Intermediary Biotechnology Service

A Biotechnology Research Management Study

Joel I. Cohen

Biotechnology Priorities, Planning, and Policies

A Framework for Decision Making

isnar

Research Report

NUMBER

6

The mandate of the International Service for National Agricultural Research (ISNAR) is to assist developing countries in bringing about lasting improvements in the performance of their national agricultural research systems and organizations. It does this by promoting appropriate agricultural research policies, sustainable research institutions, and improved research management. ISNAR's services to national research are ultimately intended to benefit producers and consumers in developing countries and to safeguard the natural environment for future generations.

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The research for this publication was financed by the Netherlands' Minister for Development Co-operation. Responsibility for the contents and for the opinions expressed rests solely with the authors; publication does not constitute an endorsement by the Netherlands' Minister for Development Co-operation.

Citation

Cohen, J.I. 1994. Biotechnology Priorities, Planning, and Policies: A Framework for Decision Making. A Biotechnology Research Management Study. ISNAR Research Report No. 6. The Hague: International Service for National Agricultural Research.

AGROVOC Descriptors

Biotechnology; decision making; planning; policy; technology transfer

CABI Descriptors

Biotechnology; decision making; planning; policy; research policy

ISSN 1021-4429
ISBN 92-9118-015-1

Intermediary Biotechnology Service

This report is the third in a series of related research and program-management reports from the Intermediary Biotechnology Service that appear as ISNAR Research Reports. Each IBS report elaborates issues involved in biotechnology research program management and policy formulation, including needs assessment. One provides a comparative description of the different approaches taken by developing-country governments to stimulate biotechnology research. Another reviews the current international debate on intellectual property protection and assesses the policy options and implications for developing countries. A forthcoming report will give an overview of international initiatives that have as a common goal the application of biotechnology to tropical agriculture. It will also review opportunities for national institutions in developing countries to collaborate with international biotechnology programs. Other forthcoming reports will address future needs and priorities for biotechnology research on livestock, and the potential effects of biotechnology on tropical beverage crops, small-scale producers, and international markets.

The Intermediary Biotechnology Service

The Intermediary Biotechnology Service (IBS) was established by an international group of donor agencies to act as an independent advisor to national programs in developing countries on matters of biotechnology research management and policy. The IBS is headquartered at ISNAR, where it represents a continuation of activities begun in 1988 under a four-year program of ISNAR, the World Bank, and the Australian government, titled Agricultural Biotechnology: Opportunities for International Development.

The establishment of the IBS resulted from a recommendation of the Biotechnology Task Force (BIOTASK) of the Consultative Group on International Agricultural Research (CGIAR). BIOTASK conducted an extensive investigation into the problems and potential benefits of applying biotechnology to agricultural research in developing countries. It recommended that a demand-driven, problem-oriented advisory service be established to make available the expertise of advanced biotechnology institutes to the developing countries. The Government of the Netherlands provided funding to implement this recommendation in late 1992.

The IBS is guided by a Steering Committee composed of representatives from client countries, contributing donors, and the implementing agency, ISNAR.

Functions

The current program of the IBS has three main functions:

- **to assist national agricultural research systems in developing countries with biotechnology research program management and policy formulation;**
- **to carry out country studies to identify priority problems amenable to solution through biotechnology;**
- **to identify international biotechnology expertise and enhance its availability to national programs in developing countries.**

The IBS also advises bilateral and multilateral development agencies on biotechnology issues affecting developing countries.

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ACKNOWLEDGMENTS

This report has benefitted from comments and review by a number of people to whom the author is especially grateful. Special thanks to Barry Nestel for his attention to the editorial, technical, and contextual aspects of the report. Appreciation is also expressed to Richard Manning of the Economic Development Institute (EDI) of the World Bank for the opportunity to prepare the paper, *Innovations in Agricultural Research*, for an ISNAR/EDI World Bank regional meeting, *Adjustment and Research In African Agriculture*, which was held in Nairobi in March 1993. This research report is based on that paper.

John Komen, information specialist for IBS, has contributed comments that have been critical to ensure the utility, relevance, and context of information provided. He also provided information contained in the sections on socioeconomics and the IBS data base, *BioServe*.

In addition, a number of specialists have contributed to the revised format, citations, and the information presented. Their names are listed in Annex 1. The report has also benefitted from and includes analysis of data gathered for the recent IBS meeting, *International Agricultural Biotechnology Programs: Providing Opportunities for National Participation.* Subsequent discussions and review of information collected by IBS on BioServe has taken place with national policymakers, agricultural research directors, and financial officers in selected developing countries.

Other reviewers at ISNAR include Howard Elliott, Pablo Eyzaguirre, Douglas Horton, Willem Janssen, Steve Tabor, and Carlos Valverde, all of whom did much to refine the discussion of the decision-making process and develop the actions and topics included. Appreciation is also extended to Hans Wessels of the Directorate General for International Co-operation (DGIS) for his review and comments. Finally, the author acknowledges the contribution of a paper by H.K. Jain, commissioned by ISNAR, for the synthesis of and introduction to the national agricultural research systems (NARS) of developing countries.

Special thanks is also extended to Isabelle Hand, Carmel van der Heijden, and Fionnuala Hawes of ISNAR for their professional secretarial, proof-reading, and type-setting support.

FOREWORD

Policymakers and researchers in developing countries face numerous challenges in developing technologies to help feed growing populations while sustaining the natural resource base. Biotechnology is regarded as a means serving both ends, contributing to increases in productivity and providing alternatives and options to safeguard the necessary means for agricultural production.

Despite the diminishing budgets available for national and international agricultural research, a growing number of countries view biotechnology as a priority for national development and have already made sizable investments in biotechnology programs. In addition, the international donor community has become increasingly involved in funding agricultural biotechnology initiatives. These combined efforts transcend publicly funded national agricultural research, and involve farmer, nongovernmental and commercial organizations, as well as research institutions external to the traditional agricultural system.

Applications of biotechnology should have special relevance for addressing food constraints faced by small-scale farmers as more than 70 percent of food production in developing countries occurs on small-scale or resource-poor farming systems. These farmers require products from biotechnology adapted to their environmental and socioeconomic conditions.

Transforming biotechnology applications, efforts and priorities into realistic programs for and in many countries, however, raises very complex issues: Which priority problems can be addressed by biotechnology? Which technologies are relevant and accessible, and what will be their likely cost and impact? How can modern biotechnology be integrated with conventional agricultural research? How must NARS deal with questions, such as those related to biosafety and intellectual property rights, that go beyond the agricultural sector? How can we ensure that investments in advanced research yield applicable products that are also appropriate to resource-poor farmers?

This report offers readers a systematic study of the issues involved in planning national biotechnology initiatives, including policies, priorities, and research management, and discusses many of the questions posed above. It serves as the centerpiece for the set of related publications from the Intermediary Biotechnology Service (IBS) dealing with management issues regarding policy, needs assessment, and planning for biotechnology. It aims to stimulate a dialogue between policymakers, scientists, and end users on these questions and to contribute to informed decision making. It also provides a means for determining opportunities and priorities for collaboration between international biotechnology programs and national agricultural research institutions. We expect IBS to play a catalytic role in this process, and are pleased to jointly present this report.

Christian Bonte-Friedheim
Director General, ISNAR

Hans Wessels
Chairperson, IBS Steering Committee

ABSTRACT

National agricultural research systems in many developing countries are evolving programs that use biotechnology to address constraints on productivity and to meet pressing agricultural needs. These programs challenge research managers and decision makers to identify relevant end users, develop national expertise, priorities, and policies for biotechnology, and to secure financial resources for implementation. This report describes a four-phase framework for decision making to assist directors of national agricultural programs and financial ministries in establishing priorities and policies for national biotechnology initiatives, determining design and implementation objectives, and considering avenues available for technology transfer. The decision-making process stimulates interaction among national, managerial, and research leaders to develop and advance a strategic approach for biotechnology activities that have often arisen independent of one another.

ABREGE

Dans de nombreux pays en développement, les systèmes nationaux de recherche agricole mettent au point des programmes où l'on a recours aux biotechnologies pour lever des contraintes à la productivité et pour satisfaire les besoins les plus pressants dans le domaine agricole. Ces programmes constituent des défis pour les gestionnaires de la recherche et les décideurs politiques : ceux-ci doivent identifier les utilisateurs ultimes, développer une expertise nationale et définir des priorités et des politiques en matière de biotechnologie, et obtenir les ressources financières requises pour mettre en oeuvre les programmes. Le présent rapport décrit une approche en quatre phases devant aider les directeurs des programmes nationaux et le personnel des ministères de finances à établir des priorités et à élaborer des politiques gouvernant les initiatives nationales en biotechnologie, à définir les objectifs au niveau de la conception et de la mise en oeuvre et à discerner les possibilités qui s'offrent sur le plan du transfert technologique. Le processus de prise de décision encourage les responsables—décideurs nationaux, gestionnaires et chercheurs—à interagir en vue de développer et de promouvoir une approche stratégique pour gérer des activités biotechnologiques qui souvent ont été lancées indépendamment les unes des autres.

RESUMEN

Los sistemas nacionales de investigación agropecuaria en muchos países en desarrollo están desarrollando programas para usar la biotecnología con el fin de afrontar problemas de productividad y para satisfacer las crecientes necesidades del sector agrícola. Estos programas retan a los líderes de la investigación y a los decidores a identificar usuarios relevantes, a desarrollar a nivel nacional la experiencia, las prioridades y las políticas relativas a la biotecnología, al mismo tiempo que aseguran los recursos financieros para la ejecución de programas. Este informe describe un marco de trabajo para la formulación de decisiones, constituido por cuatro etapas, que tiene el fin de asistir a los directores de programas nacionales de investigación y a ministerios de finanzas a determinar prioridades y políticas para iniciativas nacionales sobre biotecnología, a establecer los objetivos de diseño y ejecución, y a tomar en consideración posibles vías para la transferencia de tecnología. El proceso de formulación de decisiones estimula la interacción entre líderes a nivel nacional, a nivel de la gestión y el manejo, y a nivel de la investigación para desarrollar y promover un enfoque estratégico para las actividades de biotecnología que con frecuencia han surgido independientemente una de la otra.

ACRONYMS

ATAS	Advanced Technology Assessment System
BFZ	Biotechnology Forum of Zimbabwe
CRIFC	Central Research Institute for Food Crops—Indonesia
EC	European Community
CARN	Cassava Advanced Research Network
CBN	Cassava Biotechnology Network
CGIAR	Consultative Group on International Agricultural Research
CIAT	Centro de Investigación Agrícola Tropical
CIDA	Canadian International Development Agency
CRIFC	Central Research Institute for Food Crops
CTA	Technical Centre for Agricultural and Rural Co-operation
DGIS	Directorate General for International Co-operation—The Netherlands
FAO	Food and Agriculture Organization of the United Nations
IAEA	International Atomic Energy Association
IARC	international agricultural research center
IBS	Intermediary Biotechnology Service
ICGEB	International Center for Genetic Engineering and Biotechnology
ICRISAT	International Crops Research Institute for the Semi–Arid Tropics
IITA	International Institute of Tropical Agriculture
ILRAD	International Laboratory for Research on Animal Diseases
IPR	intellectual property rights
ISNAR	International Service for National Agricultural Research
KARI	Kenya Agricultural Research Institute
NARS	national agricultural research system(s)
ODA	Overseas Development Administration—United Kingdom
OECD	Organisation for Economic Co-operation and Development
REDBIO	Technical Cooperation Network on Plant Biotechnology for Latin America and the Caribbean
RF	Rockefeller Foundation
RFLP	restriction fragment length polymorphism
STOA	European Organization for Technology Assessment
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development

EXECUTIVE SUMMARY

Developing-country governments are having to make decisions about investments in biotechnology at a time of widespread downsizing of state institutions, liberalization of markets, increasing privatization, and deregulation of prices. The rapid expansion of public agricultural research institutes of the 1970s has ended and a reversal of this trend is unlikely. Economic adjustments, meant to help national programs deal with these financial realities, have underscored the importance of increasing the effectiveness of the agricultural sector and raising the productivity of agricultural land. Science-based innovations such as biotechnology are a key investment to help achieve these goals.

