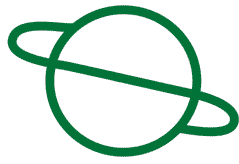




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NATIONAL BIOSAFETY FRAMEWORK

NATIONAL BIOSAFETY FRAMEWORK
ULAANBAATAR 2005

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GENERAL INTRODUCTION

From 1950 the research work of the biological science started using the physical and chemical methods which was helped to study the quality and the activity of the body in molecular level. The intensive development of the molecular genetics , which is the new sector of the biological science, started in the middle of the 20 th century. This helps us to enrich our knowledge of the live nature and also gives us the new ideas. The molecular genetics molecule is the science, which studies the molecular root of cells heredity rules.

The genetic engineering is started when the researcher P.Berg created the hybrid molecule in vitro in 1972.Genetic engineering is based on the achievement of the molecular biology, genetics, biochemistry, and microbiology. In Mongolia the researchers' work of the microbiology started in middle of the 1980.But our researcher working really hard to be on alongside with the development of the world molecular biology and molecule genetic and getting some achievement.

Acknowledging that protection of biodiversity is very important for the sustainable development of the economy and the environmental protection and is of regional and global significance in view of the balance of ecosystem. The Government of the Mongolia has set equal importance to both development of the Biotechnology and establishment of the NBF, taking appropriate measures

The Modern biotechnology is developing intensively in many countries. Besides this we have to protect human health and the environment from the possible adverse effect of the products of modern biotechnology. One example of it is the international agreements. The Mongolian is paying their attention on it and adopted the Cartagena Protocol on biosafety. The Cartagena Protocol is the international framework for biosafety, with particular reference to transboundary movement of LMOs and the ultimate aim of maximizing the benefits of biotechnology while minimizing its possible adverse effect. The protocol establishes a harmonized set of rules and procedures for regulating movements of living modified organisms from one country to another. The concept of biosafety refers to the need to protect human health and the environment from possible adverse effect of the products of modern biotechnology

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1. BIOSAFETY POLICY

1.1 INTRODUCTION

Relatively few scientists in Mongolia using the Modern biotechnology techniques such as genetic engineering in their research and development activities. Until recently this small group of experts received considerable government support but was largely isolated from the world scientific community. Since the early 1990s, however, both these circumstances have changed drastically. In regards to funding, in the days before 1991 of the Mongolian government, with adequate support from the Soviet Union and other countries Council for Mutual Economic Assistance provided financial support to more than 80 scientific research institutes existing in those days. However since 1991 support from science generally has fallen disastrously low levels making it nearly impossible for research institutes that depend only on government payment to operate effectively.

In practice the only scientist able to undertake meaningful work are those with international connections. The current status of biotechnology research reflect the general situation in Mongolian science and therefore is highly unsatisfactory to scientists and entrepreneurs alike.

On the one hand since 1991 many ways for communicating with foreign colleagues have opened up for Mongolian scientists. Further funding from various international sources has increased the possibilities for travel, allowing Mongolian researcher to participate in international meetings and take up training opportunities abroad. In this chapter we consider the history and politics that bear on Mongolian biotechnology and discuss relevant research and production activities in institutes universities and private enterprises .We then describe the major biotechnology facilities operating in the country discuss the nascent Mongolian Biotechnology association and list resources in Mongolia that may have potential for biotechnology development.

Bio-safety can be identified as the efforts and measures aimed at minimizing or eliminating the risks of possible adverse effects caused by biotechnology or the products originated thereof. In connection with the rapid growth of world population and its day to day increasing needs, at the same time due to natural resource wealth shortage, it is now crucial to make use of achievements of science and technology in economy more and more intensively. Around 40% of worldwide produced products are originated

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from the biotechnology and this tendency is thought to increase in the future. The purpose of bio-safety policy of Mongolia, directed to protect human health and conservation of surrounding environment, who imports around 70% of its foodstuff products, is to carry out ecological, social-economic and political measures, simultaneously.

1.2 Present Situation

Modern biotechnology has developed in many countries so intensively that its achievements have also been exercised efficiently in industry and practice, but on the other hand unsustainable use and production mismanagement might lead to an adverse effect. We have to be ready to act on the case of possible adverse effects.

Mongolia ratified the Cartagena Protocol on Bio-safety to the Convention on Biodiversity on 7 of November 2002. By ratifying the Protocol, Mongolia obliged to take measures of prevention from the risks possible of adverse effects of biotechnology in regard to modified living organism or products originated thereof, on Eco-system, human health and on genetic resources, in international arena.

Since 1986, modern biotechnology has been a priority policy of Government of Mongolia in developing science and technology, which was carried out on the basis of the State central policy. Several documents were developed containing the purposes to be persuaded and framework of action to be taken by the Government, policy and organizational measures were taken. For instance, the Government at that time adopted number of documents related to the biotechnology, to name just two; Conception of the development of Biotechnology Research and Industry up to the period of 2000 in People's Republic of Mongolia (1987), The Comprehensive Program of Scientific and Technical Progress up to the period of 2005 in People's Republic of Mongolia (1988).

National Program of Action of Conservation of Biodiversity was adopted by Resolution No 163 of the Government of Mongolia. The State agencies to ensure the bio-safety in Mongolia are; Ministry of Nature and Environment, Ministry of Health, Ministry of Finance and Economy, Ministry of Justice, Ministry of Trade Industry, Ministry of Food and Agriculture, Public Health Institute, Veterinary research Institute and Academy of Sciences.

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None of the agencies above can handle and resolve the risks of possible adverse effects that may face the human health and surrounding environment on its own. That's why the Government recognized the importance of involvement and cooperation of all State departments and high ranking Government officials, private sectors, civil society in the work to protect and prevent from the possible risks that may face human health and surrounding environment. The Cartagena Protocol, to which Mongolia is a Party, is an international principle guideline to regarding the importance of bio-safety.

1.3 POLICY ON BIOTECHNOLOGY AND BIOSAFETY.

A. Main Objectives

The main objectives of biotechnology and biosafety policy are;

To ensure the safe use of biotechnology in the Mongolia, and to eliminate any possible risks that may be detected in the process of introducing the achievement of research into the different fields of the national economy and to protect health of the people and conserve the biodiversity and ecological environment and,

To make up the legal network of the NBF and establish well-regulated administrative organization, supervisory body and risk assessment and data exchange body, so as to promote the scientific research, development and production of the modern biotechnology on the basis of biosafety guaranteed and at the same time contributing to ensure maximum safety for movement, handling and use of Living Modified Organism including genetically modified crops.

B. Basic principles

One of the basic principles is to preferentially ensure the protection of human health, ecological environment and the conservation and sustainable use of biological diversity.

Any research work that is hazardous to live organisms, even if its outcome is high in productivity and economic profit, should be suspended.

The export and import of GMOs is subject to the approval in advance.

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The transboundary movement of GMOs should be conducted according to the appropriate regulatory procedure and with the approval of the state.

The precautionary measures should be taken and the principle of precautionary management be maintained in the work of the sectors related to biotechnology.

Modern biotechnology should be developed and its achievements be accepted in the light of human health, biological diversity and environmental protection.

An appropriate management system should be strictly established and all the possible risk elements be reduced at an earliest time possible at each stage of research, development, environmental introduction, production, commercial activity and transboundary movement in the field of modern biotechnology.

The risk assessment, safety evaluation and the management of GMOs should be conducted on the basis of the latest scientific and technological successes and through the procedure of the sufficient scientific and technical review.

The strict labelling and packaging of GMOs shall prevent them from being possibly released in their transboundary movement, handling, use and consumption them thoroughly.

Efforts should be made to involve the public in the discussion on the problems related to the establishment of the NBF and bring them to the correct understanding of the matter through public awareness work, and openness and transparency in the dealing with the genetically modified organism be ensured.

International exchange and cooperation with the other countries should be conducted in close cooperation with the relevant international organizations such as UNEP.

The principle of pushing ahead with the capacity building of NBF, especially the work of upgrading modern scientific and technical standards and simultaneously training the specialists.

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2. REGULATORY REGIME

2.1 CURRENT SITUATION

Until today, there is no bio-safety management and lack of decision making structure in Mongolia in importing of living modified organism or products originated thereof from foreign countries and the legal environment is still absent.

The regime of National bio-safety development management is the basic international instruments such as the “Convention on Biodiversity” and “Cartagena Protocol on Bio-safety”. These instruments apply in many countries in the world. Setting up of the appropriate legal framework takes certain time.

Therefore, it is necessary to set up legal framework to ensure the country’s bio-safety; Draft Law on Bio-safety has been worked out taking into consideration also that many more rules and regulations to follow up, at the same time, a Draft of Bio-safety action Program is underway of working out. The Drafts are to be circulated to the public awareness before it is adopted by the Parliament. The main purpose of the Law is to coordinate the relations arising out of trans-boundary movement of living modified organisms or products originated thereof, their sustainable use, protection of human health and conservation of fauna and flora biodiversity.

