

THE PRIME MINISTER

DECISION No. 212/2005/QĐ-TTg OF AUGUST 26, 2005, PROMULGATING THE REGULATION ON MANAGEMENT OF BIOLOGICAL SAFETY OF GENETICALLY MODIFIED ORGANISMS; PRODUCTS AND GOODS ORIGINATING FROM GENETICALLY MODIFIED ORGANISMS

THE PRIME MINISTER

Pursuant to the December 25, 2001 Law on Organization of the Government;

Pursuant to the December 27, 1993 Law on Environmental Protection;

At the proposal of the Minister of Natural Resources and Environment,

DECIDES:

Article 1.- To promulgate together with this Decision the Regulation on management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms.

Article 2.- The Minister of Natural Resources and Environment shall assume the prime responsibility for, and coordinate with concerned ministries, branches and localities in, guiding and organizing the implementation of the Regulation promulgated together with this Decision.

Article 3.- This Decision takes effect 15 days after its publication in "CONG BAO."

Ministers, heads of ministerial-level agencies, heads of Government-attached agencies, presidents of provincial/municipal People's Committees, and concerned organizations and individuals shall have to implement this Decision.

For the Prime Minister
Deputy Prime Minister
PHAM GIA KHIEM

REGULATION ON MANAGEMENT OF BIOLOGICAL SAFETY OF GENETICALLY MODIFIED ORGANISMS; PRODUCTS AND GOODS ORIGINATING FROM GENETICALLY MODIFIED ORGANISMS

Chapter I

GENERAL PROVISIONS

Article 1.- Scope of regulation

This Regulation provides for the state management of biological safety in scientific research, technological development and assay; production, trading and use; import, export, storage and transportation; risk evaluation and management and grant of biological safety certificates for genetically modified organisms;

products, goods originating from genetically modified organisms for the purpose of protecting human health, the environment and bio-diversity.

Article 2.- Subjects of application

This Regulation applies to domestic and foreign organizations and individuals (hereinafter referred to as organizations and individuals) engaged in activities related to genetically modified organisms; and products, goods originating from genetically modified organisms in the Vietnamese territory.

Where treaties which the Socialist Republic of Vietnam has signed or acceded to contain provisions different from those of this Regulation, the provisions of such treaties shall apply.

Article 3.- Interpretation of terms

In this Regulation, the following terms shall be construed as follows:

1. Biological safety means measures to manage safety in scientific research, technological development and assay; production, trading and use; import, export, storage and transportation; risk evaluation and management and grant of biological safety certificates for genetically modified organisms; products, goods originating from genetically modified organisms.

2. Gene means a unit of heredity, a segment of genetic material of an organism determining the particular characteristics of the organism.

3. DNA (deoxyribonucleic acid) means genetic material of an organism, shaped like a double helix and composed of a lot of genes (units of heredity).

4. Gene transfer technology means the transfer of a gene of one organism to another, forcing the

DNA helix of the target organism to accept the foreign gene.

5. Genetically modified organisms mean animals, plants or micro-organisms whose genetic structure has been altered by gene transfer technology.

6. Products or goods originating from genetically modified organisms mean products or goods created wholly or partly from genetically modified organisms.

7. Release of genetically modified organisms means the deliberate introduction into the environment of genetically modified organisms.

8. Risk assessment means the determination of the potential hazard and the extent of damage which has been caused or might be caused to human health, the environment and bio-diversity in activities related to genetically modified organisms, particularly the use and release of genetically modified organisms; and to products and goods originating from genetically modified organisms.

9. Risk management means the application of safety measures to prevent, deal with and overcome risks to human health, the environment and bio-diversity in activities related to genetically modified organisms, products and goods originating from genetically modified organisms.

10. Assay means activities of testing the level of biological safety of genetically modified organisms, products and goods originating from genetically modified organisms under the practical conditions of Vietnam before they are put to production, trading and use.

*Chapter II***SCIENTIFIC RESEARCH, TECHNOLOGICAL DEVELOPMENT AND ASSAY****Article 4.-** Scientific research, technological development

1. Scientific research, technological development concerning genetically modified organisms; products and goods originating from organisms must comply with current regulations on scientific and technological management and other relevant provisions of law.