Decisions about agricultural research allocations need to be directly linked to economic objectives. Many programs and projects compete for limited budgets. For example, biotechnology can compete with conventional agricultural research for fund allocation. Thus priorities and funding for biotechnology are best determined by structured information and discussion between scientists at both the research and management levels, in conjunction with policies determined by decision makers at the national level.

This variety of financial, technical, and institutional issues highlights the complexity of the task facing national policymakers for agricultural research. It is all too easy to establish research programs that lack focus and accountability and are hampered by duplication. However, the speed of technological change in agriculture and the need for focused applications of new technologies necessitate informed decision making.

This report is aimed at national policymakers, administrative managers, and directors of research who make investment and institutional decisions regarding biotechnology for the national agricultural research system (NARS). Its purpose is to consider the potential costs and benefits of biotechnology-based research through a four-phase planning process. The decision-making framework presented considers the national policy environment and the institutional, financial, and program issues involved in setting priorities and determining needs for biotechnology-based research. The framework will help decision makers and research leaders ensure that resources allocated to biotechnology, including those activities supported by the international biotechnology programs and donors, are consistent with national objectives of efficiency, equity, security, or concern for the environment.

The four phases are as follows:

- setting policies and identifying priorities that address constraints on agricultural productivity for which biotechnology offers a comparative advantage,
- formulating a national program to address these priorities and policies,
- implementing and monitoring the research program,
- transferring and delivering technologies to end users.

In this report, the decision-making phases are introduced through an implementation sequence for agricultural research, as this emphasizes biotechnology's dependence on a strong conventional research base. Special attention is given to various aspects of biotechnology-based research where complications in planning can be anticipated. These complications include the need to develop priorities for application of the new technologies, the technology's relation to areas of public perception, such as biosafety requirements, and the additional technical expertise, funding, and institutional capacity required.

In conjunction with the four phases, the decision-making process is also analyzed from the perspective of three levels within a national program. These levels are as follows:

- research level, composed of scientists carrying out activities that may become or are already part of a national biotechnology initiative;
- management level, composed of administrative and research directors who are responsible for helping to structure the interface between research and policy; and
- national policy level, composed of decision makers from various ministries or departments responsible for national policies seeking to implement biotechnology.

Information on each phase can be used separately by national program leaders at various stages of the development cycle. In fact, topics covered in one phase relate to those discussed in others, making the development cycle a dynamic, interactive process. Time frames and objectives indicate appropriate expectations throughout the process.

In phase I, decision makers use priority-setting methods to first identify the constraints to productivity where biotechnology offers a comparative advantage and, second, to demonstrate that needs of end users are considered. These methods are discussed in Chapter 2 as well as key features of the public policy setting affecting the manner in which biotechnology research is undertaken and in which national initiatives will be planned.

In phase II, the design and development of a national biotechnology program is considered by management and research leaders in relation to relevant priorities and policies identified in phase I. As presented in Chapter 3, critical program elements are identified for management's consideration. Scientific review of both conventional and biotechnology-based research is discussed in relation to the proposed research initiative.

In phase III, special monitoring and evaluation needs are analyzed. As covered in Chapter 4, this also includes the importance of scientific accountability in relation to the priorities and program objectives established.

Phase IV discusses options to be considered by research, technology transfer agencies, and end users such that these considerations become part of the program's operational context and can be considered early in the planning process. As presented in Chapter 5, this includes options for public and private technology transfer.

1. INTRODUCTION

Following the introduction of biotechnology in most countries in Eastern Africa, the application of key technologies, particularly those relating to genetic modification, has been very slow. This mainly has been due to the acute shortage of a scientific base in biochemistry and molecular biology.

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Background on Biotechnology

Biotechnology has had major impacts on human health care during the last decade. New drugs have been developed including those that stimulate the immune system and help fight infections. New treatments are being used against renal cancer and hepatitis B and a growing number of therapeutic and diagnostic products are reaching the market (Burrill and Lee 1992).

Biotechnology also holds promise for millions of small and marginal farmers in developing countries. In the long term, it could provide a range of agricultural inputs and powerful tools for agricultural research. According to many in the agricultural development community, farmers' use of some agricultural technologies is limited because adoption requires purchased inputs such as chemical fertilizers and pesticides. Biotechnology may supplement or provide alternatives to these inputs, hence increasing efficiency. For example, new sources of genetic material can supply animals and crops with disease and pest resistance.

To take full advantage of biotechnology's applications to agriculture, however, national agricultural research systems (NARS) in developing countries must determine if biotechnology is needed to address national priorities and, if so, what changes to the national agricultural research and extension system are required to ensure their use. Biotechnology applications based on tissue culture and other related techniques are well within the reach of most NARS and can make significant contributions to agricultural production in the short term. Other applications are longer term and may require countries to take steps now to create the needed research capacity.

Defining Biotechnology

Biotechnology includes any technique that uses living organisms, or substances from organisms, to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses. Biotechnology has many traditional applications in agriculture. One simple example is composting, which builds soil fertility by encouraging microorganisms to break down crop residues. Another example is the production and use of vaccines to control animal disease; and cheese and wine making are among the many practical uses of biotechnology in the food-processing industry.

As these examples show, biotechnology is not a new development in agriculture. What is new are the modern techniques and applications derived over the last two decades.[1]

DNA—The Key Molecule

Modern biotechnology grew out of advances in biological sciences such as genetics, microbiology, biochemistry, and biophysics. These sciences have increased understanding of biological functions at the molecular level through the study of deoxyribonucleic acid (DNA).

DNA provides the molecular information that programs the growth and development of living organisms. Discrete portions of this information are referred to as genes. Each gene represents a particular functional unit of DNA. It is the genes, in combination with a range of interactions beginning in the cell and ending in the environment, that help to determine the characteristics of plants and animals. Thousands of gene combinations are possible, effecting a multitude of different traits, each of which can affect the growth and development of individual forms of life.

Genetic Engineering and Gene Mapping

Another major advance came with the discovery of two groups of restriction enzymes. One group cuts the DNA molecule at specific sites. The second group joins the pieces in new combinations. This discovery, leading to the ability to produce recombinant DNA molecules, forms the basis of genetic engineering. It has also increased scientists' ability to move genes across species boundaries, even when the species are completely unrelated, thus creating transgenic plants.

Twenty-five years ago it was unthinkable for plant breeders to transfer into rice plants genes from tomatoes or beans, and much less from bacteria. Now with the availability of recombinant DNA techniques this is not only possible, but genetic transformation of this kind has been successfully demonstrated under laboratory conditions for a wide range of agricultural crops. For example, transgenic plants of tomato, tobacco, cotton, and soybean have been developed with pest resistance derived from a group of toxin-producing genes, the so-called *Bacillus thuringiensis* or *Bt* genes from bacterial DNA. Another example is coat-protein–induced virus resistance, which has the potential to stem viral infections in tropical crops, such as mosaic virus in cassava.

It should be stressed, however, that impressive as these developments are they should be seen as supplements to conventional crop and animal improvement through breeding. This includes hybridization and selection. Sexual reproduction remains a powerful tool for producing a multitude of new gene combinations from which breeders can select for desirable traits. The strength of the new recombinant DNA technology lies in its ability to transfer specific genes across species that would not normally hybridize. Classical methods of plant breeding are still required to determine final agronomic acceptance of new high-yielding varieties.

Linkage analysis, that is, using visual or microscopic screening to determine if two or more genes generally located on the same chromosome tend to be passed on together to fu-

1 Biotechnology, as used in the rest of this report, focuses on cellular and molecular biology and new techniques coming from these disciplines for improving the genetic makeup and agronomic management of crops and animals.

ture progeny, has long been used by plant breeders to select plants carrying desirable genes. Now, modern techniques for gene mapping make available much more detailed information on gene location. This is especially important for complex traits difficult to select or determine in the field. The greater precision in linkage analysis offered by gene mapping is often accomplished through the use of restriction fragment length polymorphisms (RFLPs). These include markers for multiple-gene–determined traits. RFLP analysis is now being used to assist plant breeders in the detection and selection of newly introduced variation.

Tissue Culture—New Opportunities

The development of in vitro tissue and cell culture techniques has occurred parallel with advances in molecular biology and genetic engineering. In vitro techniques make it possible to regenerate a whole plant from a small piece of tissue, and even from a single cell, by growing it in a suitable medium. The underlying concept is the totipotency of cells, that is, a cell contains all the genetic information for the growth and development of the entire organism. Of course, this is not surprising considering that living organisms start life as a fertilized egg, which is also a single cell. For plants, tissue culture techniques can be of great value for achieving rapid multiplication of a desirable genotype, for example, a high-yielding clone of coconut. Promising biotechnologies for livestock include in vitro fertilization and embryo transfer.

Biotechnology and the NARS

Many important contributions to modern biotechnology have been made by scientists at research institutions in industrialized countries. This has resulted in a part of the technology being awarded patent protection. This fact, combined with the advanced scientific expertise needed to use these technologies, has raised concern about whether the traditional route of access to new innovations through the international agricultural research system will be sufficient to assist NARS in developing countries to initiate national biotechnology programs.

Need for Constructive National Approaches

Developing countries have many reasons to consider practical applications of biotechnology consistent with being able to maintain a strong conventional research base and the ability to develop their scientific capacity. However, first additional expertise will be required to take full advantage of relevant technologies. Developing this expertise should not be done at the expense of ongoing needs, but rather in a complementary manner. If new expertise in biotechnology addresses needs and priorities by supporting programs improving agricultural inputs, then it is farmers and consumers in developing countries who will benefit.

Second, policy concerns, such as patent protection for crop varieties and other life forms derived from the application of modern biotechnology, must be considered. There are those who argue that product patenting will stimulate investment in new research and that people making such investments should be rewarded. Others feel that patenting transgenic plant varieties will restrict free exchange of germplasm among breeders.

While discussions will continue for some time on these issues, there is general agreement that developing countries must consider relevant options to strengthen their research programs, including biotechnology, in order to build national research capabilities which apply technological advances to agricultural needs (Farrington 1989). Policy decisions encouraging biotechnological advancements derived from problem-oriented research will also increase the capacity of NARS to collaborate with the international agricultural research system.

Some developing countries have already begun this process, undertaking modern biotechnology programs, projects, or activities. These have included various combinations of scientific, institutional, and policy objectives to build national capacities in research. A number of these initiatives were recently reviewed by Komen and Persley (1993).

For other developing countries, a combination of pressing needs not requiring biotechnology, the inability to maintain a strong base for research, and lack of funding prevent such developments. Clearly, biotechnology is premature for countries with strained agricultural research infrastructures and wanting to avoid technology-led development.

Background for Priority Setting

Priority setting is an important first step in the development of a national biotechnology research program. In setting priorities, national policymakers and NARS managers should consider four factors. First, they should recognize that biotechnology is not a new discipline. Rather, it is a group of techniques that offers new approaches for addressing biological questions and problems. These relate to crop and animal production, gene identification and expression, food and feed processing, management of natural resources, and pollution control.