Because the biotechnology related actions affect mostly to all scientific, educational, production, environmental fields equally, accordingly it also creates multifaceted relations associated with the material and non-material wealth, therefore these relations are to be coordinated within the framework of a large number of Laws in Mongolia. To name just those Laws with direct connections with such relations;

2.2 Legislative regulation of biotechnology research and development in Mongolia

These days according to the global standard Mongolia is transberring to the new social system that is based on market and therefore there’s no other possibility to conduct whole biotechnology activity coordinating with the supply and demand principle. Demand is defined by any application and extend such as state, organization, community, individual and legal or non-

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legal bodies but supply is directly dependent on mental and material resource or scientific and technological potential of biotechnology sector. Therefore there is a common feature that any relations rising from the biotechnological activities could be compared to the other social relations. Besides that production supply, demand and competition depend on whether it is satisfying human desire and interest or suitable for the social security and ecological balance and how much mental potential spent on producing those things. Therefore biotechnology is involved in any sectors such as science, education, industry, and environment, and it is creating multilateral cooperation connected with material or mental heritage. Hence in the framework of our country these relations are being arranged whithing the existing legislation of Mongolia

Majority of experts knows well that the development of biotechnology depends on consumer's demand, concerns of people, human health and environmental requirements. From technological point of view biotechnology is developing extraordinary rapidly.

Biotechnology relates to almost all spheres of human life, like major science fields, especially medical and environmental sciences, education, many industry fields such as food and pharmaceutical industries, environmental issues etc. Thus biotechnology affairs can be regulated within the existing legislation of Mongolia. Below we list some related laws and regulatory documents. These are:

1. Law on Science and Techniques (1998), the purpose of the present Law is to determine the rights and obligations of the participants in science and technical operations and the relations connected with administration, principle and financing of such operations.

2. Law on Transfer of Technology (1998), the purpose of the present Law is to determine the principles of transfer of technology operations, assessment of technology level, determining the requirements to transfer of technology and other relations connected with it.

3. Patent Law (1993), the purpose of the present Law is to determine the new products, sample of products, protecting the authors' rights of constructive products, patent owners rights and the relations connected with the usage of new products, sample of products and productive idea.

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4. Copyright Law (1993), the purpose of the present Law is to protect the authors' rights and to determine the relations connected with copyright related products usage.

Package of Laws on Education (2002), the purpose of the present Law is to determine the universal principle of education, structure, substance, administration, organization and rights, obligations and accountability of participants in educational relations, ensuring the citizens' common rights to education.

5. Law on Conservation of Environment (1995), the purpose of the present Law is to ensure the human rights to live in healthy and safe environment, to associate the social and economic development with ecological balance, conservation of the environment in the interest of the present and future generations, sustainable usage of its wealth and rehabilitation,

6. Law on Environment Affect Assessment (1998), the purpose of the present Law is to conserve the environment and prevent from damage to ecological balance, coordination of nature wealth usage, environment affect assessment of projects, making decision of implementing environment related projects,

7. Law on Animal Husbandry Genealogy and Health Protection (2001), the purpose of the present Law is to coordinate the relation connected with the animal husbandry or any domestic animal genealogy and health and relations connected with them,

8. Law on Foodstuff (1999), the purpose of the present Law is to coordinate the foodstuff needs of population, its safety, the relation between state, citizen and legal entity's in connection with foodstuff production and service,

9. Law on Medicine (1998), the purpose of the present Law is to coordinate the relations connected with the human and veterinary medicines' production, import, storage, selling, distribution, usage and controlling,

10. Law on health (1998) the purpose of the present Law is to determine the state policy and its basic principles, to ensure citizens' rights to protect their health, to have the medical aid and service, and coordinate the relations in connection with obligations of the Government agencies,

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officials, legal entities and individuals, the legal environment of the health institutions and officials,

11. Civil Code (2002), the purpose of the present Law is to coordinate the relations in connection with non-material related wealth arisen between the legal entities,

12. Law on Flora (1995), the purpose of the present Law is to coordinate the relations in connection with protection, sustainable usage and rehabilitation of flora, except forestry or planted flora,

13. Law on Fauna (2000), the purpose of the present Law is to coordinate the relations in connection with protecting, rising of animals inhabited or emigrated, on the soil, water and ground, in the wild of Mongolia,

14. Law on Water (1995), the purpose of the present Law is to protection of water, its sustainable use,

15. Law on Forest (1995), The Mongolian Law on Forests (effective 5 June 1995) regulates the protection, proper use, and restoration of forests. According to this law, forest resources are divided into strict forest zones, protected forest zones, and utilization forest zones. Details on the zones and their protection and use regimes are described in the first four chapters. The remaining chapters deal with forest fire protection, maintaining and clearing forests, measures for the protection and restoration of forests, as well as forest utilization issues such as timber contracts, harvest licenses, forest users' obligations, etc

16. Customs Law (1996), This Law is formulated with a view to carry out customs policy within the territory of Mongolia for the purpose of safeguarding the sovereignty, interests and national production of Mongolia, expanding cooperation with foreign states in trade, economic, scientific, technical cultural and other fields.

17. Law on Foreign Investment The purpose of the present law shall be to encourage foreign investment, to protect the rights and property of foreign investors in Mongolia, and to regulate matters relating to the operations of business entities with foreign investment.

18. National Development Concept of Mongolia the key strategy of national development in the nearest 15-25 years.

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19. National Security Concept of Mongolia represents the status when favourable external and internal conditions are secured to ensure vital national interests of Mongolia. The ideological basis of the policy ensuring national security is national patriotism.

20. Foreign Policy Concept of Mongolia Mongolia's foreign policy is dominated by a need to secure sovereignty and economic independence

21. Government Policy on Science and Technology

22. Guidelines to carry out Science and Technological Projects,

24. Rule of Carrying out of and financing of basic theoretical research work, (Minister for Education No 93, 2000)

25. Guidelines to make Transfer of Technology Contract and its Registration
(Decree of Minister for Enlightenment, No 46, 1999)

26. Common Rule to make technological assessment, (Decree of Minister for Enlightenment, No 271, 1998)

27. Rule of submitting and usage of Scientific research work Report,
(Decree of Minister for Enlightenment, No 173, 1998)

28. Rule of Determining of assessment criteria for intellectual property, (By Decree of Minister for Justice, No 130, 1998)

29. Rule of Registration and Control of Living modified organism or the products originated thereof (Government Resolution No204, 2003)

Judging by the above mentioned list of Laws, one can conclude that the legal norms to coordinate the relations in carrying out of research work and training, or production and business activities in the field of biotechnology,

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generally have already been set up or at least the legal grounds have in general been expressed.

However, the biotechnology progress in our country is only on the initial stage of development, it is believed that with the deepening of understanding of the matter in the future, it is certain that more and more relations and complex problems will arise.

In order to, all Governmental or the NGO's to obtain a cohesive understanding, study and conclusions about the possibly would-be relations and problems in the future, they all should, by way of cooperating among each other, complete and sharpen the biotechnological legal framework coordination in our country.

3.ADMINISTRATIVE STRUCTURE

3.1 COMPETENT AUTHORITIES

Prime Minister of Mongolia signed the Convention on Biological Diversity while participating the United Nations Conference on Environment and Sustainable Development, in 1992. As the result, the Convention was ratified by the State Great Hural of Mongolia on 1 June, 1993. Consequentially, by the instruction of the Minister for Environment and Nature, a National Committee consisting of twelve members was set up to realize the provisions of the Convention throughout the country. The most outstanding scientists and experts in the field of biology are involved in the work of the Committee. The Mongolian Government, through the Ministry of Environment and Nature and National Committee, has been fulfilling the obligations of the Convention ever since then. The Government has developed its long term policy on conservation of fauna, flora and forestry, its efficient handling, thus such provisions have been incorporated into the relevant sections of the Laws passed through the State Great Hural, such as the Ecological Security Section of the National Security Conception (1994), Environmental Part of the National Development Conception (1995), Government Policy of Ecology (1997) etc.

In order to develop the biotechnology as one of the priority direction of the scientific and technological development, since 1986, the Government has played a leading role in managing the scientific institutions in certain

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ways in relation to its policy and organization, and also considering the specific feature of the biotechnology.

