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Innovation is in our DNA

BRAZIL'S BIOTECH INITIATIVES

Eduardo Giacomazzi – Head of Brazilian Biotech Association

Suport:

BNDES

ApexBrasil

Ministry of Development, Industry and Foreign Trade

BRASIL BRAZILIAN GOVERNMENT


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ApexBrasil

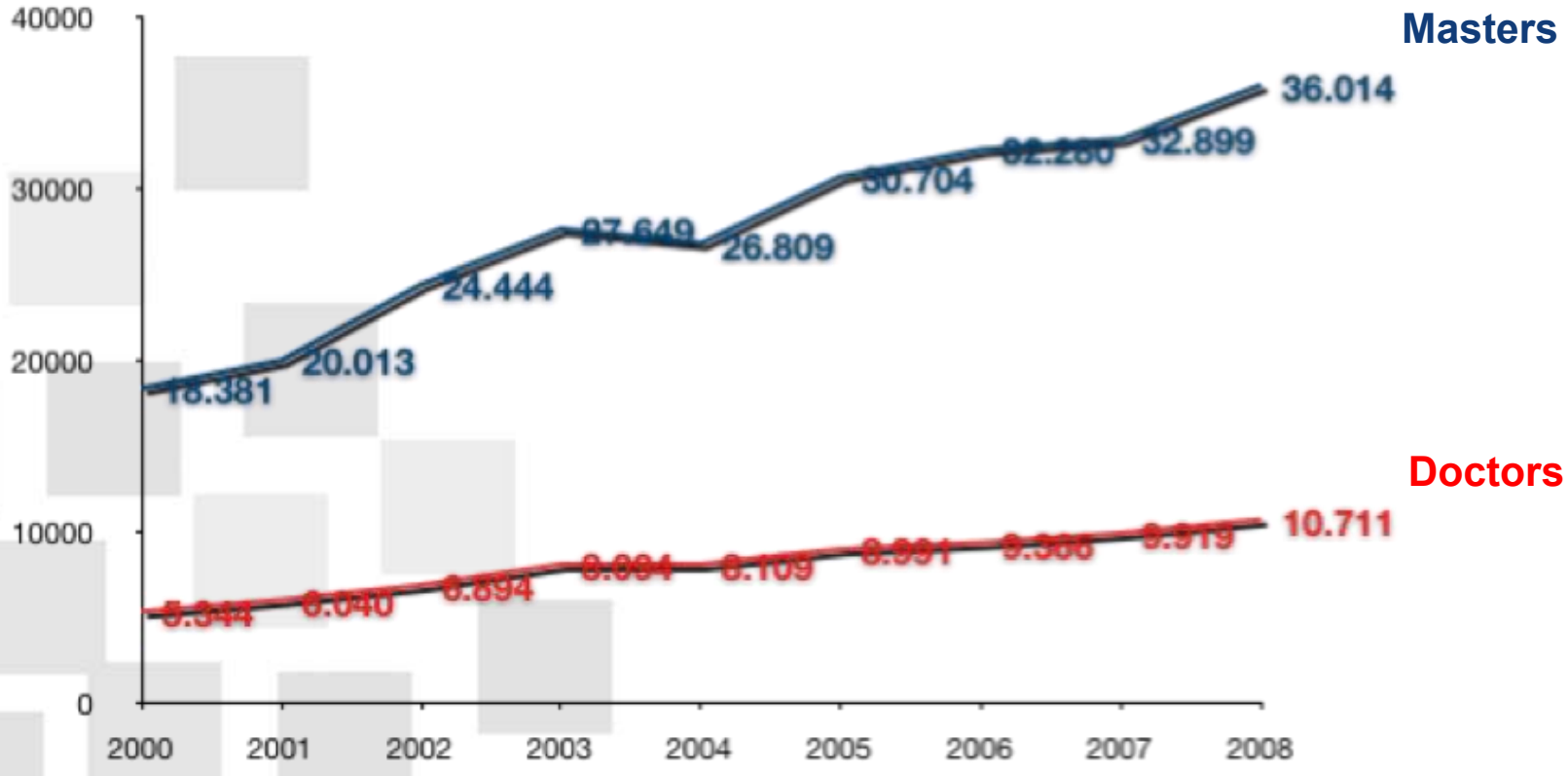
AGÊNCIA BRASILEIRA DE PROMOÇÃO
DE EXPORTAÇÕES E INVESTIMENTOS

Messages

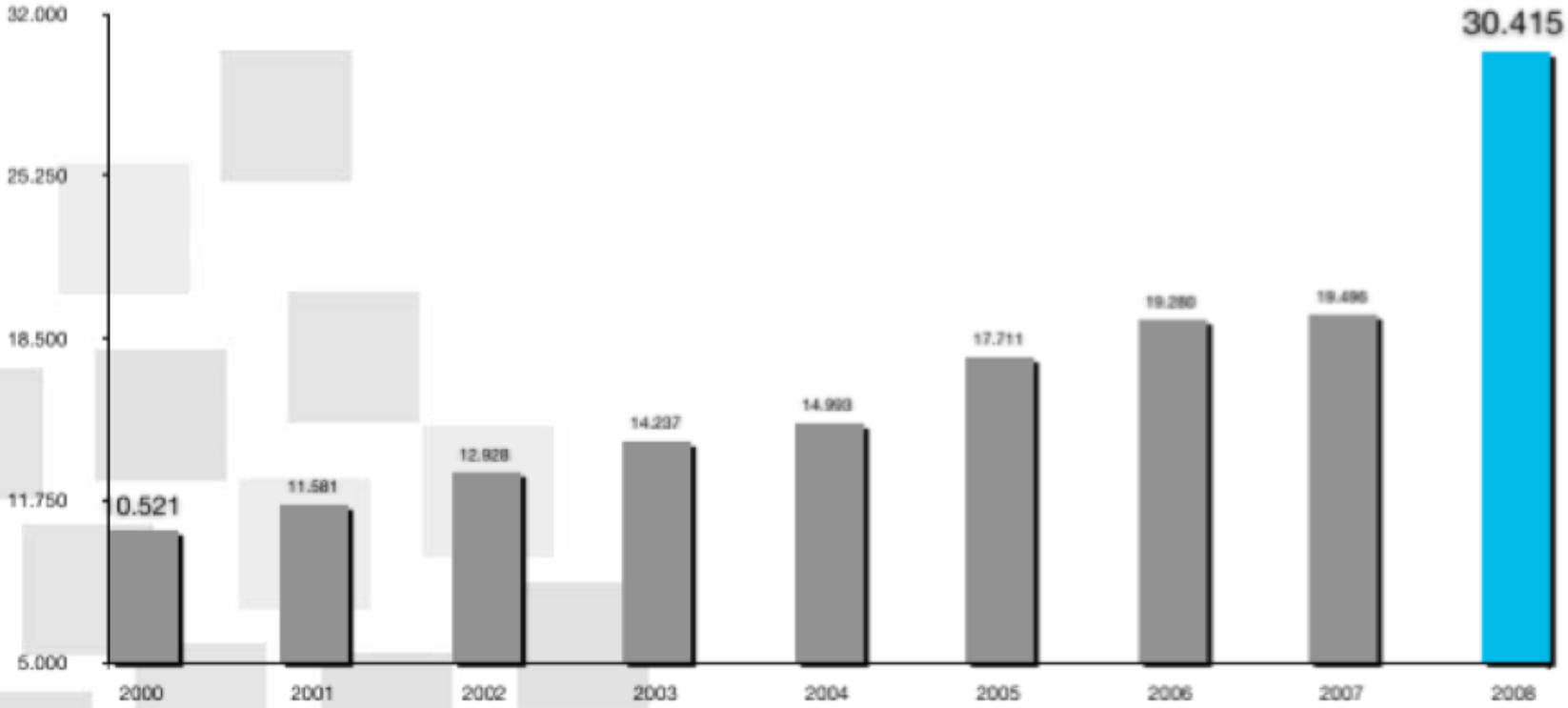
1 →Brazil has evolved in the last years

2 → Biotech is a priority for the Brazilian government

Increasing the critical mass (total)

