

Biotechnology Development Support Program
in MERCOSUR - BIOTECH

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Agreement

**Methods to Approach Consulting on the Establishment of Information
Flows and Strategic Planning in the Biotechnology Sector in
MERCOSUR**

BIOTECH- ALA-2005-017-350C3 A

Report:

Document Strategic Planning of BIOTEC SUR platform

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ABBREVIATIONS

DNA	Deoxyribonucleic acid
ITA	International Technical Assistance
LTA	Local Technical Assistance
BAC	Biotechnology Advisory Committee
CMO	Contract Manufacturing Organizations
S&T	Science & Technology
MAS	Mark-Assisted Selection
MEAP	Milenium Ecosystem Assesment Project
GDP	Gross Domestic Product
OECD	Organizations for Economic Cooperation and Development
PMU	Project Management Unit

INTRODUCTION

The process of Strategic Planning consists of establishing a mission and a vision for a particular organization (a company, public institution, country, region, etc.) within a preset time frame, identifying and developing in turn the set of Strategic Programs needed for the organization to reach the desired positioning in the medium term. Therefore, Strategic Planning consists in building a future scenario that will act as a decision-making reference framework for the organization in the present. The methodological exercise involved in such a process requires the highest level of involvement and consensus among the different members of the organization, respecting the hierarchies in the different definitions included in developing the exercise.

This document presents a detailed summary of how Strategic Planning methodology is applied to a very particular, specific organization: the Biotecsurs Platform.

The BIOTECSUR Platform is understood to mean the institutional articulating mechanism that coordinates a network of public and private MERCOSUR actors in order to generate highly competitive biotechnological products and services, internationally recognized for:

- Its efficiency in promoting bonds between the company and the R&D system
- Its support for the construction of a systemic view of regional problems and needs that can be solved by biotechnology
- Its input towards strengthening the institutions and companies in the biotechnology sector
- Its support for the development of business, academic and scientific capacities
- Its work in leveraging external resources for the growing development of regional biotechnology
- Its contribution towards identifying and formulating public policies and social legitimacy

The Strategic Planning of an organization with these features is an interesting challenge since it involves aspects that characterize the development of biotechnology in the four MERCOSUR countries at the private, academic and public levels, as well as aspects referring to features that characterize the integration process typical of the MERCOSUR. This situation in particular has led to a methodological adjustment and adaptation as well as a very intense round of consultations with the actors involved, in the form of an important series of nationwide and regional workshops under the aegis of the BAC. Within this context, the methodology applied to the Strategic Planning process, given the number of countries and actors linked to the BIOTECSUR Project, made the search for agreements and consensus at every stage of the work process the basic working premise, thus increasing the Platform's social capital and contributing towards:

- i) Building social capital based on the growing participation in the sector's organizations, institutions and companies, achieving the consensus necessary to be in a position to reach this view.
- ii) Placing people at the center of the Platform's activity, promoting its development and, by increasing the human capital in the MERCOSUR, bringing us ever closer to the needs of the knowledge society.
- iii) Being in the technological vanguard, transforming our great wealth of information into knowledge.

- iv) Proposing innovative organizational designs¹ to turn this knowledge into value for business and society, with the ultimate aim of making a significant contribution to the development of the MERCOSUR.

The work was done between March and September 2009 and consisted in a collective effort by a relevant group of regional experts in biotechnology under the direction of the BAC.

This document itemizes the development of the Strategic Planning process in each of its stages, dividing it into three chapters. The first of these compiles the elements that provide a full explanation of the strategic planning process, emphasizing the methodology used, the future scenario and the definition of the plan's focus, namely, the BIOTECSUR Platform.

The second chapter develops the strategic definitions for the BIOTECSUR Platform: Mission and Vision.

The third chapter enumerates a series of considerations regarding the Platform's Strategic Planning and the most outstanding issues tackled during the discussions and meetings held by Promesur's group of consultants and the Management Unit, the BAC and the actors from the private, public and academic sectors of the MERCOSUR.

It should be emphasized that collectively building a future for the BIOTECSUR Platform has been a highly enriching task, not just for the group of actors linked to biotechnology in the MERCOSUR, but also, and fundamentally, as an exercise in regional construction. The present report has put forward a methodological course for regional planning in the MERCOSUR. It has been shown that only by looking to the future and making agreements in the present is it possible to carry out a consistent and sustainable process of integration.

With specific reference to the BIOTECSUR Platform, this exercise afforded us some important lessons, among which we should point out that competition between the companies that belong to the biotechnology sector of the MERCOSUR can only be sustained over time within the framework of a competitive system as a whole. For this reason, it is vital to be able to move from the current state of slow growth and low coordination of actions in the MERCOSUR to one of greater development, coordination and sustainability, and this will mark the success of any sector's future development and that of the Platform as a whole.

Likewise, the idea of working on the development of a Strategic Plan to 2030 entails huge challenges. The purpose of these months of work was to reach an understanding of, and an agreement on, what changes the system is subject to and what the BIOTECSUR Platform's vision, mission, objectives and strategies are, making agreements and achieving a strong interaction with the private, public and academic sectors.

Thus understanding global changes with long-term vision, drawing implications for the biotechnology sector and defining collective strategies, implementing them and institutionalizing them as a means of incorporating them to the actors' practices were the key stages in this process, which is described in detail in the section "Methodology applied".

¹ Not just for the BIOTECSUR Platform but also for the different networks that need to be formed, in order to link the complex web of businesses, public agencies and R&D from the biotechnology sector in the MERCOSUR.

CHAPTER I

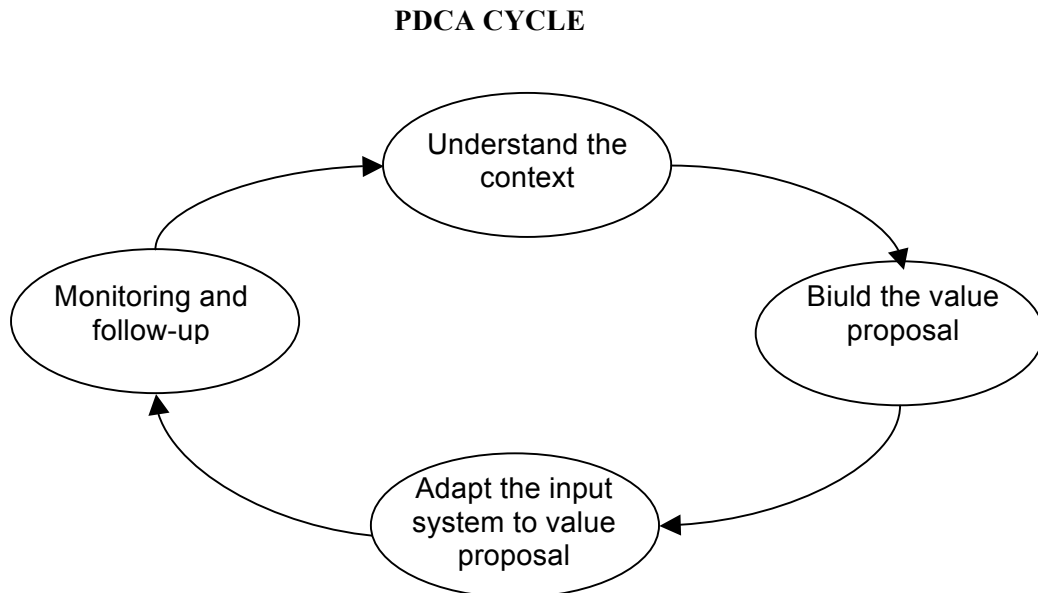
Elements that help to understand the definition of
the Strategic Plan

I.1 – METHODOLOGY APPLIED FOR THE STRATEGIC PLANNING OF THE BIOTECSUR PLATFORM

The BIOTECSUR Project aims to promote the development and operation of biotechnologies in the MERCOSUR, in order to increase in a sustainable manner the added value and competitiveness of its products in international markets.

To this end, the current stage of the project aims to design a strategy that will help to achieve the general purpose and propose to the relevant authority of each of the MERCOSUR countries, the policies agreed upon at a regional level to promote the application of biotechnologies in productive sectors.

To define the strategy, the PDCA cycle will be used as the proposed methodology's basic tool. As can be observed, defining the strategy involves working at four levels. The scope of the current agreement covers the first three stages.



The objective of the first stage was to gain an **in-depth understanding of the current context** and its future trends. In this sense, we worked on identifying the strengths and weaknesses of the current system and the opportunities and threats foreseen for the near future.

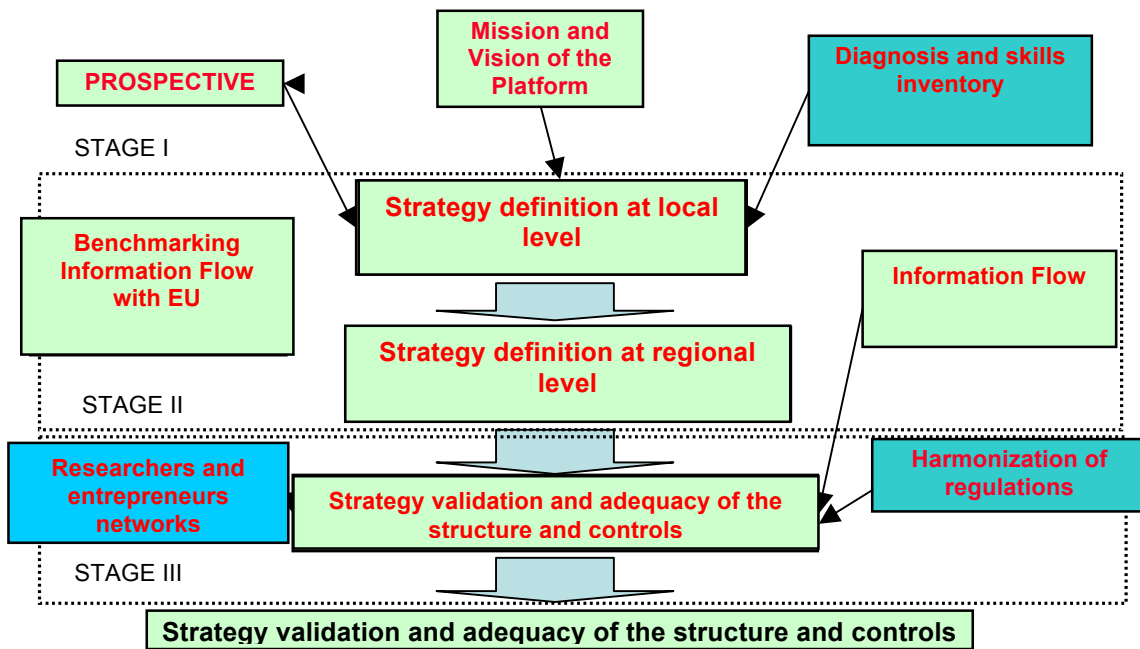
In order to execute this phase, the outputs of the work done during previous stages of the project were used (the characterization of existing capacities, a diagnosis of the general and specific regulations linked to biotechnology and their capacity to evolve within the MERCOSUR and the EU, identifying and diagnosing the financing instruments available to biotechnology companies in each of the countries, the inventory of registered patents and the assessment of the capacity for implementing certification systems in the MERCOSUR). Also used was the identification of the most important biotechnology issues for the MERCOSUR countries in the sectors of agriculture, industry and health (determining the regional demand for biotechnologies in the workshops and seminars held during November and December 2008).

