COFISA
Cooperation Framework on Innovation Systems between
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SOUTH AFRICAN BIOTECHNOLOGY FORESIGHT INITIATIVE

BIOTECHNOLOGY TRENDS ANALYSIS

Including trend information from the COFISA Foresight workshops held in the Eastern Cape, Western Cape, and Gauteng Provinces

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This document was produced as an input to the COFISA biotechnology Foresight exercise undertaken in the Eastern Cape, Western Cape, and Gauteng provinces in late 2008 and early 2009. It offers a brief review of important trends in biotechnology, both in South Africa and also in the rest of the world.

During the Foresight process, participants provided inputs and feedback on biotechnology trends that are particularly relevant to these three provinces. These inputs, in edited form, may be found in the section entitled ***Provincial biotechnology trends***, starting on page 16 below.

For more information concerning COFISA in general, and the biotechnology Foresight exercise in particular, see www.cofisa.org.za.

Introduction

Over the last ten years there have been dramatic developments in basic research and in applications of biotechnology. This report provides a picture of the major trends in biotechnology that are taking place in South Africa and the rest of the world. The focus is on biotechnology developments in the areas of health, food security, agriculture, animal biotechnology, industry and the environment and natural resources. An overview of emerging disciplines including bioinformatics, genomics, marine and terrestrial microbial biotechnology, nano-biotechnology, stem cell research, and biodiversity is provided and the report ends with a brief summation of emerging biotechnology fields that are providing new applications and uses.

One of the more important benefits of biotechnology is its contribution towards addressing the needs of the poor, particularly in the area of human health (including HIV/AIDS, malaria and TB), food security and environmental sustainability. Many developing countries are harnessing biotechnology tools to improve local socioeconomic conditions. However more can be done to accelerate efforts and increase impact to provide a real benefit to marginalised members of society.

Definition: Because of its crosscutting nature, and ever growing influence, there are numerous definitions of biotechnology. The OECD uses the following definition. Biotechnology is "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or nonliving materials for the production of knowledge, goods and services".

Biotechnology involves a diverse collection of technologies that manipulate molecular, cellular and genetic components and processes with a view to developing products and services for commercial and other purposes. The hallmarks of biotechnology are cellular and genetic techniques that manipulate cellular and subcellular building blocks for applications in various scientific fields and industries such as medicine, animal health, agriculture, marine life and environmental management.

Biotechnology has developed through three major phases.[1] Each phase builds on the science and knowledge of the previous and for this reason it is difficult to determine the exact point in time at which

[1] A National Biotechnology Strategy for South Africa, 2001.

subsequent generations became mainstream activities. As a result, one finds that first generation applications are used in second and third generation biotechnology.

The first generation largely involves the use of selected biological organisms to produce food and drink (such as cheese, beer, and yeast). The main cluster of techniques in this generation is fermentation, plant and animal breeding and the clonal propagation of plants.

The second generation is the use of pure cell or tissue culture to yield new products. This generation is associated with the production of metabolites such as antibiotics, enzymes and vitamins. Major developments in this generation include the exploitation of a growing body of scientific knowledge relating to the properties and characteristics of microorganisms such as fungi and bacteria. A characteristic of this generation is that mutagenesis and the selection of strains and cultivars are used to improve metabolite and crop yields.

Third generation, modern biotechnology, emerged in the last 30 years and is associated with recombinant DNA technology. It involves the "application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

Distinctive Attributes: Biotechnology is characterised by a number of distinctive attributes.

Firstly, it is a *crosscutting* technology. It is subject to wide application, across many sectors and biological boundaries. For example, a technique developed for and applied in human health can prove equally or even more useful in agriculture, and *vice versa*.

Secondly, the biotechnology industry is a *research-intensive* industry. While the chemicals and the pharmaceuticals industries do some biotechnology research, traditional biotechnology companies tend to be more research intensive and spend between 40% and 50% of revenue on R&D. Historically, it was the interests and enthusiasm of individual scientists and scientific institutions that led to the establishment of the biotechnology industry, sometimes in the absence of a market-pull. This close relationship between research institutions and the new biotechnology industry remains today. Economies interested in diversifying and moving towards a competitive edge in biotechnology need to take measures that will stimulate the emergence and growth of R&D-intensive biotechnology companies.

Thirdly, the development and application of biotechnology techniques requires the convergence of a variety of disciplines. It requires appropriate combinations of biochemistry, genetics, information technology, engineering and several other specialised areas. It is thus a *multidisciplinary* field.

A brief history of SA biotechnology

South Africa has a long history of biotechnology research and development largely dominated by first generation applications that have led to the successful establishment of the brewing, food and wine industries. Recent government policies and strategies are creating promising opportunities for third generation 'modern' biotechnology which includes research in gene therapy, molecular modelling, pharmacogenetics, and structural and functional genomics. Industrial applications that use biotechnology techniques and processes can be found in pharmaceuticals, agriculture, speciality chemicals, bioremediation and cleaner production methods. The earliest applications in pharmaceuticals targeted the production of proteins such as insulin, diagnostics and vaccines for viral and bacterial diseases. In agriculture the application of recombinant DNA technology has focused on the genetic improvement of crops.

In the past, biotechnology was poorly exploited in South Africa resulting in missed opportunities for benefiting socially and economically from this technological base. This is beginning to change as national and provincial initiatives in support of biotechnology activities gain momentum. An important area of investment is biotechnology for social application and uses.

The DST 10-Year National Innovation Plan sets out to accelerate South Africa's transition towards a knowledge economy. The Plan aims to establish five R&D investment areas that are expected to result in innovation and positive outcomes for the economy. Strengthening the bioeconomy is one of the five focus areas. The vision for 2018 in respect of biotechnology is captured in the excerpt below.[2]

By 2018 South Africa anticipates that it will:

Be one of the top three emerging economies in the global pharmaceutical industry, based on an expansive innovation system using the nation's indigenous knowledge and rich biodiversity

Have designed and created the appropriate technology platforms, and R&D and innovation infrastructure (including structural biology, functional genomics, etc.) that facilitate diagnostic and medical solutions

Have created and funded five theme-specific consortium–based centres of competence that focus on the five top national health priorities, linked to the growth of the local pharmaceutical industry

Increase foreign investment in South African health-related R&D (excluding clinical trials) through reinvigorated health research, with particular emphasis on pharmaceutical R&D

Have designed and created a platform in 3rd generation biotechnology for application to plant/animal improvement and biofarming

Invest in animal vaccine development and manufacturing facilities to strengthen animal health and production

Have created an active biosafety platform providing regulatory guidance and support for product development in 3rd generation plant and animal biotechnology

A key feature of this bioeconomy is that it should contribute towards addressing national priorities in terms of access to and the affordability of health care, the provision of food security, job creation and environmental protection.

