

List of abbreviations

AIA	Advanced Informed Agreement
BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
CCCGEB	Consideration Committee for Cell and Genetic Engineering for Biosafety
DNA	Deoxyribonucleic acid
GEF	Global Environment Facility
GMO	Genetic Modified Organism
LMO	Living Modified Organism
LMO-FFPs	Living Modified Organisms Intended for Direct Use as Food or Feed, or for Processing
NBCH	National Biosafety Clearing-House
NBF	National Biosafety Framework
NCCE	National Coordinating Committee for Environment
NFP	National Focal Point
NPC	National Project Coordinator
PCC	Project Coordinating Committee
RAB	Risk Assessment Board
R&D	Research and Development
SAGOST	State Administrative Guidance Organ for Science and Technology
SBC	State Biosafety Committee
UNEP	United Nations Environment Programme

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General Introduction

In the Democratic People's Republic of Korea, great endeavors are made to build a great prosperous powerful socialist country under the wise leadership of the great leader Comrade **Kim Jong Il**, the scientific research to develop the biotechnology along with the information technology and the nano-technology and the work to introduce its achievements into various sectors of the national economy are underway more briskly than ever before.

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 sere of ecosystem, the Government of the DPRK has put equal importance to both development of the Biotechnology and establishment of the NBF, taking appropriate measures.

The DPRK's natural and geographical conditions as well as biological resources and environment are varied.

Its climate and weather, conditioned by the four distinctive seasons, the land mostly occupied by mountains and consecutive periods of fine and clear days all year round with concentrated downpour of rain and heavy snow, provides a safe habitat for the plant and animal.

Hence, its feature of biological aspect is diverse and its per-unit number of animals and plants is great. Numerous world-rare species are found accordingly.

In this country with a long history of 5,000 years, the rice and millet have been cultivated and their excellent seeds selected since 6,000 years ago. The DPRK is the place of the origin of the soybean and has the history of raising the silk worm since 5,000 years before.

And it has long since developed the technology of fermenting with microbe the bean paste, soy sauce, kimchi and fish mixed with radish.

President **Kim Il Sung** has pointed out the orientation and ways for rehabilitating the ecological environment of the country and dispatched an investigation team made up of the teaching staff and students of **Kim Il Sung** University to discover the plant and animal resources of our country.

He often met botanists, zoologists and other biologists to discuss about ways for protection and sustainable development of natural resources, showering his meticulous care and solicitude upon them and leading them forward.

He also made sure that the nature preserves, fauna and flora preserves, birds preserves, marine resources preserves, and game preserves were set up in all parts of the country.

General **Kim Jong Il** who has inherited President **Kim Il Sung**'s idea on the conservation of nature has formulated a far-sighted plan to turn the country into a paradise, though he was very busy with his responsibility for all the affairs of the country.

The Government of the DPRK has attached great importance to the conservation and sustainable development of biodiversity, making great efforts for the purpose.

Recently it mapped out the "Master Plan for Layout of Land", a comprehensive plan regarding the land resources of the country, which includes the fundamentals for the preservation of biodiversity such as the set up of regional system of conservation and the protection and sustainable utilization of biological resources.

It already formulated “The National Strategy for Biodiversity and Action Plan” and “The National Report of Biodiversity” from 1998 to 1999.

It is a very important and urgent problem to establish the NBF for the protection of Biodiversity of the country.

In the 1970s, gene recombination technology, which began to be developed as a branch of molecular biology to discover life phenomena, opened a broad vista for genetically improving all of species including microbe, plant and animal, setting its definite place as the core of the biotechnology in the 21st century.

It is no exaggeration to say that the development of the biotechnology is a key to resolving the food problem, energy problem and environmental problem, which the mankind is to grapple with in the 21st century.

For this reason, both the developed and the developing countries are channeling great efforts into the development of biotechnology, and sparing nothing on this field with the prospect of enormous economic profits.

World-renowned agricultural producer and exporter countries have already cultivated GM crops including insect resistant maize and herbicide resistant soybean in 60 million hectares of farmland, for domestic consumption and export.

Namely, a gene of a certain species is processed to be transferred to other species to produce a new species with new genetic allele, and this become trendy worldwide.

Since the advent of GM technology, question of biosafety has been considered in various respects, giving rise to serious discussion about safety evaluation. Recently the matter of safety of GMOs is assuming importance all the more as the GM technology has spread beyond the experimental framework and the boundary of a single country and its products found their way on the dining table.

As far as the safety of GMOs is concerned, no scientific and technical data that have confirmed the dangerous and harmful effect on human being are available; also unavailable is the data that give a scientific explanation of its full safety.

In early 1980s genetic engineering research teams and teaching staff were organized in research institutes and universities in the DPRK. On the outset, they were engaged in the training of talents for this field and the research work to develop the basic technology of genetic engineering.

Afterwards, the range of the research objects was ramified and framework of GM technology set up. In the process, the technology for design, cleavage, processing, proliferation and analysis of genes has been developed.

And the methods of producing useful materials by GMOs have been developed, with the result that cultivation of insect-resistant rice, maize and poplar is underway on a full swing.

Previously, obsession about the possible profit from bioengineering gave rise to negligence of the problem of biosafety, leading to lack of state regulations on the treatment of GMOs and thus compelling individual institutes to formulate their respective regulations of their own accord.

Now that a number of talents in the fields of biotechnology have been trained, the range of research objects ramified and research projects aimed at practical use of GMOs facilitated extensively, the establishment of NBF poses itself as a more urgent problem, which brooks no further delay.

In the 1990s successive natural calamities fell upon the DPRK which was previously self-sufficient in food, raising the food problem as a serious issue and bringing in a large quantity of foreign agricultural products in the form of import or aid.

Given the condition, the previous customs regulations for blight control of plant and hygienic control could not prove effective to evaluate biosafety and ascertain the probable transfer of GM products, including farm crops and their processed goods to the country.

Therefore, establishment of NBF is essential to the solution of such urgent problems as encountered in the transboundary movement, handling, storage, management and treatment of GMOs.

The great leader Comrade **Kim Jong Il** said: “Because it is the embodiment of the Juche idea, our socialism is a man-centred socialism under which man is the master of everything and everything serves him.”

The DPRK would deal with the establishment of the NBF with the attitude and viewpoint of treasuring human being most as required by Juche idea, and guided by the ideal of regarding the promotion of the well-being of the people as the supreme principle of its activity.

The DPRK joined Convention on Biological Diversity in October 1994, and signed the Cartagena Protocol on Biosafety in April 2001 and ratified it in July 2003.

The Protocol stipulates *inter alia*;

“In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is 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, taking also into account risks to human health, and specifically focusing on transboundary movements.”

Scope of the Protocol and of the AIA procedure: Article 4-7

LMOs subject to the provisions of the protocol

- All LMOs which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4).

LMOs subject AIA provisions

- LMOs intended for intentional introduction into the environment (Article 7(1)).

LMOs excluded from the Protocol’s AIA provisions

- LMOs in transit (Article 6(1))
- LMOs destined for contained use in the Party of import (Article 6(2)).
- LMOs intended for direct use as food or feed, or for processing (LMO-FFPs) (Article 7(2)).
- LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse impacts (Article 7(4)).

LMOs excluded from the Protocol’s provisions on transboundary movements

- LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5).

As a party to CBD and Cartagena Protocol, the Government of the DPRK started the project on the development of NBF from February 2002 in accordance with the main spirit of the Convention and Protocol.

During the period of its implementation of project, the Government has developed the legal and administrative frameworks for the management of biosafety, the system for assessment and management of potential risks of bioengineering products and the information management system on biosafety, and worked with focus on setting up a system of public awareness, education and participation for biosafety.

Importance and significance of the NBF

a) The NBF would enable the DPRK to give full play to the advantage of its style of socialism that is centered on popular masses.

Biosafety problem is a serious problem worldwide because it is directly related to human health and environmental protection.

Many countries, regions and organizations are raising it as an urgent matter bearing upon the future and destiny of mankind.

Thus, the work of establishing biosafety framework is of great significance in promoting the advantage of the Korean style of socialism centered on popular masses under the leadership of the respected general **Kim Jong Il** who is always concerned with the people's health and environmental protection of the country.

b) The NBF would contribute to the protection of people's life and health from the possible harmful effect of modern bioengineering products.

Medical science has so far worked to diagnose, treat and prevent the elements such as bacterium or virus, which cause diseases among the people.

In the genome of these pathogenic bacterium and virus exist harmful base sequences evidently containing pathogen, toxicity, infectivity. There also exist gene-evident agents, which cause allergy or side effect.

Biotechnological methods are widely employed in the development of diagnostic reagent and vaccine of disease gene, pathogenic bacterium and virus in the process of which unexpected mutation and abnormal release may occur.

The GMOs are new artificial products hitherto unknown in the history of evolution spanning over hundreds of millions of years.

Substances such as physiological stimulants, hormone, oligo-peptide and gluco-protein produce toxic effect in the respiratory and gastric canals of man and animal; these substances may be mass-produced easily by making use of gene manipulation technology.

Most of the vectors used in the gene manipulation in the field of science are bacterial plasmid and viral plasmid, to which the anti-biotic genes and infectious genes are applied.

This gives rise to the possible arrival of new bacteria and viruses, which can hardly be treated by the conventional antibiotics and medicament.

All these facts show that the NBF is very important for protecting the health of human being.

c) *The NBF also contributes to the protection of ecological environment of the country.*

What is important for the protection of the ecological environment is to protect and increase the flora and fauna resources.

In case heterogeneous species including GMOs are introduced into the ecological environment, they would compete with the existing species, and the species which are weak to survive in the changed environment would perish.

For example, when herbicide is applied, and the herbicide-resistant GMOs would survive, while the rest, even the weeds, would perish.

And the herbicide-resistant gene, by the effect of horizontal gene transfer, may go over to other weed or plants through microbe or insects modifying them into to be immune the herbicide and result in the grater frequency of transfer even under the shower of the herbicide.

Consequently, the farm crops grown under the circumstances come to mix with the transgenic crops.

In the meantime, if the GMOs developed for the purpose of pharmaceuticals production such as vaccine flow into the environment, they may cause contamination of food and feed.

Therefore, establishment of the system for correctly assessing and managing the risks of GMOs and there products and using them within a limited scope is extremely important for the protection of ecological environment.

d) *The NBF would timely prevent the possible damage caused by GMOs and their products.*

Published data on the import of GMOs and their products and the network of information on them are not available in the DPRK.