To be able to reach a full understanding of the context, a prospective study was carried out to identify where the biotechnology sector is heading on a global level during the coming years, the main conclusions of which can be found in section I.2 of this chapter. Based on this study, the strengths and weaknesses were identified, as well as the opportunities and threats, which also served as a basis to outline a value proposal. Initially a prospective task was done which made it possible to obtain the basic elements needed to define the BAC's vision. Based on this, the opportunities and threats were identified, and the most outstanding aspects of the future scenario, which the LTA teams in collaboration with the ITA from each of the countries defined in an exploratory study interviewing qualified experts from each of the three sectors. The outputs of the four exploratory studies (Argentina, Brazil, Paraguay and Uruguay) were discussed and processed in a workshop on March 5 in Buenos Aires in which the LTAs and the ITAs linked to the project took part, as well as members of the Management Unit and PROMESUR specialists.

The Vision describes how the institution/sector wishes to be seen by the relevant actors in the environment. The guidelines for the definition emerged from the interviews and workshops held and were designed based on the three key questions for formulating the strategies: What could be done? What do we want to do? What can be done?

Once the Vision was defined and the internal and external factors (tendencies and scenarios) had been analyzed, the strategic guidelines were identified; these will then become Programs and Projects and will constitute the Strategic Agenda.

Diagram No. 1 – Stages of the Strategic Planning process

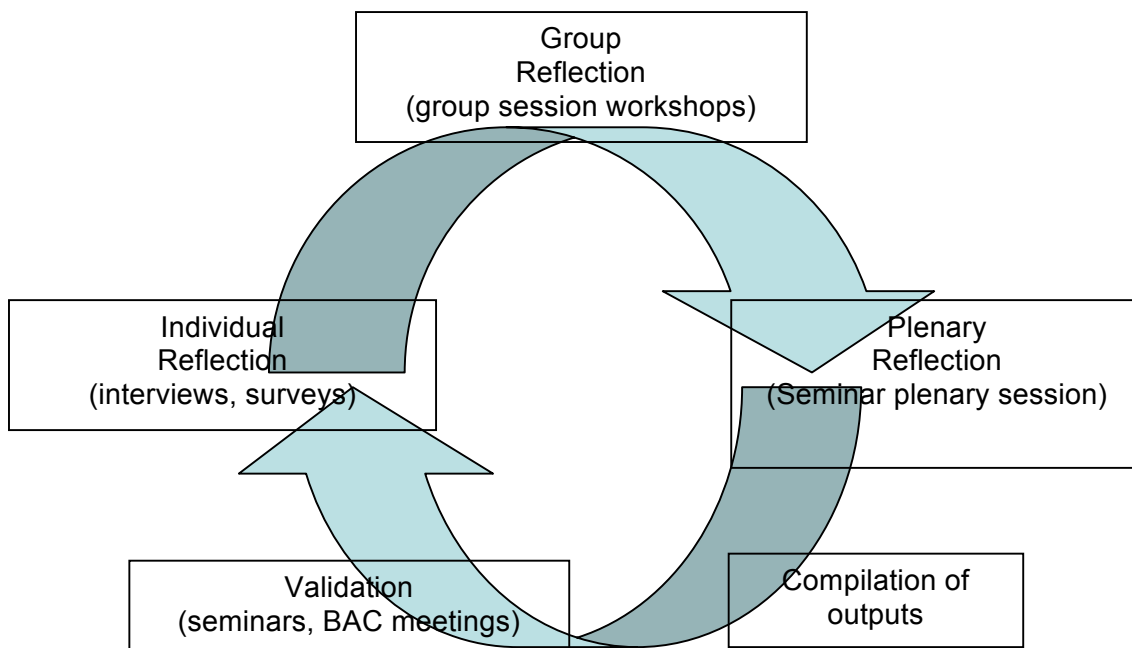


Source: Methodology Document for the Bioteccsur Platform's Strategic Plan

The outputs of this workshop were then used by the BAC to formulate the Platform's vision. Once the Vision was defined and the internal and external factors (tendencies and scenarios) were analyzed, the strategic guidelines were identified; these, once they become Programs, will constitute the Platform's Strategy Agenda.

The work was done under a system of growing reflection and consensus building, which made it possible to progress in defining strategies, according to the following diagram:

Diagram No. 2 – Process of building consensus on the strategic definitions



Source: own authorship

This is why workshops and seminars integrating the three sectors (private, public and academic) in order to reflect upon what issues are of the highest priority are essential to building consensus and must be used permanently as a work method in the Platform. This issue will be taken up again in the section “Some considerations on the organization of the platform”.

The validation of the project has been approached at different levels since it was validated by the BAC (responsible for the orientation of the project’s general strategy), the PMU (responsible for executing the project) and the actors of the private, public and academic sectors, who are a part of this collective construct.

In accordance with the methodology’s general drivers, a series of components were used as a starting point for the different stages, namely:

- a. The general and agreed upon definition of PLATFORM and in particular for the BIOTECSUR Platform.
- b. The strengths, weaknesses, opportunities and threats for biotechnology in each country per sector, and in the region as a whole.
- c. The mental maps containing the strategic lines and the activities to be developed by each country and sector.

Although the PDCA cycle contains an additional stage, in which a management panel is defined to monitor and follow up the implementation of a value proposal, this stage has not been included in this agreement. However, we deem it is fundamental for future adjustments to the Regional Vision, the Programs, the Strategic Agenda and the initial Organizational Model, to promptly build a Management Panel to enable key indicators to be monitored periodically in order to be able to objectively measure the proposals’ success, glean lessons and correct deviations.

I.1.2 – National Workshops

Working in workshops is the tool that made it possible to socialize and validate progress on the topics to cover in the Strategic Planning process, as shown in Diagram No. 1. In order to propose the policies agreed upon at the regional level for the furtherance of biotechnology applications in productive sectors to the relevant authorities of each of the MERCOSUR countries, it is necessary to use this tool to approach the steps towards building consensus. This space made it possible to stimulate creativity, to adopt a personal position and to enrich it by confronting it with the others' opinions.

Beyond these considerations, the workshops and specialized meetings are based on the philosophy of making every participant a fundamental actor in the process of collective action through democratic exchange.

The aim of the national workshops was to “define the strategic lines for the BIOTECSUR Platform in relation to the sector's problems in the country and validate the SWOT analysis compiled in previously held workshops”. To do so, and from the conceptual point of view, it was necessary to create awareness in the participants of the following:

- The idea that Strategic Planning work is an ongoing process of continual improvement.
- That this process began in the workshops held in 2008 and early 2009.
- The motivation needed to materialize an active, committed participation as part of the collective construct.

The approach methodology was based on group work with outputs analysis and growing reflection technique with an idea-sharing session through the definition of mental maps. The outputs were searched for around the definition of:

- i. what areas the platform should act in;
- ii. what actions and initiatives it should take;
- iii. what services it should lend;
- iv. how it should link with the different institutional and academic actors and economic and productive agents; with networks of interest and with other platforms.

The workshop allowed us to analyze every thematic area inwardly to determine which the most relevant issues were for which the Platform could be an instrument for overcoming limitations, creating awareness of and/or boosting capacities and taking advantage of new opportunities, and defining specific BIOTECSUR Platform actions that will enable the organization to act upon:

- Training human resources stimulating specialization both in hard scientific research and in technological applications, the skills required for working in interdisciplinary teams, the new disciplines linked to biotechnological processes and services management;
- Creating an environment and a “space” (the platform itself is a space) to stimulate business opportunities and access to new market opportunities;
- Promoting and/or facilitating interaction and synergy between academia – academia; academia – company; company – company;

- Facilitating information processes among the participants of the Platform in order to provide help in processes relating to defending copyrights and in the process of recording patents involving biotechnological events generated in the region.
- Stimulating an ongoing update and continual assessment of public policy frameworks on one hand, and of current regulations covering the activity on the other, aiming to avoid contradictions among them, within the countries or in the region.
- Facilitating information and access to funds for promoting and stimulating innovative activities relating to BT, access to financing and setting up businesses.

I.1.3 – Regional Seminars

The objective of the regional workshops was to “define the Strategic Lines for the BIOTECSUR Platform in relation to the sector’s problems in the region (MERCOSUR)”. To accomplish this, the methodology implemented in the nationwide workshops was used, starting out from the following inputs for discussion:

- **STRATEGIC LINES PER COUNTRY**
- **MENTAL MAPS**
- **COMPARATIVE TABLES**

The outputs obtained from the workgroups, using exactly the same approach as that mentioned earlier for the nationwide workshops and as part of the growing reflection described above in Diagram No. 2, were:

- **AGREED STRATEGIC LINES FOR THE REGION**
- **ACTIVITIES IN EVERY STRATEGIC LINE**

From the outputs obtained and bearing in mind that the strategic lines were defined by each of the sectors involved (industry, agriculture and health), we then proceeded to identify the strategic guidelines common to all three sectors. The purpose of this was to locate the transversal actions and define a series of activities for the platform. In this sense, the method of grouping activities was broadly approached, with no selection or filter whatsoever, but rather under the form of a “complete list” of activities, grouped only according to an identified higher category.

I.1.4 – Validation and Communication Workshops

The purpose of the seminars per country was to validate the “systematics” work developed by the consulting group and the opinion survey regarding the BIOTECSUR Platform’s forthcoming steps. The data flow work was disseminated throughout the MERCOSUR and compared with that of the EU during the same event.

