

ESTONIAN BIOTECHNOLOGY PROGRAMME

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ESTONIAN BIOTECHNOLOGY PROGRAMME (BTP)

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1. Name of the programme

The Estonian biotechnology programme (BTP) is a part of the operational plan for the Estonian research, development and innovation (RDI) strategy "Knowledge-Based Estonia 2007-2013" and is the national research and development programme (national RD programme) in the field of biotechnology. The BTP is a cooperation programme between the Ministry of Economic Affairs and Communications (MEAC), the Ministry of Education and Research, the Ministry of Agriculture, the Ministry of the Environment and the Ministry of Social Affairs.

2. Ministries involved and the responsible ministry

The lead ministry for the programme is the Ministry of Economic Affairs and Communications. Pursuant to the implementation plan for the RDI strategy for 2007-2013, the Ministry of Education and Research (MER) is responsible for the general coordination of national programmes as well as for activities related to development of research and development human resources.

The MER, MEAC, the Ministry of the Environment (ME), Ministry of Agriculture (MA) and the Ministry of Social Affairs (MSA) are responsible for implementing the various measures supporting RDI in the biotechnology programme.

Head of the biotechnology programme:

Olavi Otepalu

Enterprise Estonia

Tallinn, Lasnamäe 2, 11412

Telephone: 6279 519

Fax: 6279 701

E-mail: olavi.otepalu@eas.ee

3. Role of the programme

The role of the BTP is the following:

- to stipulate the priorities in the field of biotechnology-related research and development, to develop funding priorities on the basis thereof as well as to direct the development of biotechnology as an economic sector in the above-mentioned priority development areas.
- to coordinate the implementation of priorities in the Estonian biotechnology sector (RDI).
- to offer policy planners a regular, comprehensive overview of key indicators in the biotechnology-related higher education, research and entrepreneurial sector.
- to notify entrepreneurs of the national priorities in the biotechnology sector.
- to create the preconditions for the more flexible processing of projects in implementing agencies organizing financial instruments.
- to improve cooperation and exchange of information between ministries in the field of biotechnology.
- to increase, for the purpose of promoting technology transfer, the awareness among Estonia's traditional economic sectors and the public sector regarding the opportunities for implementing biotechnology and related economic prospects, while at the same time increasing the readiness for wider adoption of biotechnologies.
- to plan and develop cooperation within the biotechnology sector, between the sector and the state, and internationally.

4. Programme objectives and expected outcomes

In order to strengthen the Estonian economy's competitiveness and sustainability, it is important to stimulate the development of biotechnology firms that create higher value added and productivity in business areas that have the potential to significantly increase the export of innovative products and services.

As a result, the biotechnology programme focuses above all on identifying which activities to use in order to increase the level of value added in the biotechnology sector and export volumes by 2013 while increasing the proportion of the biotechnology sector in Estonia's economy. To attain these target levels, it is very important that the Estonian biotechnology sector would be able to exit the incubation phase and achieve a noteworthy critical mass in terms of sales revenue, number of employees and amount of private sector RD investments. In the long term, an additional precondition for growth of value added and export volume is that biotechnologies are more actively adopted in the Estonian traditional economic sectors. However, in order to achieve readiness in this regard, it will be initially necessary to significantly increase awareness of the possibilities for implementing biotechnologies and the economic prospects.

Expected outcomes of BTP:

- In the priority development areas in the biotechnology sector, a critical mass of financing and people with the requisite skills has been achieved, which allows the growth-related needs of local companies to be met in accordance with their development phases and to participate increasingly actively in international division of labour.
- In the priority development areas of the biotechnology programme, Estonia has become one of the Baltic Sea region's most attractive centres and cooperation partners.
- Awareness of biotechnologies has grown significantly in Estonia's traditional economic sectors and in the public sector. In order to ensure the growth of competitiveness of Estonia's traditional industry, the relevant sector will make increasing use of biotechnology applications for producing and developing products, services and technologies with higher value added and export potential.

Specific BTP target levels for 2013:

- The total sales revenue of the Estonian biotechnology sector from the sale of products and services and commercialization of intellectual property created has grown fourfold.
- The export volume of the Estonian biotechnology sector has grown 3.5-fold.
- Value added in the Estonian biotechnology sector has grown fourfold.
- The number of employees in the Estonian biotechnology sector has grown by at least 50%.
- The average volume of RD investments per year has grown at least fourfold in the biotechnology sector, with the proportion of the private sector having grown consistently in total RD investments.
- Adoption of new biotechnologies in traditional industry and the public sector.

To measure the aforementioned outcomes, the total volume from the outcomes in 2004-2008 and/or the average level will be compared to outcomes from the 2009.-2013 period. The impact of the programme is analyzed in the programme annual reports, the 2011 interim report and the programme final report. Assessment of the programme's impact in fulfilling these objectives requires thorough analysis. The BTP target levels are related to the existing basic level of information regarding the Estonian biotechnology sector, which to this point does not include quantifiable data on the Estonian foodstuff industry's biotechnology products.

It should be borne in mind that the economic impact of the indicators related to development of human resources will emerge only in the long term. On the other hand, the outcomes related to sales revenue and export volumes can be impacted within the given period by skilful and extensive support for commercialization of RD projects that are predominantly already completed and/or to be completed in the next few years.

In the years ahead, it will be important to pay more attention in BTP activities to the following critical success factors¹:

- to raise significantly the capability of managers and top specialists in the field of strategic management of protection of intellectual property at biotechnology firms, technology transfer units and research institutions.
- to develop an integrated financing chain that takes into account the life cycle of biotechnology firms as well as to create opportunities to regularly introduce outstanding RD projects to international investors.
- to draw major attention to increasing the business development capability of corporate heads and marketing specialists.
- the restructuring of technology transfer units into centres that are capable in terms of competencies and experiences (patenting, marketing, product development and business administration) to provide multifaceted support for realizing promising scientific ideas in all phases of the process.
- to develop a procedure for the purpose of assessing RD grant applications that would allow the focus to be placed on identifying and supporting technically outstanding RD projects that are of exceptional quality and have the strongest economic potential.
- to promote and support activities aimed at exchanging experiences with international biotechnology firms and academic delegations.
- to stimulate the flow of people working in RD between research institutions and companies, especially among different research areas.
- supporting awareness in the public sector and traditional economic sectors regarding potential for adoption of biotechnologies and creating the necessary readiness for adoption of biotechnologies.

5. Programme supporting documents

The Estonian biotechnology programme was developed on the basis of the Estonian RDI strategy “Knowledge-Based Estonia 2007-2013”.

The following strategic documents and studies were taken into account in developing the Estonian biotechnology programme:

- National strategy for use of structural funds 2007-2013 and implementation plans prepared for this purpose (Operational Programme for Human Resources Development and Operational Programme for the Development of the Economic Environment);
- implementation plan (for 2009-2013) for the Estonian RDI strategy 2007-2013, “Knowledge-Based Estonia”;
- Operational plan for 2009-2012 for the development plan “Estonian Entrepreneurial Policy 2007-2013”;

¹ Feasibility Study for an Estonian Biotechnology Programme, Ernst & Young, 2009.

- Industrial research study entitled “Feasibility Study for an Estonian Biotechnology Programme” (Ernst & Young, 2009) and related supplementary materials;
- The Estonian biotechnology strategy 2008-2013 prepared by the Estonian Biotechnology Association;
- Other international and Estonian biotechnology sector related research and reports.

6. Description and analysis of the biotechnology sector

6.1. Definition of biotechnology and biotechnology firm

Definition of biotechnology

In accordance with the general OECD definition, biotechnology is defined as “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services”.

To more precisely define modern biotechnology, the OECD simultaneously uses a list-based definition of biotechnology techniques. The Estonian biotechnology programme proceeds from the same terminology for the purposes of defining and delimiting biotechnology.²

Definition of biotechnology firm

A *biotechnology firm* is defined as a firm that uses at least one biotechnology (as defined in the OECD list-based definition of biotechnology techniques) for producing products or providing services and/or for biotechnology-related RD activities.

In the case of some firms, the activities related to biotechnology techniques make up only a very small part of their economic activities. Thus it has been considered expedient to classify biotechnology firms as belonging to one of two sub-groups³.

1. *Dedicated biotechnology firm*: a company where the application of biotechnology techniques for producing products or providing services and/or RD activities is related to the company’s primary activity.
2. *Biotechnology RD company*: a company that carries out biotechnology-related RD activity. A *dedicated* biotechnology RD enterprise is a company that devotes at least 75% of its RD activities to biotechnology-related RD.

Mapping of the Estonian biotechnology sector and the gathering of corresponding data is based on the definition of “dedicated biotechnology firm” and “dedicated biotechnology RD enterprise”. This approach is due to the small size of the Estonian biotechnology sector, but use of a broader definition would give a distorted picture of the biotechnology sector’s economic indicators. For this reason, similarly to the case in many other OECD countries, companies that are engaged in merely resale of equipment and accessories or providing sales-related consultations are excluded from the category.