If the system of marking and identifying GMOs and their products is established, it would be possible to acquire correct information on the import and usage of GMOs and prevent the damage caused by them. Especially, now that the worldwide concern about the safety of GMOs is growing, in case the DPRK imports food and does not demand mark and identification of GMOs, undesirable products may find their way into the country in the form of food, feed or processed food causing unpredictable damage.

e) *The NBF would render contributions to the safe development of biotechnology of the country.*

The frontier technology of modern biotechnology including gene analysis and immune array analysis is essential to assessment and management of the risks of GMO and their products.

This is no less important than developing GMOs.

Effective cooperation with the international organizations in the course of establishing the NBF would help the DPRK to facilitate its work to acquire the ability of analyzing and examining gene, scientifically assessing and controlling the risks of GMOs and their products.

It would also enable the country to strengthen its manpower resources and scientific and technological foundation for the development of biotechnology and the scientific and technological potentiality in the course of establishing the NBF and resolving biosafety problem on its basis.

f) The NBF would promote cooperation with international organizations and other countries.

Establishing the NBF presupposes cooperation with international organizations and other countries.

The NBF would facilitate timely acquisition, from the world network, of information on GMOs and the scientific data on the Biosafety and the negative influence of GMOs on the health of human being and the environmental protection, and thus expedite the process of development of NBF itself.

It would help the country to swap with other parties the experiences gained in the course of developing the NBF, and introduce and propagate its own experiences, and also refer to the useful experiences from other countries.

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Introduction to the NBF

The UNEP-GEF Project on the Development of the National Biosafety Framework of DPR of Korea started in February 2002 and ended in July 2004.

The National Executing Agency for the UNEP-GEF project was the National Coordinating Committee for Environment (NCCE).

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1. Policy on Biotechnology and Biosafety

A. Main Objectives

The main objectives of biotechnology and biosafety policy are;

- i) To ensure the safe use of biotechnology in the Democratic People's Republic of Korea, and to eliminate any risks that may be detected in the process of introducing the achievement of research into the various fields of the national economy and to thoroughly protect health of the people and conserve the biodiversity and ecological environment and,
- ii) To make up the legal framework 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 contribute to ensuring maximal safety for movement, handling and use of GMOs including genetically modified crops.

B. Basic principles

- i) 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 life, even if its outcome is high in productivity and economic profit, should be suspended.
- ii) The export and import of GMOs are subject to the approval in advance.
The transboundary movement of GMOs should be conducted according to the appropriate work order and with the approval of the state.
- iii) 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.
- iv) 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.
- v) The strict labeling and packaging of GMOs shall prevent them from being possibly released in their transboundary movement, handling, use and consumption.
- vi) Efforts should be made to involve the masses of the people in the discussion of the problem 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 should be ensured.

- vii) International exchange and cooperation with the other countries should be conducted in close cooperation with the relevant international organizations such as UNEP.
- viii) The principle of pushing ahead with the capacity building of NBF, especially the work of upgrading modern scientific and technical standards and training specialists simultaneously.

C. Priorities

The safe development and application of biotechnology with full regard for biosafety shall cover the following:

- i) The research and development of GM crop and its field experiment, its introduction into environment, production, import, sale and use.

GM crops with resistance to blight and herbicide, to salt, dryness and low temperature, to virus and bacterium, GM crops such as maize, rice, bean, wheat and potato with high productivity.
- ii) The research, development and pilot-scale experiment of GM plants, their introduction into environment, import and use with high productivity and resistance to blight.
- iii) The import, use, production, safety test and management of the GM food, feed, additive reagent and their processed products.
- iv) The use of GM microorganism.

The research, development, introduction, production, import, use and disposal of wastes of the GM microorganism which are used in food and fermentation Industry, pharmaceutical industry and micro organic fertilizer.
- v) The use of GM animal (livestock, poultry, fishing)

The use of transgenic animal for production of meat eggs and feather or hide
- vi) The research, development and application of GM plant and animal as a model for disease research in the production of useful materials and medical science.

2. Framework of State Regulatory Regime on Biosafety

A. PURPOSE FOR ADOPTING THE GMOs MANAGEMENT LAW

It is to establish a regular GMOs safety management system so as to develop the modern biotechnology of the country on a safe and sound basis and, contribute to the sustainable development of the national economy, thus eventually protecting the people's health from any potential risk and ensuring the sustainable conservation of the ecological environment and biological diversity.

B. PRINCIPLES TO BE ADHERED IN FORMULATING THE GMOs SAFETY MANAGEMENT LAW

- i) The love of the great leader President **Kim Il Sung** and the respected General **Kim Jong Il** for the motherland, the people and the land, as well as the basic ideals of the country in its dealing with the state activities running through the Socialist Constitution of the DPRK should be reflected.
 - a) Man is treasured most in the world and everything serves man
 - b) Top priority is given to the preservation of ecological environment, natural environment and biological diversity.
 - c) Biological resources of the country should be protected and improved and the natural environment such as the mountain, river and sea be built up more magnificently.
- ii) Excessive exaggeration of the risk of GMO should be avoided and the scientific and technological opportunities as well as economic development to be brought about by the safe use of modern biotechnology should be promoted.
- iii) The law should contribute to establishing regular and uniform state system for legal and administrative management of GM products, ranging from the central unit to the lowest echelon, to each and every branch, and should concentrate on making the supervision, guidance and control, survey and inspection of the GMOs proceed uniformly like one whole network.
- iv) It should ensure the scientific accuracy and objectivity in the handling and management of the GMOs so as to promote the scientific and technical development for the GMOs safety management.
- v) It should make the principle of precautionary measures run through in the GMOs safety management.
- vi) It should mobilize all kinds of news media and education network for the timely dissemination of information on the GMOs among the public and proceed to the decision-making on the GMOs on the basis of the sufficient reference to the opinions of the people.
- vii) The import and export of the GMOs are subject to prior approval procedure.

- viii) The GMOs in commercial transaction should bear the mark <GMO>.
- ix) The work of developing NBF for the GMOs should proceed amidst the international cooperation and observe the CBD and Cartagena Protocol on Biosafety.
- x) National Biosafety Clearing-House should be set up and run for the purpose of information exchange with other countries and the international organizations.

C. REGULATORY REGIME ON BIOSAFETY

I. Basic Law on Biosafety

Title:

“ Law of the Democratic People’s Republic of Korea on the Management of Genetic Modified Organisms”

The draft of the basic law is under consideration at the Standing Committee of the Supreme People’s Assembly, DPRK.

Areas Enshrined by the Law(Chapters of the Law):

1. General provisions of the GMOs Management Law
(Objective, definition, scope, principle and key requirements)
2. Application for research, development, production and export and import of the GMOs
(Application, risk assessment)
3. Consideration of the application for research, development, production, export and import of the GMOs
(Consideration, decision-making, review of decision, revocation, appeal, simplified procedure, statement of GMOs with no risk)
4. Handling of the GMOs
(Handling, transportation, labeling, package, identification, storage, sales, registration, emergency measure and disposal)
5. Information management of GMOs
(Identification, protection and statement of confidential information, information exempted from the confidentiality, NBCH)
6. Guidance and control over the management work of the GMOs
(Institutional arrangement)

II. General Regulations, Departmental Regulations

The DPRK adopted the **“Regulations on the safe management of GMOs (interim)”** by the Cabinet Decision No.64 in October 2003 (see appendix II).

According to the decision, GMOs Safety Management Committee was organized, which commenced its work from January 2004. First meeting of GMOs Safety Management Committee assigned the duties concerning the execution of

regulations and designated the Academy of Sciences as the State Administrative Guidance Organ for Science and Technology (SAGOST) responsible for execution of laws and regulations concerning biosafety system, and Branch of Cell & Genetic Engineering, Academy of Sciences and Institute of Agricultural Biology, Academy of Agricultural Sciences as Risk Assessment Boards.

The Academy of Sciences, the executive organ of biosafety laws launched in December 2003 a pilot version of the NBCH and set up on a trial basis a gene analysis laboratory dealing with analysis of GMOs in the Branch of Cell & Genetic Engineering.

Basic Principles of the Interim Regulations are:

- a) To realize the unified state management of GMOs
- b) To establish administrative system whereby supervision, control, monitoring and arrangement of measures with regard to R&D and production, import and export, storage, treatment of GMOs can be conducted timely and correctly.
- c) To ensure a unified administration and guidance from center to the basic unit.
- d) To maintain a close lateral relationship between relevant ministries and central authorities.
- e) To organize the risk assessment scientifically and objectively.
- f) To intensify monitoring and control so that release and gene leakage of GMOs into environment do not occur.
- g) To constantly upgrade the level of requirement for observance of regulations on management of GMOs in research and production, and safety measures concerning facilities and equipments.
- h) To pay special attention to setting up of NBCH to carry out data-exchange on GMOs substantially, and to training specialists and building up the material and technical foundations.
- i) To intensify the work of laying the material and technical foundations such as training of talents and provision of equipment, and to organize an agency specializing in the analysis of GMOs
- j) To organize an organ dealing with monitoring and control of GMOs and enhance the qualifications of concerned personal.

D. SUMMARY OF THE DRAFT LAW ON MANAGEMENT OF GMOs

1. General Provisions of draft Law on Management of GMOs

The general provisions address the objective, definition, scope as well as requirements for application and approval procedures on the basis of precautionary principle.

1a) Objective of draft Law on Management of GMOs

- To establish the strict system and orders in R&D, production, import and export and information management of GMOs

- To contribute to the protection of people's health and biodiversity as well as the safe development of biotechnology

1b) Definition of GMOs

GMO means any organism with a novel genetic trait made up through the use of modern biotechnology including recombination techniques and the fusion of cell beyond the taxonomic family.

The state shall prevent the adverse effects caused by any GMO and ensure its safe and efficient use in promoting the socio-economic development.

1c) Principles

- Principle to follow when applying for approval of R&D, production, import and export of GMOs:
The principle of prior consent, prior authorization shall be observed.
- Principle to follow when considering the application for approval of R&D, production, import and export of GMOs:
The principle of objectivity, scientific accuracy and prudence shall be observed.
- Principle to follow when handling GMOs:
The safe management rules and requirements shall be met in handling, storage and maintenance of GMOs.
- Principle for the investment and capacity building in biosafety management:
The investment shall be increased systemically and the capacity for biosafety management be strengthened by means of updating equipments, database and development of human resources on biosafety.

1d) Scope

- LMOs, GMOs, LMO-FFPs including organism with r-DNA or foreign-DNA, transgenic organism, transgenic crop, transgenic animal, transformed microorganism, etc.
- R&D, import and export, production, transit, transport, storage and sales of GMOs
- Exemption: any import and export of GMO-pharmaceuticals

1e) Exchange and cooperation

The exchange and cooperation with other countries and international organizations shall be further promoted.