Second, most NARS directors are under pressure from government policymakers and planners to provide usable, short-term results. If biotechnology holds promise only in the long term, then funding for programs may not be sustained. Short-term applications therefore should be emphasized initially. Most developing-country NARS would do well to start with tissue culture techniques, such as the rapid multiplication of disease-free clones of plantation and horticultural crops. They should not take the view that modern biotechnology includes only transgenic plants produced through recombinant DNA techniques, as these are long-term priorities for most NARS. Few NARS, including those of developed countries, would start research programs based on transformation alone.

The third factor relates to resources. Applications of biotechnology differ in complexity and in the demand they place on national scientific and institutional resources. Issues of resources relate directly to opportunities for the effective integration of biotechnology-based approaches with the conventional agricultural research base (Cohen et al. 1988).

Finally, biotechnology programs must conform to national agricultural research policies balanced by technical realities and needs. For example, if cassava is a particularly important crop, and the tools of biotechnology can be harnessed to increase the production, processing, and nutritive value of cassava, then cassava becomes a priority for biotechnology. A clear definition of national goals and objectives, including efficiency, equity, security, or environmental concerns, for agricultural commodities helps this process. Policy guidance can provide for a research strategy that maximizes available resources, building biotechnology capacity as an extension of the existing research capability.

Framework for Decision Making

Already biotechnology is being used to develop new and higher quality food and fiber, crops with greater stress tolerance, and new uses for agricultural commodities (Beck and Ulrich 1993). These applications, and others addressing constraints on land productivity, require a new knowledge base for creating sustainable, yield-stabilizing technologies. However, there are concerns about who will benefit from this knowledge and the length of time before these benefits will be realized.

The framework for decision making that follows requires interaction between technical, financial, and policy specialists to focus NARS' resources on relevant applications of the new knowledge base. It promotes biotechnology through resource allocation consistent with identified national objectives. Selection of appropriate research activities increases if decision makers encourage (a) scientists to focus their work on set priorities with results expected in a timely manner, and (b) national policies that provide opportunities for research development and delivery. A recent example illustrating multilevel decision making for biotechnology in the context of national priorities for agricultural, health, environment, and energy for the United States is discussed in Annex 2.

Phases and Levels of Decision Making and Implementation

Four phases, which may vary in sequence, are required in making and implementing strategic decisions regarding a national biotechnology initiative:

- Identify research priorities for which biotechnology offers a comparative advantage and serves a demonstrated need and determine relevant national policies.
- Formulate a national research program with these priorities.
- Implement and monitor the program.
- Provide for the transfer or delivery of the results.

In the following chapters, a decision-making framework based on these four phases is used for discussing questions of technologies, priorities, and economics. The phases of decision making are comparable to those used in planning and designing conventional agricultural programs. This provides for the addition of biotechnology to the conventional agricultural research system. However, this report and its decision-making framework also focus on what are now special characteristics of biotechnology-based research. These include

- high costs of development, in the face of constrained science budgets;
- special challenges in the areas of public perception, biosafety, intellectual property rights, and accountability;
- integration of biotechnology with conventional programs, bringing about institutional changes;
- opportunities for international collaboration;
- increasing the range of products emerging from agricultural biotechnology; and
- risks for national programs that do not develop an internal capacity for working with and assessing the emerging technologies.

The decision-making framework presents these special considerations in a discussion based on the three levels necessary for making decisions affecting the NARS: research, management, and national policy. Table 1 outlines the four phases with the expected time required, objectives, and integration of responsibilities between each of the three levels of decision making.

The **research level** includes practicing scientists working to develop and apply advances in biotechnology to agricultural objectives. At this level, decisions about technology and programs are based primarily on scientific expectations and research experience.

The **management level** encompasses administrative officials of the agricultural sector, including the ministry of agriculture, directors of research, and senior management with primary responsibility for research and extension. At this level, decisions are based on both policy and technical considerations in relation to the potential impact of research on institutional mandates, objectives, and sector priorities.

The **national level** includes the ministries of finance, planning, justice, and science and technology in addition to the ministry of agriculture. This level thus goes beyond the NARS. Decisions are based largely on political goals. They involve, for example, funding decisions for the agricultural sector and its research subsector and decisions regarding agricultural trade implications and general economic policy.

Finally, many national biotechnology initiatives work closely with a range of international biotechnology programs in research, training, and information exchange. Research and management-level leaders participating in the decision-making framework should be aware of this extensive collaboration and its relation to their national planning process. Elements of these international biotechnology programs are introduced in sections of this report to ensure that national program development is not discussed in isolation, to familiarize national policymakers with the scope of their efforts, and to help national program directors benefit from their experiences.

Table 1. Levels and Phases of Decision Making

Phases of decision making	Years required	Objectives	Topics for decision-making dialogue and analysis	Integrating decision-making responsibility
Phase I: Priority identification and setting national policies	1-2	(a) Identify research priorities that are in agreement with production constraints and local needs (b) Identify relevant policy considerations	• Priorities, constraints, and needs • Public perceptions, biosafety, IPR • Integration • Financing • Rate of entry	National policy, Management, Research National policy, Management
Phase II: Program formulation	1-2	Determine program elements for national biotechnology initiative	• Determination of program elements • Scientific review • Cross-sector planning	Management, Research
Phase III: Program implementation and monitoring	3-8	Implement the program as designed and develop monitoring system	• Monitoring and evaluation • Socioeconomic analysis	Research
Phase IV: Technology transfer and delivery	1-3	Develop strategies to ensure that products reach farmers, growers, and consumers	• Product orientation • Technology transfer routes	Research, Technology transfer agencies, End users

2. PHASE I: PRIORITY IDENTIFICATION AND SETTING NATIONAL POLICIES

There is a lack of methodology to select and establish priorities in agricultural fields. Several groups of priorities for agrobiotechnologies have been set by government agencies in Mexico and the public-sector agricultural research system. However, the personnel involved have only a limited knowledge of modern biotechnology. Universities have not set priorities and have very little interaction with producers or government agencies.

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The objectives of the first phase of the decision-making framework are to set priorities for research and to examine the national policy setting in which such research will be undertaken.
Regarding the identification of research priorities, it is essential that these

- address significant constraints to productivity in agriculture,
- offer a comparative advantage for the application of biotechnology, and
- demonstrate a clear need for the final product of research.

Priorities for biotechnology research are often set independently at each level of a NARS. Linking these priorities to national development objectives requires coordinated decision making at the national, management, and research levels. Identified priorities are then implemented in the context of the national policy setting, organizational options, financing available, and the agreed-upon rate of entry.

Preparing an overview of existing national policies, priorities, and activities for biotechnology should be considered as an introduction to the decision-making framework. At this point, various national research issues will be identified, leading to their inclusion and discussion in the framework (Bunders and Broerse 1991). The overview provides information for participants at each level and a starting point for considering national agricultural objectives such as equity, efficiency, security, or environmental concerns. Review of priorities and policy decisions by scientists at the research level and managers at the sector level occurs in phase II, program formulation.

Determining Priorities, Constraints, and Needs

Priority setting in biotechnology is often complicated by pressing demands on overstretched budgets. While research and sector leaders examine the implications of biotechnology for their research programs or institutes, policymakers examine implications at a broader level, facing conflicting demands for financial resources among a range of national needs. With this diversity of needs and objectives, how is a national initiative in biotechnology planned? Are research efforts consistent with national priorities? If priorities have not been set, how are decisions about biotechnology reached in their absence? Obtaining answers to these questions explores the link between research planning and priorities, institutional budgets, and the rate at which biotechnology is to be advanced.

Many immediate needs of the agricultural sector are unlikely to be met by modern biotechnology. However, evidence of the techniques' growing utility is given by the increasing range of applications being explored for enhancing food production and quality (Beck and Ulrich 1993, ATAS 1992). Priority setting, when linked to resource-allocation policies, can determine elements of national agricultural research that would benefit from the addition of new biotechnologies. Clear policies and programs can focus research on national needs while providing selectivity and concentration of resources on key objectives (Liyanage 1993).

However, complications arise in determining priorities and policies. Ad hoc approaches for biotechnology have emerged, mostly from the research level, as not all scientists' objectives coincide with national objectives for agricultural research. Scientists often do not see the need for carrying out priority-setting exercises for biotechnology alone.

Recent analysis indicates that a growing number of national, regional, and international biotechnology programs are devoting considerable effort to priority setting (USAID 1989, Toenniessen and Herdt 1989, CTA/FAO 1990, NRC 1990, KARI 1991, DGIS 1991 and 1992, BFZ 1993). These include priority setting specific to crops or livestock, donor policy and programs, project objectives, and national programs in developing countries. The need to carefully link priority setting with the identification of both constraints to higher productivity and with farmers' needs and problems was presented by Bunders (1990).

A number of these priority-setting exercises are compared in table 2. No one method has been preferred, as each serves different organizational needs. Recommendations from the examples have led to new or increased support for biotechnology, provided either to ongoing programs or to newly identified biotechnology initiatives.

A divergence of mechanisms for priority setting is evident in donors' investments in biotechnology. Some donors have adopted an ad hoc approach, incorporating biotechnology "as needed" into agricultural projects. Other donors have developed a special policy to guide bilateral biotechnology investments (DGIS 1992). In yet other cases, such as for USAID, priority-setting, policy, and planning exercises are undertaken to address specific project-level needs, with no comprehensive policy emerging (NRC 1990). Differences can also occur between research-oriented priorities and user-oriented perspectives. These distinct but related views may lead to different recommendations for the same crop (DGIS 1991).

In many parts of the developing world national biotechnology policies and priorities are noticeably lacking. This is often related to inadequate science and technology policies (FAO 1993). While countries have participated in crop, livestock, or program-specific priority-setting exercises, in general these efforts have not been extended to the national level.

For the policy and planning framework presented in this report, a balanced view of priority setting is needed, combining the technical realities and specialized requirements of modern biotechnology with identified local needs. Each national program determines a priority-setting process to address these needs and national objectives. For such a process to be effective, it should provide an environment conducive to making difficult choices, taking into account economic feasibility, time frames for expected commitments, criteria by which end users and technologies are selected, and relation of priorities to relevant national policies. This is facilitated by involving scientists in national policy making, and by preventing priorities from being set by scientists isolated from economic realities (World Bank 1993).

Table 2. Summary of Findings and Recommendations of Priority-Setting Studies for Biotechnology

Nature of priorities **Citation and date of report**	**Organizations involved in the study**	**Priorities**	**Considerations and/or criteria**
• Crop-specific (rice) • Foundation-specific The Rockefeller Foundation's International Program on Rice Biotechnology (Toenniessen and Herdt 1989)	Rockefeller Foundation	• Develop a knowledge base and biotechnology tools for rice • Genetic maps and markers • Genetic transformation • Clone/characterize rice genes • Host-pathogen interactions	Foundation sought to identify the following: • needs not being addressed by others that could attain high degree of synergy among activities, • needs allowing for eventual foundation disengagement, • a ranking of priority traits for support.
• Crop-specific (cassava) Cassava and Biotechnology (DGIS 1991)	DGIS-sponsored meeting with the Wageningen University of Agriculture, and the Free University of Amsterdam, the Netherlands; USAID; EC; ODA; UNDP; World Bank; RF; CIDA; UNIDO; ISNAR; FAO; CIAT; IITA; ICGEB; IAEA	• Improve cassava and solve constraints faced by cassava farmers • Genetic improvement of cassava • Germplasm conservation and exchange • Socioeconomic and interdisciplinary studies to understand complex and unique cassava issues	CBN assesses cassava constraints and opportunities in collaboration with cassava researchers using an interdisciplinary approach to integrated studies of cassava production, processing, marketing, consumption, and their interactions. The assessment is aimed at identifying demand-led research objectives.
• Donor policies and program Plant Biotechnology Research for Developing Countries (NRC 1990)	NRC, IARCs, NARS, USAID, USDA, private sector	Institutional priorities: • Biosafety • IPR • Training and networking Scientific priorities: • Tissue culture, micropropagation, and transformation • Plant disease and pest control • Genetic mapping of tropical crops	• Modified delphi method was used in the consideration of institutional as well as scientific priorities. • Final decisions on implementation were based on local, national, and CGIAR review.