6.2. The international context and world trends

Biotechnology as a future fundamental technology

Viewing today’s investments into biotechnology and the potential areas in which biotechnology can be applied in today’s world, there is reason to believe that biotechnology can be transformed into a fundamental technology (in the next 10-20 years) that can be applied in essentially every sector of the economy and all walks of life: medicine, food processing industry, agriculture, the timber industry,

² OECD Biotechnology Statistics 2009.

³ Ibidem.

chemical industry, energy, information technology, environmental protection, et cetera. This will in turn help raise the quality of life and economic productivity - similarly to information technology, the extensive adoption of which has accounted for about one-half of the growth in productivity of the OECD countries' economies in recent years.

The biotechnology sector cannot independently develop without synergy between different walks of life. Knowledge of biotechnology and the ability to use it will become not only a competitive advantage but a requirement for surviving amid 21st century competition.

Areas in which biotechnology can be applied

Biotechnology is generally classified as the following on the basis of the area of application:

- red – biotechnology used in medicine, one branch of which is protection against bioterrorism and the corresponding technologies to combat and prevent terrorism.
- green – biotechnology used in agriculture, environmental conservation and the food processing industry.
- white – biotechnology used in traditional industries such as the chemical industry, textile industry, forest industry and electronics industry.

The pharmaceutical industry has for decades been the leading sector in the application of biotechnology. Because it is not only developing rapidly but is becoming amalgamated with the traditional sectors of industry, economists consider biotechnology to represent a new technological paradigm. One forecast from McKinsey & Co calls for the value added generated through biotechnology in the chemical industry to rise to 22 billion dollars by 2010. Of this amount, 6-12 billion dollars stems from a decrease in the cost of production (lower prices on commodities, energy, investments) and 5-10 billion dollars will come from the value added (new materials, new value chain)⁴. The market in the field of "functional food" is seen as promising and rapidly developing in connection with growing consumer expectations that food should have health-supporting qualities⁵.

The extensive application of biotechnology in agriculture is limited in Europe by strict regulations and public scepticism about GMOs. As a result it is understandable that the genetically modified harvest yield terms of Europe's total arable cropland is extremely marginal according to OECD's 2009 statistics compared to the other continents (such as North and South America) and that this is the reason that 75% of the outdoor crop trials conducted by European research institutions and enterprises have taken place outside the region. Even though GMO is a key development direction, the use of biotechnology in agriculture extends far beyond GMOs. For instance, plant breeding in Europe is based on biotechnology (use of tissue culture, haploids and marker breeding).

General indicators and development directions for the biotechnology sector

Biotechnology is the world's fastest-growing economic sector. In 2005, the 4100 companies in the biotechnology sector employed over 5 million people, over 100 genetic technology pharmaceuticals had been introduced, the annual growth in the sector's turnover was 15% and RD expenditures were more than 34% of the sector's total sales. A number of multinational consortiums⁶ have developed biotechnology as an independent business sector.

⁴ Riese, J. (2006). *Industrial Biotechnology – Turning Potential into Profits*. McKinsey & Co.

⁵ Feasibility Study for an Estonian Biotechnology Programme, Ernst & Young, 2009.

⁶ Beyond Borders: Global Biotechnology Report, Ernst & Young, 2006.

In the first quarter of this century, new factors steering the pharmaceutical industry – the driving force behind the biotechnology sector -- will be an increase in health care costs, which exceed 15% of the gross national product in the US, the advent of personal medicine, the rise in the cost of drugs, the ageing of the population and growing demand for medicines for chronic illnesses, the increase in the importance of genetic drugs, the inability to treat about 50% of diseases, and so on. One of the most important roles in health care is played by convergence with the food processing industry, which produces biotechnology solutions using “functional food”.

In most areas of application related to biotechnology, continued growth and expansion is forecast. In a number of fields, the technological platform is being upgraded or replaced with new one, for instance development of biomarkers, new forms of therapy, new forms of therapy, new generation DNA sequencing technologies, RNA, and 2nd and 3rd generation fuels.

Potential economic impact of biotechnology in the longer term

At the moment, biotechnology is thought to account for less than 1% of the GDP of OECD countries, yet its potential economic value could be much greater. By 2030, biotechnology could make up 2.7% of the GDP of the OECD countries, which exceeds 1 trillion USD⁷. It is likely that biotechnology will play an even somewhat larger role in the future in developing countries: forecasts call for the industrial sector and commodities sector to outstrip the health care sector in terms of the economic impact of biotechnology, although due to liquid Western markets and concentration of qualified researchers, the developed countries will continue to be a predominant role in the health care.

The maximum economic impact of biotechnology by 2030 is estimated at 5.6% in the European Union and 5.8% in the US⁸: That is the same as the total volume of these regions’ commodities sector, health care sector and industrial sector that were able to use current or potential biomass and biotechnology applications in 2004. It is nevertheless possible that these indicators underestimate the actual potential of biotechnology in 2030 and that the actual impact could prove larger, for these calculations omit bio fuels, increase in value added from these applications, as well as new possible applications that are as yet unimaginable and whose impacts are not measurable in financial terms. The percentage of biotechnology in the OECD region in 2030 is projected for various applications as follows: up to 80% in the case of medicines, up to 50% for commodities (agriculture, fisheries, forestry), and up to 35% in chemistry products.

Potential percentage of biotechnology in the areas of application

Potential value added in biotechnology is projected to be greatest in 2030 in the industrial applications field (39% of the value added generated through biotechnology) followed by the commodities industry (36%) and only then by health-related applications (25%). This vision is in sharp contrast to the distribution of RD expenses to this point: according to 2003 data 87% of RD expenses were related to health care applications, 4% to the commodities industry and just 2% to the industrial sector⁹. From this, we may conclude that investment into RD related to biotechnology does not conform adequately to potential marketing opportunities. The situation that has taken shape may partly reflect the higher productivity of RD in the commodities sector and in industrial biotechnology as compared to that of biomedicine; a supportive regulatory environment, suitable stimuli, and lack of supplementary public sector investments or qualified research staff may also play a role.

⁷ The Bioeconomy to 2030, OECD, 2009.

⁸ Ibidem.

⁹ Ibidem.

As a consequence of consistent growth in the health care sector, the primary strategic risk for the health care sector is strong price control pressure and access to new health care technologies. If downward pressure on health care sector revenue increases, this will decrease incentive for research and development, except for where new technologies have potential to cut health care costs.

The specifics of the biotechnology sector

A specific feature of the biotechnology sector is the relatively large start-up investments and long payback period. Two parameters must be assessed to assess development in this sector – the economic growth of biotechnology as an economic sector and the technological maturity of biotechnology. Consultants in the field consider the so-called cross-border phases to be a new stage in the development of biotechnology at the beginning of the 21st century¹⁰:

- The prerequisite and driving force behind the development of biotechnology itself is convergence between various branches of science, which has led to new disciplines such as system biology, proteomics and theranostics. It is not only biologists who are involved in developing biotechnology products, but also technology engineers from many different disciplines, ranging from chemical engineers to engineers who develop internal combustion engines.
- Biotechnology is transcending national boundaries – development work and production are both seeing strong growth not only in Europe and North America but in Japan, India, China, Brazil, Australia and New Zealand as well.
- Modern biotechnology has grown beyond its initial area of application in medicine and the pharmaceutical sector – technologies that were once only used in health care are now seeing increasing use in agriculture, the food processing industry, textile industry, defence contracting, and other fields.
- Biotechnology is transcending product boundaries, which means that new biotechnology products have become market leaders and changed application strategies significantly. The best example of this is the rise of personal medicine, based on diagnosing the sensitivity of the individual patient to medications and determining the suitable medication.

A new trend in biotechnology is cooperation with large pharmaceutical companies (above all, this means that large drug companies finance the development), and mergers and acquisitions. Compared to 1999, the number of such transactions had doubled by 2005. In 2004, a total of 33.9 billion dollars¹¹ in investments necessary for development operations had been placed with US biotech companies through the stock exchange, venture capitalists and partnership transactions.

US companies and research facilities are in the world's biotechnology vanguard. A total of 75% of the sector's turnover is generated in North America. Compared to Europe, US biotech companies have twice as many employees, triple the RD spending, 3-4 times greater venture capital participation, four times the loan capital and twice the sector profitability. The strong advances of biotechnology into Asia makes the situation faced by Europe's companies and research facilities even more complicated. The greatest development barrier in the European biotechnology sector is underfinancing, especially with regard to the lack of suitable financial instruments for starting a business. As a result, many companies wind up after 3-5 years of operation. Whereas in 1990, Europe invested 50% more into pharmaceutical research than did the US; by 2001, the situation had turned around with the US investing 40% more. The strategies of European and US biotechnology companies are founded on creation of strong intellectual and industrial property portfolios and the percentage of companies that offer services is low. The European biotechnology sector did garner 21.2 billion euros in investments in 2004, but young and

¹⁰ Beyond Borders: Global Biotechnology Report, Ernst & Young, 2006.

¹¹ Ibidem.

recently founded companies that focused on RD in their start-up phases suffered from underfinancing. Unfortunately, investors and venture capitalists do not see RD as a source of quick profit. Yet the economic development of biotech firms would not be conceivable without RD and thus financing for both academic institutions and companies is of critical importance.

