The Biotechnology Market in Brazil

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SUMMARY

The Brazilian biotechnology market was estimated at approximately US$3.0 billion in 2001 and the projected growth for 2002 is 30%, according to market specialists. The combined sectors of human diagnosis, pharmaceuticals, seeds, generics and veterinary medicines account for approximately US$14.6 billion/year in business volume.

This report covers the market for biotechnology in the following segments:

- &nb sp; Agribusiness
- &nb sp; Bio-chemicals
- &nb sp; Diagnostics
- &nb sp; Environment
- &nb sp; Equipment and consumable products
- &nb sp; Food processing
- &nb sp; Medication

A. MARKET HIGHLIGHTS AND BEST PROSPECTS

Market Overview

Brazil is a country with a wide range of biotechnology opportunities, especially in agriculture, animal and human health, and the environment sectors. The total market size, local production plus imports, less exports, was estimated at approximately US$3.0 billion in 2001. According to market specialists, there was a 40% increase in the sector from 1999 – 2000 in the Southeastern State of Minas Gerais, where 28% of local biotechnology products are exported.

There is a large concentration of biotechnology companies in the country. A study by the Biominas Foundation identified 354 companies. These firms are interested in attracting foreign investment and products to provide an incentive for development. The number of companies grew 300% over the last nine years, from 76 companies in 1993 to 354 in 2002. Sixty percent of these companies are micro and small companies, and 17% are operating within University Centers. Ninety percent of the companies have their own R&D division.

Brazil is an important contributor to the worldwide genome sequencing effort that is having a tremendous impact on agricultural, biological, and medical sciences. Currently, there are 1,700 local research groups developing biotechnology projects.

For instance, the São Paulo State Research Foundation – FAPESP, and the Ludwig Institute for Cancer Research have a Cancer Genome Project. This project started in 1999, and it consists of six sequencing teams at the University of São Paulo. It has become one of the major contributors of gene sequencing for public databases. It is exploring the feasibility of an international public initiative to define the cancer transcriptome, a collection of all human genes expressed in cancer cells.

The information generated by the Genome Project has been an important factor contributing to the increase in number of local laboratories with expertise in DNA sequencing. A network of laboratories was established to facilitate the accomplishment of project goals.

The associated laboratories have been implementing the Cancer Genome Project have been importing the following products and equipment, which are considered essential to their research:

- Chromatography sets with low pressure - PCR Blocks
- Electrophoreses Cubes (agarose) - Electrophoreses Cubes/SDS PAGE
- Mini-centrifuges - Micropipetor sets
- 2 Pipette Aids - Shakers
- Trans-illuminators - Polaroid cameras
- Strata-coolers - Crystallization Kits

The total amount of consumable items for this project is approximately US$ 78,000, with US$28,000 for full-length DNA cloning reagents, US$30,000 for expression reagents, and US$20.000 for plastic ware and general consumables.

There is another relevant project being developed with the Sugarcane Genome. Brazil is responsible for 25% of world production of sugar cane. The project is mainly focused on mapping and application of DNA markers for sugarcane genetics, and it has formed a network with 38 research groups located in public and private universities with the participation and support of Coopersucar, the major private sugar cane institute in Brazil.

There are also some projects with transgenic plants being developed in the country, such as Brazilian corn used to produce growth hormone, papaya resistant to the Brazilian strain of ring spot virus and common beans resistant to the golden mosaic virus.

There are several biotechnology programs being developed by the private sector, such as Syngenta, a seed company resulting from the merger of Zeneca and Novartis, is investing 10% of its world sales revenues - which reached US$6.9 billion in 2000 – in Biotech Research. It is the main project being developed in Latin America related to corn and cotton resistance to pests.

Sygenta has also entered into an agreement with the Federal University of Viçosa, in the Southeastern State of Minas Gerais, for soybean improvement, aiming at the elimination of certain toxins present in its seeds.

Local companies need extensive input from abroad in order to complement their technology capabilities. Therefore, partnerships and cooperation, and associations are vital to the development of this sector in Brazil. Most of the Biotech companies are well-prepared and ready to work in cooperation and partnership arrangements. In 1995, Brazil imported US$100 million of products from the Biotechnology sector, increasing to US$500 million in 1999.

The local labor force consists of more than 28,000 people, with an average rate of 91 employees per company. The sales turnover of the sector represents 0.65% of the Brazilian GDP.

The development of the Biotechnology sector in Brazil is beginning to attract the interest of risk capital. In the first semester of 2001, approximately US$500 million was invested by Capital Risk Funds in the Brazilian Biotechnology market, corresponding to 67% of the total amount invested during the year 2000. The three biggest Venture Capital companies investing in the Brazilian biotechnology sector are Votorantim Ventures, FIR Capital and Rio Bravo. They have resources representing US$300 million, US$45 million, and US$10 million respectively.

