INTER-AMERICAN INSTITUTE FOR COOPERATION IN AGRICULTURE (IICA)

THE DEVELOPMENT OF POLICIES FOR THE DEVELOPMENT OF AGROBIOTECHNOLOGIES IN IICA MEMBER COUNTRIES

March 25, 199

The Coopers & Lybrand Consulting Group

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From: George A. Neufeld
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Subject: **Submission of Final Report**

We are pleased to present our report on **"The Development of Policies For The Development of Agrobiotechnologies In IICA Member Countries"**. The study was undertaken as Subactivity 531 of CIDA/IICA Project II concerning Technology Generation and Transfer. It was an ambitious undertaking and we trust that it will contribute to the formulation of policies on intellectual property for agrobiotechnologies in IICA member countries. We are pleased to have had this opportunity to work with you.

Yours sincerely,

George A. Neufeld

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1.
INTRODUCTION

This paper is one of a series of studies commissioned by the Canadian International Development Agency (CIDA) and the Inter-American Institute for Cooperation in Agriculture (IICA) to support a medium term plan for agricultural expansion and improvement in Latin American and Caribbean countries. The Canadian Executing Agency for the studies is the Department of Agriculture. This paper addresses one of several policy topics which have been selected for examination as part of a longer term plan by IICA to stimulate a collaborative policy planning effort among its members. This joint undertaking is intended to offset and overcome entrenched and adverse trends in the agricultural sector which have had serious economic and financial repercussions for member countries in Latin America and the Caribbean.

Since the early 1980's the economic position of many Latin American Caribbean (LAC) countries has been one of slow growth and stagnation. Tightening world financial conditions, the erosion of commodity prices and markets for agricultural produce, inflation and rising public debt levels have forced a serious and persistent economic crisis on the region.

Agriculture, which is a mainstay of the LAC region's economy, has been impacted significantly by this fundamental change in the business climate. Because it occupies such an important place in the structure of incomes and growth in the region, the agricultural sector has been recognized by the Region as an area requiring special policy and program actions.

In addressing this issue, Ministers of Agriculture of the hemisphere met in Canada in 1987 to discuss the future of agricultural cooperation in Latin-American Caribbean countries and to set priorities for the future. Ministers determined that the major objective of policies and programs must be to reassert and revitalize the formerly dynamic role of agriculture in the social and economic life of the region. They signed the Ottawa Declaration in which they agreed to promote the development and revitalization the LAC region's agricultural sector.

Following the meeting of Ministers of Agriculture, IICA prepared a detailed plan of action. In 1989 it released an action plan for agricultural reactivation (PLANLAC). The Director General of IICA, Martin E. Pinero, summarized its objective as one intended to:

> *"promote the generation of ideas and concrete proposals concerning the reactivation of agriculture and its contribution to economic development."*[1]

Studies in support of this objective began in July 1988 and have been undertaken under the auspices of CIDA, Agriculture Canada and IICA. The intentions of the programs of study have been defined as follows:

> *"The Project activities centre on the modernization and revitalization of agriculture to help bring about economic recovery in the face of widespread crises in the economies of the region. The modernization theme focuses on harnessing the region's underlying strength in agriculture through economic policy reforms, exploitation of new technologies, expansion of non-traditional exports, and recognition of small-scale farmer interests. In this sense, the project is consistent with priorities set out in the Declaration of the Ninth Inter-American Conference of Ministers of Agriculture (Ottawa, 1987).*[2]

There are five areas of Program study:

I. Agricultural Policy Analysis and Planning
II. Technology Generation and Transfer
III. Organization and Management for Rural Development
IV. Marketing and Agroindustry
V. Animal Health and Plant Protection

This paper has been prepared as part of Program II: Technology Generation and Transfer. Within Program II, there are four main activities:

- Activity 510

  Impact of emerging biotechnologies as a basis for setting policy priorities.

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[1]. Plan of Joint Action for Agricultural Reactivation in Latin America and the Caribbean; Principal Document, page 9; 1989, IICA, San Jose, Costa Rica.

[2]. Technical Assistance on Agriculture: IICA CIDA Project Number 540/13127 Inception Report, page 3, June 1989, Ottawa.

- Activity 520

  Assessment of LAC capabilities to generate, adapt and apply biotechnologies as a basis for the development of policy proposals.

- Activity 530

  Formulation of technology policy guidelines including intellectual property rights.

- Activity 540

  Development of guidelines for research management.

Activity number 520 dealing with the establishment of policy guidelines for biotechnology in agriculture is the main concern of this paper.

A companion study to this paper deals with guidelines and proposals for the establishment of intellectual property rights relating to biotechnology. The preliminary conclusions of this companion study were presented to an international policy seminar hosted by IICA in Caracas, Venezuela in November 1990.[3] The importance of intellectual property rights in the research environment was one of the key topics of that seminar. The findings of the companion study have been incorporated into this paper and complement the analysis of the key policy parameters affecting the expansion of biotechnology research and application in agriculture.

[3]. The Role of Industrial Property Protection in the Development of Biotechnologies and the Agricultural Sector; Coopers & Lybrand, Ottawa, November 1990.

2.
BACKGROUND AND CURRENT SITUATION

This part of the paper reviews the key agrobiotechnology policy issues as they have been identified and outlined in PLANLAC and in earlier studies by IICA. It doing so, it aims to preserve continuity in the approach to innovation policy in general, and to innovation in agricultural biotechnology in particular. The discussion attempts to advance the earlier examinations by other researchers and to distill, from them, a "framework of key issues" around which policy priorities, guidelines and suggested worksteps can be developed.

The sections which follow also examine specific roles, needs and opportunities for biotechnology policy. The public sector has played a crucial role for the agricultural sector in research and the dissemination of the results of research. In a period of extensive revitalization and transition for LAC countries, the public sector role will probably become more complex rather than less. It will be under pressure to orchestrate macro-changes in agriculture, set research priorities, provide research funding and to perform a variety of new facilitating roles with stakeholders.

Agrobiotechnology in the LAC region will of course evolve in a climate of research, development and commercialization which is global in nature and highly competitive. The discussion therefore incorporates the effects of issues such as the international business and trade policy climate, corporate strategies, and the role of private capital - all of which will impact on the opportunities for the LAC region.

Policy Issues Identified in Previous IICA Studies

In May 1987, the Institute for Inter-American Cooperation on Agriculture (IICA) held a policy seminar in San Jose, Costa Rica. The seminar dealt with Technological Change in Latin American Agriculture. At that meeting a paper entitled *Technological Innovations in Latin American Agriculture* was presented which was prepared by Alain de Janvry, David Runsten and Elizabeth Sadoulet of the Department of Agriculture and Resource Economics of the University of California, Berkley. The paper provided a comprehensive review of the interrelations between technology change and the major economic, social and agricultural policy issues. It

also identified the key implications for policies and programs of emerging opportunities and needs in technology change.

In a later policy document prepared as a working paper for the Inter-American Conference of Ministers of Agriculture, Eduardo Trigo of IICA prepared a review of the key policy issues relating to innovation in agriculture, entitled: *Technological Innovation in Agriculture in Latin America and the Caribbean - Problems, Opportunities and Issues.* That paper built on the foundation provided by the analysis of the consultants from the University of California. It focused on specific driving forces, policy issues and matters relating to processes, institutions and roles of the key players. It itemized thirty-two key issues relating to innovation and summarized the four main areas which required decisions and specific actions:

- Human Resources in Basic Disciplines
- Priority Setting
- Patents and Property Rights
- Collaborative Processes

The four areas of decision-making provided in the summary of the Trigo paper provide a basis for the development of strategic guidelines in policy development - both for agriculture and for supporting technologies such as biotechnology. The issues identified in the paper by the Department of Agriculture of the University of California and re-examined in the Trigo paper addressed matters of a macro order and also outlined key areas of needs relating to the improved use of biotechnology in agriculture. The *Principal Document of PLANLAC* contains an extensive review of contemporary challenges from the macro-economic and social policy perspective and it provides a description of action plans and goals. Together, these three documents provide the foundations for a classification of strategic issues which policy guidelines for agrobiotechnology will have to incorporate.

The Strategic Policy Issues For LAC Countries

The findings of earlier IICA studies concerning policy issues can be grouped under five main headings. Each heading covers a series of "strategic issues" or "strategic interests" which LAC countries share in revitalizing their agricultural sectors. The main areas of concern identified to date are:

1. Strengthening Macro Economic Conditions
2. The Economics of the Agricultural Sector
3. The Roles of the Public Sector and Research institutions
4. An Improved Climate of Intellectual Property Rights
5. The Maintenance and Strengthening of Regional Collaboration

These five areas of strategic concern capture most of the issues which are believed to condition the role of biotechnology in the agricultural sector. Within each of the five areas of interest more specific issues have been identified. These can be helpful in refining the process of developing policy guidelines. They also assist in the development of policy priorities and program criteria. The following notes summarize the main findings of IICA studies to date under each of the five key areas of concern.

1. Macro-Economic Issues for Public Policy in LAC Countries

The macro-economic crisis of LAC countries has been identified as one which requires policies and programs to target the following issues:

1.1 Improving the ***balance of payments*** with higher exports to create more fiscal flexibility for governments, reduce debt burdens and create jobs and incomes: agriculture has been identified as a central player in the resolution of balance of payments problems.

1.2 A more ***competitive pricing structure*** for domestically produced goods and services is the preferred route to import replacement and import reduction.

1.3 Increasing ***real wages and per capita incomes*** through output gains and productivity improvements is essential to reduce unemployment and reverse the decline or stagnation of living standards.

1.4 A ***reduction in government subsidies*** is necessary to lessen financial burdens on government, ease tax levels and control inflation.

1.5 ***More responsive market places*** to achieve a better allocation of resources are essential to improving productivity.

1.6 ***Industry adjustment to restructured import prices*** will be necessary to offset inflation, improve output and expand exports.

2. The Needs of the Agricultural Sector

The agricultural sector has a complex set of challenges as it responds to external and internal economic and financial problems. Among the key issues will be:

2.1 To make better use of ***LAC's comparative advantage*** in the production of agricultural commodities and food industry products.

2.2 The ***substitution of low cost inputs and production techniques for high cost inputs*** such as land, capital and agrochemicals.

2.3 ***Land-saving production methods*** which expand the opportunities and productivity of agricultural labour.

2.4 ***Reductions in the purchase and use of imported production inputs***: e.g.herbicides, pesticides.

2.5 ***Redistribution of income*** to small scale farmers.

2.6 ***A redistribution of the benefits of research*** and development activities to small scale farmers.

3. The Role of the Public Sector

The public sector's role in growth policies has been traditionally large in LAC countries. Financial and economic constraints have brought about a re-evaluation and downsizing of that role. Key issues for policy planning and development are:

3.1 Improving the ***efficiency and effectiveness of government expenditures*** on agriculture and agricultural research.

3.2 ***A larger financial and operational role for the private sector*** in research, market development, industrial adjustment, and investment decisions.

3.3 Maintenance of a special research and developmental ***role by the public sector to help small scale farmers.***

3.4 The maintenance, improvement and ***coordination between national and international research institutions*** so as to produce economies and scale and specializations.

3.5 The provision of an adequate and ***balanced supply of skilled human resources*** in science for research, development and diffusion of technology.

4. Intellectual Property Rights

The field of intellectual property rights has been recognized in IICA studies as a key to improving private sector participation in biotechnology and other areas of innovation. It is also seen as a facilitating device in achieving higher levels of technology transfer and diffusion within LAC countries. The central issues in this area of concern are:

4.1 Improving LAC country ***access to advanced technology*** and to the economic benefits agricultural production.

4.2 Encouraging a larger flow of ***private sector risk capital*** into LAC-based research and development by multi-national and domestic investors.

4.3 ***Accelerating the innovation process*** in LAC economies.

4.4 ***Harmonizing regional approaches*** to intellectual property rights among LAC countries.

4.5 Integrating intellectual property rights policies with ***international trade policies and negotiations.***

5. Regional Collaboration

The maintenance and improvement of international cooperation within the LAC region, and between the Region and other member states of IICA is a particularly high priority among the key issues of concern. The collaborative networks and consultative processes provide an important mechanism for the achievement of common goals and the sharing of resources. Among the key issues identified under this heading are:

5.1 ***Strengthening the role of horizonal regional consortia*** **and producer groups** in research and innovation.

5.2 Re-defining and focusing ***the roles of the International Agricultural Research Centres (CGIAR)*** so as make use of their comparative advantage and to adjust to changes in the role of national centres and the private sector.

5.3 Improved ***horizontal cooperation in technology transfer*** as a cost-efficient method of technology diffusion.

5.4 ***Collaboration in major areas of trade policy, economic policy, and regulatory policy*** is essential to ensure the orderly growth of the LAC market, its competitiveness in world trade and its attractiveness to the global private sector.

Later in this paper these key strategic and economic issues are refined and regrouped to provide a guiding framework for determining policy priorities and options. Before undertaking that examination it is helpful to understand the climate of opportunities and challenges in agrobiotechnology.