6.3. The Estonian context

Estonia's general position amid international competition

Due to the small size of the country and its limited resources, Estonia is not capable of competing with the US, the Nordic countries and leading Western European countries with regard to the volume of investments directed into biotechnology. In any case, Estonia's biotechnology sector is only in the incubation phase, and it will take years to reach the developed sector stage. Thus it is not realistic for the Estonian state to compete with large countries either in developing fundamental technologies or laying the groundwork for new economic sectors. But it is possible and necessary for Estonia to become an active implementer of new biotechnologies created elsewhere, analogous to the developments of the last decade in information technology, and thereby to take active part in the development of biotechnology and using the economic advantages generated thereby, including in Estonia's traditional economic sectors (such as agriculture, forestry and timber industry and the food processing industry). In order to compete and remain in competition with the other countries involved in developing biotechnology, Estonia must take advantage of all of its strengths (for example, thanks to investments 20-30 years ago, Estonia has a considerable amount of people competent in the field of biotechnology) and advantages stemming from its special character -- and it must invest in filling in the missing links.

The current status of higher education and science in the biotechnology sector

Estonia has eight research institutions where in the strict sense of the word 300 researchers are engaged in biotechnology. Besides this number, 4000 students are studying life sciences; each year 700 of them graduate and 300 are in master's or doctorate degree programmes. The number of state scholarships for natural and physical sciences students remained on the same scale in the period 2002-2006. In the period 2002-2007 about 120-140 people a year¹² graduated from programmes in genetic technology, biotechnology or food technology, molecular technology, molecular and cellular biology with degrees enabling them to enter the job market.

After Estonia joined the European Patent Organization on 1 July 2002, and in connection with the founding of biotechnology companies, patenting and commercialization of patents have both increased significantly. Biotechnology companies are not only patenting more than academic research institutions (35 and 24 protected inventions, respectively) but the patent strategies and routes for commercializing inventions and capabilities are also different.

Enterprise in the biotechnology sector

The companies active in the biotechnology sector can be classified as follows:

- 1) companies that sell goods and services,
- 2) companies aimed at RD.

Over 55 biotechnology companies had been registered in Estonia as of November 2007, which is per capita more or less the same as the average number for European countries. There are about 30 companies engaged in RD, and one-third of them were founded in 2005-2007.

¹² Kukk, P. & Truve, E. (2008). *Eesti biotehnoloogia strateegia 2008-2013*. Tallinn: Eesti Biotehnoloogia Liit.

In 2006, biotechnology companies that sold RD products had 209 employees¹³ and in 2008 companies that were related to biotechnology in the strict sense of the word had 315 employees (423 including technology development centres)¹⁴. Biotechnology companies thus tend to be small – companies with less than 10 employees. The growth of sales revenue was 16-44% per year from 2002-2006 (sales companies and RD companies together). The sector's estimated revenue was around 243 million kroons¹⁵ in 2008, with a few dozen companies boasting sales revenue over 1 million kroons. Two-thirds of the RD companies with sales turnover exported over 75% of their output. The growth of the companies in terms of both the number of employees and sales revenue was 15-20% a year in Estonia, which is similar to the growth rate for US biotech companies. However, in absolute terms, what sets Estonian companies apart from US companies is that their turnover was 100 times smaller.

Around three-fourths of the RD investments made by Estonian companies were related to developing industrial research studies and products. The biotechnology sector, where 18% of net turnover was spent on innovation, exceeds Estonia's average figure for intensity of innovation by more than sevenfold¹⁶. Companies' patent portfolios contain patent applications and patents from around 40 different patent families. Of the RD companies founded before 2005, 50% have a patent portfolio, while 90% of the companies founded in the last two years have a patent portfolio. At the same time, RD companies have weak capacity for commercializing new technologies and a weak competency base in the area of international marketing and sales and technology management.¹⁷

As of today, biotechnologies are still an area that has seen relatively little application in the food processing industry. Yet the sector's future competitiveness is sure to be determined by nutritional genomics, product functionality and healthfulness, which can only be ensured if RDI is promoted. The food processing industry in Estonia makes up 2% of GDP and about 15% of the total output of the processing industry (of which dairy industry had the greatest percentage in 2008 with 26.3%, followed by beverage industry with 19.3% and the meat industry with 18.9%)¹⁸. Estonia's dairy industry, which as of today exports one-third of its output and whose trade balance has remained positive in the last decade, is looking with greater activeness for possibilities of adding healthful functionality to dairy products. Even though the contribution of the food sector to RD has been relatively uneven, something of an increase in internal RD spending can be seen when looking at the long-term view: 41 million kroons in 1998-2002, and 153 million kroons in 2003-2007¹⁹.

¹³ **Ibidem.**

¹⁴ Source: statistics from the economic analysis division of the Ministry of Economic Affairs and Communications 2009.

¹⁵ Source: statistics from the economic analysis division of the Ministry of Economic Affairs and Communications

¹⁶ Estonian Institute for Future Studies (2006). „Innovaatiline tegevus Eesti ettevõtetes 2002-2004.“ Tallinn: Enterprise Estonia.

¹⁷ Kukk, P. & Truve, E. (2008). *Eesti biotehnoloogia strateegia 2008-2013*. Tallinn: Eesti Biotehnoloogia Liit.

¹⁸ Source: Association of Estonian Food Industry, 2009.

¹⁹ **Ibidem.**

Support for RD has critical importance for the competitiveness of Estonia's agriculture sector as well. Estonia's agricultural trade balance was last positive in 1994 and this has been followed by an increasingly clearer period in which agricultural imports have outstripped exports. A negative trade balance is above all the result of the critical condition of animal husbandry in connection with difficulties staying afloat in competition with regard to meat production. The grain products trade balance, which turned negative a couple years ago – immediately before accession to the European Union – has again remained positive, and in recent years, exports have outstripped imports by three- to fourfold. Plant breeding has an important role in preserving the competitiveness of grain products.

Public sector action supporting the development of the biotechnology sector

The largest programmes in European Union structural funds in 2007-2013 are the research institution infrastructure programme in the areas of administration of the MER (2.12 billion kroons), the research equipment modernization programme currently in preparation (1.55 billion kroons), the state-of-the-art research centre programme (700 million kroons) and various measures related human resources to development and the CC programme in the area of administration of the MEAC (1 billion kroons) and the RD projects programme (more than 1 billion kroons).

Financing for the biotechnology sector makes up a noteworthy share of many public sector programmes. For instance, of Estonia's eight CCs (competence centres), four are related to biotechnology: Competence Centre for Food and Fermentation Technology, the Bio-Competence Centre for Healthy Dairy Products, the Competence Centre for Cancer Research and the Competence Centre for Reproductive Medicine and Biological Technology. The total amount covered by financing decisions for these CCs in 2008 was more than half a billion kroons. Biotechnology plays just as significant a role in funding top research centres. Of the total amount of funding for RD projects in 2008-2009 (322.5 million kroons) more than 40% was allocated to the biotechnology sector (more than 130 million kroons)²⁰. Financing of biotechnology sector human resources has started quite well (for instance, measures aimed at bringing in top researchers, post-doctorates and doctoral candidates from abroad). A number of the MA's RD programmes (plant breeding programme, applied agricultural research and development activity programme, cooperation in the field of developing new products, methods of processing and technologies in the agriculture, food and forestry sectors) are likewise aimed at the application of biotechnology methods in agriculture and the food processing industry.

In the earlier period as well, financing of the biotechnology sector has been quite outstanding compared to other technology fields. At the same time, the view of the biotechnology sector is that based on the sector's current development phase, the measures with the highest grant application approval rate (such as the export plan programme) are less important than measures that have a lower grant application approval rate (such as the RD project grant programme).

Biotechnology research studies were funded from 2002-2006 by Enterprise Estonia in the amount of 124 million kroons (80 million kroons went to academic institutions and 44 million kroons to companies) and from the EU's Sixth Framework Programme in the amount of 133 million kroons (21 projects at academic research facilities and 9 at companies)²¹. In addition, there are research grants distributed by several foreign foundations along with targeted and fundamental financing distributed by the state and Science Foundation research grants.

Considering total state and company funding for bio-science as a total, biotechnology funding for fundamental research, industrial research and product development breaks down at a ratio of 11:5:1,

²⁰ Source: Ettevõtluse Arendamise Sihtasutus, 2009.

²¹ Kukk, P. & Truve, E. (2008). *Eesti biotehnoloogia strateegia 2008-2013*. Tallinn: Eesti Biotehnoloogia Liit.

which is opposite to the expense structure in industrialized countries²². For this reason, one of the objectives of BTP activities is to put a stronger emphasis on applicability and commercialization. Unlike funding for the Finnish biotechnology sector, where 28% of the funding for research comes from the state, 69% from companies and only 3% from outside Finland (mainly from EU framework programmes) and where the percentage of state funding is considered too low even though funding is approaching 4% of GDP, most Estonian biotechnology companies are able to direct just 15.7% of their sales revenue into RD activities (the respective percentage in the US is 45.7% and 60% in the EU)²³. This has more to do with the low sales revenue of Estonian companies and does not indicate low readiness on their part to invest in RD activities.