However, ever since then, with beginning of social and economic transition period which led the country's political and economic instability, the focal institutions were changed also many times;

With the change of the Governments, the focal institutions in relation to the scientific agencies have changed frequently as follows;

1. Between 1986 – 1987, State Planning Commission, (containing the Department of Science and Technique), State Committee of Science and Technique, State Committee of Higher, Special and Secondary Education, Academy of Sciences, and the other scientific research institutions, universities and high schools,

2. Between February 1988 – April 1990, State Committee of Planning and Economy, (containing the Department of Science and Nature), State Committee of science, technique and higher Education (containing a part-time organ “National Council on Biotechnology”), and the other scientific research institutions, universities and high schools,

3. Between April – October 1990, State Committee of Social and Economic Development (containing Department of Science and technical Progress and Nature), State Committee of Technical Progress and Standardization, Academy of Sciences, and the other scientific research institutions, universities and high schools,

4. Between October 1990 – August 1992, National Development Ministry (containing Council of Science Development and a part-time organ “Science and technology” involving the leading scientists), and the other scientific research institutions, universities and high schools,

5. Between September 1992 – July 1996, Ministry of Science and Education (containing a Department of Science and technology Policy), National Council of Science and technology (A part-time organ by the Government) Science and Education Ministry (containing Science and Technology Fund) and the other scientific research institutions, universities and high schools,

6. Between July 1996 – July 2000, Ministry of Enlightenment (containing a Department of Strategy and Planning which, in its turn consists

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a “Science and technological Development Project Team”), National Council of Science and technology (A part-time organ by the Government) Science and Technology Fund, Academy of Sciences and the other scientific research institutions, universities and high schools,

7. Since August 2000 up today, Ministry of Education, Culture and Science (containing a Department of Science, technology, and Higher education Policy Coordination), National Council of Science and technology (A part-time organ by the Government) Science and Technology Fund, Academy of Sciences and the other scientific research institutions, universities and high schools,

This is the general picture of the science and technological administration structure of Mongolia and as far as the biotechnology is an indispensable part of science and technology, the concept of “biotechnological administrative structure” should be included within the framework of this unified system of administration which bears the character of science policy and coordination.

4. OUTLOOK AND NECESSITY

Now, it is important to establish in Mongolia a national bio-safety regime and legal environment, to that end, the World Environment Foundation and United Nations Development Program have been implementing the Project “Bio-safety Development Program” in Mongolia.

States pay more and more attention on bio-safety and conservation of environment, today. This is not only a matter of concern of a single State but the matter of concern of all States within the context of globalization. Clean environment, clean production are the firm ground of peace and sustainable development.

Most of the business community and institutions in our country are well aware of importance of ecologically clean and high quality products but they left far behind many countries mainly owing to incapable of clarifying and realizing ecological policy and goal because of lack of knowledge of methods and approach or short of training as well as short of appropriate support. Therefore, it is important to develop and implement “National Program on Bio-safety” and “Law on Bio-safety”.

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In implementing the above documents, it is important;

To comply with the provisions obliged by the Cartagena Protocol to which, Mongolia is a Party,

Modern biotechnology should not threaten human health and surrounding environment,

Bio-safety development should be based on higher level expertise and experience,

To establish a stability and continuity of policy in maintenance of the public involvement

To establish a deep-rooted cooperation atmosphere

between the various institutions of different sectors in implementing the policy.

Furthermore; to establish in Mongolia world standard structure to produce internationally standard ecologically clean products, to carry out biotechnological study and research, It is important to develop the biotechnological production in keeping with the ecological balance, prevent the humankind from dangerous disease and provide with high quality foodstuff products, to improve the fauna and flora genetics, to ensure the sustainable development,

The Government should support and encourage implementation of various projects directed to intensify and increase the investment in bio-safety field overall goal of which are to strengthen bio-safety development meeting the international standard in Mongolia, work out a technology not harmful to nature, ecology, society and human health, to introduce the achievements of biotechnology in production and practice, in intensifying and improving of sub Program of “Biotechnology”,

To renovate the “National Council on Biotechnology” function of which is to improve the sub Program of “Biotechnology” and the management of and introduce into the country’s economy biotechnological training and study, improvement of coordination between the institutions, laboratories and obtaining of foreign investment in this field,

It is also necessary to advance the basic and supplementary study of biotechnology to the international level, to set up an information fund incorporating Mongolia into the international biotechnological network, to expand the assistance and support of developed countries, to improve its biotechnological production and demand

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5.MONGOLIAN BIOTECHNOLOGICAL MANAGEMENT SYSTEM

Mongolian biotechnology was directed by the State or Scientific organizations with the definite forms in the framework of policy and management and depending on the features of its activity from the professional the issue to provide with the methodological centralized management were being discussed. During this time in our country social transitional period was taking place and politics and economic situation wasn't stable. As a result of this matters directing organizations used to be changed. On the basis of "Mongolian National Security Concept" which was reflected biotechnology as the leading direction of its concern and by following the 1995, 218/102th combined resolution of Minister for Science and Education and President of Academy of Science, "Biotechnology-95", scientific and industrial national conference was organized in Ulaanbaatar in Nov, 1995 with the financial support of scientific and industrial company "Shim". In this conference emphasized that there is rising demand to support Mongolian biotechnological activity with the professional centralized leaders in connection with national security concept and made an proposal to establish non-governmental, independent and legal organization "Mongolian biotechnological Association". By this matter in the decision from the conference reflected the importance of taking support from the government and especially the importance of the cooperation with the government by the regulations. The meeting to establish non-governmental organization was held in Jan, 1995 and as the result of the meeting "Mongolian Biotechnological Association" was established.

Since its establishment this association have been initiation and organizing several activities to develop Mongolian biotechnology. One example of this is "Biotechnology" second program which is to be implemented within 1999-2005 was prepared by the Academy of Science and state administration organizations such as Ministry of Agriculture, Ministry of Science and Education and Ministry of Health and it was adopted by the government in July, 1998. The Association become the member of International Biotechnological Industrial Organization /IBIO/, one of the 600 organizations that conduct biotechnological activities, in 1997. Regarding to the recent position of the biotechnological administration system, it has been long time since the directing definition of government policy to develop biotechnology as the leading direction of scientific and technological sector

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of our country and reflection of it into the legal documents, but in the framework of state administration central organizations the suitable mechanism for directing activities hasn't provided yet and the cooperation between governmental and non-governmental agencies are in its initial stage. Even though the government has prepared special program of biotechnology and requires information from the connected ministries, it doesn't pay attention on its deficits and take policy steps. One of its definite example is at the end of the "Biotechnology" second program and after the four years of its implementation National Committee which is responsible for organizing, controlling and directing of the this program implementation, led by member of Parliament, hasn't made a meeting yet. Particularly, resolution about developing biotechnological activities on the national scale and take financial support from the national centralized or countryside budget hasn't been effected yet. In other words this program doesn't have its property guarantee

6. PUBLIC AWARENESS AND PARTICIPATION

A. Summary of System for Public Awareness, Education and Participation

The objective of public awareness and participation on biosafety is to ensure that all groups of stakeholders have the correct understanding and knowledge on biosafety-related issues including the nature of biosafety, potential adverse impacts and benefits of GMOs and participate in decision-making procedures related to biosafety.

A well-regulating system for public awareness, education and participation shall be established.

Public awareness through newspapers, radio, televisions and all kinds of publications

The draft Biosafety legislation recognizes public involvement (Through Non-governmental Organizations) in Monitoring compliance of implementation of Biosafety regulations.

Public awareness and education through the science and technology study group, works study group, science and technology propagation group and skill-training study group operated in all factories, farms, organs and enterprise in the county

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Public awareness, education, and of the masses of people through lectures on science and technology given on a regular basis Public awareness, education, and participation of the masses of the people`through scientific knowledge dissemination session, question-and-answer session on scientific knowledge, and consultations on scientific knowledge

7.CONCLUSIONS

To establish National DNA recombinant technology Advisory Council in near futureTo establish appropriate legal and technical environment for using unic Genetic resource of Mongolia in appropriate way In situation of Mongolia it could be economical way to combine both regulatory and research potential of the country in one unit for the regulatory and research functions in bio-technology.

To announce research Project from the Government aiming to elaborate appropriate methods and technology for testing of GMO products.

To issue guidelines and technologies to work with new organisms /GMO, LMO/.

To check imported food items for the GMO presence.

In solving the GMO related decisions should be used predatory principle, due to Mongolia 's limited scientific know ledge and experience

Methods already established and tested in developed countries should be widely used.

To harmonize risk assessment strategies in regional and international level is important

Mongolia 's Research Institutions already providing research in gene and cell engineering technology, therefore Mongolia has a human resource for dealing with biotechnology development and its safety issues. However they need financial and organizational support.

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ANNEX I. INFORMATION ON PROJECT IMPLEMENTATION

UNEP/GEF Project on NBF development for Mongolia has been developed within frames of Global project for countries to implement Cartagena protocol through their national biosafety framework.

NATIONAL IMPLEMENTING AGENCY:

Ministry of Nature and Environment

NATIONAL PROJECT CONSULTANT:

Ouynbileg

NATIONAL PROJECT COORDINATOR:

Sarangerel Aleksandr

NATIONAL PROJECT IMPLEMENTATION TERM:

22 months,

LIST OF MEMBERS OF NATIONAL EXECUTIVE

BIOSAFETY COMMITTEE

Head; Minister for Environment and Nature,

Members; Deputy Minister for Health,

Deputy Minister for Food and Agriculture,

Deputy Minister for Science and Education

Secretary of State for Environment and Nature,

Secretary of State for Trade and Industry,

Head of Customs Office,

Director of Biological Institute, (by approval)

Director of Veterinary Research Institute, (by approval)

Director of Public Health Institute, (by approval)

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Director of Biotechnology Production, Research and Training
Center of

Public Health Institute (by approval)

Secretary; National Coordinator for Biological Diversity Convention.

