NATIONAL PROGRAM

«DEVELOPMENT OF BIOTECHNOLOGY IN THE RUSSIAN FEDERATION FOR 2006–2015 »

(BASED ON STATE-PRIVATE PARTNERSHIP)

Approved by the third Congress of the Russian Y.A. Ovchinnikov
Society of Biotechnologists
October, 27 2005.

Moscow, 2005

WORK GROUP

VASILOV R.G. – President of the Russian Biotechnology Organization, professor, PhD in Biology (*head*)

VOROBYOV V.S. – member of the Central Board of the Russian Biotechnology Organization, candidate of science in Medicine (*secretary*)

ALEKSEYEV L.P. – Deputy Director of the SSC of Immunology, professor, PhD in Medicine

BORISENKO Y.G. – Professor, Moscow Institute of Food Biotechnology, PhD in Technology

DEBABOV V.G. – Director, state SRI Genetics, corresponding member of RAS, academician of RAAS, PhD in Biology.

ZVEREV V.V. – Director, SRI of virus preparations, RAMS, PhD in Medicine

IVANENKO A.I. – co-chairman, board of Directors of the Union of Biotechnological Enerprises, chairman of the Board of Directors, "Vostok" PLC, candidate of Economic science

The national program "Development of biotechnology in the Russian Federation in 2006-2015" has been developed by the Work group according to the Resolution of the Second Congress of the Russian Biotechnology Organization as of October 15 2004.

The Program was developed by the governing bodies and experts of the Russian Biotechnology Organization, the Union of Biotechnological Enterprises, the Information-Analytical Center of Medical and Social Problems.

The development of the Program was supported by the State Duma of the RF, the General Board of the party "Yedinaya Rossiya", Ministry of Health and Social development of the RF, Ministry of Education and Science of the RF, Russian Academy of Sciences, Russian Academy of Medical Sciences, Russian Academy of Agricultural Sciences, a number of RAS establishments (M.M. Shemyakin and Y.A. Ovchinnikov Institute of Bioorganic Chemistry, RAS, RAS Scientific Center, Puschino), profile organizations of a number of ministries and departments (SSC of Immunology,State SRI Genetics, SRI of Microbiology ME RF), non-state structures ("Vostok" PLC, "Bioprocess group of companies" LLC, "MDS Diaplus" LLC)..

The Program was developed according to the federal and regional legislation in the area discussed, statutory acts and target programmes in the area of Medicine, Biology and Biotechnology on the whole, the data from Goskomstat of Russia, the projects of the Ministry of Education and Science of Russia, foreign sources (projects, agreements, digests). Large amounts of factual material came from the regional departments of the Russian Biotechnology Organization. The databases of the leading Russian state and non-state organizations have also been used. The foreign experience of implementing target programs of biotechnology development has been taken into consideration.

The project of the concept, structure and tools of implementing the Program was discussed and approved by the Round Table of the Committee for Industry, Building and High technologies of the RF State Duma on February 8 2005. The draft of the Program was approved by the Expert Council for Biotechnology of the Committee for Industry, Building and High technologies of the RF State Duma (Protocol no. 3 as of October 11, 2005), supported by the Union of Biotechnology Enterprises (The General Meeting Decision as of June 29, 2005)

The Program was accepted by the Third Congress of the Russian Biotechnology Organization on October 27, 2005.

See the electronic version of the Program at the Russian Biotechnology Organization website at www.biorosinfo.ru.

CONTENTS

1. The contents of the problem and the substantiation of the need to solve it by means of a program approach

The national Program "Development of Biotechnology in Russia for 2006-2015" (further mentioned as the Program) has been developed according to the resolution of the Second Congress of the Russian Society of Biotechnologists as of October 15, 2004 (see appendix 1 – Program Passport).

Biotechnology is one of the scientific and practical priorities of the XXI century. The world market of biotechnology products over the year 2004 was about 40 billion dollars. It has been estimated that the figure is to increase to 100 billions by the year 1010, and if the other products made using methods of biotechnology are included, it will be over EUR 2 trillion. The long-term forecasts also confirm that the branch of biotechnology tends to grow constantly.

The share of Russia in the world biotechnology market is extremely low and doesn't correspond to the intellectual, career, scientific, organizational and economic opportunities of the state. Even according to the most optimistic scenario it is expected that in 2010 Russia will produce 0,25% of the world volume of biotechnological products. It is caused mainly by the obviously insufficient state financing of scientific and practical development in biotechnology. If we compare, in China over 1 billion dollars are spent annually on biotechnological research, in highly developed countries (the USA, the EU) – tens of billion dollars, in Russia – tens of million dollars. And at the same time there are 57 scientific centers with qualified staff and employees in Russia.

There is also a backlog of Russia in the quantity and quality of publications on physics-chemical biology and biotechnology. Here the country also lost the leading position it took 20-25 years ago long ago. The situation is practically the same with patents and copyright in biotechnology.

Hence the domestic biotechnology produces generics (which make 98% of the production) and in general these are outdated mounts

and the modern high-technology goods make only 10% of the production.