Development problems and needs in the biotechnology sector

Based on the reasons mentioned above, Estonia still has very few knowledge-intensive biotechnology companies and practically no biotechnology products that would generate considerable economic benefits. At the same time, the state invests a large part of its RD funds into fundamental and industrial research but only limited resources are directed into promoting product development, marketing and sales. This fact unfortunately stems from the specific character of the current development level of the Estonian biotechnology sector. Most Estonia biotechnology companies specialize in providing a simpler range of services due to limited human and monetary resources. When we compare the sources of funding available to companies at their founding, we see that Estonian companies have not had an opportunity to obtain seed capital. As a result, Estonian companies' business models put the emphasis on provision of services. Estonian companies lack the opportunity to involve venture capital and thus the resources they need for RD must be earned from the sale of services and goods.

According to a subjective evaluation obtained from a survey of managing directors of companies²⁴, biotechnology companies lack specialists with marketing and sales experience (score of 1.4-1.6 on a scale of 5) and business executives with the relevant training and experience. Some sectors are noteworthy for the low absorption capacity of innovation: whereas research in biotechnology takes place equally in companies and academia, industrial research has received funding at universities in the food processing industry and agriculture, but in industrial sectors the readiness for innovation is low (there are few projects). To this point, the biotechnology sector has not been able to attract funding freed up from other sources. Within the biotechnology sector, agricultural biotechnology in particular has been underfunded (plant and animal breeding, agricultural plant and animal physiology, veterinary science and phytopathology etc), the same is true for development of industrial biotechnology, including creation of the relevant core laboratories.

To sum up, Estonia is characterized by a structural discord: traditional industry with its significantly lower RD capacity for adoption of biotechnologies is economically stronger than the biotechnology sector, where economic strength and business innovation capacity is in short supply. The BTP activities will be used to try to alleviate this discord.

²² Ibidem.

²³ Ibidem.

²⁴ Kukk, P. & Truve, E. (2008). *Eesti biotehnoloogia strateegia 2008-2013*. Tallinn: Estonian Biotechnology Association.

7. Programme priority development areas

The priority development areas of BTP are the following:

- functional food
- food processing
- molecular diagnostics
- drug discovery technologies

More flexible mechanisms are being established for preferential development of BTP priority areas (subsidiary budgets, bonus points in evaluation criteria etc) for horizontal measures and/or additional forms of cooperation.

Functional food

The functional food category includes products that in addition to their conventional nutritional functions contain specific physiological active components or possess qualities derived from the use of biotechnology. Probiotic products are an example: they promote health, prevent disease and/or increase well-being.

Food processing technologies

Food processing is the collective term for biotechnology methods and techniques used to transform raw material into food and to turn food into forms suitable for human or animal consumption either in domestic households or industrial production. Use of certain types of enzymes for their catalytic effect is very common in the food processing industry. Food quality and aspects related to food safety are also included in the given BTP development area.

Molecular diagnostics

Molecular diagnostics encompasses tests and methods used on the molecular level to establish disease or propensity for disease. Various types of biomarkers are actively used in molecular diagnostics, used to diagnose and determine illness and to prognose the course of a disease and response to medication.

Drug discovery technologies

Drug discovery is a process that takes place in the early phase of drug development in which the drug is discovered and/or engineered. The phase covers identification and validation of targets, the search for drugs with mutual interactions, optimization of the properties of the drugs for generating molecules of the drug and pre-clinical trials for carrying out drug development.

8. Measures for achieving the objectives

The relevant field is supported in the framework of the national RD programmes through four sets of measures:

- 1) developing RD human resources
- 2) supporting RD
- 3) supporting technology transfer
- 4) supporting joint efforts, services that add value

8.1. Developing research and development human resources

Above all, additional funds will be directed toward activities that ensure the mobility of university students, researchers and other specialists (for instance bringing post-doctorate researchers and top researchers to Estonia). The development of curricula will also be supported along with involvement of top specialists in academic work (involvement of specialists from both the academic and non-academic sphere from Estonia and abroad).

Particular attention will be paid to promoting doctoral studies, including doctoral candidate programmes in cooperation between universities and companies, training foreign doctoral candidates in Estonia, funding doctorate programmes, opportunities for doctoral candidates to study abroad once during their studies (semester abroad). The activities under this measure are aimed at bolstering human resources at institutions that already have a high research calibre as well as restructuring the weaker structural units with the aim of creating an institution of a high research calibre in the relevant field (study group, laboratory, institute etc).

8.2. Supporting research and development

The research grants awarded by the Estonian Science Foundation support fundamental research studies that focus on the above areas and have a longer-term economic output (patents, licenses) or were commissioned by the state (e.g. in the field of plant breeding or environmental monitoring). The development grant creates an opportunity for bringing to Estonia the development units of large (foreign) corporations – that is, research groups and topics of a high research calibre are supported on condition that enterprise is also involved. Structural grants support the creation of an institution of a high research calibre in the relevant field (including support for infrastructure development). The abovementioned ways of developing RD human resources can be used to develop the human resources necessary for establishing the institution.

The Enterprise Estonia scheme for supporting research and development projects is used to support the research and development projects that have the highest technological risk and are aimed at the entrepreneurial market. The CC (competence centre) programme promotes strategic cooperation between companies and research institutions in the field of industrial research through jointly established institutions in the private law. The development staff recruitment measure supports growth of companies' international competitive ability. Export and marketing measures, Enterprise Estonia's international offices and international cooperation networks are used to support the sale of new products, service and knowledge on international markets.

In the area of administration of the Ministry of Agriculture, the development and application of new varieties and methods is supported through the agricultural industrial research and development programme and the plant breeding programme. In addition, measure 1.7.1 is being opened: "Cooperation in the field of developing new products, methods of processing and technologies in the agriculture, food and forestry sector".

8.3. Supporting technology transfer

The proof-of-concept scheme (a part of the SPINNO programme), developed by the MEAC and implemented by Enterprise Estonia, is used to support the pre-commercialization phase for innovative ideas with market potential evolving out of the RD conducted at RD institutions. In the course of this phase, the technological feasibility and costs and benefits of the idea are tested and the most suitable commercialization strategy is selected (spin-off, sale of licenses etc).

To support the broader adoption of biotechnologies, companies operating in Estonia's traditional economic sectors (such as agriculture, forestry, timber industry, food processing) are provided information, in cooperation with the relevant professional organizations, about events that introduce biotechnology applications. Funding comes from the Enterprise Estonia knowledge and skills development programme measure. The activities related to preparation and launch of the new technology transfer direction revolve around introducing suitable applications and identifying their economic prospects, and – in case of interest from the relevant sector -- supporting pilot initiatives necessary for adoption of the application, training people connected to the adoption of the technology, bringing in top researchers and development staff, developing corresponding curricula at universities and, if necessary, supporting availability of funding necessary for the relevant technology investments. Building the necessary RD competencies in the area of technology transfer is supported by ESF funds allocated to the biotechnology sector, including in fields important for the public sector (such as application of tissue culture, haploids and marker breeding methods in plant breeding, use of molecular diagnostics in phytosanitary fields, veterinary medicine and food safety, metagenomic environmental monitoring, and food safety and quality). The existence of modern infrastructure and scientific equipment is just as important in these fields. With regard to agricultural research, support is given to RD related to adoption of new technologies (through the MA), to modernization of infrastructure and development of human resources in the necessary fields (Archimedes, MER) and to cooperation in the field of new products, processing methods and technology (ARIB).

8.4. Developing joint efforts and services that add value

As a component of programme management, activities are carried out for the purpose of raising awareness of biotechnologies and their economic prospects (development monitoring, mapping technological development, profitability analyses etc), for developing the sectoral strategy, developing partnerships both within the sector and between the sector and the state (seminars, workshops, study trips etc) and introducing the programme objectives and outcomes to the public. Also important is cooperation and exchange of information with other state RD programmes, especially with regard to topics that overlap (the information technology programme in the case of bio-information science and parties to the energy technology programme in the case of bio-energy). BTP activities are used to help support the improved visibility and prospects of the Estonian biotechnology sector on the international level, by participating actively in international events and establishing contacts with international and national associations of biotechnology companies and business angels and associations of venture capitalists.

9. Programme areas of emphasis

9.1. Programme areas of emphasis according to BTP objectives

BTP activities are implemented with the focus on the objectives approved by the BTP steering committee and achieving the target levels related to these objectives. With regard to implementation of state aid measures, it is also important to take into account with sufficient flexibility the specific current status and specific problems in each development priority area.

