needs such as food, feed for animals, and vaccines to cope with diseases which threaten human and animal life. But while Nigeria may be one of the least advanced in terms of biotechnology capacity of the developing countries examined in this study, in Africa it is one of the countries with the greatest potential for developing capabilities in biotechnology related to their own economic and social needs. As a result of the structure of the international economic system and the obstacles it creates for countries like Nigeria, the country is presently in a position of dependency on developed countries to transfer technology to them, as their ability to develop entirely on their own is quite limited. In the long run, however, Nigeria may be able (with international support) to set up educational facilities to train a larger pool of their own scientists, and therefore direct research in biotechnology to meeting the specific needs of the country and region.

NOTES

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CHAPTER X

THE INTERNATIONAL CONTEXT FOR BUILDING BIOTECHNOLOGY CAPACITY IN DEVELOPING COUNTRIES 1/

It is not possible to assess the prospects for developing country policies and programmes in biotechnology without taking into account the broad contours and dominant characteristics of the emerging biotechnology industry on a global scale. As we enter the final decade of this century, several trends and characteristics in the global biotechnology industry are increasingly evident. These include:

1) The overall role of transnational corporations, which are becoming ever more dominant. Strategically, TNC actions at this stage of the biotechnology revolution cluster around the following goals:
   - Keeping their options open;
   - Assuring themselves maximum (and, if possible, preferential) access to the results of scientific research that appears to offer the potential of commercial exploitation;
   - Minimising their burden of risk by shifting it, insofar as possible and consistent with their maintaining as much control as they can over newly-developed products and processes, to others, typically the public sector;
   - Pursuing, and maintaining for as long as possible, monopoly and near-monopoly positions in the global market place.

2) Use by TNCs of patent law in both home and host countries to maintain their monopoly position in the market place. 2/

3) Phasing out of venture capital-financed firms as they are acquired by TNCs.

4) TNC cooptation of university-based research, increasingly undermining the global community of scientists.

5) Government actions, such as in the United States, to maintain their country's "competitive edge" by supporting the monopoly position of their TNCs.

6) Developing country researchers' dependence on a supply industry in biotechnology that is itself more and more "transnationalised".

7) Concerted efforts by all segments of the industry to evade accountability on the critical issue of the hazards to public health and the environment from biotechnology research, especially the experimental release of genetically engineered organisms.

8) Pressure to get high returns on investment in the short term and hence aggressive marketing of biotechnology-based products in monopoly or near-monopoly conditions.

Because so much of the global effort in biotechnology is concentrated in the industrialised countries, developing countries have a vital interest in international flows of this technology from one country to another. They also have an equally vital interest in different patterns of international cooperation that will help to increase their access on more equitable terms to emerging biotechnologies that have significant potential for application in their economies.

The context in which the vital interests of developing countries will be shaped is the changing government-industry-university interface worldwide but especially in the industrialised countries. In the paragraphs following this interface is examined with respect to the roles of government, universities, and industry. Concerns as they relate to university/industry/government links are also examined.

Government

Governments in both industrialised and Third World countries are becoming increasingly involved in the development of biotechnology for several reasons. One is the perceived importance of biotechnology through its potential impact across a number of industrial sectors such as pharmaceuticals, chemicals, energy, and food. Another is its potential role in international commercial competition.3/ Also of concern are some of the potential side effects of biotechnology - medical, environmental, social, and economic.

Recently, military implications of biotechnology - especially biological warfare - have resulted in increases in government funding of biotechnology research. The U.S. Defense Department spending on such research has increased from approximately US$5 million in 1981 to over US$40 million in 1986. The U.S. Government claims this is in response to similar U.S.S.R. research by the Soviet Union.4/

Several governments have pronounced biotechnology R&D a national priority or have otherwise devoted substantial resources to its development. In addition to the developing countries examined in this study, such as Cuba, Mexico, India, and Brazil, a number of industrialised countries have acted in a similar manner - for example, United States, Japan, France, and Canada. As we have seen, some have drawn up national plans for biotechnology while others have established national biotechnology companies to strengthen links between R&D and production such as France and the United Kingdom.5/

The strategic potential of biotechnology in achieving national economic and political goals is reflected in legislation introduced into the U.S.Congress by Senator Lawton Chiles of Florida and others. Entitled the "Biotechnology Competitiveness Act", this legislation provides for the establishment of a National Center for Biotechnology Information, and a National Biotechnology Policy Board to formulate policy recommendations that will "enhance the competitiveness of the United States in the development of commercial biotechnology-related industries and products". 6/

Because conditions of scale such as population, geographical area, and complexity of the institutional environment are similar to those found in many smaller developing countries, the emerging role in biotechnology of individual states within the United States of America may be significant and certainly bears watching. A recent survey of state-level activities related to biotechnology by the Wisconsin State Department of Natural Resources generated responses from all but six of the 50 U.S. states. Much of the activity reported is focused on regulation of biotechnology, especially the release of genetically engineered organisms 7/

Universities

In several of the countries most advanced in biotechnology R&D, universities and other research institutions have played the primary role in doing the basic research from which biotechnology techniques and processes were developed. Often the departments undertaking such basic research are funded at least in part (and often primarily) by public monies.8/

Universities are now (especially in the U.S.) engaged in a "race" for patents on biotechnology processes and products in addition to active financial and programatic links with industrial partners. Such practices have raised many questions regarding free flow of information and access to publicly-sponsored research at universities which have great importance for developing countries. These are further discussed below.