The situation is quite adequately accepted by the state and public (besides? The situation is the same in science on the whole), and at present certain measures are being taken to overcome the crisis. The acceptance of the document "The basic policy of the Russian Federation in development of science and technology up to 2010 and the further prospects", approved by president V.V. Putin on March, 30 2002 at the joint session of the Council for Security, the Presidium of the State Council and the President Council of the RF was an important milestone on this way. The document defines the two main functions of state regulation in science and hi-end technology: forecasting (developing the strategy and tactics of scientific support to the economical development of the state and society) and defining the priorities. The second task is especially important in the monopole circumstances when the country can't afford to carry out equal research in all the areas of science and technology as it used to be in the dipole world with the confrontation of two social systems.

According to these general statements the Government and all the executive bodies are expected to preserve the scientific, technological and intellectual spheres in Russia, support the basic system of institutes, scientific schools and the scientific society on the whole. Moreover, the state still has the mission of developing competitive scientific and technological branches, which is implemented in carrying out the federal target programs and supporting the most important innovation projects of state significance.

According to the minister of science A.A. Fursenko, the social structures (RAS, other academies, corporate scientific societies and associations) are offered an opportunity of choosing priority directions, including the growth points in science and technology.

It is necessary to say that over the last years in Russia a number of programs and projects in physics-chemical biology and biotechnology have already been implemented. For instance in the framework of FCSTP "Research and development in priority directions of development in science and technology" for 2002–2006 such directions as 'Human genom', "Biological variety", "Gene diagnostics

and gene therapy", "Vaccine prophylactics", several projects in agricultural biotechnology (genetically modified plants, etc.) have been financed. The program "Protection against patogenes" was supported till 2004. The FTP "National Technology base" (2002-2006) has a section on biotechnology, although it receives only 2% of finance. Biotechnology has been included into the approved "List of critical technologies in the RF". Meanwhile the state mechanism of regulating budget programs and distributing finance can't catch up with the rapid growth of theoretic, industrial and technological solutions in biotechnology. Hence it seems up-to-date to develop and implement separate individual target programs based mainly on non-budget financing, which would help to implement vital and socially important projects, defined by the experts. The compulsory condition for implementing such programs is a firmly defined mechanism of state-private partnership.

Hence the Russian Biotechnology Organization, re-established in October 2003, recognizing the priority and importance of modern biotechnology, together with the other interested public and state structures proposed the initiative of forming and implementing the complex national program "Development Of Biotechnology In The Russian Federation For 2006–2015".

The concept, structure and tools of implementing the program were presented and approved at the round table discussion "Legislature for development of biotechnological branch of industry" in the RF State Duma on February 8, 2005.

The conceptual basis of the Program is to develop a system of state and non-state activities in order to eliminate negative tendencies and create optimal conditions for development of fundamental and applied biotechnology.

It is necessary to apply program approach first of all to eliminate negative factors for the state of biotechnology in Russia, such as:

- Dramatically reduced financing of scientific research since the 1990s (this is especially relevant for biotechnology, which is absolutely dependent on the fundamental scientific achievements, first of all of molecular biology);

- Brain drain (basically, emigration of talented young people) the widespread aging of scientists, the absence of training system for young biotechnology specialists, including the new disciplines;
- A dramatic drop of the total production volume in all branches of economy резкое снижение общего объема (including the high technology industries);
- A considerable deterioration of resources in biotechnology (as well as in the other branches of industry);
- Inconsistence of legislative and normative legal acts of the federal, regional, municipal etc. levels (especially for intellectual property, status of science-towns, etc); diversification of administrative units and the growth of bureaucracy;
- Highly unbalanced and inflexible taxing policy;
- The absence of market environment work experience for most Russian citizens in the administrative and executive branches;

The Program will have to include some activities to make the influence of negative factors neutral and enable the positive factors which have recently been found in our country as well as using the useful foreign experience.

It is worth admitting that in general over the last 5 years Minpromnauki of Russia (now the Ministry of Education and Science of the RF) has done a lot to support and introduce innovation methodsa in the country. The activities became especially persistent after the well-known speeches by President V.V. Putin on February 9 2004 in the M.M. Shemyakin and Y.A. Ovchinnikov Institute of bioorganic chemistry RASand on February 24, 2004 at the meeting in Kremlin. Then he said: "**We should provide the formation of absolutely new relationships among business, science and state… the innovative environment will require new quality of state and corporate governance**". To develop such relationships the Ministry of science and education of Russia has developed an infrastructure system of support for scientific-technical and innovative activities at the federal and regional level. For instance, the "Concept of development of venture industry in Russia" has been proposed, the information portal

http://regions.extech.ru "Regional Science and Innovation" SE RINKCE, etc. On the basis of documents developed by the Ministry of Industry and Science the RF Government approved "The plan of activities for 2003-2005 to stimulate innovwtions and develop venture investments" (order of the RF Government as of 23.08.2003 # 1187-R). The list of actions in the framework of FTSTP "Research and development in the priority areas of science and technology"for 2005-2006 has also been approved and it contains a number of important biotechnology issues. Great work in this direction is done by the State Foundation of supporting small venture forms in science and technics, the Venture innovetion Foundation. The multiple techno parks, innovation technology centers, educational and scientific innovative complexes at leading universities, SRI and science towns, etc. also contribute to this. The program is planned to accept all the above mentioned achievements in order to speed up the cycle from NIOKR to implementation.