Table 2. Summary of Findings and Recommendations of Priority-Setting Studies for Biotechnology (continued)

• Donor policies and programs Biotechnology and development coop-eration (DGIS 1992)	Directorate General for International Co-operation (DGIS), the Netherlands	Recommendations for DGIS technical cooperation in biotechnology: • Agriculture • Human health care • Environmental management • Developing-country research capacity • Technology assessment and policy	Provides recommendations and areas for collaboration as sponsored by DGIS.
• National priorities for developing countries Biotechnology in Kenya (KARI 1991)	KARI, USAID, ILRAD, USDA, RF, IBPGR	Plant priorities: • Plant cell and tissue culture • Virology/plant pathology • Antigen production and diagnostic kits • Transformation for disease and pest resistance Animal priorities: • Embryo transfer • Artificial insemination	KARI used a group of experts to synthe-size plenary information and develop plan of action: • single center for plant and animal bio-technology, • scientific priorities determined for both plant and animal research, • biosafety parameters identified.
• National priorities for developing countries Appropriate biotechnology in small-scale agriculture: Interactive bottom-up ap-proach for biotechnology (Bunders and Broerse 1991)	Netherlands Organization for Technol-ogy Assessment, National Biotechnology Forums, DGIS, STOA (European Or-ganization for Technology Assessment)	Priorities are established in a structured interactive process in which the partici-pation of the client group is essential. The process consists of three phases: • Preparation • Public debate • Institutionalization	Provides methodology to help direct bio-technology towards the needs of resource-poor farmers. Currently under discussion in two African countries.

Public Policy Setting

A number of public policy issues have been identified that affect the options available for undertaking biotechnology research. The issues included in this paper and in the decision-making framework are public perception, biosafety, intellectual property rights, organizational options, and financing. National decisions regarding the rate of entry into biotechnology are then reviewed in relation to the public policy and funding issues identified.

Public perceptions

Public education, including the education of technology users and those in charge of technology dissemination, is a critical component in the transfer of technology from the laboratory to the field. This is particularly true of products involving new technologies such as recombinant DNA techniques. Here, initial public perceptions about product safety and efficacy may have far-reaching implications for further technological advancement.

Public opinion can affect the processes involved in product development and can be a powerful force in the initiation of good developmental practices for research. Initial "familiarization" efforts conducted by commercial entities in the United States have provided a better understanding of biotechnology testing at the local, regional, and national levels. Many of these efforts have been product or test specific and designed to educate the public on issues and questions regarding perceived safety issues surrounding new technologies.

Such efforts to increase the public's understanding of new approaches, coupled with a demonstrated safety record, will help reduce the "familiarity gap," which often occurs with the advent of new technological innovation. This, in turn, helps minimize regulatory hurdles. Scientists at the research level need to help structure appropriate guidance so that familiarization of the public, and hence of national decision makers, occurs in conjunction with new research developments. Such a process reflects the fact that biotechnology is part of the agricultural research continuum. Scientists are made aware of requirements for information to satisfy questions of safety. As such, scientists and public officials provide decision makers with information that better prepares them for making informed decisions regarding public perception.

Developing effective biotechnology products, which address recognized priorities, provide needed agricultural inputs, and present a comparative advantage over products already available to farmers, will do much to bolster public confidence. An essential factor in building public familiarity with biotechnology research will be the technical excellence and improvement offered by each research innovation.

Biosafety considerations

Is there a review mechanism in place to ensure the safe and efficacious application of biotechnology? If not, the formation of an institutional or national biosafety committee is desirable. However, the relevance of such a committee depends on the degree of local understanding and competence in biosafety (Plucknett et al. 1990, Persley et al. 1992). Institutional expertise can also play an important role in increasing national programs' opportunities to collaborate with programs that are applying new techniques and providing products of genetic engineering to the developing world. If national safeguards have not been established, the testing of new genetic material may be limited in scope and effect.

Data obtained through an IBS survey indicates that 12 international biotechnology programs, IARCs, or donors have conducted specific activities related to the international and national dimensions of biosafety (see Annex 4). Activities include biosafety internships, regional and national biosafety workshops, biosafety data bases, and an international code of conduct. In addition, virtually every program surveyed indicated that it is complying and collaborating with national regulatory guidance. This information indicates both the importance given to biosafety by the international community and the substantial resources available to national programs in developing countries.

As new biotechnology initiatives emerge, more thorough consideration is being given to relevant biosafety considerations and to the cost associated with providing data that addresses both safety and efficacy parameters. These can include risk, benefit, efficacy, spread or dispersal, and environmental fate. Effective guidelines for researchers preparing safety data will minimize delays in testing and facilitate reference to the extensive body of knowledge accumulated on the safe testing of engineered organisms. Established review procedures for biosafety, including the components above, will help developing countries assess experiments requested by scientists or institutions in need of testing locations in tropical environments.

Strong interagency linkages will be required to assure that the requisite parameters are understood and established. Without establishing these linkages and using them to create guidelines, scientists may be asked to repeat a review and approval cycle for a particular experiment until all relevant questions of safety are answered (Cohen and Chambers 1991). This will cause delays and increase costs, as each time a request is submitted, costs are incurred for testing and documentation. These management issues become more important as an increasing number of applications of the new biotechnologies are directed towards end users in developing countries. Thailand’s National Biosafety Committee, for example, has been approached for the testing of six diverse applications, each a product of international research (Napompeth 1993).

Intellectual property rights

The availability of IPR protection can serve as a means to increase private-sector inventiveness, to gain access to proprietary technologies, and to stimulate public-private collaboration. It can also be demanding in terms of the requisite legal expertise and the costs involved in filing for such protection. For example, in the United States, $10,000 to $15,000 is required to complete one patent application.

A strong public-sector effort in biotechnology is needed in many developed countries. However, the public sector alone may not be sufficient to meet future national agricultural and economic needs. Combined public- and private-sector efforts are more likely to satisfy national research needs.

Decisions on biotechnology and IPR are guided by these factors, as well as by national technology objectives including the extent to which national science and technology policy is increasing local innovative capacity, and different means to expand acquisition and transfer of technologies (van Wijk et al. 1993). The pros and cons of enacting IPR policies change as capacity in biotechnology becomes more productive. At the present time, many agricultural crops and innovations in developing countries are exempted from national legislation governing IPR protection, leaving those innovations in the public domain. However, this may change as national priorities for technological innovation change.

Even with the exclusion of agricultural or biological products, difficulties have already been encountered by developing-country officials responsible for determining copyrights, patents, and trademarks. Extensive time is needed to grant a patent after initial filing, often two to three years. There is growing need to develop familiarization with prior art and for collaboration with patent offices and services in industrialized countries. Also, many countries are being flooded with filings from foreign applicants. National applicants often have relatively less interest or ability to file. For example, in Thailand and Indonesia, national applications are 13 and three percent, respectively, of the total filed for 1991-93 (Rattanasuwan and Dirham 1993).[2]

Integration and Organizational Options

After setting priorities, organizational options should be reviewed. This means reviewing the institutional base required to initiate biotechnology research. One question requiring resolution is whether expertise in biotechnology should be added to existing programs (such as plant breeding) or if future research is better placed in a new institute. As far as plant improvement is concerned, biotechnology presents a complementary set of tools not to be isolated from breeding, but rather to become a part of it. For new facilities, high start-up costs should be expected, as well as long-term support for recurrent costs. Particularly important are needs for backup generators to ensure electrical supply, service agreements for specialized equipment, and ready access to growth chambers and greenhouses.

Many of these items are already in place in conventional research programs. In such cases the integration of complementary cellular and molecular technologies with conventional programs should not be difficult. Integration costs less than the installation of a new laboratory and can build collaboration between biotechnology programs and those with responsibility for the production of new varieties. Thus, biotechnology becomes an extension of the scientific base for agricultural research, requiring institutional adjustments and investments.

Establishing a separate biotechnology center can undermine the morale of the plant scientists not based at such a facility. This is especially true if different salary scales exist for scientists trained in advanced cellular or molecular biology. Biotechnology products reach consumers only through conventional development and release. Therefore, it is essential that a strong conventional technological base be maintained and supported. Plans for the integration of technologies should aim to ensure that scientists engaged in conventional and biotechnology research complement one another (Cohen et al. 1988).

The issue of integrating research highlights the need for interdisciplinary and inter-institutional collaboration. Advances in biotechnology, often based on innovation at the level of the DNA itself, may occur at institutions not working specifically on agriculture. However, studies of biotechnology in Latin America show that a lack of communication exists between institutions and that current funding policies are not conducive to interdisciplinary research (FAO 1993). Linkage mechanisms or licenses to the private sector may be necessary to increase collaboration and speed the development of products by national research programs.

Once integration has been considered, institutional strengths and mandates must be examined. Organizational decisions should aim to avoid duplication while supporting efforts to achieve targeted products as quickly as possible with the least cost. A range of institutional issues and options is highlighted by Komen and Persley (1993). An important organizational and policy consideration is if the research to be done by national institutes

2 Information from January 1991 to September 1993 for Thailand revealed that 885 applications out of 6813 were of Thai origin, while 185 out of 7074 applications in Indonesia were of Indonesian origin.

should be done alone, through research collaboration, or through contracts or licensing agreements. National initiatives in biotechnology will reflect various combinations of these three options, which in turn affect the extent to which integration of research activities will occur and the opportunities for contractual research.

Autonomous National Research

Biotechnology research undertaken by national institutions alone must directly support national priorities and needs while conforming to institutional mandates. The need for supplemental collaboration, especially for product advancement and distribution, should be anticipated early to help plan and ensure that research is efficiently transferred for final product development.

Building the national expertise needed for the acquisition, development, and verification of new technologies represents a commitment of time and resources. This requires a steady progression of development. Time must be allowed for the advanced training of key scientists and for the development of program leaders and managers. Finally, funding must be provided for training and for the upgrading of equipment, both of which will be needed by national programs not taking advantage of collaboration or contractual research.

Collaborative Research

Collaborative research offers scientists and sector leaders access to additional resources. It thereby expands the national capacity to undertake biotechnology research. A collaborative approach may involve one or more of the following groups of partners:

- other national, regional, or international research programs;
- CGIAR commodity centers;
- intermediary biotechnology programs;
- universities (public and private);
- the private sector.

Advances in biotechnology in the 1970s came largely from laboratories, both public and private, acting independently. Based on these advances, the 1980s saw international biotechnology programs and networks established in or for developing countries. These linked developed-country research in molecular and cellular biology to the agricultural needs of developing countries and to the programs of the international agricultural research centers. During the 1990s this trend grew. The number of international and intermediary biotechnology programs has expanded, with each recognizing the growing diversity of potential collaborators.

Investigating these opportunities gives national programs the potential to attain relevant new technologies cost-effectively. A recent agreement between the Indonesian government's Central Research Institute for Food Crops (CRIFC) and an international biotechnology research program, provides examples of collaboration with private-public, private-private, and public-public research linkages (Manwan 1993).