2. Application for R & D, production, import and export of GMOs

a) Basic requirements

The law sets out the basic requirements for the application for approval of R & D, production, import and export of GMOs;

- The proper filing of application for the approval of R & D, production, import and export of GMOs is an important condition to ensure the timely consideration thereof.
- The applicant institution and enterprise shall file the application with SAGOST.

b) Content of the application document for the approval of research and development of GMOs

The application shall refer to the name and address of the applicant institution, name of the task force leader, title of the R & D project and the like.

c) **Content of application document for the approval of production of GMOs**

The application shall refer to the name and address of the applicant institution, name of the proposed GMO product, purpose, quantity and location of production and the like.

d) **Content of application document for the approval of export of GMOs**

The application shall refer to the name and address of the applicant institution, name and quantity of the GMOs to be exported, name of the importing country or region and the like.

e) **Content of application document for the approval of import of GMOs**

The application shall refer to the name and address of the applicant institution, name and contact address of the exporter, name and quantity of the GMOs to be imported, name of the exporting country or region, purpose of the import and the like. A sample shall be attached

f) **Procedure of application for carrying in GMOs intended for scientific research or exhibition**

An institution or individual wishing to bring in the country GMOs intended for scientific research or exhibition shall file an application for this purpose with SAGOST.

g) **Procedure and content of information on the GMOs in transit through the DPRK**

Any agency entrusted with the GMOs in transit shall inform SAGOST in advance of the name and quantity of the GMOs in transit, status of package and labeling and the like.

h) **Designation and qualification of the risk assessment body.**

- SAGOST may designate a specific body capable of carrying out the risk assessment of GMOs.
- The risk assessment of GMOs shall be requested to the competent genetic engineering research body possessed of the necessary equipments and experts.

i) **Reporting of the risk assessment of GMOs**

- RAB shall conduct a scientific analysis and evaluation of the potential effects of the GMOs that may affect the human health, environment protection and socio-economic and cultural fields.
- Details for the criteria, items and methods of the risk assessment as well as their reporting formats shall be specified by SAGOST.

j) **Acknowledgement of receipt of application for R & D, production, import and export.**

- The receipt date of application for R & D, production, import and export shall be the date on which the application document has been received by SAGOST.
- SAGOST shall acknowledge receipt of the application, in writing, to the applicant within *ninety days* of its receipt.

3. Consideration of the application for R&D, production and export and import of GMOs

The consideration of the application for the approval of R & D, production, import and export of GMOs is an important work to decide whether or not to approve R & D, production, import and export of GMOs based on the substantial examination of the potential adverse effects of the GMOs on the human health, environmental protection and the socio-economic and cultural sectors.

a) Period of consideration

- The consideration of the application for R & D, production, import and export shall be completed within *two hundred and seventy days* of its receipt.
- The State Biosafety Committee shall determine the consideration standards, methods and other relevant necessary items with regard to R&D, export and import of GMOs.

b) Request for the additional information

Additional information required for the consideration of R&D, production, export and import of GMOs may be requested and the applicant should provide the additional document in time.

c) Consultation

Consultation should be made with the relevant ministries or central authorities according to the purpose of using GMOs.

d) The scope of prohibition and restriction

- GMOs that are confirmed to have possible adverse effects on the human health, biodiversity and environmental protection
- GMOs that are confirmed to have possible adverse effects on the fields of society, economy and culture

e) Decision making

- The State Biosafety Committee shall be responsible for approval or rejection of R&D, production, import and export of GMOs.
- The result of consideration shall be notified to the applicant in writing and the notice of rejection shall specify the reasons.

f) Reconsideration

- The applicant may apply for reconsideration within *sixty days* of his receipt of rejection notice.
- The application for reconsideration shall be filed with SAGOST.
- SAGOST shall reconsider the application and notify the applicant of the result within *ninety days* of its receipt of the application.

g) Appeal

The institution, enterprise or organization which may disagree with decision on the result of reconsideration about R&D, production, export and import of GMOs may file an appeal with the State Biosafety Committee within *sixty days* of its receipt of the decision.

The State Biosafety Committee shall deliberate on the appeal and notify the appellant concerned of the result within *ninety days* of its receipt of the appeal.

h) Withdrawal of approval (Revocation)

SAGOST may withdraw its approval of the R&D, production, export and import in the following cases:

- In the case of discovery of the adverse effects of any GMOs for which the application has been approved previously,
- In case the approval of application for R&D, production, export and import has been gained either by deception or by illegal means,
- In the case of using any approved GMOs beyond its initially proposed purpose.

j) Disclosure of risk-free GMOs (Public Information)

- Any GMOs that have been confirmed to be free of risks shall be made public through the Database of Biosafety
- The procedure for approval and consideration of such GMOs shall be simplified.

This procedure and ways shall be formulated separately by SAGOST.

4. Handling of GMOs

a) Basic requirement

The relevant institutions and enterprises shall meet the safety requirements in handling of GMOs.

b) R&D of GMOs

The institutions and enterprises engaged in the research and development of GMOs shall provide themselves with necessary equipments and the measurement apparatus corresponding to the degree of the risk and strictly observe the rules for the experimental manipulation.

c) Registering

Gene used for the R&D of GMOs shall be registered for state certification.

d) Production

In case of producing GMOs, the measure for safety shall be sought according to the characteristics of production processes and the requirements for standard operation shall be observed.

e) Transportation

The GMOs in the course of transportation shall be packed in such a way that they are not released or open to the outside.

A waybill shall be required for the transport of GMOs.

f) Package and labelling of GMOs

Any GMOs shall be packed and bear a mark <GMOs>.

SAGOST shall decide details about package and labeling of GMOs.

g) Transboundary movement

In the case of the transboundary movement of GMOs, the approval notice issued by SAGOST for the import or export of GMOs shall be presented to border inspection office.

Any GMOs brought in by individual traveler shall be declared to the customs office.

h) Inspection of GMOs for export and import

- The border inspection office shall examine the approval document, package, sealing and marking of GMOs under export and import.
- Any discovery of GMOs which lacks the approval document or violates rules for packaging, sealing and marking shall be notified to SAGOST.
- SAGOST shall review the notification and take the relevant measures such as discarding or returning of GMOs.

i) Storage of GMOs

- The GMOs storage facilities shall be provided.
- GMOs shall be stored in accordance with their physical, chemical and biological characteristics
- Any organism whose gene may transfer shall be kept isolated.

j) Sale of GMOs

- Only GMOs whose safety has been proved through the risk assessment can be sold.
- Neither unpacked GMOs nor GMOs without marking can be sold.

k) Record of the information on the management of GMOs

The information on the R&D, production, export, import, storage and sale of GMOs shall be recorded, documented and notified to SAGOST.

l) Information on the occurrence of adverse effects

- Adverse effects or risks, which may be occurred in the process of handling and storage of GMOs shall be notified to SAGOST.
- The relevant institution shall take urgent measures to remove the adverse effects

5. Information management of GMOs

a) Basic requirement

SAGOST, relevant ministries and institutions shall observe the specified rules and meet the requirements laid down for the management of the information.

b) Confidential information

The data obtained during the course of the management of GMOs shall not be released or usurped.

c) Application for protection of confidential information

- Application for special protection of the information specified in the application document may be filed with SAGOST.
- SAGOST shall check the confidentiality of the information for protection and notify the applicant of its result.
If SAGOST finds any lack of confidentiality in the proposed information, it shall specify the reason.

d) Making the information available to the public

To open the received information to the public, prior agreement with the applicant institution or enterprise shall be needed.

e) **Exemptions from protection as confidential information**

- Name, address and phone number, etc. of the applicant
- Information on the risk assessment of GMOs
- Data on the emergency response for prevention of a certain accident
Other data confirmed be of social interest

f) **Biosafety Clearing-House**

- A national BCH shall be established and its role and functions shall be strengthened.
- The NBCH shall timely collect at home and abroad the necessary data for the management of GMOs and provide the relevant service with a sense of responsibility.
- Any information proved to be confidential shall not be disclosed.

6. Guidance and control over the management of GMOs (Institutional arrangement)

a) Basic requirement

The state shall see to it that the guidance and control over the management of GMOs are intensified.

b) Guidance organ responsible for the management of GMOs

- Under the unified leadership of the Cabinet, SAGOST is responsible for the guidance on the management of GMOs.
- SAGOST is duty bound to regularly control and direct the affairs concerning R&D, production, export, import, transport, storage and sale of GMOs.

c) State Biosafety Committee (SBC)

The state shall establish the State Biosafety Committee in the Cabinet to properly implement the policy of management of GMOs.

The duties of the SBC are:

- To map out the national strategy and policy for the safe management of GMOs
- To discuss and make decision on the management program for biosafety
- To receive the report on the implementation of the Cartagena Protocol on Biosafety, and discuss and make decision on the reasonable measures.
- To identify and open to the public the risk-free GMOs, discuss and decide on important matters regarding necessary measures for prevention of the damage caused by the GMOs
- To coordinate all the biosafety related matters at the national level.

d) The Competent National Authority

As a competent national authority, SAGOST shall undertake the practical and technological functioning of SBC.

e) National Focal Point for Biosafety

The National Coordinating Committee for Environment shall act as a national focal point for the implementation of Cartagena Protocol on Biosafety.

f) National Focal Point for BCH

The National Coordinating Committee for Environment shall act as a national focal point for the set up and functioning of NBCH.

g) **Public Awareness**

Propagation of knowledge on the GMOs shall be done by mass media to involve the masses of people in the management of GMOs with great interest.

h) **Public opinion in decision-making process**

The public opinion shall be referred to in making decision on the management of GMOs.

i) **Supervision and control over the management of the GMOs**

The supervision and control over the management of GMOs shall be conducted by SAGOST and the relevant institutions.

The supervisory and control organization shall strictly supervise and control all the processes of the R & D, production, export and import application, consideration, handling, and information protection of GMOs.

j) **Legal and administrative responsibility and punishment**

- Any actions of R & D, production, export and import of GMOs conducted without approval or in violation of the rules shall be suspended and fined.
- Any actions of R & D, production, export and import of GMOs done without measures for safety management shall be suspended and fined.
- Any GMOs packed and used contrary to the requirements of the rules shall be confiscated, discarded or fined.
- Any acts of illegally releasing or usurping the data concerning GMOs shall be punished with compensation or fine.
- Any person responsible for serious consequences caused by a breach of the present law shall be punished administratively or criminally.