I.2 – Prospects for Biotechnology to 2030²

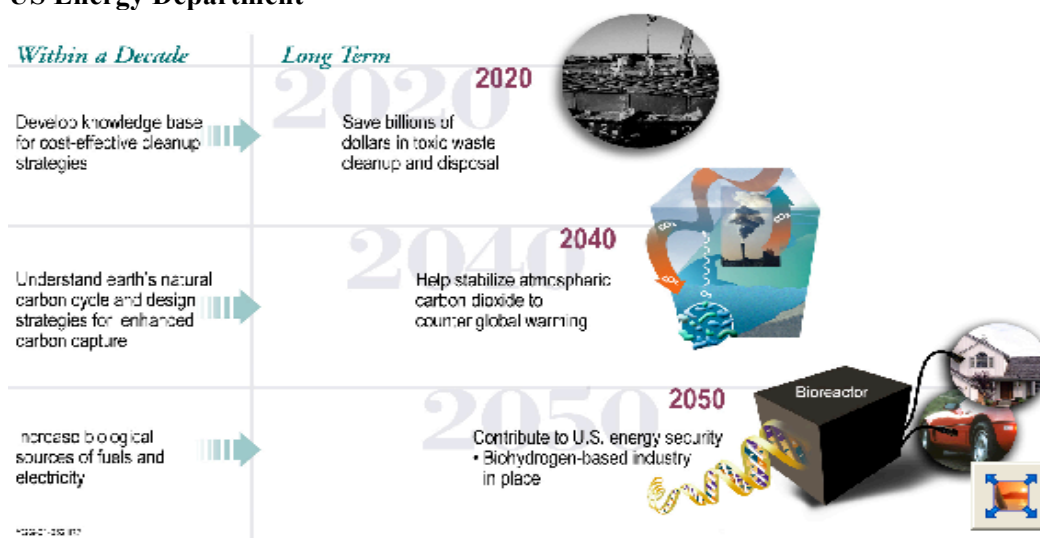
Biotechnology is knowledge combined with industry; since its beginnings, it has been a technology closely bound to science, typical of developed countries with S&T capacity; with industrial, agricultural and pharmacochemical structures and the necessary financing. In Europe it is considered one of the leading technologies of the 21st century, receiving full institutional support in an important bet as the driver of the EU's future economic development and one of the pillars of the European economy in 2030.

Modern biotechnology is currently using cellular, molecular and genetic processes to produce goods and services by means of DNA recombination technology. Thus the OECD (1981) defines this technology as the use of live organisms and their components for the production of goods and services.

These definitions carry strong implications for the MERCOSUR, since this bloc has a series of comparative and competitive advantages with which to contribute solutions to global problems. Problems linked to climate change and the rational use of alternative energy clearly exist, and their solution will surely come from biological responses. In this sense, the Energy Department of the United States in its program "Genomics for Life" poses a series of solutions to global problems. This program, described in Figure No. 1, predicts that by 2020 systems of bioremediation will be fully developed, leading to savings amounting to billions of dollars in clearing up toxic waste and the devices currently used for treating it. In this same line of thought, a system for capturing CO₂ will have been developed by 2040 which will enable man to stabilize its content in the atmosphere and counter global warming. Finally, the challenge for 2050 is the development of domestic bioreactors for generating energy based on hydrogen with direct consequences on the global energy shortage. For a sustainable economy to grow, it is indispensable to create jobs, produce energy and maintain the standard of living.

² This section has been developed according to the work by: Díaz, A. "Panorama Internacional de la Biotecnología" presented in the workshop held in Buenos Aires on March 5, 2009, Argentina, on the results of the same workshop of experts, adapted and translated from THE BIOECONOMY TO 2030: DESIGNING A POLICY AGENDA – ISBN-978-92-64-03853-0 © OECD 2009

Figure No. 1 – Developments expected by 2050 in the Genomics for Life Program of the US Energy Department



Source: U.S. Department of Energy

In this sense, it is necessary to work on new engineering bioprocesses and high crop performance plants, and basic research will be accelerated in this line of development of new technologies in other fields. A number of current events in the region show this trend within biotechnology:

- Biotechnology might have matured into an engineering science.
- New bioproduction units developed in the US, EU and recently some in Asia.
- New CMOs (Contract Manufacturing Organizations). Proteins for clinical studies.
- Extended production related R&D activities
- Formation of an Action Group made up of drug related Ministries and industrialists.

On the other hand, in the MERCOSUR there are a number of sectors with applications posing an interesting basis to lead world markets with new biotechnological products and services, such as:

- Bioethanol / biodiesel
- Textiles (use of enzymes)
- Cellulose and paper
- Chemical processes (fine chemistry)
- Biomaterials
- Biodegradable materials

1.2.1 – General Trends to 2030 and their relationship with Biotechnology

If we analyze the world demographic structure we find a very interesting series of relatively stable trends that indicate the main axes of the participation of biotechnological products and services in the world to 2030. By this year the world population is expected to have increased by 28% (from 6.5 billion in 2005 to 8.3 billion).

Said indicator is boosted by the fact that the world per capita average income will have increased by 57% (from US\$ 5,900 in 2005 to US\$ 8,600), driven mainly by the growth of the BRIC countries' economies (Brazil, Russia, India and China).

In the world today there are approximately 1,000 million consumers that drive the global demand for foods. Within the next 15 years a further 1,000 million are expected to join this group, increasing the world demand for world health services that improve life quality and longevity, as well as the demand for essential goods: foods, fodder, fibers for clothing and housing, drinking water and energy.

With the aim of meeting this future demand, production will have to grow by much higher rates than those of recent decades. The expected growth in demand for cereals suggests that it will be necessary for crop yield to increase at a much higher rate than the 1% yearly increase reported during the 1990s.

However, the way humankind is currently using up natural resources is straining the sustainability of the planet's productive ecosystems.

The MEAP (Millennium Ecosystem Assessment Project) reckons that 60% of Earth's 24 main ecosystems operated by societies (including rivers and lakes, salt water fishing, forests, etc.) are "being degraded or used in an unsustainable fashion" (MEA, 2005).

In order to provide solutions to the challenges raised by global climate change, the degradation of ecosystems, poverty and world public health, profound innovations are needed in the global governance system, in innovation policies, in economic incentives and in the organization of economic activities, among which biotechnology appears as a fundamental driver of the world economy, since in earlier crises where humankind confronted the threat of restrictions in resources, technological innovation created new resources and enabled the efficient use of existing resources.

Biotechnology can therefore improve environmental supply and sustainability in the production of food and fodder, the production of fibers, improve the quality of water, the production of renewable energy, improve human and animal health, and help maintain biodiversity. It is however unlikely that biotechnology will fulfill its potential without a corresponding development of regional, national and global policies to support its development and application.

What are the odds of different biotechnologies becoming a commercial success in 2030?

In order to answer this question two key factors must be taken into account: i. the speed at which biotechnological research produces successful innovations, and ii. changes in regulatory policies and institutional promotion³.

The OECD in its document "The Bioeconomy to 2030: Designing a Policy Agenda" - ISBN-978-92-64-03853-0 (2009) takes these two factors into consideration as key factors for a future projection and adopts a conservative perspective. Firstly, the appraisal assumes the existence of a necessary standard period in order to develop a discovery and turn it into a commercially viable application. This appraisal was made by means of a historical record of biotechnologies in the OECD countries.

Secondly, the appraisal assumes that the majority of the changes to regulatory and institutional policies tend to be adaptive. Policy changes require profound economic changes or alterations to the *status quo* that are far harder to apply and therefore less likely.

³ The BIOTEC SUR Platform should operate on these two key factors and find an equivalent in the strategic guidelines.

Taking these premises into consideration and in no particular order, Table No. 1 lists the possible types of biotechnologies that may be available by 2030. Many of the biotechnologies on this list are already commercially available or close to their commercial phase.

In primary production, biotechnology is a method widely employed in diagnosing diseases in plants and animals and for developing new varieties of trees, crops, cattle and in improving aquaculture species with high value characteristics. The use of biotechnology in primary production will have become widespread by 2030, in both vegetable production and fodder as well as the production of foodstuffs and fibers.

Three uses of biotechnology are identified for primary production in the face of economic or social barriers: cloning animals, the use of GM technology, and the use of GM to develop functional foodstuffs. In 2030, the most likely use of animal cloning will be to produce high reproductive value and progress in genetic value and in obtaining biodrugs. The main hurdle to a greater use of cloning may be public opposition to consuming cloned meat. Applying GMO to crops for small markets does not face any great technical obstacles, but might be restricted by regulatory costs. Functional GM foods in developed countries also face limitations of production costs when compared to less costly alternatives such as food fortification. The most likely use of biotechnology in functional foodstuffs in developing countries will aim to increase the levels of the essential minerals and vitamins they contain.

As regards health, there are certain features that characterize the pharmaceutical industry, namely:

- International: stable and dynamic.
- Highly concentrated.
- High R&D expenses: 10 leading companies spend 80% of the total investment.
- Regulation (FDA, EMEA): GMP, GLP, GCP.

Looking at 2030, virtually all research will be aimed at developing or applying new diagnoses (paper diagnosis) and pharmaceutical products from the application of biotechnology. The exception to this is generic drugs developed prior to 2015, although even here prescription practices will be increasingly influenced by Pharmacogenetics. Tests for the diagnosis of serious genetic diseases will be widely used over the years and at increasingly lower costs.

Both Pharmacogenetics and linked medical records will improve the safety and efficacy of therapeutic treatments. Finally, this will allow researchers to link prescriptions, behavior factors and genetic data to long-term health results. This will significantly improve public health by making it possible to identify adverse reactions to drugs, undesired drug interactions and other factors that affect public health results both positively and negatively. It will also reduce the potential market for therapies that are only effective or safe for specific subgroups, and could lead to the removal of drugs with excessive contraindications. Several hundred genetic biomarkers could be validated for their use in drug prescription.

The promises of regenerative medicine and of predictive and preventive medicine will be fulfilled only in part. Although many of the technologies required and the findings from the research of these two biotechnologies are being developed, there are as yet many technical, economic and social challenges that need to be overcome. However, several types of regenerative drugs will be available by 2030. The substitution of complex organs such as the heart, the lungs or the liver are likely to appear further in the future. Biotechnology currently presents solutions that are very close to more complex commercial developments such as:

- The production of human proteins for therapeutic uses
- The production of these proteins on an industrial scale
- Safer and more controllable products

- The production of proteins for diagnoses similar to the former
- Less costly productive processes

The use of biotechnological processes in industry is rapidly increasing and is likely to continue to do so through to 2030, but several results are possible. The future use of biotechnology to produce chemical products, polymers and fuels, in bulk is uncertain, partly due to the fact that competitiveness will depend on public investment in order to create markets. Industrial biotechnology will also have to compete with alternative technologies from other technological fields. For example, biofuels compete with other sustainable sources of energy such as: i. wave, ii. geothermic, iii. wind, iv. solar and v. nuclear energy.