Contractual Opportunities

Opportunities for undertaking contractual research are expanding in certain developing countries. Contracting the leading laboratories of industrial nations for specific research can help minimize demands on national programs still developing their own expertise. As local expertise and human resources become available, developing countries can also undertake contractual research **for** advanced laboratories. Contracts offer new means of both developing and acquiring applications of biotechnology, particularly where equitable protection of intellectual property rights exists.

Developments in the Pacific Rim countries, in particular, illustrate research opportunities available through contractual relations. Opportunities are also increasing in countries such as Thailand, Malaysia, and Singapore as a result of the long-term stability of their political systems and policies effecting greater privatization and diverse, liberal investment policies (Pietrzyk 1992). Research abilities in Asian countries open new opportunities in terms of international competitiveness, increasing not only contractual research, but also providing for the long-term growth of the commercial research and development sector.

Financing Biotechnology Initiatives in Developing Countries

Decision makers at the national level may establish biotechnology policies. However, due to stringent austerity programs, they are often unable to provide secure funding to address their priorities. For biotechnology to achieve targets of national priority, planners must estimate correctly and provide total costs and financing. The participation of management in decision making and planning can help define realistic needs for additional resources and recurrent costs. Planning for financial expenditures is also critical for providing the means to retain research personnel who can find employment in many advanced countries developing biotechnology expertise.

When funding for biotechnology has been secured, strategies vary among developing countries. Funding approaches usually mix limited national program and institutional support with financing from international donor agencies, development loans, international biotechnology programs, competitive grants, and other sources. National finance, planning, and technical managers are increasingly aware of the international base of financial support available for biotechnology and its increasing significance among donors.

Trends related to funding for international biotechnology programs and collaborating national programs were recently reviewed by IBS through its data base on international collaborative programs (Annex 4). As noted above, it found that a growing number of bilateral and multilateral donor agencies are supporting international biotechnology initiatives such as networks, programs, and informational data bases. In the period 1985-95, a combination of donors, foundations, commercial, and national programs will have provided about US $260 million for international biotechnology activities. Of this, $206 million will have been provided to 25 identified international agricultural biotechnology research programs. Of the remaining, about $7 million went to four international biotechnology networks, while some $47 million was spent by four surveyed donor agencies on a wide range of projects.

For programs using such collaboration, the majority of funds were from foundations and either multilateral or bilateral donor organizations (figure 1). This potential funding, which relegates national funding to a position of lesser importance, can lead to concerns of donor-driven programs or programs operating without agreement of needs and objectives of national significance. Of the total funds reported for international biotechnology programs, matching funds from developing country national programs accounted for only 4.1 percent (figure 1). However, positioning allocations of funds in such a manner allows finance and planning leaders to attribute national expenditures to priorities other than biotechnology.

Funding available from international donors and international biotechnology programs presents opportunities additional to those available from national programs alone. Without such funding, NARS directors are often not able to find resources for advanced

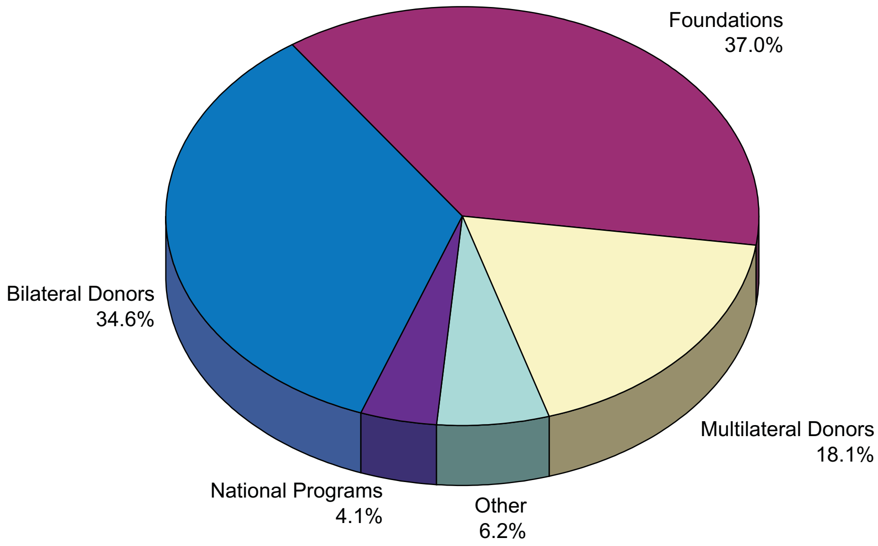

Figure 1. Sources of funding for international biotechnology programs

training and research. However, this places a long-term responsibility on international donors to provide resources over the time frames necessary for program completion. In the meantime, national financial ministries and designated research institutions are determining how to assume anticipated program costs. Regardless of the institutions selected for implementation, strategies are needed to ensure that the necessary resources are planned for and received. Realistic budgets and cost estimates are required, coupling the right institutions with the requisite critical mass and expertise, for the right target and time frame needed for development.

Rate of Entry in Research

An important policy consideration is the rate at which national programs enter the biotechnology arena. Rate of entry is determined by the pace of the following activities:

- development of national expertise as related to abilities available from conventional agricultural research programs;
- acquisition and development of new technologies;
- verification of technologies under local conditions;
- time frame required for distribution of improved products to farmers, consumers, and other users.

Development of national expertise is essential, as it ensures an internal capacity to observe, choose, and use new techniques for crop and livestock improvement programs. This is often a particular challenge for small countries where there are few researchers (Eyzaguirre and Okello 1993). Scientists are needed who are able to keep up with technological advances, appreciate them, judge whether the advances will be useful, and demonstrate accountability for research undertaken. These scientists will need to understand both molecular and cellular genetics and agricultural research. They must also be able to bridge the gap between the basic and agricultural sciences. Access to information is required, as well as proper equipment, containment facilities, and field-testing sites. Universities have an increasingly important role to play in anticipating human resource development needs and providing periodic research opportunities to keep scientists abreast of current developments.

National programs have various options for acquiring and developing new technologies. However, national legal issues are often involved, particularly if proprietary technologies are acquired or if there is a need to provide demonstrated protection of IPR. Technologies from the public sector, international programs, or the IARCs are more accessible than those from the private sector, but care must be taken that these are freely available and can be used without inadvertent infringement. Finally the assimilation of foreign technology requires corresponding strengths in the national scientific structure (Liyanage 1993).

Newly acquired technologies often must be verified under local conditions or in local germplasm or varieties. Verification may take two to three years and require review by institutional or national biosafety committees. It is essential that such reviews be done routinely, before new varieties are released or recommended to farmers.

Timely distribution of products must be ensured. Without efficient distribution, allowing time for the completion of safety and performance data, end user demand will not be satisfied and issues of accountability will be raised. The development, testing, and release of the products of biotechnology research, especially those involving genetic engineering, have their own time frame that must be considered in addition to that for conventionally derived products. This is especially true in the start-up period of a biotechnology initiative, when integration among parties concerned is unlikely to have occurred. Also in the start-up period, costs for capital investments and staff are high and public confidence and familiarity with new technologies is tentative.

Determining Timing, Scope, and Scale of Entry

Involvement in biotechnology, even at a very modest level, holds considerable merit for developing countries that can effectively integrate additional research with strong conventional agricultural programs, support existing and anticipated infrastructure requirements and can provide for the anticipated technology delivery requirements. However, it should be stressed that entry into biotechnology should follow a needs and priority assessment process. This will increase the proportion of need-determined research in comparison with technology-driven research.

Table 3 presents some key requirements, and their respective advantages and considerations, which help determine when and at what scale a country should or should not embark on a national biotechnology initiative. As shown, the table begins by addressing information needs necessary to prepare research managers for the planning required by new institutional mandates and by the expertise needed for making policy decisions. This is followed by the execution of research partnerships and building of relevant human resources. Entry helps institutions to anticipate new needs while becoming more proactive in seeking the required support. It prepares national policymakers and NARS directors for the range of issues accompanying the new technology environment and strengthens national abilities in the review and approval processes necessary for field testing and distributing biotechnology products.

Entry requires an immediate development of the scope and scale of the human resource base. A foundation must be built of trained scientists and informed policymakers who can work together to assess national priorities. Human resource development also provides time for the institutional integration needed to initiate new research efforts and the accompanying policy changes. Taken together, these activities provide a learning while doing environment, which increases familiarity with new technologies.

Building biotechnology expertise also helps national programs to be stronger collaborative partners. Without appropriate knowledge and experience, national programs will face difficulties in entering contractual arrangements and will be at a continual disadvantage in negotiating with countries, programs, and commercial entities having greater technical experience.

Difficulties or complications should also be anticipated as biotechnology-based research is implemented. Experience with new technologies may change institutional structures and budgets and create new demands on staff. Addressing information and communication needs presents major problems, yet is essential for successful performance. Also, training priorities will be altered as new technologies are incorporated, thereby changing demands and planning at the conventional research program level.

Once established, biotechnology programs require extensive improvement of infrastructure and laboratory equipment. This includes costly capital goods as well as chemicals and supplies. Recurrent costs for equipment, supplies, and power place new demands on existing budgets. As shown in table 1, the time frame for program and research development in biotechnology spans several years. Returns on investments are thus gained years after the initial investment.

Table 3. Scope and Scale of Entry: Requirements, Advantages and Conditions

Requirements	Advantages	Considerations
1. Build an information, networking, and communication base	Provides a means to communicate and network with scientists in advanced laboratories and minimizes isolation of scientists	Efforts to minimize the isolation of national scientists should begin with program implementation
2. Anticipate new institutional mandates and challenges	Institutional mandates can be changed to include more basic or strategic science	Research directors will be considering new needs for research on natural resource management and the environment as well as biotechnology
3. Provide expertise for technical and policy decisions	Practical involvement in national biotechnology research builds hands-on familiarity with both policy and scientific matters	Lack of practical experience leaves program leaders and scientists vulnerable to bad information
4. Develop stronger and more effective research partners	Timely involvement builds stronger institutional capacities, leading to more equitable partnerships in global biotechnology	Partnerships needed for collaboration should be developed in agreement with identified priorities, constraints, and end users
5. Build human resources for advanced technologies	Implementation of a strategic training program in relation to national needs and institutional abilities may prevent an expertise lag	Training needs in biotechnology may be extensive and will require a large share of training budgets

3. PHASE II: PROGRAM FORMULATION

Various studies conducted during the last five years show that the main limiting factors for plant biotechnology development in the Latin American and Caribbean region are lack of human resources, limited operating budgets, lack of training and information networks, limited use of multidisciplinary team approaches, little definition of common strategies and priorities, and weak links among the academic and productive sector.

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The objective of phase II of the decision-making framework is to translate priorities into tangible national programs. Each program will differ depending on the research and policy priorities identified in phase I and the type of institutions and funding involved. A comprehensive national program may be recommended, encompassing numerous research projects. Or a limited-scale program may be required. Regardless of size, decision makers should first identify the program elements to be included, then engage relevant scientific and sector communities in planning.

Program Elements

Program formulation follows priority setting by taking into account the policy environment and priorities established in phase I. It requires the identification of scientific and policy elements that will provide the foundation for a national initiative in biotechnology.

Research-level participation during program formulation is essential to ensure that relevant scientific and investment considerations are addressed. These include, for example, access to proven research methodologies, ability to integrate new biotechnologies with conventional research, support for advanced training opportunities, as well as downstream issues such as technology transfer (Cohen 1993). Scientific review also helps in the identification of users for the proposed research. Finally, it provides estimates of program funding requirements.