2. Organizations and individuals may conduct scientific research, technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms only when they have all conditions regarding material foundations, equipment, technology and professional personnel suitable for scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms.

3. Organizations and individuals, when conducting scientific research, technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms, must register such activities with the Ministry of Science and Technology and ministries managing this issue.

4. Organizations and individuals conducting scientific research, technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms shall have to safely preserve

genetically modified organisms and other related dangerous materials and keep them from leaking into the environment.

Article 5.- Assay

Organizations and individuals assaying genetically modified organisms; products or goods originating from genetically modified organisms must observe the following provisions:

1. Conditions for registration of assaying activities:

a/ Having adequate material and technical foundations, technology and specialized staff suitable for the assay of each kind of genetically modified organism, product or goods originating from genetically modified organisms for the efficient control and handling of risks under regulations of the concerned managing ministry;

b/ Genetically modified organisms, products and goods originating from genetically modified organisms which need to be assayed must be the outcome of the process of scientific research which has been tested and accepted by a competent state agency;

c/ Having risk monitoring and management measures in the assay process;

d/ The area where an assay takes place must be isolated from population quarters and nature conservation zones according to regulations of the concerned managing ministry.

2. A registration dossier consists of:

a/ An application for registration of assay;

b/ Written consent of the People's Committee of the province or centrally-run city where the assay is planned to be conducted;

c/ Papers proving full satisfaction of the conditions specified in Clause 1 of this Article;

d/ Other necessary relevant information as requested by the registry.

3. Order and procedures:

a/ Dossiers of registration of assay shall be sent to the concerned ministry;

b/ Within 60 days after receipt of complete and valid dossiers, the concerned ministry shall have to evaluate the dossiers and issue decisions to permit the assay in cases where all conditions are met; if refusing to permit an assay, the dossier-receiving ministry must issue a written reply, clearly stating the reason therefor.

4. When permitting an organization or individual to conduct an assay, the concerned managing ministry shall have to report it to the Ministry of Natural Resources and Environment, the focal point of the Government.

Chapter III

PRODUCTION, TRADING AND USE

Article 6.- Conditions on production and trading

1. Organizations or individuals may produce, trade in or put to use genetically modified organisms; products and goods originating from genetically modified organisms when they fully meet the following conditions:

a/ Having biological safety certificates for genetically modified organisms; products or goods originating from genetically modified organisms;

b/ Genetically modified organisms, products or goods originating from genetically modified

organisms are on the list of those permitted for production, trading and use under regulations of the concerned ministries.

2. Organizations or individuals that produce, trade in or put to use genetically modified organisms, products or goods originating from genetically modified organisms must have relevant production or business registration certificates.

Article 7.- Labeling

Organizations and individuals that have products or goods being genetically modified organisms, products or goods originating from genetically modified organisms circulated and traded on the market must comply with current provisions of law on goods labeling and print on their packings the following words: "Products using gene transfer technology" for consideration and selection by consumers.

Article 8.- Monitoring, supervision and reporting

Organizations and individuals that produce and/or trade in genetically modified organisms, products or goods originating from genetically modified organisms must regularly monitor and supervise their level of safety for human health, the environment and biodiversity; when a risk occurs, they must immediately report it to the Ministry of Natural Resources and Environment and the concerned managing ministries.

Chapter IV

IMPORT, EXPORT, STORAGE AND TRANSPORTATION

Article 9.- Conditions on import of genetically

modified organisms

1. Genetically modified organisms imported into Vietnam for research purposes must satisfy the following conditions:

a/ Having been permitted by the exporting country for use for the same purpose in its territory;

b/ Having effective risk management measures.

2. Genetically modified organisms imported into Vietnam for assay, production, trading or use purposes must satisfy the following conditions:

a/ Having been permitted by the exporting country for use for the same purpose in its territory;

b/ Having gone through risk assessment in the practical conditions of the exporting country; in case of import for production, trading or use purposes, genetically modified organisms must have also undergone risk assessment in the practical conditions of Vietnam;

c/ The exporting country has established an effective safety management mechanism for such genetically modified organisms.