The commercial environment for biotechnology has many features common to any field of emerging technology, such as the requirement for high levels of risk capital and the initial disappointments and unmet expectations. However, it also has features unique to itself which impact on the kind of opportunities which are likely to arise in the next decade. The next section reviews some of those special features, outlines the business and operating climate for the industry and identifies some of the emerging international trends that will shape the industry's options in LAC countries.

3.
POLICIES AND STRATEGIES OF SELECTED ADVANCED INDUSTRIALIZED COUNTRIES

The Policy Environment - Industrial and Technological Factors

In this section we discuss some of the factors which are influencing the development of agrobiotechnology in OECD countries, particularly: a) worldwide agriculture industry and markets; and b) the emergence of biotechnology. We have not performed a comprehensive market and industry study of the agricultural sector or of biotechnology. Rather, we have concentrated on those factors which are relevant to the development and implementation of policies for the revitalization of agriculture in IICA countries.

BIOTECHNOLOGY IS EXPECTED TO HAVE A MAJOR IMPACT ON THE AGRICULTURE AND AGRI-FOOD SECTORS

Several industry sectors in OECD countries, are likely to be affected, including: diagnostic and therapeutic pharmaceutical, food processing, plant and animal agriculture, chemicals, mineral processing and waste management (9).

Assessments in the European Economic Community (EEC) and the United States (US) indicate that biotechnology is one of a small number of technologies which are critical to agriculture and food processing sectors over the next ten years (3). The potential impacts of biotechnology on agriculture include:

- Increased rates of development for new plant and animal species having desired characteristics;
- Substitutes for agrochemicals (pesticides, herbicides, and fertilizers) which are less costly to use, and produce less harmful environmental effects;
- More efficient food processing operations; and
- A greater diversity of agricultural and agri-food products.

THE COMMERCIALIZATION OF BIOTECHNOLOGY IS TAKING LONGER THAN PREVIOUSLY EXPECTED

Although scientific knowledge related to biotechnology is being generated increasingly rapidly (8), early predictions that biotechnology would soon dominate many markets have not been realized. Revenues earned by biotechnology start-up firms have been primarily from contract research, licensing fees, and sale of research materials rather than from the sale of end-use products. Most products that have been commercialized are in the pharmaceutical and health care fields. So far, there has been relatively less commercialization of biotechnology in other areas such as agriculture, forestry, and chemical production. (This excludes long established food processing technologies which are part of biotechnology, e.g., production of alcohol from foodstuffs and cheese from milk.)

The situation in agrochemicals illustrates the small degree of commercialization of products based on the new biotechnology. Current sales to the agricultural sector of products based on biotechnology were approximately $50 million in 1989 whereas the world market for agrochemicals in is the tens of billions of dollars (15). Although some commercial products in areas such as food processing, animal health products and embryo transplantation have appeared, the overall impact of biotechnology on agriculture has so far been very limited. Products such as bioengineered plants and microorganisms are expected enter the market in the 1990's but will take decades to achieve a significant role in agriculture (15).

Several reasons for the slow rate of commercialization of agricultural biotechnology have been cited:

- In some areas, significant basic research is needed before practical advances can be made (5);
- Scaling up processes from laboratory to commercial scale often requires significant technical developments (9);
- The agri-food sector tends to respond to major technology advances, including biotechnology at a slower pace than more research intensive industries (3);
- Public opinion and reaction from producers can also have a significant effect on the rate of introduction of biotechnology into agriculture, (e.g., Bovine Growth Hormone is facing opposition from both consumer groups and dairy farmers) (15).

In spite of the slow rate of commercialization of biotechnology, the view is widely held among both government and corporate planners that biotechnology will have a profound effect on agriculture in the coming decades.

Biotechnology is seen by companies and governments as a means for protecting or increasing market share in a relatively low growth world market for agricultural products.

Although the need for a continued increase in global food production capacity is well established (1), this has not resulted in positive growth rates for agricultural markets. International trade in agricultural products is characterized by weak demand, low commodity prices and growing use of export subsidies. In the 1980's, there has been a contraction in markets for agricultural products in both industrialized and developing countries. Increasing overcapacity within industrialized nations has resulted in: declining prices, increased use of subsidies and trade barriers. There has also been fierce competition among industrialized countries to supply agricultural goods to developing countries. Demand in developing countries, however, has been weak, due to a lack of foreign exchange (6).

Because biotechnology has the potential to increase agricultural productivity and hence lower production costs, it is perceived as an opportunity for producers in industrialized countries to increase sales and exports. Government policy makers, concerned with the health of domestic agricultural sectors, are thus interested in increasing farm productivity to support farmers while at the same time increasing the world's food supply.

The manufacture of agriculture inputs, e.g., products used by the agriculture sector such as seeds, agrochemicals, and animal health products is a major industrial activity within industrialized countries. As production of some products, such as agrochemicals, has spread to developing countries, companies based in industrialized countries have been faced with declining world market shares. Companies such as Monsanto, Dupont and Chevron have embarked on ambitious R&D programs, particularly in biotechnology, to counter the trend towards decreasing market share in some agrochemicals such as pesticides. European and Japanese firms are also pursuing agrobiotechnology research for similar reasons (5).

INDUSTRY STRUCTURE, MARKET SIZE AND GROWTH RATES VARY SIGNIFICANTLY AMONG AGRICULTURAL SUB-SECTORS WHICH WILL BE AFFECTED BY BIOTECHNOLOGY

Biotechnology is expected to play a role in production of inputs to agriculture, farm operations, and downstream processing. The paragraphs below discuss some of the key business and technological factors which may influence the introduction of biotechnology in several major areas of agriculture:

The animal health products sector, which has annual sales of around $10 billion world wide, is expected to grow at an annual rate of 6% over the next few years. Because there are barriers to global marketing, i.e., transport, regulatory, import costs, the world market is highly regionalized.

Technological developments which may potentially impact on the market shares of various competitors include fermentation technology and development of biotechnology-based residue detection systems (5). The US has a strong position in emerging technologies such as microbial recombinant DNA, monoclonal antibiotics and animal cell culture technologies (5). However, the dominant position of US industry may be eroded as innovative new products are introduced by foreign competitors (5).

The nutritional animal ingredients industry has annual sales of around $30 million and an annual growth rate of about 1%. The US is the major producer and consumer of animal feeds, accounting for about one-third of world production. A few large firms such as Ralston-Purina, Farmland Industries, Cargill, Central Soya and Continental Grain have the major share of North American market. Other countries with significant production include the Soviet Union, (about one-sixth of world production), Canada and Australia. The practice of destination milling tends to keep imports low in industrialized countries. The overall growth rate of this market, which is tied to meat and poultry sales, will remain low for the foreseeable future.

Pesticides, including herbicides, fungicides, and insecticides, are a multibillion dollar market. There are approximately 400 firms worldwide, the top twenty-two of which have half of the world market (5). World wide sales of pesticides in the order of $20 billion. The US, which is the largest producer and user of pesticides, is also a significant exporter (5). Some firms in industrialized countries have been losing some market share, partially due to development of production capacity in Asia and Latin America. Agrochemical companies in OECD countries are developing pesticides which are based on genetically modified forms of microbes. The market for microbial pesticides has been estimated to be $2 billion by the turn of century (15).

Fertilizers: Growth in world demand for chemical fertilizers will continue to be strong (5). Fertilizers supply plants with three major plant nutrients, nitrogen, phosphate, and potash. The US, Morocco, Jordan and Tunisia are major exporters of phosphate containing fertilizers, which are derived from phosphate rock. Canada and the USSR are major suppliers of potash. Nitrogen-containing fertilizers use ammonia as feedstock, a chemical industry product whose price has been increasing in recent years. There is considerable interest in the use of biological nitrogen fixation (conversion to a form usable by plants) as an alternative to chemical fertilizers. These products, which would be nitrogen-fixing bacteria or crops which are genetically altered to perform their own nitrogen fixation, could reduce the market for chemical fertilizers. The US is particularly interested in this area of biotechnology since it is an net importer of nitrogen-containing fertilizers.

Animal Breeding: Meat sales have been flat in industrialized countries in recent years. However there are some high growth segments due to changing consumer demand, e.g., poultry. Historically, the industry has not been strongly affected by international competition. However, technological advances which allow storage and transportation of embryos and other materials are increasing international sales in genetically superior breeding stock. Annual sales of embryos in the US in the 1980's was estimated in the $20-$30 million range. Many small farms practice animal breeding, however, in the last decade, corporations have begun to dominate the industry (5). In Canada, joint ventures involving government and Canadian industry have established domestic and export markets.

Plant Breeding: Worldwide sales of seeds are in the order of $30 billion and are expected to grow at about 5% annually. The industry in industrialized countries is mature, being dominated by a few large companies, some of whom have been acquired by multinational agrochemical companies. Large seed companies are integrated operations which perform research to develop new strains, conditioning, production and marketing. Growth has been increasing in last decade due to changing agricultural practices such as increased seeding rates. This is particularly true for hybrid corn, the seed species with the highest sales volume (5). Although the US is the dominant exporter, the Japanese and Dutch have entered the market by acquiring multinationals which have seed businesses.

Plant breeding has increased the yield of crops throughout the world about 1% per year since 1930 (8). Biotechnology, in combination with conventional plant breeding techniques, can potentially increase the rate at which new varieties are developed.

The food processing industry is becoming more globalized with increased multinational corporate ownership, trade flows and linkages with international partners (3). Significant consolidation and rationalization of food and beverage companies has occurred during last ten years (3).

The potential for biotechnology applications appears greatest for low-priced, high-volume products sold in large markets, if biotechnology-based processes can be scaled up to operate at lower production costs than the equivalent natural products (3).

Markets for some agricultural products are growing relatively faster. For example, changing consumer habits have resulted in increased markets for healthier, low calorie foods, and for foods which are easier to prepare (3). The growth among consumers of concern about pesticides, and chemical additives may create markets for biotechnology applications.

THE PRIVATE SECTOR IN OECD COUNTRIES IS MAKING SIGNIFICANT INVESTMENTS IN AGRICULTURAL BIOTECHNOLOGY

The United States, Japan, Britain, Sweden, Canada and Finland have significant industrial biotechnology activities. The size of private sector investment varies by several orders of magnitude among OECD countries. The US is the leading country in industrial biotechnology with private sector expenditures of over $3 billion, roughly equal to that of similar expenditures in the public sector (9). By the mid 1980's, there were about 350 US companies involved in biotechnology, divided about evenly between established and start-up companies (9). Approximately one third of the companies in each group were focusing on agrobiotechnology. About 16% of US private sector R&D expenditures or $500 million annually is made on agriculture applications (15). By contrast, private sector spending on agricultural biotechnology in Canada, the US's largest trading partner, was in the $30-$40 million dollar per year range.

As with other areas of biotechnology, the US and Japan appear to be the world leaders. US industry has the advantage of direct access to the basic research performed in university and government laboratories. In addition, the combination of US-based multinational agrochemical companies and R&D oriented, start-up firms with expertise in agrobiotechnology provide considerable opportunities for synergy. Japan's well-established expertise in commercial fermentation processes is expected to provide a major advantage in commercialization of biotechnology (3). Japanese companies have; utilized biotechnology for production of foods and pharmaceutical since the turn of the century; used microbial physiology to produce sake, miso (bean paste), and soy sauce; and applied molecular genetics to the industrial production of

amino acids. Companies such as Tanabe Pharmaceutical developed continuous fermentation processes utilizing immobilized microorganisms and enzymes (13).

European countries became involved in biotechnology later than the US and Japan (9). Within Europe, Britain and France are the leading countries in biotechnology. The UK appears to lead in commercial developments of commodity foodstuffs whereas France has several companies concentrating on specialty food product development. West Germany is developing new enterprises within established processing companies (3). Biotechnology companies are beginning to emerge in the Netherlands and Switzerland.

BIOTECHNOLOGY START-UP FIRMS FORM A MAJOR PART OF THE BIOTECHNOLOGY INDUSTRY, PARTICULARLY IN NORTH AMERICA

There are a large number of small, R&D intensive biotechnology firms in the United States and Canada. Many of these firms are spin-offs of university R&D groups and have been successful in attracting funding from venture capitalists and large, multinational corporations. One study estimated that equity funding of the biotechnology industry in the US and Canada in the mid 1980's was approximately $5.4 billion and $378 million respectively (9). Public and private financing has been the major source of this equity, accounting for about 80% in US and 65% in Canada. Contract research accounts for 15% in US and 25% in Canada, grants account for 6% in US and 10% in Canada (9). The major source of funds for start-up biotechnology companies has been contract research and equity funding, with relatively little funding coming from sale of products (9).

European countries with significant numbers of start-ups are Britain and Sweden, with some in the Netherlands (12). There are virtually no start-up companies in Japan where the private sector effort in biotechnology is concentrated almost entirely in large corporations (9).