The so-called cluster approach has been widely used abroad recently. It involves uniting, expansion, agglomeration - in the functional, and more often in the geographical sense - of different establishments and industries around one intellectual brain center (as a rule a well-known university, like Harvard). This approach to biotechnology has been used successfully in the USA, in Europe – the UK, Germany, Finland, in Asia – Japan, South Korea, Israel (lately Singapore has been trying to do the same).

The triad "science-education-practice" as an analog of cluster approach has been widely used in Russian medicine, social sphere, industry, education. The Program will also use this triad.

The particular characteristic of the Program is ranging the projects according to the following groups:

1. National priority projects.
2. Federal projects.
3. Regional (inter-regional, district) projects (programs).
4. Target projects (non-budget, international, etc. projects).

The national priority projects include the most important scientific and practical areas, defined by experts, which are in fact significant for the general development of the state. This group has to in-

clude a maximum of 5-7 projects. The content part of the projects has to be based on their interdisciplinary and interdepartmental character and wide methodology base, which allows to introduce the results to various branches of national economy. The results of implementation of the projects give rapid effect for economy and provide the growth of the state well-being and the increase of its competitiveness.

Federal projects are the most significant directions in theory, methodology and practice of biotechnology, development of which will have an effect on the whole state.

Regional projects include clearly defined directions aimed at solving national economy problems relevant for a given region of Russia. In some cases the level of the projects may be risen to a wider program of local importance or grow into an inter-regional (district) project..

The target projects group includes continuously selected most prospective and highly commercial projects implemented as a rule, on the non-budget basis. The international projects, presenting mutual interest for the parties can be included here.

All the above mentioned groups of projects are in turn divided into 4 categories by the degree of preparedness for implementation itself (an exclusion is made for fundamental works):

- Null preparedness of the project;
- The starting phase of project formation;
- Incomplete readiness (the presence of a technical task, a calendar plan and a business plan);
- Complete readiness (including financing decision).

The no 1 priority for the Program is forming the national priority projects in biotechnology and attracting investments for their implementation ..

On the whole all the projects may be divided into two types (not dependent on the group): fundamental and applied.

In fundamental science – the theory and methodology of biotechnology – the newest directions corresponding to the post genomic period of microbiology development: proteomics, metabolomics, etc., will be supported. Research will be done into bioinformatics, cell and nanotechnologies.

Equal attention will be given to the questions of staff training, keeping in mind the work for the future, not to prepare yesterday specialists according to matrix principle, but to form the 21st century staff.

In the practical (applied) aspect the most prospective projects in medical, food, industrial and agricultural biotechnology and other spheres using biotechnology will be supported with the target to achieve a certain level of import replacement.

The legal part of the program, where it is planned to marshal federal and regional legislation for biotechnology tasks is also very important..

A separate stream is devoted to the material and technical biotechnology base development, which is going to solve the problems of upgrade, reconstruction and building new facilities.

The program will give special attention to forming and supporting regional projects (programs) and non-budget target projects for biotechnology development. Here it is planned first to practice pilot typical regional models and then to spread them across a maximum number of regions, taking into account their specialization and the strategy of the general country development. Non-budget projects will be formed continuously while working with investors. In this case the questions of theory, methods, innovative schemes and scientific and practical support will be provided by the group of federal projects of the program.

And finally there is a task to develop and include into the national program a separate stream as a FTP "Priority scientific and practical directions of biotechnology (2009-2015)". This is required for the complex program to have a state status.

2. Basic aims, targets and stages of the Program implementation.

The objective of the program is:

- Development of work in theoretical and practical biotechnology in Russia based on modern innovative approaches to produce import-replacing domestic biotechnological products.

The tasks of the Program are:

- Forming and implementing national priority projects in biotechnology;
- Developing the theory and methodology for funadamental biotechnology;
- Introducing the most important achievements in genomics, bioinformatics, nanotechnology according to the most important priorities (genetic passport, biochips, etc.);
- Creating modern educational programs and the system of staff training for biotechnology;
- Implementing target practical projects in medical, agricultural, food, ecological, industrial biotechnology and other directions to provide domestic biotechnological products for the population;
- Creating an effective legal, economical, informational and organizational basis for biotechnology development.

Implementation of the Program is planned in theree stages: Stage I – 2006-2008, stage II – 2009-2011, stage III 2012-2015. There are intermediary tasks for each stage, aimed at achieving the final result of the program.

3. The system of program activities (a list of projects and basic activities)

The list of Program activities (see Appendix 2) supposes solving in the framework of the 4 parts particular problems, interconnected and coordinated in time, resources and responsibilities, including scientific research and experimental construction, material, technical, staff, information, legal, normative and economic support.

The structure of the Program includes 4 parts:.

Part1. National priority projects.

Part 2. Federal projects.

