

## **Part I. LEGAL DOCUMENTS**

### **THE GOVERNMENT**

#### **Decree No. 69/2010/ND-CP of June 21, 2010, on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms**

#### **THE GOVERNMENT**

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

*Pursuant to the November 29, 2005 Law on Environmental Protection;*

*Pursuant to the November 13, 2008 Biodiversity Law;*

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

#### **DECREES:**

#### *Chapter I*

#### **GENERAL PROVISIONS**

##### **Article 1. Scope of regulation**

This Decree provides for biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms.

The biosafety management of genetically modified organisms, genetic specimens and products of genetically modified organisms used as pharmaceuticals complies with the law on pharmaceuticals.

##### **Article 2. Subjects of application**

This Decree applies to domestic and foreign organizations and individuals (below referred to as organizations and individuals) engaged in activities related to genetically modified organisms, genetic specimens and products of genetically modified organisms in the territory of the Socialist Republic of Vietnam.

##### **Article 3. Interpretation of terms**

In this Decree, the terms below are construed as follows:

1. Biosafety certificate means a document issued by a competent state agency certifying that genetically modified organisms are safe for the environment and biodiversity and permitted to be released into the environment under specific conditions.

2. Product of genetically modified organism means a product wholly or partly containing constituents originating from genetically modified organisms, including genetic specimens of genetically modified organisms which cannot themselves create new individuals under natural conditions.

3. Donor organism means an organism which supplies a needed gene to be transmitted for creating a genetically modified organism.

4. Host organism means an organism which receives a transmitted gene for creating a genetically modified organism.

5. Biosafety means managerial measures to ensure safety for the environment, biodiversity and health of humans and domestic animals.

##### **Article 4. Biosafety for genetic specimens of**

genetically modified organisms

1. Genetic specimens of genetically modified organisms which can themselves create new individuals under natural conditions shall be managed under the law on biosafety for genetically modified organisms.

2. Genetic specimens of genetically modified organisms which cannot themselves create new individuals under natural conditions shall be managed under the law on biosafety for products of genetically modified organisms.

### *Chapter II*

## RISK ASSESSMENT AND MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS

**Article 5.** Principles of assessment of risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals

1. Risk assessment of genetically modified organisms must ensure scientificity and transparency and be conducted by methods and techniques nationally or internationally recognized by competent agencies.

2. Risk assessment of genetically modified organisms shall be conducted on a case-by-case basis, depending on genetically modified organisms, their use purposes and their receiving environments.

3. Risks of genetically modified organisms shall be assessed on the basis of comparing disparities between genetically modified organisms and host organisms under the same conditions.

**Article 6.** Contents of assessment of risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals

1. Identifying potential hazards and possible risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals.

2. Identifying safety measures to prevent, handle and deal with risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals.

**Article 7.** Reporting on assessment of risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals

1. Information on the assessment of risks of genetically modified organisms shall be presented in reports on assessment of risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals.

2. Reports on assessment of risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals shall be made according to the forms provided in Appendices IV, V and VI to this Decree.

3. Reports on assessment of risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals must be appraised by competent state agencies.

4. A report on assessment of risks of genetically modified organisms to the

environment, biodiversity and health of humans and domestic animals serves as a basis for the grant of a biosafety certificate; a written certification of genetically modified organisms' eligibility for use as food; and a written certification of genetically modified organisms' eligibility for use as animal feed.

**Article 8.** Responsibility for management of risks of genetically modified organisms to the environment, biodiversity and health of humans and domestic animals

1. Organizations and individuals engaged in scientific research, technological development; assay, production, trading, import, export, transportation or storage of genetically modified organisms shall take risk management measures to ensure biosafety under law.

2. When risks occur, organizations and individuals shall promptly take measures to deal with such risks and report them to provincial-level People's Committees in localities where risks occur.

3. Organizations and individuals that fail to comply with risk management measures shall, depending on the severity of their violations, be administratively sanctioned, examined for penal liability or pay compensation under law.

4. Line ministries and provincial-level People's Committees shall direct and organize risk management and report it to the Ministry of Natural Resources and Environment when risks occur.