VENTURE CAPITAL FIRMS HAVE BEEN MAKING INVESTMENTS IN BIOTECHNOLOGY START-UP FIRMS, PARTICULARLY IN THE UNITED STATES

Venture capital firms have been very active in financing biotechnology start-up firms for several years. The United States is the major source and market for venture capital, however, European countries such as Britain, the Netherlands, France and Germany have significant amounts of venture capital invested. Only about half of this venture capital is invested in small, technology-intensive start-up firms. Approximately 10% of it is invested in foreign firms, located principally in the United States (12).

Venture capitalists have been moving away from early stage investments towards more certain ventures with shorter payback periods. Seventy-seven percent indicated they were at least moderately satisfied with biotechnology investments. Ninety-two percent of those venture capital firms who have previous invested in biotechnology indicated they will do so again given the right opportunity. Fifty-five percent said they would continue to fund very early stage ventures (18).

MULTINATIONAL COMPANIES IN THE AGRICULTURE, AGROCHEMICAL AND FOOD PROCESSING SECTORS WILL PLAY A MAJOR ROLE AS USERS AND SUPPLIERS OF AGRICULTURAL BIOTECHNOLOGY

Large, established companies in the resource processing, chemicals, pharmaceutical, and food markets have been investing in biotechnology. Approximately 30 major US corporations have in-house development programs in biotechnology, about one-third of them related to agriculture. They include: Allied Chemical Corp., American Cyanamid, Dow Chemical, Eli Lilly, General Foods, W.R. Grace & Co., Miller Brewing Co., and Monsanto (9).

These multinationals, as well as mid-sized, established firms, been investing in small, start-up biotechnology companies and financing R&D performed by these companies and by university research groups. Arrangements whereby larger firms finance R&D by small, technology-oriented firms in return for licensing rights have been used as an alternative to direct investment, thus allowing the smaller firms to retain some independence. Similar arrangements are also being used with universities and, to a less extent, government laboratories. This has created considerable controversy within and outside these laboratories because of: a) a perceived loss of independence in choosing research topics; and b) the privatization of research results, i.e., they are not universally available.

Multinationals perform or fund the major share of the applied R&D done in the private sector in OECD countries. More importantly, their financial resources and stability make them the most likely ones to succeed in commercializing agricultural biotechnology, and they have the marketing capabilities needed to obtain an adequate return-on-investment. Countries such as the United States, Britain, Sweden, France and the Netherlands have a base of domestically-owned multinationals who have major involvements in biotechnology. Industrialized nations such as Canada, who do not have multinational companies and whose biotechnology industry is made up of small, R&D oriented companies may have serious difficulty competing in a global economy increasingly dominated by multinationals (9).

There is considerable variation among OECD countries regarding the number, size and ownership of established multinational companies whose business is relevant to biotechnology. Countries such as the US, Britain, Sweden, and Switzerland have large and medium-sized multinationals who are in a position to capitalize on biotechnology. In France, the government has majority ownership in virtually all of the large chemical and pharmaceutical companies, e.g., Sanofi, Rhone-Poulenc, Elf-Aquitaine (12). German multinationals have been fairly conservative in entering biotechnology field, but have recently begun to do this (12). The close working relationship between biotechnology start-up companies and large multinational companies which is prevalent in the US is less well-developed in Europe (12).

COMPANIES IN OECD COUNTRIES HAVE BEEN FORMING INTERNATIONAL STRATEGIC ALLIANCES, JOINT VENTURES AND OTHER MECHANISMS TO POSITION THEMSELVES TO EXPLOIT DEVELOPMENTS IN BIOTECHNOLOGY

The interaction among OECD countries in biotechnology, particularly between Japan and the US, is characterized by both intense competition and strategic alliances (9). Alliances with US companies are useful to Japanese companies since they gain access to US R&D results and expertise. In return, US firms expect to gain access to Japanese production capabilities and far east markets (9). Japanese companies also look for small, innovative start-up firms in other countries besides the US. One firm has licensed technology for microbial product used in production of specialty dairy foods from a Canadian firm (3). European companies are also forming alliances with US firms, although these have been mostly in the human health care field.

Policies and Priorities Relevant to Agrobiotechnology

In this sub-section we provide an overview of government policies and priorities which are prevalent in OECD governments that are having a significant influence on biotechnology programs. These cover the areas of: a) agriculture; b) the environment; c) decentralization; d) fiscal restraint; e) industrial restructuring; and f) strategic technologies.

1. Government Priorities and Strategies Relevant to Biotechnology

AGRICULTURAL POLICIES DEALING WITH FARM SUBSIDIES, PRICES AND TRADE MAY HAVE A MAJOR INFLUENCE ON THE APPLICATION OF BIOTECHNOLOGY TO AGRICULTURE

Industrialized nations are concerned about maintaining the viability of their domestic agricultural sectors. Although a relatively small proportion of the population in industrialized countries works in primary agriculture, a much larger number of people work in food processing and distribution. Loss of domestic agricultural production would necessitate significant industrial restructuring, beyond what industrialized nations are already dealing with. In addition to economic reasons, there are political and philosophical reasons for maintaining the viability of domestic agriculture which are not likely to change in the near future.

Government-funded agricultural R&D programs in developed countries are aimed at helping producers become more productive. These objectives of these programs are to help farmers stay in business while at the same time increasing the world's food supply. It has been argued that, while these are worthy goals, spending increasingly greater amounts of money on R&D designed to maximize production of food in high production cost countries is an inefficient use of global resources (7). OECD countries have utilized subsidies and concessional financing by government agencies to promote the export of agricultural goods (6). Incentives provided by the governments of industrialized countries to support domestic agriculture act to favour production in high-cost industrial countries rather than in low-cost developing ones (6). These practices distort the balance of trade in agricultural goods and services from what would exist based on purely economic factors.

Policies dealing with prices and imports of agricultural products have implications for agrobiotechnology. For example, artificially high sugar prices in the US, designed to protect domestic producers, led to the commercial production of fructose from corn starch (3). Agricultural subsidies could also inhibit innovation by lowering the return-on- investment below what would be obtained if true market prices could be obtained.

INCREASED SCIENTIFIC KNOWLEDGE AND PUBLIC PRESSURE HAS LED GOVERNMENTS IN INDUSTRIALIZED COUNTRIES TO UNDERTAKE SUBSTANTIAL REGULATORY, SCIENTIFIC AND INDUSTRY SUPPORT INITIATIVES

Government policies on sustainable development include sustainable agriculture as a key component. The agricultural objectives stated in Canada's Green Plan are representative of OECD countries:

- Conserving and enhancing natural resources that agriculture uses, i.e., soil, water, genetic diversity;
- Compatibility of agriculture with other natural resources, e.g., minimizing pollution from agricultural wastes, pesticides, etc; and
- Being proactive in protecting agri-food sector from environmental impacts caused by other sectors and factors external to agriculture, e.g., industrial pollution.

Because agrochemicals are widely considered to be responsible for significant negative environmental impacts, governments are being pressured to restrict their use. Not surprisingly, the amount of product testing required to obtain regulatory approval for new agrochemicals, and the associated costs to manufacturers, have increased substantially in OECD countries in recent years.

THE CURRENT PRESSURES TO REDUCE PUBLIC SECTOR SPENDING IN SOME OECD COUNTRIES IS HAVING A SIGNIFICANT INFLUENCE INDUSTRIAL & TECHNOLOGICAL DEVELOPMENT PROGRAMS

Besides affecting the overall level of available funding, these pressures influence the way that government laboratories conduct their operations. In Canada and Britain, government laboratories are being increasingly directed to achieve at least partial cost recovery through a variety of mechanisms for working with industry. These directives are also aimed at making R&D performed in government laboratories more market-driven. There is no consensus among the groups involved on whether the increased emphasis on cost recovery will be beneficial. Efforts are being made to privatize government research institutes, particularly in Britain.

GOVERNMENTS IN OECD COUNTRIES HAVE UNDERTAKEN OR ARE CONSIDERING MAJOR PROGRAMS TO REVITALIZE INDUSTRY THROUGH SUPPORT FOR STRATEGIC TECHNOLOGIES

Governments in OECD countries have recognized biotechnology as one of a small number of strategically important technologies including microelectronics, information technology, and advanced materials. Several OECD countries have set up national biotechnology strategies and programs in biotechnology. The goals of these programs include: funding support, promoting changes in the structure of the R&D establishment, and establishing a political consensus in support of biotechnology (12). The programs generally involve extensive consultation between government and private sector groups with the aim of building consensus. Programs in France, Germany, and Canada involve all relevant departments and agencies. Japan and Britain have programs which are coordinated by individual ministries and agencies (12). The role of these programs in R&D, technology transfer and commercialization will be discussed in the following paragraphs.

IN SOME OECD COUNTRIES, THERE IS CONSIDERABLE POLITICAL PRESSURE FOR DECENTRALIZED PROGRAMS AND INSTITUTIONS

This trend is evident in some European countries, particularly Belgium (12). Science and technology programs in Switzerland are already highly decentralized, with federal government expenditures being about one third of the total. The current constitutional developments in Canada will likely accelerate the decentralization of government services to provinces which has been occurring for several years. The implications for biotechnology of increased decentralization are not clear at this time. It could possibly limit the effectiveness of national programs on strategic technologies by making them little more than "packaging" of what are actually independent programs. On the other hand, decentralized decision making and control may allow closer collaboration between public and private sector efforts.

2. Research & Development Programs

In OECD countries, there are several important sources of expertise relevant to development and use of agrobiotechnology, including: federal and provincial agriculture departments, university faculties of agriculture, agricultural community colleges, agricultural crown corporations, marketing boards, cooperatives, NGO's, consulting, manufacturing firms (6). In the following paragraphs, we describe some of the key features of public sector support for agrobiotechnology R&D.

THE ROLE OF GOVERNMENTS IN FUNDING AND PERFORMING BASIC AND APPLIED RESEARCH AND DEVELOPMENT VARIES AMONG OECD COUNTRIES

In all OECD countries, basic research is principally the responsibility of the national government. It is performed mostly in universities and to a lesser extent in national research institutes (12). There is a diversity of approaches in funding and performing applied R&D in OECD countries. In the US, funding of applied R&D is limited mainly to defence. An exception Japan, on the other hand, has a long tradition of government intervention in the economy, setting long-range goals, managing programs to meet them (2).

In Canada, there is increased emphasis on more applied, market-driven R&D. Agriculture Canada laboratories are entering into collaborative R&D projects with individual and groups of companies, whereby the companies receive the rights to an exclusive use of the technology developed, in return for financial or in-kind support. By contrast, the US Department of Agriculture has been directed to perform more basic research, and leave applied R&D to the private sector. Although the trends in the United States and Canada reflect different philosophies regarding the role of public sector labs, the net result is the same: decreasing public availability of applied R&D results.

IN SOME OECD COUNTRIES, NATIONAL RESEARCH INSTITUTES ARE PLAYING A MAJOR ROLE IN BIOTECHNOLOGY RESEARCH

Countries with national research institutes include: Canada, the US, Japan, Britain, Germany, France, Sweden, Norway and Spain. Switzerland, the Netherlands, Denmark, Italy and Finland do not have national institutes performing significant amounts of biotechnology (12).

In some countries, national research institutes have been organized into networks, e.g., the CNRS in France, the MRC in Britain, and the Max Planck Society in Germany. In the US, the National Institutes of Health and certain biological programs of the national laboratories operate in a similar manner (12).

Research in the principal labs of OECD countries has evolved by a combination of influences: the initiatives of individual investigators, peer review, and the historical development of the laboratory - not as a component of national biotechnology strategy (12).

MAJOR EMPHASIS IS BEING PLACED ON RESEARCH PROGRAMS FUNDED JOINTLY BY GOVERNMENT AND INDUSTRY

These programs, which are increasingly being used in Europe, Canada and Japan, involve participation of both government and university laboratories. Agriculture Canada's jointly funded programs have involved both Canadian and multinational agrochemical and seed companies. The National Sciences and Engineering Research Council has put in place several mechanisms for funding research projects in which one or more companies provide a percentage of costs of university-based R&D programs. Canadian companies such as Semex Canada, Allelix Inc. and Shaver Poultry Breeding farms have contributed from $100 to $400 thousand to five year funding agreements. NSERC's contribution has been from one to four times the industry contribution (10).

GOVERNMENT FUNDING OF BIOTECHNOLOGY R&D VARIES CONSIDERABLE AMONG OECD COUNTRIES

As can be seen from the data below, US public sector funding of biotechnology, which was close to $3 billion annually in the late 1980's, is by far the largest of the OECD nations. Other OECD countries such as Japan, France, West Germany and the UK spend several hundred million each annually (9).