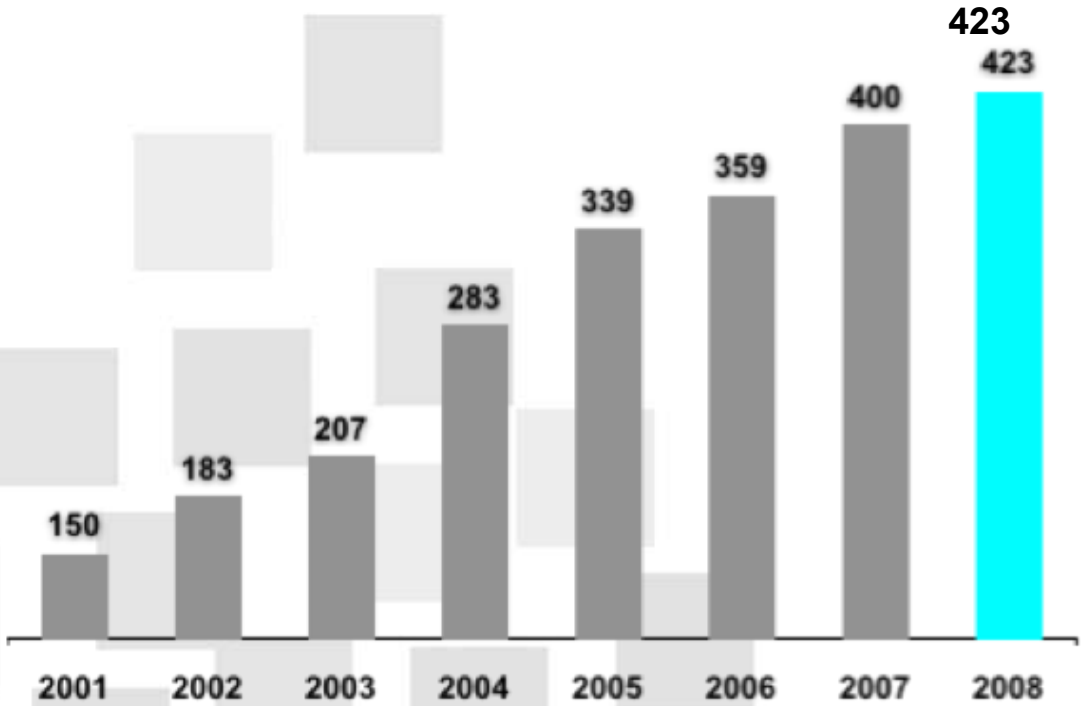


Published Papers



1.4% ← World Articles → 2.6%

Incubators = science + entrepreneurship



6,300 companies

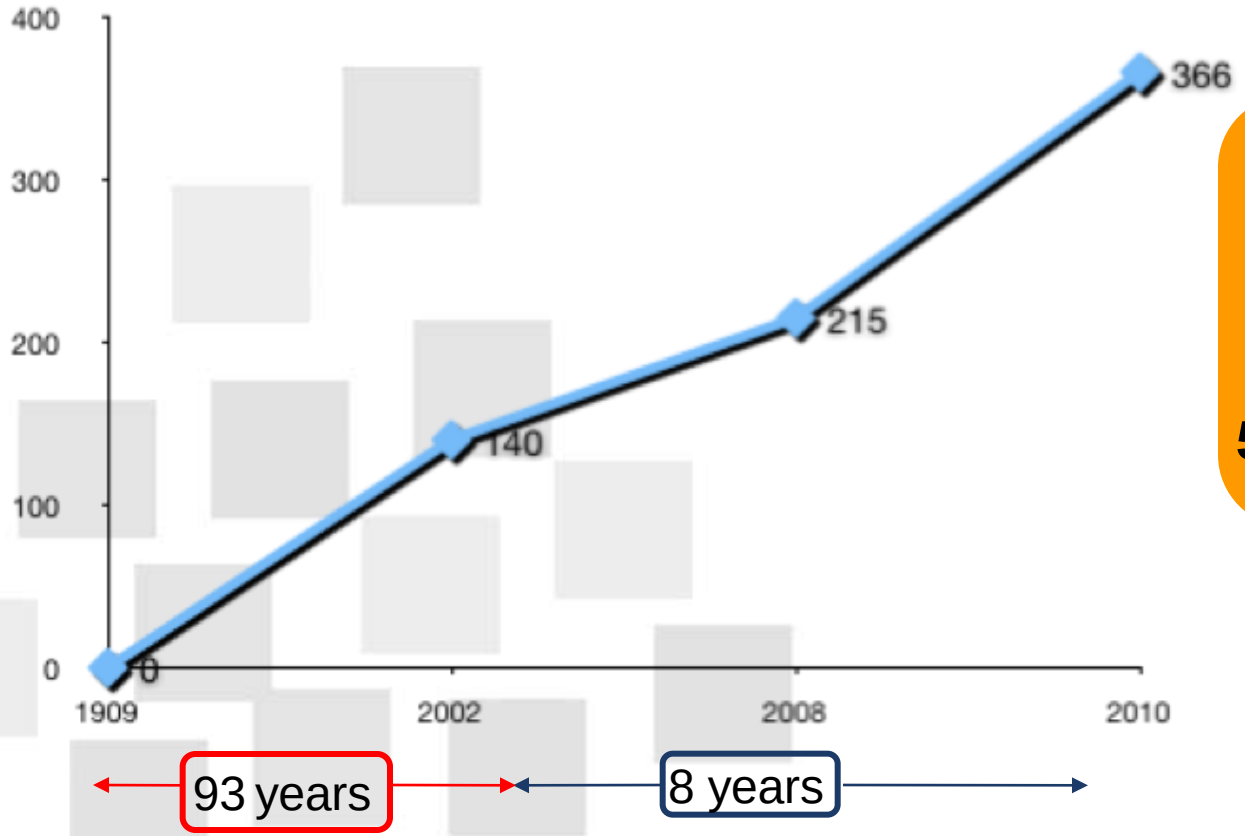
US$ 1.2 Billion

33,000 jobs

74
technological parks

25
busy

Technical Schools



226 new schools

US$ 550 Million

500,000 new positions

Some info on Brazil

- 5th largest population ethnically diverse

- 1st in biological diversity

- 44 of the 50 largest international companies are installed in the country

- 1st country to recuperate from the recent economic crises

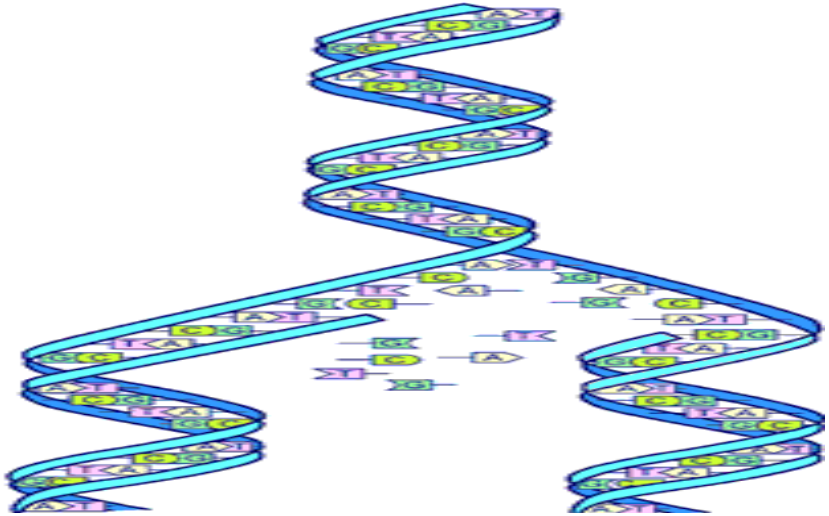
BRAZIL EVOLVES

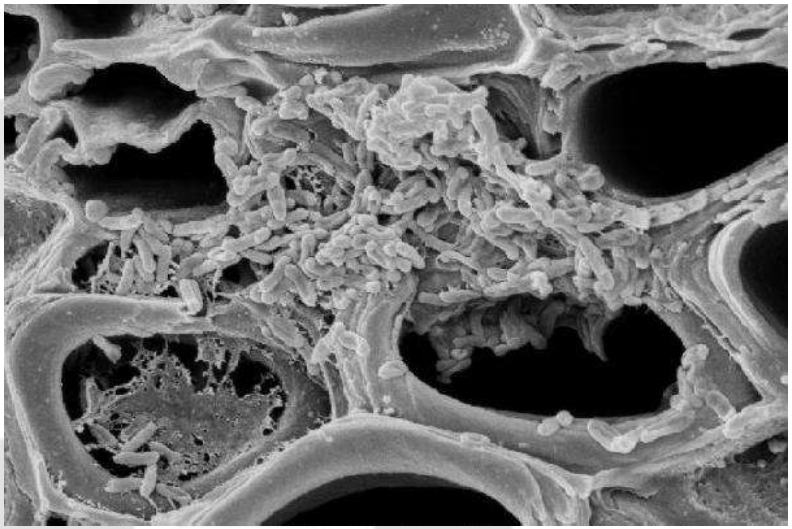
1st in energy production from renewable sources of energy

The biggest fleet of flexfuel cars

One of the world's leaders in agriculture technology and production

Human Genome Project





Xylella fastidiosa Genome Project

Focus on Innovation (2008-2010)

Productive Development Policy

US$ 150 billion
(US$ 3 billion for innovation
US$1 billion for Biotech)

Science & Technology Action Plan

US$ 20 billion

INNOVATION

Sustainable Growth

The National Biotech Policy

REGIONAL DISTRIBUTION

The geographic distribution of biotech companies reveals a concentration in the Southeast (São Paulo, Minas Gerais, Rio de Janeiro), with companies operating mainly in agriculture (22.5%), materials (21.1%), animal health (18.3%), human health (16.9%), environment (14.1%), bio-energy (4.1%) and mixed (2.8%).