Article 10.- Conditions on import of products and goods originating from genetically modified organisms

1. Products and goods originating from genetically modified organisms imported into Vietnam for research purposes must comply with the provisions of Clause 1, Article 9 of this Regulation.

2. Products and goods originating from genetically modified organisms for assay, production, trading or use purposes must satisfy the following conditions:

a/ Having been permitted by the exporting

country for use for the same purpose in its territory;

b/ Having gone through risk assessment in the practical conditions of the exporting country;

c/ The exporting country has established an effective safety management mechanism for such products or goods originating from genetically modified organisms;

d/ Where the exporting country and Vietnam have a document on mutual recognition of products and goods originating from genetically modified organisms, the conditions on the import thereof shall comply with such document.

Article 11.- Import procedures

The import of genetically modified organisms, products or goods originating from genetically modified organisms must comply with current provisions of law on import. Besides, the following procedures must be carried out:

1. Importing organizations or individuals shall send written applications for permission for import, which are enclosed with necessary information specified in Appendix I to this Regulation (not printed herein) to the concerned managing ministries for consideration.

2. The concerned managing ministries shall examine dossiers and issue written decisions regarding safety in the import of genetically modified organisms, products or goods originating from genetically modified organisms and notify the Ministry of Natural Resources and Environment for knowledge and joint monitoring.

Article 12.- Export

The export of genetically modified organisms, products or goods originating from genetically

modified organisms to abroad must comply with legal provisions on export of Vietnam and the exporting country as well as treaties which the Socialist Republic of Vietnam has signed or acceded to.

Article 13.- Storage and transportation

1. In the course of storage or transportation, genetically modified organisms, products or goods originating from genetically modified organisms must be carefully packaged, applied with leak-preventing safety measures, and labeled in accordance with current provisions of Vietnamese law and international practices.

2. In case of domestic transportation, before commencing transportation of genetically modified organisms, products or goods originating from genetically modified organisms, their owners must send written notices thereon to the concerned managing ministries, clearly stating information printed on their labels, place of manufacture, warehouse, preservation measures, means of transport, place of departure, place of destination, measures to ensure safety in the course of transportation and the specific duration of transportation.

3. In case of transit of genetically modified organisms, products or goods originating from genetically modified organisms through the territory of Vietnam with discharge thereof at port, their owners must send documents containing necessary information, made according to a set form, to the concerned managing ministries for consideration. The General Department of Customs shall carry out relevant procedures only after having received opinions regarding biological

safety of the above-said products or goods from the concerned managing ministries.

4. In case of transit of genetically modified organisms, products or goods originating from genetically modified organisms through the territory of Vietnam without discharge thereof at port, their owners must send written notices on measures to ensure safety in the course of transit to the concerned managing ministries for consideration and decision. The General Department of Customs shall carry out relevant procedures only after having received opinions regarding this issue from the concerned managing ministries.

Chapter V

RISK ASSESSMENT, RISK MANAGEMENT AND GRANT OF BIOLOGICAL SAFETY CERTIFICATES

Article 14.- Risk assessment

1. Organizations and individuals, before releasing genetically modified organisms, products or goods originating from genetically modified organisms into the environment or producing, trading in or using them, must conduct risk assessment in order to determine the possibility of risks which may be caused by such genetically modified organisms, products or goods to human health, the environment and bio-diversity according to regulations of the ministries responsible for this issue.

2. Risk assessment must be conducted using the methods and techniques of risk assessment already recognized and based on information specified in Appendix II to this Regulation (not

printed herein) and other relevant scientific evidence.

3. Risk assessment must be conducted under the supervision of one or more specialized scientific agencies whose supervisory capabilities have been recognized by the concerned managing ministries.

4. The results of risk assessment shall be recorded in risk assessment reports made by risk-assessing organizations or individuals according to a set form.

Article 15.- Risk management

1. In scientific research, technological development, assay; production, trading and use; import, export, storage, and transportation of genetically modified organisms, products and goods originating from genetically modified organisms, risk prevention, handling and remedy measures must be taken.

2. Organizations and individuals conducting scientific research, technological development, assay of genetically modified organisms, products and goods originating from genetically modified organisms must assist concerned organizations and individuals in applying measures to prevent, handle and overcome risks in the process of assay and application of genetically modified organisms, products or goods originating from genetically modified organisms which they have created.