The Votorantim Group, the largest Brazilian industrial conglomerate, via its Votorantim Ventures Capital, has agreements to develop biotechnology research with most of the important Brazilian Universities. And one of its activities includes research of eucalyptus wood for industrial usage, including biotechnology development of new types of trees. Eucalyptus is currently used to supply the furniture industry and it is used as wood poles and pallets. Vallée, a Brazilian company that develops and upgrades a number of veterinarian products such as vaccines, therapeuticals, antiparasitics and supplements will increase its production of injectables by 100%. And Biolab Farmacêutica is currently buying small biotechnology companies to increase its production.

By the end of 2002, approximately 70% of the Brazilian biotechnology companies will have ISO 9000 Certification. That reflects the concern for quality on an international level, and willingness to engage in constant improvement of practices, technologies and business, focused on international markets.

In the last fifteen years, Brazil's participation in International Scientific Publications increased from 0.5 to 1.5%. Presently, the Brazilian scientific output in the sector accounts for nearly half of what that is produced in Latin America.

Brazil is promoting the biotechnology sector to stimulate industrial development. The Federal Government has increased the biotechnology sector budget by 180%, it is continuously improves its policy concerning foreign capital investment, simplifying its regulations for goods and services, and facilitating imports of equipment.

The Brazilian government invested US$5 million in a biotechnology center in the Amazon region. The Amazon Biotechnology Center, with 20 laboratories, was established in 2002 to promote research of profitable pharmacological drugs and to boost the sector in the region.

The use of biotechnology to exploit natural resources of the Amazon rainforest is a strategic priority for the country's technological progress. The vast opportunities in the Amazon are attracting companies and researchers from all over the world.

Currently, Japan is developing a project on an oil substance extracted from cupuaçu, a very popular fruit in the region. The cosmetic and perfume sector is also taking off in the city of Manaus, capital of state of Amazon, with 300 items, of which 70% are cosmetics and perfumes, and 30% are jewelry manufactured exclusively from natural products.

Bio-fuels also offer an attractive opportunity in the country. Used to conserve and save conventional fuels such as petroleum and diesel, Brazil is the leader in bio-fuel usage, where it has been used in automobiles for over 25 years. Brazil currently produces 13 billion liters of bio-ethanol from sugarcane, fuelling over 3.5 million vehicles with pure ethanol. The rest of the vehicles run with approximately an 80% blend of ethanol and gasoline.

The bio-informatics market is a growing business throughout the country. It has been increasing approximately 24% per year, and 300 Biotech Companies are operating with the storage system

that has been used in the human health, research and government sectors.

IBM, Compaq, Sun Microsystems, Dell, Silicon Graphics, HP and Oracle are the main Bioinformatics suppliers. They are developing projects for cell biology, genome research and molecular evolution projects.

There are also companies dealing in e-commerce. For instance, I-bio, a company from the state of Minas Gerais, a joint venture consisting of a number of incubators that sell local production via Internet.

The I-Bio was established in 2001 and currently sells 2,367 products from 150 Brazilian laboratories, including test kits and equipment.

Minas Gerais Cluster

According to the Inter-American Development Bank (BID), Belo Horizonte, the capital city of the Southeastern State of Minas Gerais, is the most important Biotechnology center in Latin America.

There is a cluster with 58 companies located in the state capital of Belo Horizonte, and in seven other nearby towns. There are 161 Biotechnology PhD experts at UFMG – The Federal University of Minas Gerais that account for a vast amount of production.

In 1999, taking advantage of the academic expertise at the UFMG and the experience accumulated by the Biominas Foundation, the Federation of Industries of the State of Minas Gerais (FIEMG) launched the Cresce Minas Project, a cluster that has already yielded very good results. The project called for an increase in jobs from 1,800 to 5,600 in five years, and it has reached 4,273 already. This means that 76% of the initial target has already been met. While the sector revenues grew 18% yearly, between 1996 and 1998, that rate increased to 40% in 2000, to reach a total US$227.81 million.

Figures for the Minas Gerais Cluster:

- 58 companies,
- 4.273 jobs created,
- US$154.13 million in revenues in 1999,
- US$227.81 million in revenues in 2000,
- 47.8% growth rate from 1999 to 2000.

Company segments in the Cluster:

- 18 human diagnosis companies (Diamed, CEPA, In Vitro, Biobrás Diagnósticos, Labtest, Hereditas, Microbiológica, Bionn, Biocod, Biokits, Diagon, Katal, Micra, Analisa Diagnóstica, Bioeasy, Gene, Quibasa),
- &nb sp; 11 pharmaceuticals (Biofar, Bravir, Biobrás Div. Farmacêutica, Belfar, CIFARMA, Hipolabor, FUNED, Laboratório Globo, Hypofarma, Osório de Moraes , Quiral),
- &nb sp; 9 support services (Biobrás Software, Biotech Agency, Cetec, EMLAB, Fundação Biominas, LM Laboratório de Biotecnologia, René Rachou, Santa Casa de Misericórdia, and Theriaga),
- &nb sp; 5 biomaterial companies (Einco Biomaterial, Ferrara Ophtalmics, JHS, Labcor, Tri-Technologies),
- 5 veterinary companies (Vallée, Hertape, Tecsa, Phoneutria, and Lema Biologic),
- 3 phytotherapeutical firms (Belém Jardim, Catedral, and Caiçara),
- &nb sp; 2 environmental companies (LM and Biológica),

- 2 equipment manufacturers (R.Chapman and Spectrolab),
- 2 industrial firms (CONAP and Biocarbo),
- 1 agro-biotechnology companies (Santa Helena Sementes).