Biofuels have an inherent advantage in applications related to transportation because they are the only renewable source of liquid fuels, since some kinds of biofuels do not require substantial changes in the existing transportation infrastructure. However, advances in the technology for self-rechargeable battery-powered devices and in generating renewable electricity could provide electric vehicles powered by solar energy – or other sources of electricity – with an edge.

The most likely industrial uses of biotechnology in 2030 are: i. producing enzymes for a series of industrial processes, ii. synthesizing high-value chemical products and plastics with microorganisms, iii. in bioreactors and the production of high density energy, iv. producing biofuels from sugar cane and cellulose, v. large-scale commercial production of chemicals or biofuels from microorganisms or algae, without the use of biomass, primarily on account of the innumerable technical difficulties for increasing production to commercially competitive levels.

Table No. 1 – Expected developments at 2030 in Primary Production, Health and Industry

Primary Production	Health	Industry
Generalized use of MAS in the production of vegetables, cattle, fish and farmed seafood.	Many new pharmaceutical products and vaccines based on biotechnological knowledge receiving approval for annual marketing	Improvement of enzymes for a broad and growing range of applications in the chemical industry
GM varieties of the main crops and improvement of forestry for the production of cellulose, biofuels and lignin content to improve the industry, transformation and conversion.	A greater use of Pharmogenetics in clinical trials and in prescribing practices, with a fall in the percentage of target patients for a given therapy.	Improvement in the microorganisms that can produce an increasing number of chemical products in a single step, some of which are based on genes identified through bioprospecting.
GM plants and animals for pharmaceutical products and other high-value compounds.	Improved safety and efficacy of therapeutic treatments, as a result of linking data from pharmogenetics, prescription of medical records for the long-term improvement of public health.	Biosensors for real-time monitoring of environmental pollutants and for biometric data for identifying people.
Improved varieties of agricultural food crops with: i. greater yield, ii. resistance to plagues and iii. resistance to water stress, developed through GMO, MAS, intragenics or cisgenesis.	Broad selection of multiple genetic risk factors for high-impact diseases such as arthritis, some of whose main causes are genetic.	Development of biofuels produced from sugar cane and from cellulose biomass sources.
Molecular markers for identifying genetic features and diseases in cattle, fish and seafood.	Improvement in drug supply systems through the convergence of biotechnology and nanotechnology.	Greater market share for biomaterials such as bioplastics, above all in market niches where some competitive edge is possible.
Cloning high reproductive value animals, which will improve the production indices in cattle rearing.	New nutraceutical products, some produced by GM microorganisms and others from vegetables or marine extracts.	
The main basic crops for industrial transformation will improve with vitamins and trace elements by applying GM technology.	Low cost of genetic risk tests, chronic disease factors, heart disease and some forms of cancer.	
	Regenerative medicine will afford better management of diabetes and some types of damaged tissues stemming from different affections.	

Source: OECD 2009

I.2.2 – The Bioeconomy to 2030

The level of integration of the bioeconomy in 2030 will be influenced by the competitiveness of the biotechnological solutions as compared to other technologies. An unknown factor is the future production of biomass. If biomass offers an economical and environmentally sustainable solution for the production of raw materials for the chemical industry and for the production of fuel, there will be a broad integration between primary production and industrial biotechnology. On the other hand, if other technologies, including synthetic biology, afford more efficient and effective solutions, the level of integration will diminish.

In 2030 the bioeconomy will merge with other sustainable technologies for the reduction of the limitations of natural resources and environmental problems, as part of a global shift towards greater social and economic sustainability. Some chemical substances may be produced from oil, while others might be more efficiently produced from biomass. The production of energy will be based on a combination of renewable energies, using a specific combination linked to the availability of local resources.

The growing role of developing countries in biotechnology will influence the placement of qualified human resources, of R&D, markets, competition and trade.

In all applications of biotechnology, companies will increasingly adopt a global strategy in order to take advantage of the research capacity, the technological advances and the markets in developed and developing countries.

Biotechnology is likely to make a strong contribution to economic activity in 2030. Many industrial processes will continue to depend on current technologies in 2030; however, using biotechnology it will be possible to contribute up to 35% of all the production of chemical substances for that year. Biotechnology in countries belonging to the OECD will contribute to the development and production of virtually all new pharmaceutical products in 2030. In 2005, generic drugs accounted for between 10% and 40% of the pharmaceutical market in European countries (Perry, 2006). The share of non-biotechnological generic drugs should diminish over time, so a generous estimate is that their share will be 20% of the pharmaceutical industry VAB in 2030, against 80% of the products derived from biotechnological applications. In primary production, biotechnology could contribute towards half of the agricultural production and almost 100% of aquaculture and forestry activities, amounting to a total of approximately 50% of the primary production.

This consideration could have a direct consequence on the percentage of biotechnology's share of the GDP in developing countries, owing to the greater importance of primary production and industrial activities in relation to OECD countries. In contrast, the percentage of the pharmaceutical industry and health technologies' share of the GDP is likely to be greater in developed countries owing to the concentration of research capacity and markets in the OECD area. Most of the new technologies in health will be high value technologies for a large proportion of the world population. This will limit the benefits of many health biotechnology products in 2030 for a population of a billion in developed countries, where per capita incomes will be sufficient, and possibly another billion high income people in developing countries.

The different descriptions indicate that many factors influence the development of the bioeconomy. Some of the factors are random and depend on the competitive behavior of the different technological advances in biotechnology in relation to others with greater performances. Other factors constitute the main challenges the world must face, such as the scarcity of food owing to climate change and drought, or pandemics, cattle diseases, etc.

How do governments react to financial crises? Can food scarcity or pandemics configure the future development of the bioeconomy?

The future is also influenced by international cooperation, above all in developing countries, and the incentive structures for research and markets. In this sense the MERCOSUR has a competitive edge it can offer the world for the development of biotechnologies that afford solutions to regional and global problems with a broad sense of economic, social and environmental sustainability. The MERCOSUR will be one of the main food producing regions, improving its efficiency in productive terms based on biotechnology, also producing consumer goods from biotechnological platforms for the prevention and control of priority diseases in the region and the world, producing foodstuffs and supplies and identifying opportunities in the needs of other worldwide production centers.

Table No. 2 – Main Bioeconomy Drivers in 2030 in Primary Production, Health and Industry

		Implications for			
	Situation in 2030	Bioeconomy	Primary Production	Health	Industry
Population and Economy	The world population will reach 8.3 billion. 97% of this growth will occur in developing countries. The world GDP will double its 2005 level, but many will still be living on 2 dollars a day. The per capita income in OECD countries will continue to be 3 to 6 times the world average.	The greatest investment in R&D for biotechnology will be made in non OECD countries. Increase in the per capita income of world consumer habits with regard to eating, health, etc.	The increase in population and the demand for meat and fish will drive the development of biotechnologies that impact on productivity growth rates. The negative impact of the lack of food on poor populations will increase acceptance of biotechnological solutions for production.	At the highest income levels there will be an increase in the demand for sanitation for a world population 28% higher.	The growth of the population poses environmental challenges, creating opportunities for industrial biotechnology (IB).
Demography and Human Resources	The world workforce will increase by 25%. Capitalization of the demographic dividend will be observed in a good deal of developing countries. There will be a clear decrease of the young workforce in developing countries. Educational levels and an increase in jobs shift from agriculture to industry and services.	Increases in levels of education, particularly the number of people with tertiary education, will make more human resources available for R&D.	Mechanization of agriculture in developing countries will increase the demand for energy.	Old age populations will increase the demand for sanitary assistance, especially long-term attention. There will be an increase in degenerative disorders.	As agriculture becomes increasingly mechanized in the developing world and demand for fuel increases, IB will be used to convert agricultural waste into fuel.
Energy and Climate Change	The increase in the demand for energy will be met by fossil fuels and greenhouse gas emissions will increase. Global temperature will increase by 1°C and sea level will rise.	Increase in R&D for generating biofuels and mitigating climate change.	Depleted crop yields, drought and water salinity in some regions will boost the development and adoption of varieties offering greater yield.	Temperature increase will lead to the propagation of diseases to new geographical regions. Public policy will view biotechnology as a solution.	High energy prices and strong environmental regulations will provide incentives for the use of IB to reduce energy consumption and greenhouse gas emissions.

Source: OECD 2009

I.3 – Definition of Platform

In order to determine what to Plan Strategically and bearing it in mind as a fundamental element that helps to understand the outputs obtained, the concept of platform needs to be reviewed.

To this end it was necessary to review the concepts and distinguish two types of conceptual definitions, and in fact two situations become apparent in practice. In this sense, it should be emphasized that the institutional definition of platform is stressed rather than those of a technological nature, and that the focus of our plan will be based on the institutional definition.

There are therefore two different types of concepts:

- The concept of scientific – technological instrument: refers to a package of knowledge and techniques used to develop a certain application. For example:
 - The Agrobacterium platform for plant transformation
 - At a more complex level, the concept may refer to research support units equipped with the latest technology and highly specialized staff to work in a particular area, for example, that of proteomics, where technology is offered (capacities, equipment) to carry out everything from the separation and analysis of protein expression by means of two-dimensional electrophoresis to large-scale protein identification.
- The institutional concept:
 - Collaborative stages led by industry bringing together the participation of a range of actors in the form of networks whose purpose is to coordinate national, regional and industrial perspectives in relation to specific emerging areas or sectors of technological application, deemed to be strategically important (biotechnology related to plants, biofuels, forestry, foodstuffs).

Within this framework, Platforms (BIOTECSUR in this case) involve the explicit identification of a *Vision*, the development of a *Strategy* and the application of an *Implementation Plan* that integrate the perspectives of all the stakeholders in the development, marketing and use of the technology in question.

It is a “formalized” institutional framework in order to coordinate actors from the private, public, and academic sectors around a series of objectives that enable the development of the sector in a collective effort to coordinate actions. In the case of the BIOTECSUR Platform, this coordination is given as a complex system with a regional approach, between four countries with different degrees of progress and scale in the biotechnology sector. This type of platform attempts to work upon:

- A common vision for the development of the technology or of a particular sector
- Mobilizing a critical mass of innovative resources and effort
- Defining a strategic R&D agenda
- Facilitating the installation of an appropriate political/institutional/economic environment for the development of the innovation process.