2.1. Stream «Fundamental biotechnology».

2.2. Stream «Medical biotechnology».

2.3. Stream «Agricultural biotechnology».

2.4. Stream «Food biotechnology».

2.5. Stream «Industrial biotechnology».
2.6. Stream «Ecological biotechnology»
2.7. Stream «Legal, economic, informational and organizational support for biotechnology development».
2.8. Stream «Material and technical base for biotechnology».
2.9. Stream «Staff training for biotechnology».
2.10. FTP «Priority scientific and practical directions in biotechnology (2009–2015)».
Part 3. Regional (interregional, district) projects (programs)
Part 4. Target projects (non-budget, international, etc. projects).

To implement the given parts and streams it is necessary to solve the following particular problems (consequently, in 3 stages)

At the first stage (2006–2008):

- Complex estimation of the state of biotechnology in the country, forming databases, defining priorities;
- Working out the questions of fundamental biotechnology;
- Perfection of the current and development of the new federal and regional legislative base according to the tasks of biotechnology including the provision for innovations, solution to the intellectual property problems, the problems of science towns, territories of scientific and technical development, etc..;
- Forming a list and starting to implement the national priority projects in biotechnology, including the immediate actions to preserve biological collections and genetic resources of Russia, industrial development, etc.
- Forming and starting to implement pilot models of regional biotechnology projects (programs) in 5-7 RF regions;
- Selecting and implementing ready investment and innovation projects;
- Development of FTP " Priority scientific and practical directions in biotechnology (2009–2015)".

At Stage II (2009–2011):

- Full expansion of national priority projects with the emphasis on solving the problems of foodstuff supplies and ecologically clean nutrition, improvement of life quality on the basis of modern biotechnology;
- Wide-scale implementation of regional and interregional projects (programs) in biotechnology across about 30 regions of the RF;
- Launching the domestic production of biodrugs for diagnostics, treatment and prophylactics of socially important diseases (biogenerics, vaccines, diagnosticums, etc.);
- Start of implementation of the FTP " Priority scientific and practical directions in biotechnology (2009–2015)";
- Solving practical problems of ecological biotechnology;
- Solving present-day problems in biological diversity and biosafety;
- Perfection of the innovation system of biotechnology;
- Creating a modern system of staff training and retaining for biotechnologists.

At stage III (2012–2015.):

- Wide-scale implementation of national priority projects, including those in energetics with introduction of 5% volume of bioethanol and biodiesel in the structure of fuel balance, in chemistry – transition to renewable raw materials, not less than 10%;
- Mass production of biotechnology produce with the target to replace import by 30%, including ferments, biopesticides, polysaccharides, etc.;
- Finishing the implementation of the FTP "Priority scientific and practical directions in biotechnology (2009–2015)";
- Introduction of the latest achievements in genomics, bioinformatics and nanotechnologies according to the most important priorities;
- Creating a system of providing the ecological well-being using biotechnology;

– Forming a chain of bioresource centers across the country.

To implement the Program activities it is supposed to use actively the intellectual potential of RAS, RAMS, RAAS, the leading profile centers of the country (IBCh, IMB, Puschino scientific center RAS, IOGEN, IBP, CIN, etc.), big universities, including Lomonosov MSU, Kazan State Lenin University, Timiryazev Agriculture Academy, Sechenov MMA, etc. and associated scientific research establishments and organizations. The potential of such organizations as GosNIIgenetika, SSC "Vector" (Novosibirsk), SRI of microbiology ME RF (Kirov), "Biodrug" PLC, "Vostok" PLC (Kirov), "Bioprocess" group of companies LLC, "MDS DIAplus" LLC, "ChimRar" LLC, etc. will be used. Interaction is planned with the SRI of the Ministry of Education, the Ministry of Industry and Energetics, Ministry of health and social development, RAS, RAMS, RAAS selected on competitive basis. The mechanism of creating target work groups and other scientific organizational approaches will also be used.

It is planned to use such basic element as primary formation of a regional target program with the federal resources joining later on as part of FTP or target financing.

The national program involves wide international cooperation using the grants mechanism and joint projects.

4. Program resources

At present the volume of financing for domestic biotechnology in comparison with the other countries is miserable (Russia – 0,04 billion dollars a year, China – 1 billion dollars a year, the USA – 100 billion dollars a year).

The tasks set by the Program demand for a radical change in the state financing of biotechnology. According to preliminary calculations, only for implementation of the national priority projects at least 2 billion dollars are required. It is obvious that such financing needs special resolutions from the RF Government.

In case of target financing from federal budget the planned economic effect will be much higher than the investments.

Besides the federal budget finance, the Program activities will be implemented with the help of regional RF budgets and non-budget sources (see Appendix 3 for volumes).

The total financing of the Program is 150000,0 million rubles a year, including 15000 million rubles (10%) from the Federal budget, 45000 (30%) million rubles from the regional budgets and 90000 million rubles (60%) from non-budget sources.

The financing from the regional budgets will be used to implement special projects and programs solving the problems of the given region.

The volume of financing from the regional budgets of the RF have to be agreed by the customer and the executive bodies of the region.

5. Implementation of the Program and control of its implementation

The Program involves different organizations, scientific establishments and private persons.

Those who are responsible for separate activities of the Program are selected on competitive basis..

To organize assistance to the implementation of the Program the Russian Biotechnology Organization creates an assistance group (coordination group) with a two-level expert council.