The vast majority (85%) are micro and small enterprises. In all Brazilian territory, business incubators and science parks play an important role in creating a biotech company, since they are responsible for a growing number of companies in several states across the country.

INDUSTRY SEGMENT & MARKET FOCUS

Medicine and Health

Technological development of recombinant proteins; Biomaterials using rapid prototyping technology to form the models; Biomaterials for bone tissue regeneration, repair and reconstruction; Biomaterials for dermatological and cosmetic uses; Reagents for in-vitro diagnostic; Immunochemistry reagents, immunoassay, cytometry flow, rapid antilogous cell vaccine and anti-cancer; Human Vaccines, diagnostic kits.

Animal Health

Products for the animal nutrition and health; Biopharmaceuticals and biotechnological processes for animal health; Human and Animal Vaccines.

Biopharmaceuticals

Technology for the recombinant human insulin production and other therapeutic proteins; Biopharmaceuticals and biotechnological processes for human health; Monoclonal antibodies for cancer treatment usage and antibodies for clinical use.

Bio-energy and Bio-fuels

Technology for the production of enzymes and second-generation ethanol (cellulosic ethanol); Technology to enzymes production to fabricate bio-fuels.

Services

Clinical trials aimed at validating new drugs; Research services, consulting, development, production and marketing of biotechnology products.

Agricultural Industries

PHB and PHB-HV biodegradable plastics made from sugar cane; Genomics, post-genomics and proteomics.

Cloning and heterologous expression of proteins; new technologies in animal breeding and plant.

Agricultural biotechnology, improved food / nutraceuticals; Nitrogen fixing bacteria.

Environment

Bioremediation; Use of residues for biomaterials production, new platforms for biological pest control; Bio-prospecting the biodiversity and genetic heritage, water treatment, waste gas, solid waste and industrial residues.

BRAZIL'S BIOTECH POLICY

Biotech Policy issued in February 2007

Backing action

- National legislation and regulation
- International agreements
- Human resources

Articulation

- Technological Parks
- Public budget coordination
- Public consultation

Attack

- R&D funding
- Commercial promotion
- Enterprises financing
- Business roundtable

BRAZIL'S BIOTECH POLICY

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Biotech Forum
- Industry guidance

Comitê Nacional de BIOTECNOLOGIA

National Committee on Biotech – CNB

- budget articulation
- policy formulation & evaluation

- Access and Benefit Sharing
- Technical regulations (CTNBio, ANVISA, Ministry of Agriculture, etc.)

REGULATORY FRAMEWORK

Convention on Biological Diversity

COP 10 MOP 5

いのちの共生を、未来へ

Life in Harmony, into the future

BRAZIL'S BIOTECH POLICY

CBA

Centro de Biotecnologia da Amazônia

Investments on 7 Biotech Centers

CENARGEN – Brasília
CNPAE (agroenergy) – Brasília
CTE (ethanol) – São Paulo
Toxicology – Santa Catarina

FIOCRUZ - CIBPR (scale up)
- CDTS (R&D)

BRAZIL'S BIOTECH POLICY

Direct financing of 14 companies → US$40 millions of US$1 billion available for pharmaceuticals
(May 2008/Dec 2009)

INVESTMENTS IN COMPANIES + BUSINESS PROMOTION

2nd National Biotech Meeting
Minas Gerais, August 19-22, 2010

enconit biotec
Encontro Nacional de Inovação Tecnológica

Biotech cooperation opportunities with Singapore and Germany

R&D FUNDING AND INNITIATIVES

Direct funding of more than 125 projects or US$ 150 millions

(May 2008/Dec 2009)

Some technologies under development

- ✓ nitrogen fixation
- ✓ 2nd generation ethanol
- ✓ diagnosis of leishmania
- ✓ fast test of leptospirosis
- ✓ rotavirus test
- ✓ meningitis C vaccine
- ✓ human insuline
- ✓ yellow fever

Challenges – Next Steps

1) Consolidating the scaling up infrastructure
2) Improving public procurement rules
3) Developing the Brazilian Biotech Portal on web
4) Coordinating measures for the development of Biotech clusters in the Amazon region
5) Assembling a National Association of Biotech Companies