**Article 9.** Inspection and examination of the application of risk management measures to genetically modified organisms

1. Line ministries and provincial-level People's Committee shall periodically or extraordinarily inspect and examine the application of risk management measures to genetically modified organisms under their management and promptly handle violations under law.

2. The Ministry of Natural Resources and Environment shall conduct inter-branch or extraordinary examination and inspection of the application of risk management measures to genetically modified organisms.

### Chapter III

## SCIENTIFIC RESEARCH AND TECHNOLOGICAL DEVELOPMENT REGARDING GENETICALLY MODIFIED ORGANISMS AND PRODUCTS THEREOF

**Article 10.** Requirements on scientific research and technological development regarding genetically modified organisms and products thereof

1. Scientific research and technological development regarding genetically modified organisms and products thereof must comply with current regulations on scientific and technological management and other relevant regulations.

2. Research activities to create, analyze and test in isolation genetically modified organisms and products thereof may be carried out only in genetically modified organism laboratories accredited by the Ministry of Science and Technology under Articles 11 and 12 of this Decree.

**Article 11.** Conditions on genetically modified organism laboratories

1. A genetically modified organism laboratory must fully satisfy the following conditions:

a/ Having suitable professional staff for conducting scientific research and technological development regarding genetically modified organisms and products thereof;

b/ Having suitable equipment for scientific research and technological development regarding genetically modified organisms and products thereof;

c/ Having an operating process which satisfies biosafety requirements.

2. The Ministry of Science and Technology shall specifically guide Clause 1 of this Article.

**Article 12.** Competence, order and procedures to accredit, or revoke decisions accrediting, genetically modified organism laboratories

1. The Ministry of Science and Technology shall accredit, or revoke decisions accrediting, genetically modified organism laboratories.

2. An organization registering for the accreditation of a genetically modified organism laboratory shall submit three (3) dossier sets to the Ministry of Science and Technology. Such a dossier comprises:

a/ A written registration for accreditation of a genetically modified organism laboratory, made according to the form set by the Ministry of Science and Technology;

b/ Copies of all decisions on the organization's functions and tasks;

c/ Explanations about the laboratory's capability, made according to the form set by the Ministry of Science and Technology;

d/ Relevant documents evidencing the laboratory's satisfaction of the conditions specified in Article 11 of this Decree.

3. Within 7 working days after receiving a dossier, the Ministry of Science and Technology shall notify its acceptance of the valid dossier to the registering organization or request the organization to supplement and complete the dossier under regulations. The time for dossier supplementation and completion will not be included in the time for dossier appraisal.

4. Within 45 days after receiving a valid dossier of registration for accreditation of a genetically modified organism laboratory, the Ministry of Science and Technology shall set up a council to appraise the dossier.

The council's appraisal results serve as a basis for the Minister of Science and Technology to decide to accredit a genetically modified organism laboratory.

5. Within 30 days after obtaining appraisal results, the Minister of Science and Technology shall examine them and accredit a genetically modified organism laboratory. In case of refusal, he/she shall issue a written notice clearly stating the reason to the registering organization.

6. The Ministry of Science and Technology shall guide in detail the order and procedures for accrediting genetically modified organism laboratories and periodically examine the operation of these laboratories. In case a genetically modified organism laboratory fails to satisfy any of the conditions specified in Article

11 of this Decree, the Ministry of Science and Technology shall consider the case and revoke a decision accrediting such laboratory.

7. The Ministry of Science and Technology shall notify the Ministry of Natural Resources and Environment and relevant line ministries of the accreditation of, or revocation of decisions accrediting, genetically modified organism laboratories.

**Article 13.** Biosafety in scientific research and technological development regarding genetically modified organisms and products thereof

1. Scientific research and technological development regarding genetically modified organisms and products thereof must be conducted within the framework of approved projects under law. A project on scientific research and technological development regarding genetically modified organisms created from donor organisms and host organisms which are likely to greatly affect the environment, biodiversity or health of humans and domestic animals must be licensed by the Ministry of Science and Technology.

2. An explanatory document on a project on scientific research and technological development regarding genetically modified organisms and products thereof must contain biosafety details. In case such a project requires import of genetically modified organisms for scientific research and technological development, its explanatory document must contain the information specified in Appendix I to this Decree.