CHAPTER II

BIOTECSUR Strategic Definitions

II. 1 – Vision and Mission Statements

Working out a regional vision for the BIOTECSUR Platform demanded building upon the results of every MERCOSUR member state's exploratory work, in order to identify common grounds in the biotechnology sector in all four countries. Bearing this in mind, the following main features describing MERCOSUR's biotechnology sector were found:

- Countries need to increase the value of bio-regional products.
- In general, two high-priority sectors are agriculture and health. Particularly in agriculture, biofuels represent a high-potential sector where MERCOSUR may achieve worldwide leadership.
- Its human resource base requires strengthening, greater future exploitation, etc.
- Biotechnology goes across several productive fields, contributing with innovation in all of them.
- The industrial sector's active and orienting involvement is considered essential.
- All four countries have different situations. Each one has different starting points and development expectations. In this sense, there will be opportunities for regional collaboration.
- It is essential to develop and consolidate the region's industrial sector.
- Currently there are problems regulating and connecting product sales within the region and from the region to the world.
- There is a need for a critical mass of skills, which is currently a barrier for development.
- A public policy strategy that promotes biotechnology development and cooperation is needed.
- MERCOSUR possesses great biodiversity, which must become a source of competitive advantages for the region.
- MERCOSUR must be acknowledged as a region that produces/offers food with added value by using biotechnological techniques in the foods and services area.
- Lack of state leadership.
- Limited online work systems.
- Limited health-related biotechnology development.
- Need to train human resources.
- Limited public/private sector connections.
- The region's financial resources are scarce.
- Lack of normative and intellectual property harmony.
- Low industrial and commercial escalation of biotechnological products.
- Lack of connection policies linking with multinational companies.

In this sense, it is considered that BIOTECSUR should become a mechanism for institutional articulation that coordinates a network of public and private MERCOSUR actors. The purpose would be to generate highly competitive and globally known biotechnological products and services. Thus, the platform should be based on a combination of skills involving:

- Efficiency and effectiveness to promote greater links among businesses and R&D systems.
- Aid the construction of a systemic vision on regional problems and needs that may be solved through biotechnology.
- Contributions to strengthen institutions and businesses related to the biotechnology sector.
- Aid to develop business, academic, and scientific skills.
- Work to leverage external resources to continuously develop regional biotechnology.
- Contribute to identify and frame public and social legitimacy policies.

Taking all these factors into account, the CADB and sector actors have defined the following Vision and Mission statements:

BIOTECSUR 2030 VISION

“BIOTECSUR is MERCOSUR’s biotechnology platform designed to drive and articulate public and private actors for a sustainable solution to regional and global problems. It is globally acknowledged for its effective and efficient creation of highly competitive biotechnological goods, services and processes.”

BIOTECSUR MISSION STATEMENT

- **Make sustainable use of MERCOSUR’s natural resources such as biodiversity, abundant water reserves and farming lands, and wide climatic ranges.**
- **Efficiently consolidate and make use of MERCOSUR’s scientific and biotechnological skills.**
- **Promote innovation by strengthening business and science & technology capacities and consolidating links between them.**
- **Foster a positive regulatory environment to frame public and social legitimacy policies that stimulate investment to develop and apply biotechnology.**
- **Leverage MERCOSUR’s financial resources, stimulating international co-financing and cooperation to develop regional biotechnology.**

These definitions are based on a series of factors that currently condition the development of MERCOSUR’s biotechnology system. Among these factors we find:

- Current limited online work systems that allow for a true regional *netchain*. Actors in the public, academic and private sectors agree upon the need to integrate a net of networks covering MERCOSUR. This network should focus on sharing experiences and resources and improving communications, taking advantage of opportunities in the global market.
- Local and short-term visions due to national (Argentina, Brazil, Paraguay, and Uruguay) and regional conditions adverse to long-term thinking and planning. In this sense, having a Vision helps long-term thinking as it aligns regional actors with this idea.
- Need to actively facilitate the transfer of knowledge. And depending on information flows, there is also a need to transform knowledge into solutions for high-impact, regional and global problems.
- Limited creation of new innovating businesses and inadequate focus on the “production chain” or “value chain”. This signals the need to move forward in terms of creating regional businesses with a global productive scale and outreach.
- Lack of harmony among laws and regulations regarding development and promotion of biotechnology, focusing on matters of biosecurity and intellectual property.
- Currently, sector businesses are working with high expectations (which equals opportunities), but do not find the necessary mechanisms to grow.
- Lack of evidence of an active businessmen involvement in developing a strong biotechnological sector. This is basically due to disbelief in the possibility of public,

private, and academic sectors working together. Businessmen in the sector lack long-term vision and collective actions in issues such as pre-competitiveness.

The BIOTECSUR Vision and Mission Statements also take into account different aspects that show biotechnology's regional growth potential, including the following findings:

- There is clear growth potential in the health, agriculture, industrial and biotechnological service sectors for the next 12 years.
- Progress has been made concerning integrated health actions and the development of biodiversity knowledge bases, making use of advanced techniques in genomics and bioinformatics.
- Work has been made to channel financial aid to promote the creation of biotechnology service firms, especially in Brazil.
- Improved “creative science” efforts in universities, focused to create a scientific base integrated into key areas, such as bioenergy.
- In MERCOSUR, actions must be coordinated following a regional integration logic – especially actions involving biotechnological research, development and information–, using cooperation and strategic alliances as the region's political instrument.

II. 2 – Strategic Guidelines and Activities Definition

The strategic planning process is a group of procedures that allows to prioritize and define which topics must be addressed in a particular organization within its context. This effort helps to build a future that works as a framework for companies following it. The same goes for personal growth and community involvement, which are the foundations of social capital. Therefore, a strategic guideline definition allows to:

- a. **Set a posture.** Building BIOTECSUR's strategic guidelines equals taking a stand on which are the keys to develop the biotechnology sector, its importance and its role in the global context.
- b. **Consolidate a process.** Understanding that this kind of work is permanent and that actions performed so far do not end in a document is essential; moreover, actions must lead to a methodology of strategic and managerial definitions.
- c. **Create a place for learning and collective agreement.** Interactions between private, public, and academic sectors turn essential when facing the commitment to execute the strategic guidelines. Business sector motivation to get involved and develop biotechnology is the center of attention when trying to consolidate joint efforts among these actors.
- d. **Construct power. Defining a regional strategic plan, with a clear involvement by the private and academic sectors,** shifts the work paradigm followed until now towards constructing long-term visions. This logic improves the contextual relation system and grants priority to biotechnology before multilateral credit agencies and commercial blocs, providing greater power to MERCOSUR actors in the sector.
- e. **Build social capital.** Joint efforts and confidence building among MERCOSUR actors lead to create high impact, regional businesses and projects.
- f. **Build a framework guiding towards collective action.** Strategic guidelines offer a roadmap to guide the Platform's actions. This is a sign of the systemic approach needed to address current biotechnology problems in the region.

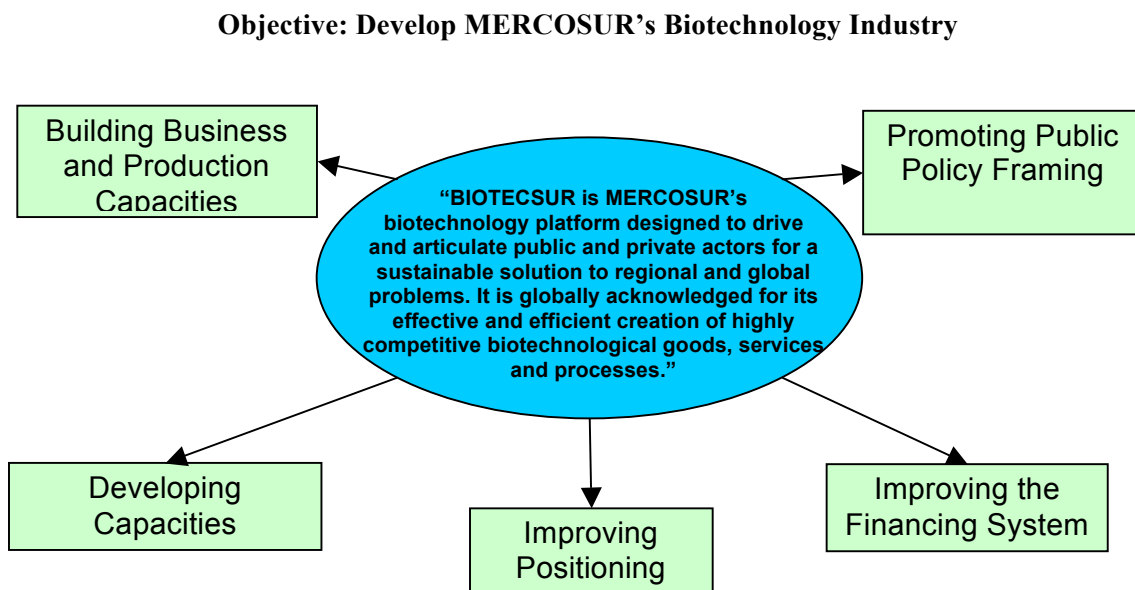
Therefore, the group of strategic guidelines defined by means of the active involvement of regional actors represents a navigation chart that goes way beyond a written product:

- It means generating consensus.
- It represents a framework for defining objectives and collective actions.
- It is a win-win process, in the widest sense of the term, leading to improve MERCOSUR biotechnology sector's competitiveness.
- It is the road leading to materialize the BIOTECSUR vision.

BIOTECSUR's strategic guideline definition has considered the results of the regional strategy definition seminars and has been compiled bearing in mind the three sectors' common denominator. The main scopes for the strategic guidelines were also identified through a similar process. This has allowed to classify actions following different application orientations or focuses.⁴

Five Strategic Guidelines have been identified which systemically address different factors affecting the internal (Strengths and Weaknesses) and external (Opportunities and Threats) environments. The five identified Strategic Guidelines are presented in Figure No. 3.