Country	Biotechnology Funding, 1985/6 ($millions)
United States	$2,835
Japan	$ 412
France	$ 335
West Germany	$ 327
Britain	$ 267
Sweden	$ 150
Denmark	$ 134
Switzerland	$ 120
Canada	$ 79
Italy	$ 69
Belgium	$ 49

GOVERNMENTS IN OECD COUNTRIES ARE FUNDING RESEARCH IN AGRICULTURAL BIOTECHNOLOGY (12)

The US and Japan are the major players in agricultural biotechnology. The US leads in basic research while Japan's extensive experience in industrial fermentation will be an important asset for supporting commercialization. In Europe, the leading countries are Britain, Denmark, France and West Germany (3). In Britain, government programs have given priority to biotechnology particularly in new plant breeding techniques and in enzyme engineering with increased emphasis on food research (3).

National R&D programs, which are aligned with national technology strategies, seek to strengthen areas where there are deficiencies. Although each country has specific strengths and weaknesses, several critical areas which require strengthening have been identified in most European countries. have been identified by most European countries.

SEVERAL JOINT INITIATIVES HAVE BEEN UNDERTAKEN BY EUROPEAN COUNTRIES

International programs are designed to maximize the effectiveness of available R&D resources and to access broader capabilities and results.

The EUREKA program which involves joint participation of European nations in R&D related to strategic technologies includes a biotechnology component (11). Longer term, high risk projects are the focus. The EUREKA organization is based on national coordinators in each member country and the EEC and a secretariat with central authority which helps to organize ministerial conferences and high-level group meetings (2).

The Commission of the European Economic Community has established a biotechnology program to encourage R&D in member countries as part of a five-year biotechnology mobilization strategy. The program emphasizes pre-competitive research aimed at enhancing long-term industrial and agricultural competition (9).

The European Laboratories Network, which involves the labs of twenty-one member states aims to encourage cooperation between small European research teams wishing to participate in EEC programs (11).

Another effective means of expanding national access to the results of basic research is through international exchanges of personnel, e.g., postdoctoral fellowships, visiting faculty positions, graduate fellowships for study abroad. A recent review of personnel exchanges between European countries indicated that the US is acting principally as a host country and is not sending its scientific personnel abroad (12). Similar findings have been reported with respect to Japanese personnel exchanges.

3. Technology Transfer and Commercialization Programs

Improving the rate of technology transfer and commercialization is a priority in OECD countries where the view is widely held that R&D intensive and high growth industries need government investment to share risk of investment. The rationale is that part of the return-on-investment accrues to society. The role of government in assisting the creation of world-class competitive businesses is considered particularly critical in countries with few indigenous strong companies such as Canada.

Government-funded or operated technology transfer institutes have been used in Canada, Japan and most European countries, particularly Britain. However the United States has not used them and some European countries such as Italy, Norway Spain and Switzerland have been slow to do this (12).

Mechanisms to speed up transfer and commercialization of technology used by European countries, include: technology transfer institutes, funding of applied R&D performed in universities, research institutes, and the private sector, tax credits for industrial R&D and innovation, loans & grants for new products & processes, and risk capital for new companies (12).

Product sharing risk funds in Sweden, France, and Japan are based on conditionally reimbursable loans, repayable only if the project succeeds. They are intended to fill the gap between support for R&D and capital funding for fully commercialized products (2). Typically these funds cover 50% of the new product risk and use careful screening of recipients.

Some countries, including France, Germany and Canada, have programs to disseminate information on biotechnology (12). There are also international programs. The EEC and the British Library have set up the European Biotechnology Information Program (12).

OECD countries use several types of formal and informal mechanisms for transfer of technology from universities to industry. Many universities have technology transfer offices which may receive funding from government programs. In Japan, there is a history of university-industry cooperation in biotechnology. Many of the leading industrial researchers in biotechnology are graduates of faculties of agriculture of Tokyo and Kyoto Universities. Some professors at these universities are board members of industrial companies and others hold directorships of industrial labs (13).

The US places less emphasis on technology transfer institutes and more on funding and incentives. About half of the state governments have supported venture capital corporations which provide financing and management expertise to start-up companies (2). Governments provide the financial support by a variety of mechanisms including: selling bonds, tax incentives to investors in the fund, allowing pension funds to be invested and appropriations (2).

4. Industrial Development and Restructuring - Programs and Incentives

In addition to support for biotechnology R&D and commercialization, programs which support the creation of new businesses or expansion of existing ones can play an important role in the commercialization of biotechnology. These programs, which have been evolving over many years, are critical to the efforts of industrialized countries in restructuring their economies. The need for restructuring has resulted from declining revenues and employment in mature industries. This has been caused by a number of factors, including: changing technologies, rapid industrialization of low wage countries, ease of technology transfer, and changing global trade patterns. Industrial development programs also address the need for development of poorly industrialized regions.

While R&D and technology commercialization programs are provided primarily at the national government level in OECD countries, the relative roles of national, regional and local governments in industrial assistance programs is somewhat more variable. The US stands out as having a federal government which does not provide significant incentives, compared to more local levels of government (4).

Incentives are aimed at the following types of industry: a) specific industry sectors (sectoral incentives); b) economically depressed regions (regional incentives); and c) companies who contribute to the balance of trade (export incentives) (4). Sectoral initiatives include those directed at R&D intensive industries, high growth industries, and those industries which add value to locally available natural resources. Manufacturing sectors are generally favoured (4). Incentives provide support for the following types of activity: building new facilities or expanding & modernizing existing ones, employing local persons, and increasing R&D (4). Regional incentives are

directed at regions: have chronic high unemployment, which have suffered negative consequences of industrial re-structuring, or are border regions.(4)

International agreements limit some types of incentives. In the European Economic community, member countries are limited in the extent to which they may apply regional incentives. The Canada - US Free Trade Agreement provides limits on certain types of industrial incentives which had previously been used. (4)

THERE ARE SIMILARITIES BETWEEN INCENTIVES IN INDUSTRIALIZED AND DEVELOPING COUNTRIES

Incentives in both types of countries are directed at similar sectors of the economy and provide support for similar industrial activities. The types of incentives used in both groups of countries include: grants, guaranteed and/or subsidized loans, reduced corporate taxation rates, accelerated depreciation and other tax exemptions, sale of land at reduced prices, availability of infrastructure services (rail links, electricity, industrial parks, etc.), exemptions on import duties, reduction or exemptions on sales taxes and value-added taxes, provision of contacts with investors, suppliers, and other relevant organizations, and training subsidies.

The principle of providing monetary incentives as matching funds - with industry spending, is used in both developed and developing nations (4). Both industrialized and developing countries make incentives available to domestic and foreign-owned companies but tend to give preference to the former (4). In some countries, incentives may be negotiated between the participating levels of government and the applicant company on a case-by-case basis, e.g., France. (4)

Both industrialized and developing countries are constantly reviewing and revising their incentive programs. Many of the programs are of limited duration so that a review is performed prior to their being continued. While the levels of incentives fluctuate, depending on government priorities, there does not appear to be an overall trend among OECD countries (4).

5. Intellectual Property Regulations

An extensive discussion of intellectual property (IP) regulations in OECD countries for biotechnology and agriculture was provided in a previous paper. In this sub-section we review the key issues surrounding IP regulations which are relevant to agricultural biotechnology.

There is increased recognition of the importance of IP as OECD countries restructure to knowledge-based industries and the globalization of industrial R&D and production. The United States, in particular, has been working to increase standards of IP protection through the GATT, the WIPO and bilateral discussions. Other OECD countries have generally supported the US led efforts.

There is substantial and growing uniformity in intellectual property protection mechanisms in OECD countries. This includes administrative aspects such as filing and disclosure regulations, protection periods, and the extent of coverage.

The emergence of biotechnology presents special problems of legal definition, property rights enforcement. The roles of patents and plant breeders rights in protecting innovation in plant biotechnology has generated some controversy. There is a need to be fair to conventional methods, which will play continue to play a significant role and be enhanced by new biotechnology, while at same time, accommodating new areas of knowledge. National governments and the international bodies are working on harmonizing the two systems.

6. Biotechnology Regulations

The products of biotechnology could, in principle, pose serious hazards to the environment and human health. Governments in OECD countries have recognized this and are attempting to develop regulatory policies which protect the public and environment while avoiding placing unnecessary obstacles to commercialization.

While biotechnology regulations are necessary to safeguard the environment and human health. they have potential to impede progress in biotechnology by: a) increasing the costs, time and risks of commercialization; and b) functioning as unnecessary or unfair non-tariff trade barriers. In particular, Denmark has passed extremely stringent biotechnology regulations and Germany has proposed similar ones. Critics argue that these regulations are unnecessarily strict and will act to stifle industrial innovation (12). In order to develop regulations which provide adequate protection without undue restrictions on biotechnology research and commercialization, considerable emphasis is being placed on the need for scientific risk assessment. Biotechnology research programs will be required to provide the knowledge base to support scientific risk assessment (12).

The level of administrative complexity is another factor being considered. In Canada, there are over thirty laws administered by eleven governments that can effect the commercialization of biotechnology-related R&D (9).

In most OECD countries, a committee infrastructure has been set up to deal with regulatory issues and their interaction with other areas of public policy relevant to biotechnology (14). Key objectives of these efforts are to a) ensure that the priorities of all relevant government departments and the private sector are adequately taken into consideration; b) streamline procedures for complying with regulations, and c) disseminate information to biotechnology companies.

OECD countries are working towards international harmonization of regulations related to biotechnology (10). The OECD Committee for Scientific and Technological Policy had a group of experts from member countries develop a set of guidelines for Agricultural and Environmental Applications of Organisms Derived from Recombinant DNA Techniques, which were published in 1986 (14). Countries with biotechnology legislation or guidelines have generally found the OECD guidelines to be useful. Countries with no regulations or non-specific regulations have questioned the need for specific guidelines but have established committees to study this (14).

Guidelines are being written in member countries for large-scale contained applications and environmental releases, the latter lagging somewhat behind the former (14). New issues being addressed include accidental release of genetically modified organisms and waste disposal (14).

In Canada, the National Biotechnology Advisory Board has identified the following characteristics of successful regulatory policies (10):

- engenders public confidence
- makes economic sense
- allows industry planning for development and commercialization
- has international compatibility
- flexibility to accommodate new developments
- clarifies jurisdictional responsibilities and avoids duplication
- based upon risk assessment principles
- defined responsibilities for risk management
- draws upon independent scientific advice

Experience with Program Effectiveness

R&D PERFORMED IN GOVERNMENT LABORATORIES HAS NOT GENERALLY BEEN EFFECTIVE IN GENERATING COMMERCIALIZED TECHNOLOGY

Government laboratories in several OECD countries have not been particularly effective in this area. (12) Government-owned multinationals have indicated their priority is to acquire technology from foreign start-up firms and to do R&D in-house. Similar results have been found in Canada. As a result of relatively little transfer of technology from government laboratories to industry, there has been a major effort in recent years to increase the amount of government-funded research performed by industry.

It should be noted that developing technology for commercialization and providing technical support to industry are not the only goals of government research laboratories. They are also involved in providing the scientific knowledge for government regulations and policy.

GOVERNMENTS CAN PLAY AN IMPORTANT LEADERSHIP ROLE AS A CATALYST AND FACILITATOR

Industrial policies aim to enhance the development of profitable firms which can compete in global markets. They must also take into consideration a broad range of social and economic goals, including redistribution of wealth and regional development. Priorities for science and technology should be established by a consensus of government, industry, labour and other stakeholders (2). Countries such as Japan, West Germany and Sweden have intricate institutional frameworks for setting priorities, gaining consensus and concentrating resources in strategic competitive areas (2).

Policy makers in most OECD countries believe that the appropriate role for government is to create the science and technology infrastructure needed to support new industries, not to create or manage the companies themselves (2).

INDUSTRY SHOULD PLAY THE MAJOR ROLE IN IDENTIFYING MARKET OPPORTUNITIES

A recent comparative analysis of government programs in industrialized countries concluded that governments should avoid trying to identify market opportunities or pick specific products or types of products as "technological winners", except where it is the natural purchaser of the product. Thus French government efforts in aerospace and computers, areas where government is a major purchaser, have been very successful. Similar success has not been achieved in biotechnology, where the market consists of large numbers of non-government purchasers. Japan's successful science & technology programs have been based on industrial priorities. This is why Japan locates major research facilities near major industries (2).

POLICIES SHOULD ENCOURAGE INDUSTRY PARTICIPATION IN R&D AND INDUSTRY INVESTMENT

One of the weaknesses identified in Canada is the high percentage of R&D spending done in government labs relative to that done in the private sector. In recent years, much of Canadian government policy on R&D has sought to increase the relative amount done in industry. This amount has been slowly increasing.

Provision of incentives on a matching basis to companies is considered to be an effective way of increasing private sector investment in R&D. On the other hand, providing support through contract R&D has sometimes resulted in the creation of firms whose only line of business is to supply R&D services to government. This is appropriate if the purpose of the R&D is to help government fulfil its mission, but not if the R&D funding was intended to help companies develop new products for other markets.