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Translation unofficial

ANNEX II. STATUTE OF THE NATIONAL BIOSAFETY COMMITTEE

ONE. GENERAL PROVISIONS

1. The National Executive Bio-safety Committee /hereinafter referred to as the “Committee”/ is an ad-hoc organ to ensure the overall bio-safety issue, to monitor the implementation of the Cartagena Protocol of the Bio Diversity Convention, Bio-safety Law and their implementation throughout the country.
2. The Committee will work within the framework of environmental conservation law as well as science and technology laws, regulations and the present Statute.
3. The Members of the Committee shall be approved by the Government. The Committee may have its sub-Committees in provinces and capital city under the authority of the Committee.
4. The Committee shall approve the Members and Statute of the sub-Committees.
5. The Committee consists of not less than 11 members and sub-Committee not less than 7 members.
6. The Head of the Committee shall be Member of the Government in charge Environmental issues and the Chairman of the sub- Committee shall be the Governor of the Province or the Capital city.
7. The Committee shall use the imprinted paper and stamp of the Central Administrative organ on Environment.

TWO. SUPERVISION AND STRUCTURE

8. A Meeting of the Committee shall carry out its operational functions. The Meeting of the Committee shall adopt a Resolution signed by the Head and Secretary of the Committee. The Committee may adopt records or

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recommendations if it deems necessary. Related entities, organizations and officials take appropriate measures to implement the records or recommendations and response to the Committee the actions taken and the consequences.

9. The meeting of the Committee shall be convened at least once in a quarter to discuss the measures taken and the consequences in implementing the provisions of the Cartagena Protocol, Bio-safety Law or any other Resolutions of the Committee.

10. The agenda of the meeting shall be adopted by the Meeting of the Committee. The Meeting shall be chaired by the Head of the Committee, in case of his or her absence, by Deputy Head of the Committee.

11. The Secretary of the Committee shall ensure to arrange for and service of the Meetings, to circulate the Resolutions to the related Ministries or establishments and monitor their implementation and to perform such other daily functions. The seating of the Secretary shall be the Ministry of Environment and Nature.

12. At the Decision of the Committee, a project team or a working group may be established with the participation of the related Ministries, agencies, scientific researchers and entities to carry out particular issues if the Committee deems necessary.

THREE. THE RIGHTS AND OBLIGATIONS OF THE COMMITTEE

13. The Committee has the following rights;

a) To give permission or reject, restore or cancel the licenses issued to any entities, organizations or individuals that wish to carry out operations within the framework of the bio-safety.

b) To monitor the implementation of the bio-safety related laws, the Committee's Resolutions and recommendations and where necessary to demand for information and data,

c) To demand for any necessary information and data from the related organizations and individuals, to make proposals and conclusions and make contracts,

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- d) To set up a fund of documentation files on license holders operations,
- e) To provide guidance and advice and monitor the local sub-committees,
- f) To adopt proposals and recommendations to advance the development of the bio-safety related laws and regulations,
- g) To hold or host international or local conferences, consultative meetings, seminars and workshops within the framework its functions,
- i) To incentive the entities, organizations and individuals whose effective participation ensured the bio-safety,
- j) To notify officially the competent authorities in higher stances on those entities, organizations and individuals failed to fulfill the Committee's Resolutions and Recommendations and take appropriate legal responsibility,
- l) To cooperate with foreign states and international organizations in studying and researching, change of information and carry out projects within the framework of the bio-safety.

14. The Committee has the following obligations;

- a) To ensure to carry out an unified and integrated bio-safety guidance and policy throughout the county,
- b) To coordinate and organize the internal monitoring system on quality and safety of bios-safety in all stances of its production, transportation and trading, to improve the connection between them,
- c) To monitor the decisions and implementation of plans and reporting,
- d) To carry out specific training's and general training's for the public,
- e) To encourage the initiatives of the entities, organizations and individuals on bios-safety issues and cooperate with them,
- f) To cooperate with law enforcement authorities on bio-safety, such as frontier authorities, customs office and tax authorities,

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g) To cooperate with scientific research authorities and any other research establishments on bio-safety,

i) To organize dissemination activities on the activities and its outcomes of the Committee to the public through mass media.

FOUR. MISCELLANY

15. The Committee shall plan its work every half year and on yearly basis.

16. The Committee shall submit to the Government annual report on its operation and outcomes.

17. The operating cost of the Committee and the sub-Committees shall be financed from the State budget.

NATIONAL BIOSAFETY FRAMEWORK

Draft

ANNEX III. IMPLEMENTATION AND CAPACITY-BUILDING PROGRAMS OF THE NATIONAL BIOSAFETY FRAMEWORK

One. GENERAL INTRODUCTION

Introduction

World science development trend is spilled in nature and social interconnection, and main aim of today's world is becoming to establish powerful industry and technology with high capacity due to accommodate everyday increasing human Intellectual and corporeal necessity, to keep ecology equilibrium, to save resources of energy.

Due to economical weak efficiency and poor situation of the developing countries there is less possibility to develop space and atomic energy technology that need considerably higher investment. Respectively low investment is needed for biotechnology development; there is a good chance to develop biotechnology in developed as well as in developing countries. In this way it is important and beneficial technology.

For instance, food, forage production, health, veterinary and beauty bio preparations are produced, and both new brand of the animals and new sort of the cultivated plants are created. Moreover scarce animal and plant's genetic funds are saved, enlivened and reproduced constantly and animal, plant and mineral oriented raw materials are processed. All above-mentioned work is done by main method of the genetic engineering and bacterial synthesis.

Modern biotechnology is developing intensively in many countries, and its effect already released in industrial practice. Herewith it is certainly known that if activity isn't arranged in proper way, human lives and their activity and surrounding environment will be affected in contrary way.

Biotechnology development is strongly become as one of the leading direction of the science and technology that assuredly to develop under State

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policy since 1986. Numerous documents that should be done under State framework notably main tasks of State and Government, research, experiments, planned works for industries were processed; and some activities on policy and arrangement of biosafety were completed during that period.

Remarkably ‘Conception on development of Biotechnology research, experiments and industry of People’s Republic of Mongolia until 2000’ /1987/, and ‘Complex program on Science and Technology development of the People’s Republic of Mongolia until 2005’ /1988/ were approvingly warranted.

Parliament of Mongolia approved International convention on Biological diversity by its 163rd resolution in 1996.

In addition, there were approved “Mongolian National Security Abidance” /1994/, “Development abidance of Mongolia” /1995/, and “State Policy on Ecology” /1997/.

Cartagena Protocol on Biosafety has approved by Parliament of Mongolia on the 7 October 2002. Therefore Mongolia has obliged to arrange biosafety issues in front of International scale. The Cartagena Protocol on Biosafety aims “to contribute to ensuring an adequate level of protection in the field of the safe

transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

It is very important to constitute of National security frame, economic and social regulatory system; and reason of it GEF/UNEP project of “Development of the National Biosafety Framework for Mongolia” is in account risks to human health, and specifically focusing on transboundary movements”.

Needs and constraint of the Program elaboration

World countries highly concerned on their biosafety and nature conservation. Biosafety issues considerably became one of the main topics in global scale already and outward from one country’s problem. In this

NATIONAL BIOSAFETY FRAMEWORK

way, world countries adore to strengthen clean development mechanism and national manufacture, to live in peace and quietude. Therefore all above-mentioned topics are taken as a basis of the sustainable development.

To keep ecological equilibrium, to prevent our world from dangerous diseases and to provide with high quality food and to improve animal and plant breed is very significant for biotechnological development.

Biotechnology's base and additional researches should be ranged in international level, and there is needed to improve biotechnological industry and its application. Along with there is needed to integrate into biotechnology international network, and with its help to obtain assistance from highly developed countries.

Related with rapidly growth of the world population and people's increasing needs and nature resource deficiency, there is a high compulsion to use intensively the science and technology achievements in economics.

Today about 40% of the world total GDP covered by biotechnological production and further it is expected to increase. About 70% of total food production is imported from foreign countries, Mongolian State policy arrangement on health and biosafety trend to be combined ecology, social and political activities.

Two. Mission of the NBF

Mission of the NBF is to use modern science and biotechnology achievement in appropriate way, to accommodate human health and sustainable development.

Three. Purpose of the Program

The following purposes are taken into implementation.

3.1. To accomplish Biosafety regulatory regime, and to improve economic situation

3.2. To form and conduct national biosafety framework production

3.3. To increase biotechnology researches and experiments

NATIONAL BIOSAFETY FRAMEWORK

3.4.To expand biotechnology production

3.5.To develop international and local cooperation on arrangement of biotechnology and risk assessment of LMO's.