Figure No. 3 – BIOTECSUR's Strategic Guideline Definition



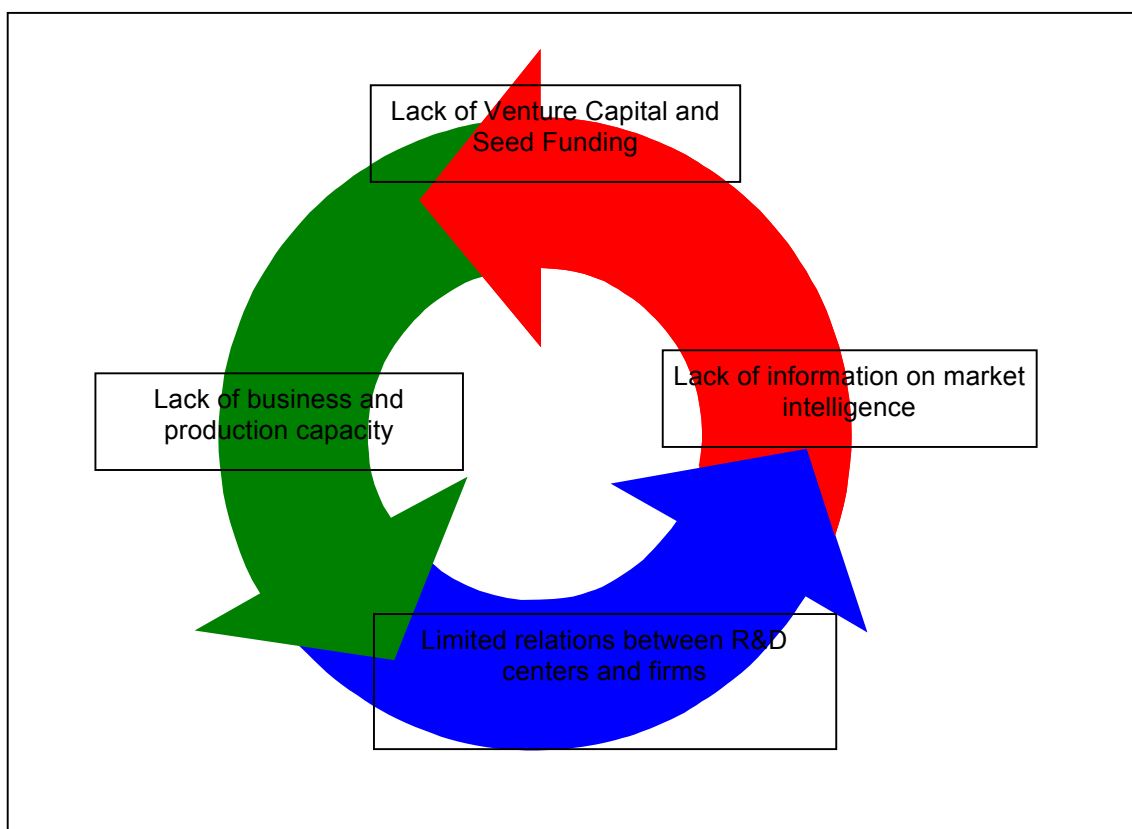
1. BUILDING BUSINESS AND PRODUCTION CAPACITIES

The identification of this guideline is based on the fact that the region lacks a business capacity needed to drive the development of biotechnological products and services. More often than not, the creation of knowledge in the region does not lead to address a concrete market. Although the main hurdle is the lack of connections between R&D centers and sector firms leading to create

⁴ The concept of strategy “scope” allows focalizing and separating actions involved in the generic definition of a strategic guideline. On the other hand, such a guideline must focus on a few key concepts that grant it cohesion and force. However, when applying the guideline, one has to identify on which aspects of the system it will relate to.

new businesses, a lack of a productive scale is also limiting some developments, mainly in the biopharmaceutical sector.

Figure No. 4 – Problems Related to Building Business and Production Capacities.



In most cases, business capacities depend not only on the lack of an entrepreneurial spirit, but also on the lack of concrete forms of aid linked to the availability of venture capital and seed funding for high economic impact enterprises. One of the main issues here is the limited knowledge on concrete business opportunities, which is due to the lack of organizations focused on market and competitiveness intelligence. Such organizations could help businesses and R&D groups to create solid projects that may attract venture capital.

Within this Strategic Guideline, the following activities have been identified:

- ▶ Provide institutional support to develop competitive alliances between large corporations and small organizations.
- ▶ Promote precompetitive business alliances.
- ▶ Develop biotechnological incubators and parks.
- ▶ Business creation and consolidation. Promote entrepreneurship.
- ▶ Systematize regional information flows.
- ▶ Build databases.
- ▶ Competitive intelligence observatories.

2. DEVELOPING CAPACITIES

Just like Guideline 1 suggests building business capacities –assuming that focus on this point will drive the entire system–, it is essential to provide the regional biotechnological complex capacities that allow it to respond to business demands. The foundation for this is an increased ability to identify opportunities. In this strategic guideline, three scopes have been recognized that help to classify the identified actions:

- **Human capital**
- **Knowledge management**
- **Infrastructure and business capacities**

Human Capital: Developing greater Human Capital skills is essential to increase the system's competitiveness. Improved human capital relates to training the people involved in the system. It is also related to actions that favor mobility within the region and an increased critical mass of both businessmen and researchers. On the other hand, network creation is considered essential to improve training of human resources that are part of the complex. In this sense, we defined that training must orient towards greater administration, negotiation, managerial and innovation skills. This has the purpose to align the search for market opportunities with greater skills to transform knowledge into products and services with strong market penetration.

Within this Strategic Line, the following activities have been identified:

- ▶ Identify regional training needs. Regional courses in businesses, academia, and governments (on subject matters such as business and innovation, law, organization, negotiation, intellectual property, management, and patents).
- ▶ Create networks.
- ▶ Promote regional human resource mobility.
- ▶ Regional integration of new and existing biotechnology postgraduate programs.
- ▶ Professional, technological, and business training, that allows working within the science-industry interface.
- ▶ Train technicians who specialize in industrial matters (e.g., biofuels).
- ▶ Joint development of businesses and businessmen and technological internships in companies.
- ▶ Promote developing researchers, leading to a greater appreciation for technologists' activities.

Knowledge management: Knowledge is understood from two different perspectives: as access to information and as a process. Although it has been suggested that knowledge management is a process of applying experience, knowledge must also be stored so other people can have access to it. The act of defining a computerized capacity, resource, business, and researcher directory is based on the fact that knowledge involves both management and creation of information. There is a constant interaction between wisdom and its application, because this perspective focuses on information flow and the processes of creating, sharing, and distributing knowledge. Even though developing a “competitive intelligence observatory” was classified in

the “building business capacities” guideline, the multidimensional and systemic nature of the strategy also relates the observatory to this strategic guideline. In other words, this knowledge perspective is an extension of knowledge as an object, emphasizing accessibility to information.

Within this Strategic Line, the following activities have been identified:

- ▶ Computerized capacity, resource, business, and researcher directory.
- ▶ Improve management and co-development of regional projects.
- ▶ Promote and strengthen links between the academic and private sectors.
- ▶ Information exchange and knowledge building on intellectual property.
- ▶ Competitive intelligence (market prospects, finding opportunities, and resource search).
- ▶ Create a service and skills platform to solve emerging problems.
- ▶ Create regional offices to connect health-related biotechnological actors.
- ▶ Regional knowledge integration (e.g., develop a biotechnology bank with industrial applications).

Infrastructure: One of the negative factors regarding the internal environment (weaknesses) found in the four countries was the lack of laboratory infrastructure suited for the growth expected and suggested in the Platform’s vision. On the other hand, a need for infrastructure capacity is matched by the region’s need for production equipment to address a growing industry. Thus, the suggestion to promote a service platform to develop biotechnology becomes essential if MERCOSUR firms are expected to match international competitiveness standards. In the health sector, as mentioned in the “building business capacities” section, it is important to promote the construction of upscale commercial plants for biopharmaceutical products.

Within this Strategic Line, the following activities have been identified:

- ▶ **Increase laboratory capacities.**
- ▶ **Promote upscale facilities.**
- ▶ **Strengthen and broaden infrastructure and equipment by promoting the creation of businesses that produce equipment within the region.**
- ▶ **Promote the creation of a regional R&D center.**
- ▶ **Promote the creation of laboratories with regional outreach (e.g., biological material referents).**

3. PROMOTING PUBLIC POLICY FRAMING

One fundamental aspect of building a highly competitive biotechnological sector is designing public policies oriented to develop biotechnological solutions to people’s problems. As a regional structure, the Platform has no direct impact on the design of public policy, but it may act as a “catalyst” or “facilitator” to frame each of the member states’ national policies or of MERCOSUR as a whole.

In this sense, the Platform must establish a first-class “consulting group” permanently analyzing policy scopes in each country and how regulations harmonize in MERCOSUR as a whole. Although every strategy has a structural place in the platform, this strategic guideline shows an evident need to operate with a permanent structure exerting strong consulting and coordinating actions before national authorities framing public policy. Two clearly separated scopes have been identified in this sense:

- **Normative**
- **Organization and Instruments**

Normative:

- ▶ Harmonize biosecurity regulations.
- ▶ Study and harmonize the Intellectual Property Regulative framework.
- ▶ Encourage the creation of laws and regulations that promote biotechnology.
- ▶ Propose a regulatory bill to mutually acknowledge trials.
- ▶ Propose a regional biodiversity management and access bill.
- ▶ Propose a regulatory bill making Member States demand biotechnological products and services in the region within a competitive market.

Organization and Instruments:

- ▶ Regional tax incentives.
- ▶ Create a think tank with regional influence on policy framing.
- ▶ Integrate and harmonize the work of regulatory state agencies.
- ▶ Foster the institutions necessary to develop biotechnology in the different countries.

4. IMPROVING THE FINANCING SYSTEM

Financing different activities linked to creating knowledge, technological innovation, pilot-test production, upscale production, access to markets, etc. is a key aspect of the dynamics and speed with which knowledge transforms into innovation and then into a concrete product or service offered in the market. The “time to market” of a certain form of knowledge demands different types of involvement from a financial point of view. Although certain differences have been found among the four countries comprising MERCOSUR, in some cases there is an urgent need to reach further lengths with the financing schemes related to financial sustainability during the business cycle. In other cases there is a need to increase state funding to promote science and technology.

Thus, we must address this strategic guideline from the Platform’s wide point of view to later address each country’s particularities, through actions with different scope and focus. In this sense, two scopes have been defined for this category:

- **Tools**

➤ Attainment and management

Tools: Given the scarce financial resources and the biotechnology sector's peculiarities, from an actor's point of view, whether in the public, private or academic sector, it is clearly necessary to move forward on the development of new funding instruments. Especially in the business sector, the need for venture capital and seed funding represents a limitation when starting a project. On the other hand, fee-related issues involving researchers and technologists in regional research projects demand an additional effort when trying to create alternatives to motivate human capital and leverage funding, which is measured in pesos earned versus pesos invested.