Main areas of investment (emerging)

While the industrial (mainly food and beverage) and agroprocessing field continue to play a dominant role in biotechnology applications in South Africa, a new area of biotechnology investment is emerging in human health applications, particularly involving: gene therapy; genetic engineering; nanotechnology;

[2] DST 10 year National Innovation Plan, 2008.

pharmacogentics and drugs; vaccines; and diagnostics research to address the challenges of communicable diseases, namely malaria, tuberculosis and HIV. [3]

In the energy sector, biofuels are creating great interest and to an extent, so are biotechnology applications based on South Africa's local biodiversity. In the agricultural and food security arena, genetically modified crops and foods have increased in importance and application.

Global context

On the international front, the Human Genome Project has made a significant impact on the advancement of genomics globally, and as a consequence, has resulted in major impacts in respect of practices and production processes that are based on living organisms. Even though the human genome project was said to be complete in 2003, it will take much time to determine and map the 28 000 to 35 000 genes identified and to understand how they interact with one another. The project has generated an unprecedented amount of knowledge about human genetics and health. This is made evident by the proliferation of genomics research clusters globally. Although the US leads in biotechnology research, there are excellent scientific groups in the developing world, including Cuba and Brazil in Latin America, as well as China, Korea and India in Asia.

Biotechnology in the health sector is expected to continue delivering incremental changes at least for the next five years. This is based on the preliminary analysis of global clinical trials which indicate that an average of 15 new biopharmaceuticals will be introduced into the market annually up until 2015. While biopharmaceuticals have historically offered a significant therapeutic advantage over small molecule therapeutics, they will continue to account for a relatively small share (approximately 14%) of all new pharmaceuticals. Despite this, in years to come, biotechnological knowledge will be so pervasive, for example for the identification of drug targets, that all new therapies could be based in part on biotechnology.

In agriculture, the use of biotechnology techniques, including both genetically modified (GM) cultivation and marker assisted selection (MAS), is a major success story even though many governments have been reluctant to support these applications. The share of all crops planted that use biotechnology has been rising rapidly over the past 10 years and this trend will likely continue into the future. If it does, well before 2030, all major food crop varieties will have been developed using some form of biotechnology and these crops could account for approximately half of the global output of food, feed and feedstock crops. In some respects, genetic engineering is not much different from other types of genetic manipulation that are routinely carried out to create organisms with desirable characteristics. After all, conventional plant breeding also involves the controlled transfer between organisms of genes that code for economically valuable traits. Where genetic engineering differs from conventional breeding, however, is in allowing genes to be transferred more easily across taxonomic boundaries. With genetic engineering, genes can be transferred not only between closely related organisms (for example, when a gene coding for disease resistance is transferred from a wheat plant to a rice plant), but also between completely different organisms (for example, when a gene coding for cold tolerance is transferred from a fish to a strawberry plant). In conventional breeding, biological reproductive processes impose limits on genetic recombination by erecting barriers against the successful crossing between biologically distinct

[3] Ernst and Young South African Biotech Review: Discussions with industry stakeholders

organisms; either the crossing fails completely, or else the progeny are sterile. With genetic engineering, the "natural" limits do not always have to be respected. For this reason, some people consider genetically-modified organisms (GMOs) to be "unnatural" organisms that violate the laws of nature. Others consider this distinction arbitrary, countering that most foods consumed today have been radically modified over thousands of years through deliberate selection or accidental mutation.Industrial applications of biotechnology are growing rapidly to incorporate unique processes involving enzymes and probiotics technologies Furthermore, a partial shift from petroleum feedstocks to biomass will depend on the economic competitiveness of industrial biotechnology compared to other solutions. While in some regions biofuels could play a substantial role, local supply and geographic conditions may lead to other technologies, such as solar and wind, being deployed (these are more environmentally benign sources of carbon neutral energy). Policy will need to be carefully designed to promote the most environmentally and economically efficient solutions. [4]

KEY BIOTECHNOLOGY SECTORS

Current global biotechnology activities

1. ***Health***

   Research and development activities in human health are broadly directed at therapeutics (e.g., biopharmaceuticals such as biotechnology-derived proteins, antibodies and enzymes, and genetic therapies), medical diagnostics (e.g., tests for specific gene or protein markers), and preventives (e.g., new vaccines developed through recombinant DNA methods).

   Human tissue engineering is an emerging, multidisciplinary biotechnology technique focusing on the regeneration of diseased human tissues. The development of this novel biotechnology promises to change medical practice profoundly and heralds new treatment possibilities for patients.

   Important contributors to the total disease burden are infections like HIV/AIDS, tuberculosis, malaria, respiratory infections and chronic diseases affecting the heart and blood vessels, neuro-psychiatric disorders, diabetes and cancer. The development of vaccines against infectious diseases will be guided by increasing knowledge about pathogen genomes and subtypes, host responses to infectious challenges, molecular determinants of virulence and protective immunity, a better understanding of the mechanisms underlying escaped immunity, and ways to develop novel immunogens. Translational research and the ability to rapidly evaluate multiple candidates in clinical trials can help accelerate the pace of vaccine development.

   Biotechnology offers promising health solutions for the treatment and diagnosis of HIV/AIDS, tuberculosis and malaria, all of which are major diseases that mainly affect the poor. By understanding the cellular and molecular actions associated with these infectious diseases it is

[4] OECD Biotechnology review

possible to produce more effective, efficient and safe treatment, prevention and diagnostic technologies.