Industry

In the U.S. and several other industrialised countries (including Canada, the U.K. and France), there are two main types of industrial actors in biotechnology, although the importance of each varies - namely, transnational corporations and specialty biotechnology companies.

The involvement of TNCs takes many forms. They may enter into contractual research arrangements with universities or venture capital-financed firms; they may acquire partial or total equity interest in venture capital firms; or they may establish joint ventures with such firms.9/

In the United States and a few other industrialised countries, TNCs first entered the field cautiously, funding other R&D programs at universities and small companies in exchange for "windows" on the developing technology, and then creating their own in-house R&D capabilities. TNC strategies have, in general, been risk-minimizing and have been described elsewhere.10/ With the growing need to market products as these are developed - as well as to get them through often protracted regulatory mechanisms - and as the impact of biotechnology becomes increasingly evident to a greater number of TNCs, these companies are playing a more active role, both through in-house efforts and through acquisition of other companies and funding of research in universities and other institutions.11/

The second major group of industrial actors are the smaller, often venture capital-financed, specialty biotechnology companies, most numerous in the U.S., but also extant in the U.K., Canada, France, and a few other industrialised countries. In the U.S. alone, there are some 200-300 such companies. Some distinguishing features differentiating these companies (most of which have appeared only in the last 10 to 15 years) are already apparent.

These firms (such as Genentech and Cetus in the United States, Celltech in the United Kingdom, and Transgene in France) are relatively small in size (compared to the transnationals) and are usually established under the leadership of a prominent scientist, primarily to engage in research. They typically start off as privately held and with very low levels of capitalisation. After they establish themselves, the next stage in their evolution is to "go public" by offering equity investments through stock to any interested party. Their main "product" is R&D consultancy and services.

The final stage, which more such firms can be expected to achieve by the beginning of the 1990s, is their acquisition by TNCs. At that stage, most will "go private" again by becoming wholly owned subsidiaries of TNCs.12/

By far the most significant actors in the biotechnology industry, however, are transnational corporations active in several different industrial sectors: pharmaceuticals, chemicals, energy, food and beverage and, to a more limited extent, construction and design. These TNCs have developed strong linkages with universities and venture capital firms and also are establishing their own R&D, manufacturing and marketing activities in biotechnology.

Industry-University Links in Biotechnology

One of the features which differentiates the development of biotechnology products and processes from that of other advanced technologies is the extent of interaction between industry and academia through direct funding of R&D programs and institutes, through the setting up of separate companies by university-based researchers, often with support of larger corporations, and through agreements with individual scientists.

Many of the industry-university agreements set precedents for the dollar amounts of money concerned, and several of the earlier ones have raised concerns about academic freedom.

Funding of academic research is not the full extent of the industry-university interface. In the U.S. especially, several universities and local governments have gone to great lengths to attract industrial financing through other means. The setting up of industrial parks adjacent to universities is one such attempt. Among the first universities to be involved were the University of Missouri, Yale, the Polytechnic Institute of New York, Princeton and Stanford.

Trends in Industry-University-Government Arrangements

In the U.S., where industry-university links are perhaps most numerous, for example, nearly half of the companies which are engaged in biotechnology R&D, or which support such R&D, have arrangements with universities. A study undertaken in the mid-1980s indicates that as much as one-fourth of all biotechnology research at universities is supported by industry in the U.S.13/

More recent studies simply reconfirm the basic picture of growing industry-university links in biotechnology and suggest that, if there is a trend, it is toward intensifying those links. One of the largest data bases has been assembled by Sheldon Krimsky of Tufts University and now comprises some 800 "dual-affiliated scientists". Such DAS scientists include 30 per cent of the membership of the U.S. National Academy of Sciences in biomedical science.14/

One result of industry-sponsored research is that biotechnology faculty members at U.S. universities working with industry funds are much more likely to claim that their research has resulted in trade secrets and that their research directions have been influenced by industry priorities than those not receiving funds.15/ The impacts which such trends are having are discussed below.

Concerns Regarding University-Industry-Government Links

Since 1980, concerns over the extent of industry-university links have been expressed in a number of ways, especially in the United States.16/ Several conferences17/, articles, and reports by government and private institutions have discussed the implications of such links, as well as the benefits arising from them.