The budget component of the program is controlled according to the current legislation and normative acts. In case of opening financing from the state budget the corresponding organization structure is created (the board of directors, coordination council, etc.).

6. Expected results and estimation of social-economic efficiency of the Program

The main result of the Program implementation will be provision of domestic biotechnological products for the population and solving the vital social and economic problems.

The implementation of the program will solve the following problems:

- Give Russia the status of a state with knowledge-based economy;
- Provide mass production of socially important biotechnological produce;
- Form a prospective stable import-replacing product and service market (foodstuffs, medications, diagnosticums) – the figures for all products are planned and real to achieve;
- Provide conservation and rational disposal of Russian genetic resources;
- Solve the problem of biological and ecological safety.

The social effect of the program will be significant if the planned figures are achieved (solving the problem of unemployment, preserving qualified staff, etc.). High economic efficiency of the program is forecast due to the commercial character of biotechnological industry.

7. Appendices

Appendix № 1
to the Program
«Development of biotechnology in Russia for 2006–2015 »

PASSPORT

Program
«Development of biotechnology in Russia for 2006–2015»

Name of thje Program	National Program «Development of biotechnology in Russia for 2006–2015» .»
Name, number and date of decision to develop the Program	Resolution of the second Congress of Russian Society of Biotechnologists as of 15.10.2004
Program ordered by	Russian Y.A. Ovchinnikov Society of Biotechnologists
Basic designers of the Program	Russian Y.A. Ovchinnikov Society of Biotechnologists, Union of Biotechnology Enterprises, Information-analytical center of medical and social problems
Objective of the Program	Development of work in theoretical and practical biotechnology in Russia based on modern innovative approaches to produce import-replacing domestic biotechnological products.
Program Tasks	Forming and implementing national priority projects in biotechnology; Developing the theory and methodology for funadamental biotechnology; Introducing the most important achievements in genomics, bioinformatics, nanotechnology according to the most important priorities (genetic passport, biochips, etc.);

	Creating modern educational programs and the system of staff training for biotechnology; Implementing target practical projects in medical, agricultural, food, ecological, industrial biotechnology and other directions to provide domestic biotechnological products for the population; Creating an effective legal, economical, informational and organizational basis for biotechnology development.
Terms for the Program	2006–2015
System of program activities (list of projects and basic activities)	The structure of the Program includes 4 parts, solving particular problems. Part1. National priority projects. Part 2. Federal projects. 2.1. Stream «Fundamental biotechnology». 2.2. Stream «Medical biotechnology». 2.3. Stream «Agricultural biotechnology». 2.4. Stream «Food biotechnology». 2.5. Stream «Industrial biotechnology». 2.6. Stream «Ecological biotechnology» 2.7. Stream «Legal, economic, informational and organizational support for biotechnology development». 2.8. Stream «Material and technical base for biotechnology». 2.9. Stream «Staff training for biotechnology». 2.10. FTP «Priority scientific and practical directions in biotechnology (2009–2015)». Part 3. Regional (interregional, district) projects (programs) Part 4. Target projects (non-budget, international, etc. projects).международные и иные проекты). To implement the given parts and streams it is necessary to solve the following particular problems (consequently, in 3 stages) At the first stage (2006–2008): Complex estimation of the state of biotechnology

	in the country, forming databases, defining priorities; Working out the questions of fundamental biotechnology; Perfection of the current and development of the new federal and regional legislative base according to the tasks of biotechnology including the provision for innovations, solution to the intellectual property problems, the problems of science towns, territories of scientific and technical development, etc..; Forming a list and starting to implement the national priority projects in biotechnology, including the immediate actions to preserve biological collections and genetic resources of Russia, industrial development, etc. Forming and starting to implement pilot models of regional biotechnology projects (programs) in 5-7 RF regions; Selecting and implementing ready investment and innovation projects; Development of FTP " Priority scientific and practical directions in biotechnology (2009–2015)". At Stage II (2009–2011): Full expansion of national priority projects with the emphasis on solving the problems of foodstuff supplies and ecologically clean nutrition, improvement of life quality on the basis of modern biotechnology; Wide-scale implementation of regional and interregional projects (programs) in biotechnology across about 30 regions of the RF; Launching the domestic production of biodrugs for diagnostics, treatment and prophylactics of socially important diseases (biogenerics, vaccines, diagnosticums, etc.); Start of implementation of the FTP " Priority scientific and practical directions in biotechnology (2009–2015)";

	Solving practical problems of ecological biotechnology; Solving present-day problems in biological diversity and biosafety; Perfection of the innovation system of biotechnology; Creating a modern system of staff training and retaining for biotechnologists. At stage III (2012–2015.): Wide-scale implementation of national priority projects, including those in energetics with introduction of 5% volume of bioethanol and biodiesel in the structure of fuel balance, in chemistry – transition to renewable raw materials, not less than 10%; Mass production of biotechnology produce with the target to replace import by 30%, including ferments, biopesticides, polysaccharides, etc.; Finishing the implementation of the FTP "Priority scientific and practical directions in biotechnology (2009–2015)"; Introduction of the latest achievements in genomics, bioinformatics and nanotechnologies according to the most important priorities; Creating a system of providing the ecological well-being using biotechnology; Forming a chain of bioresource centers across the country.
Responsible organizations	M.M. Shemyakin and Y.A. Ovchinnikov Institute of bioorganic chemistry RAS, Puschino Scientific Center RAS, N.I. Vavilov Institute of general genetics RAS, GosNIIgenetika, Institute of microbiology ME RF, "Biodrug" PLC, "Vostok" PLC, "Bioprocess"group of companies LLC, "ChimRar" LLC,

