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BIOECONOMY
An Agenda for Brazil

Partnership:

CNI
Confederação Nacional da Indústria

CNI. A FORÇA DO BRASIL INDÚSTRIA

BIOECONOMY
An Agenda for Brazil

SELO DE CONFORMIDADE
Mapa Estratégico
DA INDÚSTRIA
2013-2022
CNI

Introduction

Bioeconomy is the result of an innovative revolution in the field of biological sciences. It is directly linked to inventions and to the development and use of biological processes in areas of human health, of productivity in agriculture and livestock, and of biotechnology. And so it involves a number of industrial sectors.

Opportunities for the global growth of bioeconomy are related to population increase and aging, to income per capita, to the need to increase supplies of food, healthcare, energy and drinking water, and to matters of climate change.

This scenario indicates greater global demand for goods and services in the decades ahead, and gives Brazil an opportunity to establish itself as a competitive power in the sector. But this calls for planning and assertive policies, to seek better alternatives in the use of natural resources and technology, and in the organization of economic activity, without affecting the sustainability of the ecosystem. The purpose of this agenda for bioeconomy is to indicate what paths should be taken.

Under its Corporate Mobilization for Innovation (MEI) initiative, the National Confederation of Industry (CNI) launched its agenda for stimulating innovation in Brazil in 2011. Among the strategic highlights are factors related to biotechnology and biodiversity. In October 2012, as a follow-up to the MEI initiative, the CNI, in partnership with the Harvard Business Review Brazil (HBR Brazil), held the "Bioeconomy Forum: Developing an Agenda for Brazil". This event was the first multisector and international debate on the subject in Brazil, in response to Brazilian industry's desire to make economic, social and environmental progress in developing the country's bioeconomy.

Participants were keen to discuss the matter more deeply, and so CNI and HBR Brazil went on to arrange a 2nd Forum the following year. On this occasion, the challenge is to propose an agenda for bioeconomy for Brazil. With this in mind, the institutions organized three debates in the first half of 2013. Specialist consultants, company representatives, members of academia and government employees held discussions which would serve as input for creating the agenda.

To analyze the Brazilian bioeconomy scenario and identify opportunities and sticking points, as well as to confirm the sector's potential for growth, field research was carried out for the first time, with the participation of 369 specialists, executives and others with an interest in the matter. The results of the survey are included in this paper.

We are very pleased to present the document *Bioeconomy: An Agenda for Brazil* to the general public. It is written in an up-to-date and objective language, based on three debates' contributions, experiences and reports of national and international professionals, as well as on current technical literature.

The document is in line with the 2013-2022 Strategic Road-Map for the Industry. Published by the CNI, this road-map indicates the steps that the industry and Brazil must take to increase levels of productivity and efficiency, so as to attain a high degree of competitiveness without ignoring criteria for sustainability. Our wish is that this Agenda may serve as an instrument of reference to broaden discussion and action in the corporate, academic and governmental sectors, and contribute to the development of the bioeconomy in Brazil.

We hope you enjoy the reading!

Robson Braga de Andrade
President of the National Confederation of Industry (CNI)

Chapter 1: The Emerging Bioeconomy

Over the past thirty years, much of the money made in the world depended on one simple formula; the price of processing digital code halves every 18 months, and the power of digital devices doubles, time and again… At first this transition from an analogue world, which used needles on phonographs to play music, chemicals to develop pictures, automobiles that were primarily mechanical, was very slow. As late as 2006, only 6% of global data was digital. Today it is 99%. It is those countries, those businesses that understood this wave, and surfed it successfully, that became rich and powerful. This is the wave that took a feudal nation Korea, an African-like nation, Singapore, and catapulted them into the first world. It is a wave much of Latin America failed to catch…

It is easy to look smart when you understand, and ride, a trend that systemically doubles every eighteen months for decades. Not every company or initiative will be a success, but overall you have a far better chance of succeeding than if you try to double a country's GDP by selling in sectors that grow 3-5% per year like agriculture, steel, beer, soft drinks or cement. This does not imply that you cannot have some very successful and creative entrepreneurs, and companies, in these areas. But it does imply that it is hard to double employment and output in a country using businesses with relatively slow worldwide growth trends.

However if, as occurred in the digital code transition, the overall world growth trends are double digits, then you can take an economy like that of India, educate a few of the smartest, and end up as the second largest software producer on the planet. This, in turn, leads to 9-12% growth in the overall economy, despite massive challenges in infrastructure, overall schooling, politics, regional security, and bureaucracy. High growth allows, and mitigates many sins and economic flaws.

So as Brazil, which has already enjoyed the fruits of some restructuring --- infrastructure investment, investment in education, commodity outputs, and democratization--- begins to think of how it can double its overall income and continue to massively increase the middle class… then it faces a key question: What trends are fast moving, relatively predictable, and sustainable enough to bet on?

Fortunately, technology and discovery are moving so rapidly that there are many ways, many fields, many discoveries which can lead a nation, in a single generation, out of poverty and into a developed country status. Korea was smart, ambitious, strategic, and hardworking enough to catch the tail end of the first digital and off shoring manufacturing wave. The effort was focused enough, and the educational excellence good enough, that the country began competing in, and then partly dominating, entire industries. Suddenly once dominant Japanese steel, ship, auto, computer, TV, and phone companies faced massive competition. This led to a new set of global household names; Samsung, LG, Hyundai, SK…

Brazil partly understood and weathered this transition, from high tech Embraer, through Petrobras, and powerful financial and agricultural conglomerates. But despite some inroads and examples, it is far from an IT, digital company global leader. Most of the country's universities, its students and entrepreneurs were not prepared for, nor understood, how fast and how far the digital revolution would go.

So it is especially important, as we again enter a massive revolution in how and where things are made, that Brazil understand, and play a leading role in life sciences. See, we are yet again in a period of rapid change in language; we now understand not just how life is coded (genomes), but also how to copy this life code (cloning). Because we can clone, once we find the right formula, for a bacteria, algae, seed, or animal, we can reproduce it time and again. So if we are able to make a bacteria that makes a vaccine, it is easy to make a lot of vaccine very quickly. The same goes for specific strains of corn or soy. And the same is true if one can program algae to make fuels or chemicals.

But the real change, the key accelerator, has come in the past couple of years. Not only can we read and copy life code, we can also edit it. At first this process is clumsy and cumbersome, but as it accelerates, as we develop standardized editing and assembly techniques, the world fundamentally changes. It means that, in a standard and reproducible way, we can begin to program cells, bacteria, algae, seeds to make a very broad range of products. It means we can industrialize life code.

And as cost curves collapse and output grows, one is beginning to see, in the life sciences, a phenomenon that is similar to that which occurred in digital code. At first digital code was an obscure language used by nerds, today it is a ubiquitous language used by everyone on earth.

Today it is not just expensive, long term, and complex pharmaceutical products that emerge from life code. It is most major crops. It is a very broad set of products processed through and by life sciences including cosmetics, animal feeds, fuels, animals, information storage and processing, leathers, vaccines, vitamins, colorants, plastics, and a wealth of other products. Already some of the world's largest companies depend on life code for their fundamental inputs, production methods, and products.

This trend is absolutely critical for Brazil. Much of what Brazil makes, what it is competitive in, what it exports, is already being altered by life sciences. And decisions to block life science products, not to become a leading research hub in the field, not to attract some of the best and the brightest post docs and professors from the world to work with Brazilian universities and companies… well that would be a serious mistake.

One can get a sense of what can happen just by observing the different policies followed by Brazil and Argentina over genetically modified crops. The Brazilian attitude was far more cautious and conservative. But the margins in agriculture are razor thin. So when the neighboring country begins widespread adoption of technologies that decreases fertilizer use, decreases pesticide use, reduces drought exposures, and/or increases productivity per acre, then you have a rapid erosion in competitiveness. This eventually led to a black market in seeds because even with an overall more rational agricultural policy in Brazil, and a far more business friendly government environment than that of Argentina, the technology gains, compounded year after year, became serious drivers of a competitive advantage.

Life code is beginning to permeate, to alter, to drive ever more economic fields. And it is important, for Latin America to understand, adopt, adapt, and lead these changes, just as, a few decades ago, Taiwan, Singapore, Korea, and parts of India did with emerging digital code. As life sciences and many other technologies continue to change industries as diverse as shoes, clothes, fruits, grains, energy, chemicals, medicine, beauty, and information technology, it is important Brazil keeps up. Starting broad, not terribly expensive, initiatives to train, seed invest, partner, develop, research, and grow a couple of viable life science clusters will help drive academic, business, and export competitiveness.

Genetic nationalism has little future in a networked world. Countries that restrict open source research, complicate visas, fail to attract smart brains will be at a disadvantage. Brazil's extraordinary diversity and biosphere can be a spectacular magnet for research and investment. Hopefully initiatives aimed at simplifying regulations, becoming more business and research friendly, partnering with a broad set of smart global actors will continue and expand.

There are many reasons why Brazil can and should be a leader in the life sciences. First of all it has a young, smart, hard working population. With more selective focus, training, support, networking and immigration, this population can become a key hub in research and deployment of new technologies. But sometimes inertia allows pockets within bureaucracies to say "no" when faced with overwhelming change. Brazil should continue to be vigilant in protecting and promoting emerging technologies, while at the same time understanding and mitigating new risks and challenges.

Life sciences is already establishing itself as the main language for the 21st century. The new global hubs and winners will be those that understood the emerging language early and deployed it intelligently. The seeds of a core life science community are already sprouting in Brazil, but it is still a

community that needs, help, love, support, patience, funds, and direction. There are a few companies that, despite obstacles have done well, Embraer´s in the making if you will. But one, three, a dozen successful entrepreneurs and companies is far too small, given the importance for the Brazilian economy of products that are natural and organic. Natural and organic in the sense of made by nature, by organic chemistry, by various companies processing food, feed, fiber, chemicals for a myriad of uses.

So please pay attention to the case studies, proposals, opportunities presented in this book. They are written by people who know Brazil far better than I. People who want their country to generate and lead a new economy. People who want to bet on the hardest of all things to achieve: change. And life code will certainly drive change.