The first well publicised such conference was the so-called Pajara Dunes conference. Heads of five universities and 11 corporations met in early 1982 to discuss issues relating to university-industry ties. Concern focused on whether contracts between the two should be public18/, whether universities should grant exclusive licenses to companies which support research leading to a marketable product, what university policy should be regarding patenting, and whether agreements should be made between a university and a company in which a university researcher or administrator has a significant equity interest and/or is on the board of directors. While those who attended the conference were able to agree that these were all problems which needed to be addressed in drawing up such agreements, consensus was not reached on such issues, and several persons attending (especially university members) expressed concern over the impact of these issues on academic freedom and conflict of interest.19/

In 1982, David Noble published an article in The Nation on "The Selling of the University" in which he examined the agreement between the Massachusetts Institute of Technology and Whitehead for the formation of the Whitehead Institute.20/ The article goes beyond the concerns already mentioned (regarding academic freedom, possible distortion of a university's primary functions in teaching and advancing knowledge, and open dissemination of that knowledge), to discuss a larger public interest.

Much of the basic research which led to the development of biotechnology took place not in corporate labs but in university and other research institutes with a very significant infusion of government (i.e., public) money. Indeed, according to a recent article in the New York Times, 80 per cent of Harvard University's medical research is financed by the U.S. government.21/ That such publicly supported research should now lead to private profit for a few is another major concern in the development of biotechnology.

The 1984 study by the U.S. Congressional Office of Technology Assessment on commercial biotechnology22/ identifies five types of university-industry arrangements in biotechnology (consulting arrangements, industrial associates programs, research contracts, research partnerships and private corporations) and looks at problems relating to such arrangements, with a special concern for implications for international competitive positions in biotechnology. The OTA study notes four areas of concern in such relationships: increased secrecy on the part of university faculty; skewing of research toward profitable lines of inquiry; lawsuits for damages from products developed from university research; and a change in emphasis from universities competing for the best faculty to competing for the most lucrative lines of inquiry.23/

An additional concern raised by Professor Krimsky is that the number of ties between university-based researchers and industry has a bearing on the existence of an independent, "impartial" community of scientists on whom government and the public can rely for opinions regarding safety and environmental issues related to biotechnology. A sample of 291 biotechnology firms showed 362 academic scientists serving on scientific advisory boards of the companies. Of these, 64 were members of the National Academy of Sciences, 48 served on the National Institutes of Health Public Advisory Committees or Study Panels from 1982-1984, 235 were National Science Foundation research proposal reviewers from 1983-1984, and 19 served as U.S. Department of Agriculture proposal reviewers.24/

Another concern raised by university-government-industry ties is the increased funding of military-related biotechnology research (see section on Government above). The governments of the U.S. and U.S.S.R. are currently undertaking such research purportedly for defensive reasons.25/

The foregoing trends in and concerns about government-industry-university links in biotechnology have important implications for developing countries. In the paragraphs following several of these implications are discussed, including privatisation and the related issue of patenting, R&D priorities, and social impact, especially on the poor in developing countries.

Privatisation

One of the most significant features of the revolution in biotechnology in the industrialised countries is its predominantly private character. Approximately two dozen transnational corporations which play a leading role in manufacturing and marketing pharmaceuticals and petrochemicals are in the forefront of this revolution. That fact, coupled with the increasing private and proprietary character of biotechnology research in the United States and other developed countries, raises several crucial concerns for developing countries.

Privatisation inevitably creates problems of access: what was freely accessible earlier becomes, as a result of privatisation, either totally inaccessible or accessible under restricted conditions which are often onerous and usually more costly. For developing countries, in addition to lack of or restricted access, privatisation leads to the perpetuation of technological dependencies, inappropriateness of "packaged" technologies, and inequities regarding the costs and terms on which access to such "privatised" technologies can be secured. Moreover privatisation, whenever it occurs, restricts the free flow of research information, thus inhibiting the diversity, if not the pace, of technological innovation.

Privatisation also creates some important problems in the industrialised countries. It reinforces trends towards vertical integration among the giant transnational corporations. The takeover of seed companies and of small agrigenetic research corporations by a handful of major petrochemical, pharmaceutical, and other TNCs is a good example of this.

The problem of restricted access to technology is exacerbated by the increasing secrecy surrounding biotechnology research. Researchers in most private industries are restrained in the discussion of their work by corporate policies that seek to keep R&D results secret. This is also beginning to affect research being undertaken in universities. The commoditisation of science and the growing industry-university linkages in industrialised countries have endangered the traditional concepts of free access to the results of scientific research being undertaken within an "open global community of scholars" and of evaluations thereof by that community.

Proprietary concerns over advances in scientific work with potential commercial applications often get mixed up with foreign policy and national security issues in countries like the United States where there is widely perceived to be a close alliance between government agencies concerned with these issues and private industry.26/

There is increasing need in the industrialised countries to evolve guidelines which will ensure that the university remains a place for open, free and objective inquiry and that public funds are used by the universities in the public interest. From the developing country point of view, this trend of co-option by TNCs of public sector research institutions in the industrialised countries is justifiably alarming as yet another mechanism for reinforcing the trend toward privatisation of biotechnology.