Other emerging areas of biopharmaceutical research as seen in Europe, Canada, the US, Japan and Finland include:

- Prevention, diagnosis and treatments of diseases to improve public health
- Personalised or patient-targeted medicine
- Biodiagnostics, bioinformatics, and medical technologies
- Identification of biomarkers combined with molecular imaging (diagnosis and treatment uses)
- Development of broad reactive synthetic vaccines for human health, especially for the treatment of infectious diseases
- Regenerative medicine – disease-specific stem cells; precursor cells
- Therapeutics for heart disease, arthritis, and rare diseases
- New anti-aging and anticancer drugs
- Neurobiology and brain research.

2. *Food*

Despite the negative consumer response to GM foods in Europe and some other parts of the world, genetically modified crops are emerging to be an important technology with respect to food security and industrial opportunities. The first generation of genetically modified crops focused primarily on improving agronomic traits for the benefit of the farmer, such as herbicide tolerance and pest resistance. The second generation is expected to try to improve food attributes such as nutritional value, colour, texture, flavour and processing properties.

Several US-based biotechnology companies are involved in agroprocessing. Many products are created by applying natural or engineered microbes to products in order to preserve, extend shelf life or enhance nutritional characteristics.

In India there is significant food biotechnology research being undertaken, including the development of:

- tools for evaluating food safety;
- rapid diagnostic kits for the detection of various food borne pathogens;
- analogical methods for the detection of genetically modified foods and products derived there from;
- nutraceuticals, health food supplements, and functional foods for holistic health;
- pre-cooked, ready-to-eat, nutritionally fortified food for school-going children;
- suitable pro-biotics for therapeutic purposes;
- biofood additives.

Reducing micronutrient malnutrition of the poor is possible through enhancing the iron, zinc, and vitamin A content of basic food grains. Fortified crops can significantly improve the health, immunity and well-being of the poor who cannot afford to eat more expensive foods for these nutrients.

3. Agriculture

India, together with many African countries, is conducting extensive research on agriculture, soil and water conservation, animal husbandry, fisheries, dairying, forestry and agricultural education. Special research activities on plant biotechnology have been established at several research institutions where work on staple crops such as soyabean, maize, cassava, potato, rice, cotton, brasica and brinzal is being carried out. Many countries, including India, South Africa, Tanzania, Uganda, Kenya, and Ethiopia, have a growing seed industry where the main type of activity is the production of hybrid seeds for improved crop production and pest resistance. Some research institutions within these countries are beginning to enter the field of DNA fingerprinting, and they also provide identification facilities for viral diseases in plants and animals. Some are starting to employ data mining techniques to harvest additional value from their existing databases. Other areas of research include the production of biofertilisers, as well as the development of better formulations and cost–effective, commercially-viable biopesticides including microbial pesticides, parasitoids and bacteria.

The application of modern biotechnology methods to agriculture has been hailed as the next agricultural revolution, capable of sustaining agricultural production to meet the dietary needs of an expanding world population, as well as increasing demands for improved food and environmental quality. Most commercial agricultural biotechnology products have production-enhancing traits that complement or replace traditional agricultural chemical inputs. Crops generally are designed to be herbicide-tolerant or pest-, virus-, or fungus-resistant. Biotechnology is also used to improve agronomic characteristics of crops, including crops that use nitrogen more efficiently or are developed to better tolerate stress, such as drought, alkaline soils, or frost. Nutraceuticals and health benefits from agricultural products are another growing research area. Such applications play an important role in enhancing food security and access to nutritional crops in developing countries.

In the US, agricultural biotechnologies are increasing crop yields significantly while reducing reliance on chemical herbicides and pesticides. For example, the addition of vitamin A to rice has the potential to save the lives of millions of children in the developing world each year. Similar advances in bioagriculture will help feed a rapidly growing world population with healthier foods.

The US and Canada in the developed world, and China, India, South Africa, Argentina and other Latin American countries in the developing world, are showing a wider adoption of transgenic crops and transgenic crop cultivation. Across the globe, biosafety regulations are being established and implemented to monitor the large-scale and commercial application of GMOs.

Applying biotechnology to marine “farming” (aquaculture) also promises to improve aquaculture production, a goal that has become more critical for meeting increased consumer demand as natural seafood stocks have dwindled.

4. *Animal biotechnology*

The broad objectives of biotechnology applications related to animal health are largely the same as in human health applications, that is, applying advances in genetics and molecular biology to discover and create new and more powerful:

- therapeutic products (proteins, antibodies, enzymes, genetic therapies),
- diagnostic tools (e.g., for gene or protein markers of disease conditions), and
- preventive measures such as vaccines.

Infectious diseases such as foot and mouth, SARS, avian flu and BSA are a great public health concern due to the increasing emergence of diseases transmitted from animals to humans.

In addition, biotechnology is providing powerful new tools for improving farm animal breeding programmes, including genetic mapping methods to identify both disease-resistant animals and certain specific genes related to animal health weaknesses and defects. In livestock production, biotechnology is being used to develop animals that have better growth and muscle mass and improved disease resistance, and that can utilise feed more efficiently.

Two complementary initiatives have been launched by the European Commission in the area of animal biotechnology. The one is a project aiming at stimulating an informed, public debate across Europe on farm animal cloning and ensuring public participation in the forming of policies. The second is a study on animal cloning and genetic modification and derived products. The studies aim to provide a comprehensive, worldwide picture of research and commercial activities involving animal cloning and/or genetic modification and current and future products that may be obtained, and:

- to identify the potential benefits, risks and socio-economic impacts;
- to compare regulatory frameworks worldwide, and
- to assess new policy implications of the developments of these technologies and of the commercialisation of their products in the EU.

The next phase of agricultural biotechnology products promises improved quality and end-user traits. Some examples of quality-enhanced foods that are being developed include foods with lower saturated fats, increased vitamin content and improved flavour and shelf life. Biotechnology applications in aquaculture will be able to produce larger fish with less feed, improve spawning, and reduce the time for fish to gain market weight.

On the laboratory side, genetically modified mice and other laboratory testing animals are important tools in modern biomedical research. They provide valuable information on gene functions and serve as models for human diseases. Countries such as Finland have established laboratory facilities for the physiological analyses of transgenic animals. The focus of such facilities is to develop methodologies for small animal physiology studies with an emphasis on the investigation of, for example, cardio-vascular function *in vivo* and *in vitro*.