E. FOLLOW UP ACTIONS FOR THE ESTABLISHMENT OF WORKABLE REGULATORY REGIME ON BIOSAFETY

- I) The biosafety basic Law on the management of GMOs shall be developed, adopted and enter into force.
- II) The existing departmental Laws and GMOs-related Laws are to be fine-tuned to include the profiles of GMOs handling. (See Appendix I)
- III) New implementing regulations and detailed rules are to be established in the field of treatment of GMOs:

a) **Regulations on management of transgenic crops**

- Detailed rules on the management of transgenic crops

b) **Regulations on transgenic animal**

- Detailed rules on the management of transgenic animal

c) **Regulations on transgenic microbe**

- Detailed rules on the management of transgenic microbe

- d) **Detailed rules on the management of LMO-FFPs**
- e) **Detailed rules on the management of transboundary movement**

The institutions responsible for the implementation of these regulations and rules are:

- The State Biosafety Committee
- The State Administrative Guidance Organ for Science and Technology
- General Customs Administration
- Quality Inspection Administration Office for Foreign Goods
- Ministry of Agriculture
- Other relevant ministries or central authorities

IV) The legal experts on biosafety and personnel responsible for interpreting and applying the law and regulations shall be trained.

3. System to handle notifications or requests for authorizations

A. PROCEDURES OF APPLICATION AND APPROVAL OF GMOs

The organization and enterprise shall present to the State Administrative Guidance Organ for Science and Technology the application for approval of R & D, production, export, import, handling, carrying, storage of GMOs.

I. Procedures of application for GMOs, its consideration and decision making process

- a) Application for approval of R & D, and production of GMOs shall be filed with the corresponding ministries (or central authorities) through the deliberation of the biosafety section of the institution or enterprise concerned.
- b) Corresponding ministries (or central authorities) shall check the application and other required documents and get them ratified by their respective ministers or CEO before forwarding them to SAGOST.
- c) SAGOST shall check for the completeness of the application before requesting the Consideration Committee for Cell and Genetic Engineering (CCCGE) to conduct the substantial consideration thereof.

CCCGE shall request the Risk Assessment Board (RAB) to carry out the risk assessment.

RAB shall assess the risks and report its result to CCCGE.
- d) CCCGE shall review the risk assessment report, conduct the consideration of the application and then submit the report on the result of consideration as well as the report on the risk assessment to SAGOST.

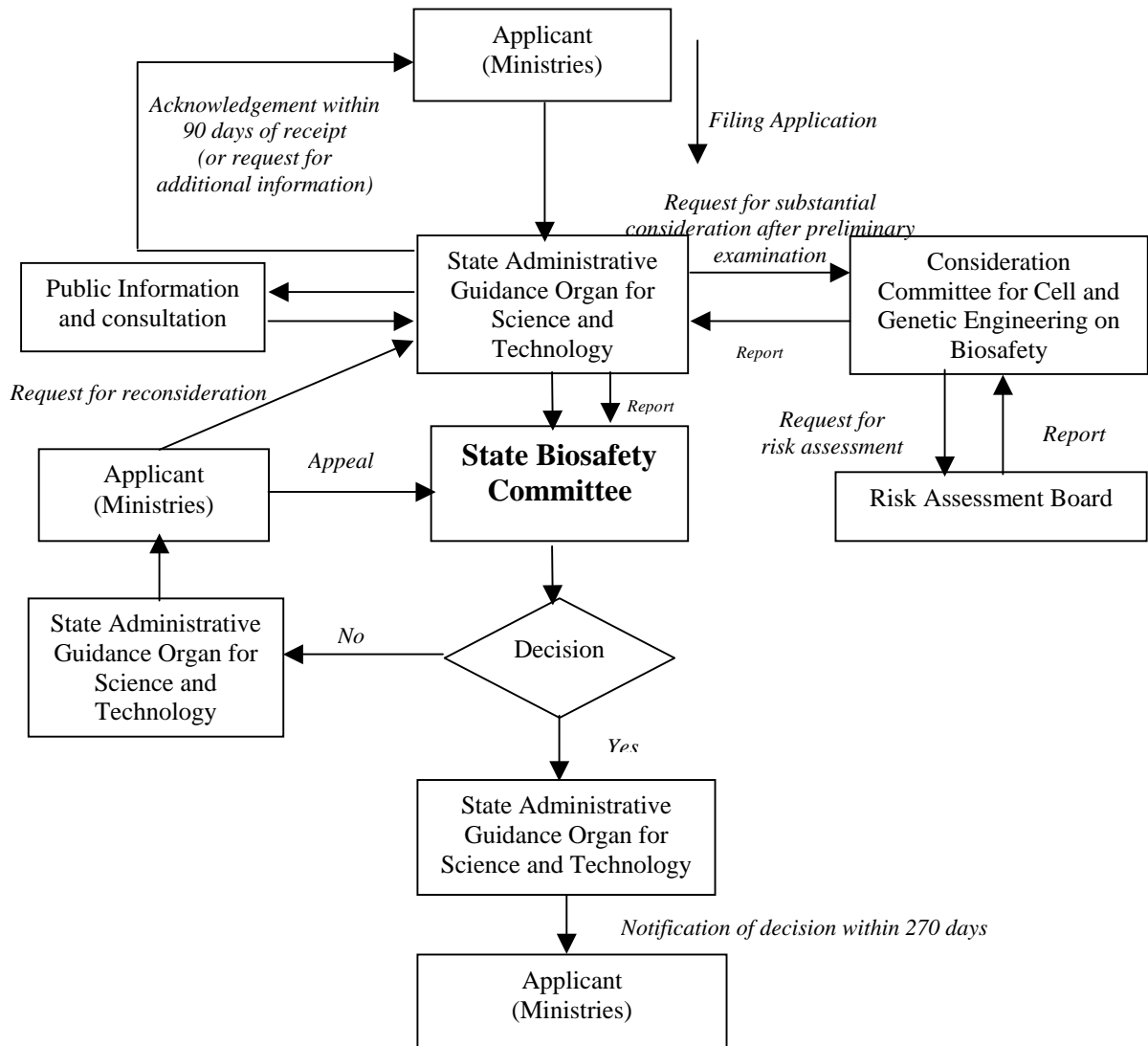
SAGOST shall present the application and consideration report to the State Biosafety Committee (SBC).
- e) SBC shall make a decision and send either the approval or refusal down to SAGOST.
- f) SAGOST shall send either the approval or the refusal down to the relevant ministry or central authority, which shall issue a notice of approval or refusal to the applicant organization or company

II. Procedures of application for import and export of GMOs, and its consideration and decision making process

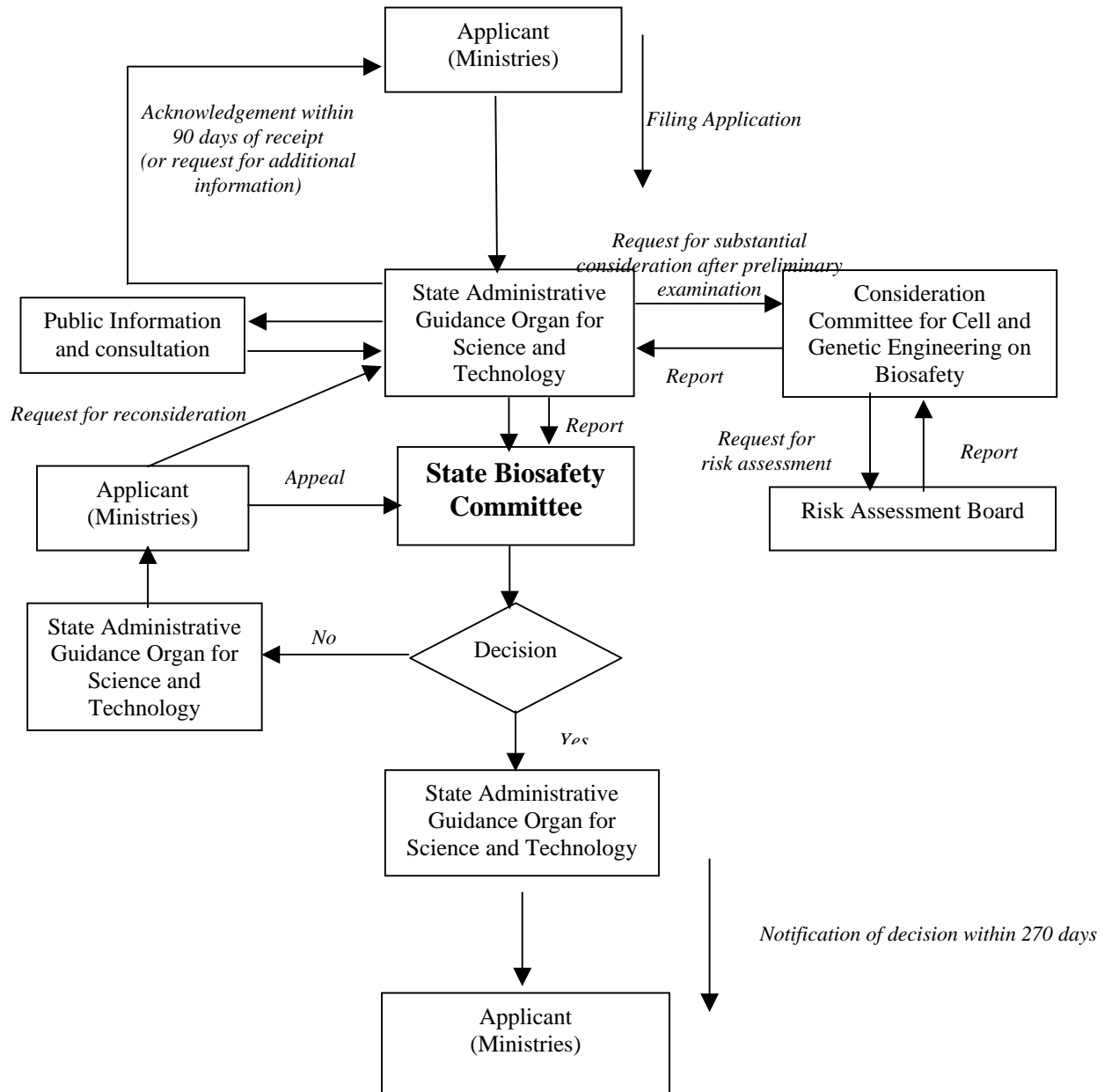
- a) Application for approval of import and export of GMOs shall be filed with the corresponding ministries (or central authorities).
- b) The relevant ministries (or central authorities) shall check the application and other required documents, get them ratified by their respective ministers or CEO before sending them to the Ministry of Foreign Trade.
- c) After reviewing the application, the Ministry of Foreign Trade shall submit the application document as well as her permission to SAGOST.