In addition to Belo Horizonte, there is a second city that also plays an important role for this cluster: located in northern region of Minas Gerais, Montes Claros has 306,928 inhabitants and its municipal government offers fiscal benefits to attract Biotechnology investments. Biobrás, the only insulin manufacturer of Latin America and Vallé, a manufacturer of veterinary products, are established in Montes Claros.

Biorgânica, a Brazilian manufacturer of chemical-therapeutic products for cancer, intends to sell its products to the pharmaceutical, chemical and food sectors. In the area of oncology, no Brazilian company produces medicines derived from agents found in national plants, and a single anti-cancer product can generate revenues around US$1 million annually. Biorgânica has been researching opportunities in this area.

Gene - Núcleo de Genética Médica, a center for medical genetics, is conducting research on chromosomes and molecular medicine. It investigates paternity by means of DNA tests, produces kits for paternity tests and supplies them to labs all over the country. The company is part of the cluster because it is a service provider and may become a buyer of products used in DNA tests. Currently, such products are imported.

Labtest Diagnóstica, a Brazilian industry of reagents, invested US$1.2 million this year to expand its present capacity. The company is seeking partnerships to trade products for diagnostic applications, especially in immune-chemistry.

Bio-Rio Cluster

In the state of Rio de Janeiro, there is a Biotechnology cluster called Bio-Rio. Besides being an incubator, it is an industrial park operating with some of the following established companies:

COMPANIES	SECTOR
AMBIO	Stations to Treat Effluents and Equipment for the Purification of Water
Baktron	Diagnostic Kits, Culture Media and Quality Control Analysis
Brasco	Pharmaceutical Products
Dalmatia	Cosmetics
Ecobac	Production through Biodegradation of Organic Materials used to Treat Effluents
Extracta	Research and Development of Natural Molecules
M & N	Pharmaceutical Products
Nutriente	Enteral and Parenteral Nutrition and Chemotherapy
Q-Controll	Software to Control Processes and for Practice
Silvestre	Labs of Medicines and Antiseptics
Trianel	Advisory in the Elaboration of Protocols and Analysis of Data in the area of Health
Vectron	Diagnostic Kits
Vitrogen	Micro-propagated Sprouts

Best Sales Prospects

The best foreign import prospects in the Biotechnology sector include:

- Rapid tests,
- Molecular diagnostics,

- Laboratory equipment (Mini-centrifuge, Micropipetor Set, Pipette Aid, Shaker, and Trans-illuminator),
- ELISA,
- Identification of transgenic,
- Immunological tests,
- Turbidimetry,
- Animal diagnostics (kits for diagnosis of equine anemia, foot and mouth disease, bovine brucellosis and tuberculosis, canine cynomosis),
- Tests for evaluation of the quality of foods, products and raw materials,
- Rapid tests of animal health and reproduction,
- Selective ions,
- Self-tests (home care),
- ecotoxicity and mutagenicity tests of agents which affect the aquatic biota,
- Diagnostics of micotoxins, endotoxins, biocorrosion of microprocessors,
- Pollution bio-indicators,
- Reagents for life sciences research,
- Molecular biology reagents,
- Instruments for the life sciences and medical research,
- Laboratory testing services for agricultural diagnostics,
- Tests for early detection of cancer, heart disease, fertility, infectious diseases and drugs,
- In vitro diagnostic kits,
- Scientific instruments.

Statistical Data (Estimated Values, in US$ billion)

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	2001	Projected Avg. Annual Growth Rate for 2002
Import Market	0.9	15 %
Local production	3.1	35 %
Exports	1.0	20 %
Total Market	3.0	30 %

B. COMPETITION

Domestic Production

According to the Biominas Foundation, a Biotech Company Incubator, 90% of the Brazilian biotechnology companies are located in the South and Southeast of the country. The Southeastern states of São Paulo, Minas Gerais and Rio de Janeiro concentrate 81% of the biotechnology activities. Three percent of the companies are in the North and Northeast areas, 6%

in the Middle West area, and 10% in the South.

The capital city of Belo Horizonte, in the Southeastern State of Minas Gerais, has the largest biotechnology pole in Latin America. The sales in the biotechnology sector in Belo Horizonte increased by 47.8% in 2000. There are 58 companies established in the city. Their combined revenues went up from US$154.13 million to US$ 227.81 million from 1999 to 2000.

Breakdown of Brazilian biotechnology companies, per state and sector:

State	Percentage
São Paulo	42%
Minas Gerais	29%
Rio de Janeiro	9%
Paraná	5%
Distrito Federal	3%
Rio Grande do Sul	2%
Others	10%

Sector	Percentage
Human Health	24%
Government and International Biotechnology Companies	22%
Consumables Suppliers	17%
Equipment	17%
Agribusiness	12%
Animal Health	4%
Environment	4%

Geographic focus of bioscience in Brazil, per state:

Established Biotech Centers	São Paulo, Minas Gerais, Rio de Janeiro
Emerging Biotech Centers	Paraná, Santa Catarina, Rio Grande do Sul, Distrito Federal, Goiás, Mato Grosso do Sul, Pernambuco, Paraíba, Pará

Largest pharmaceutical and biotechnology companies conducting research, investment, and production centers.