An initial analysis of international biotechnology programs has identified major program elements and indications of their respective percentage of expenditures and effort (figure 2, see also Annex 4). Elements of primary importance are:

- research and development;
- human resource development;
- collaboration with national programs in developing countries;
- program planning, policy, and management issues;
- information and communication; and
- infrastructure development.

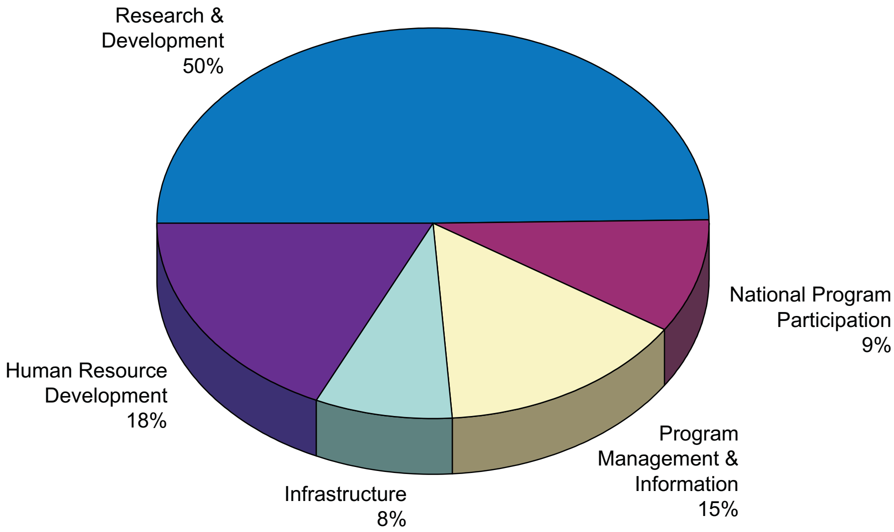

Figure 2. Major program elements and percent of effort attributed to them by international biotechnology programs

As defined for the IBS data base, research and development included activities accounting for almost 50 percent of the total program effort. Human resource development accounted for training opportunities in both long-term and short-term advanced programs, including post-doctoral positions. Collaboration with national programs included money set aside to facilitate research and exchanges with national programs in developing countries. Program planning included internal management issues and their relations to issues such as biosafety. Information and communication documented expenditures and effort for electronic linkages, newsletters, and data bases. Finally, infrastructure development included resources for laboratory and computer equipment.

These elements may serve as indicators for the design of national biotechnology initiatives and are suggestive of elements and percent of effort that can be planned. The managers of a national biotechnology initiative should consider whether the relative percentage of efforts are consistent with the objectives and design of the program. While research is of primary importance, sufficient resources for training, exchange of information, and enhanced communication are needed to connect national scientists with the international agricultural research system. Without these, research efforts may be delayed or redundant.

The relative effort and funding attributed to each element will vary over time. For example, during the first five-year period, the majority of resources may be placed in infrastructure development and training, with research assuming more importance as indigenous capabilities increase. Then, greater emphasis may shift to collaborative research opportunities and communications linkages such that trained scientists are not isolated from their prior collaborators.

Program support for research, infrastructure, and human resource development will have to take into account difficulties in obtaining inputs such as reagents, chemicals, and enzymes in a timely, cost-effective manner. Lack of operating funds at national laboratories will impair collaboration. Special effort is required to ensure that supplies and operating funds are available when needed to guarantee continuity of effort (Thro 1993).

Scientific Review of Research Priorities

Research-level review is recommended once research and development is identified as a program element. It is best done through multidisciplinary peer review. This complements input received from other sectors. The review team can include not only cellular or molecular experts, but also representatives of conventional breeding, agronomy, private sector, sociology, and extension. If continued throughout the program's operation, research-level review can ensure technical excellence.

Scientific evaluation of research priorities begins with a review of the conventional agricultural research base. This is followed by an assessment of the potentials of biotechnology-based research. Beginning with a review of the conventional research base ensures that biotechnology is seen as part of the agricultural research continuum and not as stand-alone activities.

Conventional Agricultural Research Base

Examining on-going agricultural research programs provides preliminary information about biotechnology's role in addressing needs, how existing constraints can best be overcome, and the potential for investment in biotechnology. Such a review must be done by scientists who can assess not only research capacities, but also the agricultural services available to the farmers, growers, and consumers identified as potential clients.

Not all problems can be resolved through biotechnology. Local expertise, technologies, and cultural practices should also be evaluated in the review. As shown in Annex 3, alternative technologies or cultural practices **that do not** require biotechnology may be identified as addressing priority constraints (see also Ruttan 1990). If effective agronomic evaluation and distribution of improved genetic materials cannot be ensured, then there will be limited impact from introducing biotechnology. In such cases it is advisable not to introduce biotechnology to a plant breeding program. In the rest of this report, modern biotechnology is considered specifically in terms of plant breeding, as this is likely to be one of its principal uses and offers a good basis for discussing the decision-making process.

A Biotechnology-Based Research Approach

If the review of existing plant breeding programs indicates that (1) a biotechnology-based approach is warranted and (2) an established framework exists for developing and transferring new technologies, then additional discussions will be needed on the following:

- understanding potential traits of interest as related to program priorities,
- tissue culture expertise, and,
- products of genetic engineering.

Understanding the Traits of Interest

Selecting for improvement traits that address program priorities begins by assessing the degree of understanding of each trait at the molecular and genetic level. Such understanding, coupled with the analysis of new genes in varieties of agronomic importance, is critical for effective incorporation and expression of novel genes.

However, the advantages derived from increased genetic or molecular understanding of traits do not, in themselves, necessitate genetic engineering. For example, once the trait of interest is selected, a wide range of germplasm may be searched to identify genes providing the type of expression desired. This search should include sources of material such as the IARCs, other national programs, and universities, as well as elite lines from foundation seed companies, commercial materials, and relevant plant genetic resources. Each of these sources presents opportunities for plant breeders to initiate selection and modification. The availability of germplasm containing genes for a particular trait will reduce the need for investments in biotechnology.

Molecular mapping is a development of modern biotechnology that increases the information available about particular genes. It locates their position on chromosomes of plants and animals and, perhaps more importantly, provides an association between traits of interest and selectable markers at the molecular level. These markers provide a new tool for crop improvement.

Presently, molecular markers can expedite backcrossing of simply inherited traits. However, applications of these techniques are also being attempted for selection of complex desirable traits, which are difficult to screen through conventional techniques and breeding programs. An example is the reduction of saturated fats in canola oil. This effort is using RFLPs to provide selectable markers that correlate with expression of improved oil content in canola plants (Erickson 1992). Modification of complex traits using molecular mapping entails detailed analysis of several hundred plants to obtain the expression of desired traits in combination with selectable markers. Close collaboration with breeders and agronomists is essential and allows breeders to interface conventional programs with RFLP-assisted strategies to improve precision in the selection of important traits.

Tissue Culture

Expertise in tissue culture serves many needs, beginning with mass propagation, disease elimination, and germplasm exchange and storage. These essential components of biotechnology-based research complement the information described above regarding information available on genes and traits of interest. Expertise in tissue culture includes in vitro techniques such as meristem culture, embryo production, and shoot production. These techniques are particularly important for germplasm of tropical crops, as these are prone to viral infection and are mainly propagated vegetatively.

In many cases, competence in timely, quality-controlled tissue culture production of planting material is an immediate concern of farmers and growers. This may be a national biotechnology priority in itself, as there are growing needs for increased efficiency and diversity of techniques (Mantell 1989). As such, it is critical that innovative results from national and university tissue culture programs are not isolated from priorities for a national biotechnology program. Such tissue culture capabilities provide the foundation for the regeneration of tropical crops, which is essential for the application of advanced techniques of genetic engineering.

Products of Genetic Engineering

When tissue culture expertise is available, but sufficient diversity is lacking from germplasm collections or proves too difficult for breeding, the plant breeder may consider the incorporation of novel genes, especially for single-gene traits such as disease resistance. These genes are often products of genetic engineering and present opportunities to introduce genetic material not readily available from conventional methods, which target priority traits of interest.

Examples include genes for herbicide tolerance, such as glyphosate or Sencor, and for viral and insect resistance, such as potato viruses x and y and coleopteran and lepidopteran insect pests. Novel genes are made available through unique vectors, or molecular packages, which combine the gene of interest with a suitable delivery mechanism. In some cases, the genes and vectors may be proprietary, that is, protected through some form of intellectual property rights. In such circumstances, examination of these rights is needed prior to use.

It is important to assess the likelihood of success in obtaining and expressing relevant traits of interest through transformation and regeneration of crops of local importance. The ability to perform routine transformation and regeneration of a crop is fundamental to the application of genetic engineering. Application of these complex technologies are impeded if not yet routine for tropical crops. For many developing countries, an important option for transforming tropical germplasm is to incorporate, using tissue culture techniques, the products of genetic engineering and molecular mapping available from advanced laboratories elsewhere.

Novel genes become available once new genetic material is stably expressed in agronomic germplasm. National programs can then access products of genetic engineering through normal hybridization by crossing local varieties with those containing novel genes. The genes, now stably expressed, are routinely transferred.

As shown above, biotechnology increases scientists understanding of the genetic material and their ability to produce it through tissue culture and genetic engineering. This is creating new products from agricultural research, including detailed molecular maps, isolated genes and vectors for their transfer, and selectable marker information, to name but a few. These new biotechnology-based research products, complementing conventional programs, challenge research managers to provide the infrastructure and resources needed to attain such developments and to determine which products best serve identified priorities.

Cross-Sector Planning and Review

The complexity of the anticipated biotechnology program determines the extent of collaboration among various institutes and across sectors. Research managers can provide advice to the national level and direction to the research level for collaboration beyond the traditional agricultural or commodity sector. Reflecting the importance of cross-sector planning for upcoming challenges to NARS, ISNAR has defined NARS as follows:

> all of a country's entities responsible for organizing, coordinating, or executing research that contributes to the development of its agriculture and the maintenance of its natural resource base. (ISNAR 1993)

This definition transcends the traditional boundaries of many government agricultural research organizations. The inclusion of concerns for the natural resource base in the agricultural sector reinforces changes in planning now occurring in response to pressing issues of environmental quality, competition for natural resources, and growing population pressure (Meyer 1993). This reflects the advantages expected from multi-institutional and cross-sector planning for biotechnology, as new technologies in agriculture are targeted towards the needs of environmental quality as well as productivity.

Broader environmental concerns regarding agricultural practices emerge as urban populations expand into traditionally agricultural areas. Cross-sector planning can increase the interface between environmental concerns about agriculture, growing populations, and needs for increased productivity (Crosson and Anderson 1993). This is facilitated by incorporating sustainability objectives in research efforts and international biotechnology programs (NRC 1990). For example, safer biotechnologically produced pesticides are beginning to replace environmentally hazardous ones, plants are being used to extract harmful elements from polluted lands now being encroached upon by growing urban areas, and microbial pesticides are being used to control pests such as gypsy moths (USG 1993).

4. PHASE III: PROGRAM IMPLEMENTATION AND MONITORING

When Thailand started its national biotechnology program, it faced the task of filling gaps between conventional agricultural research and "academic" research in molecular biology and life sciences. The great challenge was to bridge the gap between the user and supplier of technology and between the conventional and the modern, so that the benefit of the new technologies reached the ultimate user, the farmers.

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There are specific issues related to the implementation and monitoring of national initiatives in biotechnology. These include finding expedient institutional arrangements for the special monitoring and evaluation requirements and planning for socioeconomic analysis.