- d) SAGOST shall request CCCGE to consider the application document.
CCCGE shall request RAB to conduct a risk assessment.
RAB shall carry out the risk assessment and report its result to CCCGE.
- e) CCCGE shall consider relevant documents and forward the risk assessment report and consideration report to SAGOST.
- f) SAGOST shall disclose the fact through BCH to collect the public opinion about it.
- g) SAGOST shall submit to SBC the application for import (or export), the risk assessment report and the consideration report of CCCGE.
- h) SBC shall make a decision on approval (or refusal), taking into account the consideration report of CCCGE, risk assessment report, application document and public comments gathered.
- i) According to the decision of SBC, SAGOST shall send the notification in writing of approval (or refusal) to the Ministry of Foreign Trade.
- j) The Ministry of Foreign Trade shall send that notification in writing to the relevant ministry or central authority.
- k) The relevant ministry or central authority shall notify the applicant institution or enterprise of the decision in writing.

III. The procedures for approval of R&D and production of GMOs



IV. The procedures of application and approval for import(or export) of GMOs



V. Application Form

Application for R&D, Production

1. Title of Research Task (or Product name):

Period:

2. Name of Task Manager (or Production Manager):

Position:

3. Target GMOs:

4. Genes (origin) to be used and acquisition source:

Host

Promoter

Vector (plasmid)

Marker

5. Process diagram for manipulating genes:

6. Type and Scale of Test:

Crop: - Lab
 - Greenhouse (m²)
 - Field test (minor) *chongbo*
 - Field test (middle) *chongbo*
 - Field test (large) *chongbo*

Bioproduct: - Lab experiment (ℓ)
 - Pilot test (ℓ)
 - Plant scale (ℓ)

7. Location of Testing Site (or place for Introduction):

8. Information of Risk Assessment:

Task Manager:

Name of institution or enterprise:

Manager or President:

Date:

Application for Import (or Export) of GMOs

1. Name of exporting (or importing) country:
2. Name of GMOs to be imported (or exported):
3. Date of delivery:
4. Name of exporting (or importing) agency or body:
5. Name of manager or president from exporter (or importer):
6. Embarkation point:
7. Disembarkation point:
8. Name of manufacturer and origin:
9. Trait of GMO-FFPs:
 - 1) Transferred gene and acquisition source
 - 2) Host used
 - 3) Promotor
 - 4) Vector
 - 5) Marker
10. Risk Assessment:

Position of Applicant

Signature of Applicant

Name of institution or enterprise

Name and Signature of Manager or President

B. ADMINISTRATIVE STRUCTURES

I) State Biosafety Committee (SBC)

- a) SBC is the top guidance institution entrusted with the mission to manage GMOs in the DPRK.
- b) SBC is accountable for its work to the Cabinet.
- c) SBC shall be composed of chairman, vice-chairman, secretary, and members.

The committee also consists of administrative officials of GMOs-related ministries and commissions such as Ministry of Agriculture, Ministry of Health, Ministry of Land and Environmental Protection, Ministry of Fishery, Ministry of Education, Academy of Sciences, General Customs Administration, Ministry of Foreign Trade, General Bureau of Pisciculture, and Bureau of Quality Control, and experts including those in the Academy of Sciences, and officials of educational institutions such as **Kim Il Sung** University.

The duties of SBC are:

- To map out a national strategy and policy for safety management of GMOs
- To discuss and decide on the national project for biosafety management
- To get reports on the implementation for CPB, and discuss and decide on relevant measures
- To make decision whether to approve or reject the application
- To identify, and release the risk-free GMOs, and discuss and decide on important matters regarding necessary measures for prevention of the damage caused by GMOs
- To consider appeal filed with regard to management of GMOs
- To coordinate any activity related to biosafety of different stakeholders in the country.

II) State Administrative Guidance Organ for Science and Technology (SAGOST)

The State Administrative Guidance Organ for Science and Technology is a competent authority dealing with the national biosafety framework under the Cabinet assignment.

The Academy of Sciences, being SAGOST for the establishment of safety system of GMOs, commenced its work to implement laws and regulations.

- a) SAGOST dispatched the Cabinet Decision No. 64 to relevant ministries and their subordinate institutions and research institutes.
- b) It adopted measures concerning implementation of laws and regulations for GMOs
- c) It organized consultative meetings on the application for R&D, production, import and export of GMOs, explained procedures for approval of application and notification, and took relevant measures.
- d) It instructed border posts on their immediate tasks with regard to the transboundary movement of GMOs

Duties of SAGOST are:

- To convene sessions of SBC according to its plan, and implement in time the decisions adopted at the sessions.
- To convene in time sessions of the Consideration Committee for Cell and Genetic Engineering for Biosafety to conduct the scientific and technical considerations on problems raised and take relevant measures based upon the consideration.
- To take relevant administrative measures to complement, update and complete the NBF
- To establish system and order in the work for management of GMOs, such as R&D, production, import, export, usage and risk assessment, and step up the supervision and control so that the management of GMOs is conducted under the unified leadership.
- To establish a rigid discipline in the registration, safe storage and management of GMOs and their products, genes, vectors, promoters, etc. which are at the disposal of scientific research institutes, educational institutions, relevant organs, enterprises, associations and individuals.
- To establish a rigid discipline and order whereby experiments for cultivation, breeding and feeding of GMOs should be conducted only provided that research projects and experimental programs concerning modern biotechnology, research institute and laboratories, project manager in charge of them, and corresponding researchers in charge and pilot plants have been registered and approved according to the decision of SBC
- To establish a rigid system and order whereby relevant institutions and enterprises should address the treatment, storage, circulation and use of GMOs only with prior notification and approval.
- To establish administrative and practical measures for management of biosafety and build database for management of biosafety
- To promote actively public awareness and education so that the masses of the people can involve themselves voluntarily in the management of biosafety, and take measures for the public opinions to be fully reflected in the process of decision-making on biosafety.
- To facilitate cooperation and exchange with international organization in order to enable DPRK to fulfill its obligations as a party to the Protocol.
- To take issue in time with violations of laws, rules and regulations on biosafety and impose punishment corresponding to the extent of violations.

III) Consideration Committee for Cell and Genetic Engineering for Biosafety(CCCGEB)

The Consideration Committee for Cell and Genetic Engineering for Biosafety was organized with election of a chairman, vice-chairman, and members in December 2003.

It discussed about the orientation of its work and its duties and made appropriate decisions.

It deliberated on research projects to be implemented in biotechnological sector according to a five-year plan for scientific and technological development between 2003 and 2007, and reported the results to the Academy of Sciences, the Cabinet and the Biosafety Management Committee for GMOs.

It also deliberated on the biotechnology research tasks for the year 2004 and forwarded the report on the results to the Academy of Sciences.

The duties of the CCCGE are:

- To consider scientific and technological problems related to biosafety and prepare and submit relevant documents, as an organ for scientific and technical consideration working under the guidance of SBC and SAGOST.
- To contribute to the formulation of national strategy for biosafety in terms of scientific and technological issues.
- To undertake a scientific and technological consideration in regard to the risk assessment and management of GMOs.
- To review issues raised by SAGOST and provide suggestions for relevant measures.

IV. Risk Assessment Board (RAB)

The Branch of Cell & Genetic Engineering of the Academy of Sciences and the Institute of Agricultural Biology under the Academy of Agricultural Sciences have been designated as RAB.

They devised some practical measures regarding the risk assessment.

- Risk assessment of recombinant DNA experiment
- Risk assessment of field trial

The Laboratory of Gene Analysis was organized in the Branch of Cell & Genetic Engineering in December 2003, and it embarked on preliminary experiments and literature examination to determine the method of analyzing recombination of DNA of GMOs using PCR.

The duties of RAB are:

- To undertake the risk assessment and management of GMOs in dealing with biosafety.
- To conduct a risk assessment and management on the basis of internationally recognized methods.
- To check the information on the risk evaluation provided by applicant and conducts an appropriate risk assessment.
- To make a scientific and transparent assessment of risk and send the risk assessment report to CCCGE.
- To improve constantly the risk assessment undertaking including principles, procedures, objects and contents of risk assessment, and intensify scientific research for upgrading the risk assessment.

V. National Biosafety Clearing-House (NBCH)

A pilot version of NBCH was organized within the Branch of Cell & Genetic Engineering, Academy of Sciences in December 2003.

The staff of NBCH to be set up in the future with the pilot version as a model will be entrusted with the mission to exchange scientific and technological data in the field of

biotechnology and biosafety, environment and laws, experiences on handling and use of GMOs and their products at home and abroad.

The duties of NBCH are:

- To build and manage databases in the field of biosafety and Biotechnology, and provide necessary data to international BCH and relevant organizations.
- To provide science and educational institutions, and producers of GMOs such as agriculture, animal-husbandry, food industry, pharmaceutical industry, forestry, and pisciculture with scientific and technological information, experiences and trends concerning the risk assessment and management, measures taken against damage.
- To accumulate and provide data on international laws, conventions, and agreements in the field of biotechnology and biosafety as well as domestic and foreign laws, rules, regulations and national strategies.
- To accumulate and provide data concerning the import and export of GMOs and their products, and data on the world tendency.
- To accumulate and provide data on safety assessment of environment and human health.
- To accumulate and provide data on technology of analysis and its results concerning biosafety.

C. FOLLOW UP ACTIONS FOR THE ESTABLISHMENT OF PROCEDURES FOR HANDLING REQUESTS FOR AUTHORIZATION OF ACTIVITIES RELATED TO BIOSAFETY

- I) The systems for application, consideration and decision making shall be established and updated.
- II) The departmental coordination on biosafety related issues shall be enhanced to ensure the stated unified control system.
- III) The system for risk assessment and management of GMOs shall be set up.
- IV) The system for decision-making shall be set up and strengthened..
- V) The specific bodies in charge of risk assessment with appropriate equipments and facilities of GMOs shall be established.
- VI) Experts for the risk assessment of GMOs in different sectors shall be trained
- VII) The procedures and methods for risk assessment shall be adopted.