POORLY FOCUSED POLICIES HAVE NOT BEEN SUCCESSFUL

Policies have sometimes lacked focus in the following ways (2):

- failure to distinguish between traded and non-traded products;
- not focusing on building strong companies capable of competing internationally rather than propping up sheltered industries; and
- confusing industrial development with regional and social development.

The following mechanisms have a strong track record in OECD countries (2):

- R&D tax incentives and matching grants;
- risk-sharing funds for new product development and market expansion;
- prototype end-user purchasing for high technology products;
- strategic procurement in government purchasing; and
- applied research consortia of industries, universities and government.

ALTHOUGH UNIVERSITY RESEARCH IN OECD COUNTRIES IS GENERALLY OF A HIGH QUALITY, VARIOUS INSTITUTIONAL PROBLEMS HAVE BEEN IDENTIFIED

European university research, which is organized differently than in the United States, has been criticized for providing few opportunities for independent research among young researchers (12). Researchers there do not usually acquire responsibility for managing their own research until their early forties, compared with early thirties in the US (12). It also fosters an attitude towards industrial R&D. Universities in OECD countries are having difficulty reorganizing their programs to accommodate the rapid growth of knowledge in the biological sciences. Lack of available faculty positions is a problem in attracting high calibre researchers in new fields such as those related to biotechnology. Because university infrastructure funding is separate from research funding, research funding has increased and infrastructure funding has decreased. This is believed to limited the effectiveness of increased university R&D budgets in priority areas such as biotechnology (12).

In the United States and Canada, serious problems have been identified with respect to the allocation of research funding. Many university research groups indicate that their equipment is becoming outdated and point to a need to re-vitalize the research infrastructure. There have also been widespread discussions about whether too many research groups are being funded at too low an average level.

4.
POTENTIAL OPPORTUNITIES, THREATS AND CHALLENGES ASSOCIATED WITH THE DEVELOPMENT OF AGROBIOTECHNOLOGIES IN LAC COUNTRIES

In this section we describe potential opportunities and threats for LAC countries which may emerge from the application of biotechnology to agriculture, and challenges which they will face in managing agricultural biotechnology. The information is based on a review of several key documents, including previous reports on IICA studies. The material in this section is not intended to be an exhaustive treatment of the topics discussed but to provide an overview which can form a basis for the discussion on policy options in Section V.

Potential Opportunities

BIOTECHNOLOGY CAN MAKE A SIGNIFICANT CONTRIBUTION TO THE AGRICULTURE SECTOR IN IICA COUNTRIES

Biotechnology offers numerous opportunities for LAC countries, including: a) improving agricultural productivity and quality; b) substitution of imported inputs such as agrochemicals; and c) expanding and diversifying the markets for food and beverage products (3). Representative opportunities in these areas, which have been described in detail elsewhere (19), are briefly discussed in the paragraphs below.

AGRICULTURAL PRODUCTIVITY AND QUALITY

As discussed in section III-A, biotechnology may allow farmers increase their productivity through improved crops, farm animals, herbicides, pesticides and fertilizers. Examples of problems in LAC countries which might be addressed by biotechnology are shown below (6, 7):

- increasing productivity of basic food crops (mainly cereals), and high energy and high protein products from minor crops (.e.g, root crops, pulses, legumes) and livestock;

- producing larger yield of animal feed per unit acre of land than under present production systems, in countries with adequate seasonal rainfall;
- improving the uniformity of quality of agricultural products;
- elimination of chronic diseases such as hoof and mouth disease and pests, such as fruit flies;
- enhancing the genetic production potential of farm animals; and
- overcoming adverse effects of tropical climate on productivity and reproductive efficiency of livestock, and on the nutritive value of the forages they consume.

Biotechnology is not a unique source of solutions for the problems discussed above. The use of conventional plant and animal breeding techniques, agrochemicals, and animal health care technologies have resulted in large increases in productivity over several decades. However, the rate of productivity increase from these methods has been declining in recent years, indicating that existing technologies are reaching the point of diminishing returns (20). Biotechnology offers new approaches to increasing productivity which may result in a substantially higher return on R&D investment.

DOMESTIC PRODUCTION OF AGRICULTURAL INPUTS

LAC's could use biotechnology to produce agricultural inputs such as biological herbicides, pesticides and fertilizers, thus reducing dependence on imports. In addition to the favourable effect on balance of trade, domestic capabilities in R&D and production could ensure the availability to farmers of modern products suited to conditions in LAC countries.

EXPANDING AND DIVERSIFYING MARKETS

There may be opportunities to produce food products targeted at export markets and to overcome non-tariff trade barriers to exports to industrialized countries which are based on product quality, e.g., caribbean fruit flies problem; South American beef - hoof and mouth disease problem.

There could also be opportunities for production and export of non-food products made from agricultural feedstocks, e.g., fuels, specialty chemicals, and materials.

Potential Threats

USE OF AGRICULTURAL BIOTECHNOLOGY IN LAC COUNTRIES COULD RESULT IN MULTINATIONAL CORPORATIONS EXERTING INCREASED INFLUENCE OVER AGRICULTURE

If multinationals are the predominant source of improved agricultural inputs developed by biotechnology, they may be able to charge monopoly prices for them. Farmers may be constrained to using proprietary "biotechnology packages", e.g., seeds plus agrochemicals which increase their dependence on foreign multinationals.

The increasing involvement of the private sector in agricultural R&D in OECD countries will likely increase the cost of R&D results and decrease their availability to IICA countries. (7). This could result in public sector scientists in LAC countries not having access to the underlying science and technology behind the proprietary products being used. Under these circumstances, they would be less able to provide useful assistance to LAC farmers (17). Some inputs may be unavailable to LAC farmers at any price - either because of competitive reasons or unavailability of products adapted to conditions in LAC countries.

DEVELOPMENT AND APPLICATION OF AGRICULTURAL BIOTECHNOLOGY IN OECD COUNTRIES MAY JEOPARDIZE EXISTING MARKETS FOR LAC COUNTRIES

In recent years, there have been several instances of agricultural production moving from developing to industrialized countries as a result of technological innovation. The introduction in the US of high fructose corn syrup, produced using immobilized enzymes, has hurt LAC sugar exports. The ongoing development of low calorie sweeteners using biotechnology threatens to further erode the LAC sugar exports (15). The production of cacao butter through tissue culture techniques or replacement of cacao butter by palm and soyabean oils from modified plants could be a serious problem. Multinationals such as Nestle, in the US, and Ajinomoto, in Japan, are working in this area and have collaborative research projects with universities (15).

LAC producers's share of domestic markets could also be threatened by biotechnology. In particular, the trend towards increased uniformity of markets, whereby locally available products and consumer traditions are subordinated to global consumption patterns could be a serious problem (16).

Challenges

In this subsection we discuss some of the administrative and managerial challenges faced by LAC countries formulating policies for agrobiotechnology and in developing and delivering programs.

1. Developing effective mechanisms for setting priorities and program planning

IT IS CRITICAL TO ACHIEVE A BALANCE BETWEEN CENTRAL PLANNING AND MARKET FORCES

If government does not take a lead role in the development of agricultural biotechnology in LAC countries, the following consequences are possible:

- Biotechnology R&D in LAC public sector laboratories will be uncoordinated, resulting in unnecessary duplication of research projects and efforts in areas which are not commercially feasible in LAC's.

- Mechanisms for technology transfer between public sector laboratories, industry and producers may not develop sufficiently.

- Where biotechnology is adopted, benefits could accrue unevenly, with income levels of small farmers falling further behind or small farms becoming economically non-viable.

- If technology transfer to LAC countries is determined by the priorities of foreign multinationals; lasting benefits to LAC countries would be largely coincidental.

* The potential of biotechnology to contribute to linkages between agriculture and industry in LAC countries may not be realized.

On the other hand, too much central planning by governments could result in the following negative consequences:

- The environment in which public sector R&D is performed will may not be conducive to innovation.

- Industrial activities in biotechnology may be overly influenced by priorities of government bureaucrats rather than market demand.

- All of the potential negative consequences associated with too little government planning could occur because public sector efforts fail to generate significant market-oriented industrial activity.

To avoid the consequences listed above, planning mechanisms will need to involve all relevant stakeholders. As pointed out in an earlier study, there is a need to develop systematic, institutionalized linkages between government economic planners, research institutes and producers (19).

EFFECTIVE PROCEDURES ARE NEEDED FOR DESIGNING R&D, TECHNOLOGY TRANSFER AND OTHER INDUSTRY SUPPORT PROGRAMS TO HAVE A MAXIMUM ECONOMIC AND SOCIAL IMPACT

This can be accomplished by linking the objectives of programs, institutions and overall government objectives with respect to agriculture.

The social and economic objectives of government intervention in agriculture were articulated in detail in PLAN-LAC (16). Generally, they are focused on sectors which are important from a socioeconomic viewpoint but which are unable to benefit from biotechnology without assistance from public sector. The economic and social needs of large, medium and small landholders, landless labourers, private enterprise, will have to be considered in this context. In supporting different sectors, the need has been recognized to balance efforts on behalf of domestic and export production and to ensure adequate utilization of comparative advantages.

Although the objectives of government institutions should be consistent with overall government agricultural objectives, the focus can and should vary among institutions. For example, some institutions would be expected to play a lead role supporting international competitiveness while others concentrate on the need of the small farmer.

Program planners working in the agricultural biotechnology field will have to link program objectives with institutional and overall agricultural objectives as outlined above. In the absence of systematic procedures for linking project objectives with institutional and overall agricultural objectives, resources will likely be allocated to benefit groups who are already in a privileged economic or political position (6).

2. Obtaining necessary investment

THE INVESTMENT REQUIREMENTS FOR TAKING ADVANTAGE OF BIOTECHNOLOGY WILL LIKELY BE SUBSTANTIAL

Although biotechnology has been portrayed as requiring relatively little capital investment compared with conventional technologies, a distinction should be drawn between the investment requirements of R&D and those for commercialization. The latter are expected to be sufficient in many cases to make it difficult for anyone but large companies to successfully bring a product to commercialization (15).

Overall public and private sector investment in agriculture in IICA countries has not been high relative to size of the economy. Less than ten percent of investment goes to agriculture in spite of its relative importance, e.g., agroindustry accounts for about one quarter of industry production. Increasing private sector investment in agriculture has been identified as a major priority in PLAN-LAC (16).

While the current investment situation is problematic for agrobiotechnology, the principle solutions may fall outside the scope of policies dealing strictly with technological innovation in agriculture. Clearly, macroeconomic policies will be required to play a vital role in stimulating investment in agriculture. PLAN-LAC has recognized that, to achieve this, policy makers working in the agricultural sector will require adequate input to the process of formulating macroeconomic policy (16).

Specific roles which LAC governments could play in promoting investment in agrobiotechnology include:

- providing a good climate for investment through an effective intellectual property system, balanced biotechnology regulations, and tax incentives;
- acting as a facilitator between investors, entrepreneurs and researchers;
- leveraging private sector investment in specific areas through matching funds; and
- working with international development agencies to secure funds to leverage private sector investment from OECD countries.

3. Developing and acquiring technology

RESEARCH & DEVELOPMENT AND ACQUISITION OF FOREIGN TECHNOLOGY ARE BOTH NECESSARY

Given the large amount of resources being allocated to R&D in OECD countries, much of it expressly aimed at increasing global competitiveness, it is worth considering how performing R&D can assist IICA countries to compete successfully with OECD countries. R&D aimed at producing more sophisticated products or producing them earlier than parallel efforts in OECD countries would be a waste of resources.

The short-to-medium term opportunities for IICA countries in agrobiotechnology are likely based on becoming early and effective adopters of technology rather than developers of technology from basic research, e.g., gaining access to new reproductive materials, equipment, know-how, working on a collaborative basis with governments and companies from developed countries.

As in the case of Japan with many manufacturing technologies, one can start by putting in place the infrastructure necessary to use the new agrobiotechnology commercially and build on this by incrementally expanding backwards through the innovation chain - initially in product development, subsequently in applied research and finally basic research. Following this approach, product development will evolve from mainly minor improvements and adaptations to development of new products having significant competitive advantages.

Technology acquisition from external sources and the development of one's own technology (by preforming R&D) are not necessarily substitutes for one another. There are unlimited opportunities for conducting applied R&D associated to support the adoption of external technology, e.g.,

- assessing limits of existing technologies;
- assessing technologies prior to commercialization;
- adapting technology to local conditions, practices, etc; and
- developing incremental improvements.

IICA COUNTRIES WILL NEED TO CONDUCT SOME BASIC RESEARCH IN BIOTECHNOLOGY FOR AGRICULTURE

Potential objectives of this research are to maintain the knowledge level required to evaluate the basic research done in OECD countries and to characterize LAC agricultural resources and problems. Much of the world's germplasm has not been characterized genetically to facilitate its use in biotechnology (8). This could be an opportunity for researchers in IICA countries. The knowledge generated from this type of basic research will be essential for commercial adaption of biotechnology to conditions in IICA countries.