Region	Company
Northeast	Biogene, TMED
Southeast	Genesearch, Biominas, Biobrás, FAPESP, Biosoft, Fiocruz, Interbiotech, In vitro, Hormogen, Microbiológica, Nichols
South	SIMBIOS, Nano Endolumial, FK

The top four Bio-Science Research Universities in Brazil:

University	Location	Patents
University of São Paulo	São Paulo, SP	Biodiversity, Genoma, Animal Toxines
University of Campinas	Campinas, SP	Biodiversity, Genoma, Animal Toxines

Paulista State University	São Paulo	Biodiversity, Genoma, Animal Toxines
Federal University of São Paulo	São Paulo	Health, Medicine

Biotech Company Incubators

The first bio-company incubators in Brazil were established in 1984 - 1986, in Florianopolis, São Carlos, Campina Grande and Brasilia. Currently, according to the National Association of Entities that Promote Advanced Technology Enterprises – ANPROTEC, there are 32 Brazilian incubators in operation and more than 15 to be established.

The most active Brazilian incubators are the following:

Biominas Foundation, Minas Gerais State, Southeastern Region.

Incubation Center of Technology Companies (CINET), São Paulo State, Southeastern Region.

Managerial Center for the Elaboration of Advanced Technologies (CELTA), Santa Catarina State, South Region.

Technology Plant Foundation, Paraíba State, Northern Region./

C. END-USER ANALYSIS

Diagnostics

Fifty percent of the total number of companies identified as doing business in the biotechnology sector in Brazil is from the diagnostics sector, and large test laboratories are the main users of its products. Imports of reagents, antigens, antibodies and, human diagnostics are increasing. Most of the 8,000 Brazilian clinics are acquiring analyzers. Distributors and government development centers are all seeking sources and technologies abroad.

The two areas of major interest for investments by the diagnostics sector are immunology and rapid tests, both of which are also technically inter-linked. On the other hand, there is an undeniable interest in expanding the capacity for performing molecular diagnostics.

Medication

The year 2002 is expected to be a good year for the biotechnology sector in Brazil, due to the record number of products ready to be released in the market. With investments of US$13.4 billion in 2001, analysts believe the market will increase more than 11% in 2002. A record of more than 304 new biotechnology products are in a final test phase and a set of ten should be introduced to the market in 2002.

Generics are the fastest growing segment in the pharmaceutical industry in the country, and a great market for imports. The Brazilian companies are looking for cardiovascular, antibiotic, dermatology, gastro-enterologic and anti-diabetic generics. Products in anesthesiology for hospitals and injectables are also desired.

Animal Health

Brazil is the largest animal health market in Latin America and is the fifth largest in the world. Swine vaccines are very attractive at this moment, all types including Mycoplasma Hyopneumoniae. Brazil's swine population exceeds 35 million and the bovine herd, has 165 million head. The sector has grown rapidly and Brazilian beef, pork and poultry products have increased in European and Asian supermarkets.

Brazilian distributors are also casting their eyes on the pet market: there are 35 million cats and dogs owned by an affluent middle class in the larger cities. A promising outlook for vaccines, diagnostics, food supplements and therapeutics are growing each day.

Agribusiness

The biggest impact of Biotechnology in Brazil is expected to be on agriculture, which represents 10% of the Brazilian GDP, 40% of exports and 25% of the labor force. Due to its immense agricultural areas and favorable climate, the country became a giant market for biotechnology with

a US$30 billion market niche within its nearly US$200 billion agricultural market.

The employment of Biotechnology for the development of products and processes related to agriculture will represent a fundamental strategic factor as the quality and quantity of basic production increases in the country.

Biotechnology companies are engaged in a variety of activities. Such as plant and micro-propagation improvement, production of bio-pesticide inoculates, food, pulp, and embryos and disease diagnosis.

The Pbio – Program for Basic Biotechnological Research, is an important instrument that promotes new technologies, by adapting technologies already used by other countries. In partnership with the private sector, it tests new products to resolve problems facing Brazilian agriculture. This program is very important for the redefinition of a Biotechnology development policy of EMBRAPA - Brazilian Corporation for Agriculture Research and the SNPA – National Agricultural Research System.

According to Embrapa, the main biotechnology applications in agriculture, include the following areas:

- Vegetal production and silviculture: genetic improvement, propagation, growth and nutrition;
- Animal production, aquaculture and fishing: genetic improvement, sanitation, and nutrition;
- Agro-industry: fermented products, biomass, and food processing, energy and equipment production;
- Environment: Bio monitoring, bio-recuperation of degraded ecosystems,
- Handling of waste and pollutants, and biologic control of diseases.