4. Monitoring and Enforcement

A. SYSTEM FOR MONITORING EFFECTS ON ENVIRONMENT

I. Monitoring the effects on environment was conducted in DPRK by adding biosafety surveillance function to the existing environment & field surveillance system which is mainly comprised of ;

- a) The Ministry of Land and Environmental Protection and its subordinate monitoring posts: forest surveillance post and river surveillance post
- b) The Ministry of Agriculture and its subordinate field surveillance post
- c) The Academy of Agricultural Sciences and its subordinate field surveillance post
- d) The Ministry of Urban Administration and its subordinate water supply & drainage surveillance post

II. Basic principles for monitoring effects on environment are:

- a) To establish a well-organized system of monitoring impacts of the release and use of GMOs on environment.
- b) To establish the national, sectoral and regional network for surveillance of biosafety.
- c) To set up a post for monitoring effects of GMOs on environment as terminal unit of biosafety surveillance network in order to conduct a sustainable and long-term surveillance.
- d) To acquire modern methods of monitoring influences of GMOs on environment, constantly improve components of surveillance and procure technical means for surveillance post.
- e) To accumulate systematically data on surveillance over influence of GMOs on environment so as to create a solid basis for surveillance.
- f) To promote the research work on surveillance over influence of GMOs on environment, and train experts in this field.

B. SYSTEM FOR ENFORCEMENT

The relevant provisions for enforcement shall be included in the articles of law and regulations to be developed and adopted.

I. Contents of enforcement

- a) Punishment of illegal acts of R&D, production, import and export of GMOs
Any acts of research and development, production, import and export of GMOs without approval or in violation of the approved scope shall be suspended and punished with a fine.

- b) Punishment of violation of requirements for the safe management of GMOs
Any acts of research and development, production, import and export, transport, storage and sale of GMOs without measure taken for safety management shall be discontinued and fined
- c) Punishment of violation of requirements for the handling of GMOs
Any GMOs products which have not been packed, marked and closed according to the requirements shall be discarded or confiscated and fine shall be imposed.
- d) Punishment of violation of requirements for the information protection
Any illegal leakage or abuse of information of GMOs shall be punished with compensation for damage or fine.
- e) Administrative and criminal punishment
Any officials of institutions, enterprises and organizations or individuals who are liable for serious consequences arising from violation of the law shall be subject to the administrative or criminal punishment.

II. Enforcement System

SAGOST is in direct charge of execution of law and regulations and is duty bound to check and review the state of law execution regularly and step up supervision and control of violations.

- a) R&D and production of GMOs

SAGOST shall

- be responsible for supervision and control over the execution of laws and regulations on scientific R&D and production,
- supervise and control the execution of laws through the relevant supervisory and control organs,
- conduct a supervision and control through Bureau for Seed Management, Seed Management Centre, Bureau for Animal Husbandry Administration and Stockbreeding Management Centre under Ministry of Agriculture, General Bureau for Pisciculture under Ministry of Fishery, Bureau for Scientific and Technological Consideration under Ministry of Education, Bureau for Science and Technology and General Bureau for Pharmaceutical Industries under Ministry of Health, Bureau for Science and Technology under Ministry of Land and Environmental Protection, and Bureau for Food Administration under Ministry of Light Industry.

- b) Import and Export of GMOs

SAGOST shall

- be in direct charge of supervision and control over the execution of laws,
- supervise and control the execution of laws through the relevant supervisory and control organs,
- supervise and control the execution of laws on import and export of GMOs at the border posts such as airports, railway stations and sea ports, the

customs stations under jurisdiction of the General Customs Administration through plant quarantine post of Central Office for Plant Quarantine under Ministry of Agriculture, hygienic supervision post of Central Office for Hygienic Quarantine under Ministry of Health, and foreign goods inspection post of Inspection Office for Foreign Goods under Bureau of Quality Control.

III. Institutions in the charge of enforcement

Academy of Sciences, Ministry of Agriculture, Ministry of Health, Bureau of Quality Control, General Customs Administration, Ministry of Education, Ministry of Land and Environmental Protection and Ministry of Foreign Trade

C. FOLLOW UP ACTIONS FOR THE ESTABLISHMENT OF THE SYSTEM FOR MONITORING AND ENFORCEMENT

- I) The infrastructure for monitoring and enforcement shall be founded.
- II) The experts for monitoring and enforcement shall be trained.
- III) Personnel who will be carrying out monitoring and enforcement shall be trained.
- IV) The technical means for monitoring shall be provided.
- V) The monitoring parameters and criteria shall be identified and the internal rules for monitoring and inspection shall be produced.

5. System for Public Awareness and Public 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 process related to biosafety.

A well-regulated system for public awareness, education and participation will be established.

- Public awareness through newspapers, radio, televisions and all kinds of publications will be raised.
- Public awareness through the Grand People's Study House, and libraries in every county, city, and province will be promoted.
- An educational network involving scientists, technicians and experts of the Federation of Science and Technology and the Federation of Nature Protection will be created.
- Public awareness and education through the science and technology study group, workers study group, science and technology propagation group and skill-training study group, which are running in all factories, farms, institutions and enterprises in the country will be updated and strengthened.
- Public awareness, education and participation of the masses of people through lectures on science and technology which are being held on a regular basis will be improved.
- 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 will be promoted.
- SAGOST, the mass media, education bodies, nature conservation bodies etc will carry out among the public the propaganda and diffusion of the knowledge on GMOs using different means and methods to involve the public in the management of GMOs.

B. FOLLOW UP ACTIONS TO IMPROVE PUBLIC AWARENESS AND INVOLVEMENT SYSTEM

- I) Develop plans for public awareness and education on biosafety and safe use of biotechnology.
- II) Make plans for study on approaches of public information and involvement in decision-making process.
- III) Prepare education materials on biosafety.

- IV) Raise the public awareness using mass media including TV, radio, newspapers, gazettes, homepage on biosafety.
- V) Prepare appropriate materials for disseminating the scientific knowledge and information on biosafety in the ordinary education stage and research field.
- VI) Publish and use various explanatory guidelines, books, scientific films, electronic media and other reference materials.
- VII) Develop the tools and approaches for public information on biosafety and collection of the public comments.
- VIII) Identify key points in the decision-making system on biosafety;
- IX) Organize consultative meetings for promoting the public information and involvement on a regular basis.

Appendix I

GMOs-related Laws

1. Law of DPRK on Agriculture
2. Law of DPRK on the Prevention of Veterinary Epidemics
3. Law of DPRK on Veterinary Medicine Administration
4. Law of DPRK on Inspection of Animals and Plants on Borders
5. Law of DPRK on Forest
6. Law of DPRK on Fishery
7. Law of DPRK on Fish farming
8. Law of DPRK on Socialist Commerce
9. Law of DPRK on Science and Technology
10. Law of DPRK on Public Health
11. Law of DPRK on Pharmaceuticals Administration
12. Law of DPRK on Food Hygiene
13. Law of DPRK on Public Hygiene
14. Law of DPRK on Hygiene Supervision in Boundary
15. Law of DPRK on Environment Protection
16. Law of DPRK on Pollution Prevention in Sea
17. Law of DPRK on Protection of Useful Animals
18. Law of DPRK on Protection and Control of Territory and Environment
19. Law of DPRK on Supervision of Import and Export Goods
20. Law of DPRK on Standardization
21. Law of DPRK on Trade Mark
22. Law of DPRK on Foreign Trade
23. Law of DPRK on Import and Export of Techniques
24. Law of DPRK on Quality Control
25. Law of DPRK on Medicine

Appendix II

Regulations on the Safe Management of GMOs(interim)

Chapter 1. General Provisions

Article 1 These regulations are intended to ensure the proper establishment of the system and order for the safe management of GMOs in an effort to protect peoples' health and eco-system by implementing the instructions of he Great Leader Comrade Kim Il Sung and the Great General Comrade **Kim Jong Il** thoroughly.

Article 2 In these regulations, GMO refers to the living organism with its traits alternated through the use of modern biotechnology, and they may include the organisms with such traits and their products including food, feed and medicine, etc.

Article 3 These regulations shall apply to the institutions, enterprises and associations (hereinafter called institutions and enterprises), DPRK citizens, DPRK compatriots residing outside the territory of DPRK, foreign-invested enterprises and foreign individuals related to management of safety of GMOs

Article 4 The Academy of Sciences (hereinafter called State Administrative Guidance Organ for Science and Technology-SAGOST) shall exercise a uniform supervision and control over Biosafety issues.

Article 5 SAGOST and relevant institutions shall create a sound database, improve its material and technical conditions and promote public education and awareness so that the public can participate in this work voluntarily.

Article 6 SAGOST shall develop exchange and cooperation in the field of biosafety with other countries and international organizations.

Chapter 2. Storage and Maintenance of Genes and Genetically Transferred Organisms(GTOs)

Article 7 The storage and maintenance of Genes and GTOs shall be undertaken by the relevant institutions and enterprises in safety.

The only institutions and enterprises designated by SAGOST can store the Genes and GTOs, which must be registered at SAGOST.

Article 8 The individuals are not allowed to store Genes and GTOs, but if necessary, they can store them in the designated institutions and enterprises and use them with approval of SAGOST.

Article 9 The institutions and enterprises that are possessed of the Genes and GTOs shall make the inventory thereof and mark them.

Article 10 The institutions and enterprises desiring to extract novel genes for use, shall submit to SAGOST an application in writing specifying the purpose and subjects of research, gene-processing design and gene-introduction target for approval.

Article 11 The institutions and enterprises desiring to export and import Genes and GTOs shall submit to SAGOST an application for approval, and timely inform and record the progresses.

Article 12 The institutions and enterprises which have the genes and GTOs are not allowed to hand them over other institutions, enterprises and individuals without any approval.

Chapter 3. Risk Assessment

Article 13 The institutions and enterprises desiring to be involved in R & D, introduction and use of GMOs shall go through the risk assessment thereof.

Article 14 SAGOST shall organize and operate the Biosafety Management Committee for the risk assessment of GMOs.

The Biosafety Management Committee shall be comprised of scientists, experts and the relevant officials from ministries, central authorities, and academic institutions in biological area and related fields.

Article 15 The institutions, enterprises and individuals desiring to conduct R & D, introduce and use GMSs shall file an application with SAGOST in accordance with the specified form.

Article 16 SAGOST shall review the application and submit it to the Biosafety Management Committee for examination.

In case the application is insufficient or the additional information is required, the Biosafety Management Committee may return it or request the relevant information.

Article 17 The Biosafety Management Committee shall ensure that risk assessment is carried out on the basis of internationally recognized scientific data and evidence and in principle until the safety can be verified.

Article 18 The risk assessment of GMOs shall be carried out as follows:

1. The effect of GMOs on the ecosystem shall be assessed.
2. The occurrence and results of the adverse effect shall be evaluated.
3. The overall risk assessment shall be carried out based on the evaluation of the separate adverse effects and their results.