As mentioned in the previous chapter, establishing an external technical advisory group is an efficient way of undertaking the scientific review of proposed biotechnology activities. If this advisory group is retained during the program implementation, it offers one means of achieving accountability for research as well as for the other objectives of the initiative. A means of achieving both technical peer review and increased accountability is to involve outside reviewers from the international agricultural research system. Such involvement has recently been undertaken by Taiwan's National Health Research Institutes, which are insisting on international technical review of proposals submitted for funding (Kinoshita 1993).

Monitoring and Evaluation

Monitoring and evaluation of biotechnology programs requires the assembly of highly technical reviewers who are not competitors or collaborators with the ongoing research program. This can be difficult in such specialized areas. The need to monitor biosafety regulatory requirements also distinguishes certain aspects of modern biotechnology from conventional practices.

National biotechnology initiatives also require new approaches for indicating success and accountability. Traditionally, success in agricultural research has been measured by the rate of adoption, market share, or number of hectares planted. For biotechnology, however, reliable end-of-project or program indicators can be reached in the laboratory. These results may then require further testing under field conditions to ensure that the final product is acceptable for use by growers, farmers, or consumers. Field-proven performance therefore may require two to three years of testing following the completion of laboratory work.

Field testing of biotechnology-derived products, especially those products aimed for use in the tropics but reliant on initial development in industrialized countries, requires environments in which collection of relevant data can be assured. Preliminary quarantine-type tests are necessary and can often be performed in temperate countries. Eventually though, testing in tropical environments may be best for achieving locally-adapted germplasm and for detecting expression of, for example, disease resistance genes under indigenous conditions. Some form of local testing will be essential for verifying the utility of the improved material. Testing in tropical countries should conform with national biosafety guidance so that the proposed tests maximize expected results and ensure safe experimental procedures. Many developing countries offer little or no such guidance. However, to date both public and private technology developers have made significant efforts not to take advantage of weak regulations in developing countries.

The need for testing in tropical locations and its relation to the completion of project goals is further complicated if relevant end users, priorities, and needs established in phase I are taken into account. Although research may have achieved new technological breakthroughs, these breakthroughs must also be evaluated in the context of the broader objectives of the program.

Indicators of success and relevant biosafety protocols will be essential in reports provided for institutional and donor review. Contributions by management and program leaders to the monitoring and evaluation process can help to assure that relevant scientific and environmental concerns were addressed in program design and that suitable indicators are being established to determine if program objectives have been met. Box 1 outlines basic parameters to be considered in the monitoring and evaluation of biotechnology research.

Box 1. Monitoring and Evaluation of Biotechnology-Based Research

I. Monitoring and evaluation of experiments

- Analyze efficacy and safety measures to ensure good developmental practices
- Review tests in relation to relevant and regulatory protocols
- Ensure that adequate containment facilities are available
- Design trials so that data substantiating expression of the improved trait can be taken from multiple locations
- Include competitive varieties of agronomic importance for comparison

II. Monitoring and evaluation of program

- Establish measurements of impact and results
- Formulate discrete program objectives and activities with time tables and expenditures to facilitate accountability
- Identify the end user and the extent to which the program is responsible for final delivery of products
- Ensure quality review of the technical aspects of the program as well as compliance with general objectives
- Establish a multidisciplinary technical advisory team for regular review of the program

Socioeconomic Analysis

Socioeconomic analysis is needed to fully assess the potential benefits and shortcomings of biotechnology as applied to agricultural research. National-level contributions to this effort help to ensure that the analysis is undertaken in agreement with country objectives and is aimed towards the users identified as most needy of the products derived from the biotechnology initiative. Discussion at the national level of the socioeconomic analysis also provides guidance for sector and program leaders as to clients and expectations for economic impact. These will of course need verification with local client groups (Bunders 1990).

Ex ante evaluation of the socioeconomic impact provides guidance for program formulation, design, and priority setting. Ex post evaluation assesses whether a biotechnology program achieved its socioeconomic objectives. It also provides guidance for organizing future programs. Both types of evaluation are complicated by the fact that to date there are few products available from biotechnology research, and these are largely marketed in developed countries. Systematic evaluation of the socioeconomic impact on developing countries is therefore still in its infancy. Also, considerable variation exists among economic models for impact evaluation so that any prediction of socioeconomic impact of biotechnology in developing countries must be regarded with great caution.

Ex ante analyses of biotechnology applications are often based on the ex post evaluation of the Green Revolution. While the debate on the socioeconomic impact of the Green Revolution continues, one thing has been made clear: evaluations should not concentrate only on output but on a set of related goals, including growth, income distribution, security, and environmental concerns.

Analysis of the impact of biotechnology is more complex than that for the Green Revolution technologies. This is partly because there is a much wider range of applications for biotechnology. Other reasons also can be identified:

- Biotechnology affects agriculture at different stages of the production cycle. The Green Revolution had its immediate impact at the level of the farmers' fields. Immediate direct benefits of biotechnology may not affect farmers. For example, improved food-processing techniques primarily benefit food manufacturers and consumers.
- Biotechnology is not only focused on increasing yields. Rather, many of its applications will have a production-stabilizing and input-reducing effect, for example, by obtaining pest-resistant or drought-resistant varieties. Therefore, biotechnology can directly benefit small-scale farmers in less-favored areas.
- Biotechnology can affect various food or cash crops. Its impact depends on markets. The Green Revolution was focused on staple foods for which demand was both income-elastic and price-elastic. Both the consumers and the producers shared benefits. For some crops, such as cocoa, demand may be inelastic and yield-increasing technology may transfer all benefits to consumers in rich countries rather than to producers in poor countries.

5. PHASE IV: TECHNOLOGY TRANSFER AND DELIVERY

A key issue for technology transfer as related to agricultural biotechnologies is the lack of technical understanding of such technologies by the extension agent at the farm level. The capacity to produce high-quality seed derived from biotechnology at reasonable prices also constrains technology transfer to the grass-roots level.

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Decisions about the production and delivery of products to identified users should be considered early rather than late in structuring the research program. For national biotechnology initiatives, program formulation and execution are primarily the responsibility of the public sector. As stated earlier, conventional agricultural research will be the primary conduit for delivering the products of agricultural biotechnology. The agricultural extension system too will play an invaluable role, as they will be responsible for determining farmer, consumer, and grower acceptance of products arising from research.

However, depending on the clients, agroservices, and the technology-transfer routes available, the commercial sector may also play an important part in producing and delivering the product. Regardless of whether distribution is done by the public or private sector, a recognized route for distribution must be established. Otherwise research results will go undeveloped, resulting in wasted resources.

The following discussion of product orientation considers whether the product will be targeted for public or commercial distribution. Various routes of distribution are examined. Phase IV of decision making requires action at the management and research levels, effectively engaging appropriate technology transfer agencies, extension workers, and end users. While national research scientists themselves are not responsible for technology transfer, managers of such research, especially once the research is considered as part of a national biotechnology program, share responsibility for results reaching identified end users.

Product Orientation

Is the product of the research under consideration geared for public or commercial production? This question is especially relevant where there are pressures on government to privatize public research and development efforts (Emmerij 1992). Decisions must be made about which approach is best able to bring products to completion, what this decision means in terms of ownership or public distribution, and what type of balance is proposed between existing public and private research institutions. For example, biotechnology research begun in the public sector may become crucial to commercial initiatives addressing productivity constraints related to national economic problems. In such situations, managers must consider the type of institutional arrangements necessary, if sufficient private-sector expertise exists, and what policies are in place to encourage commercial growth.

If a decision is made in favor of product development in the public sector, it will be necessary to clarify how the products can be produced and delivered to the public in a timely and effective manner. Public distribution may be particularly relevant where programs using biotechnology have targeted applications to crops of importance for equity or food security reasons. If biotechnology has a role to play for these crops, will public-institution budgets alone assume the added costs? Given the current global trend towards the privatization of research, a balance between public and private research will probably be needed.

Technology Transfer Routes

There are multiple methods for the transfer of technology into and within developing country agricultural research institutes. As identified in the IBS analysis of international biotechnology programs, technology transfer opportunities for biotechnology include the following:

- public sector (NARS and other government institutions);
- IARCs, which release material through international testing programs;
- nonprofit institutions such as universities and land-grant institutions; and
- commercial organizations.

As shown in figure 3, the largest effort is expected to occur through the public sector, as most applications of biotechnology supported through the international donor community target crops or production systems traditionally serviced by national extension and research programs. Crops such as rice, beans, potato, sweet potato, and cassava, for example, are often planted from seed or planting material saved by farmers. Incentives for large-scale private-sector investment are therefore lacking. For these crops, improved planting materials distributed by IARCs, universities, or other international programs will have to be registered for release by each developing country and this is primarily a national program responsibility.

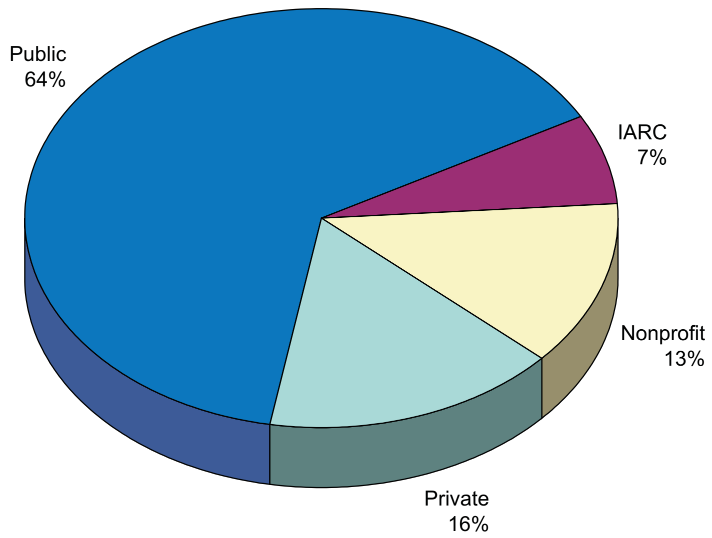

Figure 3. Primary technology transfer routes identified for use by the international biotechnology programs

The private sector is playing an increasing role in the transfer of technology into countries through affiliated or licensed research centers, as shown by applications pending for biosafety review in developing countries (Napompeth 1993). However, this technology does not reach the public sector. It is retained by proprietary developers.

In this regard, national and public institutions also benefit from collaboration with international biotechnology programs. The international programs provide access to both public and proprietary-domain technologies. The role for commercial technology transfer originating from these international programs is shown in figure 3. These new opportunities build on the traditional collaboration of IARCs and developing-country NARS with public-sector institutions in developed countries for advances in basic research.

These changes reflect the fact that the traditional route of donor, IARC, and developing-country access to biotechnology through public institutions is being affected by the increasing trend towards privatization (Cohen and Chambers 1992). This fact, coupled with pressures on national agricultural programs to divest production and distribution responsibilities, may reduce opportunities for public-sector technology transfer. Commercial producers may be encouraged to assume some of these responsibilities.

If technology transfer through the private sector is an option for the NARS then communication with the private sector should occur at an early stage. This helps to ensure that products are appropriate for private production and will be geared to the identified clients or users of the research as identified by the NARS. In such cases, programs may consider contractual mechanisms for technology transfer, such as collaborative research and development agreements, which itemize the terms of development between public research institutions and private producers.

6. SUMMARY

Policymakers in developing countries are increasingly faced with difficult decisions about investment in biotechnology. The decisions are difficult because they involve high costs and uncertain results in areas where developing countries are concerned about being left behind. Such decisions are also being made in the context of complex political, economic, and biological issues. These issues could dissipate the opportunities derived from new technologies if consideration is not given to priorities, policies, and programs for biotechnology.