- To double sales revenue and export volumes, the focus is placed on aid measures related to support for commercialization of RD projects that have been completed or are to be completed (export marketing, joint marketing and foreign trade fair support, marketing staff involvement measures, cluster development grant) and supporting activities (entrepreneurial studies and related supporting activities, Enterprise Estonia international office services, international cooperation networks, biotechnology programme marketing plan).
- To double value added and triple the volume of RD investments, the focus is placed on the most promising industrial research and product development projects in the BTP focus sectors (aid for RD projects, development staff recruitment measures, competence centre grant, knowledge and skills development grant, innovation voucher measure) and supporting activities (e.g. participation in international RD projects and cooperation networks, establishing cooperative ties in nearby regions with business angels and venture capital associations, introducing biotechnology applications to Estonia's traditional economic sectors).
- To increase the number of biotechnology sector employees by at least 50%, the focus is placed on training and/or importing a sufficient number of qualified workers (various human resource development measures to increase the number of researchers with master's degrees, doctorates, post-doctorates and top researchers) including workforce with multifunctional skills and interdisciplinary knowledge (development staff involvement measures, knowledge and skills development grant, measures for strengthening research-related cooperation between universities and companies, master's degree studies in technology management and entrepreneurial studies).
- To support the more extensive adoption of biotechnologies in various sectors of the economy, the focus in the upcoming years will be placed, with the help of foreign experts, on carrying out technology seminars on the possibilities for application of and the economic prospects of biotechnology on topics of interest to traditional economic sectors and/or the public sector (various ministries and government agencies). It is very important in this regard to brief other undertakings on the outcomes of pilot programmes conducted in companies in Estonia's traditional economic sectors, including, if necessary, to ensure state aid measures for placing corresponding technology investments. In terms of continued activities, it is important to support training and/or import of specialists related to the relevant biotechnologies, including if necessary, availability of the corresponding technological investments or funds.
- To improve the effectiveness of funding targeted at biotechnology sector development activity and cooperation between various parties (biotechnology sector, professional association in economic sectors, various ministry and government agencies, international cooperation partners), an annual evaluation of the productivity of the biotechnology programme is held at sessions of the BTP steering committee and the advisory board, including feedback on the effectiveness of aid measures, as well as an analysis of trends seen by biotechnology-related indicator in institutions of higher education, research and entrepreneurial sector and, if

necessary, development of amendment proposals and initiating introduction of the relevant measures into regulations. State representatives take part more actively in the biotechnology sector at the international level (working groups, cooperation networks, seminars etc). Multilateral (including international) cooperation also takes place with regard to preparing and carrying out the biotechnology sector marketing plan and biotechnology-related information events.

9.2. Programme areas of emphasis in priority development areas

In the case of several activities (such as human resource development, programme joint activities, support for technology transfer) the food processing industry and the biomedicine sector require similar reinforcement. From the aspect of comparing the development topics in the two sectors, the main focus lies on increasing the capability of RD in the food processing industry and increasing the capacity of export and business development in the biomedicine sector. The food processing industry continues to require additional investments into technology. In the field of biomedicine, on the other hand, it is also considered important – aside from measures aimed at raising business development capacity – to enter into cooperation agreements with international MBA programmes, which would allow biotechnology thematic modules to be passed by distance learning or in short study stints abroad. Besides students, it is necessary to make this study opportunity available to the heads of biotechnology companies. The differences in the areas of emphasis in development sectors are expressed in the differentiation of conditions established for the measures.

Description of the functional food and food processing technology areas

Companies related to the Estonian food processing industry have some capacity for conducting development activities within the company (primarily activities related to product development) and for implementing new technologies to produce more competitive products with higher value added. The Estonian companies with potential to develop functional food and food processing technology primarily operate in the dairy industry, bread and confectionery product manufacturing and fish product manufacturing sectors.

The share of RD investments made into the food processing industry represents less than 5% of all RD investments made in Estonia. The importance of industrial research in RD related to the food processing industry has risen, and food processing is currently the second-largest development activity area. However, product development is still the largest development area in the food processing sector.

Strengths of the Estonian food processing industry:

- 2 CCs that are engaged in industrial research proceeding from the companies' interests and real needs:
 - the Competence Centre for Food and Fermentation Technology (cultivation technologies for microorganisms of greater complexity, biology of systems of microorganisms, food stability, quality and healthfulness, modelling of human digestive tracts etc),
 - the Bio-Competence Centre for Healthy Dairy Products (improving the quality of the milk needed for producing dairy products, developing probiotic dairy products).

The CC is in terms of its structure a form of cooperation that allows top specialists in the field – as well as the necessary funds – to be consolidated in one place. As a result, effective technology transfer and mobility of employees takes place through the CCs.

- A number of universities have considerable competence in their field:
 - The Tallinn University of Technology's food institute (food fermentation, cellular metabolism, microorganism modelling).
 - The Estonian University of Life Sciences food science and health department and the animal feeding department (microbiology and food biotechnology, production and processing of plants, meat, milk and fish products, food quality and quality control, technical processing of food, functional food, pathogenic microbes in animal feed, food microbiology, food safety).
- Existence of a critical mass of academic research of a high international calibre. Internationally recognized leaders in their field.
- A unique success story: *Lactobacillus fermentum* ME-3.

Weaknesses of the Estonian food processing industry:²⁵

- Low level of cooperation between enterprise and industry.
- Low number of dedicated development units at companies.
- Lack of technology transfer capacity related to the food processing sector, including lack of a proof-of-concept phase that would assist in adopting companies' new technologies.
- General low capability for registering patent applications pursuant to international requirements.
- Lack of venture capital that is familiar with the food processing field and possesses knowledge that could be used to raise the conformity of products to international standards and would be able to effectively support top-quality strategic management of companies.

Description of the biomedicine sector

The companies operating in the Estonian biomedicine field (diagnostics and drug development pre-clinical trials) are primarily small companies with fewer than 50 employees. At the same time, the companies have very high RD capability. Because Estonian biomedical companies are in an early development phase, the number of patent applications is still low and companies' business models are primarily based on provision of services. In the case of the service provision business model, the time necessary to reach market is relatively short, but compared to the product-based business model, it involves a limited economic return and the companies have a relatively low market value. To develop a sustainable business model, Estonian companies should move to a product-oriented business model (which could include, as one component, provision of service in order to establish turnover) along with a strong industrial property portfolio.

Strengths of Estonia biomedicine:

- two state-of-the-art international research centres engaged in industry-leading research:
 - State-of-the-art centre for transfer medicine (virology, immunology, clinical metabolomics, molecular pathology etc)
 - State-of-the-art centre for genomics

²⁵ Feasibility Study for an Estonian Biotechnology Programme, Ernst & Young, 2009.

- 2 CCs that are engaged in industrial research proceeding from the Estonian companies' interests:
 - Competence Centre for Reproductive Medicine and Biology Technology (human fertility medicine diagnostics, reproductive technologies)
 - Competence Centre for Cancer Research (development of cancer drugs, development and implementation of technologies for the early diagnosis of cancer and prognosis).
- 3 universities: Tallinn University of Technology, the University of Tartu's Institute of Molecular and Cellular Biology and Tartu University Hospital, and the Estonian University of Life Sciences
- Researchers recognized on a high international level and their research groups.

Weaknesses of Estonian biomedicine²⁶:

- Small number of patent applications and specific patent knowledge.
- Lack of venture capital targeted at biomedicine.
- Small size of companies and limited material resources.

10. Assessment of programme outcomes

Assessment of biotechnology programme objectives and outcomes of completed activities

Assessment of BTP and implementation of BTP will take place in the activity report prepared once a year. In addition, the programme impact will be evaluated in the BTP interim report to be prepared in 2011 and the programme final report.

Among other things, the following will be evaluated in the BTP activity report:

- 1) Fulfilment of the BTP objectives.
- 2) The outcomes of activities supported by BTP and their effect on the field and the economy as a whole.
- 3) Need to change the BTP priority directions.

Once a year, the steering committee will assess the target levels related to BTP objectives and compliance with the BTP activity plan. The implementing agencies shall evaluate the outputs and outcomes of the specific measures on the basis of the general output indicators. The precise output indicator target levels for BTP are determined by the programme director, if necessary, in cooperation with the implementing agencies for the measures. The output indicators are coordinated with the lead ministry responsible for carrying out the measure.

Regular monitoring of the development of the biotechnology sector

The role of the BTP is also to offer policy planners a regular, comprehensive overview of key indicators in the higher education, research and entrepreneurial sector related to biotechnology, in order to assist them in making biotechnology-related decisions.

The following indicators are evaluated in the area of administration of the MER:

1. Absolute and relative number of biotechnology-related topics/grants (SF, ETF) (increase in number and percentage year by year, proportional comparison with other research fields on a yearly basis)
2. Funding for biotechnology-related topics/grants for each year in the near future (dynamics of the percentage increase, including in comparison with funding for research as a whole).
3. Human capital employed by the biotechnology-related topics/grants (quantity, quality): number of researchers with a doctorate, percentage in comparison with total human capital employed.

²⁶ Feasibility Study for an Estonian Biotechnology Programme, Ernst & Young, 2009.

4. Number of biotechnology-related foreign grants (EL, ESF, Wellcome Trust and others), funding and human capital.
5. State-of-the-art biotechnology-related research centres, funding and human capital.
6. Biotechnology-related doctoral degree programmes, effectiveness (number of certified doctoral candidates and number of graduates of doctoral programmes and % of all students who commenced studies/students).