Four. Implementation measurement

NBF program will be implemented with assistance of State and NGO's, as well as professional organizations and public participation.

To make a Biosafety policy and to control for its implementation and State organization responded for environmental issue control for above-mentioned topics.

To establish biosafety regulatory regime.

To integrate into biosafety international network, and on its basis to set up national information fund.

To organize operations that will perform risk assessment of LMO's.

Five. Implementation term

Implementation period of the Program is divided into 3 stages.

- | | | |
|----|--------------|-----------|
| a. | First stage | 2005-2008 |
| b. | Second stage | 2008-2012 |
| c. | Third stage | 2012-2015 |

Ministry of Nature and Environment of Mongolia is an execution agency. In the Programm will be participated with Ministry of Food and Agriculture, Ministry of Industry and Commerce, Ministry of Justice and external affairs, Ministry of Health, Ministry of Finance and Ministry of Education and Science.

Six. Source and assignment of the Programm finance

Program is financed by:

State budget

Foreign and International organization's projects, investment and loan and

Organization and public

Seven. Effect and estimation of the Programm

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7.1. Program implementation achievements will be to the following:

- a. National Biosafety Framework method and organizational activity will be reached to international standard.
- b. Ecologically pure products and services satisfying customers are provided
- c. Due to National production and service quality enhancement and using international standard competing venues will improve
- d. Negative impacts for environment will decrease due of domestic products to conducting clean production Principles.

Organizing training on Environmental conservation and LMO's is important for

Public awareness and education and creative cooperation

7.1. Programm implementation fulfillment will be reached to the following efforts:

Biosafety framework achievement will be met international standard of the method and administration.

National product and service that recommended by customers will be increased

National product and service quality will be improved. Therefore competition ability go up due to using international standard.

Negative impact for environment will be decreased due to conducting a Clean production mechanism

Organizing education classes and advertisement on environmental protection and Living modified organism, public awareness and environmental education level will be rised also creative cooperation in that field will be strengthened.

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ANNEX IV. LAW ON BIOSAFETY

PART ONE

GENERAL PROVISIONS

Article 1. Objective

1.1. The Objective of this Law is to regulate genetically modified organism or any products originated from it, its transboundary movement, sustainable use and conservation of biological diversity of flora and fauna taking into consideration human health.

Article 2. Biosafety Legislation

2.1. Legislation on Biosafety of Mongolia will be based on Constitution of Mongolia, Law on National Security, Law on Verification of transboundary movement of animal and plant originated raw materials and products, this Law and/or any other legislation adopted in is consistent with this Law.

2.2. International instrument shall prevail, if it is stipulated other than in any international instrument into which Mongolia is a Party.

Article 3. Use of Terms

3.1. For the purpose of this Law;

3.1.1 “Genetically modified organism” means any genetic materials/products/ that possesses a novel combination of genetic materials that obtained through the use of modern technology;

3.1.2 “Biotechnology” means any technological application that uses biological system, genetic organisms or derivatives thereof, to make or modify products or processes for specific use

3.1.3. “Modern biotechnology” means the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

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b. Fusion of cells beyond the taxonomic family,

3.1.4 “Use of genetically modified organism” means processing of genetically modified organisms or raw materials and products originated thereof through a scientific research method, directed to supply the market;

3.1.5. “Contained use” means any operation, undertaken within a facility, installation or other physical structure which involves genetically modified organisms that are controlled by specific measures that effectively limit their contact with and their impact on the external environment;

3.1.6 “Danger” means any unintentional occurrence that may have adverse effect to human health and external environment in using of genetically modified organisms or raw materials and products originated thereof during contained system use

3.1.7 “Risk” means any risk increasing likelihood of consequences that may have adverse effect on human health, or environment during a certain period from the genetically modified organisms or raw materials and products originated thereof when crossing the border or usage period;

3.1.8. “Accepted risk” means the risk level that considered having no adverse effect on human health or environment;

3.1.9 “Risk assessment” means the process to assess biological and economic consequences caused due to access and spread of adverse effective organisms through the use genetically modified organisms or raw materials and products originated thereof in the territory of imported State;

3.1.10. “Reduction of risk” means process of identifying, selecting and implementing of an appropriate method to reduce the risk level to an acceptable norm.

PART TWO

FULL POWERS OF STATE AUTHORITIES ON BIOSAFETY

Article 4. Full Power of State Great Hural

4.1. The State Great Hural has the following full powers;

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4.1.1. To determine the State Policy and monitor its policy implementation;

4.1.2. To Grant State financial support including loan grant for those manufacturers of genetically modified organisms or raw materials and products on the basis of biotechnology that has no adverse effect on human health and environment, at the initiation of Government.

4.1.3. Any other full powers as stipulated in Laws

Article 5. Full Power of Government

5.1. The Government has the following full powers;

5.1.1. To develop and implement appropriate measures to carry out State policy and laws on biosafety;

5.1.2. To enter into international agreements with foreign countries and international organizations on cooperation in biosafety sphere including genetically modified organism, or raw materials and products originated from it;

5.1.3. To establish National Committee on Biosafety and adopt it's Rule;

5.1.4. To locate transboundary points to transit the genetically modified organism and products originated from it;

5.1.5. To adopt Regulation on State Registration and Verification of genetically modified organism and products originated from it;

5.1.6. To establish required fund and working condition at transboundary points to implement the verification of genetically modified organism and products originated from it;

5.1.7. Any other full powers as stipulated in law.

Article 6. Full power of State Administration Focal Establishment

6.1. State Administration focal Establishment responsible for Environment and Nature has the following full powers;

NATIONAL BIOSAFETY FRAMEWORK

6.1.1. To license or annulling of licenses of those entities and institutions involved in processing of, manufacturing, access to cross border issues or carrying out research or testing activities related with genetically modified organism or any raw materials and products originated thereof;

6.1.2. To adopt risk assessment rules in recording of genetically modified organism or any raw materials and products originated thereof;

6.1.3. To adopt Operational Rule of genetically modified organism or any raw materials and products originated thereof;

6.1.4. To establish biosafety Fund, and its adopt its spending regulation;

6.1.5. Any other full powers as stipulated in law.

PART THREE RIGHTS AND OBLIGATIONS OF ENTITIES, INSTITUTIONS AND INDIVIDUALS ON BIOSAFETY

Article 7. Rights of Entities, Institutions and Individuals

7.1. The Entities, Institutions and Individuals have the following rights on biosafety;

7.1.1. Cross the border, processing or use of genetically modified organism or any raw materials and products originated thereof without adverse effect to human health and environment provided that it has the appropriate permission;

7.1.2. Access to and distribution of biosafety information;

7.1.3. Cooperation with public institutions on biosafety;

7.1.4. To complain about non-compliance cases on cross border, processing and using of genetically modified organism or any raw materials and products originated thereof, to the competent authorities and officials.

Article 8. Obligation of Entities, Institutions and Individuals

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8.1. The Entities, Institutions and Individuals have the following obligations on biosafety;

8.1.1. To notify in advance and apply for to cross border, process or use of genetically modified organism or any raw materials and products originated thereof, to the competent authorities;

8.1.2. To comply with the laws and regulations or lawful decisions of competent authorities and officials on biosafety;

8.1.3. To submit reports on any actions taken in regard to the genetically modified organism or raw materials and products originated thereof, to the State Administration focal Establishment responsible for Environment and Nature or the National Committee on Biosafety

8.1.4. To bear financial responsibilities in regard to analyzing to identify or disinfection of genetically modified organism or raw materials and products originated thereof

PART FOUR CROSS BORDER OF GENETICALLY MODIFIED ORGANISM OR RAW MATREIALS AND PRODUCTS ORIGINATED THEREOF

Article 9. Requirements to cross border the genetically modified organism or raw materials and products originated thereof

9.1. The following requirements to be fulfilled to cross the border the genetically modified organism or raw materials and products originated thereof;

9.1.1. To observe the provisions of any international agreements on Biosafety that Mongolia has concluded with foreign countries or norms, guidance and recommendations of any international instruments into which Mongolia is a Party to;

9.1.2. Customs clearance procedures, cross border of exporting States' or domestic competent authorities' fully licensed genetically modified organism or raw materials and products originated thereof;

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9.1.3. To carry out the customs clearance procedures of genetically modified organism or raw materials and products originated thereof right at the border points or at the Central Customs office arena;

9.1.4. To carry out verification procedure of genetically modified organism or raw materials and products originated thereof at expertise laboratories in case of detecting any adverse effect on human health or environment safety and permit to cross the border provided that it has been contained.

Article 10. Requirements to import the genetically modified organism or raw materials and products originated thereof

10.1. The following requirements shall apply to in addition of common requirements of Article 9 in importing of genetically modified organism or raw materials and products originated thereof,

10.1.1. Provided that the genetically modified organism or raw materials and products originated thereof obtained from safe and secure State or area where considerable human or animal serious infected disease has not been spread or quarantined

10.1.2. Provided that the acceptable risk assessment has been carried out prior to import.

Article 11. Requirements to export the genetically modified organism or raw materials and products originated thereof

11.1. The following requirements shall apply to in addition of common requirements of Article 9 in exporting of genetically modified organism or raw materials and products originated thereof.