Juan Enriquez
Designer of the Bioeconomy concept

Chapter 2: Bioeconomy in the Era of the Third Industrial Revolution

Bioeconomy offers a new paradigm for long-term sustainable development in the 21st century. Its driver involves a rapid increase in the opportunities offered by the biological sciences, and their use to resolve complex and weighty problems.

Meeting this challenge requires knowhow and strategic planning on the part of governments, companies, academia and society, on a global scale. It is essential that an innovative and appropriate regulatory framework be structured to allow Bioeconomy to function. The establishment of a political agenda for bioscience should guarantee good governance practices, international cooperation and competitiveness, so that biotechnological innovations can contribute to new and better products, benefiting various aspects of human existence.

The development of the Bioeconomy is likely to be impacted by public support for regulation, intellectual property and social attitudes, and research, development and innovation (R&D&I) efforts. Its creation depends on an advanced understanding of genes and of complex cellular processes, the use of renewable biomass and the multi-sectorial integration of applied biotechnology.

Today's Bioeconomy

Perhaps nothing reflects better the so-called "Third Industrial Revolution" than the development of countless new polymers for 3D printers; the creation of new enzymes, prebiotics, probiotics and molecular gastronomy; the forecasting processes of the social media and a new understanding of biosynthesis in yeasts and its application in the field of biofuels; or the development of artificial neural networks (autonomous chemical "perceptrons") which are capable of learning and have unlimited uses as biosensors. Recent scientific publications on the engineering of genetic circuits, biological programming language and the genomes editing, have brought synthetic biology much further forward than could have been foreseen just a few years ago.

In the context of manufacturing and industrial production, it is now accepted as fact that this Revolution is based on "3-D Printing", "Big Data" and "Pattern Recognition" technologies, which are the totally contemporaneous components of a new industrial production process that has been adapting the infrastructure and logistics of the production and trade of goods worldwide.

And so the planet is on the threshold of a new technological revolution, possibly much greater in scope and in its effects than has been the case of the new information and communications technologies (ICTs) during the last thirty years. These are in fact no more than a few of the tools for the disruptive transformation wrought by the unraveling of the genetic code.

The key concept can be formulated like this: the genetic code is likely to be the basis for creating economic wealth for nations in the decades ahead. The natural diversity and variability of genes, resulting from the countless possibilities for recombining them, allied to modern techniques of molecular biology for programming genes, offer the world a practically inexhaustible source for the engineering and manufacture of new biological products.

This new revolution is making yet another change in the paradigm of the economy: the language of the modern world is moving from the digital binary code [0-1] to the genetic code [A-T-C-G] contained in the DNA.

Evolution of Programming Language

For the country to take advantage of the opportunities offered by this new paradigm of progress, commitment on the part of the Brazilian Government is essential, to be given expression in a National Policy for Bioeconomy. This calls for a coherent listing of priorities, investment and the modernization of the regulatory framework, to truly promote and carry out actions that will impact science, technology and innovation, and of the policies to support corporate development in the fields embraced by the so-called bioeconomy.

Highlights of the Universe of Bioeconomy

Industrial Biotechnology	Primary Production	Human Health
Processing and productions: chemicals, plastics, enzymes	Crossing and improving plants and animals	Diagnostic theraples
Environmental applications: bioremediation, blosensor, methods for reducing environmental impacts	Veterinary applications	Pharmacogenetics
Production of biofuels		Functional foodstuffs
		Medical equipment

Source: OCDE, 2009.

Why a National Policy for Bioeconomy?

First, because the challenge is multi-dimensional: a) the medium and long-term impact of new discoveries in the sphere of synthetic biology, with implications for society that clearly transcend even those that we would expect of innovations thought of as radical; b) the scope and complexity of the technology and tools used in scientific and technological research, as well as the speed of advance, with the result that the current of innovation grows at what may be an unparalleled rate; and c) the practically limitless set of products and services that will arise from the convergence of biological and physical sciences and engineering.

Second, because of the opportunities that will arise for Brazil due to its comparative advantages of being at the frontier: a) the greatest range of biodiversity on the planet; b) lower costs of biomass production, especially from sugarcane; and c) advanced tropical agriculture, underpinned by the application of science and technology.

Third, because the choices between legitimate objectives are difficult — on one hand, the risks to human health and the environment of introducing new products must be mitigated; and on the other, economic activity must be encouraged in an area where agility, speed and flexibility are required, in a context of accelerating change in the scientific and technological fields. From this point of view there are several questions to be borne in mind: coordination of government policies and putting them into effect under the terms of laws that are complex and out of date; and the inflexibility of public sector institutions, in terms of hiring staff and purchasing goods and services, which prevents them from exploiting their potential.

And **fourth,** because of the fragility of the culture of innovation among companies and in the scientific and academic communities, with partnerships with companies only just beginning. This is particularly critical in biotechnology, where there is often a need for close proximity between the scientist and the entrepreneur.

Chapter 3: An Agenda for the Development of the Bioeconomy in Brazil

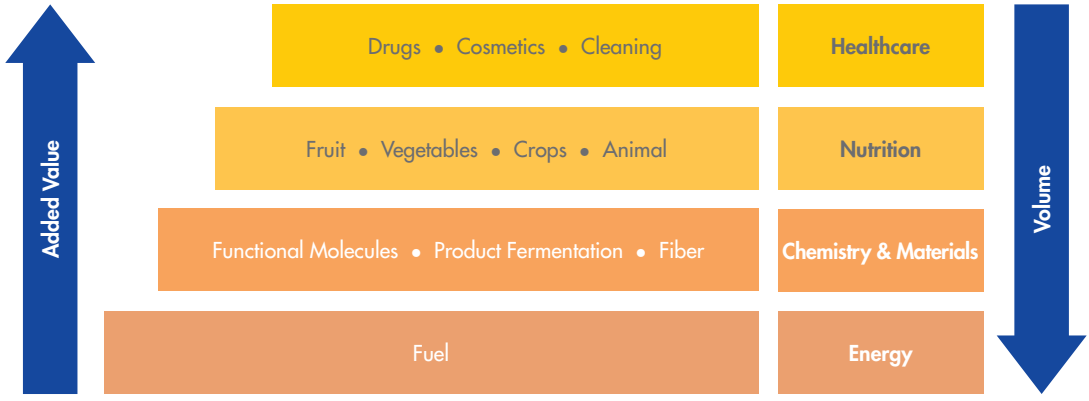
The starting point of the Agenda is to recognize that innovative solutions in the field of bioscience are anchored on knowledge. It becomes necessary to reinforce and expand the human resources' base and laboratory infrastructure in order to follow lines of advanced research related primarily to synthetic biology, genomics, proteomics and biomaterials.

The objective is to generate a critical mass of qualified researchers, so that new talents and leaders in the field of science and technology can emerge in Brazil. For this it may be necessary to create or to reinforce, on a basis of competition and meritocracy, a more restricted set of highly qualified research groups, facilitating their interaction with well-known international institutions, so that these groups may become leaders in the frontiers of bioeconomy.

Bioeconomy means a real opportunity for the country. The interests of the Brazilian State must be considered, as well as those of the corporate and academic sectors and of society as a whole, and the basis must be respect for sustainability and the conservation of natural resources, as well as the guarantee that domestic industry can compete in the global market.

The approach of Wageningen University in Holland to the value chain in the Bioeconomy contains important elements for a country like Brazil, given its profile, as the following chart shows.

Value Chain in the Bioeconomy
(based on the schematic view of Wagegingen University, Holland)



In general terms, regulation at the bioeconomy level is complex, and sometimes excessively bureaucratic. Its modernization is possibly one of the most critical elements for the country to produce science and technology of quality and to generate wealth. It is essential that these policies guarantee structural conditions, through regional and international cooperation, and that they are flexible enough to adapt to the new opportunities that are to come.

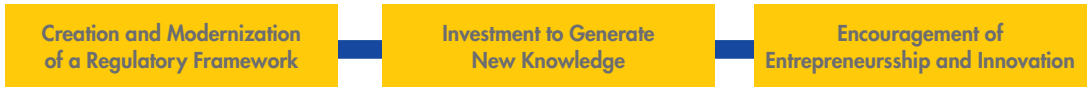
The bioeconomy needs a researcher-entrepreneur-innovator, and it needs scientific and multidisciplinary groups to be formed that can relate effectively and efficiently to the business world. We need to remove the barriers that prevent scientific and technological knowledge being transferred from academia to companies. We need to disseminate knowledge about strategies of protection, marketing

and management of intellectual property, specially about patents.

The sectors covered by the bioeconomy are quite different from the more traditional ones, where productivity is more linked to physical capital, since their key differential is human capital and knowledge of the frontiers of science, where new companies and market sectors will be created.

In short, the ambition to set up a vibrant bioeconomy sector in Brazil - based on our comparative advantages - will be shaped by restrictions in the sphere of knowledge; by the challenge of establishing an advanced regulatory framework which is pro-science, pro-innovation and pro-production; and by the possibility of providing lift-off for a still fragile base of entrepreneurial and innovative scientists and technologists.

Encouragement of Entrepreneurship and Innovation



Chapter 4: An Agenda for the Development of the Three Dimensions of the Bioeconomy in Brazil

The agenda for the development of the bioeconomy in Brazil, in its three basic dimensions: (industrial biotechnology, the primary sector and human health) requires the Government to prioritize actions that will serve as a single platform which, together with specific actions, will lead to important scientific, technological and corporate results, bringing social, economic and environmental benefits for the country. The convergent actions considered critical for the development of the Brazilian bioeconomy are shown below:

Convergent and Critical Actions to Develop the Brazilian Bioeconomy

# 1	Modernization of the regulatory framework
# 2	Increased investment in R&D
# 3	Consolidation of scientific and technological base
# 4	Expansion and modernization of laboratory infrastructure
# 5	Stimulus to entrepreneurship
# 6	Dissemination of culture of innovation

1. Modernization of the Regulatory Framework for Bioeconomy

CURRENT SITUATION

The regulatory framework that has a direct impact on sectors of the bioeconomy needs improvements. Adjusting and updating this set of laws, decrees, regulations and standards means direct action by the Government to deal with different government bodies which have their own views and focus. The following areas require special attention: legislation on access to genetic resources and the sharing of benefits, and on biosafety, sanitary protection, innovation and intellectual property.