The following indicators are evaluated in the area of administration of the MEAC:

1. Number of biotechnology-related research and development projects, funding and human capital used.
2. Effectiveness of biotechnology-related RD projects (new jobs, foreign capital involved, value added, sales revenue and export of new products/services following completion of the project).
3. Companies' RDI investments into biotechnology-related developments (including foreign investments).
4. Biotechnology-related CCs and their effectiveness (publications, defences of master's and doctorate degrees, patent applications and protected patents, income received from sales of licenses and later, also sales revenue from new products/services of the CC's partners in enterprise).
5. International biotechnology-related development projects (EUREKA etc): number of participating companies and financial volume.

The following indicators are evaluated in the area of administration of the MA:

1. Number of biotechnology-related research and development projects, funding and human capital.
2. Absolute and relative number of biotechnology-related topics (increase in number and percentage year by year).
3. Effectiveness of biotechnology-related RD projects (new jobs, foreign capital involved, value added, sales revenue and export of new products/services following completion of the project).
4. Companies' RDI investments into biotechnology-related developments (including foreign investments).
5. International biotechnology-related development projects: number and financial volume.

Of the most important indicators for RDI strategy, the following general indicators are additionally evaluated in the biotechnology sector:

- growth in the percentage of employees employed in RD;
- improvement in the cooperation between companies and research institutions (e.g. placements of doctoral and master's candidates in companies, research institutions' income from sale of services and/or intellectual property to companies);
- increase in the number of internationally registered patents;
- increase in the companies' productivity per employee.

11. Programme funding

11.1. Programme funding volume

The list of programme measures with regard to which it is most important to reinforce the BTP subsidiary budgets (throughout the entire programme) are specified in the following funding table, along with the responsible persons, the implementing agencies and sources of funding. These are estimated amounts, as a result of which the programme steering committee will make the final decision regarding the amount of, and need to implement, each measure and the activities listed below each measure.

Table 1. Estimated subsidiary budgets for horizontal measures related to the biotechnology programmes.

List of measures with regard to which a BTP subsidiary budget is approved (minimum volume for 2010-2013).	Responsible ministry	Implementer	Budget 2010-2013 (millions of kroons)
1. DEVELOPMENT OF HUMAN RESOURCES IN PRIORITY FOCUS SECTORS (Human resource development operational programme, RD human resources development priority direction 80)			
1.1. Creating opportunities for top researchers in sectors in preferred development areas to work in Estonia	MER	ETF	
1.2. Developing the position of post-doctorates	MER	ETF	
1.3. Strengthening cooperation between universities and companies	MER	Archimedes	
1.4. Increasing the number of specialists with a doctorate through involving capable foreign universities in doctorate programmes	MER	Archimedes	
1.5. Supporting international cooperation in the field of research (short-term research projects by visiting PhDs, migration by master's and doctor's candidates)	MER	Archimedes	
Human resources development operational programme; Knowledge and skills for innovation-minded enterprise			
1.6. Knowledge and skills development programme	MEAC	Enterprise Estonia	5
1.7. Development staff involvement measure	MEAC	Enterprise Estonia	40
2. STRENGTHENING RD COMPETITIVENESS (Economic environment development operational programme; Priority direction for strengthening Estonian RD competitiveness*)			
2.1. Biotechnology research and development project aid programme	MER	to be specified	145
Economic environment development operational programme; priority direction for strengthening Estonian RD competitiveness*			
2.2. Export marketing, joint marketing and foreign trade fair support	MEAC	Enterprise Estonia	20
2.3. Research and development project assistance	MEAC	Enterprise Estonia	125
2.4. Cooperation in the field of developing new products, methods of processing and technologies in the agriculture, food and forestry sector	MA	ARIB	100
2.5. Technology investments by industrial entrepreneurs (to the food processing industry)	MEAC	Enterprise Estonia	30
3. SUPPORTING TECHNOLOGY TRANSFER			
Raising awareness for application of biotechnologies in traditional economic sectors is funded from the Enterprise Estonia measure "Knowledge and skills development programme".		MEAC	Enterprise Estonia
The building of the technology transfer direction is financed from supplementary funds intended for financing ESF's RD activities (measure 2.1 in the table).		MER	ESF
4. SUPPORTING JOINT EFFORTS, SERVICES THAT ADD VALUE			
BTP's managerial budget, including for supporting the shaping of the sector strategy and marketing; developing PPP and international partnership, etc.	MEAC	The preparation and implementation of the activity plan is organized by the BTP programme director, if necessary involving professional associations and implementing agencies.	8

* The following measures are being opened or have not yet been opened: Supporting international cooperation at RD institutions, modernizing research equipment and instruments; support for experimental and semi-industrial laboratories.

11.2. Programme funding principles

- Existing financing instruments and implementing agencies will be used in a coordinated fashion, avoiding overlap between different financing instruments.
- The implementing agencies are responsible for the project selection and quality.
- The steering committee is responsible for the conformity of the measures to the programme objectives.
- The combined effect and orientation of the measures to conformity with the objectives of the national programme is ensured through allocation of the subsidiary budgets oriented at the programme's development directions and topics, and through the organizing of project competitions.

11.3. Incentive for target groups involved in the programme to participate in the programme

The incentive for research institutions and undertakings to participate in the national RD programme is to bring the partnerships between the following parties – state, research institutions and entrepreneurs – closer together and to develop activities that result equal benefits. On one hand, the state receives from the biotechnology sector the input necessary for planning measures related to the field, while participation in the programme will create the opportunity for entrepreneurs and research institutions to contribute to shaping the long-term visions for the sector. One of the greatest impacts of the national programme is the creation of an innovative and development-intensive environment, the elements of which are better conformity of the research and development on offer to the needs of companies, increase in the number of people with the high qualifications necessary for development activity, and development of infrastructure.

Through the exchange of information taking place in BTP, representatives of traditional economic sectors get information about the biotechnology used in their field in general as well as about the capability of Estonian research institutions and entrepreneurs to offer relevant products, services and technologies. For biotechnology companies and research institutions, BTP is a platform where it is possible, through establishing contacts with companies in traditional economic sectors, to find customers for products, services and technologies developed by the companies and institutions. Cooperation within the sector and between different parties helps coordinate and plan training of researchers, specialists and skilled workers of different levels, based on future workforce demand.

11.4. Involving investments from the private sector

The primary form for involving private sector investments is companies' self-financing into carrying out projects. An important part of the process of selecting the programme development topics is negotiations between private sector and research institutions; this establishes the topics in the case of which companies have an interest and readiness to participate in the programme.

In addition, the objective is to involve investments from companies into financing individual programme measures (for instance, development of curricula, bringing foreign researchers to Estonia, supporting technological development in a specific development topic etc). Involvement of investments from companies takes place in the form of separate cooperation agreements and on the matching-cost principle, which means that if necessary and possible, the state increases the levels of funding it provides for specific measures.

12. Assessing the quality of applications

The implementing agencies assess applications pursuant to the conventional assessment procedures for the measures implemented by them, taking into consideration as an additional programme-specific criterion how well a given project is oriented to fulfilling the programme objectives. If a project does not prove to be in conformity with the programme objectives, it will not be financed from the programme budget and if necessary it is re-directed to the sector-neutral application round under the same measure.

The following criteria are applied globally to all of the RD projects related to the BTP development areas:

- 1) clear timeline (advisably up to 3 years of research activity, up to 2 years for commercialization),
- 2) higher value added,
- 3) higher economic benefits,
- 4) higher export capacity,
- 5) increasing the field's private sector RD investments,
- 6) developing RD human resources in the field,
- 7) increasing the income gained from sale of intellectual property rights.

13. Principles for programme management and development

A separate organization will not be formed for realizing BTP. The programme is headed by a steering committee and implementation is coordinated by the programme in cooperation with persons implementing the programme measures in the implementing agencies or the ministries (at least one from each agency). The programme director and employees of the implementing agencies and/or ministries related to the programme comprise the programme team. The areas of responsibility and competencies of the various parties in BTP (the steering committee, programme director, advisory board and programme team) are described in the BTP programme document statute (Annex 1).

The programme development proposals are developed and presented to the steering committee for approval by the programme director and the programme team members. The steering committee – the body with the supervisory function – may issue guidelines for amending the programme to the programme director, who shall develop and discuss them with the ministries participating in the programme, formulate detailed amendment proposals and present them to the steering committee for approval.

As the sources of the programme budget funds are the various priority directions of different structural funds, it is not possible to change the purpose of use of funds originating from a specific source without the approval of the European Commission.

Thus the development proposals can treat the following:

- introduction of amendments and addenda to the programme objectives, development directions and topics;
- increase in the size of the budgets allocated to the programme in the framework of specific measures (with the consent of the ministry responsible for the measure);
- introduction to the biotechnology programme of other measures financed from structural funds;
- addition of new measures to the programme on the basis of state budget financing (the required relevant budget application is to be submitted through the development plan of the responsible ministry and the State Budget Strategy);

- introduction of amendments to the terms and conditions of existing measures as well as to the procedures for implementation of existing measures.

The programme amendments are approved by the Government of the Republic as part of the resolution to amend the operational plan for the RDI strategy for 2007-2013, entitled "Knowledge-Based Estonia".

14. Programme implementation timetable

The duration of the programme is four years – from the 1st quarter of 2010 to the end of the fourth quarter of 2013.