3. Organizations and individuals exporting, importing or using genetically modified organisms, products and goods originating from genetically modified organisms shall have to apply appropriate control measures to prevent, detect in time and handle risks so as to overcome their

consequences; when a risk occurs in their activities, they must promptly report it to the Ministry of Natural Resources and Environment and concerned managing ministries for handling.

Article 16.- Grant of biological safety certificates

1. After having undergone assay and risk assessment, if meeting all conditions on biological safety according to the provisions of Clause 2 of this Article, genetically modified organisms, products and goods originating from genetically modified organisms shall be considered, granted biological safety certificates and included by the concerned managing ministries on the lists of those permitted for production, trading and use. The managing ministries which have granted biological safety certificates for genetically modified organisms, products or goods originating from genetically modified organisms shall be entitled to withdraw such certificates.

2. Genetically modified organisms, products and goods originating from genetically modified organisms shall be recognized to have ensured biological safety if they fully meet the following conditions:

a/ Not causing any toxicity or allergy to human health;

b/ Not causing adverse impacts on the environment and biodiversity.

3. The managing ministries shall have to report to the Ministry of Natural Resources and Environment, the focal point of the Government, on the grant of biological safety certificates for genetically modified organisms, products of goods originating from genetically modified organisms

which meet all the above-said conditions.

Chapter VI

TASKS OF MANAGEMENT OF BIOLOGICAL SAFETY

Article 17.- Contents of state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms

1. Formulating and promulgating strategies, mechanisms, policies, plans and legal documents on, genetically modified organisms; products and goods originating from genetically modified organisms;

2. Building and developing a system of information and database on biological safety of genetically modified organisms; products and goods originating from genetically modified organisms;

3. Evaluating the registration of assay, release, production, trading, use, export, import, storage and transportation of genetically modified organisms; products and goods originating from genetically modified organisms; granting and withdrawing certificates and permits relating to biological safety of the above-said objects;

4. Conduct training, propaganda and education to raise the awareness of genetically modified organisms, products and goods originating from genetically modified organisms among organizations and individuals;

5. Undertaking international cooperation and implementing treaties on genetically modified

organisms; products and goods originating from genetically modified organisms;

6. Inspecting and supervising the observance and implementation of the provisions of law on biological safety of genetically modified organisms; products and goods originating from genetically modified organisms.

Article 18.- Tasks of the Ministry of Natural Resources and Environment

1. Acting as the focal point of the Government for managing biological safety of genetically modified organisms; products and goods originating from genetically modified organisms, having the task of assisting the Government in performing the unified state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms throughout the country;

2. Formulating and submitting for submission or promulgating according to its competence strategies, mechanisms, policies, plans and legal documents on genetically modified organisms; products and goods originating from genetically modified organisms;

3. Organizing and directing the coordination of activities of concerned agencies in performing the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms;

4. Coordinating with concerned ministries and branches in conducting training, propaganda and education to raise the awareness of biological safety of genetically modified organisms; products and goods originating from genetically modified

organisms among organizations and individuals;

5. Receiving from concerned managing ministries, organizations and individuals and processing information and data on genetically modified organisms; products and goods originating from genetically modified organisms; building and developing a system of information and database on biological safety of genetically modified organisms; products and goods originating from genetically modified organisms; acting as the focal point in exchanging information on this issue with the international community;

6. Supervising, inspecting and handling violations connected with genetically modified organisms; products and goods originating from genetically modified organisms.

Article 19.- Tasks of the Ministry of Science and Technology

1. Performing tasks of state management of scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

2. Formulating and submitting for submission or promulgating according to its competence mechanisms, policies and legal documents on scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

3. Providing guidance for organizations and individuals on procedures for, and specific conditions on, registration of scientific research and technological development concerning genetically

modified organisms; products and goods originating from genetically modified organisms. Evaluating, selecting, approving and directing the implementation of programs, schemes and projects on scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

4. Building and developing potentials in service of scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

5. Regularly supplying information and data relating to genetically modified organisms; products and goods originating from genetically modified organisms to the Ministry of Natural Resources and Environment, the focal point of the Government in charge of this issue.