Three concurrent strategies seem essential if concerns relating to the above are to be effectively addressed:

1) Development of indigenous capabilities in developing countries. This must be accorded highest priority and, in particular, the role of public sector institutions must be strengthened.

2) Strengthening of an international system built around the International Centre for Genetic Engineering and Biotechnology (ICGEB), the International Agricultural Research Centers (IARCs), and comparable networks.

3) Strengthening the negotiating capacity of developing countries which need (in the short run at the very least) selective linkages with the private sector in the U.S. and other industrialised countries in order both to gain access to technology from abroad as well as to speed up the commercialisation of indigenously-developed technologies.

Research and Development Priorities in Biotechnology

The directions which the present development of biotechnology processes and products has taken thus far are determined largely by the commercial potential of the products and processes and the size of their anticipated markets. Major investment has been made in the development of products for which a significant demand exists from consumers who are able to pay - and, even better, pay well - for such products. There has been relatively less concern for products of interest primarily to developing countries because even though the demand may be great, they cannot pay enough.27/

Biomass conversion technologies, for example, are at present not economically attractive to biotechnology companies in the industrial countries even though they are of great importance to developing countries. Many of the pressing needs of developing countries are ideal subjects for modern biotechnology: vaccines against tropical diseases, protein-rich food sources, alternative energy and pollution control. However, the dominant role played by the TNCs in biotechnology R&D is much more likely to lead to skewed research priorities that are determined by and subordinate to their own global strategies.

Patenting of Biotechnology

Because of the commercial gains to be derived by the private sector from privatisation of biotechnology, there has been an increasing tendency in the industrialised countries to create property rights in such technologies by affording them patent protection through international conventions for protection of intellectual property such as the Paris Convention and the Union for the Protection of New Varieties of Plants (UPOV).

Developing countries should give serious attention to alternatives to joining such international conventions. These countries, of course, have a legitimate interest in safeguarding indigenous technological innovations. But this can be achieved in a variety of ways other than by creating property rights in such innovations. Within the country itself, for example, the person or institution responsible for the innovation can be rewarded through a variety of devices such as user fees or royalties on sales.

A more complex problem occurs when, for example, a new plant variety developed in Mexico was patented in the United States by a U.S.-based TNC and then marketed around the world. To prevent a recurrence of this kind of situation one possible strategy would be for the developing country inventor to obtain patents in the relevant industrialised countries, although this might prove both expensive and burdensome. Developing countries need to take steps to secure clarification of the law governing international recognition of such patents so that patents obtained through stolen inventions will be denied international protection.

Biotechnology and Social Dislocation

Developing countries are confronted by a vexing dilemma in biotechnology. On the one hand, applications of this technology offer important and significant opportunities to improve human welfare. On the other hand, the path along which biotechnology is now developing, primarily in the industrially advanced countries, makes it very likely that the diffusion of these technologies will lead to major social dislocations and adverse impacts on significant segments of the populations of developing countries.28/

In short, there is no place to hide from such a revolutionary technology in the late twentieth century, and even "bystander" countries - and groups in these countries - are going to be affected. A good existing illustration of the kind of developing country product displacement that is likely to occur through the development and application of biotechnology in the years ahead is that of sugar, for which fructose made from maize grown in the industrialised countries is emerging as an effective substitute.

This displacement has spelled disaster for sugar-exporting countries as they no longer can control the price or quantity of their exports. Whenever the relative price or availability of maize makes it a preferable alternative, the overall demand for sugar will fall.

Another example of crop displacement in a developing country is provided by Mexico's experience with steroids. Mexico used to be one of the major growers and exporters of diosgenin from the barbasco plant. Diosgenin was one of the basic materials used in the production of steroids, a class of drugs of major importance to the pharmaceutical industry. Several TNCs, including Upjohn, Searle, Mitsubishi, Schering and Gist-Brocades, were able, through genetic engineering, to bypass the need for diosgenin from barbasco in producing steroids.29/

Yet another form of displacement occurs when tissue culture technology displaces a traditional industry in which plants are the source of a chemical or pharmaceutical. Often developing countries will be the source of the plant genetic material which will be used abroad to produce the compound through tissue culture.

Some developing countries are developing a counter-strategy by starting their own indigenous tissue culture laboratories (as India has done with German assistance regarding certain rare Indian medicinal plants). But this means that the country may end up competing with its own primary products.30/ It is hardly surprising, therefore, that many developing countries are beginning to realise that their plant genetic resources represent a valuable resource which they have been too liberal in providing to all who request it. They are now negotiating for a more equitable international arrangement to be undertaken governing the exchange of such resources.31/

Governments, universities, professional bodies, and public interest groups in developing countries need to monitor developments in biotechnology R&D in industrialised countries and devise "early warning systems" regarding displacement of their products through the application of biotechnology.