Biotechnology also offers, via genetic transformation, strategies for the control of pests and diseases. Such strategies are being implemented for viruses, insects and pests, through genetic engineering. In the Brazilian agriculture framework, viruses represent huge losses in the production of potatoes and beans.

Environment

The Brazilian market for environmental products, water treatment and purification, and residue treatment continues to grow in all sub-sectors, including municipal as well as agricultural applications.

Alternative techniques have also been employed to avoid environmental contamination, to control the consequences of biological processes and human activities such as eutrophication, a natural and gradual process in which contaminated waters are used for fertilization. Biotechnology has been used to recover Brazilian lakes, and this technology has pioneering characteristics in Latin America.

The Biotech companies in Brazil are undergoing rapid modernization, involving growing investments in acquisition of environmental technologies, products and services. For example, LM Tratamento de Resíduos, a company specialized in waste treatment and environment services is conducting research on a type of fertilizer extracted from a flour made of phosphate rock, without chemical treatment.

Food Processing

Cultivation of GMO – Genetically Modified Organisms in Brazil is a legal activity, but the Laws prohibit trading of transgenic products. The government promises to encourage discussions and resolution through the CTNBio (The Brazilian Technical Commission for Biosafety). This Commission is also going to revise the standards applied for risk assessment aimed at approving GMOs. This initiative is part of the National Biotechnology Program. By 2003, the Brazilian Ministry of Science and Technology plans to have allotted some US$114 million to the program.

With Europe being the main market for GMO-free soybeans, there is pressure on Brazilian producers to comply with stiffening European requirements. In a few years, transgenic test kits will

be one of the best prospect products for imports.

Currently, Brazilian laws allow imports of genetically modified seeds on a case-by-case basis, and the country also is a major importer of feed grains, With its population of 170 million inhabitants, Brazil is the biggest consumer market in South America. Brazil imports about US$70 million in food products from the United States, possibly including some that contain genetically modified ingredients.

Bio-chemicals

Fine chemistry and enzymes are vital for the Brazilian biotech industry. Enzymes and proteins are being used for the development of Biotechnology programs and products in the country.

Companies, incubators and universities are investing in the development of enzyme production technology and there are many projects on the use of enzymes for clinical diagnostics, enzymatic processes, biological processes for waste water and technology of microbial metabolites (alcohol and organic acids).

Agrochemicals have also been used for a long time in Brazil. The Brazilian agrochemical market moves approximately US$2.5 billion per year. Herbicides represent the largest portion in Brazil.

Equipment and Consumables Suppliers

Biotech equipment and consumables are essential for every Brazilian laboratory and public institution to develop its Biotechnology projects, products and services. The Brazilian market offers particularly attractive opportunities for the following products:

- Reagents for life sciences research,
- Molecular biology reagents,
- Instruments for the life sciences and medical research,
- Laboratory testing services for agricultural diagnostics,
- Tests for early detection of cancer, heart disease, fertility, infections disease and drugs,
- In vitro diagnostic kits,
- Scientific instruments,
- Biotech instrumentation,
- Laboratory equipment.

D. MARKET ACCESS

General aspects of Brazilian environmental legislation and companies in the diagnostics sub-sector.

The normative and legal structure for environmental protection in Brazil is contained in article 225 of the Federal Constitution of 1988.

Currently the Ministry of Environment, Water Resources and the Amazon Region is in charge of coordinating, on a federal level, Brazilian environmental policy. The National Environmental Council [Conselho Nacional do (CONAMA), which is responsible for the definition of environmental standards in general and for the country as a whole, is subordinated to this Ministry. CONAMA is responsible for determining the environmental standards and the pollutant emission limits for polluting sources, as well as the overall environmental licensing requirements.

The state environmental control bodies are in charge of the enforcement of these standards, and are to this end allowed to establish specific norms for environmental licensing, as well as to establish stricter environmental standards within their own jurisdiction. In Minas Gerais, environmental control is in the hands of the State Secretariat for Environment and Sustainable Development. Subordinated to this Secretariat are the State Environmental Federation [Federação Estadual do Meio Ambiente] (FEAM) and the State Forestry Institute [Instituto Estadual de Florestas] (IEF). The municipalities also have a Municipal Environmental Secretariat.

From the standpoint that the techniques, methods and substances involved in the productive activities, services and marketing of the Diagnostics Sub-sector involve to some degree potential life, environmental and quality of life hazards, government authorities require that all companies engaged in this business. i.e. the various companies, which would be potential participants in an international cooperation program, have their operations controlled by licensing. The laws foresee three types of licensing by the competent state authorities. In the case of Minas Gerais, these are the State Secretariat for Water Resources and Environment [Secretaria do Estado de Recursos Hídricos e Meio Ambiente de Minas Gerais] and the Municipal Environmental Secretariat [Secretaria Municipal de Meio Ambiente]. The operating licenses to be issued are the following:

- Preliminary License [Licença Prévia] (LP): obtained in the preliminary phase of the planning of the activity, containing the basic requirements to be met in the steps of determining location and installation, in compliance with the municipal, state and federal rules for land use;
- Installation License [Licença de Instalação] (LI): authorizing the beginning of the installation, pursuant to the specifications contained in the approved detailed design project;
- Operating License [Licença de Operação] (LO): authorizing, after the necessary verification, the start-up of the licensed activity and the operation of the pollution control equipment, pursuant to the specifications contained in the Preliminary and Installation Licenses.