THERE IS A NEED TO RE-ORGANIZE THE SCIENTIFIC INSTITUTIONS INVOLVED IN AGRICULTURAL RESEARCH IN IICA COUNTRIES

Previously this research has been very applied and has been weakly linked to basic sciences - a situation which been reported existing to some extent in European countries but less so in Canada, Japan and US and the US. The development of personnel with the necessary training to work effectively in agrobiotechnology research will be a major consideration. Advanced training opportunities in the new scientific disciplines underling biotechnology are limited within LAC countries (16). This problem could be addressed by strengthening the linkages between research and training institutions in IICA and OECD countries (6). However, the decline in available resources for training abroad coupled with increased costs will have to be considered.

The need for allocation of R&D responsibilities among international and national institutions within regions has been recognized in PLAN-LAC (16). International research centres are expected to place more emphasis on generic R&D in strategic areas while national institutions move to assume principal responsibility for applications-oriented programs (16). There is also a need to build on existing collaborative activities among national institutions of LAC. However, a limited number of priorities should be established since collaboration on too many projects could decrease the effectiveness of programs making them too fragmented (16).

Achieving the reorganization initiatives described above will be difficult given the reduction in R&D budgets which occurred in the 1980's. (16).

MOST OF THE GENERIC OPPORTUNITIES FOR AGROBIOTECHNOLOGY IN OECD COUNTRIES AND THE BASIC RESEARCH BEING CONDUCTED AIMED AT THESE OPPORTUNITIES ARE RELEVANT TO IICA COUNTRIES

Much of the agricultural produce of IICA countries is also produced in OECD countries (6), including: livestock (cattle, hogs, poultry); basic cereals (wheat, barley and corn); oilseeds (canola and soya); forage plants (clover and alfalfa); pulses (beans, peas, chick peas, lentils); and some fruits and vegetables.

Potential goals of agrobiotechnology in OECD countries are relevant to IICA countries, i.e., crops with increased food yields and disease resistance, more effective and environmentally benign fertilizers and pesticides, and more effective health care products.

Many of the R&D results obtained in OECD countries are relevant to problems in IICA countries, including:

- results of basic research on plants and animals, identification of useful genes, microbiology, immunology, etc;
- techniques for modifying and replicating genetic material, and producing new plant and animal species; and
- process engineering technology for fermentation, and other food processing operations.

SUCCESSFUL USE OF AGROBIOTECHNOLOGY IN IICA COUNTRIES WILL REQUIRE ADAPTING GENERIC INNOVATIONS IN BIOTECHNOLOGY TO LOCAL AGRICULTURE

Much of the basic research results and underlying techniques used in agrobiotechnology, which are being developed in industrialized countries, can be applied to LAC countries. However, there will be requirements to adapt technology to the local conditions such as climate, plant varieties and livestock, and farming methods. Government and the private sector in LAC countries will likely want to take the lead in adapting technology in cases where there are there is no incentive for multinationals to do so. For example, seed companies tailor their most profitable varieties to environmental conditions in the developed world where farmers can afford expensive seeds (8).

THE SIZE OF AGRICULTURAL OPERATIONS IN IICA COUNTRIES COULD BE A PROBLEM FOR DEVELOPMENT OF AGROBIOTECHNOLOGY

An earlier study, sponsored by IICA, characterized the "small country problem", i.e., situations where the national production of a particular crop would not justify economically the cost of a supporting R&D program (19). Based on the annual production of crops in IICA countries, the study concluded that there are very few cases where a reasonable percentage of revenues, could provide the budget for a minimum R&D program geared at crop improvement. (The study chose 1% of revenues and a minimum budget of about $300K as reasonable parameters for the calculation).

To solve this problem, it will be necessary to broaden the scope of research objectives beyond national interests. This could potentially be accomplished through regional research programs and collaborative programs with governments or multinationals outside the region. In either case it will be necessary to define common research objectives, roles and ownership of intellectual property.

4. Adoption of Agrobiotechnology

Successful commercialization and adoption of agrobiotechnology in LAC countries will involve the following groups:

- large, medium and small farmers.
- companies which supply the inputs to agriculture, e.g., fertilizer, seed, breeding animals, equipment; and
- companies involved in marketing and distribution of agricultural products.

For each of the above groups, the following issues should be considered: a) What needs do they have which could be addressed through agrobiotechnology?; and b) What capabilities would they need to adopt the results of agrobiotechnology?

For farmers to benefit from improved agricultural inputs, e.g., plant varieties, live stock, fertilizers, pesticides, animal nutrition or health care products, the following conditions are necessary:

- there must be adequate means of production and distribution;
- inputs must be affordable; and

- procedures for use must be feasible, adequately promoted and explained.

To benefit from adoption of agrobiotechnology, farmers will need access to marketing and distribution channels which are adequate to sell increased farm production due to biotechnology, e.g., storage facilities, packaging, transportation, etc.

5. Securing international cooperation

The discussion in the previous sub-sections indicated the benefits of accessing technology, investment, and markets in OECD countries. IICA countries will want to maximize the effectiveness of their technical, financial, production and natural resources by entering into mutually beneficial arrangement with groups in OECD countries. To accomplish this, strategies on macroeconomic, sectoral and business venture levels will be needed.

THERE ARE SOUND ECONOMIC REASONS WHY BIOTECHNOLOGY SHOULD BE UTILIZED IN IICA COUNTRIES AND WHY OECD COUNTRIES SHOULD PROVIDE ASSISTANCE TO ACCOMPLISH THIS

Most of today's food exports are grown in high-cost industrial countries and consumed in low-cost developing countries (6). Most of future growth in demand for food products is expected to come from developing countries (6). Thus the developing countries are in danger of a deteriorating situation regarding their balance of trade with the industrialized nations.

Governments in OECD countries should be encouraged to support: 1) transfer and adaption of their technology to IICA countries aimed at harnessing local resources in IICA countries; and 2) investing in operations in IICA countries. Should involve private sector partners, local institutions (6). Supporting improvements to agriculture in IICA countries from biotechnology is consistent with government policies in OECD countries. They are motivated to help developing countries because: agricultural development can act the foundation for industrialization, resulting in improved agricultural employment and income which can create markets for local industrial goods and eventually goods of industrialized nations (6).

There are barriers to international cooperation on both public and private sector levels. Disputes between industrialized and developing countries concerning rights to use IP and access to germ plasm can have a damaging effect on everyone. An alternative approach to using barriers to trade and intellectual property protection as "levers" in dealings between OECD and IICA countries would be to "work around" them on a case-by-case basis.

It should be possible to enter into technology transfer agreements with companies from OECD countries which are mutually beneficial to both parties. In addition to technology transfer through direct investment, companies of all sizes transfer technology for several reasons: lack of capital, lack of manufacturing expertise, need to get market access, and unwillingness to assume risks associated with manufacturing.

Involvement of the private sector is essential for increased international cooperation in agriculture, but the interests of private sector firms can make this difficult. Manufacturing firms in industrialized countries have the capability to undertake turnkey projects but are not often willing to do so because of perceived risks involved (6).

Although the relationship of multinational agrochemical companies and LAC countries has not always been satisfactory, the emergence of biotechnology will increase the motivation of both parties to work together. LAC countries could benefit from cooperation with multinationals by gaining access to technology and marketing networks. Multinationals have the financial and technical capabilities to take advantage of genetic diversity in germplasm using biotechnology. The potential of biotechnology to isolate, characterize and transfer genes from one species to another is increasing the value of germplasm. Because the IICA countries cover four of the world's twelve centres of genetic diversity, they should be in a good position (8).

Effective cooperation between IICA and OECD countries on agrobiotechnology will involve interaction between a diverse groups in both countries including: governments, universities, biotechnology companies, multinational agrochemical and seed companies, and producers. Governments can play a key facilitator role. For example, they can support forums at which companies and research organizations can meet to discuss mutual technology and commercial development objectives. This can also lead to international strategic alliances (3).

6. Ensuring sustainability of agriculture

Sustainable agriculture generally refers to systems that do not damage the environment, or degrade agricultural resources (land, water, genetic diversity), and are profitable to the producer (7). A discussion of priorities of OECD governments with respect to sustainable agriculture was provided in Section III-B. Agrobiotechnology may play an important role in addressing these priorities. For example, substitution of biological pest control for herbicides and pesticides may substantially reduce negative effects on the environment and the health of farm workers. However, biotechnology also has the potential to cause adverse environmental effects. For example:

- The introduction of new technologies which intensify production could have long-term negative impacts on land, water and ecosystems. (6)

- Reduced animal mortality resulting from improved vaccines could contribute to overgrazing and ultimately lead to less agricultural production (7).

- Plant breeding is used to make crops more uniform so that they can be produced more uniformly.... however, decreased genetic diversity in crops being planted can increase risk of major crop failure due to disease (8).

- Biotechnology could increase the loss of genetically important germ plasm by speeding up the development and production of new varieties which are subsequently adopted by farmers globally (8).

The negative problems associated with use of agricultural chemicals, e.g., pesticides, herbicides and fertilizers are well documented. Biotechnology holds the promise of delivering benefits without these negative impacts. There is no guarantee that this will happen. There are potential negative impacts associated with biotechnology which are analogous to those occurring with agrochemicals. However, if biotechnology applications are developed within the context of the farm as an ecological system, this may be avoided.

IICA governments will maximize the potential contribution of biotechnology to sustainable agriculture while minimizing negative effects. The following categories of policy issues will likely be important:

- regulation of the manufacture, importing and use products which is consistent with sustainable development, e.g., adequately balances risks, costs and benefits to farmers, industry, and the general population;

- the effect of regulations on agricultural trade; and opportunities for international harmonization of regulations;

- developing and maintaining an adequate scientific knowledge base to support the development and implementation of regulatory policies;

- monitoring the environmental and health impacts of agrobiotechnology (both positive and negative impacts); and

- providing adequate training and motivation among farmers, and other workers to ensure that the products and methods of agrobiotechnology are used according to best available practice.

5.
OVERALL GUIDELINES FOR DEVELOPING POLICY OPTIONS FOR AGROBIOTECHNOLOGIES IN LAC COUNTRIES

This part of the paper develops an approach to the development of policy options. It suggests a way of linking biotechnology priorities with other areas of policy, particularly economic policy; and, it advances proposed Policy Guidelines which can be applied to setting up the policy and priorities planning process.

The international experience suggests that there are a number of methods that can be used for a science and technology policy planning and implementation process. The choice of approach will depend upon the cultural setting and the institutional structures that are available to deliver programs.

In the case of LAC countries, biotechnology begins with a fundamental problem of positioning itself as a newcomer in a wide and competitive array of public policies in a situation of extreme scarcity of resources. Similarly, its position in private sector investment priorities is not high and needs to be strengthened. There are two immediate challenges in establishing a unified approach to policy development: first, the intended ultimate role of biotechnology in relation to other public policies; and secondly, the starting position from which it must reach this preferred position. This paper assumes that the intention is to position biotechnology so that it can have a larger role not just in science and technology policy, but in the total structure of government policy planning where resource allocation is determined. A second and equally important positioning role for biotechnology policy is to ensure that its operations influence private sector investment decisions in a positive manner.

There seems to be general agreement, from various previous studies, that biotechnology has not yet established a uniformly high and competitive level of priority in public policies throughout the LAC region. Its position can probably be characterized as one of a minor, but potentially productive, contributor to the solution of major economic and agricultural policy issues. The choice of process and analytical approaches must therefore be such as to improve the competitive position of biotechnology in attracting both public and private sector resources.

Guideline #1: ***The policy planning process should recognize that the case for making biotechnology a high priority for public policy is yet to be proven and needs to be demonstrated in a comprehensive way.***

THREE CHALLENGES FOR BIOTECHNOLOGY POLICY IN THE LAC REGION

One determinant of the choice of a policy planning process is the existence of special challenges, or constraints, to the introduction an diffusion of biotechnology. They are of particular importance when choosing the analytical tools best suited to the shaping of policies and programs. The studies conducted by IICA to date indicate that there are three basic challenges to the acceptance and use of biotechnology in the Region.

- The constraints imposed on the availability of financial, physical and human resources by **Macro-Economic Conditions.**

- The high level of **Policy and Program Coordination** required between member countries.

- The potential for economic/environmental **Risks and Uncertainties** associated with biotechnology.

The notes which follow provide more detail on the rationale for giving special recognition to these three factors in policy formulation and how they influence the choice of a policy development process.

LINKING BIOTECHNOLOGY POLICIES WITH MACRO ECONOMIC AND OTHER MAJOR POLICY AREAS

The kind of policy formulation process adopted for biotechnology will be shaped by the way in which biotechnology is to be positioned alongside other major public policy areas. Policy areas such as macro economics, agriculture and trade are central aspects of public policy and are not only given high priority but also generally exert a powerful influence on the allocation of budgetary resources among programs competing for government support. At the present time, its position as a priority in the Region's overall public policy domain is uncertain and variable. To be effective in acquiring resources and policy priority, it is essential that agrobiotechnology policy be viewed as an active ingredient in the Region's economic policies. It should aim to gain acceptance in particular, as a legitimate and effective tool in the resolution of macro economic, agricultural and trade policy issues which have been identified as having a strategic significance to the region.