5. *Industrial biotechnology*

Industrial biotechnology refers to the use of biotechnology techniques and processes in manufacturing (chemicals, materials, energy) at every stage in the process, from the supply of raw materials to end-of-pipe and clean-up. For instance, industrial biotechnology research is expected to provide a smooth transition from a fossil-based economy to a bio-based economy. Canada, the US and Japan are providing strong support to industrial biotechnology while several European countries have launched their own initiatives and public-private partnerships to promote industrial biotechnology. An international dialogue is also taking place at the OECD level.

One aspect of industrial biotechnology (also referred to as white biotechnology) involves the use of biological systems for the production of useful chemical entities. This technology is mainly based on biocatalysis and fermentation technology in combination with recent breakthroughs in molecular genetics and metabolic engineering. This new technology known as biorefinery, has developed into a main contributor to so-called green chemistry, in which renewable resources such as sugars or vegetable oils are converted into a wide variety of chemical substances such as fine and bulk chemicals, pharmaceuticals, biocolorants, solvents, bioplastics, vitamins, food additives, biopesticides and biofuels such as bioethanol and biodiesel. The biorefinery concept is analogous to today's petroleum refinery, which produces multiple fuels and products from petroleum. By producing multiple products, a biorefinery takes advantage of the various components in biomass and their intermediates therefore maximizing the value derived from the biomass feedstock. A biorefinery could, for example, produce one or several low-volume, but high-value, chemical or nutraceutical products and a low-value, but high-volume liquid transportation fuel such as biodiesel or bioethanol. The biorefinery simultaneously could generate electricity and process heat, through combined heat and power (CHP) technology, for its own use and perhaps enough for sale of electricity to the local or national grid. A significant amount of research is taking place in the area of biomaterials, especially of biomaterials that display multiple uses and biodegradability.

A European – US collaboration has been established to bring together experts from plant and industrial biotechnology to identify opportunities with respect to plant-based bioproducts. Research that is taking place includes enhancing plants for the purpose of producing bio-based products and bioenergy as well as creating value from renewable biological resources. As a renewable energy source, biofuels can supplement hydrocarbon fuels, assist in their conservation, as well as mitigate their adverse effects on the climate. Two major biofuels for the transport sector, bioethanol and biodiesel, are fast becoming popular in many countries around the world. While bioethanol (called ethanol) is produced from raw materials such as molasses, beet, sugarcane juice, grains and tubers, biodiesel is produced from oil (derived from oil-bearing seeds such as *Jatropha curcas*, *Pongamia pinnata* i.e.karanja).

Given Finland's abundant forest resources, it is well placed to utilise biomass as an energy source. Finnish technology is already in use to make efficient use of biofuels. Botany and plant breeding as well as genetic engineering are being harnessed for the development of biofuel production. South Africa is also making use of biotechnology to improve the quality of forest trees, however in this case, for higher-quality paper and furniture production.

Advanced measurement methods and technologies are used both in bioprocesses for purposes of producing chemicals and new materials, for quality control purposes in the food industry and in studies on the state of the environment. In industry, new measurement technologies are needed for instance in bioenergy production.

Biological processes offer the prospect of cheap and renewable resources, lower energy consumption and less waste products. They also raise opportunities for zero greenhouse gas emissions, reduced dependence on (imported) petroleum and new markets for agriculture.

6. *The Environment and Natural Resources*

Biotechnology has tremendous potential for application to a wide variety of environmental issues including the conservation and characterisation of rare or endangered taxa, afforestation and reforestation. It can help in many ways, including:

- the rapid monitoring of environmental pollution,
- eco-restoration of degraded sites such as mining spoil dumps,
- treatment of effluents discharged by industries (oil refineries, dyeing and textile units, paper and pulp mills, tanneries, pesticide units etc.),
- treatment of solid waste.

In the US, biofuels represent an important avenue, not only to reduce dependence on oil, but also to improve the quality of the environment. In addition, enzymes identified or designed through biotechnology offer ways to clean up waste while reducing pollution caused by industrial processes or accidents.

Several companies in the US are actively researching bioleaching, biopulping, biobleaching, biodesulfurization, bioremediation and biofiltration. The economic and social impacts of environmental applications can include greater manufacturing efficiency and lower production costs, less industrial pollution, and resource conservation. Enzyme-catalysed processes are generally more efficient than chemical processes because input yields are higher and fewer steps are involved. Much of the current environmental biotechnology research is focused on the manipulation of enzymes or enzymatic reactions. However, research groups, especially in the US, are working to create new industrial products from engineered bacteria or cells. In the immediate future, the most promising applications may be in plastics and fuels.

Examples of biotechnology applications that have impact on the environment and natural resources include:

- Air, water and soil quality (e.g., biofiltration, diagnostics, bioremediation, phytoremediation)
- Energy (e.g., microbiologically enhanced petroleum recovery, industrial bioprocessing, biodesulphurization)
- Mining (e.g. microbiologically enhanced mineral recovery, industrial bioprocessing,

biodesulphurization)

- Forest products (e.g., biopulping, biobleaching, biopesticides, tree biotechnology, industrial bioprocessing)

The conflict between food and fuel is, at base, an environmental issue. There are many ad hoc initiatives that are attempting to address usually one or other of these, but are in reality counterproductive, at least in the long term. There are also already moves towards much more integrated and coordinated strategies, such as the IAASTD.

EMERGING DISCIPLINES

1. **Bioinformatics. genomics and proteomics, pharmacogenetics, bioimaging**

Bioinformatics:
India, Korea, and to a lesser extent South Africa, have established substantial infrastructures for bioinformatics. Specific techniques include gene shuffling, protein engineering, extremeophiles, molecular breeding, high-level gene expression and protein expression, high-throughput screening, fermentation research, creation of DNA libraries, and subsequent assay development. Bioinformatics holds out strong possibilities of reducing the cost and time of development of new products such as new drugs and vaccines, plants with specific properties and resistance to pests and diseases, new protein molecules and biological materials. As the full genome sequences, data from micros arrays, proteomics as well as species data at the taxonomic level became available, integration of databases formed during genome research require sophisticated bioinformatics tools. Organising these data into suitable databases and developing appropriate software tools for analyzing the same are some of the research challenges.