1) Successful policy developments

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- Established policy and organized institutional arrangement on biotech, led by the National Biotech Committee (CNB). The demands from the private sector are organized in the Competitiveness Forum on Biotech and forwarded to the CNB.
- Public companies and laboratories (EMBRAPA, FIOCRUZ & BUTANTAN) with important R&D departments and productive systems.
- 24 research groups, financed by CNPq & CAPES grants, working in network.
- PSI / APEX BRASIL project

2) Policy inefficiencies

- Some aspects of the regulatory framework on biotech are disassociated with the Productive Development Policy. (Innovation Law, Access and Benefit Sharing).
- There is a recent interaction movement between ICT and companies towards innovation.
- Inefficiency in analyzing patent processes and products.

3) Policy gaps

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- Sectorial clusters policy established, but lacking specific public financing for the companies.
- Lack of scale-up facilities and technological services.

4) Policy incoherence across relevant sectors

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- Despite the good figures in Masters and Doctors courses and degrees, there is a lack of human resources with adequate training to assist the industry demand related to entrepreneurship and innovation management.
- Because biotech is not a considered a sector in the economic structure of the country, but a transversal technology, there is lack of statistics which could contribute to the decision-making process of the biotech public policy.

Business demands:

Critical points for doing business in biotechnology in Brasil

Critical points for doing business in biotechnology in Brasil

To outline the Brazilian biotechnology future, is key to seize this time opportunity and route forward the latent structure issues to the respective government agencies for the sector. The most critical points highlighted by the participating companies of Brazil's pavilion at BIO/2010 Convention are listed below, it was addressed individually to the relevant government agencies, targeting to provide support to these bodies in the necessary direction to obtain solutions and definitions that satisfy the market and taxpayers.

Critical points for doing business in biotechnology in Brasil

- Legislation to Genetic Resources Access and Biotechnology Patents
- Patents "Evergreen"
- Expectations from the Brazilian Government support at BIO/2011
- Application of regulations to Pre-clinical Research Services
- Term for Clinical Trials authorization
- Obstacle to establish International Partnerships
- Lack of Infrastructure Production Funds in Brazil
- International Contracts
- Slowness of Brazilian government agencies
- Laws giving encouragement to research funding
- Specific support for SMEs
- Brazil internal costs

BRBIOTEC BRAZIL expects that this informations contained in this document can result in the necessary resolutions from the respective official governmental institutions involved.

Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity

To: Members of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing of the Convention on Biological Diversity

Cc: Convention on Biological Diversity Secretariat

From: The Heads of Biotechnology Associations: Asia, Europe and the Americas

The Biotechnology Industry

- Is uniquely suited to collaborate and partner with organizations and institutions around the world
- Is working in the medical sector to produce the medical needs.

Biotechnology is growing the economy worldwide in the agricultural field:

- By increasing food supplies
- Reducing pesticide applications
- Conserving natural resources of land, water and nutrients
- Increasing farm income.
- Leads the creation of alternative fuels from renewable sources without compromising the environment.

Members:

- Small and medium sized-enterprises
- Majority of these companies are not profitable
- The industry as a whole invests tens of billions of dollars developing ideas
- Companies must attract funding from private investors to exist by showing that their technological innovation has promising commercial applications and can be protected and can deliver a strong return on an investment.

The four pillars for biotech innovation:

- Sufficient research capacity – both in terms of capital and human resources, to initiate the quest for novel technologies;
- An efficient mechanism to transfer basic research from laboratories into the hands of those who can further develop it through innovation;
- A transparent and strong intellectual property system to incentivize the development of these technologies;
- An enabling, science-based regulatory environment for the development of new products.

The importance of creating a global regulatory environment (ABS Protocol)

- Biotechnology product development often takes many years and millions of dollars of investment.
- To provide sufficient incentives, there is a critical need for strong and predictable intellectual property protection, and specifically patent protection.
- If implemented the patent disclosure requirements or including intellectual property offices as mandatory "checkpoints." It would add great uncertainty into the intellectual property system and undermine the incentives for innovation

The solutions to some of the world's most pressing challenges are possible through biotechnology. If we get the appropriate incentives and cooperation, our companies can achieve the following goals:

- Greater access to innovative medicines and therapeutics
- Increase crop yields and conserve natural resources through new agricultural advances
- Stop the climate changes by developing alternative fuel sources
- Creating jobs and economic growth

Bolshoe Spasibo!

Muito Obrigado!

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