Biotechnology and the Poor

Biotechnology is, at least in theory, a neutral set of technologies. In developing countries it may be employed with a variety of results, ranging from enhancing socio-economic equality to exacerbating historical inequalities of ownership and power.

Agro-forestry, for example, can provide the "raw material" for several biotechnology applications. This might result in strong pressure to withdraw land currently under cultivation with low-cost food crops of particular importance to the poor. Already in some developing countries with a growing meat industry (for export or consumption by local elites), an unfortunate competition is emerging between man and beast for food.

The application of tissue culture technology may further displace local labor. Given the advantages of tissue culture techniques, it is likely that there will be an increasing shift to use of those techniques. But this will have a labor-displacing effect since the number of workers required for tissue culture production tends to be much lower than in traditional industries that produce chemicals from plants.32/

Biotechnology, at least in theory, offers the possibility of break-throughs which can be targeted to the poor - e.g., the development of high-yielding, disease-resistant strains of cassava and other food stuffs.

There are other important implications of developments at the global level that have significant implications for developing countries such as the impact of biotechnology products and processes and their testing on the environment. But the issues addressed in the foregoing discussion are indicative of the critical significance of global trends in biotechnology in assessing the effectiveness of and prospects for biotechnology policies and programmes in individual developing countries.

NOTES

1. This chapter has been adapted from David Dembo, Clarence J. Dias, and Ward Morehouse, "The Vital Nexus in Biotechnology: Relationship Between Research and Production and its Implications for Latin America" (paper prepared for Symposium on Policies for Biotechnology, Ibero-American Congress and Cuban and International Seminar on Biotechnology and Interferon, Havana, 17-22 April 1989). See also David Dembo and Ward Morehouse, Trends in Biotechnology Development and Transfer, UNIDO Technology Trends Series No. 6, Vienna: UNIDO, June 1987.
2. Of patents granted in the U.S., for example, from 1963 to 1984, 85 percent of 222 patents in genetic engineering were granted to corporations (87 per cent of U.S. patents to foreigners were to corporations - primarily Japan, the Federal Republic of Germany, France, and the United Kingdom). Office of Technology Assessment and Forecast, U.S. Patent and Trademark Office, "Technology Profile Report: Genetic Engineering", 1984.
3. See, e.g., "Draft Report by a U.S. Government Interagency Working Group on Competitive and Transfer Aspects of Biotechnology", Washington, D.C.: McGraw Hill Publications, 1983, and U.S. Congress, Office of Technology Assessment, Commercial Biotechnology: An International Analysis Washington: Government Printing Office, January 1984.
4. In 1986, for example, the U.S. Pentagon announced plans to spend $42 million to fund 57 biotechnology projects. The U.S. claims that such expenditures are necessary to counter perceived Soviet advances in this area. "Controversy Grows over Pentagon's Work on Biological Agents", Wall Street Journal, September 17, 1986.
5. See, for example, OTA, 1984, op. cit., p. 323, for analysis of various countries' governmental support of biotechnology.
6. U.S. Congress, "Biotechnology Competitiveness Act of 1988" (S.'966, passed by the Senate on June 17, 1988, and introduced into the House of Representatives on June 22, 1988), Section 202(4)(B). The bill died in the House in 1988, but even though Senator Chiles has since retired from the Senate, observers of the Congressional scene expect it or a similar bill to be reintroduced soon. These observers believe that there are good prospects for a new bill passing both houses of Congress and being signed by the President into law as long as it does not involve large expenditures of money (which the original Chiles bill, S.1966, did not).
7. Wisconsin Department of Natural Resources, State Agency Biotechnology Report and Survey Results: Legislative and Regulatory Activities, Madison, Wisconsin: The Department, December 1987 (Final Report).
8. See the discussion, by way of illustration, of lessons to be learned from development of microelectronics in OTA, op. cit., p.415.
9. Examples of TNC relationships with biotechnology companies and universities are explored in David Dembo and Ward Morehouse, Trends in Biotechnology Development and Transfer, UNIDO Technology Trends Series No. 6, June 1987.