Genomics and proteomics:
Genetic testing is a growing discipline within the genomics field. Genetic profiles are used to determine an individual's health predisposition. In Europe new applications of genetics are emerging that lie at the interface between *in vitro* fertilisation techniques and pre-implantation genetic diagnosis. Amongst others, Korea is involved in extensive genome and gene therapy research (e.g., gene identification, gene constructs, and gene delivery).

Japan has been concentrating on the development of functional genomics related to health and food and to regenerative medicine and post-genome research. Several countries in Europe (Denmark, Norway, Estonia and Sweden) and also some in the developing world have established biobanks to store information generated during genetic tests.

Pharmacogenetics:
Pharmacogenetics is the study of inter-individual specific genetic variation related to response to medicines. It is often said that pharmacogenetics might enable the pharmaceutical industry to significantly enhance the productivity of drug discovery and development, allowing also the re-evaluation of drugs that have failed because of low response rates in the general population.

India has elected to focus on programmes for understanding the processes underlying molecular genetics and control of gene expression, genetic manipulation of microbes, recombinant DNA products, engineering new protein molecules/new chemical entities, development of immuno-diagnostics and biotechnology of prospective medicinal and aromatic plants.

One important area of research is disease susceptibility gene identification, especially for communicable diseases like leprosy and tuberculosis, noncommunicable diseases such as rheumatic fever, and genetic diseases such as thalassemia.

Bioimaging:

Bioimaging research is an interdisciplinary area that concentrates on developing imaging techniques ranging from molecular to cellular, from single molecule to whole animal imaging, from single-cell analysis of sub-cellular events to high-throughput screening. Living systems have the ability to respond to changing environmental and physiological conditions in a dynamic fashion. Imbalance of these processes leads to disturbed development and disease. The complex cellular and molecular signalling and regulatory processes underlying development and homeostasis can only be understood comprehensively by analysis in the intact living organism. Molecular interactions are frequently transient and context-dependent, necessitating *in vivo* analysis to generate relevant insights into the molecular mechanisms. Biomedical research and drug development have thus an increasing need to analyse and monitor these dynamic processes in cellular physiology, development and disease in the living organism using bioimaging technologies.

Molecular imaging technologies are being developed to examine the integrative functions of molecules, cells, organ systems and whole organisms. The organisms range from viruses to bacteria to higher order species, including humans, and in each case, molecular imaging is used to examine the structure and regulatory mechanisms of their organised functions.

Biomedical imaging refers to methods that open new ways to see the body’s inner workings, measure biological functions, and evaluate cellular and molecular events using less invasive procedures. While X-ray imaging is a familiar example, it represents only one aspect of this fast growing field. Biomedical imaging allows physicians to detect disease and injury at their most curable stage and enables the delivery of less invasive and highly targeted medical therapies. Cellular and molecular imaging techniques combine new molecular agents with traditional imaging tools to capture pictures of specific biological pathways and processes in a living organism. These approaches help researchers study normal biological processes and to diagnose and manage diseases.

Advanced, multimodal imaging techniques, powered by new computational methods, are changing the face of biology and medicine. These new imaging modalities produce information about anatomical structure that is linked to functional data, as described by electric and magnetic fields, mechanical motion, and metabolism. This integrated approach provides comprehensive views of the human body in progressively greater depth and detail, while gradually becoming cheaper, faster, and less invasive. As a result, imaging becomes more common and more familiar, which in turn produces new scientific specialties that rely on particular combinations of imaging, computer science, and medicine.

2. Marine and terrestrial microbial biotechnology

In the US, Canada, Germany and Japan, there is a growing number of institutions involved in the research of microbial biotechnology applications. The application of biotechnologies to micro-organisms is a relatively new area in the discipline. In the expanding search for biological organisms that can be used in the prevention, diagnosis, and treatment of diseases or for industrial applications, companies are investigating marine and terrestrial organisms that have adapted to extreme conditions such as high pressure or heat, or total darkness. In the oceans and in extreme conditions on land, these types of "extremeophiles" and other, better-known types of microorganisms are beginning to provide some commercial biotechnology products. For example, recent studies and research suggest that products derived from diverse microorganisms, including green algae and a painkiller derived from snails, have the potential to be potent weapons in fighting cancer. Other applications include:

- processes related to fermentation, bioprocessing, and biotransformation extractions, purifications, and separations;
- microbiology, virology, and microbial ecology; and
- diagnostic tests and antibiotics.

Inspired by the mechanisms of sea urchins and Venus flytraps, researchers in the US have developed a new gel that could be used to make microscopic drug releasing devices and water-repellent clothes.

The economic potential of the sea as a source of novel genes and gene products, biopolymers, novel enzymes, new therapeutic leads, and other value-added products such as osmo-tolerant crops, has hardly been explored. Marine organisms also present immense potential as biosensors for pollution monitoring as well as bioreactors for production of novel products. The study of deep-sea organisms including marine microbes may well have tremendous implications for human health. Bioprospecting from marine bioresources are common research activities in South Africa, Korea, New Zealand and Australia.

In Finland, facilities have been established to offer support and services in bioprocess development and production of biomolecules by way of different fermentation strategies with micro-organisms, plant cells and eukaryotic cells. The activities include molecular genetic work, production of recombinant proteins and purification of cellular components.

3. Nano-biotechnology

Nanosciences and nanotechnology are important for underpinning the advances in life sciences and biotechnology. The convergence of inorganic nanotechnology and biotechnology into nano-biotechnology has the potential to yield breakthrough advances in medical diagnosis, targeted drug delivery, regenerative medicine and chemicals screening.

Europe is establishing a nanotechnology research platform and the priority research areas chosen include:

- nanodiagnostics including medical imaging
- targeted drug delivery and release
- regenerative medicine.

Integrated nanotechnology research is increasing. An example of such research is the application and integration of nanotechnology, advanced materials and computer science. Nearly every country with a biotechnology strategy is targeting nanotechnology research initiatives that mainly comprise activities in medical applications.

Researchers in India and South Africa are working on developments in novel biomaterials for micro-particle and nano-particle encapsulated drugs, proteins and other molecules. These offer improvement in quality of many therapies with minimal side effects. Nanoscale structured materials and devices hold a great promise for advanced diagnostics, biosensors, targeted delivery and smart drugs. The application of nanotechnology in bioengineering together with biotechnology offers a wide new range of advanced biomaterials with enhanced functionality; and combined with tissue engineering, it has the potential to provide true organ replacement technology.