The main disadvantage of the current regulatory structure for bioeconomic activities is legal uncertainty. This has to be minimized, so that stability of regulations can ensure constancy in the rules and the establishment of unambiguous concepts, enabling users of the system (both academics and

businessmen) to know in advance what impact their decisions will have, and whether they are legal, and to understand government actions more easily..

PROPOSALS

- **To enhance the regulatory framework for access to genetic resources and the sharing of benefits.** Provisional Measure (MP) 2.186-16/01 has direct practical implications for the development of research, for new technology and for the new products created out of genetic resources and the associated traditional knowledge; and it has a direct impact on matters to do with marketing these products. Improvements in the framework must concentrate on immediately reducing the bureaucratic barriers to access to genetic resources; on defining objective criteria for sharing benefits; on providing incentives for R&D&I; and on encouraging the regularization of activities that do not comply with the current legislation. Premises to be taken into consideration for the new law:
  - Genetic resources are for the common use of the public, with the State managing both the assets themselves and the access to associated traditional knowledge, as set forth in Supplementary Law No. 140/11;
  - By their nature, genetic resources have potential economic value – real economic value only arises in the shape of inputs, products or processes;
  - The obligation to share benefits arises from the economic exploitation of a product or process resulting from R&D&I of genetic resources, and may be in the form of an agreement, the establishment of funds, a project etc.;
  - There must be alternatives to the methods of sharing benefits;
  - There must be more policies providing incentives for R&D&I for the sectors using biodiversity;
  - The use of biodiversity for research or to exploit genetic resources must be sustainable, so as to ensure conservation of biological diversity and the balance of the ecosystems accessed;
  - There must be differentiated treatment of sectors of agribusiness, taking account of current international treaties such as the TIRFAA, and of the special characteristics of R&D&I in agriculture;
  - The new Brazilian regulatory framework must not have an adverse effect on the competitiveness of Brazil's industry.
- **To improve the Biosafety Law (Law Nº 11.105/2005),** which determines the standards of safety and mechanisms for supervising construction, cultivation, production, manipulation, transport, transfer, import, export, storage, research, sale, consumption and release in the environment, and the disposal of genetically modified organisms (GMOs) and their derivatives. Critical points:
  - To use the legislation covering biosafety related to research, production and sale of GMOs in an efficient manner.
  - To review the Genetic Use Restriction Technologies (GURTs), since they are an important biotechnological tool for controlling gene flow in transgenic crops that might, for example, be used as biofactories.
  - To reinforce the powers of the National Technical Commission on Biosafety (*Comissão Técnica Nacional de Biossegurança*, or CTNBio), introducing measures to encourage active participation by members of the Commission.
  - To speed up the analysis procedures of CTNBio.
- **To revise Normative Resolutions Nos. 2 of 2006 and 5 of 2008 of the National Technical Commission on Biosafety (CTNBio)** as suggested below:
  - To create differentiated approval flows for GMOs, according to the class they belong to

(Class 1 to Class 4), so as to speed up the commercial release of those that are proved not to present risks to human or animal health;
– To establish operating criteria for containment compatible with operations on an industrial scale, and not only at laboratory level.

- **To update the Industrial Property Law (Law Nº 9.279/1996),** so as to:
  – Provide wider patent protection for biotechnological products, also permitting patenting of substances or matter extracted from living beings which meet the requirements for patentability.
  – To speed up the process of examining and granting patents by the National Institute of Industrial Property (INPI), giving it the means to work within standard international deadlines.
- **To revise the Law of Innovation (Law Nº 10.973/2004),** in order to:
  – Enable adoption of modern mechanisms for the transfer of technology developed in joint projects between the academia and the business sector, guaranteeing adequate legal safeguards and commercial management of this activity, as well as intellectual property rights and compensation for any financial gain from products deriving from these collaborative efforts;
  – Permit second-hand equipment, including pilot plants, to be imported free of IPI (industrial products tax), if it is proven that they are for technological research and development. This possibility is currently ruled out by MDIC Ordinance 235/2006.
- **To amend the Technology Innovation Incentive Law (*"Lei do Bem"*, Law Nº 11.196/2005)** so that legislation on incentives may:
  – Allow expenditure on technological research, development and innovation to be effectively deducted in double for tax purposes.
  – Allow the surplus over real profit and the calculation base for Social Contribution on Net Income (CSLL) to be used in subsequent years (up to three years).
  – Eliminate any restrictions on hiring other companies for external R&D, even if they do not declare tax on a real income basis, making it clear that the tax benefits of the Technology Innovation Incentive Law may only be used by the principal.
  – Replace subsidies for hiring university graduates and doctors with a device allowing companies to deduct for tax, in double, additional expenses for personnel dedicated exclusively to R&D activities.
  – Amend the law to allow the use of economic subsidies for capital expenditure.

2. Increase of investment in R&D&I

CURRENT SITUATION

Countries such as South Korea, the United States and Germany have been increasing expenditure on R&D&I even in the adverse climate imposed by the economic crisis. Brazil needs to spend more in this area and to introduce means of reinforcing long-term competitiveness and innovation as part of its recovery policies.

Although Brazil has institutions and instruments to support the process of innovation, spending on R&D&I continues at a low level, and the Sectorial Funds have produced no significant change in levels of innovation. The bottlenecks are mostly related to the sustainability, scale and operation of the instruments. If the country's bioeconomy is to develop, the government must make a commitment to innovation in the field of bioscience, guaranteeing that the Ministry of Science, Technology and

Innovation (MCTI) and its agencies are adequately funded through the budget, and not subject to contingent limits.

The supply of funds for research and development on the part of development agencies has increased substantially in recent years, but the portion of GDP invested in R&D is still very low. On the government's side, in addition to public tenders, capital investment and tax breaks act as a major incentive. Investment in R&D, however, must also be part of the corporate sector's agenda, instead of its traditional posture of depending on public funds.

PROPOSALS

- To implement adequate mechanisms, based on open and transparent negotiation, to support strategic projects of major impact on the areas covered by the bioeconomy, that involve productive chains, universities and institutes of technology, with clear goals and an appropriate allocation of resources.
- To promote a system for commissioning projects to develop platforms that will demonstrate technology in bioeconomy-related areas.
- To adopt systems for monitoring and assessing the results of major projects, to allow the public and the regulatory authorities a clear view of the benefits of applying resources in this way.
- To support the development of a financial system to assist Small and Medium Companies (SMEs) in the field of technology, by establishing a venture capital industry, integrating and reinforcing the operations of the Brazilian Development Bank (BNDES) and FINEP (BNDESpar, Inovar and Prime).
- To expand and reinforce the operations of researchers under the Innovation Law, through lines of credit and seed capital support, similar to the Inovar and Criatec schemes.
- To provide government guarantees for the financing of technological development projects. A similar mechanism to that used by the US government to minimize the use of public funds and maximize the number of projects supported. Today Brazil works almost exclusively with government finance (through BNDES or FINEP).
- To include Biotechnology as a strategic sector for the country in the Bigger Brazil Plannew industrial policy *Plano Brasil Maior* (PBM). To include biotechnology in the "2nd Structural Directive — Expansion and Creation of New Technological and Business Skills", putting it on a par with the ITC, Defense and Aerospace sectors. Although the 2nd structural directive already covers the pharmaceutical sector, the Biotechnology Sector is bigger than the drugs industry. The inclusion of the biotech sector in the PBM will allow it to enjoy all the tax relief measures and investment stimuli applying to the other sectors.

3. Enhancement of the scientific and technological base

CURRENT SITUATION

Most research and scientific production comes from the graduate programs system which, in Brazil, is highly organized, with defined production metrics and permanent assessment procedures centered on the Coordination for the Improvement of Higher Education Personnel (CAPES). In general, new programs are created as a result of spontaneous demand and the great majority of them are academic in nature. This policy generates a huge number of graduate and post-graduate researchers (educated in Brazil and overseas) in the academic environment, and they themselves organize new research and new programs. It is rare for a curriculum to contain strategic programming for the current and future

needs of the country, based on interaction with the corporate sector. The result is a gap between the supply of researchers trained in basically academic fields and the demand for researchers trained in strategic areas which add value to the market.

PROPOSALS

- To widen the supply of undergraduate and graduate courses focusing on the three sectors of the bioeconomy.
- To set up modern, multi-disciplinary programs with syllabuses covering areas such as biology, physics, chemistry, bioengineering and design, entrepreneurship, innovation, intellectual property and the regulatory environment.
- To create a new type of researcher-entrepreneur, to meet the demand for human resources for bioeconomy, and who can be absorbed into the business sector within a horizon of 15 to 20 years, so that an efficient strategy can be established for investing in infrastructure and human resources.
- To encourage partnerships between groups of academic researchers and companies, to develop technological thesis and projects of interest to the productive sector.
- To promote the creation of corridors of innovation in the three areas of bioeconomy, linking Brazilian and foreign centers of excellence.
- To expand international exchange events and programs, such as the "Science Without Borders" Program and sandwich scholarships, for people to attain skills in specific areas of strategic importance to the bioeconomy.

4. Expansion and modernization of laboratory infrastructure

CURRENT SITUATION

It is undeniable that funds available for science and technology have increased considerably in recent years. The principal government development agencies (FINEP and CNPq), and the state foundations for supporting research, have made a direct contribution to improving Brazil's research laboratories. The public calls for tender made by FINEP's PROINFRA program, for their part, represent the principal instrument whereby scientific institutions can expand and modernize their technological parks. The expansion of research into the area of bioscience, whether in the academic or the corporate field, depends on a sophisticated laboratory structure, with modern equipment and quality inputs. This infrastructure needs to be more highly developed and expanded in order to meet world standards of research and development.

PROPOSALS

- To increase government investment in recovery, modernization and expansion of the platform of laboratories in the areas of bioeconomy.
- To encourage the use, on a multi-user basis, of specialized and strategic equipment in research centers so as to optimize local and regional investment in infrastructure.
- To stimulate the adoption of good laboratory practices to disseminate a new culture for the way that academic laboratories are operated.
- To encourage laboratories to obtain certificates, under domestic and international regulatory standards, for the production of reliable research data, to serve as a basis for the process of developing products, thus saving time and reducing costs.