The timelines for granting of licenses are established by CONAMA, depending on the technical nature of the activity. In the specific case of companies in this Sub-sector subject to the regulation of products and services in the Pharmaceutical and Pharmaceutical/Chemical Sector, the State Secretariat of Sanitary Inspection grants the operating licenses and permits.

In addition to this broader environmental legislation, under which all establishments with potential environmental impact must comply with the requirements of article 225 of the Brazilian Federal Constitution, and to the licensing of their operation, the companies of the Diagnostics Sub-sector, viewed from its broadest perspective, including human and animal and plant health, as well as environment, are subject to inspection pursuant to specific laws.

Thus, for producers of relative products and services, these companies are also subject to (i) the regulation of products, establishments and services of the Pharmaceutical and Pharmaceutical/Chemical sector, and (ii) the specific regulations of the Health Ministry and the National Agency of Sanitary Inspection [Agência Nacional de Vigilância Sanitária] ANVISA. With regard to the companies active in the field of animal and plant health, the regulating and inspecting entity is the Ministry of Agriculture.

Specific legal framework for the diagnostics sub-sector.

The Diagnostics Sub-sector is subject to the specific regulation of products, establishments and services of the pharmaceutical and pharmaceutical chemical sector established by the laws of 1976/77 (Law no. 6360 dated 23 September 1976 and Decree no. 79.094 dated 5 January 1977). Once classified as a "correlato", the activity is subject to the specific legislation of the Health Ministry, pursuant to administrative rulings of the former Sanitary Inspection Secretariat [Secretaria de Vigilância Sanitária] and the current entity (from February 1999 on), the Agência Nacional de Vigilância Sanitária (ANVISA), the body responsible for the establishment of standards for products, services and environments which present health hazards, the registration of products and licensing of activities in the pharmaceutical and pharmaceutical chemical sector.

Pursuant to the legislation, sanitary inspection authorities oversee medication, drugs, pharmaceutical consumables, personal hygiene products, cosmetics, perfumes, and household cleaning agents and products for esthetic correction.

Only companies which have received proper authorization from the Health Ministry, and whose establishments have been licensed by the sanitary authority of the state in which they are based, may extract, produce, fabricate, transform, synthesize, purify, fraction, package, re-package, import, export, store or ship such products.

Laws and Decrees

Legislation defines these products and related aspects and also addresses their withdrawal when their prejudicial effect on human or animal health is proven. The relevant laws include Law no. 6,360 dated 23 September 1976 and Decree no. 79,094 dated 5 January 1977, which regulates it:

Law no. 6,360 dated 23 September 1976

Provides for the ongoing inspection of medication, drugs, pharmaceutical consumables and related products, cosmetics, cleansing agents, and other products, among other measures.

In dealing with these issues, Law no. 6,360 dated 23 September 1976 presents 17 Titles:

I. &nb sp; Preliminary provisions
II. &nb sp; Registration
III. &nb sp; Registration of drugs, medication and pharmaceutical consumables
IV. Registration of Correlatos (equipment)
V. Registration of cosmetics, personal hygiene products, perfumes, and others
VI. Registration of household cleaning agents
VII. Registration of diet products
VIII. Authorization for companies and licensing of establishments
IX. Technical liability
X. Labeling and publicity
XI. Packaging
XII. Shipping modes
XIII. Violations and penalties
XIV. Inspection
XV. Control of medication quality
XVI. Sanitary inspection authorities
XVII. Final and transitory provisions

Decree no. 79,094 dated 5 January 1977
Regulates Law no. 6,360 dated 23/9/1976

Decree no. 79,094 dated 5 January 1977 regulates Law no. 6.360 and presents 16 corresponding titles. The decree regulates the registration of products and the authorization and licensing for the operation of companies, and the competencies of the sanitary inspection authorities.

The Sanitary Inspection Secretariat is responsible for the:

- Definition of standards for products, services and environments which present health hazards,
- Planning and coordination of programs to control quality and certify health products,
- Definition and coordination of the national system of sanitary inspection,
- Definition of standards and enforcement of sanitary inspection at ports, airports and borders,
- Opinions on the importation of dental/ medical/ hospital products by non-profit institutions for purposes of income tax exemption,
- Conciliation of the technical/sanitary regulations within the Mercosur,
- Coordination and monitoring of the pharmacological and toxicological inspection system for products.

Related Products ("Correlatos") - Definitions and Categories

Health equipment and materials considered to be "Related Products" are apparatus, materials or accessories for the use or application related to the protection of individual or collective health, personal hygiene or environmental hygiene, or diagnostic or analytic purposes, cosmetics and perfumes, and also diet products, optical, hearing, medical, dental and veterinary products. See item IV of Art. 2º, Decree no.79.094, dated 5 January 1977. This universe, for purpose of application of sanitary legislation, encompasses the following products defined in Administrative Rulings nº 2,043, dated 12 December 1994 and nº 686, dated 27 August 1998:

Diagnostic Equipment
Equipment, devices, apparatus or instruments for medical, dental or laboratory use intended for the detection of information on the human body to assist in clinical procedures.