	organizoрганизации, выбранные на конкурсной основе
Volume and sources of finance for the Program	Financing of the Program 2006–2015 total – 150000,0 million rubles, including: federal budget – 15000,0 million rubles ; RF regional budgets – 45000,0 million rubles; Non-budget sources – 90000,0 million rubles
Expected final results of the Program	Give Russia the status of a state with knowledge-based economy; Provide mass production of socially important bio-technological produce; Form a prospective stable import-replacing product and service market (foodstuffs, medications, diag-nosticums) – the figures for all products are planned and real to achieve; Provide conservation and rational disposal of Rus-sian genetic resources; Solve the problem of biological and ecological safety.
Organization and control system of the Program	To organize assistance to the implementation of the Program the Russian Biotechnology Organization creates an assistance group (coordination group) with a two-level expert council. The budget component of the program is controlled according to the current legislation and normative acts. In case of opening financing from the state budget the corresponding organization structure is created (the board of directors, coordination coun-cil, etc.).

8. Explanatory note

to the national program "Development Of Biotechnology In The Russian Federation For 2006–2015" (based on state-private partnership)

1. **Introduction.**

As well as informatization biotechnology has become one of the main scientific and practical directions of the 21st century, which define the level of world civilization. Hence development of biotechnology is a strategy objective for Russia, necessary to establish the status of a great empire..

Products, obtained by means of industrial biotechnology are used almost in all the branches of national economy: medicine (antibiotics, hormones, vaccines, ferments, diagnostic systems), agriculture (feed protein, amino acids, means of protection for animals and plants), food industry (leaven, spirit, glucose syrups), chemical industry (polysaccharides, biodegrading polymers, biocatalysts), energetic industry (bioethanol, biogas, biodiesel), ecology (bioremediation and preserving biological diversity).

Besides solving the current and short-term problems biotechnology is important as a means of solving long-term problems, such as transition to renewable raw materials. This objective is itself a global geopolitical task because of the lack of natural mineral resources, the changes in climate and the population growth, and it has to be achieved by the humankind on the whole and the separate states in particular. The leading world countries (the USA, the UK, China) have already approved the corresponding programs, Russia still hasn't got one.

It is worth noting that the world financial circles, the state leaders , the leading scientists and experts and the public recognized the key role of biotechnology in the new century long ago**.** It can be seen by the investments into the branch, the market growth for biotechnological production, the improvements in legislation, etc There has also appeared the term "bio-based economy", i.e. economy based on biology and industrial biotechnology.

Unfortunately, Russia is an outsider here according to all the formal indicators. The share of Russia in the world volume of biotechnological production is less than 0,2%, although 25 years ago the figure was 5%. At the same time a paradox can be noted – the material base, the staff and the scientific workers of the branch which was once the leading one in the country have been retained.

Over the last few years the situation has come to be adequately estimated by the government, the society and the business representatives. As a result of activities in the field part of biotechnological production can replace imported products (immune biological drugs, veterinary drugs). Nevertheless on the whole the situation in the range of biotechnological products is extremely unpleasant for Russia, with an almost 100% dependence on the import (insuline, antibiotics, amine acids, etc.). The scientific community and the ministries and departments monitoring the life sciences, including biotechnology, have expressed stable interest and constantly supported biotechnology (there are projects in FTP, grants, target budget financing, etc.), but the efficiency of investments is insignificant and it doesn't correspond to the level of the branch objectives.

Having estimated the present state of domestic biotechnology, the Russian Biotechnology Organization has proposed an initiative of creating a long-term state complex program based on different tools of budget and non-budget support and aimed at the accelerated development of biotechnology in the country. Over the last two years the experts have developed the concept, structure and methods of implementing the program, which got the name of the Program of state-private –public partnership "Development Of Biotechnology In The Russian Federation For 2006–2015".

2. The Concept of the Program.

The main idea of the Program consists in integration of the state, business and public opportunities to promote biotechnology and implementation of priority projects on the state and regional level to solve the economic and social problems.

The Program is settled for 10 years and includes a list of up-to-date project proposals and sub-programs, arranged according to

their priority: from the national (state) to the regional and ordinary state projects.

The Program is structured according to the traditional program-target principle, accepted in the budget state federal and regional programs (FTP, RTP). This way of planning and concentration of sources has proved to be effective before and at present. First of all the designers tried to avoid isolation, inconsistence and insufficiency of target development for the program activities, which is characteristic of most existing programs.

The proposed program clearly indicates the main target, the tree of targets and particular tasks and quantity parameters which have to be achieved within its implementation period and at the end of it.

The Program includes a set of interconnected projects, each of them subjected to expertise and estimation of the degree of preparedness and sources of finance. For each project the business-plan, technical task, etc. are developed. It gets a co-ordinator in charge (manager). It is supposed to have regular re-expertise and program correction and exclude non-prospective projects to include the new ones.