5. Encouragement of entrepreneurship

CURRENT SITUATION

International experience shows the importance of small undertakings in the production of innovations, in fields such as biotechnology. The company incubators associated with academic institutions and technological parks have a huge potential for permitting knowledge and products developed at laboratory benches to generate successful sales in the market.

However a large proportion of companies in the incubator fail when they transfer from research to market, at the stage of developing their product: this has come to be known as the "death valley". Reasons for this lack of success include inexperience of business on the part of the academic entrepreneurs, the absence of infrastructure to assist in the transition to industrial scale, and the high costs of meeting regulatory requirements.

PROPOSALS

- To reinforce and expand technological parks and business incubators, and to endow them with an "intelligent" network, offering the "guest" undertakings not only space but also material, financial and human resources sufficient to support planning, commercial decisions and matters related to intellectual property. Shared scaling and production units should also be provided, and the entrepreneurs should be guided on the need to comply with the regulatory stages essential for their business.
- To set up a network for carrying out tests and trials, taking advantage of the potential skills of the academic institutions themselves, thus helping to rationalize and reduce the costs of developing innovative products.
- To broaden and improve lines of credit for new bioeconomy businesses with public or private funds, and to promote the development of ideas and inventions for products that are both technically and commercially viable, including those that come out of the business incubators and technological parks.
- To arrange events for academic entrepreneurs and businessmen to publicize portfolios of technological supply and demand and to expand opportunities for partnerships and investments.
- To define a specific public policy for cellulosic ethanol, with a strategy to modernize the Sugar and Alcohol sector in Brazil and to stimulate investment. The public policy should include special conditions for financing biorefineries.

6. Dissemination of the culture of innovation

CURRENT SITUATION

It is essential to promote a culture of innovation to make domestic industry more competitive and to encourage the creation of a network of companies and a production chain based on biotechnology.

The Brazilian regulatory framework for technological innovation is based on three pillars: to provide incentives for innovation in companies; to encourage the participation of science and technology institutions in the innovation process; and to establish an environment in which strategic partnerships between universities, technological institutes and companies will flourish. This last dimension — the integration of companies with research institutes and universities — remains as one of the major

bottlenecks for innovation in the country. There have been relatively few cases of successful transfers of technology to become market products.

PROPOSALS

- To regulate the devices intended to promote the integrated use of mechanisms for developing corporate R&D&I and government purchases, with the new instruments for promoting strategic partnerships between universities, technological institutes and companies, encouraging the use of the rules of private law.
- To strengthen the technology and innovation hubs (NIT) of research institutions and give them the autonomy they need, in addition to their own human, financial and material resources, so that they can act as catalysts for transfers of technology.
- To give additional tax breaks on investments that suit the specific needs of bioindustry.
- To map skills hubs, laboratory infrastructure, demand for strategic research in bioeconomy and opportunities for financing as a way to develop partnerships, and to publicize them in academic and business circles.
- To reduce red tape in public sector research bodies, principally in regard to the common rules of hiring staff, which are inconsistent with the competitive reality and dynamics of the bioeconomy.
- To thoroughly revise the legal framework governing relations between public research institutions and the private sector, with the involvement of controlling authorities such as the Federal Public Prosecutor's Offices, the Office of the Comptroller General, the Attorney General's Office and the Federal Court of Auditors, with the aim of guaranteeing legal certainty and the establishment of agile, efficient and transparent partnerships, fully backed up at every level.

Chapter 5: An Agenda for Industrial Biotechnology

CURRENT SITUATION

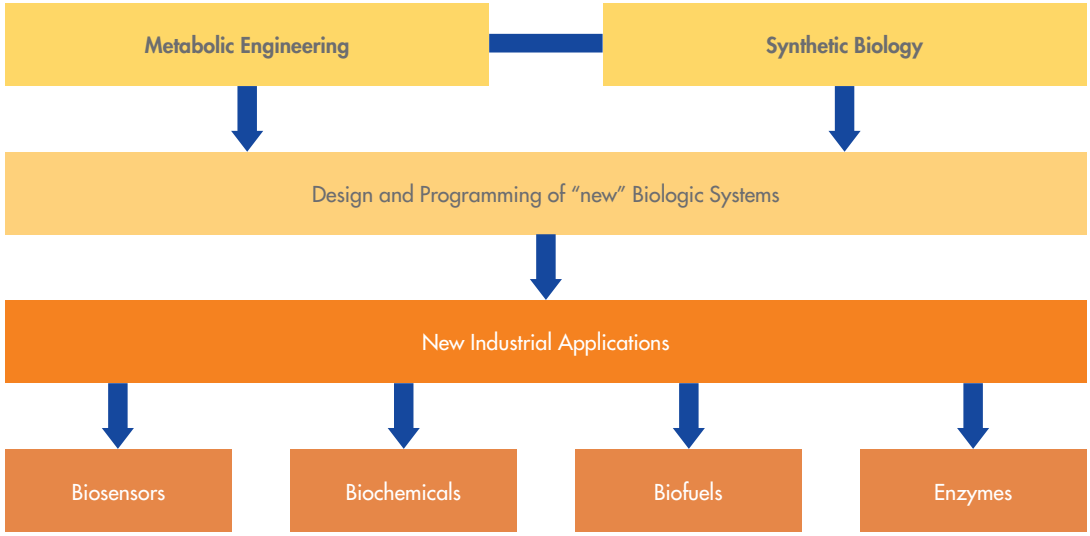
Among all recent discoveries and innovations in molecular biology that offer new possibilities for the field of industrial biotechnology, possibly none has a greater impact than the one that allows reprogramming of gene functions, either individually or as part of gene circuits.

Enzymes are now understood as commuters or relays with high cognitive capacity. Thus, the functional reprogramming of components or sections of genome and cell metabolism may be achieved through the development of biological programming languages, certainly the most impacting field of studies and applications in industrial bioeconomy. This biological programming language, important both for natural organisms and organisms arising from synthetic biology *in silico* or *in vivo*, is able to define, interconnect, edit and operate cell processes in genomic scale.

The power of biological systems lies primarily on their rich diversity and evolution complexity. The skill of rationally drawing new biological systems carries the promise of wide applications to the sector of industrial biotechnology, in terms of polymers, enzymes and biosensors. Regarding the development of polymers for medical and industrial applications, bacteria may synthesize a wide range of these components through a number of biological functions. The understanding of the key processes regulating bacterial gene expression has created opportunities for protein and metabolic engineering approaches to increasing efficiency and customizing the production of polymers such as polysaccharides, polyamines, polyesters and polyanhydrides. Renewable biopolymers are expected to replace a

large portion of the synthetic polymer market, given the increasing availability of new genetic systems and metabolic engineering techniques.

Possibilities for Industrial Biotechnology



As regards applications of industrial biotechnology, Brazil is particularly interested in the production of biofuels, specifically in obtaining ethanol from sugarcane and corn. Two synthetic biology processes may be used to produce biofuels: the first one by means of synthetic enzymes that act on the biomass pulp to obtain fermentable sugars; the second one by designing microorganisms that may directly produce biofuels. In case of synthetic enzymes, a typical biorefinery model can produce any type of fuel or another industrial chemical product. This happens through the development of synthetic organisms for direct or indirect biosynthesis of new molecules (whether polymers, enzymes or biofuels). Likewise, the design of yeasts for conversion of plant sugars in a series of molecules for which there is industrial interest now relies on a new genetic engineering procedure with actual potential to synthesize "de novo".

An energy production model is a synthesis of fatty acids that may be refined as fuels by algae. A considerable number of institutions and companies develop applications in industrial scale for these organisms, focused on biofuels derived from synthetic biology processes. The use of genetic engineering for production of ethanol by algae, based on carbon dioxide, water and sunlight is, in fact, an approximation to the usual energy generation mechanisms of the planet. This method may reach production levels six times greater than those achieved with the processing of sugarcane and sixteen times greater than those achieved with the processing of corn.

CHALLENGES

It is not simple task to suggest specific proposals for industrial biotechnology in such a complex situation, basically due to the fact that there is no clear lever that can stimulate this segment, as there is for primary production and human health. Regarding primary production, one of the comparative advantages of Brazilian agriculture is the existence of a group of prime institutions focused on applied

research and technological development. As far as human health is concerned, the Government, through the Unified Health System (SUS) and the drugs purchase program, enjoys an induction power possibly unparalleled in Brazil.

Industrial biotechnology is supported by two core elements: the Brazilian biodiversity (also relevant in case of the other dimensions of the bioeconomy), and mainly the competitiveness in biomass production. From this point of view, the focus of the agenda on industrial biotechnology would be linked to the usage of biomass by advanced methods and technologies.

Brazil needs to strengthen its competences in recombinant DNA technology for biomass. Currently, there are significant efforts and results with the use of unconventional biotechnology in new plant varieties, such as eucalyptus, soy and corn, assuring the country's strong position in agriculture and forestry. These efforts are generally organized as collaborative networks among universities and companies, under the coordination of a highly reputable institution and are stimulated by private companies which aim at material results on a timely basis. The Genoliptus project network, for example, encompasses 11 universities and 14 companies, under the coordination of the Brazilian Agricultural Research Corporation (Embrapa).

Just like Embrapa is the leading institution in the application of advanced biotechnology techniques in agriculture, Fiocruz is the leading institution in the health area, but there are no institutions that meet the coordination requirements of public and private players in the industrial biotechnology area. In addition, the critical mass of scientists and technicians lies with universities and research institutions, and is basically focused on the health area. Finally, there are no interlocutors able to voice the needs of industrial biotechnology, which is potentially crucial for the Brazilian economy in the next few years.

Brazil's challenge is to make wise use of its comparative advantages in industrial biotechnology based on innovation throughout the value chain.

PROPOSALS

- To expand the dissemination of biotechnology, its processes and products, aiming at reducing the barriers of negative perception regarding this area of science.
- To organize and stimulate think tanks to develop strategic thinking and forecasting on synthetic biology, metabolic engineering and other important topics for the progress of industrial biotechnology in Brazil.
- To establish a macro policy for biofuels at the Federal Government level to leverage national production.
- To involve society in the formulation of legislation and draw lawmakers attention to the nature and safety of biotechnological products and processes.
- To encourage private investments by means of initiatives that allow the adjustment of different timings among the agendas of the private sector, public research institutions and the Government.
- To stimulate the country's "zoning by suitability" approach regarding the areas of Bioeconomy, in terms of production of commodities and establishment of niches, both regarding supply of the domestic market and the export of goods.