With this need in mind, a decision-making approach for national biotechnology planning and policies has been presented in four phases: the identification of priorities and setting the policy agenda for biotechnology, the formulation of programs, special concerns for implementation and monitoring, and the transfer of technology to end users. A dialogue among national-level policymakers, research managers, and practicing scientists is encouraged. This combination of levels of expertise and phases of decision making builds channels between conventional agricultural research and new innovations from biotechnology.

Undertaking this decision-making framework is the first step in identifying the way in which various elements, institutions, and priorities for a biotechnology program are brought together. As each national program evolves, an increasing need for management emerges, which can ensure technical excellence while focusing on the identified needs that these technologies address. The decision-making process helps identify and build national competence in policy and management as well as in the scientific and technological areas presented by directing financial investments to technologies addressing identified needs and priorities in an agreed time frame with the required institutional commitment. When completed, the process provides relevant background information, priorities, and objectives for a national biotechnology initiative that can be presented to various international funding agencies and to national finance ministries.

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BIOTECHNOLOGY GLOSSARY

Cell Culture: A group or colony of cells propagated from a single cell in a specifically formulated nutrient medium.

Chromosome: A thread-like body found in cell nuclei, composed of genes arranged linearly. While genes are the units of heredity, chromosomes are the units of transmission of genes from one generation to the next.

Clone: A collection of genetically identical cells or organisms derived asexually from a common ancestor. All members of a clone are identical in genetic composition.

DNA (deoxyribonucleic acid): The macromolecular polymer that carries the genetic hereditary message and controls all cellular functions in most forms of life. The twin strands, in the form of a helix, are composed of successive units of the sugar deoxyribose, phosphate, and the bases adenine, cytosine, guanine, and thymine, through which the strands are cross-linked: adenine to thymine and cytosine to guanine.

Enzymes: Specific proteins that act as biological catalysts to stimulate essential biochemical reactions in all living organisms. Enzymes may be biologically synthesized, extracted, and employed to catalyze laboratory or industrial biochemical reactions.

Gene: The linear units of heredity transmitted from generation to generation by sexual or asexual reproduction. In modern molecular biology each gene is a segment of nucleic acid carried in the DNA encoded for a specific protein. More generally, the term gene may be used in relation to the transmission and inheritance of particular identifiable traits.

Genetic engineering: Artificial procedures whereby individual genes are removed from one organism and introduced into another. Modern biotechnology methods permit the movement of genes between organisms that would not normally be able to exchange such material.

Gene expression: Evidence or manifestation of a genetically controlled characteristic. All of the chromosomal genes in an organism are by no means active at all times. In a plant nucleus as little as five percent of the DNA may be producing protein at any one time. Thus all genes may be active or silent. The manner in which they are switched on and how the on-off “switches” are regulated is yet to be determined by molecular biologists.

Gene Mapping: Determining the relative locations of different genes on a given chromosome.

Genotype: A group or class or organisms that share a common specific genetic constitution.

Germplasm: Often synonymous with genetic material, germplasm is the name given to seed or other material from which plants are propagated. An early theory of inheritance advanced the notion that hereditary characters were contained in an immutable plasm transmitted unchanged from parent to offspring.

Hybrid: A cross between organisms that have different genetic compositions. Hybrids are most commonly formed by sexual cross-fertilization between compatible organisms, but techniques for the production of hybrids from widely differing plants are being developed by cell fusion and tissue culture.

In vitro: Experimental reproduction of biological processes in isolation from a living organism. Literally means “in glass”.

Meristem culture: A cell culture developed from a small portion of the meristem (growing tip) tissue of a plant. Either a stem shoot or root meristem can be used.

Monoclonal antibody: An extremely pure antibody derived from a single clone of an antibody-producing cell. A single spleen cell exposed to a specific antigen can be fused with a myeloma (cancer) cell. The resultant fused cell, called a hybridoma, continually produces an antibody specifically directed against the antigen. It will therefore seek out and identify the specific antigen. Hybridomas can be cloned and cultured to produce quantities of the pure monoclonal antibody.

Novel genes: This refers to products of genetic engineering, such as genes available for incorporation into plants and animals.

Nucleic acid: A chain of sugars and phosphates, with a base attached to each sugar. The sequence of these bases makes up the genetic code.

Pathogen: Any disease-producing organism.

Recombinant DNA (r-DNA): A strand of DNA synthesized in the laboratory by splicing together selected parts of DNA strands from different organic species or by adding a selected part to an existing DNA strand.

Regeneration: Development of a whole organism from a single cell culture.

Restriction enzyme: An enzyme that cuts and effectively excises a piece of a DNA molecule. Some restriction enzymes cut the DNA at specific points, others appear to cut at random. Restriction enzymes, of which hundreds have been identified and isolated, are important tools in the transfer of specific gene sequences from one organisms to another.

RFLP: Restriction fragment length polymorphisms are the lengths of DNA between the sites at which various restriction enzymes recognize and cut DNA.

Tissue culture: In vitro methods of propagating cells from animal or plant tissue.

Transformation: The process whereby a piece of foreign DNA is transferred to a cell, thus conferring upon it novel characteristics.

Vaccine: A preparation of a pathogenic microorganism or virus that has been killed or attenuated so that it has lost its virulence but carries antigens. When a vaccine is injected into a living animal the immune system is stimulated to produce antibodies, which remain in the living system and provide immunity against subsequent potentially pathogenic infections by the pathogen or virus.

Vector: In genetic manipulation the vehicle by which DNA is transferred from one cell to another. Literally means “a carrier.”

Virus: The smallest known type of organism. Viruses cannot reproduce alone but must first infect a living cell and usurp its synthetic and reproductive facilities.

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ANNEX 2: A Recent Example—Analyzing National Biotechnology Initiatives in the U.S.

The need for a strategic approach to biotechnology was recently recognized by 12 different federal agencies of the United States government, each of which had independently developed its own biotechnology research program. Representatives from these agencies, with representatives of the Office of Management and Budget and the President's Office of Science and Technology Policy, were organized as the Biotechnology Research Subcommittee under the Federal Coordinating Council for Science, Engineering and Technology. This subcommittee was asked to develop a goal, objectives, and strategy for a combined public investment in biotechnology (USG 1992).

The subcommittee's report outlines agency programs in biotechnology research and describes a way to maximize the effectiveness of public investments in these programs. To accomplish this, a baseline of activities and funding levels was developed and agency programs and national strategic objectives were highlighted. The first interagency biotechnology research budget was developed for fiscal year 1993. Various budget scenarios were considered. The final approved budget was based on the strategic nature of the overall goal, objectives, and programs presented.

This strategic approach, undertaken because of fiscal realities, initiated interagency coordination in the application of biotechnology. The report presented federal initiatives in a manner that led to an increase in agency funding for the programs included. Through such coordinated efforts, technical needs identified by scientists are better focused on society's needs and on the fiscal priorities identified by national leaders.

The example above is from a developed country. However, its importance as an example of a combined, interagency and multilevel approach to biotechnology is equally important for developing countries. Variants of this type of coordinated analysis and subsequent program- and policy-based recommendations already have been undertaken by China, India, and Thailand and may offer useful models for other countries with multiple agencies involved in biotechnology research.

ANNEX 3: Concerns Facing the Agricultural Sector over the Decades Ahead

Identified need for the agricultural sector	Example of improvement that can be achieved	Opportunity for application of modern biotechnology
Institutional development	• Initiate a research program on incentive-compatible institutional design • Improve the effectiveness of institutions	• None • None
Accommodation of research on natural resource management in the NARS	• Strengthen capacity to monitor agricultural sources of environmental change • Conduct research on environmentally compatible farming systems	• None • Provide new sources of disease and pest tolerance to minimize pesticide use
Development of food systems that meet population and productivity demands of the 21st century	• Investigate alternative land use, farming, and food systems • Improve cultural practices to enhance local productivity • Increase opportunities for technological innovations to overcome productivity constraints	• None • None • Contribute enhanced understanding of genetic innovations
Timely delivery and provision of agricultural inputs	Improve agroservices to farmers	Produce improved seeds and tubers in disease-free and certified conditions
Conservation of genetic resources for agriculture (Agenda 21)	Improve conservation facilities and technologies at national and international levels	Apply in vitro storage, characterization, and exchange of germplasm
Reductions in postharvest losses	Develop new technologies for postharvest storage and preservation	Use molecular biology to conduct research on curtailing ripening and shelf loss
Development of infrastructure and markets	Provide better access to roads and markets to encourage diversified production	None
Improvements in pricing and macroeconomic policies	Reform agricultural commodity and income support policies	None
Improvement in policies towards agricultural research	Better understanding by policymakers of opportunities for agricultural development	Addition of biotechnology enhances view of agriculture as a dynamic sector

ANNEX 4: IBS BioServe Data Base

The information presented in figures 1, 2, and 3 is based on the analysis of data collected by IBS through a survey conducted in the period June to October 1993. The survey was undertaken to help fulfill IBS's objective of compiling a registry of expertise in international biotechnology. This registry, named *BioServe*, currently includes information from international agricultural biotechnology programs, defined as organizations or programs that conduct, fund, or coordinate biotechnology-related research, focusing on developing-country agriculture.

The first aim of BioServe is to provide IBS's primary clients with up-to-date details of international biotechnology programs. Primary clients include national policy-making bodies, NARS, and other research organizations, both public and private, in developing countries. BioServe may enable them to identify prospective partners in particular regions or in specific areas of biotechnology research, research management, or policy formulation.

In order to obtain the relevant information in a systematic manner and to ensure utility for analysis by national programs, three different survey forms were designed for the categories of organizations identified below:

- research-based biotechnology programs at national or international public institutes, including the IARCs;
- international or regional biotechnology networks;
- bilateral or multilateral donor organizations that finance biotechnology initiatives for developing countries.

Respondents included 17 programs, six networks, five IARCs, and four donors. This was a combined response of 32 from a total of 38 survey forms mailed. Each survey requested information on, among other things, overall goals and priorities, agricultural and regional focus, training opportunities, research management, research and development, funding, and expenditures. The analysis of data is based on completed surveys checked for accuracy. Upon receipt by IBS, the information collected was reviewed and then entered into a computer data base using REFLEX.

Summing the programs and IARCs provides data for 22 international biotechnology programs. Total funding level cited is derived from the total expenditures analyzed from all sources mentioned above. The figures are based on calculations from the information collected from the 22 international biotechnology research programs, excluding the figures submitted by networks and donor agencies. The figures given on program *funding sources* are averages for nonrecurrent research grants, which is by far the predominant type of finance for international biotechnology programs. It excludes (annually) recurrent funding. Figures for recurrent and nonrecurrent funding have been standardized by IBS, to make valid calculations for *expenditures* by program element.

The 22 international programs submitted information on 167 distinct research projects, out of which 131 have an identified primary route for *technology transfer*. Figure 3 gives the relative distribution of technology transfer routes for these 131 projects.

A complete analysis of BioServe issues and implications is planned as a forthcoming IBS publication. It will be distributed with a complete directory of the international program networks and donors that participated in the IBS exercise.

Covers: Chlorine-free paper
Inside pages: Recycled paper

Produced by ISNAR Publications Services

Text editor: A. Michelle Luijben
Printer: Rapporten Service Drukkerij B.V., Rijswijk, The Netherlands

ISBN 92 9118 015 1

Biotechnology Priorities, Planning, and Policies: A Framework for Decision Making

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