4. Other

Bionics:

Bionics is an area related to biotechnology where ideas are taken from nature and implemented in new applications and machines. Bionics (also known as biomimetics, biognosis, biomimicry, or bionical creativity engineering) is the application of biological methods and systems found in nature to the study and design of engineering systems and modern technology. Examples of bionics in engineering include the hulls of boats imitating the thick skin of dolphins; sonar, radar, and medical ultrasound imaging imitating the echolocation of bats.

In the field of computer science, the study of bionics has produced artificial neurons, artificial neural networks, and swarm intelligence. Evolutionary computation was also motivated by bionics ideas but it took the idea further by simulating evolution in silico and producing well-optimized solutions that had never appeared in nature. Countries such as Korea have invested extensively into biosensors, biomimics and biomems.

Biodiversity:

Biotechnology is widely utilised to add value to traditional knowledge, as well as to tribal and folk medicine. Medicinal plants are the prime targets of bioprospecting initiatives. The tools of biotechnology are being used for conservation and genetic characterisation of plants. Research efforts of this nature are taking place in Korea, South Africa, India and many other countries in Africa and Latin America. Most research effort is directed at special programmes for the collection, assessment and preservation of the genetic sources of biodiversity.

Stem cell Research:

Stem cell research continues to be a hotly debated and contentious area of biotechnology. Stem cell research involves taking human cells either from human embryos that are less than two weeks old that will never be transplanted into a woman's body, or from the blood in umbilical cords. These stem cells can be used to grow new cells to treat certain diseases in any part of the body. Embryonic stem cells hold promise for the development of organs of the body. Denmark, Italy, UK, Hungary and the Netherlands are the leading European countries in this area of research.

Stem cells are not only obtained from embryos, but can also be taken from adult tissues and organs such as bone marrow, fat from liposuction, regions of the nose, and even from cadavers up to 20 hours after death. These stem cells can grow or differentiate into different cells and tissues of the body. Stem cells have been used in cancer treatments either to grow new healthy cells or eliminate cancerous cells through inducing the generation of a "new" immune system. Thus said, the use of adult stem cells is limited by the fact that there are very small quantities of adult stem cells in the body and they are difficult to isolate. Furthermore, adult stem cells may not have the same capacity as embryonic stem cells to multiply in the laboratory, and they may only be able to develop into certain kinds of tissues.

Concluding remarks

The next generation of biotechnology research involves combining advanced technologies in fields such as nanotechnology, materials and electronics with technologies and know-how in the life sciences. Countries that have a high level of research expertise in biomaterials, bioenergy, bio-ICT and bioinformatics, and the integration of these different fields will be well-positioned to capitalise on opportunities that open up in the intersections of these fields.

Provincial biotechnology trends

During the biotechnology Foresight exercise in the Eastern Cape, Western Cape, and Gauteng, in late 2008 and early 2009, participants in the process provided inputs and feedback on biotechnology trends in their province. These are presented in the three sets of tables below.

For the purposes of these inputs, a biotechnology activity is considered to be part of a trend if all of the following are valid:

- The activity is part of a wave of related activities (or an emerging wave) involving multiple institutions.
- Some generic biotechnology technique, approach, or domain etc. forms a common thread through the wave of activities.
- There is evidence associated with a trend of a growing or sustained momentum, in terms of resources being expended on activities by multiple institutions.

The *Status* of the trend may be described as:

- **Nascent** (there are very early signs of an emerging trend)
- **Emerging** (there is a clear build-up of momentum in this area)
- **Established** (considerable resources have been and continue to be expended in this area)

A biotechnology trend must involve multiple institutions, but these institutions need not all be located in the target province. There are two possibilities:

- **Pioneers**: An institution (or more than one institution) in the target province may be involved in a biotechnology trend that includes institutions outside of the province, either in the rest of South Africa, or internationally. This type of trend will often involve pioneering work, i.e. work that is new globally.
- **Followers**: Several institutions in the target province may be involved in a trend that is local to that target province. Very often this would involve activities that are not novel from a global perspective, but are new to the province (and of some particular value at this time). These institutions are therefore followers, rather than pioneers.

In some cases, participants provided information as to whether the institutions involved in the trends are acting as pioneers or followers.

Eastern Cape biotechnology trends

1 Food, agriculture and animal (livestock) biotechnology			
Activity	**Institution(s)**	**Trend Status**	**Issues & Comments**
Production of natural biopesticides for cereal crops	River Bioscience	Established, pioneer	
Essential oils research to produce suitable cultivars	CSIR, WSU, and essential oils businesses	Established	
Proteomics research	University of Fort Hare & Rhodes University	Nascent	
Molecular structure modelling for drug development	Rhodes University, departments of pharmacy and chemistry, and others	Established	
Tissue culture projects, models and plant propagation	WSU	Nascent	
Sustainability science in the forestry area	Saasveld campus, NMMU	Nascent	

2 Health: Animal & Human biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Use of aloe for applications relating to drug development	African Aloe, Uniondale	Nascent	See also in Table 3 below.
Bioprospecting from sea marine life in the area of marine biology: sourcing new drug candidate from fish and ocean plants	NMMU and Rhodes University	Nascent	

2 Health: Animal & Human biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Chemicals manufacturing	Institute for Chemical Technologies	Nascent	

3. Industrial biotechnology and the Environment and Natural resources			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Industrial farming of indigenous plants e.g. the aloe	South Cape Aloes and a number of other businesses	Established	See also in Table 2 above
Aquaculture: reseeding and rehabilitation of mussels for community sustainability	WSU	Nascent	
Biopesticides	Citrus Research International (research) River Bioscience (production)	Established	