Chapter 6: An Agenda for Human Health

CURRENT SITUATION

The human health sector is strongly based on science. Intense research studies and production of knowledge clearly reflects increased generation of new products in the area. Based on the potential for innovation, noteworthy are certain future promising areas that may impact the improvement of quality of life for populations.

In the therapeutic area, the traditional chemical synthesis of drugs has been overcome by the adoption of technologies for development of biomedicines. A large part of the most promising current therapeutics are molecules or biologically derived products (proteins, antibodies, vaccines, stem cells). This arsenal of biomedicines opens new possibilities to treat chronic and degenerative diseases such as cancer, tropical infections, orphan and neglected diseases, offering new possibilities for population access to these health technologies.

With the resources of pharmacogenomics, a whole new area of customized medicine begins to take shape. The steep decrease of costs for the use of tools for identification, sequencing, and comparison of genes enable them to be used to anticipate the individual response to certain treatments. Thus, the predictability of therapeutic response of groups of individuals is gradually being replaced by specific individual conditions. By selecting customized treatment parameters, we will be able to optimize highly complex and costly resources, and to offer better chances of therapeutic success.

The manufacturing of diagnosis kits and medical equipment based on monoclonal antibodies, recombinant proteins and biosensors derived from molecular and cell biology techniques has been increasingly revolutionizing diagnosis capability. Creativity in the use of these resources, taking biology closer to design, engineering and technology, allows achieving high sensitiveness and specificity for early detection, monitoring and even treatment of several clinical conditions.

Nutraceuticals may also work as tools for a prolific strategy for public health policies, with biofortified nutritional products or items specifically designed to meet dietary needs or adding vitamins, mineral salts, vaccines or elements for prevention and treatment of diseases.

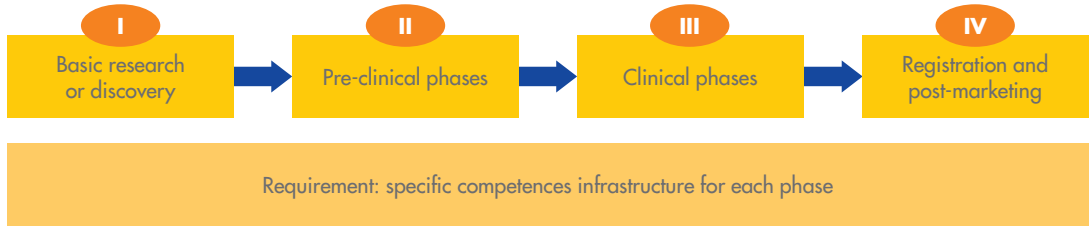
Possibilities of Innovations in the Human Health Sector

Brazil has established the largest public health system worldwide, with universal access to products, services and input, giving rise to a demand for purchase and incorporation of new and increasingly complex and costly technologies. The era of Bioeconomy may become an opportunity for expansion and consolidation of the Brazilian competence in important sectors of health, also representing the opening of new opportunities in other markets, combining the scientific, technological, social and economic development.

In general, the path of a product designed for human health up to its availability in the market place is one of the longest, most costly and demanding among all economic sectors, and therefore it is considered one of the segments with higher value added.

A product or process identified in the basic research as significant for human health should have its role established in proofs of concept and undergo a number of assessment phases. The arrival of a new compound in the market place is the result of the sorting of thousands of others which are discarded along the process. This may be unfolded in four phases: basic research or discovery; pre-clinical phases; clinical phases; registration and post-marketing. Each one of these phases requires specific competences and infrastructure.

Products for Human Health: Innovation Process Phases



A significant portion of the basic research or discovery phase is conducted in research institutions, particularly in universities and public science and technology institutes. In Brazil, research culture is focused on scientific production, i.e., number of publications. Together with this scenario, there is also lack of information about strategies to protect knowledge by means of intellectual property systems in the Brazilian academic and research environments. In case of research studies with potential to generate innovative products, scientific publications made with no consideration to protection strategies may, for example, render the granting of a patent unfeasible. The lack of institutional incentive mechanisms partially explains why Brazil, where scientific production is sizeable, holds relatively few patents. In this phase one can note the lack of a culture of Good Laboratory Practices (GLP) and certifications, which frequently prevents data produced from being acceptable according to international standards.

The so-called proofs of concept and exploratory testing are used to discard, as soon as possible, the unsuccessful products or those with issues regarding estimated safety and effectiveness. Thus, before proceeding to pre-clinical trials, a sorting can be conducted to select the best possible products, implying a reduction of time and costs in the subsequent phases.

Exploratory testing is much cheaper and has a significant market, in the sense of acting as an initial filter. Competences and easiness to conduct these tests are disseminated across research institutions. They need to be continuously mapped and widely spread in the academic and corporate communities, since they could make the development of new products much easier.

Compounds, products or processes that become promising in the basic research phase should undergo development in proofs of concept, pre-clinical and clinical trials. Particularly regarding pre-clinical trials, the Brazilian scenario is extremely deficient. It is important to clarify that pre-clinical testing refers to a set of trials required by regulatory authorities to prove the safety and effectiveness of products for human health, before authorization to conduct testing in humans. Potential toxicity and side effects noted in living organisms or *in vitro* systems are the main purpose of this development phase.

There is a high probability that a promising compound that posts safety or effectiveness issues be discarded in this phase. It is estimated that less than 1% of the new compounds developed effectively

get to the subsequent phases. The quality and efficiency of pre-clinical testing in identifying and excluding inappropriate products and processes means an expressive reduction in subsequent investments required to complete the other phases.

CHALLENGES

The effective adoption of public policies for the development of Bioeconomy depends largely on the integration of actions by different government bodies and sections at the three levels: federal, state and local. Particularly in the human health area, incentive standards, rules and programs are scattered over ministries, offices and agencies, making the path tortuous, doubling and harming the achievement of results.

All plans, actions and programs implemented require established deadlines, with clear progress indicators and periodic review for adjustments.

In order to enable a considerable advance of the national technology in the human health area, in addition to the issues converging to the aforementioned bioeconomy areas, Brazil needs to implement, update and expand world-class research centers particularly focused on areas that are strategic for public health; to foster projects for cooperation with international reference and excellence centers, and also to establish successful partnerships with the corporate sector. Such actions will directly contribute to consolidate new competences, as well as to assure the provision of services in the technological development chain and their adjustment to regulatory requirements, transforming the results of promising research studies into efficient and effective products to promote the citizen's health and well being.

Requirements for Structuring a Promising Environment for the Development of Innovations in Humam Health

# 1	Network of pre-clinical assessment centers*
# 2	Network of animal testing centers*
# 3	Network of laboratories of alternative methods for pre-clinical assays
# 4	Network of laboratories for exploratory trials*
# 5	Network of clinical assays*
# 6	Network of pharmacosurveillance*

(*) Certified and adjusted to international standards

PROPOSALS

- To modernize and align the legal framework and regulatory actions regarding human health so as to ensure security and effectiveness of products without creating barriers to innovation and introduction of products to the market, thus discouraging investments. Celerity and modernization of the regulatory framework implies:
    - modernizing the National Agency for Sanitary Surveillance (ANVISA), which should have optimized processes, provide clear rules, operate with computerized systems, expand the publication of specific guides and manuals, and ensure permanent dialog in order to reduce the time and costs for companies in the development of new products.
    - Fostering a regulatory culture among domestic companies and the academia so as to provide for greater effectiveness when meeting the requirements of ANVISA, since a greater part of the reports for submission of registrations is subject to extended times of analysis due to technical and documentary requirements that are not satisfactorily met.
    - creating regulatory intelligence groups with the participation of networked academic and corporate institutions that, in network, would be able to identify bottlenecks and validate alternative methods, besides cooperatively meeting regulatory assistance demands.
- overseeing the change in healthcare paradigms so as to predict important changes in the concepts, health system management, methods and supply of health inputs and services, including the growing incorporation of high technology procedures, individual care, ability to regenerate organs, tissues and functions; and prevention of diseases. These transformations have important consequences that may possibly require:
    - adopting a unified health registration for individuals, which should include information on their birth, growth and development, previous diseases, history of reactions to medical drugs and their pharmacogenomic profile.
    - developing and incorporating cutting edge technologies in line with public and private initiatives that may be able to face the issues included in the National Agenda of Research Priorities of the SUS (Unified Health System), which should include the use of the purchasing power of the public health system to leverage innovative initiatives.
    - Increasing coordination among the various levels regarding regulations, research funding, production and government purchases so as to enable the potential of Bioeconomy in human health.
- deploying pre-clinical assessment centers that are internationally certified and harmonized, and able to perform *in vitro* trials with experimental animals or alternative methods that may assist the decision making of researchers and enable the continuity of the development of promising medical products.
- stimulating, supporting and financing animal experiment centers enjoying international accreditation standards so as to fulfill a large gap, which is seen as a bottleneck to the development of human health products in Brazil.
- encouraging, supporting and financing the deployment of centers and laboratories that may offer alternative methods for pre-clinical trials, which are also seen as a priority in the fulfillment of the sector's demands, incorporating the global trend towards replacing animal experiments with alternative *in vitro* methods.
- developing and disclosing, throughout the country, a digital portfolio (regularly updated) including the names and contacts of institutions, skilled service providers, and laboratory facilities that are suitable for the performance of exploratory tests for screening and initial selection of promising substances and active ingredients, leading to a reduction in the time and cost of subsequent phases in the process of development of new products.
- fostering basic research relating to taxonomic studies, mapping and inventory of Brazil's biodiversity, aiming at developing products for the promotion of health.