11.1.1. Provided that it has been met, if any, the relevant provisions of agreements on quarantine with the importing State, or in compliance with norms, guidance or recommendations of international organizations or of international agreements, conventions to which Mongolia is a Party.

11.1.2 Provided that it has been met the exporting requirements and properly licensed by the competent authorities.

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Article 12. Requirements to transit the genetically modified organism or raw materials and products originated thereof

12.1. The following requirements shall apply to in addition of common requirements of Article 9 in transiting of genetically modified organism or raw materials and products originated thereof.

12.1.1. Provided that the transiting Party has submitted its application to transit the genetically modified organism or raw materials and products originated thereof through the territory of Mongolia to the State Expertise Monitoring Authority of Mongolia and has been received appropriate notification within 30 days prior to transit.

12.1.2. Provided that the genetically modified organism or raw materials and products originated thereof obtained from safe and secure State or area where considerable human or animal serious infected disease has not been spread or quarantined and transported by special means of transport.

12.1.3. The stamp and stomp of the container of the genetically modified organism or raw materials and products originated thereof not to be damaged.

12.2. When transiting through the territory of Mongolia it is not allowed to unload the genetically modified organism or raw materials and products originated thereof from the means of transport without prior permission from the Monitoring Authority.

12.3. The provision of Article 12.2. Shall not apply to in the event of the genetically modified organism or raw materials and products originated thereof to be unloaded from the means of transport due to force major factors.

12.4. In the event of detecting of any human or animal infected serious disease or quarantine when transiting the genetically modified organism or raw materials and products originated thereof through the territory of Mongolia, the Monitoring Authority of Mongolia shall notify immediately the competent Monitoring Authorities of importing or exporting State and Articles 13, 14, 15, 16 of this Law shall apply.

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Article 13. Banning to cross the border or to transit the genetically modified organism or raw materials and products originated thereof

13.1. It is banned to cross the border or transit through the territory the genetically modified organism or raw materials and products originated thereof in the following events;

13.1.1. Provided that it has not been met the requirements of Articles 10.1 or 11.1;

13.1.2. Provided that it has not been passed the quarantine verification processes or the given details in the application has been differed or it is found out during the verification processes that the waybill or documentation's are faulty;

13.2. It is banned to transit through the territory of Mongolia, if any genetically modified organism or raw materials and products originated thereof that not met the requirements of Articles 12.1.2 or 12.1.3 and the State Monitoring Authority shall notify the competent Authorities of exporting State immediately;

13.3. A Notification of banning shall be given to the responsible entity, institution or individual if any genetically modified organism or raw materials and products originated thereof that not met the requirement of Articles 13.1 and 13.2, by the State Inspector.

13.4. The notified entity, institution or the individuals are obliged to ship back the genetically modified organism or raw materials and products originated thereof to the exporting State.

Article 14. Temporary Detaining to cross the border or to transit the genetically modified organism or raw materials and products originated thereof

14.1. If it is detected that the genetically modified organism or raw materials and products originated thereof on transit have been damaged or spoilt during the quarantine verification processes, the State Monitoring Authority has the right to temporary detain the genetically modified organism or raw materials and products originated thereof up to 21 days and

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a due notification to be given to the responsible entity, institution or individual.

14.2. The notified entity, institution or individual are obliged to unload genetically modified organism or raw materials and products originated thereof under the control and decision of the State Monitoring Authority, at the special arena of Custom Office to go through a full verification.

14.3. The State Inspector shall carry out a full verification and a test sample of genetically modified organism or raw materials and products originated thereof to be submitted the relevant Laboratory analysis. The Laboratory shall notify back the result of the analysis within 14 days.

14.4. Depending on the ground of observation during the quarantine period and results of Laboratory analysis the Monitoring Authority of Customs Office shall make an appropriate decision whether to cross the border the genetically modified organism or raw materials and products originated thereof, or not.

14.5. If the Laboratory analysis results have been positive of any human or animal infected disease or quarantine, the genetically modified organism or raw materials and products originated thereof and the used packaging materials or any other accessories are to be liquidated in accordance with Article 15.2 of this Law.

14.6. Any genetically modified organism or raw materials and products originated thereof that are not meeting the requirements of Article 12.1.1 shall be temporary detained and the relevant authorities of the exporting State to be notified immediately. Only after the appropriate measures have been taken to meet the requirements of Article 12.1, a decision to transit the territory shall be given.

Article 15. Liquidation of genetically modified organism or raw materials and products originated thereof that banned to cross the border or to transit

15.1. Any genetically modified organism or raw materials and products originated thereof are to be liquidated in the following events;

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15.1.1. The exporting State rejected to collect back genetically modified organism or raw materials and products originated thereof that had been notified to in accordance with Articles 13.1 or 13.2 of this Law;

15.1.2. Provided that serious human or animal infectious disease or quarantine necessity have been detected in the genetically modified organism or raw materials and products originated thereof,

15.1.3. Provided that the damage or harm occurred to the genetically modified organism or raw materials and products originated thereof due to careless transportation, or storing in consequences of which serious adverse effects on human health or environment has occurred;

15.1.4. Provided that chemical, biological or nuclear acceptable norms occurred in the genetically modified organism or raw materials and products originated thereof are not meeting the internationally conventional norms and standards.

15.2. The liquidation process shall be carried out by a Working commission at the decision of the Customs Office Authority and province Administration Authority under the auditing of State Inspector in accordance with appropriate rule.

15.3. In implementing the measures stated in Article 15.1, it is recommended to use a harmless method, in manner with no adverse effect to human health or environment is required.

Article 16. Hygienic Sanitation and disinfection of genetically modified organism or raw materials and products originated thereof

16.1. A qualified Institution or expert personals are to carry out hygienic Sanitation and Disinfecting measures to the genetically modified organism or raw materials and products originated thereof in the following events;

16.1.1. If it is detected that the genetically modified organism or raw materials and products originated thereof have been infected with any other infectious disease rather than serious human or animal infectious disease;

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16.1.2. Any means of packaging, wrapping or similar accessories used to transport the genetically modified organism or raw materials and products originated thereof in accordance with Article 16.1.1;

16.1.3. Any means of transport, container or similar means used to transport the genetically modified organism or raw materials and products originated thereof in accordance with Article 16.1.1;

16.1.4. Any storage arena, house, possibly infected earth and surrounding complexes that in any way has been in contact with the genetically modified organism or raw materials and products originated thereof;

16.2. The genetically modified organism or raw materials and products originated thereof are to be permitted to cross the border provided that hygienic Sanitation and Disinfecting measures have been completed in accordance with Article 16.1.

PART FIVE.

PREVENTATION FROM AND LIQUIDADTION OF DAMAGES CAUSED DUE TO GENETICALLY MODIFIED ORGANISM OR RAW MATERIALS AND PRODUCTS ORGINATED THEREOF

Article 17. Prevention from and Liquidation of damages caused due to genetically modified organism or raw materials and products originated thereof.

17.1. Any Entity, Institutions or individuals that carrying out activities related to the genetically modified organism or raw materials and products originated thereof are obliged to implement appropriate measures to prevent from and liquidate the consequences of damages caused due to genetically modified organism or raw materials and products originated thereof, at their own expenses, in accordance with an especially developed program.

17.2. National Committee on Biosafety shall determine the causes and level of damage and organizes appropriate measures to liquidate the consequences of damage caused due to genetically modified organism or raw materials and products originated thereof;

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17.3. Under the authority of State Emergency Commission, the National Biosafety Committee, the Disaster Prevention Authority and all other relevant Institutions are to be involved and participated depending on the level of damage, in liquidation of the consequences of damage caused due to genetically modified organism or raw materials and products originated thereof;

17.4. The Government shall bear all expenses in case of widespread serious damage caused due to genetically modified organism or raw materials and products originated thereof and a compensation to be paid back by the faulty Party afterwards;

Article 18. Public involvement in Prevention from and Liquidation of damages caused due to genetically modified organism or raw materials and products originated thereof.

18.1. Non Governmental Organization, within its framework of law, may involved in and cooperated with the Government agencies in observing the compliance of implementation of biosafety regulations for the public awareness and supervision and in liquidating the damage caused due to genetically modified organism or raw materials and products originated thereof.

18.2. The Non Governmental Organization may obtain financing from the State budget in implementing measures stated in Article 18.1.

18.3. Stipulations in Article 18.1 should not, in any way, prejudice any other Party's reputation or public order.

PART SIX. MISCELLANY

Article 19. Financing of biosafety activities

19.1. Expenses related with biosafety activities shall be financed by State budget.

Article 20. Settlement of Dispute concerning cross border, sustainable

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use of genetically modified organism or raw materials and products originated thereof

20.1. In the event of arise of a dispute concerning cross border and sustainable use of genetically modified organism or raw materials and products originated thereof, between any individuals, legal or natural persons and State Inspector, the dispute shall be resolved by the State Expertise Monitoring Authority, and if not agreed with the decision, any involved Party may complain to the Court.