Article 20.- Tasks of ministries managing various branches or domains

1. General tasks of managing ministries

a/ Ensuring necessary conditions for activities of specialized agencies; building and enhancing the capacity of agencies expertising and evaluating biological safety of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

b/ Implementing and directing activities of state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

c/ Formulating and promulgating according to their competence legal documents and branch standards on scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

d/ Providing for the order, procedures and conditions for assessing risks of activities related with genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

e/ Designating specialized scientific agencies to supervise the process of assessing risks of activities related to genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

f/ Evaluating the registration of assay, release, production, trading, use, export, import, storage and transportation of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

g/ Evaluating, granting and withdrawing certificates of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms; and preparing lists of genetically modified organisms, products and goods originating from genetically modified organisms permitted for production and trading within the scope of their respective management;

h/ Supervising and inspecting the observance and implementation of the provisions of law on

biological safety of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

i/ Directing the handling and remedy of risks and incidents caused to the environment and human health by activities related with genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

j/ Regularly supplying information and data relating to genetically modified organisms; products and goods originating from genetically modified organisms to the Ministry of Natural Resources and Environment, the focal point of the Government in charge of this issue.

2. Specific tasks of some ministries

a/ The Ministry of Agriculture and Rural Development shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in agriculture and forestry;

b/ The Ministry of Fisheries shall perform state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the fisheries sector;

c/ The Ministry of Health shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the health sector; biological safety and food hygiene and safety of genetically modified organisms; products and goods originating from genetically modified organisms used as pharmaceuticals, food

or cosmetics.

d/ The Ministry of Industry shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the industrial sector.

Article 21.- Tasks of People's Committees of provinces or centrally run cities

1. Performing the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in their localities;

2. Conducing information, propaganda and education activities to raise the awareness of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms among organizations and individuals in their localities;

3. Coordinating with concerned ministries, branches, organization and individuals in properly implementing activities related to genetically modified organisms; products and goods originating from genetically modified organisms in their localities;

4. Formulating plans on areas for assay, production of genetically modified organisms; products and goods originating from genetically modified organisms in their localities;

5. Inspecting and supervising and handling violations in activities related to genetically modified organisms; products and goods originating from genetically modified organisms according to their competence in their localities.

Chapter VII

HANDLING OF VIOLATIONS

Article 22.- Handling of violations

1. Organizations and individuals that commit acts of violating this Regulation's provisions on management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms shall, depending on the nature and seriousness of their violations, be disciplined or administratively sanctioned; if causing any damage, they must pay compensate therefor according to the provisions of law.

In case of committing violations resulting in serious consequences, individuals shall be examined for penal liability according to the provisions of law.

2. Those who abuse their position and powers to violate the provisions of law on management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms shall, depending on the nature and seriousness of their violations, be disciplined or examined for penal liability; if causing any damage, they must pay compensate therefor according to the provisions of law.

Article 23.- Handling of violations in import activities

1. In a contract for import of genetically modified organisms; products or goods originating from genetically modified organisms into the Vietnamese territory, the importer must request the exporter to commit to paying compensation for damage

caused by the use of his/her products or goods; commit to making technical and financial contributions to handling and remedying adverse consequences on human health, the environment and biodiversity in places where such risks have occurred.

2. Where the importer deliberately imports genetically modified organisms; products or goods originating from genetically modified organisms even though he/she has failed to reach agreement with the exporter on measures to ensure safety as provided and commitments to pay compensation for damage caused by possible incidents, he/she must compensate for damage caused to human health, the environment, biodiversity, economic or social activities by the use of such imported products or goods and bear all expenses for handling and remedying consequences from genetically modified organisms. If causing serious consequences, the importing individual shall be examined for penal liability according to the provisions of law.

Chapter VIII

IMPLEMENTATION PROVISIONS

Article 24.- Implementation provisions

In the course of implementation of this Regulation, ministries, branches and localities should report on any contents which should be amended and/or supplemented to the Ministry of Natural Resources and Environment for sum-up and reporting to the Prime Minister for consideration and decision.

For the Prime Minister
Deputy Prime Minister
PHAM GIA KHIEM