Therapy Equipment
Equipment, devices or instruments for medical or dental use, intended for the treatment of pathologies, including the replacement or modification of anatomy or physiological processes of the human body.

Medical/hospital Support Equipment
Equipment, devices or instruments for medical, dental or laboratory use intended to provide support to diagnostic, therapeutic or surgical procedures.

Disposable Materials and Articles
Materials and articles for medical, dental or laboratory use, usable only once, in a transitory or short-term manner.

Implantable Materials and Articles
Materials and articles for medical or dental use, intended to be introduced totally or partially in the human body or orifice thereof, or intended to replace an epithelial or eye surface, through medical intervention, remaining in the body after the procedure for a long term, subject to removal solely by

surgical intervention.

Materials and Articles for Medical/Hospital Support
Materials and articles for medical, dental or laboratory use intended to provide support to diagnostic, therapeutic or surgical procedures.

Products for "in-vitro" Diagnostics
Reagents, instruments and systems which, together with the instructions for their use, contribute to carry out a qualitative, quantitative or semi-quantitative determination in a biological sample, and which are not intended to fulfill any anatomical, physical or therapeutic function; which are not ingested, injected or inoculated in human beings, and which are used exclusively to provide information on samples collected from the human body.

Relevant Administrative Rulings

Several administrative rulings ("portarias") and normative instructions from the Health Ministry and the Sanitary Inspection Secretariat and the National Agency for Sanitary Inspection (ANVISA), created in January 1999, complement and update the legislation in the pharmaceutical and pharmaceutical/chemical sector with regard to the related products which encompass the sub-sector of diagnostics. The most relevant "portarias" are the following:

- **Portaria n. 2043 dated 12 December 1994,** which regulates the quality assurance system of Related Products.

- **Portaria SUS n.8 dated 23 January 1996,** which provides on the registration of products for *in vitro* diagnostics with the Sanitary Inspection Secretariat, indicating the documents required for the registration, validation, alteration, exemption or cancellation of registration with this entity.

- **Portaria n. 646 dated 22 March 1996,** which institutes the Technical Commission for Guidance for Related Products concerning Diagnostics Reagents for in vitro use, subordinate to the Sanitary Inspection Secretariat.

- **Portaria n. 71 dated 29 May 1996** updates the norms and procedures related to the authorization for the operation of the companies and registration of products, considering the need to adopt technical standards for Mercosur companies and products.

- **Portaria SVS n. 686 dated 27 August 1998** incorporates the Mercosur Resolution GMC n. 65/96 which establishes the requirements for compliance with Good Manufacture Practices (GMP) and control in establishments, which produce Diagnostic products for in vitro use.

Mercosur Legislation for Related Products

Mercosur, the Southern Cone common market, with its legal basis as the Asuncion Treaty, has an institutional structure formed by 11 Working Subgroups, which debate and conciliate the laws of the member states.
The legislation on Related Products is addressed in the Ad-Hoc Groups of medical products and Diagnostics products for in vitro use, of the Health Product Commission SGT n.11: Health. This harmonized legislation is submitted to the Common Market Group [Grupo do Mercado Comun] –

GMC, as a recommendation, which after its approval by the GMS becomes a resolution to be incorporated by the member states.

GMC Resolutions on Products for in Vitro Diagnostics

- **Resolution GMC n.79/96**

Provides on the intrazone registration of products for in vitro Diagnostics for member states.

- **Resolution GMC n.65/96**
  Establishes the requirements for GMP and Control of Products for In Vitro Diagnostic.

Resolution GMC n. 38/98

Approves the Guide for Verification of Compliance with Good Manufacturing Practices and Control of Products for In Vitro Diagnostics.

Regulation of Products, Establishments, and Services Related to Human Health, Agriculture and Animal Production, Involving Genetically Modified Organisms (Transgenics).

In areas where there is overlap with biology and molecular Diagnostics, subject to genetic manipulation and engineering, and involving genetically modified organisms, the companies are subject to the regulation of products, establishments and services related to human health, agriculture and animal production, under the law of biosafety, n. 8,974 dated 5 January 1995, Decree no. 1752 dated 20 December 1995 regulating the Biosafety Law, and defining the attributions of the National Technical Commission on Biosafety [Comissão Técnica Nacional de Biossegurança], CTNBio[2] and finally Decree 2577 dated 30 April 1998.

Laws and Decrees

Law no. 8,974 dated 5 January 1995 (Biosafety Law) – Regulates items II and V of paragraph 1 of art. 225 of the Federal Constitution, establishes the norms for the use of genetic engineering techniques, and discharge into the environment of genetically modified organisms, authorizes the Executive Power to create, under the Presidency of the Republic, the National Technical Commission on Biosafety [Comissão Técnica Nacional de Biossegurança], CTNBio, and provides for other matters.