CONSISTENCY AND COMPATIBILITY AMONG POLICY AREAS IS IMPORTANT

This kind of positioning strategy would aim to develop a systematic and unified analysis of the economic and social benefits of biotechnology and the role it can play as an auxiliary but meaningful contributor to the Gross National Product and welfare of LAC countries. Such a position requires quantified arguments to secure a larger slice of aggregate public sector resources. It also involves the setting of broad priorities for policy implementation at the sub-regional level which can be demonstrated as being consistent with the LAC countries strategic interests and the broad spectrum of public policies for economic and social welfare.

The present policy sets of LAC countries which influence biotechnology need to be assessed for their internal consistency: the objectives for import substitution can easily conflict with objectives to improve international competitiveness; and the objectives for consumer pricing can be in conflict with the need to have access to research and development and new technology. Biotechnology is frequently in the position, in LAC countries, of having to either conform with protectionist approaches to economic development or to demonstrate alternative policy routes. The complexity and size of this challenge require a policy formulation process which can deal systematically with issues of consistency and compatibility.

Guideline #2: ***Policies for biotechnology will be more likely to find acceptance at the political and technical level if they are generally consistent among each other and with other related policy areas. PLANLAC provides the basic framework for checks of internal and external consistency for biotechnology policies.***

THE ALTERNATIVE IS A STAND-ALONE POSITION FOR BIOTECHNOLOGY POLICIES

The extreme alternative, perhaps more characteristic of the present system, is that biotechnology position itself as an effective component of science and technology policy with highly focused results of a local, sectoral or project nature. This latter positioning strategy would entail a process which called for the development of a more limited and opportunistic system of prioritizing, possibly involving broad program criteria but based on a case-by-case evaluation of projects. There would be no particular reference to the impact on the LAC region's collective interests and arguments for additional resources would be based on the economics of local rates-of-return. The "return-on-investment" approach to biotechnology is, however, essential for attracting private sector participants and investors but, by itself, it does not offer a sufficiently broad foundation for the structuring of policies and policy priorities.

Guideline #3: ***It is helpful therefore, in deciding what kinds of policy measures are needed to support biotechnology, if the broader economic and social significance of its application to agriculture can be evaluated and measured. The choice of policy and program priorities will be more defensible if they can be shown in a systematic way to be compatible with the LAC region's long term economic and social goals.***

For example, the selection of policy options for biotechnology can be based purely on the effectiveness with which their implementation can help solve specific production problems for a particular crop in a particular country; this is a valid first-step approach to prioritizing a budgetary allocation. However, the general case for biotechnology must be differentiated from particular cases. Put another way, the case for individual biotechnology projects should be advanced within a unifying framework which will influence the public sector's resource allocation in general. It is imperative that the policy formulation and planning process be able to evaluate and compare the impact of aggregate expenditure options for biotechnology on issues such as: the balance of payments; fiscal policy; the costs of government subsidies to farmers; and the investment climate.

MEETING THE NEEDS FOR POLICY AND PROGRAM COORDINATION AMONG MEMBER COUNTRIES

The experience of more advanced countries and of larger international trading areas suggests that, for agrobiotechnology to develop successfully throughout the LAC region, it will require a wide range of coordinated national and international actions.

Guideline #4: ***The coordinating and harmonizing actions of government will need to extend beyond the provision of research and program funding. They will require agreement and common action in areas such as the commercialization of research, the diffusion of technology, the training of human resources, the provision of a supportive regulatory climate, the development of incentives for the private sector, and inter-governmental arrangements to facilitate the international movement of ideas, resources and skills.***

Given the small scale of the production of many national agricultural production systems and the limitations on financial and human resources, the need to collaborate and share resources is a key priority for the LAC region. The experience of other mature and emerging trading blocs also suggests that collaborative actions in areas such as research, technology diffusion, business climate enhancement and trade

policies could result in high levels of common benefit at relatively low cost. The need for collaborative approaches will have a profound influence on the processes selected for arriving at policy priorities, on the substance of the policies, and on the optimization of their delivery as programs.

DEALING WITH RISK AND UNCERTAINTY IN POLICY PLANNING AND PROGRAM DELIVERY

Biotechnology presents a problem which it shares with any new area of technology. As an emerging science it has high levels of risk and uncertainty in both research and the commercial application of the results. Processes and analytical tools which assess the comparative risks of success or failure of potentially usable technologies are essential to the successful development of priorities. It is also advantageous to include in policy development process information systems which can identify and evaluate the potential of existing and emerging areas of biotechnology.

In advanced countries it has been a frequent weakness of public and private sector expenditures on science and technology that programs have lacked the support of good technology evaluation and economic impact analysis.

Guideline #5: ***To reduce the risks of low economic returns, duplication of international effort or failed public sector investments, policy planning for agrobiotechnology must include the use of analytical tools such as technology evaluation and assessment, economic impact analysis, and risk assessment in deciding on priorities and resource allocation.***

Competitive assessment which is the study of the strategies of one's competitors, is a growing area of private and public sector strategic planning. It uses specialized analytical tools and information systems. It has several dimensions: marketing strategies of competitors, customer satisfaction studies, the evaluation of production strengths and weaknesses, and the evaluation of the research and development strategies and programs of competitors. It can also include an analysis of the main public sector investments in biotechnology by other countries and ways of improving the accessibility of foreign research findings and new technologies to LAC countries.

Even in advanced industrial nations, the use of competitive assessment by governments is not uniform. In Japan and Sweden it is highly developed, in the United States and Canada it is left more to the private sector. As a tool for public sector policy, it has a great deal of underutilized potential. For specific fields of a highly technical and capital-intensive nature where a public sector role is necessary, it

is an essential tool for policy development and for budgetary and program management.

Properly applied it can provide an effective guide to the development of a strategic understanding of where the emphasis in industrial and agricultural policy should be. Decisions as to whether to focus on basic research, developmental research or the licensing of available biotechnology can have a significant impact on the cost and the probabilities of success for public policies and programs.

Guideline #6: ***Regular assessment of LAC region's competitive use of biotechnology in the agricultural sector is essential for effective policy planning. Policies and programs for biotechnology will require information from the continuous and systematic evaluation of the main specializations of research institutes in other countries, of the state of product R&D by transnationals, and of the marketing strategies of the main private sector international players.***

6.
A PROPOSED PROCESS AND OPERATIONAL GUIDELINES FOR THE DEVELOPMENT OF POLICY

Exhibit 1 provides a schematic for a proposed Policy Planning and Priorities setting process. It outlines the steps, linkages and outputs for a methodology to overcome the three barriers which impede the establishment of effective policy planning for agrobiotechnology and which are presented near the beginning of Section VI.

The proposed approach utilizes existing IICA findings on "key issues" which biotechnology has to address. However, it organizes those issues into four sequential phases so as to differentiate between policy results and policy instruments. In doing so, the intention is to structure a framework of work tasks which have to be completed in order to develop comprehensive policy options. Some of these tasks have already been started in the present CIDA/IICA program of studies. The development of policy priorities consists of a four-part chain of inter-related activities and tasks. The four phases are outlined below:

Phase I: Establish the strategic policies and goals for the Sub-Regions: these can be readily assembled for the Region from existing material. The key issues for macro-economic and agricultural policy will not be exactly the same for each sub-region and the differences could be important in arriving at consistent and compatible policies.

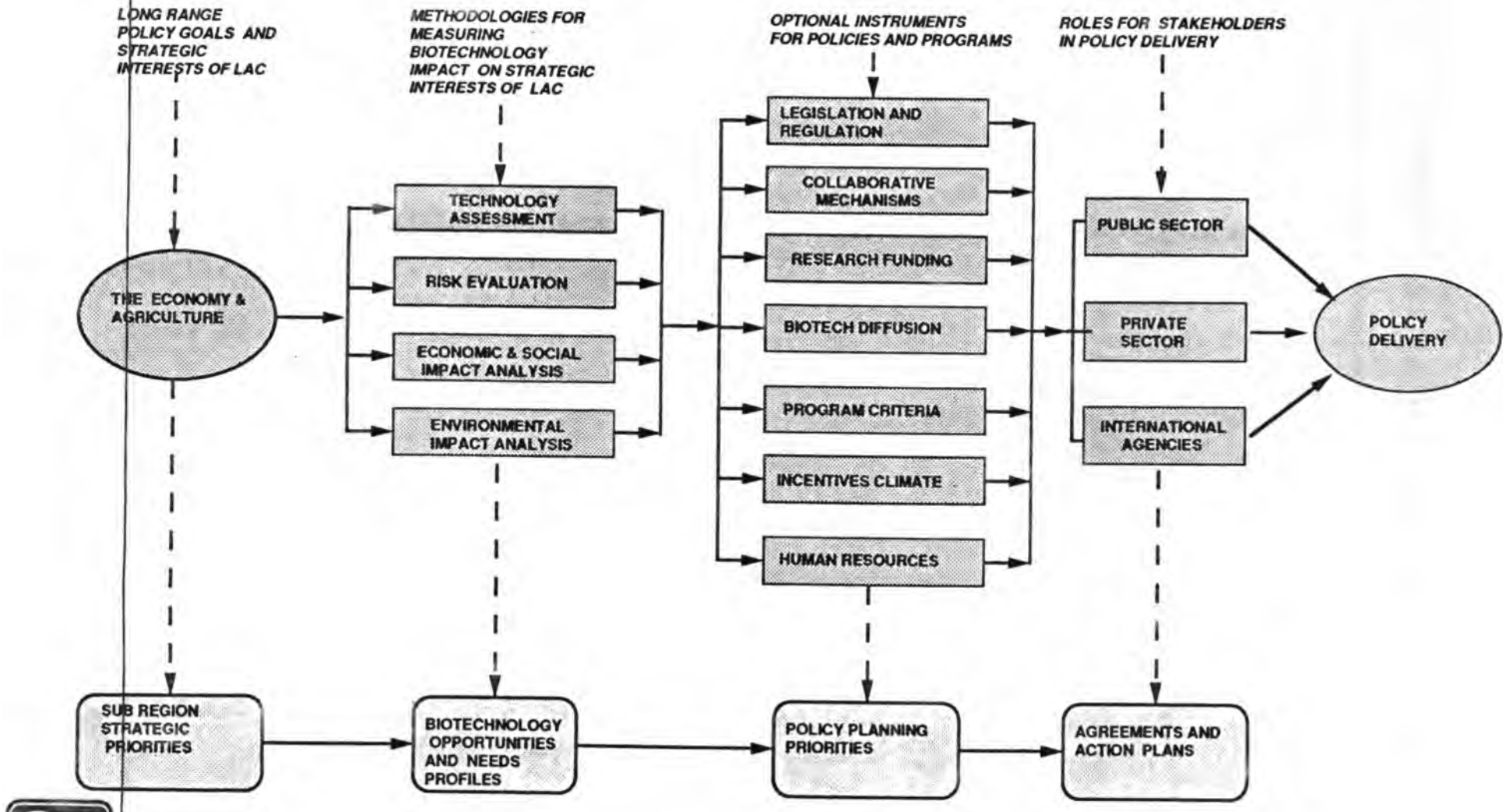
Phase II: Develop an inventory of specific opportunities and needs for the use of specific biotechnologies in agriculture. Prioritize the inventory by sub-region.

Phase III: Develop priorities for the public policy instruments required to implement biotechnology policy.

Phase IV: Establish and negotiate the roles and responsibilities of the major stakeholders in the public and private sectors and among international agencies.

The sections which follow, outline in greater detail the tasks involved in each of the four phases of policy development and suggest ways of providing consistency in the rationale for priorities.

EXHIBIT 1
AGROBIOTECHNOLOGY
A FRAMEWORK FOR POLICY AND PRIORITIES PLANNING



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Phase I: Relating Biotechnology to Strategic Priorities for the Sub-Regions

Exhibit 1 shows the starting point as the long range policy goals and strategic interests of LAC countries. These produce specific goals for the economy and for agriculture which can be translated in to economic, social and agricultural priorities for each sub-region.

Policy for a specific field such as biotechnology needs to relate to higher level policy sets dealing with the strategic goals for the countries involved. For agrobiotechnology these umbrella goals will be drawn from the strategic intentions for the macro-economy and for agriculture in particular. They will include the kinds of issues outlined in Section II of this report, particularly issues 1.1 through 1.6 and issues 2.1 through 2.6, e.g., balance of payments improvements, lower government subsidies, and larger role for the private sector.

It is to be expected that the key strategic issues will be modified to reflect the more specific challenges in each sub-region.

These parameters define the strategic interests of LAC as a region, and where there are significant differences in emphasis, those of each sub-region. It may, for example, be agreed that a reduction in the cost of factor inputs for small scale farmers is important in all sub-regions, but, that in some sub-regions it is less of a priority than others.