Several programme measures became available to the biotechnology sector immediately after the opening of relevant measures of the structural funds for 2007-2013. The set of programme measures is supplemented in accordance with the amendment proposals made in the course of carrying out the biotechnology programme. Some of the measures are not yet ready for implementation in connection with the time-intensive nature of preparing the 2007.-2013 structural fund measures.

The interim assessment of the programme implementation will take place at the end of the second year of activity – in the 4th quarter of 2011. The assessment of the programme outcomes and impacts is planned for the 4th quarter of 2013.

ESTONIAN BIOTECHNOLOGY PROGRAMME

approved by the resolution of the Estonian biotechnology programme steering committee of 7 December 2009

Annex I to the Estonian biotechnology programme

PROCEDURAL RULES FOR THE ESTONIAN BIOTECHNOLOGY PROGRAMME

GENERAL PROVISIONS

1. These procedural rules govern the operational plan for the Estonian RDI strategy 2007-2013 -- "Knowledge-Based Estonia" -- as well as the operation of the programme established on the basis of the "Biotechnology Programme" (Estonian Biotechnology Programme or BTP), which is an annex to the operational plan.

The BTP is a voluntary interministerial cooperation programme, the joint implementation of which will contribute to the achieving of biotechnology-related objectives.

The procedure describes the parties and activities related to implementation of BTP, as well as the mechanisms for BTP monitoring (including the role of the steering committee, advisory board, programme director and programme team and the relationships between the ministries and implementing agencies related to the programme in connection with implementation of BTP).

On the basis of these procedural rules, the authorized representatives of ministries and/or implementing agencies introduce the necessary changes to the procedures and administrative acts governing the work of ministries and/or implementing agencies (regulations for terms and conditions of measures, administrative agreements between intermediate bodies and implementing agencies for use of structural funds etc). These procedural rules shall serve as the basis for the conclusion of any agreements between the programme and ministries and/or implementing agencies necessary for specifying cooperation and responsibilities in greater detail.

2. The work of the BTP shall take the following forms:

- a. meetings of the steering committee, resolutions of steering committee meetings;
- b. opinions of the BTP advisory board and proposals made to the steering committee regarding the making of decisions;
- c. meetings of the programme team, resolutions of programme team meetings;
- d. public events organized by the programme director;
- e. implementing agencies' procedures for conducting proceedings on RDI projects;
- f. proposals of the programme director to the steering committee and the advisory board.

3. BTP budget and payments made in the framework of the BTP.

a. BTP is not a legal person.

b. The budget for measures to be implemented via BTP consists of the project funding budget and the managerial budget. The budget for measures coordinated by BTP shall be comprised of the subsidiary budgets of the ministries and implementing agencies.

c. The basis for executing payments by ministries and/or implementing agencies in the framework of the BTP managerial budget shall be an expense document signed by the authorized representative of the ministry and/or implementing agency and the programme director.

d. Disbursements shall be made to projects funded in the framework of BTP in accordance with the conventional practices of each implementing agency and in the case of structural funds (SF) in accordance with the SF disbursement procedure.

e. implementing agencies that administer BTP managerial expenses shall keep separate accounting on BTP managerial expenses and submit to the programme director a quarterly report on BTP expenses.

AREAS OF RESPONSIBILITY

4. The area of responsibility of ministries related to the programme (MEAC as the lead ministry, MER; MA, ME and MSA):

- a. to organize cooperation with BTP in its area of responsibility pursuant to the procedural rules as well as pursuant to amendments introduced by ministries into administrative acts of ministries on the basis of the procedural rules;
- b. to introduce into implementing acts (regulations, agreements etc) amendments enabling the BTP to be carried out;
- c. to ensure the BTP funds approved by the steering committee in the ministry's area of responsibility;
- d. to ensure that implementing agencies or programme implementers comply with resolutions of the steering committee;
- e. the lead ministry must ensure that minutes are kept of steering committee meetings.

5. Area of responsibility of the steering committee:

- a. to approve the BTP objectives and activity plan contributing to achievement of the objectives for each development direction;
- b. to approve the necessary list of measures and terms and conditions of funding for achieving the BTP objectives;
- c. to approve the BTP priority development directions;
- d. to assess the performance of BTP;
- e. to carry out supervision of BTP implementation, including approving reports;
- f. to endorse, on the basis of proposals of the programme director and the advisory board, amendments to the BTP objectives, measures or means for implementation of objectives and measures, or the BTP procedural system (including deciding on the introduction of matching cost projects);
- g. to decide, on the basis of proposals from the programme director, participation in development monitoring in the field and on organization of research and analysis.

6. Area of responsibility of the programme director:

- a. to organize cooperation between the agencies related to implementation of BTP, as well as the work of the programme team, pursuant to the procedural rules;
- b. to prepare the plan for implementation of BTP objectives and measures, and, if necessary, to prepare amendments of the BTP procedural system and to submit it to the steering committee for approval;
- c. to coordinate activities related to implementing BTP;
- d. to engage in public relations for BTP;
- e. to document materials related to the work of the steering committee, advisory board and programme team and to retain documents;
- f. to contribute to improvement of international cooperation in the biotechnology sector, coordinating international cooperation in the framework of the BTP and representing the BTP at key international events in the biotechnology field.

7. Area of responsibility of the advisory board:

- a. to describe consensually the biotechnology field, including RDI, vision statements and long-term objectives;
- b. to submit, to the BTP steering committee and programme manager as well as other BTP-related agencies, proposals regarding implementation of BTP.

8. Area of responsibility of the implementing agency:

a. to evaluate the financing applications of projects in the field of the BTP and of the implementing agency, to organize financing and to perform supervision pursuant to legislation, administrative acts and procedures in force in the implementing agency;

b. to cover aspects related to BTP activities on the implementing agency's website as well as, on the basis of the evaluation of the programme director, in the framework of other public events held by the implementing agency.

9. Area of responsibility of programme team members:

a. to ensure the implementation of measures related to funding of BTP priority development directions pursuant to the resolutions of the steering committee and the terms and conditions set forth in the administrative acts of the participating ministries;

b. to provide consultation to ministries regarding the introduction into implementing acts (regulations, agreements etc) of amendments enabling the BTP to be carried out;

c. to organize BTP monitoring and to make conclusions and summaries.

STEERING COMMITTEE

10. The steering committee is the strategic management body of the BTP and decides on the general BTP budget and the individual components of the budget, approves the BTP procedural rules and other documents that regulate the functioning of the programme, as well as its coherence with other analogous programmes in Estonia and elsewhere. The steering committee shall engage in cooperation with the programme team in the case of relevant coherence.

The steering committee shall decide if necessary to establish special audit and if necessary shall make proposals to the Government of the Republic regarding dissolution, division, merger or transformation of BTP.

11. The steering committee shall approve the annual BTP activity plan and managerial budget prepared by the programme director and approved by the MEAC in the latter's capacity as lead ministry.

12. The steering committee shall approve the time, volume, level of support and content of implementation of the aid measures participating in BTP and prepared by the programme director.

13. The steering committee shall lead the activity of the programme director and the programme team.

14. The members of the steering committee shall be the MEAC representative, the MER representative, the MA representative, MSA representative, the Enterprise Estonia representative, Estonian Science Foundation representative and the Archimedes Foundation representative. The chairman of the steering committee shall be appointed by the MEAC.

15. The members of the steering committee shall be appointed and removed by the head of the relevant institution. The powers of the members of the steering committee shall be valid without a term. The work of the members of the steering committee shall not be remunerated.

16. A meeting of the steering committee shall have a quorum if at least one-half of the steering committee members take part in the meeting. A member of the steering committee may be substituted for at the steering committee meeting by the member's representative. The representative must have a valid written letter of authorization. The head of the relevant agency may appoint a representative for a steering committee member, who may substitute for that steering committee member if necessary. On the basis of a respective resolution of the programme director, programme team members may take part in a steering committee meeting.

17. The meeting of the steering committee shall be convoked by the programme director or steering committee chairman, giving notice of the time and location of the meeting. The steering committee shall be convoked after a reasonable amount of time has passed since the day on which the steering committee members received or should have received the invitation. A steering committee meeting must be convoked if at least one-half of the steering committee members so demand. The steering committee must be convoked within no more than two weeks of the day on which at least one-half of the

steering committee members so demanded. If the steering committee meeting is not convoked during the time sought, the steering committee members shall be entitled to organize the steering committee meeting themselves, determining the time and place for the meeting.

18. The agenda of steering committee meeting shall be prepared by the programme director and approved by the steering committee chairman.

If the steering committee meeting was convoked on the basis of decision by the members of the steering committee, the agenda shall be determined by the steering committee meeting. Changes to the steering committee meeting agenda shall be decided by the steering committee meeting.

19. A resolution of the steering committee shall be considered passed if all of the participants at the steering committee meeting vote in favour of the resolution. A reason must be provided for every vote against a resolution and a written edited version of the resolution must be submitted, reflecting the wording in the case of which the steering committee member would consent to vote in favour of the resolution. If the draft resolution is still not passed after three voting rounds, considering the received versions of the resolution in the course of the votes against, the question in dispute shall be passed to the secretaries general of the ministries for resolution. If the secretaries general of the ministries do not find a consensual solution to a disputed matter, the matter shall be decided by the votes of 2/3 of the steering committee's total membership. A resolution shall not be passed, regardless of the votes in favour of 2/3 of the steering committee if the representative of the ministry that represents the field of the given matter votes against it.