- strengthening and expanding the National Network for Clinical Research in Teaching Hospitals as a result of the partnership between the Ministries of Health, and Science, Technology and Innovation, particularly regarding the incorporation of qualified human resources in the areas of epidemiology, statistics, regulatory matters and management of innovative projects, in addition to health professionals, so as to enhance the provision of services from phase I to phase IV of clinical studies and meet the growing demand from Brazil's public health system and the manufacturing sector.
- establishing a sound network of studies in regulatory issues in order to identify the bottlenecks existing in this process and promote validated alternative methods and procedures that may satisfactorily meet the demands without jeopardizing security requirements and the effectiveness of the products.
- using the purchasing power of the Government to encourage the incorporation of frontier technologies, for example, research on stem cells, and cell and tissue banks, in a direct contribution for the development of products and innovative processes that may represent an important differential for Brazil in the incorporation of technologies anticipated for the coming years, within a privileged market, and thus assure return of the investments required.
- fostering and supporting pharmacosurveillance in order to reduce morbidity and mortality rates associated with the use of new medicines, through early detection of safety issues in these products for patients, in addition to improving the selection and rational use of medicines by health professionals.
- establishing permanent and effective communication channels with society, taking into account the latter's perceptions, and actual or imaginary concerns regarding the planning and execution of public R&D&I public policies on health, as well as the introduction and trading of new products.

Chapter 7: An Agenda for Primary Production

CURRENT SITUATION

Brazil has the unparalleled opportunity to participate even more significantly in the bioeconomy in the scope of primary production. In 2010, the sector's GDP accounted for 22% of Brazil's wealth. According to the Ministry of Agriculture, Livestock and Supply (MAPA), it should increase by 25% in 2014.

Particularly regarding the primary sector, the development of the bioeconomy strengthens the relationship between agriculture and industry. In this sense, the change in the energy matrix towards renewable biologic sources, and the supply of raw materials and bioactive molecules for various manufacturing sectors, are expected to expand the range of application of biological systems, creating the opportunity for agriculture to gain more space and rank among the most sophisticated in the world.

In 2007, Brazil instituted the Biotechnology Development Policy, which, regarding agribusiness, seeks to encourage the generation of strategic products aiming at new competition levels and at food safety by means of differentiated products and the launch of innovations that enable entry into new markets. In this context, agribusiness comprises agriculture and livestock, as well as related services, forestry production, fishing and aquaculture.

The development of bioindustries requires huge investments and appropriate government policies. To this end, some specific areas must be given priority. Applications of frontier areas in agribusiness include the following: bioreactors, forestry biotechnology, assisted plant reproduction (tropical agricul-

ture), genetically modified organisms, assisted animal reproduction (molecular markers for bovines), collection and conservation of germplasm, plants resistant to abiotic and biotic stress, blue biotechnology, bioprospection (enhancement of plants for resistance to water stress and genes for production of proteins in plants or resistance to diseases).

Agribusiness frontier areas

- Blue biotechnology
- Bioreactors
- Assisted plant reproduction
- Assisted animal reproduction
- Forestry biotechnology
- Germplasm collection and conservation
- Plants resistant to abiotic and biotic stress
- Genetically modified organisms
- Bioprospection

CHALLENGES

The importance of bioeconomy and the pressure for environmentally sustainable production systems indicate the need to streamline conservation, characterization, and value adding processes, and the use of plant, animal and microbial resources.

As the fifth largest country in the world regarding territorial extension, Brazil has a huge potential for agricultural, livestock and ecological activities, being able to achieve great benefits from the adoption of biotechnological tools. The country has a privileged location in a tropical zone, with high levels of solar energy, proper rainfall levels and large reserves of land, which enables the planning of the agricultural use on sustainable bases, without compromising major terrestrial biomes.

Comparative Advantages of Brazil regarding Activities in Agribusiness

5th largest country in territorial extension (8.514.215km)
13,7% of the world's reserve of fresh water
Holder of technological platform for tropical agriculture
Great production capacity

One of Brazil's biggest challenges is to add value to its significant agricultural production. In order to do so, the country must give priority to its areas of activity and establish structuring actions regarding investments, infrastructure, human resources and the regulatory framework. Mechanisms for overseeing and assessing the performance of such actions should also be implemented.

As previously mentioned, to enjoy the benefits of bioeconomy, the country needs to count on a steady and safe regulatory framework, appropriate infrastructure, continuing public and private investments in R&D&I, development of human resources with focus on the demand from the industrial sector, and proper credit and tax policies.

PROPOSALS

To revise the Cultivar Protection Law (Law nº 9.456/97) to:

- Expand the coverage of the Cultivar Protection Law, to any vegetable kind and species that is, cumulatively, distinct, uniform and stable.
- Increase the reach of the breeder's right, curbing the unauthorized sale of protected cultivation and regulating more precisely the exceptions to this right.
- To expand the development of techniques to enhance production of fish and sea organisms for food and pharmaceutical applications (blue technology), ensuring a sustainable aquaculture with the integrated use of improved lines assessed from the point of view of proper dietary supply, with low impact on the environment, biosafety and traceability.
- To stimulate the development of genetically modified plants, animals, bacteria and fungi that are used as bioreactors for production of new bioproducts in large scale to various manufacturing segments. Bioreactors applications include: production of proteins for pharmacological and industrial use in plant tissues, production of enzymes for industrial use, manufacturing of food supplements and polymers, such as collagen, spider silk and biodegradable plastic.
- To consolidate the knowledge about reproduction assisted by molecular markers, so as to enjoy the economic, social and environmental benefits from research lines regarding both livestock and tropical plants.
- To expand the use of forestry biotechnology, where Brazil is a world leader, and support the deployment of governmental policies that may favor a change in the perception of planted forests, which should be considered as fiber production units.

- To build and maintain banks of germplasm - a critical input for the permanent development of Brazil's agribusiness — to enable greater access to and conservation of organisms, in addition to its use in genetic improvement programs.
- To increase the investment in technologies for production of plants resistant to abiotic and biotic stress, favoring productivity enhancement for commercial plantations.
- To organize a biotechnology infrastructure program intended to encourage the implementation and improvement of: R&D&I laboratories, biologic collections (germplasm banks, microorganisms, animals, plants, zoological collections and herbariums).
- To encourage, through favorable financing conditions, the enhancement of plant genetics by domestic industries, aiming at increasing the participation of this sector in the market.
- To support the structuring of service providers dedicated to the performance of distinguishability, homogeneity and stability (DHS) tests required by the Cultivar Protection Law.

Chapter 8: Quantitative Research

The current scenario of bioeconomy in Brazil

From June to July 2013, the Harvard Business Review Brazil and the National Confederation of Industry (CNI) held the first survey on bioeconomy in Brazil. The study counted on the participation of 369 experts, executives and persons interested in this subject, as well as persons who did not have specific knowledge on the issue. Its purpose was to analyze the country's maturity regarding not only the understanding and knowledge about bioeconomy, but also to assess Brazil's competitiveness levels and growth potential.

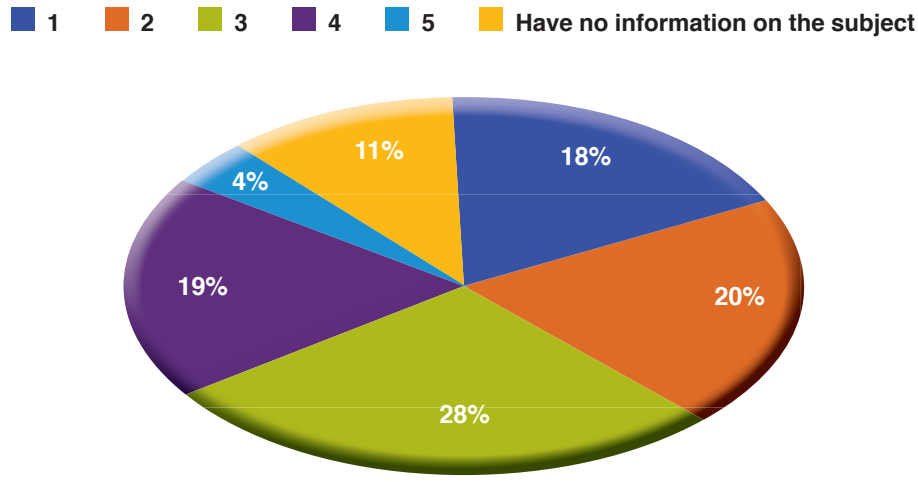
As it is known, Brazil's territory includes one the world's largest reserves of natural resources. As a country, its fauna and flora surpass Europe's in terms of diversity and volume. However, there is a discrepancy between the maturity of the economy and the production of social and economic outputs from the conscientious, intelligent and sustainable exploration of this diversity if compared to some European countries, such as England and Germany.

As affirmed by Juan Enriquez, who coined the term "Bioeconomy" when he founded and worked in the Life Science Project of the Harvard Business School, jointly with another expert in the subject, Rodrigo Martinez (Life Science Strategist — Ideo, EUA), it must be understood that life science, as well as the technological revolution, will provide for countries like Brazil to become world leaders in high value added segments within the value chain, as well as in those segments in which the country already stands out, such as agribusiness and mining.

A possible explanation for such disparity between Brazil's potential in this field and its reality is the lack of knowledge of Brazilians about the issue. Some 50% of the respondents had little or no knowledge at all about bioeconomy and its current and future impact not only on the economy, but also on the behavior of society regarding the use of natural resources and the consumption of byproducts (figure 1). Even more critical is the fact that many of these persons represent institutions that are directly related to segments of the bioeconomic value chain, and where bioeconomy plays an essential role in business.