Within this Strategic Line, the following activities have been identified:

- ▶ Create a Regional Cooperation Fund which optimizes resources and provides investment sustainability.
- ▶ Promote private investment funds and other instruments to access the capital market.
- ▶ Develop regional consortiums for public-private investment.
- ▶ Develop joint projects: businesses – entrepreneurs.
- ▶ Finance equipment and input development projects for the biotechnological industrial chain.
- ▶ Develop and promote new financial instruments to export biotechnology and launch new products.
- ▶ Resources to obtain and maintain patents.

Attainment and management: Just like working on new financing tools proves to be essential, working on these two key aspects to drive funds from other sectors into biotechnology is also a must. Attaining funds both from multilateral credit agencies and international aid must be part of a fund designed to finance regional integration and financial sustainability for emerging businesses. At this stage, the platform must not only gather funds, it must also manage them efficiently.

Within this Strategic Line, the following activities have been identified:

- ▶ Available capital for incubating businesses and seed funds.
- ▶ Financial sustainability for emerging biotechnology firms.
- ▶ Regional, national, and international search for financial resources.
- ▶ Financial management for high impact regional projects related to solving problems specific to the region, preferably involving all countries.
- ▶ Promote investment in productive scaling plants.

5. IMPROVING POSITIONING

BIOTECSUR must seek positioning at two different levels: i. positioning biotechnology as a “source of solutions and economic development for MERCOSUR’s society”; and ii. competitive positioning of MERCOSUR as a global leader in biotechnological solutions. Both these perspectives emerge from the need to communicate –with a scientific and market basis– biotechnological features meant to improve public perception at different levels. On the other hand, this is essential to forge the BIOTECSUR brand as a sign of quality. Spreading biotechnology’s growth potential to all four countries is a key issue to achieve the platform’s objectives. In this sense, biotechnology and the platform must position themselves according to two different scopes:

- **Positioning towards society**
- **Competitive positioning**

Positioning towards society: Biotechnology belongs to the four countries’ social imaginary. Thus, biotechnology needs to be communicated to MERCOSUR’s society with a scientific, far-reaching basis. One might say that this positioning should be “indoors”, within the region, in order to show the advantages of biotechnology in terms of health and nutrition, and as a solution to global warming and energy issues.

Within this Strategic Line, the following activities have been identified:

- ▶ Aimed at two levels: massive and specific opinion builders.
- ▶ Identify main agents, interest groups, and their relations.
- ▶ Sensitize social actors (decision makers and opinion builders) to improve social/public and interest group perceptions.
- ▶ Promote biotechnology’s visibility.
- ▶ Popularize scientific contents.
- ▶ Create a regional biotechnology communications system.

Competitive positioning: In its Vision statement, BIOTECSUR envisions to provide global society with “sustainable solution[s] to regional and global problems. It is globally acknowledged for its effective and efficient creation of highly competitive biotechnological goods, services and processes.” This should be the basis for the Platform’s communications and competitive positioning as a MERCOSUR instrument intended to develop biotechnology-based solutions.

Within this Strategic Line, the following activities have been identified:

- ▶ Represent a sign of quality in high impact projects.

Table No. 3 – BIOTECSUR Platform Strategic Guideline and Activity Summary.

STRATEGIC GUIDELINES	SCOPE	ACTIVITIES
BUILDING BUSINESS AND PRODUCTION CAPACITIES	Organization and Instruments	<ul style="list-style-type: none"> ▶ Provide institutional support to develop competitive alliances between large corporations and small organizations. ▶ Promote precompetitive business alliances. ▶ Develop biotechnological incubators and parks. ▶ Business creation and consolidation. Promote entrepreneurship. ▶ Systematize regional information flows. ▶ Build databases. ▶ Competitive intelligence observatories. ▶ Joint development of businesses and businessmen and technological internships in companies. ▶ Network creation. ▶ Promote and strengthen connections between the academic and private sectors.
	Human Capital	<ul style="list-style-type: none"> ▶ Identify regional training needs. Regional courses in businesses, academia, and governments (on subject matters such as business and innovation, law, organization, negotiation, intellectual property, management, and patents). ▶ Create networks. ▶ Promote regional human resource mobility. ▶ Regional integration of new and existing biotechnology postgraduate programs. ▶ Professional, technological, and business training, that allows working within the science-industry interface. ▶ Train technicians who specialize in industrial matters (e.g., biofuels). ▶ Joint development of businesses and businessmen and technological internships in companies. ▶ Promote developing researchers, leading to a greater appreciation for technologists' activities.
DEVELOPING CAPACITIES	Knowledge Management	<ul style="list-style-type: none"> ▶ Computerized capacity, resource, business, and researcher directory (Build an open MERCOSUR databank including information on biotechnology businesses, existing networks, active biotechnology (research) groups and institutions (including consultants and service providers)). ▶ Improve management and co-development of regional projects. ▶ Promote and strengthen links between the academic and private sectors.

	<ul style="list-style-type: none"> ▶ Information exchange and knowledge building on intellectual property. ▶ Competitive intelligence (market prospects, finding opportunities, and resource search). ▶ Create a service and skills platform to solve emerging problems. ▶ Build a Biotechnology Service Technological Platform Network where to register and coordinate activities relating to: Genomics, Proteomics, Mono/Policlonal Antibodies, recombinant protein production, Biomolecule synthesis (DNA, RNA, Peptides), Bioinformatics, Confocal/Electronic Microscopy, Cytometrics/high capacity sorting, Bioprospection, Biotests, Biotechnological collections, Clinical trials, Real Time PCT. ▶ Create regional offices to connect health-related biotechnological actors. ▶ Regional knowledge integration (e.g., develop a biotechnology bank with industrial applications).
<p style="text-align: center;">Infrastructure</p>	<ul style="list-style-type: none"> ▶ Increase laboratory capacities. ▶ Promote upscale facilities. ▶ Strengthen and broaden infrastructure and equipment by promoting the creation of businesses that produce equipment within the region. ▶ Promote the creation of a regional R&D center. ▶ Promote the creation of laboratories with regional outreach (e.g., biological material referents).
<p style="text-align: center;">PROMOTING PUBLIC POLICY FRAMING</p>	<ul style="list-style-type: none"> ▶ Harmonize norms. ▶ Study and harmonize the Intellectual Property Regulative framework. ▶ Encourage the creation of laws and regulations that promote biotechnology. ▶ Propose a regulatory bill to mutually acknowledge trials. ▶ Propose a regional biodiversity management and access bill. ▶ Propose a regulatory bill making Member States demand biotechnological products and services in the region within a competitive market.
<p style="text-align: center;">IMPROVING THE FINANCING SYSTEM</p>	<ul style="list-style-type: none"> ▶ Regional tax incentives. ▶ Create a think tank with regional influence on policy framing. ▶ Integrate and harmonize the work of regulatory state agencies. ▶ Foster the institutions necessary to develop biotechnology in the different countries.
	<ul style="list-style-type: none"> ▶ Create a Regional Cooperation Fund which optimizes resources and provides investment sustainability. ▶ Promote private investment funds and other instruments to access the capital market. ▶ Develop regional consortiums for public-private investment. ▶ Develop joint projects: businesses – entrepreneurs. ▶ Finance equipment and input development projects for the biotechnological industrial chain.
	<ul style="list-style-type: none"> ▶ Organization and Instruments
	<ul style="list-style-type: none"> ▶ Tools

	<ul style="list-style-type: none"> ▶ Develop and promote new financial instruments to export biotechnology and launch new products. ▶ Resources to obtain and maintain patents.
<p style="text-align: center;">Management</p>	<ul style="list-style-type: none"> ▶ Available capital for incubating businesses and seed funds. ▶ Financial sustainability for emerging biotechnology firms. ▶ Available funding for clinical research. ▶ Regional, national, and international search for financial resources. ▶ Financial management for high impact regional projects related to solving problems specific to the region, preferably involving all countries. ▶ Promote investment in productive scaling plants.
<p style="text-align: center;">POSITIONING</p>	<ul style="list-style-type: none"> ▶ Aimed at two levels: massive and specific opinion builders. ▶ Identify main agents, interest groups, and their relations. ▶ Sensitize social actors (decision makers and opinion builders) to improve social/public and interest group perceptions. ▶ Promote biotechnology's visibility. ▶ Popularize scientific contents. ▶ Represent a sign of quality in high impact projects.
	<p style="text-align: center;">Society</p>
	<p style="text-align: center;">Competitive</p>

Source: Regional health, industry and agricultural workshops within the BIOTECSUR Project framework.

II. 3 – Some Considerations on BIOTECSUR’s Organization and Government Model

Organization of the Platform

The organization must be capable of and flexible enough to:

- ▶ Structure heterogeneous actors (public, private, and academic) and mobilize resources in a context with different levels of development, scientific-technological progress and productive systems, along the four countries in the region.
- ▶ Promote the development of policies, mechanisms, and instruments within and among the region’s different countries, taking into account different institutional development situations, and guaranteeing sustainability and plurality for the region’s biotechnological development.
- ▶ Foster promotional, developmental, and regulative public policies and instruments, in order to guarantee a greater private sector involvement. The benchmark will be current platforms in the European Union.
- ▶ The starting point shall be the current CADB, which will gradually evolve into a predefined organizational structure. It shall be hierarchical, representative, and powerful enough to implement the strategic guidelines which lead to accomplish the agreed vision.

The design of the institutional structure (government model) shall take into account the following issues:

- ▶ Institutional integration into MERCOSUR.
- ▶ Representing the different actors, focusing on private sector involvement.
- ▶ Redefining the institutional status of the Management Unit and the functions assigned to it.
- ▶ Institutional relations between the MU and the Platform’s board of directors (CADB).
- ▶ Identifying the tools and resources the MU should have in order to implement its assigned functions.
- ▶ Providing a proper environment for national platforms to participate in the proposed government model and for them to relate operationally with the MU.

CHAPTER III

Final Considerations and Suggestions on the Next Steps

III. 1 – Final Considerations

One must notice that the strategic definitions proposed in this document are the result of a collective construction undergone by agents belonging to MERCOSUR's biotechnology sector. This system, based on consultations, debates, and building agreements among agents from the public, private, and academic sectors, should be BIOTECSUR's permanent working scheme. Application of this methodology during the last year has yielded knowledge thanks to the involvement of different actors. Such knowledge can be classified into the following topics:

On consensus building...