20. The steering committee may use the assistance of competent experts in the passing of its resolutions. Involvement of the relevant experts shall be decided by the chairman of the steering committee on the basis of a proposal from the programme director.

The experts may participate in the meeting of the steering committee with regard to discussion of the agenda items for which they were summoned. The work of the experts shall be remunerated from the BTP managerial budget.

21. In the case of urgent or unimportant matters, where there is no justification for convoking a steering committee meeting, the steering committee chairman may organize written proceedings for the approval of resolutions. In such a case, the programme director shall at the proposal of the steering committee chairman send the steering committee members the draft resolution accompanied by any related documents. The members of the working group shall have the right to submit proposals regarding the draft resolution within 5 working days of the sending of the documents.

22. Written proceedings shall be conducted electronically. The programme director shall organize the conducting of the written proceedings.

23. A draft resolution stipulated in written proceedings shall be considered passed when no more than three votes against from steering committee members are received.

24. Each vote against a resolution must be justified and a written version of the resolution must be submitted, reflecting the wording in the case of which the steering committee member would consent to vote in favour of the resolution. The justifications for voting against shall be sent electronically by the steering committee member voting against to all members of the steering committee and to the programme director. A vote against a resolution in the course of written proceedings may be justified with the desire to discuss the given matter at a steering committee meeting.

25. The programme director shall, within 3 working days of the end of the written proceedings send the members of the committee a decision regarding the outcome of the written proceedings, specifying the matter under discussion, the place of approval, the names of the working group members who were for, against and undecided, and the resolution.

26. The expenses of steering committee meetings shall be borne by the MEAC, unless agreed otherwise in an individual case.

PROGRAMME DIRECTOR

27. The programme director is the organizer of the work of BTP, and the programme director's primary functions are the following:

- a. to prepare the plan for carrying out the BTP (among other things the objectives, priority development topics, measures and financing proposals) in cooperation with the programme team, and to submit them to the steering committee for approval, and to introduce amendments pursuant to steering committee resolutions.
- b. to organize the carrying out of the BTP, to prepare the BTP programme document, procedural rules and other essential acts that govern the work of the BTP, to develop and to submit them to the steering committee for approval and to establish and implement them on the basis of the steering committee resolution.
- c. to organize cooperation with the ministries and implementing agencies.
- d. to organize cooperation with the BTP's entrepreneurial and research partners and with non-governmental organizations, as well as with institutions that support biotechnology innovation in Estonia and abroad.
- e. to create the network of experts necessary for carrying out the BTP and to organize cooperation with the experts.
- f. to analyze and document the outcomes of implementation of BTP, and to submit proposals to the steering committee regarding assessment and analysis of BTP priority fields, BTP procedures, and legal acts related to the implementation of aid schemes.
- g. to submit proposals governing the functioning of BTP to the steering committee for the making of a decision.
- h. to engage in public relations on behalf of BTP, among other things to create and administer the website.
- i. to submit to competent institutions proposals pertaining to the biotechnology sector, on the basis of analysis conducted as a result of implementation of BTP.
- j. to document and retain the materials related to BTP's work.

28. In his or her work, the programme director shall draw on cooperation with ministries, implementing agencies and other institutions. The form of cooperation, content and rules are based on legislation and the administrative acts and procedures of ministries and implementing agencies. The programme director shall have the right to hire up to 2 employees reporting directly to him or her and whose duty is to organize BTP administration and documentation and archival of materials. The expenses related to such employees shall be covered from the BTP managerial budget.

29. The proposals of the programme director to the steering committee shall be formulated in writing by the programme director as proposals of the programme director. Other resolutions related to organization of the work of BTP shall be formulated in writing as resolutions of the programme director.

30. The programme director shall exercise its functions independently, drawing on the resolutions of the steering committee.

31. At least once a year, the programme director shall submit a report to the steering committee summarizing BTP activity. The respective report shall be submitted by 1 April of the year following the reporting period. The opinion of the BTP Advisory board shall be an annex to the reports summarizing BTP activity.

MEMBERS OF THE PROGRAMME TEAM

32. The programme team consists of the programme director, the employees of the implementing agencies and programmes involved in implementing BTP (programme team members). The programme team members shall be appointed by the head of the relevant implementing agencies. The duties of the programme team member shall be specified upon appointment. One representative from each implementing agency shall serve on the programme team.

33. The work of the programme team shall be headed by the programme director.

34. The programme team members along with the representative of the relevant implementing agency shall ensure the implementation of the BTP-related measure funded by that implementing agency pursuant to the resolution of the steering committee and in accordance with the terms and conditions set forth in the administrative acts of the participating ministries.

35. The programme team member shall decide essential matters related to implementation of the measures in cooperation with the programme director. Among other things, essential matters shall include specifying expert opinions in greater detail if necessary, evaluating conformity of grant applications to the BTP programme, approving project reports, drawing on the outcomes of project management conducted by the implementing agencies. If necessary, a member of the programme team and the programme director may involve competent experts in deciding essential matters. The work of the experts shall be remunerated from the BTP managerial budget.

36. Members of the programme team shall organize monitoring of their implementing agency's measures participating in the BTP, and draw conclusions and summaries stemming from the monitoring.

37. Programme team members shall prepare reports summarizing BTP activity pertaining to their implementing agency and submit them to the programme director.

38. Resolutions of the steering committee based on resolutions of the programme team on organization of division of labour and the relevant proposals from the programme director to the steering committee shall be the basis for organizing division of labour in the biotechnology sector between ministries and implementing agencies.

39. The work of the programme team members in the framework of BTP shall be evaluated by the programme director.

BTP ADVISORY BOARD

40. The BTP advisory board is a non-profit organization providing counsel to the steering committee, programme and programme team members, charged with the following functions:

- a. to describe the biotechnology field, including RDI, visions and long-term objectives;
- b. to submit proposal to institutions related to the BTP in matters of implementation of the BTP.

41. The activity of the BTP advisory board consists of submitting evaluations, opinions, recommendations and vision statements (opinion of the advisory board). Opinions of the advisory board shall be submitted as an obligatory annex to the BTP activity report.

42. Members of the BTP advisory board shall be appointed by the professional associations in the biotechnology sector and related sectors at a rate of one representative per association (Estonian Biotechnology Association, Food Association, Estonian Forest Industries Estonian, Estonian Association of Chemical Industry, Chamber of Agriculture and Commerce) and one expert representative per biotechnology sub-sector (biomedicine, industrial biotechnology and agriculture and environment-related biotechnology), one representative of the higher educational sector by the Council of Rectors and 1 representative of the science sector by the Academy of Sciences. In addition, the chairman of the BTP steering committee and the programme director participate in the work of the Advisory board. The identities of the Advisory board's members shall be coordinated with the steering committee before appointment.

43. The members of the Advisory board shall be appointed and removed by the head of the relevant institution. The powers of the members of the Advisory board shall be valid without a term. The head of a relevant institution may appoint a representative for a member of the advisory board, who shall substitute for the member of the Advisory Board if the need arises.
44. The chairman of the advisory board shall be appointed by the MEAC.
45. The work of members of the advisory board shall not be separately remunerated.
46. The meetings of the advisory board shall be convoked by the chairman of the advisory board or programme director.
47. The agenda of the meeting of the advisory board shall be prepared by the programme director, coordinating it in advance with the chairman of the advisory board. Changes to the agenda of a meeting of the advisory board shall be decided by the meeting of the advisory board.
48. Proposals, recommendations and opinions made by the advisory board to the steering committee and/or the programme director shall be voted on. A resolution shall be considered passed if over 2/3 of the members of the advisory board vote in favour of the resolution. All dissenting opinions shall be recorded in the minutes. Upon the non-passage of a resolution, the members who voted against the resolution shall have the right to submit, in writing, amendment proposals and an edited version, which in order to be passed must garner 2/3 of the votes of the advisory board members.
49. The visions and long-term objectives of the biotechnology sector, including RDI, described by the advisory board shall be decided on by the advisory board based on consensus.
50. The advisory board may involve experts in its work with the consent of the programme director and the steering committee. The work of the experts shall be remunerated from the BTP managerial budget.
51. In the case of urgent or unimportant matters, where there is no justification for convoking an advisory board meeting, the chairman of the advisory board may organize written proceedings for the approval of resolutions. In such a case, the programme director shall at the proposal of the chairman of the advisory board send the steering committee members the draft resolution accompanied by related documents. The members of the working group shall have the right to submit proposals regarding the draft resolution within 5 working days of the issue of the documents.
52. Written proceedings shall be carried out electronically. The programme director shall organize the carrying out of the written procedure.
53. A draft resolution set forth under written procedure shall be considered passed if no more than three votes against from the advisory board's members are received
54. The programme director shall, within 3 working days of the end of the written proceedings, send the members of the committee a decision regarding the outcome of the written proceedings, specifying the matter under discussion, place of approval, names of the working group members who were for, against and undecided, and the resolution.