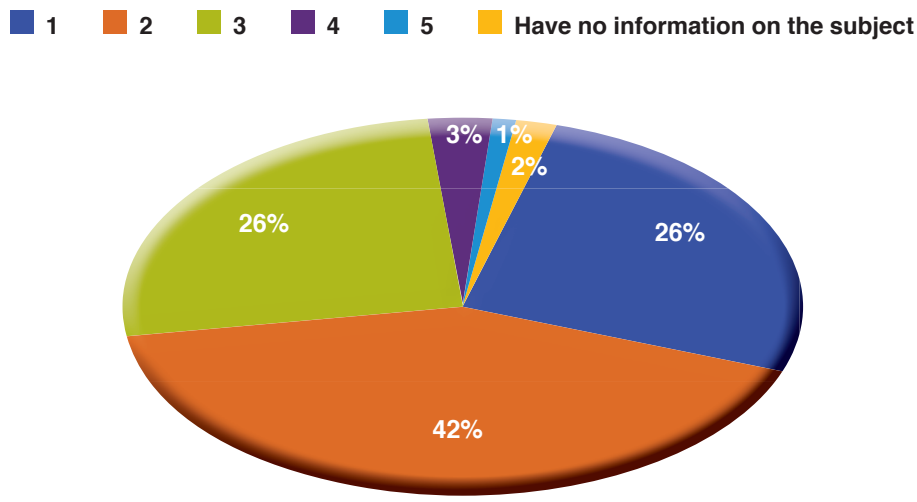
Additionally, 68% of the participants classified Brazil as "low competitive" and with "low maturity" in related areas (figure 2), due to deficiencies that include from low qualification or absence of workforce to the lack of legal certainty for investments in research and development. Added to these points, the respondents also mentioned issues such as a complex and bureaucratic regulatory framework for analysis and concession of patents for new products, as pointed out by an executive of a large steel-making company, as well as difficulties in the access to biodiversity, once again, due to the lack of legal certainty and the complexity of Brazil's regulatory framework.

**What is your knowledge about Bioeconomy?
Within a scale from 1 to 5, in which 5 means "full knowledge"**



(Figure 1)

In your opinion, what is the level of maturity and competitiveness of Brazil regarding Bioeconomy? Within a scale from 1 to 5, in which 5 means "mature and competitive"



(Figure 2)

What refrains us from taking the next step?

In virtually all economic sectors, the principal bottlenecks that inhibit, render difficult and delay growth and development are seen as structural barriers where the primary sector needs to act to cause impact, whether positive or negative. Such bottlenecks are not exclusive of Brazil, and in some cases, the country has made considerable advances despite ranking among the last positions on the "Doing Business Index" of the World Bank/IFC, which compares the countries based on the level of easiness or difficulty to start or operate a business venture. The respondents were asked to identify the major barriers to the advance of bioeconomy in Brazil. As concluded, such barriers are part of this reality.

Brazil ranks 130th in the index, just above India (132nd), considering the group of BRIC countries. South Africa (39th), Russia (112th) and China (91st) achieved better rankings.

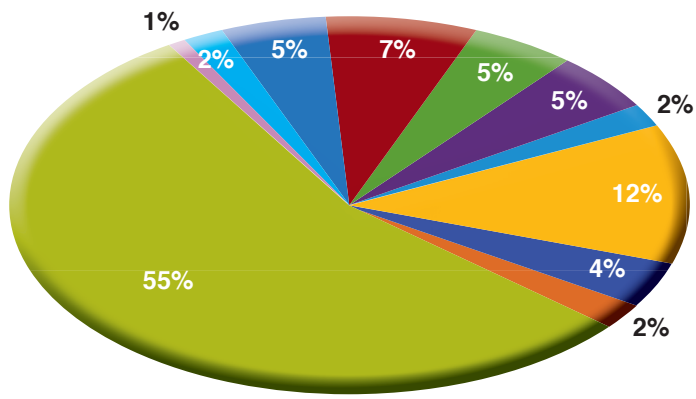
It is clear that the performance of Brazilian companies also relates to internal factors and indicators, such as installed production capacity, proper environment and technology that may stimulate innovations, absence of defined processes for the deployment of strategies, and many others. Comparatively, and only for a few exceptions, Brazil's productivity (the country ranks 56th on the 2013/2014 competition ranking of the World Economic Forum) is below that of countries such as Holland (5th) and England (10th).

However, the inefficiency and apparent inaction of the public administration in providing a favorable business environment to Brazilian businessman, entrepreneurs and researchers are, indeed, the principal causes pointed out by the respondents to justify the low competitiveness levels of the country and the institutions that operate here **(Figure 3)**. An improper, vague and complex regulatory framework, insufficient basic infrastructure, absence of government investments, among others, were indicated as critical barriers.

This scenario is reflected in the pessimistic feeling of the participants in the survey conducted by the Harvard Business Review Brazil in partnership with the CNI. According to the survey, some 40% of the participants indicate a period above 12 years for Brazil to become a power in bioeconomy and in the production of life science byproducts **(Figure 4)**. The lack of investments in biotechnology and research and development projects involving products derived from the access to biodiversity may also be seen, although not exclusively, as a consequence of this unfavorable and adverse environment **(Figure 5)**.

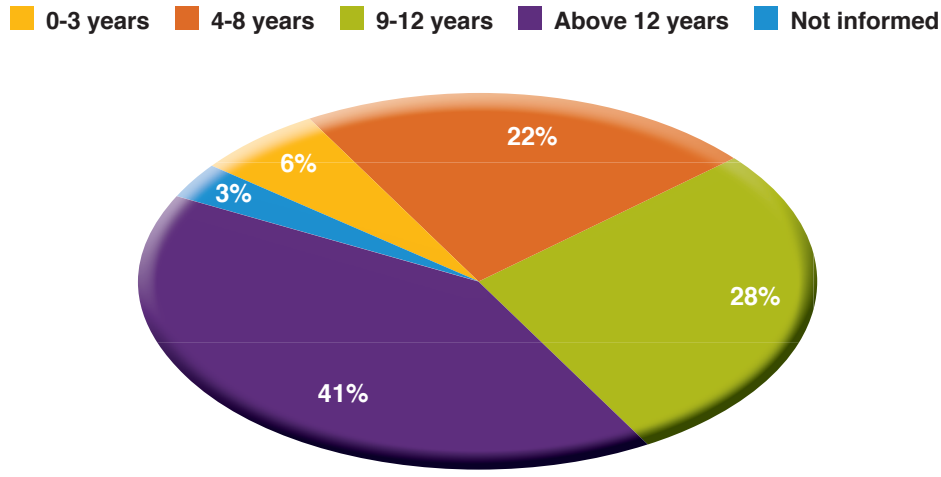
Which is the main barrier to the development of the bioeconomy in Brazil?

- Lack of qualified and specialized human capital
- Vague and complex regulatory framework
- Weak basic infrastructure for development of a cutting-edge industry
- Lack of governmental investments in research and development
- Lack of legal safety for private companies that intend to invest in research and development
- Lack of synergy among the private sector, the government and the academy
- Lack of a federal policy for the sector
- Lack of integration among the various governmental instances
- All of the above
- None of the above
- Not informed



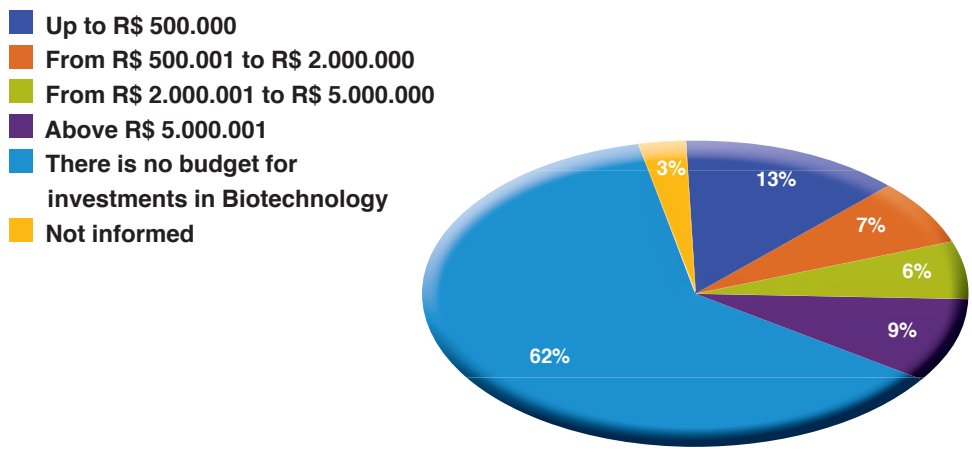
(Figure 3)

How long do you think it will take for Brazil to become a leading power in Bioeconomy?



(Figure 4)

What is the expected investment to be made by your company/organization in Biotechnology or in the research of products and services originated from the access to Biodiversity in the next 5 years?



(Figure 5) Note: The survey also comprised companies that are not included in the bioeconomic value chain.

Growth potential and the future of the bioeconomy

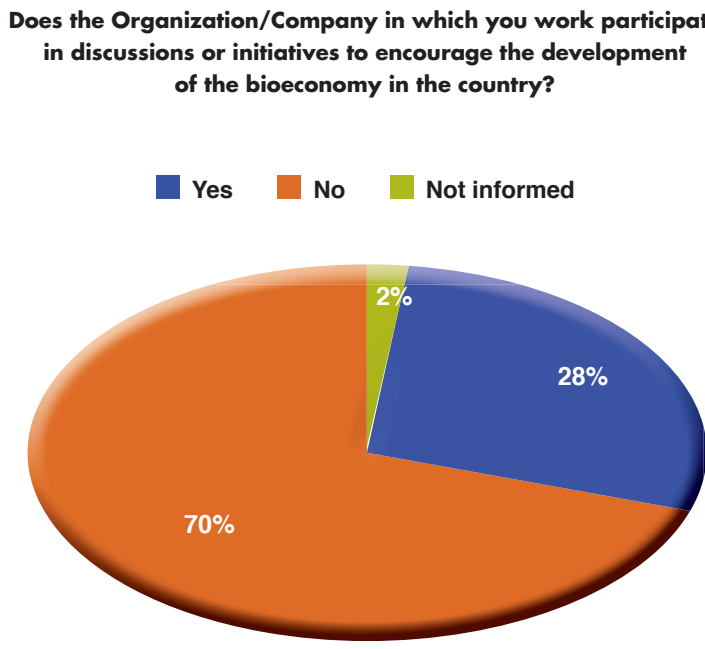
According to the Ministry of Environment (MMA) and the Ministry of Agriculture, Livestock and Food Supply (MAPA), Brazil ranks first in biodiversity on the planet, with more than 20% of the world's living species in its territory. However, the country is facing a paradox. Despite this variety and wealth, a greater portion of Brazil's production, particularly that originating from agribusiness activities, comes from exotic species or from species imported from other nations.