Western Cape biotechnology trends

1 Food, agriculture and animal (livestock) biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Fruit industry: Biomarkers to predict spoilage time (harvest to shelf)	Genetwister	Established: Biomarkers as a predictability mechanism	Drivers include: export industry; food shortages; preference for fresh fruit (as part of a general trend to healthier eating)
Working with small scale farmers to test technology *in situ*	Bio-Africa Merah Mas Industrial Biotech – pioneer Eastern Cape	Nascent: difficulty in convincing industry players of benefits, and in establishing trust. Significant barriers to entry.	Very important: small scale farmers' needs must be identified and addressed, to exploit delocalised 'production units for biotech', to create a win-win situation between agriculture and industrial biotech. Africa's agricultural culture is different to the West or the East, and can benefit greatly from biotech input, BUT we cannot afford to alienate the farmers.
Novel wine yeast technologies and extracts Use of selected yeast strains to (i) reduce chemical antioxidant usage (ii) express nutraceuticals (iii) improve processing .	Institute of Wine Biotechnology	Market trend is the increased commoditisation of wines. Don't believe there is a yeast technologies trend in RSA.	An alternate is the use of the cultivar to impart beneficial properties to the wine
Barley and hops production	SAB	Emerging/Established	Good 'waste nutrients'
Mushroom production and research	Cape Gourmet Mushrooms, Rhodes University	Emerging/Established	This is another good avenue for waste resource utilisation
Aquaculture	SUN, Merah Mas Industrial Biotech	Nascent	

2 Health: animal and human biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
TB research including TB treatment and diagnostics and TB in relation to HIV/AIDS	SUN, UCT, UP, Biotec Labs SA	Established: Trend in point-of-care *diagnostics*, including those that can operate in co-infection scenarios. Nascent: Trend in *therapeutics* appropriate for co-infected individuals.	
The development of molecular diagnostics and medical devices such as digital x-rays and mammography, heating devices, TB imaging and diagnostics.	MRC, UCT, SUN, UP, Medical Devices CoC (CBT)	Nascent: Increased interest in developing and commercialising medical devices locally and building this sector	There are a number of local medical device companies involved too
Investigating immune related diseases such as asthma and allergies	CPGR, MRC	Established	
Investigations into high infant mortality rates due to disease and illness	MRC, UCT etc.	Established	This is a very broad term and it could be said that even NGOs in the WC are involved in social related research in this area
Cardio heart valves	UCT SU	Nascent: Trend in the biomaterials aspect of the device	
Cancer research, including in particular Oesophageal cancer research	MRC, UCT/Groote Schuur Hospital	Established	
Human vaccine development - such as the development of a HIV vaccine, bacterial based vaccines and edible vaccines from plants,	MRC, UCT, NICD etc	Focus on developing HIV vaccines: Emerging trend	
Plant-based production of bio-pharmaceuticals for the production of human and animal vaccines	Azargen, BioVac, Stellenbosch University UCT/CSIR, MRC	Established	

2 Health: animal and human biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Sports medicine research involving: • Tendon risk injury • High performance • Nutritional enhancement • Genetics	MRC, UCT	Established	

3 Industrial biotechnology, including the environment and natural resources			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Bio-control, residue free products (Cryptococcus albulus – post-harvest fruit spoilage prevention)	BCP, Natal Anchor Yeast	Established: Focussed on commercial agriculture	
Natural transition to bio-based energy and chemicals	UCT: CeBER, Merah Mas Industrial Biotech	Nascent: Isolated companies already in existence	
Biofuels and algal biodiesel research	UCT: CeBER, CSIR, WITS, DUT, EBRU (Rhodes)	Nascent	Need viable reactor designs Indigenous species Enhanced productivity Data processing systems development . Cost viability challenges
Rural development driven biofuel economy – incl small scale biofuels production	Government SAPPI, AD research CSIR	Emerging/Established: Biodiesel economy exists	Need, sustainable resources development (algal most NB) and distribution chain development
Using waste as a renewable resource	CeBER, Merah Mas Industrial Biotech	Nascent/Emerging: Research and pilot plant.	

3 Industrial biotechnology, including the environment and natural resources			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Biotechnology for 0% waste policy implementation	CeBER, Merah Mas Industrial Biotech	Nascent. Research level and pilot plant scale. Isolated existing examples worldwide, most notably Scandinavia	Difficult to implement Industrial Ecology as an add-on, but real cost and energy savings are possible when considered from the design stage – so perfect for Africa.
Environmental damage (e.g. seasonal floods and soil erosion)can be fixed through biotechnology to improve rural livelihoods	UCT (CeBER), Merah Mas Industrial Biotech	Nascent: Research level, have been targeted by AGRA (Alliance for a Green Revolution in Africa) as important	Still very early and dependent on community buy-in, but it can be revenue driven

Gauteng biotechnology trends

1 Food, agriculture and animal (livestock) biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Ornamental biotechnology	ARC, Sylvean Biotech	Established	
In vitro culture systems for indigenous crops and development of new and improved protocols	CSIR Biosciences, ARC Vegetable and Ornamental Plant Institute	Established, pioneer	
Plant metabolomics involving nutritional profiling	CSIR Biosciences, ARC, UJ	Emerging	Plant metabolomics in general is an emerging trend, on a range of plants.
Sorghum biofilms for post harvest quality control	CSIR Biosciences, UP Food Science Department	Emerging	Being done in collaboration with EU partners

2 Health: animal and human biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Plant-based vaccine production	CSIR with international collaborators	Emerging	Focus is on production of pharmaceuticals in plants, not only vaccines
Production of biological inoculants	Mycoroot, ARC	Established	Some commercial activity

2 Health: animal and human biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Pharmaceuticals development: - In biologicals (e.g. recombinant therapeutics) - Bioprospecting and drug discovery, in respect of malaria, HIV and TB.	Bioclones CSIR, UP, WITS	Established at the discovery end of the chain Still emerging at the next step (development) Recombinant erythropoietin – pioneer in SA but follower globally Bioprospecting with indigenous plants – emerging	This is a very active area in Gauteng and nationally
Diagnostics development that includes: - antibodies - genomics, proteomics, metabolomics - preventative and intervention genotyping - rapid tests - biomarkers e.g. cancer - high content diagnostics	University of Pretoria, CSIR, UKZN, CPGR	TB diagnostic – nascent Established in some components, newer technologies still emerging	Some activity in Gauteng but probably more in KZN and Western Cape
Development of recombinant vaccines	Biovac, CSIR	Emerging	Not an area of strength in Gauteng
Drug delivery	CSIR, Wits, UP, AMPATH	Emerging Using nanotechnology: Nascent	Drug delivery systems are a major focus in the region. Some use nanotechnology but not all.
Prevention based on genomic profile (personalised medicine)	UP, Wits	Nascent	There is a lot of interest in this area but it still needs to build momentum
Probiotics (first generation – nutraceuticals)	CSIR	Established	
Biobanks – stem cell storage	Netcells, Lazaron and Cryosave, National Zoo, CSIR	Nascent	