Article 19 The risk assessment of GMOs shall include

1. The general characteristics of recipient organism and vectors, genetic modification and the marker trait.
2. The scope of habitat where the recipient and donor organism may persist or proliferate in the natural environment.
3. The effect of GMOs, on ecosystem, human health and animal growth.
4. The socio-economic consideration and the experiences of risk assessment carried out in the other regions.
5. The risk management measures and monitoring method.

Article 20 The Biosafety Management Committee shall make the collective decision on the basis of risk assessment and notify in writing the institutions, enterprises and citizens in question within 270 days of the receipt of application.

Article 21 The institutions, enterprises and citizens shall inform immediately SAGOST in case a potential adverse effect on human health and eco-systems can be found even after approval.

Article 22 SAGOST may cancel the approval or request that appropriate measures should be taken if any GMOs proved to affect the human health and ecosystem.

Article 23 The institutions, enterprises and individuals shall disinfect thoroughly the GMOs whose approval has been cancelled and treat the affected soil in physical and chemical manner.

Article 24 The institutions, enterprises and individuals shall carry out the risk evaluation and monitoring of approved GMOs on a regular basis(except the case a proof is given that there is no risk on human health and ecosystem) and timely report the results to SAGOST.

Article 25 When any escape of GMOs occurs, the institutions, enterprises and individuals shall evaluate the detailed contents and adverse effects of GMOs in time and take the emergency measures and then inform SAGOST accordingly.

Article 26 The institutions and enterprises desiring to transport the GMOs shall ensure the containment, package and proper labeling to prevent the escape of GMOs, and take appropriate measures so as not to affect the human health and the environment in case of embarkation and disembarkation.

Article 27 The customs office shall authorize the transboundary movement of the only Genes and GMOs that have been approved, to pass through the border and port, but where the GMOs are exported or imported without grant of approval it shall confiscate them to hand over to SAGOST.

Chapter 4. Supervision and Control

Article 28 SAGOST and relevant supervising and controlling organs shall be responsible for the supervision and control over the biosafety of GMOs.

Article 29 SAGOST and relevant supervising and controlling organs shall strictly monitor, supervise and control the processes of R&D, introduction, use of GMOs on a regular basis.

Article 30 In case of breach of these regulations, those who are convicted of offence on these regulations shall be liable to the administrative punishment such as the cessation of R&D, introduction, moving of GMOs, compensation for damages and fines according to the severity of the cases and even to the criminal penalties.

Contents to be included on future rules and regulations on the handling of GMOs

1. Experiment on gene recombination

- a) An institution, enterprise or organization wishing to conduct gene recombination experiment, should apply to SAGOST for approval.
- b) An institution, enterprise or organization applying for the approval of gene recombination experiment should specify in the application its name and address, the name of project manager, project title, purpose, method, material, means, specifications of the object of research and development, economic efficiency. Risk grade of R & D and measures taken for safety management.
- c) The consideration of the application for approval of gene recombination experiment shall be undertaken by SAGOST.
- d) The gene to be used in gene recombination experiment shall be registered at SAGOST and subject to the state certification.

The gene which has not been registered or certified shall not be allowed for gene recombination experiment.

- e) An institution, enterprise or organization wishing to develop GMOs shall be equipped with the necessary facilities and measurement apparatus according to the risk grade of relevant R & D and strictly meet the requirements laid down in the regulations for experiment.

SAGOST shall determine the risk grade in the R & D of GMOs.

- f) The chief of the institution, enterprise or organization desiring to conduct gene recombination experiment shall organize its own GMOs safety management committee and convene its meeting on a regular basis in order to;
 - Supervise and control to ensure that the requirements of technical standards on the safety in the handling of recombinant DNA are met,
 - Examine and sum up the degree of knowledge and understanding of employees about the requirements for handling and use of recombination DNA and GMOs on a monthly, quarterly, and yearly basis.
 - Check and identify every member taking part in gene recombination experiment whenever the experiment takes place.
 - Prepare details about facilities, apparatus and technical standards of operation and measures for safety management required for the relevant level of gene recombination experiment and submit them to SBC for approval.
 - If approved, supervise and control so that gene recombination experiment can be conducted according to the relevant procedure.

- Intensify the law-abiding education in respect of GMOs management among researchers so that they can observe the relevant law and regulations strictly.
- i) An institution, enterprise or organization, wishing to carry out gene recombination experiment, shall meet the main requirements for safety management as follows:

Every member taking part in gene recombination experiment should be possessed of good basic biological knowledge about organism used in experiment and sterilization method, make all necessary preparations to detect and tackle any potential adverse effects and record the state of preparation regularly.

- The door to the laboratory should always be closed
 - Participants in the experiment should wear laboratory suit in action.
 - Storage of foodstuff in the laboratory or carrying the foodstuff into the laboratory is prohibited.
 - Eating, drinking or smoking in the laboratory is forbidden.
 - Leftovers from the experiment should be sterilized thoroughly.
 - Any animals and plants which are not used in experiment, should be exterminated.
 - After experiment, the surface of the worktable should be sterilized and the broken vessel or apparatus should also be sterilized.
 - Positive measures should be taken to exterminate any harmful insect or rodents.
- j) Evaluation of the risk level of gene recombination experiment

The system of gene recombination experiment is composed of the recombinant DNA involving gene vector and target DNA and the host cell.

The risk of the system of gene recombination experiment can be categorized according to following factors:

- Origin of DNA
Pathogenic microorganism is more dangerous.
- Number of independent recombinants, which are gained in the first experiment
The higher the number is, the greater is the occurrence probability of recombinant with potential risk.
- The specificity of host-vector system
The greater the homogeneity of the base sequences between host cell and vector is, the higher the potential risk of the given host organism.
- Degree of homogeneity of DNA used for recombinant experiment.
The risk of isolated and identified recombinant DNA is very low.
The level of protection depends on the specific condition and object experiment.
The protection level may be brought down one unit lower in case of using purified individual genes.
When the host cell gains the quality new resistance, the protection level may be increased as high as one unit.

The animal cell culture can be found in the cloning system whose risk is lower than bacterium.

If it is identified that recombinant DNA includes potential risk genes, the protection level should be increased as high as one unit.

In case of using recombinant DNA composed of elements, which are involved in the various biological categorical groups, the protection level is determined according to the most risky element.

Any release into the environment of recombinant genes, which are identified to be dangerous to human health, animal and crop is prohibited on all accounts.

- k) The institution, enterprise or organization which carries out gene recombination experiment, should, according to the risk level of gene recombination experiment, take the following physical closure measures:

The physical closure measures imply that the activity will prevent any release of the recombinant DNA, by making use of the physical means involving relevant facilities and apparatuses.

They are composed of three elements involving laboratory, facilities or apparatus and experimental operation, and it is categorized into four classes of P1-P4 according to the closure level.

Class P1

This is applied to the recombinant experiment, which is identified to be risk-free; the experiment is conducted with ordinary microbiological experimental facilities and by the relevant operation method.

It does not need any specially designed laboratory-isolation facilities and the participants in the experiment may freely move in and out.

The work in this laboratory may proceed on the exposed surface of desk without the specific protection equipment, but the processes of sterilization and disinfections of the leftovers should be thoroughly gone through.

Class P2

This refers to the recombination experiment, whose risk is identified to be low. The number of participants should be limited and the laboratory should be equipped with an autoclave.

The handling and operation of the apparatuses such as mixer, pump, lyophilizer, ponticator and shaking mixer which can form aerosol should take place in the safe laboratory or isolated laboratory equipped with the high-performance microelement filter or supplied with the negative pressure.

Class p3

This is applied to the recombination experiment, whose risk is identified to be at the medium level.

The isolated laboratory should be prepared and both external and internal doors of the exit should never be opened.

It should have a drawing room furnished with a dressing room.

Air should flow from the drawing room into the experimental area and the air exchanger which filters air to the outside should be available.

All members who work in the laboratory, when carrying out experiment, should wear the special experiment suit with a front side being fully covered, and gloves. The suit and gloves should be thoroughly disinfected after experiment.

The vessel with a lid being opened, which contains recombinant DNA or sample to be tested should be handled only in the isolated room supplied with the negative pressure.

Sterilization should be conducted in the isolated room or on the isolated desk, equipped with air exchanger, filter and experimental gloves, and the sample should be drawn out from unbroken, closed box.

This closed box should be picked out through the hole which can be sterilized by chemical disinfectant tank, auto clave and ultra violet ray or it should be picked out after disinfection of the whole isolated room.

The operators should observe requirements of the laboratory:

- It is essential to make special markings on the various storage boxes, samples and the door in the laboratory and also on laboratory animal or samples which have been tested by living mediator considered to be dangerous from the biological point of view.
- Only those who have been selected in advance for the experiment are allowed to enter the laboratory.
- The operators should use defined protection facilities, work suit, laboratory suit and individual primal protection equipment.
- The laboratory suit should not be worn outside the laboratory and should be disinfected before they are sent to the laundry.
- After the experiment, the isolated laboratory or the surface of isolated desk and equipment should be sterilized.
- After experiment using recombinant DNA and before getting out of the laboratory, hands should be washed with disinfect out solution.
- The glass vessel used in the experiment should be sterilized in the laboratory or put in the air-tight box before it is carried out of the laboratory.

Class P4

In this experiment, the strictest experimental conditions should be provided so as not to allow microorganisms which are potentially dangerous to human being, animal and plant to be spread,.

Experimenters should wear the laboratory suit and the laboratory should be located in the detached building or in the clearly distinguished district.

Any access to the laboratory is forbidden.

The door of laboratory should bear a universal bio-risk mark and the laboratory be equipped with emergency air tank, alarm device, emergency power source, light and communication devices.

All waste solutions from the experiment should be auto claved before being discarded and the process of hands washing and shower bath of researchers should go through chemical sterilization.

The laboratories should meet the following technical specifications:

- The closed wall, floor and ceiling, which have all engineering holes, such as air tube, electric wire tube and water tube should be made air-tight to ensure the physical isolation of the laboratory and prevent biological samples from being released outside.
- An individual air-exchange system that maintains the air negative pressure should be available.
- A device for disinfecting air before it flows outside should be made available.
- Every tube from the laboratory should be protected by the highly efficient filter system.
- An air-tight door through which equipment, various vessels, animal and samples can be brought into laboratory should be made available.
- The air-tight door should be closed by mechanic or electronic devices.
- The sanitary disinfections room may be located in the main building of the institute or in the other separate building connected with production building through closed corridor.
- The sanitary disinfections room should be equipped with a shower bathroom, a wardrobe, working suit, waste store and special working suits.

l) Movement of recombinant DNA and GMOs

In order to protect carrying people and the surrounding environment, the recombinant DNA-containing microorganisms should be put into the special vessels and transported according to the requirements laid down in regulations and guidelines in regard to the storage, use, supply, import and export of micro plasma such as microorganism and bacterial toxin and the toxin stemming from animal or plant such as virus, bacterium, rikkechia, fungi and protozoa.