Decree no. 1752/95 - Regulates Law no. 8,974 dated 5 January 1995, and it provides directions on competency and composition of the National Technical Commission on Biosafety [Comissão Técnica Nacional de Biossegurança], CTNBio, and on other matters.

Decree 2577 dated 30 April 1998
Regulates Law no. 8974 dated 5 January 1995, provides guidance on the competency and composition of the National Technical Commission on Biosafety [Comissão Técnica Nacional de Biossegurança], CTNBio, and on other matters.

Main safety aspects of the handling and discharge of genetically modified products into the environment, as defined by the Brazilian Biosafety Law.

In its 18 articles, the Biosafety Law defines the pertinent technical terms, establishes safety norms and mechanisms for inspection of use of genetic engineering techniques in the construction, cultivation, manipulation, transportation, sale, consumption, release and disposal of genetically modified organisms (GMOs), seeking to protect life, human health, animal and plant health, and the environment. Some important aspects of the regulation are addresse d in the paragraphs below:

- Only legal entities can engage in activities related to GMOs, as individuals are forbidden to do so.

- Both state and private organizations, national and international financing agents of activities and projects involving GMOs, should ascertain the technical/scientific soundness and the full compliance of the funded parties, contractors and the like, with the norms and mechanisms of safeguarding foreseen in Law no. 8974, demanding the presentation of the biosafety certificate.

- The following entities are responsible for the oversight of activities related to the GMOs: 1) the Health Ministry; 2) the Ministry of Agriculture, Supply and Agrarian Reform; 3) the Ministry of Environment, Water Resources and the Amazon Region. These organizations are to carry out inspection and control within their competencies, in keeping with the conclusive opinion of the CTNBio. Said competency includes the issuance of registration of products containing GMOs, authorization for the operation of laboratories and institutions, and authorization of the entry of GMOs into the country when coming from abroad. They are also to maintain a list of the institutions and professionals who engage in activities, which involve GMOs in Brazil.

- The following activities related to GMOs are prohibited: 1) genetic manipulation of living organisms or in vitro handling of natural DNA or recombinant DNA (rDNA), which are not in compliance with Law no. 8974; 2) genetic manipulation of human stem cells; 3) intervention in human genetic material in vivo, except in the case of treatment of genetic defects, with the prior approval of CTNBio; 4) the production, storage and manipulation of human embryos intended for use as available biological material; 5) the in vivo intervention in genetic material of animals, except when approved by CNTBio; 6) the discharge or disposal into the environment of the GMO in non-compliance with the CTNBio norms and existing regulations.

- The CTNBio and competent authorities must authorize the introduction of products containing GMOs originating from other countries and intended for industrialization and sale.

- Entities which employ genetic engineering must form an internal biosafety commission (CIBio) which will keep the community informed of activities, establish preventive programs for inspection and assured operation of the facilities, maintain a list of the activities involving GMOs, inform the public as to the risk assessments performed, investigate accidents and near-accidents.

- CTNBio is authorized to establish the value of penalties in the cases of violation. The performance of forbidden activities constitutes a crime, with penalties, which ranges from 3 to 20 years of imprisonment, depending on the gravity of the situation.

Main Biotechnology Trade Events

Event: Industrial Biotechnology Congress

Date: November 13-14, 2002
Location: Rio Othon Palace Hotel
Organizer: ABRABI – Associação Brasileira das Empresas de Biotecnologia
& nbsp; info@abrabi.org.br

Event: III Bio Security Congress
Date: September 24-26,2003
Location: Mar Hotel, Recife, and Pernambuco State
Organizer: ANBIO – Associação Nacional de Biossegurança
& nbsp; www.anbio.org.br

Event: Brazilian Biotechnology Society Congress
Date: November 2003
Location: São Paulo
Organizer: IETEC – Instituto de Educação Tecnológica
& nbsp; www.pjeventos.com.br

Key Contacts

Academia Brasileira de Ciências
www.abc.org.br

Associação Nacional de Biossegurança
www.anbio.org.br

EMBRAPA – Recursos Genéticos e Biotecnologia
www.cenargen.embrapa.br

Universidade Federal do Rio Grande do Sul – Centro de Biotecnologia
www.ufrgs.br/cbiot

CIB – Council for Biotechnology Information
www.cib.org.br

CNPQ – Conselho Nacional de Desenvolvimento Científico e Tecnológico
www.cnpq.gov.br

FIOCRUZ – Instituto Oswaldo Cruz
www.fiocruz.com.br

FAPESP – Fundação de Amparo à Pesquisa do Estado de São Paulo
www.fapesp.br

Laboratório de Biotecnologia Genômica
www.ucb.br

Revista Biotecnologia e Desenvolvimento
www.biotecnologia.com.br

Universidade de São Paulo
www.usp.br

Universidade Federal de Viçosa
www.ufv.br

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[1] Complemented by hundreds of Administrative Rulings and Normative Instructions of the Health Ministry, of the former Secretariat, and the current Sanitary Inspection Agency.

[2] Law 8.974 of 1995 established the rules for the use of genetic engineering techniques and the release of genetically modified organisms into the environment. The law was regulated by Decree 1.752/95 which grants CNTBio competency to regulate any activities involving GMOs.