2 Health: animal and human biotechnology			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Biobanks – human tissue banks	University of Pretoria ARC	Established	There is considerable emphasis on improving plant gene banking in Gauteng. DNA banking is starting.
Aquaculture namely fish farming, beneficiation of waste to produce fish feed	CSIR	Established	CSIR has strong involvement in this area with various other partners
Markers for breeding and looking for novel traits in cattle, e.g. Nguni	ARC Irene, UP, CSIR	Emerging	There is a specific project being funded by the Innovation Fund concerning Nguni cattle.
Vaccine development in animal health	UP	Established	Mainly UP (Onderstepoort and others) with international partners
Species identification	UP, ARC	Established	Phylogenetics has been a research focus for a long time

3 Industrial biotechnology, including the environment and natural resources			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Cassava as an industrial crop – improved starch content for application in paper production and reduction of cyanide containing compounds	Wits	Established	Wits has a number of partners outside the region
Biopesticides	Wits, UP	Established	
Algal biotechnology for the production of value add products	CSIR	Established	CSIR has various partners within and outside the region
Bio-farming, cell or bio-factories relating to plants and algae	CSIR	Established	CSIR is involved with major international players

3 Industrial biotechnology, including the environment and natural resources			
Activities	**Institution(s)**	**Trends Status**	**Issues & Comments**
Bioprospecting sampling e.g. fynbos and coral reefs	CSIR	Established	CSIR has linkages to a number of players nationally and regionally
Bioprospecting, including microbes and animals	CSIR, UP, Wits etc.	Established	This is a very broad topic and most institutions are involved to some degree
Novel enzymes for industrial application	CSIR, TUT	Established	Some significant international collaborations
Bioleaching using micro-organisms for mining, nuclear and any other waste	Mintek	Established	Commercial processes have been in place for many years already
Industrial – synthetic biology	CSIR, UJ and others	Emerging	CSIR invested in this as an emerging research area with the support of DST. DST is busy developing a national strategy

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Glossary of terms

Bioinformatics	Bioinformatics derives knowledge from computer analysis of biological data. Such data can consist of the information stored in the genetic code, but it can also be experimental results from various sources, patient statistics, and scientific literature. Research in bioinformatics includes method development for storage, retrieval, and analysis of the data. Bioinformatics is a rapidly developing branch of biology and is highly interdisciplinary, using techniques and concepts from informatics, statistics, mathematics, chemistry, biochemistry, physics, and linguistics. It has many practical applications in different areas of biology and medicine.
Biomass	Plant material, vegetation, or agricultural waste used as a fuel or energy source.
Biopharmaceuticals	Simply put, biopharmaceuticals are drugs created by means of biotechnology, especially genetic engineering. They are products which are derived using living organisms to produce or modify the structure and/or functioning of plants or animals with a medical or diagnostic use.
Enzyme	A protein (or protein-based molecule) that speeds up a chemical reaction in a living organism. An enzyme acts as a catalyst for specific chemical reactions, converting a specific set of reactants (called substrates) into specific products.
Gene	The basic biological unit of heredity. A segment of deoxyribonucleic acid (DNA) needed to contribute to a function.
Gene therapy	The goal of gene therapy is to cure a genetic disease by repairing the damaged gene responsible for the disease. It involves introducing a normal copy of the gene into cells containing the damaged version. The cells then can produce the normal protein.
Genetically Engineered Microorganism (GEM)	This term refers to bacteria, fungi, yeast or other microorganisms that have been genetically altered using molecular genetics techniques such as gene cloning and protein engineering. GEMs are a subset of GMOs.
Genetically Modified Organism (GMO)	This term refers to plants, animals or microorganisms that have been genetically altered using molecular genetics techniques such as gene cloning and protein engineering.
Genome	All of the genetic information, that is the entire genetic complement and the hereditary material, possessed by an organism. It is the total DNA present in the nucleus of every cell of an organism.
Genomics	The study of genes and their function. Genomics aims to understand the structure of the genome, including mapping the genes and sequencing the DNA. Genomics examines the molecular mechanisms and the interplay of genetic and environmental factors in disease.

Human tissue engineering — Tissue engineering / regenerative medicine is an emerging multidisciplinary field involving biology, medicine and engineering, and entails restoring, maintaining, or enhancing tissue and organ function. In addition to having a therapeutic application, where the tissue is either grown in the patient, or outside the patient and then transplanted, tissue engineering can have diagnostic applications where the tissue is made *in vitro* and used for testing drug metabolism and uptake, toxicity, and pathogenicity.

Immunogen — A substance that produces an immune response when introduced into the body.

Nano-biotechnology — Nano-biotechnology sits at the interface between the chemical, biological and physical sciences. It is concerned with nanometre-scale systems that may be produced from either a top-down approach, where larger units are disassembled, or a bottom-up approach involving component assembly. Utilising nanofabrication and/or processes of molecular self-assembly, nanotechnology allows the preparation of a range of materials and devices including tissue and cellular engineering scaffolds, molecular motors, and arrays of biomolecules for sensor, drug delivery and mechanical applications.

Pharmacogenetics — The merger of pharmacology and genetics into a field that pertains to the hereditary responses to drugs. It is the is the study of how the actions of and reactions to drugs vary with the patient's genes

Probiotics — Bacteria that are beneficial to a person's health, either through protecting the body against pathogenic bacteria or assisting in recovery from an illness. Probiotics counter the decimation of helpful intestinal bacteria by antibiotics. Probiotics given in combination with antibiotics are therefore useful in preventing antibiotic-associated diarrhoea.

Proteomics — The study of the proteome, the complete set of proteins (their roles, their structures, their localisation, their interactions, and other factors) produced by a species, using the technologies of large-scale protein separation and identification. Proteomics analyses, for example, the proteins of human fat cells , corn leaves, or an organism like the bacteria .