The special information and organizational support and interaction with the legislative and executive bodies of the federal and regional levels are an important aspect of the present program.

One of the relevant features of the Program consists in the presence of a package of regional sub-programs and projects which allow to involve a large number of RF regions having the opportunity to develop biotechnology locally into real activities. The federal center, the principals and the co-ordinators of the Program will have to provide modern methods, highly professional staff and assist in development of inter-regional co-operation and trade markets.

3. The Structure.

The Program is based on the following approaches:

- The program is to become a system integrator of existing projects and programs and a self-developing mechanism generating new ideas, project proposals and investment (innovation) projects of different degree of preparednessи;

- The program has an indicating character, formulates priority ideas and objectives, defines possible ways of implementing (planned costs, supposed sources of finance, outlets, forecasts, informational backup, etc.);
- The program is to include regional projects with specialization, opportunities for inter-regional co-operation and solving federal problems; in this relation it can be viewed as one of the elements of space development of Russia.

The Program consists of 4 sections:

- National priority projects;
- Federal projects
- Regional (inter-regional, district) projects (programs);
- Target projects (non-budget, international, etc. projects).

The section "National priority projects" includes 6 projects, selected by experts, including the extra-important preserving of national biologic and microbiologic collections and the prospect of forming National bioresource centers. It also includes such projects as transition of energetics and chemical industry to renewable raw materials (biodiesel, biodegrading polymers, biocatalysts, etc.), large-scale production of feed protein for animal farming and poultry, developing large-scale production of glucose syrups for food industry.

The section "Federal projects" includes 10 streams, such as fundamental biotechnology, medical, agricultural, food, industrial, etc. Biotechnology, and also the FTP "Priority scientific and practical directions of biotechnology (2009-2015)", which is to be developed in the next 2-3 years and will include the questions of methodology, legislative backup and co-ordination

The section, devoted to the regional projects is to include 5-7 region at the first stage of implementation and then the number is to become 30.

The section "Target projects" includes non-budget projects ready for implementation and also projects for international co-operation in biotechnology with different states (the CIS, the EU, China, India, the USA, Latin America).

All the sections and streams include a list of projects with estimated costs, possible sources of finance and degree of preparedness.

4. **Implementation tools. Financing.**

The present Program has in fact no precedents – it is targeted at uniting state and non-state mechanisms, aimed at one target: to overcome the crisis in domestic biotechnology and make it an efficient tool providing material well-being of the country and creating a society based on knowledge. In fact, an experimental model of forming and implementation of interdisciplinary program **based on state-private partnership** is being created, which has many times been decklared necessary by the state leaders.

The necessity of implementation of this program is set by rigid time limits. If the state, business and society don't unite the efforts to develop the most prospective hi-technologies, including biotechnology, within the next 5-7 years, our country will take the place of raw material source for transnational corporations for the next few decades. This is particularly important as Russia is going to become a WTO member. .

Hence the Program gives priority to ready investment projects. Such projects have already been prepared by a number of organizations in the Union of Biotechnology Enterprises ("Vostok" PLC, "Bioprocess" group of companies LLC, "Medic-technological holding" PLC, "Biodrug" PLC, FSUE SIU "Microgene", etc.) In case organizational issues are discussed, including outlets, legal provision of taxing preferences and favorable loans, etc. they can provide the vital drugs for medicine, agriculture, etc. (see business-plans for the corresponding volumes).

The Russian Biotechnology Organization, being the main designer and coordinator of the Program places high expectancies on domestic organizations using new hi-technologies, such as "ChimRar" LLC, Medical center "Avitsenna" PLC, etc., which are integrated in the world market and may be useful for the development of Russian biotechnology.

Becoming part of the Program gives each participant the following bonuses: using the databases of the Russian Y.A. Ovchinnikov Society of Biotechnologists; ability to attract additional investments, HR assistance, development of consolidated state-private positions to perfect legal and economic federal and regional mechanisms.

A special place in the Program is devoted to supporting high quality domestic inventions, e.g. production of gene-engineering insulin (IBCh RAS), industrial microbiological synthesis of a number of biologically active substances (State SRI Genetics), producing recombinant proteins for medicine, including hepatitis and AIDS treatment (SSC "Vector", SRI OChBP), wide-scale production of therapeutic monoclonal antibodies (Russian cardiology SIC), etc. Here the question of finance can be solved using the budget or attracting non-budget investors.

The greatest need for finance is in the implementation of the part "National priority projects". It has been preliminary estimated that the projects here will require over 60 billion rubles for 10 years. It is clear that it will be a long-term investment which is impossible without the key role of the state. At the same time, state activity will provide attractiveness for private investors. Implementation of this part of the program even incomplete will in fact be enough for the country to overcome the crisis in biotechnology.

The key principle of Program financing is to create an efficient state-private partnership mechanism and to plan the projects in a flexible way. The projects to be included in the program are selected individually, considering the balance of interests and share of the clients and providers.