DNA, vectors and non-pathogenic host cells derived from non-pathogenic microorganisms and animal or plant are not included in this category.

The transfer of microorganisms containing recombinant DNA which are approved by the relevant regulations or used for the gene engineering research to other institution shall be permitted only after deliberation of the formal request document presented by the chief of the institution concerned.

m) Measure for the prevention of the biological propagation.

It implies defining the right host or vector so that recombinant DNA cannot exist in the nature or nor can it be transferred to another organism.

If the risk is higher, the measure should be taken to use host and vector whose rate of existence and the transmission possibility is low.

In case of using the prokaryotes and low encrypts as the host, classes B1 and B2 should be defined.

- Class B1 measure for prevention of the propagation.

It has been identified to be effective for the prevention of recombinant propagation because the transfer ability of the vector and the capacity of survival of the host in the natural environment are low.

EK1 host-vector system

The host-vector system in which E.coli k12 is the host and the plasmid or phage that has no contact transfer ability is the vector is defined as B1 level and called EK1 system.

The host-vector system SC1 in which *Saccaromyces cerevisiae* and 2 microplasmid vector are used and the system BS1 whose host is *Bacillus subtilis* are system B1.

- Class B2 measure for prevention of propagation.

Class B2 is the host-vector system whose effect for preventing biological propagation has been identified ultimately high because of the use of the vector whose possibility for natural existence is especially lower than the class B1 host and the host-dependence is very high.

EK₂ host-vector system

This system has been identified to be highly effective for preventing biological propagation as it uses the special host, which can exist only in the specific cultural condition EK1 condition, and also uses the vector with high dependence on the host.

This is the host-vector system under which the rate of existence of recombinant is $1/10^8$ day after its cultivation for 24 hours.

Combination table for EK₂ host-vector system

Host	Vector
X 1776	PSC101
	PCT1
	PMB9
	PBR313
	PBR322
DP 50 supF	λ WES λ B
	λ gtw JZ - λ B
DP 50 orDP50 sup F	charon 3A
	charon 4A
	charon 316A

The host-cell system except EK₂

As regards the host-cell system whose host is prokaryote or low eucalypti, it is class B₂ that is identified to be effective for prevention of transfer.

- When the institution, enterprise or organization has developed a new GMO, it should register it at SAGOST and get a GMO registration certificate issued.

Without the certificate, GMO should not be introduced into production.

- In the case of the registration of the newly developed GMO.

SAGOST should strictly review the specifications of the said GMO, its scientific and technological reliability, possibility of its introduction into production, economic effectiveness and safety.

The GMO with insufficient above-mentioned conditions cannot be registered.

- The relevant institution, enterprise and should store and manage the gene and gene-transferred strain with a sense of responsibility.

The gene and gene-transferred strain should be registered at SAGOST and be stored only at the approved institution and enterprise.

- Individuals are not permitted to store the gene and gene-transferred strain but, if necessary they can use them which are stored at the prescribed institution and enterprise with an approval of SAGOST.
- The institution and enterprise storing and managing the gene and gene-transferred strain are bound to draw up a list of the genes and strains and make a relevant marking.
- The institution and enterprise wishing to separate and use the new genes should prepare application describing the purpose of research, research object, the design of gene processing and the object of gene introduction, and submit it to the SAGOST for approval.
- The institution, enterprise or individual wishing to import or export the gene and gene-transferred strain should submit the application to SAGOST for approval and timely notify SAGOST of the record of export or import of the approved gene and gene-transferred strain and register them at SAGOST.
- Without any approval, the institution and enterprise in possession of the gene and gene-transferred strain should not transfer them to other institution, enterprise and individuals.
- The relevant institution, enterprise and organization should regularly review and record any research, development, production, import or export, transport, storage and sale of GMOs and notify SAGOST of the process.

The document in which gene recombination experiment, production, import or export, transport, storage and sale of the recombine genes have been recorded should be preserved.

The GMO information data defined as confidential for protection should not be made available to the other institution, enterprise, organization and individual without approval.

2. The field trial for risk assessment of the GM crops

A. Procedure for application and approval for the field trial for risk assessment of the GM crops

I. The institution, enterprise and individual wishing to conduct a R & D on GM crops or use them should submit the application for the risk assessment to SAGOST.

The GM crops whose safety is guaranteed at the laboratory level and whose applicability to production is sufficient shall be eligible for the field experiment for their risk assessment.

II. The application for the field experiment for risk assessment should contain the following:

- a) Name of species of the relevant GM crop, name of its family, state and prospect of its cultivation.
- b) Purpose of developing a GM crop, its applicability to production, scope of its extension etc.
- c) Information as to whether any similar experiment has ever been carried out in the country or the relevant GM crop has ever affected the human being or animal during its lifetime in the country
- d) Any possibility whether the said GM crop may destroy the ecological system of the natural environment or cause adverse effects to the human health.
- e) Origin of the introduced DNA
Information as to whether the introduced DNA is derived from the organism which can cause disease to human being, animal and plant and the name and origin of the regulator, structural gene, promoter, terminator, marker contained in the gene structural body.
- f) Procedure for gene engineering conducted at the laboratory level, and the level of risk assessment in the room and applied technical methods and means
 - How many copies of the gene are inserted in which chromosome?
 - What sorts of vectors have been used in the transformation and what is the host range?
 - Is the recombinant vector contained in the last product? If not, how has it been removed?
 - How has DNA been introduced?
- g) By what symbol can the GMO be distinguished in the laboratory or field?
- h) Previous data on the current state of the cultivation in the country of the crop to be tested, and the blight and weed

III. SAGOST should check the application and request the Consideration Committee for Cell and Genetic Engineering for its consideration.

IV. CCCGE should request RAB to conduct a risk assessment in regard to the approved projects under the supervision of SAGOST.

B. Competent authority and time period for the risk assessment of GM crops

- I) The risk assessment of the GM crops should be carried out in the experimental field of the risk assessment board.
- II) The permanent group composed of 3 to 5 specialists of agriculture and biotechnology and headed by the deputy directors in charge of scientific matters of the relevant institutes should undertake field experiment for the risk assessment.
- III) The risk assessment of the domestically developed GM crops should proceed for one to three years according to the technical specifications of the relevant crops.
- IV) In case of cultivating GM crops which have been developed in foreign countries and whose safety has been checked, the risk assessment of these crops should take place for one year provided that the risk assessment report and safety certificate have been submitted by the relevant country.

C. Selection of the experimental field for the risk assessment of GM crops

- I) The risk assessment of GM crops should be carried out in the selected field having the land condition under which the propagation and transfer of GM crops by water, soil and air could be prevented and the soil is uniform.
- II) The size of the experimental field for risk assessment should be defined according to the nature and purpose of the experiment, technical specification of the crop, soil fertility and topographical conditions. The manuring and cultivation as well as the investigation of the growth of GM crops should be carried out according to experimental methods for the relevant crop.

D. Factors for the risk assessment of GM crops in the field experiment

- I) The main phenotypic mutation and its frequency found in the field phenotype as a result of genetic modification should be investigated and recorded.
- II) The difference between the GM crop and relevant non-transformed plant (contrast) in terms of the rate of growth and development should be recorded.
- III) The frequency of the restoration and disappearance of the genetic mutation found through the annual experiment should be checked and recorded.
- IV) The pollen fertilization ability of GM crop, transmission rate by the insect media and living range of the mediator should be examined.
- V) The kinds and numbers of the weed plants which have the sexual compatibility with the GM crop in the surrounding environment and the experimental field,

and the possibility of survival of plants generated by cross-fertilization should be investigated.

- VI) Is fruit set of the GM crop proceeding regularly or does the seed drop quickly after fruit set?
- VII) What selection precedence does the modified phenotype enable the GM crop to occupy over the non-transformed plant.
- VIII) How long is the dormancy time of the seed and has it the ability to exist even after its dropping on the ground too?
- IX) How does the introduced phenotype of the GM crop change in the course of the agricultural production and in the natural environment
- X) Is there any possibility for the GM crop to leave or release specific substances on the soil?
- XI) Has the emergence of transformed gene in the GM crop any impacts on the agricultural phenotype (the decrease in salt resistance, the increase in the proliferation of the blight and the decrease in the yield so on)?
- XII) Can the natural disintegration ability of the plant be changed by the introduced gene?

E. Analysis and summing-up of the result of field experiment

- I) The field experiment group for the GM crop should report to the SBC twice a year the results of the risk assessment conducted at every stage of the growth of GM crops.
- II) The report of the field experiment group should include the results of observation and investigation according to the evaluation factors provided in D, and the following:
 - Location of the experimental place, and soil and climatic conditions, irrigation and drainage, and surrounding environment, etc.
 - The number of the individual GM crop tested, ways in which the number of the individuals have been counted and identified in the course of transporting GM crop from the laboratory and green house to the field.
 - How have GM crops been planted or transplanted and how have the manuring and cultivation, examination and observation of the GM crop been carried out and how has the result of investigation been achieved?
 - Which methods have been used to evaluate the homogeneity of the GM crop?
 - How have the rate of survival of the GM crop and their transfer to other species been tested and, suppose the introduced gene might be transferred to another organism, giving rise to adverse effect, what sorts of measures have been taken to minimize the effect?
 - Can the introduced gene increase the toxicity of the relevant crops among human being and animals

- What type of the second economic effectiveness can be expected in the cultivation of crops as a result of the introduction of the GM crops (increase in the effect of herbicide use, improvement of the pathogen-resistance etc.)?
 - What method or technique has been used to prevent any possible risk of transmission of GM crop in the process of the experiment?
 - How has the GM crop been disposed of or destroyed after the field experiment and what methods and means have been employed to test the process?
- III) SAGOST should suggest introduction into production process of the species of crops, which have been confirmed to be risk-free through the annual test, and should demand absolute incineration of the testing crops, which have been proved to possibly cause risk to human health and ecological environment.

SAGOST should take appropriate measures to prepare the experimental conditions for evaluation and analysis of the adverse effects of GM crops on human health.