Alone, Brazil's agribusiness sector accounts for over 22% of the country's GDP with the expectation of reaching 25% in 2014. However, competition experts recognize the importance of fostering the development of economic sectors in which the value added of products and services stands on the top of the value chain, as happened with Singapore, South Korea and India.

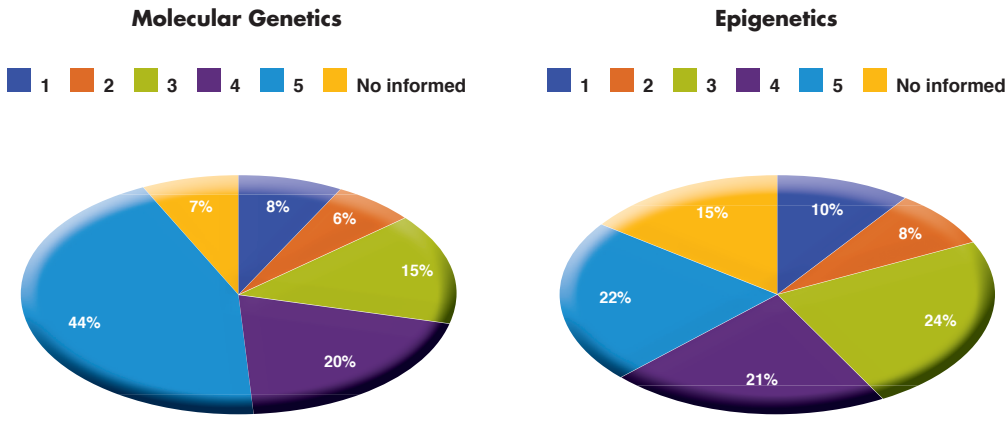
This scenario shows Brazil's potential to become a world power if it manages to overcome the barriers indicated in the survey, since the chances for improvement are ample and indispensable. Adding to these points, the factor "knowledge and interest of all social sectors," (private companies, government and civil society) regarding the risks resulting from the lack of investments in the development of policies and updated practices for use of resources originated from biodiversity and the development of products and services placed on the top of the value chain, is extremely important, since we verified that approximately 70% of the participants in the survey conducted by the Harvard Business Review Brazil and the CNI mentioned that this matter is not included in their institutions' discussions and initiatives **(Figure 6)**.

The factor investment in research and development, and investments to stimulate innovation in high value added sectors such as biomedicine, energy and alternative fuels, biotechnology applied to food production, among others, appears as a priority in the above mentioned survey **(Figure 7)**. The need to invest in mechanisms to make this transformation feasible is in line with these demands **(Figure 8)**. As mentioned by a top executive of a major technologic and innovation hub in Brazil: "investment in physical infrastructure and human resources, together with tax incentives for a high value added production" are part of the public policies that must be given priority by the government.

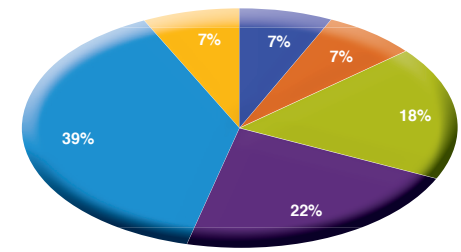
Despite the adverse feeling indicated in the survey, it is possible to notice the advances made towards the development of a more favorable environment regarding the bioeconomy and its evolution in Brazil. Initiatives like the Entrepreneurial Mobilization for Innovation (MEI), headed by the CNI, and the entity's "Agenda for Innovation" indicate an important entrepreneurial leadership in the face of the challenges posed by the maintenance of competitiveness levels of the national industry. We must also mention the recent incorporation of EMBRAPII (*Empresa Brasileira de Pesquisa e Inovação Industrial* - Brazilian Research and Industrial Innovation Company), as result of the partnership between the CNI and the Federal Government and intended to stimulate innovative projects jointly performed by research centers and companies. The program named "Science without Borders" is an important step towards the acquisition, from other countries, of strategic technological competences for Brazil and enhancement of post-secondary education programs for human resources. The classification of national companies such as Natura and Bug Agentes Biológicos among the most innovative companies in the world by international rankings also indicates that we are on the right path, although, as shown in the survey, there is still a lot to be done.


Does the Organization/Company in which you work participate in discussions or initiatives to encourage the development of the bioeconomy in the country?
Yes
No
Not informed
2%
28%
70%

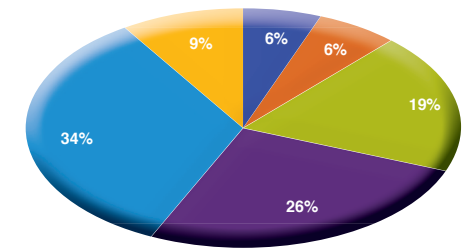
(Figure 6)


Molecular Genetics
1
2
3
4
5
No informed
7%
8%
6%
15%
44%
20%
Epigenetics
1
2
3
4
5
No informed
15%
10%
8%
22%
24%
21%

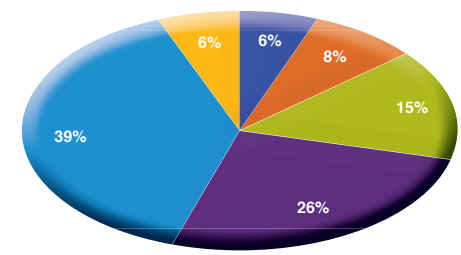
Molecular Biology



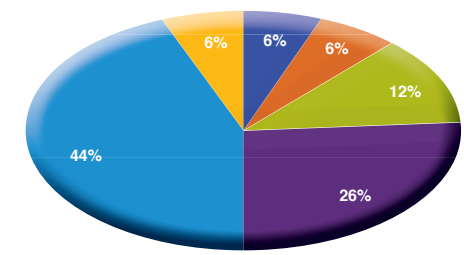
Systems Biology



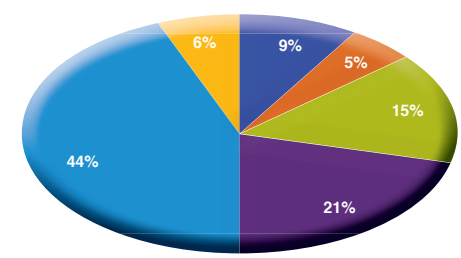
Organic Chemistry



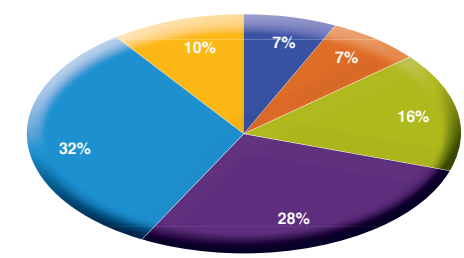
Biochemistry



Genetics

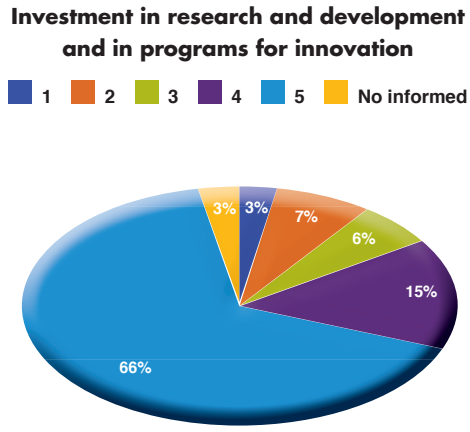


Synthetic Biology

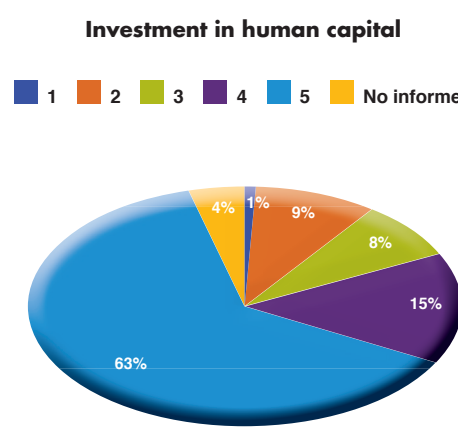


(Figure 7) What is the relative importance (1=less important; 5=very important) you would give to the following topics and tecnologies, in terms of its contribution to Bioeconomy in Brazil, within the next 5 years?

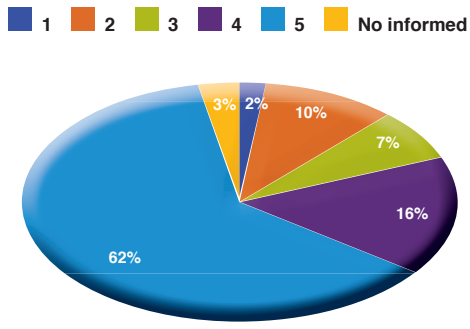
Investment in research and development and in programs for innovation



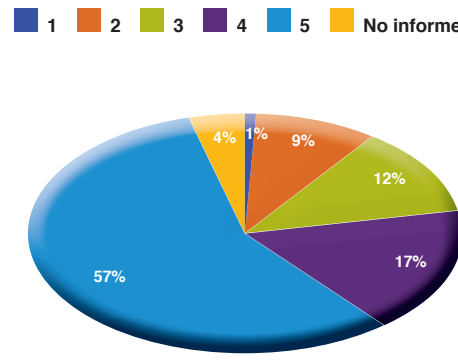
Investment in human capital



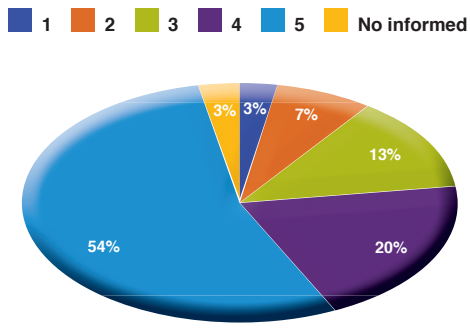
Debureaucratisation and modernization of public policies for access to biodiversity and protection to intellectual property and innovation



Incentive to partnerships among companies and universities



Incentive to partnerships among the country and other economies for the exchange of intellectual capital



(Figure 8) In order of relevance, which areas must be given priority for leveraging bioeconomy in Brazil? (From 1 to 5, where 5 has the greatest relevance)

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