On the whole the Program financing is planned in the following proportions: the total financing is 150000 million rubles, including 15000 million rubles (10%) from the Federal budget, 45000 (30%) million rubles from the regional budgets and 90000 million rubles (60%) from non-budget sources. These planned figures are given for estimation, real financing will be carried out as the investments are attracted.

The Foundation for domestic biotechnology support is planned as one of the sources of finance for the Program.

5. Expected results.

The implementation of the program will solve the following problems:

- Give Russia the status of a state with knowledge-based economy;
- Provide mass production of socially important biotechnological produce;
- Form a prospective stable import-replacing product and service market (foodstuffs, medications, diagnosticums) – the figures for all products are planned and real to achieve;
- Provide conservation and rational disposal of Russian genetic resources;
- Solve the problem of biological and ecological safety.

The social effect of the program will be significant if the planned figures are achieved (solving the problem of unemployment, preserving qualified staff, etc.)

The projects of the program are on the most part highly commercial, in some cases reinvestment in the area is possible within the 10 years. According to specialists, the average term payback is no more than 5 years. Besides, it is forecast, that the total price for biotechnological produce of the program participants will be about 300 billion rubles by 2015.

6. Informational and organizational support.

The unusual character of the program (the principle of state-private partnership is meant) suggests special conditions for organizational assistance. The role of informational support becomes more important as the analysis will be required for the projects outside the Program as well as for the ones in it, and the market for biotechnology products as well has to be constantly monitored. The methods of economic and mathematical modeling and making middle and long-term forecasts will be widely used.

To provide these tasks the Russian Biotechnology Organization has the necessary expert staff and database, including the latest server technologies.

Project selection will be done by assistance group with a two-level expert council.

The budget component of the program is controlled according to the current legislation and normative acts. In case of opening financing from the state budget the corresponding organization structure is created (the board of directors, coordination council, etc.).

The assistance group of the Program, the Central Government of the Russian Biotechnology Organization, the Expert council for biotechnological industry of the RF State Duma will carry out constant monitoring of open domestic and foreign grant competitions in biotechnology. The mechanism of gathering information through partnership with other public organizations, associations, academies in the RF and other countries (the Society has partnership relations with some of them – RAS EFB). will also be used.

7. Interaction with State authorities.

The national, federal and regional projects will be formed in close interaction with the corresponding state structures. The federal level will be implemented through interaction with the RF State Duma, The RF Government, profile ministries and departments**.** At present the Russian Biotechnology Organization has contacts with most of them. The regional level is provided through interaction with the legislative and executive bodies of the regions.

8. Forecasts (different scenarios for biotechnology development in Russia).

The Russian Biotechnology Organization has done preliminary estimation of forecast scenarios for prospects of biotechnology development in Russia and its influence on the social and economic status of the country. There are 2 ways – not interfering or actively supporting biotechnology.

The possible scenario of the country development in case domestic biotechnology is not supported (including the case of not accepting a special national program).

- Dependence upon import for the vital medical drugs (antibiotics, hormones – insulin, etc., oncological and antivirus drugs);

- Deficit of optimal nutrition for the population;
- A drop in life quality and its progressive decrease for most of the population;
- A growing load of ecological and energy problems;
- Absence of basis of counteraction towards bioterrorists and solving the problem of biosafety on the whole;
- Economical backlog and loss in qualified staff.

The alternative way of development in case of domestic biotechnology support (in case of accepting a special national program):

- Import replacement by not less than 20% for the vital medications;
- Providing high quality foodstuffs for the population;
- Increase of life quality according to the modern level of science and practice;
- Solving the problems of biodegrading, reconstruction of energetic and chemical industry based on renewable raw materials (not less than 10%);
- Introducing new technologies to the system of bioterrorism counteraction and providing biosafety;
- Increase of economical state and solving the problem of unemployment.

9. Conclusion.

Thus, biotechnology is one of the powerful forces of raising national economy. The competition in biotechnology is growing all over the world. Each country is trying to find its place in this race, have its own face, get its "biotechnological passport". According to experts, it is the level and state of biotechnology development that will be one of the important criteria of estimation for the development of a country in the 21st century.

Development of biotechnology is in many ways defined by the needs of the market, as the demand for foodstuffs, medications, energy, etc. is constantly growing. It may seem that being highly

commercial, biotechnology doesn't need any special regulations. Nevertheless the program target method still hasn't been used to the full in the modern world. For instance, even such country with market economy as the USA accepted a long-term biotechnology program till 2025 with the final target to make the level of chemical production using renewable raw materials 25% (the Biomass Law, 2001). In this connection one has to mention the experience of Cuba, which currently takes the 7th place in the world biotechnological rating. This small country, if we compare it with Russia having giant natural and human resources, was able to achieve such impressive results because a corresponding program of national biotechnology development was accepted here in 1985 with the direct participation of vice-president of RAMS , academician Y.A. Ovchinnikov. The growth of biotechnology over the last years in such states as China, India, Brasil, etc. with their great potential due to direct governmental support is well known.

Implementation of the Program "Development of biotechnology in Russia for 2006-2015" will allow the country to overcome the crisis in the sphere that is so strategically important, contribute to the development of new economy, based on knowledge, provide its competitiveness in globalization environment, allow to solve a number of important problems of economical and social development.