10. See Dembo and Morehouse, UNIDO, op. cit., especially Chapters II and V.
11. As of 1983, for example, some 83 of the 500 largest U.S. corporations and 62 of the largest non-U.S. were active in biotechnology (Ward Morehouse and David Dembo, Transnational Corporations in Biotechnology (Draft Report prepared for the United Nations Centre for Transnational Corporations, New York), December 1983. Revised Draft, October 1984, pp. II-10 to II-19).
\- This transition is already evident in some recent takeovers, including the Eli Lilly purchase in 1985 of Hybritech, one of the first biotechnology companies to bring products (diagnostic kits based on monoclonal anti-bodies) to market; Monsanto's takeover of G.D. Searle and Continental Pharma, S.A. (Belgium) to improve its production and distribution systems; Kodak's equity stakes in Genencor, Inc., Amgen Corporation, Immunex Corporation, Cetus and Engenics, Gibco's purchase of Bethesda Research Labs; Johnson & Johnson's purchase of Immunotech; etc.
13. David Blumenthal, et al, "Industrial Support of University Research in Biotechnology", Science, January 17, 1986.
14. Sheldon Krimsky, "University Entrepreneurship and the Public Purpose", paper being published by the American Association for the Advancement of Science, Washington, D.C., pp. 35-36 (proof copy). See also his "The New Corporate Identity of the American University", Alternatives (date uncertain).
15. David Blumenthal, et al, "University-Industry Research Relationships in Biotechnology: Implications for the University", Science, June 13, 1986.
16. In other countries, the concern is often the opposite. The U.K., the Federal Republic of Germany, and France, for example, have been equally concerned with how to improve and increase ties between universities and industry. In these countries it is often felt that the university-based researchers would be "contaminated" through contact with industry. For such reasons, governments in these countries have become actively involved in pushing such links, either through setting up biotechnology companies to bring the two together (e.g., Celltech), or through funding joint research programs (e.g., the research "club" formed between six universities and five companies (including Celltech) and the Science and Engineering Council in the U.K. or the BMFT/corporate funding of national centers of excellence in the Federal Republic). "Biotechnology Taking Root in West Germany", Bio/Technology, April 1984; "Industry and Universities Prepare to Study Proteins", New Scientist, June 20, 1985; "German Firms Move into Biotechnology", Science, December 24, 1982; "France Seeks a Biotechnology Payoff", Chemical Week, March 10, 1982; "France Entices Its Biotechnologists into Industry", New Scientist, March 25, 1982; "Oil Firm Pins Its Hopes on Genetic Research", New Scientist, March 11, 1982.
17. In addition to the Pajaro Dunes conference discussed below, similar topics have been discussed at the University of Pennsylvania December 1982 conference on university-corporate relations in science, at the New York Academy of Sciences in 1983, and at hearings before the U.S. Congress. "University-Academic Ties: Profit Over Progress", New York Times, February 1, 1983.
18. The Hoechst-Massachusetts General Hospital agreement was made public through U.S. Congressional pressure. While Harvard generally does not make such documents public, Stanford University, also represented at the conference, does. "Pajaro Dunes: The Search for Consensus", Science, April 9, 1982.

19. Ibid., and "Biotechnology Firms and Academics Meet on Research Accords". Wall Street Journal, March 29, 1982; and "Conflict of Interest on the American Campus". The Economist, May 22, 1982.
20. David Noble, "The Selling of the University". The Nation, February 6, 1982.
21. "Harvard to See Research Profits", New York Times, September 15, 1988.
22. OTA, 1984, op. cit., Chapter 17.
23. Ibid., p. 412. The OTA presents the recommendations of the Subcommittee on Investigations and Oversight and the Subcommittee on Science, Research, and Technology joint hearings on these issues:
    1) universities should prepare guidelines for industrially sponsored research that require open disclosure of all faculty consulting and contractual agreements; and
    2) full-time faculty should be discouraged from holding equity or directing such firms. The subcommittee further recommended that there be continued review by universities, industry, and the Federal Government of the benefits and problems resulting from large-scale corporate support for and involvement in university research programs in biotechnology.
24. "Corporate-Academic Ties in Biotechnology", Genewatch. September-December 1984.
25. The .S. Department of Defense claims, for example, that it needs to develop vaccines against viruses that the "enemy" might develop using genetic engineering to attack.
26. See for example, letter to the Editor from Professors Barry R. Bloom and Anthony Cerami, MD. New York Times, November 1, 1988.
27. The malaria vaccine provides an example of this. Research by Ruth and Victor Nussenzweig at New York University was funded by the U.S. Agency for International Development and by the World Health Organization. Genentech had expressed interest in marketing the vaccine, but in 1983, it is said to have withdrawn from the project because it was unable to obtain an exclusive license.
28. Two useful recent collections of articles which examine social dislocation and other developing country concerns regarding biotechnology are Research and Information System for the Non-Aligned and Other Developing Countries, Biotechnology Revolution and the Third World: Challenges and Policy Options, New Delhi, India: RIS, 1988, and Biotechnology - The Will to Manipulate is Human But What do we Want?, special issue of Development, Rome: Society for International Development, 1987 (No. 4).
29. Daniel Goldstein, "Three Case Histories of Biotechnology in Latin America", ATAS Bulletin: Tissue Culture Technology and Development. Issue I, November 1984.
30. Frederick Buttel, Martin Kenney and Jack Kloppenburg, "From Green Revolution to Biorevolution: Some Observations on the Changing Technological Bases of Economic Transformation in the Third World", Economic Development and Cultural Change, Vol. 34, No. 1, pp. 31-56.
31. For further information on the current debate on plant genetic resources, see ICDA Seedling, May 1987.
32. For example, animal feed may be replaced by a process that uses genetically-engineered organisms and new fermentation techniques to produce single cell protein from feedstocks such as methanol. One such process, developed by Imperial Chemical Industries in the United Kingdom, requires only one-tenth of the labor power employed in the production of soybean meal, a product it could replace.