Article 21. Responsibility

21.1. If the nature of break of Biosafety Laws and Regulations is not classified as criminal, the Court or the authorized State Inspector may employ some administrative penalties depending on the seriousness of break of law, as follows;

21.1.1. Unloading of genetically modified organism or raw materials and products originated thereof from the means of transport without prior permission from the State Inspector, during quarantine verification processes; penalty for individuals, from 5000 to 50000 tugrics, and legal persons from 50000 to 150000 tugrics;

21.1.2. Hygienic sanitation and disinfection have not been completed as required in Article 16.1, of this Law; for individuals, from 25000 to 50000 tugrics, and legal persons from 50000 to 150000 tugrics;

21.1.3. All genetically modified organism or raw materials and products originated thereof to be banned to cross the border and expropriated to the State if there is no appropriate Licensing on import or export, Certification details are found faulty or expired or not in compliance with other waybills and documentation's and penalty for individuals, from 1000 to 50000 tugrics, and legal persons from 150000 to 250000 tugrics;

21.1.4. All genetically modified organism or raw materials and products originated thereof to be expropriated to the State in the event of break of Biosafety Laws and Regulations and penalty for individuals, from 25000 to 50000 tugrics, and legal persons from 50000 to 150000 tugrics;

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21.1.5. In case of break of provisions of Article 8 of this Law; penalty for individuals from 10000 – 50000 tugrics, for legal persons from 25000 – 100000 tugrics

21.1.6. In case of break of provisions of Article 12.1 of this Law; penalty for individuals from 25000 – 50000 tugrics, for officials from 50000 – 250000 tugrics

SIGNATURE

NATIONAL BIOSAFETY FRAMEWORK

Translation unofficial

RESOLUTION OF GOVERNMENT OF MONGOLIA

17 December, 2003

No

Ulaanbaatar

On National Committee and Regulation

To implement the Convention on Biological Diversity and Cartagena Protocol on Biosafety, the Government of Mongolia has adopted the following RESOLUTION:

1. To amend Appendix No 11, Government Resolution No 138, dated 3 July 2002 on “Government Commission, National Council, Committee and Working Group” as follows;

To add as; “47. National Committee on Biosafety, Minister for Environment and Nature”

2. To adopt the Regulation on Registration and Verification of modified living organism or products originated thereof, as an Appendix herein.

Prime Minister

N. Enkhbayar

Minister for Environment and Nature

U. Barsbold

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ANNEX V. REGULATION ON REGISTRATION AND VERIFICATION OF MODIFIED LIVING ORGANISM OR PRODUCTS ORIGINATED THERE OF

One. General Provisions

This Regulation shall apply to registration and verification of modified living organism or products originated thereof developed as a result of research work within Mongolia or imported through transboundary movement, at National level.

National Biosafety Committee (hereinafter referred to as the “Committee”) shall register and verify the modified living organism or products originated thereof.

Convention on Biological Diversity and Cartagena Protocol on Biosafety or any other relevant agreement that Mongolia is a Party shall also apply in registering and verifying of living modified organism and products originated thereof as referred to in Article 1 of this Regulation.

Two. Registration of modified living organisms or products originated thereof

Any Entity or Organization is obliged to register the modified living organism or products originated thereof, developed as a result of research work within Mongolia or imported through transboundary movement, at the Committee.

The Entity or Organization wishing to register the modified living organism or products originated thereof, developed as a result of research work within Mongolia or imported through transboundary movement shall submit an application to the Committee. The application shall contain, at the minimum, the following information;The requesting Entity or Organization’s State Registration Number, Individuals’ Family Name and Name, Registration Number, ID Card Number, Tel No;

Assigned Name of the modified living organism or product thereof;

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Genetic modifications and its applied technology, as the result of research work the specific characteristic description of modified living organism;

The classification status, common name, location, description of either primary or donor organism of modified living organism or the product;

Full assessment report done in accordance with Annex III of the Cartagena Protocol on Biosafety;

Information on the intended use of modified living organism and the product thereof; Safety, keeping, transport, handling, packaging, documentation, labeling

Three. Verification of modified living organisms or products originated thereof

11. Based on the state registration certification issued for modified living organisms or products originated thereof, either developed as a result of research work within Mongolia or imported through transboundary movement, entity or organization is obliged to prepare a biosafety guideline and seek approval. A guideline must include management plans for removing risks related to organisms or products originated thereof. The Chairman of the committee shall approve the guideline.

12. The committee is responsible for conducting assessment according to management plans described in the approved guideline for modified living organisms or products originated thereof with high probability of risks, either developed as a result of research work within Mongolia or imported through transboundary movement. The committee shall determine a party to conduct the inspection.

13. Entity or organization is obliged to inform the committee and seek prior inspection before importing modified living organisms or products originated thereof.

14. Entity or organization is obliged to provide all data and information related to modified living organisms or products originated thereof for

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importing, exporting, using, keeping, selling, storing, destroying, and manufacturing new products using genetic engineering, or providing biosafety conditions for newly developed living organisms in order to assist the inspection process.

NATIONAL BIOSAFETY FRAMEWORK
ANNEX VI REVIEW OF WORKSHOPS

1.WORKSHOP TOPIC: “*Biotechnology development and safety, its management in international and national level*”

Ulaanbaatar. 13.10.2003

Total participants;79

Any given country is streaming to develop nanotechnology, biotechnology, information technology and power generation technology etc.

Biotechnology is the intersectional new direction originated in the meeting point of Biology, Chemistry, Genetics, Microbiology and technical Sciences. New complex methods are developing in research and production using the processes going in living cell, organ or outside the cells.

The biotechnology practice is transferred from ancient time by making yogurt, cheese, beer etc. From the XIX century is developed microbes and cell research identifying the functions of them, in 1930-1940 were developed methods of antibiotics production. In 1953 was identified the fine structure of DNA . Since the beginning of 1970 were put the basement of developing modern biotechnology by transferring the gene from one organism to another and by synthesizing the separate gene.

The human genome Project is finished by sequencing of 3 billion base pair of human DNA sequences in 2001. Some animals were cloned and talking on human clone experiments. Now days, when we are talking on globalization and biotechnology research and development is expanding Mongolia, the country having waste territory and having much potential of biological diversity should not stay behind the world development.

Therefor the need for development of biotechnology is urgent and we have to develop its legal, economical and management issues aiming to harmonize in international level.

2.WORKSHOP TOPIC: “*Biosafety it’s legal environment*”

Ulaanbaatar. 14.01.2004

NATIONAL BIOSAFETY FRAMEWORK

Total participants: 40

Biosafety is a concept of wider understanding including the both danger of agents of infectious diseases and possible risk of modern DNA recombination by humans, aiming to develop efficient technology for food and drugs. Possibly the next 4 directions:

The prevention of ecology misbalance caused by GMO and LMO

The prevention of possible risk by food, developed by modern DNA technology

The protection of total biosphere genetic resource including the human genome

The danger of infections disease agents including the problem of bio terrorism

So, there is important to develop legal environment including all these aspects

3.WORKSHOP TOPIC: “*Public Awareness on Biosafety*”

Total participants: 40

Ulaanbaatar. 19.03.2004

The Biotechnology is the prioritized science and technology development in any country. The biotechnology products are the millions even billion dollars in some countries ; However the prevention of possible risk of modern biotechnology is the key question in national and international level.

Next are important:

To support the non governmental organizations for founding the information fund involved in biosafety problem

To elaborate the education programme on biotechnology and biosafety for the public to give the correct and honest information to them at first step

To use all possible channels for the information: Radio, TV, Internet and media etc

To organize the workshops, seminars and exhibitions

The publication of books, brochures

4.WORKSHOP TOPIC: “*Risk assessment and risk management*”

Ulaanbaatar,

NATIONAL BIOSAFETY FRAMEWORK

Total participants: 40

The risk is the concept of occurring of negative effect on environment

- 1.The probability of occurring this event
- 2.The procedure to prevent the negative effect step by step

In risk assessment and in management is important the intersectional cooperation. The basic principles are next:

Assessment should be based on science knowledge and methodology and should be transparent to the public

The lack of information on risk should not be the base to conclude that there is no risk

The risk from 2 MO should include to the parental and donor organisms

The assessment should be done in every case and should be based on Laio nature and receiving environment

Next methods are important to reveal the Trans genes:

- Southern Blotting
- Western Blotting
- Northern Blotting
- Polymerize Chain Reaction (PCR)
- Dot Blotting

The revealing of Laid to environment will consist of next 3 step and each step needs

Period before the release to environment

Period releasing to environment

Period after releasing to environment

1. 13.10.2003. “Biotechnology development and safety, its management in international and national level”