- ▶ (1) Prior efforts recognize baseline actions taking place in all four countries and MERCOSUR as a whole, eliminating the concept of “scorched earth” and fostering further construction. This leads to value experiences and knowledge in the biotechnology sector and develop actions that boost whatever measures implemented so far. With this spirit in mind, consensus building finds fertile grounds and should become a common practice for the Platform in the future.
- ▶ (2) The strategic planning process carried out this year has shown how useful and powerful the definition of strategic priorities has been for MERCOSUR biotechnology. This collective construction will be valid as long as it is rooted on efforts from the three sectors (public, private, and academic). This involvement should grow continuously and reach greater heights than any prior effort.
- ▶ (3) Beyond verified consensus of BIOTECSUR's strategic guidelines, some issues were verified in the workshop plenary meetings. The main issues include: i) there is a high degree of consensus on the importance of BIOTECSUR developing biotechnology regionally; ii) consensual Vision and Mission statements, as well as strategic guidelines, may be framed for the four countries and the three sectors, despite existing differences and asymmetries within the region. In this sense, the contribution of an ordered and sequential methodology proves to be essential in the consensus building process.

On private sector involvement ...

- ▶ (4) Private sector involvement in forging the Platform's Vision is based upon some basic principles. These basic principles include allowing BIOTECSUR to support market-effective projects that drive MERCOSUR countries' economic growth and allowing biotechnology to become the center of development in the medium term, plus guaranteeing resource sustainability for funding biotechnology promotion. This involvement is the key to cooperate and find solutions to the many problems biotechnology faces in the region, and to establish a perspective that reflects every member state's specific circumstances.
- ▶ (5) By virtue of the framework, private sector involvement must be seen considering its catalyst function in the Platform, not the other way around. The Platform has an environment-creating function and a motivational role. However, BIOTECSUR's success will revolve around sector involvement and on the sectors' ability to lead the implementation of the identified strategic guidelines.
- ▶ (6) When financial needs are high, such as in Argentina, Uruguay, and Paraguay, the private sector is needed in able to leverage research funds and make use of the knowledge developed. This improves the reception of biotechnological products into

the market. Thus, a more formalized private sector involvement will be needed, exceeding the platform's scope. Such involvement should address science and technology issues in each member state.

- ▶ (7) BIOTECSUR's Management Unit will have a fundamental and intransferable role in communicating and motivating the private sector. In order to achieve this function, tasks such as i) comprehensive actor search; ii) building interaction maps among actors by sector; iii) identifying referents; iv) creating a MERCOSUR database with continuous updates; and v) identifying activities directly related to turning potential businesses into reality (negotiation rounds, linking potential partners through a complementarity identification system, platform business memberships, etc.)⁵, will prove to be helpful.
- ▶ (8) Biotechnology firms' limited interest in working in networks (dealt with in point 9) motivates a search for creative ways to achieve this goal. Thus, the possibility of designing this kind of networks in business chambers should be considered. These chambers would then act as nodes in the MERCOSUR networks.

On communication systems...

- ▶ (9) Network integration takes place in a highly interconnected environment where barriers related to MERCOSUR's vast geography and the lack of a positive interaction as a common practice hamper the possibility of integration. Evidence gathered during the production process of this project show that businessmen have limited interest in developing networks. This situation represents a bottle neck when trying to define a communication strategy for the Platform.
- ▶ (10) The project found deep information asymmetries which were classified within the "weaknesses" category while preparing the SWOT analysis for each sector analyzed. Such asymmetries were verified in every country comprising MERCOSUR, among the academic, private, and public sectors, and among different actors within the same sector. Thus, the Platform should address the issue of reversing these information asymmetries by developing a competitive intelligence observatory, as proposed in the strategic guidelines.
- ▶ (11) The importance of interconnectedness and communication among the different referents (actors) of the biotechnology sector and the Platform is evident. Creating a virtuous circle between "thought" and "action" requires involvement of (both private and public) actors during the execution of the strategic guidelines. Thus, an intransferable task of the Management Unit will be the administration, management, origin, and operation of communications among MERCOSUR's biotechnological referents.

On the strategic guidelines...

- ▶ (12) People are convinced that BIOTECSUR should support decision making both in the public and private sectors, as well as in academia. The key to transform

⁵ This matter was brought up during the validation and spreading workshops held in Montevideo on August 20, 2009, as a proposal to motivate private sector involvement.

MERCOSUR into the “leader in creating biotechnological solutions to global and regional problems” is a strong organizational reengineering of the (main) regional actors within the sector. This challenge involves new ways to relate and cooperate among actors and new systems to work together, set priorities and act. In this sense, the Platform is destined to carry out a fundamental role.

- ▶ (13) After setting the Platform’s strategic guidelines, one must bear in mind that they are based upon the “approach regionalization” strength, meaning that the strength of the four countries is greater than the strength of one, in areas such as sanitary defense and approval of sanitary biotechnological solutions.
- ▶ (14) Oral-based communication systems are limited across MERCOSUR, especially in Paraguay and Uruguay. Massive attendance to different events such as seminars, congresses, and sector meetings shows the effectiveness of the strategy. BIOTECSUR must provide the necessary tools to develop this information channel and create bonds among the different actors in the biotechnology sector. These bonds will be the foundation of network construction.

On MERCOSUR’s information flows compared to those in the EU...

- ▶ (15) One of the essential features of information flow in the EU is that it is bidirectional. In Europe, new information and communication technologies constitute a prevailing channel for information flow among actors. In MERCOSUR, on the other hand, the flow goes basically in one direction, erratically articulated among R&D groups and the private sector, without an organic approach that allows sector development. Brazil has some organizations with very strong bidirectional connections, and it should be considered a benchmark to implement these systems in MERCOSUR as a whole. BIOTECSUR should work to create mechanisms that allow bidirectional flows in the region’s existing structures.
- ▶ The lack of formalized business platforms in MERCOSUR as a whole represents an obstacle towards the development of efficient information and knowledge flows leading to greater joint competitiveness. In this sense, the EU shows platform development in different levels: i. technological; ii. clusters; iii. business; and iv. mixed. Business platforms handle tools that allow to produce information on markets, business networks, and contacts with governmental agencies; most platforms are state initiatives. In such places, information exchanges between policy makers and actors in the bioscience sector are promoted. In MERCOSUR we find some recent public initiatives relating to the field of science and technology. These initiatives may be described as incipient and geographically fragmented or absent. Thus, BIOTECSUR will have to think on how to insert business sector platforms within its own structure, from an organizational point of view.
- ▶ (17) MERCOSUR communication means are text-based, while in the EU oral means prevail. In this sense, one might say that the region’s “protoplatforms,” which clearly bear technological objectives, have a graphic communication basis. Meanwhile, in the European platforms –more business oriented– the prevailing means of communication are oral (seminars, workshops, conferences, etc.).
- ▶ (18) The sector’s work methods in the four countries comprising MERCOSUR seem to be in a prior evolutionary state. At first glance, one finds very deep differences. However, after analyzing the situation in detail, one finds a series of *ad hoc* organizations that are the embryos of possible future business platforms in MERCOSUR. These organizations do not have formalized operations or a corporate image that allows them to spread their activities. Yet they are the base upon which to

build platforms comparable to the ones in the EU. BIOTECSUR will bear the essential task of identifying these structures and catalyzing their evolution towards operation schemes similar to those in the EU.

- ▶ (19) Concerning cluster creation, the EU has innovated and made progress in the field based upon technological platform structures. Clusters are mainly composed of businesses, as well as academic institutions, where financing is mixed. This type of structure is almost non-existent in MERCOSUR. In this sense, BIOTECSUR must seek far less complex forms of online work. Some examples could be sector specific platforms and business and researcher networks, which are much more advanced networking techniques.

On financing biotechnological development...

- ▶ (20) Funding for promotion and development of biotechnological structures (platforms, networks, research centers, etc.) usually comes from the state, with limited involvement of the private sector. International agencies make important contributions to finance these systems. Thus, work is needed to reach a mixed financing system (public-private) on regional initiatives, with a strong orientation towards generating businesses that drive private funding. This task is very important when defining BIOTECSUR's actions, since activities related to the design of a market intelligence observatory have a direct impact on the chances to channel a private funding flow into the development of biotechnological products. From another point of view, activities intended to create market information not only aim at improving information flow, they also have an influence on commitment, involvement, and creation of knowledge networks and the mobilization of private funding related to biotechnological businesses.

III. 2 – BIOTECSUR's Next Steps

Implementation of a strategic plan is seen as a continuous process ranging between thought and action. Therefore, this document must be the starting point to design an organization based on what the system's actors defined in the strategic guidelines. Thus, next steps must be related to:

- a. A coherent sequence of actions that have to be carried out.
- b. Understanding that there are some obstacles that must be addressed immediately if the vision towards 2030 is to be met.

After reviewing these two types of priority actions, we suggest the following:

- ▶ In order to kick off the strategy, an action plan and a way to manage the financial resources needed to make it happen must be designed. In this sense, every single one of the five strategic guidelines must become a strategic project or program to be executed through BIOTECSUR.
- ▶ The current organization must be redefined in the future. A new structure and government model, which includes external technical support, must be agreed upon, meeting the action plan's demands. This particular topic must be addressed by the CADB, with help from the Management Unit and organization specialists. Something else to bear in mind is that organization does not equal structure. According to the strategic guidelines, work needs to be done related to: i. the systems (control, training, management, etc.); ii. personnel; iii. capabilities and skills; and iv. leadership style, which are all fundamental aspects of the Platform's organization.

- ▶ Simultaneous work is needed to identify “drivers” within MERCOSUR. At first glance, it seems that the key issue here is biofuels, where the region has installed capacities and potential. With this starting point, a regional pilot test could be devised to try to develop a complex network. This would mean installing a business platform with identified projects and available funds, and to test its operations as a sample.
- ▶ Formalizing the Platform as an institution will improve its functioning across MERCOSUR. In this sense, recognizing RECyT will prove to be essential so BIOTECSUR has the necessary operational margin to work with autonomy and thus be able to implement MERCOSUR’s Strategic Plan to develop biotechnology.
- ▶ A key issue and a step forward in responding to a general claim by MERCOSUR actors would be to develop a study to harmonize regulations. Meeting this objective requires concrete regional initiatives and coordinated operations. BIOTECSUR progress in this sense would be a substantial achievement which would lead to an important adherence by the private sector. This issue, as commented in points (4), (5), (6), (7), (8), and (9) of the final considerations, is a major obstacle that should be tackled in order to reach the 2030 vision.

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