CHAPTER XI

ASSESSMENT OF AND LESSONS FROM DEVELOPING COUNTRY EXPERIENCE IN BIOTECHNOLOGY

As the preceding chapters on individual countries reveal, various approaches to strengthening national capacity in biotechnology are being pursued. They range from the creation of a separate government department (e.g., India) or a "national programme" (e.g., Argentina and Brazil) with responsibility for stimulating, coordinating, and facilitating work on biotechnology to the establishment of major R&D institutions with significant concentrations of resources, both human and material (e.g., Thailand and Cuba).

The experience with these various approaches is relatively limited in time. Almost all have been initiated in the last decade, and in a number of cases, within the second half of that decade.

Even those efforts that were initiated in the early 1980s have not yet accumulated enough of a track record to make possible any kind of definitive assessment of their impact and the extent to which they have been able to achieve the goals set for them. And for national programmes in biotechnology that have gotten underway more recently, it is even more difficult to make such an assessment.

Both because of these considerations and because the situation in each developing country is distinctive, explicit comparisons about the relative effectiveness of different approaches to building national capacity in biotechnology are impossible - certainly at this stage and very likely even in the future when there is more historical experience on which to make assessments of the progress of individual countries. Suffice it to say that other developing countries considering the next steps in strengthening their capacity in biotechnology would do well to consider a variety of possible approaches and then evolve a pattern distinctive to their own needs and opportunities. In doing so, it almost certainly will be useful to look closely at the experience of other countries of roughly comparable character. Toward that end, governments about to make a move in biotechnology will want to have those responsible for designing such a move visit other developing countries to acquire first-hand understanding of the problems encountered and achievements realised. They may also want to involve scientists, administrators, and policy makers from other countries as consultants in their own planning process.

While definitive evaluation and comparison of the experience of specific developing countries in strengthening capacity in biotechnology is not possible at this stage, some lessons are beginning to emerge from what these countries have done so far. These lessons do not, of course, apply equally to all countries but they do seem to be found in a significant proportion of those countries included in this study.

First and foremost is the wide gap which exists between plans on paper and what is actually happening on the ground. That there should be some gap is understandable; even in the most advanced industrialised countries, paper plans will always be ahead of actual performance. But in too many of the countries included in this study, the gap is very wide indeed, and a concerted effort will need to be made to diminish that gap if these programmes are in fact to contribute significantly to the achievement of the goals set for them.

Another important characteristic of these national programmes in biotechnology is that most of them lack a sharp enough focus to be effective. Not only is the gap between policy and performance very wide but the formulation of specific programme components is much too ambitious for the resources, financial and human, available.

Closely related are two further points. One is the inadequate commitment of resources, especially financial, to the programmes that have been set forth - an obvious reason for the gap between policy and performance. The other is the frequent lack of well defined objectives. This is, of course, a widespread problem in R&D programmes everywhere, but especially in developing countries where resources are much more limited. The understandable disposition of those responsible for defining objectives and allocating resources is to be "additive" - i.e., to include, at least to some extent, most, if not all, of the schemes of research workers within R&D institutions which they are supposed to be coordinating. This disposition to include at least a little of almost everything results in a proliferation of research activity in many different directions. And those research workers proposing different schemes are likely to overstate their objectives in order to justify increased support.

Yet another concern is the tendency to follow research priorities that are fashionable in the industrialised countries. This leads to efforts which are at best only marginally relevant to the most urgent economic and social needs of the countries concerned. At the same time, it needs to be recognised that this is not an easy problem to address for those responsible for planning and administering biotechnology programmes in developing countries. Because of the cumulative nature of scientific research, the most significant advances on which to build future research work are taking place where the concentration of scientific effort is greatest - i.e., the industrialised countries - and that research naturally reflects economic and social conditions in those countries. The problem is further compounded because the highly privatised character of the development of biotechnology in industrialised countries, which was discussed in the preceding chapter, puts major emphasis on developing products for which there is strong market demand from customers who can afford to pay.

Furthermore, because companies with biotechnology-based products often enjoy a monopoly or near-monopoly position in the market and thus are able to exact very high prices for "unique" products for which there is keen demand, the customers should be able to pay very well. A classic example is the anti-blood coagulating medicine developed by Genentech, TPA, which is typically administered to heart attack victims right after they have suffered attacks and is reputed to be a life-saving measure. When Genentech first came on the market with this product, it was priced at $2,000 a dose!