	<i>NAME</i>	<i>TITLE</i>	
1	N.Oyundar	Ministry of Nature and Environment	

NATIONAL BIOSAFETY FRAMEWORK

2	D.Dorjgotov	Ministry of Nature and Environment	
3	A.Sarangerel	Ministry of Nature and Environment	
4	M.Altanzul	Ministry of Nature and Environment	
5	N.Saijaa	Ministry of Health	
6	L.Tsetsgee	Ministry of Food and Agriculture	
7	Z.Narmandah	Ministry of Food and Agriculture	
8	U.Lkhagvaa		
9	D.Amarjargal	Ministry of Industry and Commerce	
10	M.Otgon	Ministry of Environment	
11	L.Jargalsaikhan	Ministry of Environment	
12	L.Natsagdorj	National Agency of Meteorology, Hydrology and Environment	
13	B.Ochirkhuyag	National University of Mongolia	
14	D.Monkhoobor	National University of Mongolia	
15	Bydsyren		
16	E.Bat-Erdene		
17	J.Tsermaa		
18	P.Odonmajig	Institute of Chemistry and Chemical Technology	
19	B.Pyrevsuren		
20	L.Radnaasuren		
21	Ts.Batnasan	Ministry of Social Welfare and Labour	
22	B.Mendjargal	Ministry of Food and Agriculture	
23	M.Delegmaa	Ministry of Education, Culture and Science	
24	O.Enkhtsetseg	Ministry of Foreign Affairs	
25	Monkhdelger	Ministry of Health	

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26	N.Jargalsaikhan	Ministry of Health	
27	Ch.Dashchirev		
28	Bat-Erdene		
29	R.Sanjaatogtokh	Veterinary serves and Animal Be Department	
30	A.Olziitsetseg	Fire protection Authority	
31	Chilkhaasuren		
32	Ya.Delgertsetseg	State board Civil Defense of Mongolia	
33	D.Bolormaa	Livestock institute	
34	Ch.Javzan	institute of Geo-Ecology	
35	Ts.Lkhavgasuren	Academy of Biology	
36	D.Magsar	Academy of Botanic	
37	Sh.Ydenbor		
38	T.Bulgan		
39	S.Tuul	Geological laboratory	
40	D.Baasanjav		
41	Jamts		
42	S.Enkhbold		
43	Oyuntsetseg	City profession Inspection office	
44	E.Olziiburen		
45	Ya.Nyamdavaa		
46	S.Ichinkhorloo		
47	B.Batchimeg		
48	S.Oyundelger		
49	B.Sosorbaram		
50	Sh.Enkhtsetseg		
51	Oyuntsetseg		
52	B.Sosorbaram		
53	Sh.Enkhtsetseg	Ministry of Health	
54	Purevsuren	Translator	
55	D.Sumkhuu	Journalist	
56	S.Batbayar	Journalist	
57	Ts.Baatarsuren	Journalist	
58	G.Bayantor	Journalist	
59	Ch.Munkhbayar	Journalist	
60	Ts.Davgadorj	Arkhangai	
61	N.Akhitkhan	Bayan-Olgii	
62	D.Tserendorj	Bulgan	

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63	L.Mandal	Bayankhongor	
64	L.Tyvд	Govi-Altai	
65	B.Magsar	Govisumber	
66	B.Lkhasuren	Darkhan-Uul	
67	Kh.Tsendsuren	Dundgovi	
68	D.Suren	Dornogovi	
69	Sh.Ganbat	Dornod	
70	L.Bandi	Zavkhan	
71	G.Tsengelzaya	Selenge	
72	Z.Borgil	Sykhbaatar	
73	D.Gombo	Orkhon	
74	G.Bayasgalan	Ovorkhangai	
75	D.Baraaduuz	Omnogovi	
76	T.Tolya	Tovaimag	
77	Ch.Nyamdavaa	Khovsgol	
78	G.Dolgorsuren	Khentii	
79	P.Baigalmaa		

2. 14.01.2004 “Biosafety it’s legal environment”

	<i>NAME</i>	<i>TITLE</i>	
1	N.Oyundar	Ministry of Nature and Environment	
2	A.Sarangerel	GEL/2716-02-4527	
3.	M.Altanzul	GEL/2716-02-4527	
4	B.Dorjgotov	Ministry of Nature and Environment	
5	P.Sainbayar	Ministry of Nature and Environment	
6	Sh.Mongontsetseg	Ministry of Health	
7	D.Narantuya	Ministry of Health	
8	N.Udaanjargal	Ministry of Justice	
9	Z.Batsukh	Mongolian National Veterinary Research Institute	
10	N.Galmandakh	Mongolian National Veterinary Research Institute	
11	J.Erdenebaatar	Mongolian National Veterinary Research Institute	

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12	S.Tsoodol	Public Health Academy, Biotechnology production research and Training center	
13	T.Tumurkhuu	Public Health Academy, Biotechnology production research and Training center	
14	D.Dandii	Public Health Academy, Biotechnology production research and Training center	
15	B.Sainchimeg	Public Health Academy, Biotechnology production research and Training center	
16	B.Mijiddorj	Livestock Institute	
17	T.Sayapolda	Livestock Institute	
18	Ya.Byambasuren	Livestock Institute	
19	Ts.Oyunsuren	Academy of Biology	
20	A.Bayanmunkh	Academy of Biology	
21	N.Tumennast	Academy of Biology	
22	N.Narantsetseg	Academy of Biology	
23	J.Bold	Academy of Botanic	
24	Ts.Tsegmid	Academy of Botanic	
25	I.Tuvshintigtokh	Academy of Botanic	
26	T.Amarjargal	Ministry of Trade and Industry	
27	G.Bat-Ochir	Ministry of Trade and Industry	
28	P.Hergui	Ministry of Trade and Industry	
29	B.Dashnyam	Biotechnological Association	
30	Ts.Tsendehkuu	Biotechnological Association	
31	D.Buudaihkuu	Biotechnological Association	
32	D.Suvd	Biotechnological Association	
33	B.Ochirkhuyag	National University of Mongolia	
34	O.Bayarlkhagva	National University of Mongolia	
35	T.Enkhbat	State Pedagogical University	
36	L.Oyunbat	State Pedagogical University	
37	S.Purevdulam	State Pedagogical University	
38	T.Bayarkhuu	Journalist	
39	S.Gantugs	Journalist	
40	J.Bayarbaatar	Journalist	

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3.19.03.2004 “Public Awareness on Biosafety”

	<i>Name</i>	<i>Title</i>
1	N.Oyundar	Ministry of Nature and Environment
2	B.Dorjgotov	Ministry of Nature and Environment
3	A.Sarangerel	GFL/2716-02-4527
4	M.Altanzul	GFL/2716-02-4527
5	Sh.Mongontsetseg	Ministry of Health
6	G.Bat-Ochir	Ministry of Trade and Industry
7	B.Ochirkhuyag	National University of Mongolia
8	O.Bayarlkhagva	National University of Mongolia
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18	D.Amarjargal	Ministry of Industry and Commerce
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21	N.Akhitkhan	Bayan-Olgii
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24	L.Tyvd	Govi-Altai
25	B.Magsar	Govisumber
26	B.Lkhasuren	Darkhan-Uul
27	Kh.Tsendsuren	Dundgovi
28	D.Suren	Dornogovi
29	Sh.Ganbat	Dornod
30	L.Bandi	Zavkhan
31	G.Tsengelzaya	Selenge
32	Z.Borgil	Sykhbaatar

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34	G.Bayasgalan	Ovorkhangai
35	D.Baraaduuz	Omnogovi
36	T.Tolya	Tovaimag
37	Ch.Nyamdavaa	Khovsgol
38	G.Dolgorsuren	Khentii
39	Z.Batsukh	Mongolian National Veterinary Research Institute
40	Ch.Javzan	institute of Geo-Ecology

4. “Risk assessment and risk management “

	<i>NAME</i>	<i>TITLE</i>	
1	N.Oyundar	Ministry of Nature and Environment	
2	B.Dorjgotov	Ministry of Nature and Environment	
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4	A.Sarangerel	GFL/2716-02-4527	
5	M.Atanzul	GFL/2716-02-4527	
6	D.Narantuya	Ministry of Health	
7	Sh.Mongontsetseg	Ministry of Health	
8	N.Udaanjargal	Ministry of Justice	
9	Z.Batsukh	Mongolian National Veterinary Research Institute	
10	N.Galmandakh	Mongolian National Veterinary Research Institute	
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24	Ts.Tsegmid	Academy of Botanic	
25	I.Tuvshintigtokh	Academy of Botanic	
26	T.Amarjargal	Ministry of Trade and Industry	
27	G.Bat-Ochir	Ministry of Trade and Industry	
28	P.Hergui	Ministry of Trade and Industry	
29	B.Dashnyam	Biotechnological Association	
30	Ts.Tsendehkuu	Biotechnological Association	
31	D.Buudaihkuu	Biotechnological Association	
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38	T.Bayarkhuu	Journalist	
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40	J.Bayarbaatar	Journalist	