Guideline #7: ***Policy formulation should begin with sub-regional economic and agricultural issues, policies and goals and work towards a region-wide resolution of those issues.***

Guideline #8: ***The definition of sub-regional strategic goals for agriculture and the attachment of some order of priority to those goals, is an important aspect of maintaining flexibility and precision in policy planning.***

This process of isolating key "results-oriented" issues, (e.g. the reduction of fertilizer costs, or the improvement of corn yields) is also one of the necessary aspects of providing a rationale for sub-regional specializations in biotechnology. The next step in the schematic focuses on using methodologies to measure the potential feasibility and strategic impact of using biotechnology in agriculture.

Phase II: Determining Opportunities, Needs and Challenges for Specific Fields of Biotechnology

Setting orders of priority for the various fields of biotechnology is the second step in the policy planning process. To some degree the present collaborative arrangements for R&D for agricultural products, and the work of the international research centres is aimed at this challenge. In order to improve existing arrangements there needs to be: a strengthening of the comprehensiveness in the analysis and evaluation of the opportunities for biotechnology and their impact on the economy; the resource and institutional needs for their implementation; and the challenges for policy in terms of barriers to change.

This stage allows and requires a comparative analysis and evaluation of which key areas of biotechnology which are most likely to make a significant contribution to the realization of sub-regional and regional strategic goals. It begins the process of integrating in a systematic way, biotechnology policy with LAC region's strategic interests and policies which will have been identified in Step Phase I.

Guideline #9: ***Policy development requires an operational framework expressed as defined tasks, resources, priorities and time lines for selected biotechnologies in each sub-region.***

Guideline #10: ***Taking should be based on an inventory of specific economic and agricultural opportunities for biotechnology, and an assessment of the cost-effectiveness and impact of realizing the opportunities.***

Guideline #11: ***Biotechnology, to be an effective contributor to the resolution of strategic issues, will need an assessment of the resource needs and policy changes necessary to realize the economic opportunities.***

In the initial pass through the process, this stage may have to be kept at a broad level of categorization in order to maintain simplicity. In later "passes" or "cycles" through the process, more detail of the specific fields of biology can be introduced. These priorities derived from the analytical studies which evaluate and analyze biotechnologies in terms of stage of development, reliability, feasibility, economic impact, commercial risk, international competitive conditions and environment significance.

The completion of this step will produce:

- a prioritized list of biotechnologies which are the most likely to achieve positive economic and social results for each LAC sub-region - the opportunities;
- an assessment of the financial, physical and human resources necessary to realize the key end results - the needs; and
- an evaluation of the main challenges for change, including structural changes in institutional arrangements, incentives, legislation, regulations, collaborative mechanisms - the barriers to change which policy must address.

To be usable in policy options the inventory of biotechnology opportunities, needs and challenges should be categorized by sub-region. The third phase examines these prioritized biotechnologies in terms of means of realizing the best results in a prioritized program for biotechnology.

Phase III: Setting Policy Planning Priorities for Instruments and Programs

Once the analysis and justification of priorities for the development or use various biotechnologies is complete, the planning process moves on to consider the instruments that can be deployed to achieve the end results. The choice and blending the optional tools requires a consideration of their comparative costs, effectiveness, feasibility and timing.

Guideline #12: ***The development of policy options and priorities will include the analysis at the sub-regional of alternative combinations of policy and program instruments. These include instruments such as legislation and regulation, collaborative arrangements, research budgets and programs, technology diffusion programming, measures to improve the investment climate, the supply of critical skills and program criteria.***

Guideline #13: ***To be effective, policies for agrobiotechnology should prioritize the required changes to specific instruments of public policy at a sub-regional and LAC-Region level.***

To a degree, there will be policy and program structures which are generic to all aspects of biotechnology. It is reasonable however, to anticipate, differences in need and emphasis among sub-regions It is also prudent to expect that some policy

instruments and programs may be more readily available than others for reasons of budgetary or institutional constraints. As a hypothetical example: a decision might be reached, after determining key priorities, that improved access to fermentation technology would best meet a long term need to improve the competitive pricing of the food processing and exporting sector of a sub-region. Removing the barriers to access that field of technology might require: legislation on patents and on environmental regulations; government-backed financial guarantees; the negotiation of a special international understandings; or a climate for joint ventures among universities, research institutes, governments and the private sector. The availability of these options might not be uniform. It would be necessary to evaluate them in terms of the feasibility of implementation. From these evaluations, recommendations for the future direction and emphasis of policy can be distilled.

The last step in the development of options and a plan for biotechnology policy is that of determining the roles of the key players and stakeholders in the delivery systems.

Phase IV: Establishing Agreement on Roles and Undertakings

For a vital position to be established for agrobiotechnology in LAC economic and other policies, it will be necessary to re-align and possibly renegotiate the roles and responsibilities of key stakeholders. These stakeholders are governments, farmers, private sector investors and international agencies.

Guideline #14: ***Once the options for policy instruments have been determined and assessed, the roles of the various stakeholders in policy and program implementation will need to be defined and optimized so as to produce a feasible balance of commitments and activities.***

Guideline #15: ***Incentives and responsibilities should also be agreed, prioritized and included in the policy delivery framework.***

Guideline #16: ***The development of agreement on roles and responsibilities will require a consensus facilitating process among the major stakeholders in the public sector, the private sector and international agencies.***

Some of the stakeholder roles will have been made explicit by the policy options process. There will still be a need to work towards a condition where the "balance" of roles and the delivery of long term results is made explicit in the form of agreements and undertakings. To move beyond a technical evaluation of roles and responsibilities will also require the development of a special process of internal consensus on roles and responsibilities. In part, this can be achieved through seminars and workshops among key players. In part, it will be achieved through the institutional and political processes of LAC countries. The broad facilitating role of IICA will be a central component of this aspect of the policy formulation process.

7.
SOME INSTRUMENTS FOR FACILITATING THE POLICY DEVELOPMENT PROCESS

Phases II and III of the policy development process can use simple matrices to assist in the ranking of priorities. If there is a need for more a more sophisticated and technically oriented process, there are other available systems for optimising decisions, such as decision trees.

The matrix approach requires policy planners to consider the implications of actions which are external to the immediate field of concern. Exhibit 2, on the next page, provides an example.

The information in the cells can be quantitative or qualitative, or both. The method of weighting and aggregating the results can similarly be flexible. The scope and depth of the analysis is optional and will depend on relevancy and available resources. The essential feature is that the analysis should focus and simplify the findings on key implications. The intention is to assist the process of establishing broad priorities which can lead to the selection of policy and program parameters.

Guideline #17: ***The presentation methods for the evaluation of priorities should be simple and condensed so as to permit focused discussion and easy comprehension. Standardized matrix analysis and presentation can best achieve this. However, the technical evaluations which support the conclusions presented may be as complex as is necessary in order to improve the reliability of the results.***

The matrix approach does present an apparently formidable array of analytical tasks, but in reality the process can be streamlined by "expert" advice, by the elimination of cells where the implications are manifestly trivial, or by the use of Delphi and other intuitive techniques. One of the most useful products of matrix analysis is the isolation of the "key interface" cells where the probabilities and options for high levels of policy results can be estimated through further analysis.

Exhibit 2

LAC - Sub-Region "A"
Implications of Investing in Selected Fields of Biotechnology

Impact on: Field of Expenditure	JOBS	INCOMES	INVESTMENT	TOTAL IMPACT
PLANTS				
ANIMALS				
MICROBIAL				

qep

AN EXAMPLE OF USING MATRICES TO PRIORITIZE THE OPPORTUNITIES AND NEEDS FOR AGROBIOTECHNOLOGY

Exhibits 3, 4 and 5 on the pages following provide an example of a simplified three-step method for assessing the potential beneficial impact of biotechnology on strategic economic and agricultural issues. The strategic economic issues relate to macro-economic goals and are drawn from the framework of issues that is presented in Section II of this report (more specifically, items 1.1 through 1.6). The strategic agricultural issues may be modified to fit the particular region. These are drawn from previous IICA studies list (see items 2.1 through 2.6 in Section II of this report). For the sake of simplicity, biotechnology has been condensed into three major branches although it will need to be more refined for the purposes of impact studies.

Exhibit 3 explores the implications if economic policy should achieve certain agricultural goals such as income redistribution, import substitution, factor cost reduction and comparative advantage. It uses economic and social impact analysis to determine the implications and assigns broad priorities to the achievement of the goals.

Exhibit 4 looks for the best potential role for biotechnology in the pursuit of these goals. This would include the development of an understanding of the alternative ways in which selected biotechnologies can be utilized to agricultural performance. To develop that understanding may require an expansion of the agrobiotechnology analysis to include: technology assessment, competitive assessment, R&D risk evaluation, and environmental impact analysis.

Exhibit 5 assembles the results of an analysis of key challenges, constraints and needs which policy must address. In each cell, the key barriers to change would be identified and the key resources needs would be inventoried.

Clearly, the design of the matrices can be flexible and will depend upon the significance and relevance of the parameters to the sub-region in question.

The evaluation of biotechnology's potential benefits will utilize the tools of economic and social impact analysis to assess the relative importance of potential changes in the agricultural sector for changes in the economy at large. This can take the form of a measurement of i) the reasonable scope or room for improvement in agricultural performance; and, if that is realized, ii) the most likely value of the benefits of that improvement for critical concern in the performance of the economy.

The weighting of the desirable results is a matter which may have already been provided by policy goals for the economy. Alternatively, it can be estimated after consultation with government officials and an evaluation of the economic needs of the sub-region.

This first pass or filter establishes a sense of the priorities among the potential agricultural improvements i.e., which of the improvements can generate the most attractive aggregate economic returns. The next step uses technology assessment to determine which areas of biotechnology are potentially best suited to achieve the prioritized agricultural improvements. In outline form the matrix is as follows:

Similarly, the process of filtering out priority areas of policy emphasis for biotechnology can be extended to include other desirable policy outcomes such as environmental acceptability and commercial feasibility.

Guideline #18: ***Each sub-region should be responsible for preparing regular updates of the potential economic, agricultural and social impact of the biotechnologies they consider key to their agricultural sectors. They should also provide assessments of the adaptability and commercial feasibility in their regions of key biotechnologies. These should be translated into proposed policy and program targets for the realization of the preferred results.***

Properly designed, an analysis of this kind can illustrate where action in a given policy area will have the maximum scope for impact on fields of biotechnology rated as having a high priority because of their importance to the economy and to agriculture.

USING MATRIX ANALYSIS FOR THE POLICY INSTRUMENTS

Policy instruments tend to be complementary rather than mutually exclusive. The policy planning process will use the findings of the impact studies to set goals, and propose alternative ways of using the available instrumentation to achieve the desired goals. Assume, for example, that it had been determined that a LAC sub-region would get a high level of economic benefit from giving the highest priority to improved seed strains. The policy options for the region could include actions in most of the key instruments:

- intellectual property rights
- collaborative mechanisms
- research funding
- biotechnology diffusion
- program criteria
- incentives climate
- human resources

The central question for policy planning is: which instruments, applied in what combination, will best achieve the desired results? The solution, as in most cases, is probably going to involve a contribution from all the major instruments. The role for policy planning is to determine the most efficient and effective blend.

Exhibit 6, on the next page, suggests an example of how the elements of the policy options matrix could be constructed.

Guideline #19: ***The measures of the comparative effectiveness of optional policy delivery mechanisms should include cost, timing, feasibility and compatibility with other policy measures.***

Guideline #20: ***Measures of the comparative effectiveness of proposed new policies should include an assessment of their compatibility and consistency with established policies.***

Exhibit 3

The Potential Impact of Agricultural Sector Improvements on the Performance of the Economy

Ec. Issue / Agr. Issue	1.1 Bal of Paym'ts	1.2 Comp. Pricing	1.3 Real Wages	1.4 Gvt Subsidies	1.5 Markets	1.6 Ind Adj	TOTAL IMPACT
2.1 Comp Advantage							
2.2 Cost Substitution							
2.3 Land Saving							
2.4 Import Substitution							
2.5 Income Redist							
2.6 Redist Research							

qep

Exhibit 4

Impact of Biotechnology on Agricultural Performance

Agricultural Goal: Biotech Field	Comp Advantage	Low Cost Inputs	Land Saving	Import Subs	Import Red.	Redist Res. Ben	Total
PLANT							
MICROBIAL							
ANIMAL							

qcp

Exhibit 5

KEY CONSTRAINTS/BARRIERS TO CHANGE AND CRITICAL NEEDS FOR POLICY RESOLUTION

---AGROBIOTECHNOLIGY PRIORITIES-------

	Technology 1	Technology 2	Technology 3
Legislation Regulations			
Collaborative Mechanisms			
Research Funds			
Biotech Diffusion			
Program Criteria			
Incentives Climate			
Human Resources			

qep