The problem of defining research priorities that are directly related to critical economic and social needs within the countries concerned is thus an inherently difficult one. The fact that there are very many critical economic and social needs does not make the task of defining research priorities any easier. And while there may be a tendency, for some of the reasons indicated, to follow research priorities that are fashionable in the industrialised countries, there is also a serious effort, found in varying degrees in the national biotechnology programmes examined in this study, to relate priorities in those programmes to specific needs within the countries concerned.

Addressed too infrequently in national programmes for biotechnology is the urgent need for regulating the health and safety of workers involved in developing products and processes and the exposure of people and the environment to such products and processes when released. And when safety issues are addressed, there appears to be a tendency to follow what is being done in the industrialised countries. Such procedures and regulations may or may not be suitable for developing countries, where quite different economic and social conditions exist. It needs to be recognised, furthermore, that in some industrialised countries at least, safety standards and regulations are heavily influenced by private industry and may not adequately protect the public and the environment, even in those countries.

Not all of the lessons of the 1980s are to be found in the developing countries themselves. At least as significant are trends in the industrialised countries which were discussed in the preceding chapter and which often have adverse effects on what is being attempted in the developing countries. The distorting impact of research priorities in the industrialised countries has already been noted. Also crucial is the continuing drain of some of the best scientific talent in biotechnology from developing countries to major R&D centres in the industrialised countries. And the pervasive phenomenon of privatization of not only commercial development but also supporting scientific work makes the access of developing countries which are serious about building their national capacity in biotechnology much more difficult. As has been noted in the individual country chapters in this study, developing countries are attempting to take initiatives to counter these trends - for example, involving scientists from those countries now working in the industrialised countries as consultants in planning or evaluating research work. Yet another initiative is to try to attract some of these scientists, especially younger ones, back to their country of origin through offers of research support and other facilities.

A related issue arises from cases reported of industrialised countries using developing countries to avoid safety and environmental regulations and other restrictions on R&D work in biotechnology. Thus, developing countries become "testing grounds" for biotechnology-related products and processes in situations where it would be much more difficult to undertake similar testing in industrialised countries. There is an understandable concern in developing countries, reflected in the national experience of several countries examined in this study, that their peoples not be used as "human guinea pigs" in clinical trials of new pharmaceutical products that are likely to be marketed primarily in industrialised countries or that would be prohibitively expensive and therefore out of the reach of all but a tiny handful of the populations of developing countries even if they were marketed there as well.

One other critical issue mentioned in the preceding chapter deserves repetition because of its vital importance to the future of biotechnology in developing countries. This concerns the protection of intellectual property through patents and patent-like arrangements. Developing countries, including some covered by this study, have been experiencing considerable pressure from some industrialised countries to bring their national systems for protection of intellectual property into conformity with the arrangements that prevail in many industrialised countries. This applies particularly to patent protection of micro-organisms and new life forms. Developing countries would do well to examine very closely the negative, as well as positive, impacts of adopting these arrangements for themselves in their efforts to develop and use biotechnology to serve critical and widespread economic and social needs of their peoples.

Another important lesson from the 1980s needs to be mentioned. There is an urgent need for much greater coordination among international agencies and development institutions concerned with the promotion of biotechnology and the regulation of its impacts in developing countries. In Latin America, for example, there are at least ten different agencies involved in this effort. The tendency is for each of them to insist upon an identifiable programme activity to which that particular agency is linked - even if this means duplication of existing or similar programme arrangements and the diffusion of scarce human and other resources. The inevitable result is that all too many initiatives remain at a sub-critical level and are unable to achieve effectiveness.

At the same time, international cooperation has a vital role to play in strengthening biotechnology in developing countries. Indeed, that role becomes all the more important because of trends in industrialised countries such as privatisation that are making access to significant developments in biotechnology more difficult. And new international institutions like the International Centre for Genetic Engineering and Biotechnology offer the hope not only of assisting developing countries in strengthening their own work in biotechnology and in facilitating the sharing of developing country-based expertise but also in building bridges to at least some of the industrialised countries that are prepared to be more forthcoming in their dealings with developing countries in different areas of application of biotechnology to vital needs in human health, agriculture, energy, and other sectors of society.

Finally, it should be emphasised that, while there are many problems facing developing countries in their efforts to strengthen their capacity in biotechnology, there are substantial achievements as well. The chapters on individual country programmes in this study provide numerous examples of such achievements. In general it can be said of most, if not all, of the countries included in this study that they have managed in the 1980s to put in place a basic infrastructure for further work in biotechnology and to get started on the necessarily long-term capacity of building up their human resources and research facilities in biotechnology. Certainly, they are better positioned to try to take advantage of what biotechnology may be able to offer in the 1990s than are those developing countries which have thus far made little or no effort to build up their capacities in this vibrant and rapidly changing arena of scientific work and its application to vital economic and social needs.

As we enter a new decade and the possibilities for potential economic and social benefit from biotechnology become ever closer, nonetheless, it is crucial that the lessons from the 1980s noted above be taken into account in the ongoing endeavour to build capacity in biotechnology in developing countries.

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