3. Genetically modified organism laboratories

must observe biosafety regulations.

The Ministry of Science and Technology shall specify contents of biosafety in genetically modified organism laboratories.

#### *Chapter IV*

### ASSAY OF GENETICALLY MODIFIED ORGANISMS

**Article 14.** Requirements on assay of genetically modified organisms

1. Genetically modified organisms used for release, including culture, growing and purposeful release into the environment, must be assayed.

2. Assay of genetically modified organisms must be conducted step by step, from restricted assay to wide-area assay. Assay zones must be far enough from conservation zones and densely populated areas as stipulated.

Restricted assay shall be conducted under isolation conditions under regulations.

Wide-area assay shall be conducted in different eco-zones for which appropriate management and supervision measures are required, but not isolation.

3. Upon detecting that genetically modified organisms cause uncontrollable risks to the environment, biodiversity or health of humans or domestic animals, licensed assaying organizations or individuals or assaying institutions shall terminate the assay of genetically modified organisms and take emergency measures to deal with the risks and concurrently destroy such genetically modified organisms.

4. The Ministry of Agriculture and Rural Development shall guide in detail Clause 2 of this Article.

**Article 15.** Contents of assay of genetically modified organisms

1. Assay of genetically modified organisms means the process of monitoring and assessing genetically modified organisms' effects on the environment and biodiversity under Vietnam's specific conditions.

2. Assay of genetically modified organisms covers the following principal contents:

- a/ Their danger of becoming weeds or pests;
- b/ Their danger of adversely affecting non-target organisms;
- c/ Their danger of causing disadvantageous changes to the surrounding eco-system;
- d/ Other unfavorable impacts.

3. The Ministry of Agriculture and Rural Development shall guide in detail Clause 2 of this Article.

**Article 16.** Conditions for accreditation of genetically modified organism-assaying institutions

1. To be accredited as a genetically modified organism-assaying institution, an organization must fully satisfy the following conditions:

- a/ Having suitable material and technical foundations and equipment for the assay of genetically modified organisms;
- b/ Having suitable professional staff for the assay of genetically modified organisms;
- c/ Having an assay process which satisfies biosafety requirements.

2. The Ministry of Agriculture and Rural Development shall guide in detail conditions for accreditation of genetically modified organism-assaying institutions specified in Clause 1 of this Article.

**Article 17.** Competence, order and procedures to accredit, and revoke decisions accrediting, genetically modified organism-assaying institutions

1. The Ministry of Agriculture and Rural Development may accredit, and revoke decisions accrediting, genetically modified organism-assaying institutions.

2. An organization registering for accreditation of a genetically modified organism-assaying institution shall submit three (3) dossier sets to the Ministry of Agriculture and Rural Development. Such a dossier comprises:

- a/ A written registration for accreditation of a genetically modified organism-assaying institution;
- b/ A copy of the decision on the organization's functions and tasks;
- c/ An explanatory document on the institution's capability, made according to the form set by the Ministry of Agriculture and Rural Development;
- d/ Relevant documents evidencing the institution's satisfaction of the conditions specified in Article 16 of this Decree.

3. Within 7 working days after receiving a dossier, the Ministry of Agriculture and Rural Development shall notify its acceptance of the valid dossier to the registering organization or request the organization to supplement and

complete the dossier under regulations. The time for dossier supplementation and completion will not be included in the time for dossier appraisal.

4. Within 45 days after receiving a valid dossier of registration for accreditation of a genetically modified organism-assaying institution, the Ministry of Agriculture and Rural Development shall set up a council to appraise dossier.

The council's appraisal results serve as a basis for the Minister of Agriculture and Rural Development to decide to accredit a genetically modified organism-assaying institution.

5. Within 30 days after obtaining appraisal results, the Minister of Agriculture and Rural Development shall examine them and accredit a genetically modified organism-assaying institution. In case of refusal, he/she shall issue a written notice clearly stating the reason to the applying organization.

6. The Ministry of Agriculture and Rural Development shall guide in detail the order and procedures for accrediting genetically modified organism-assaying institutions and periodically examine the operation of these institutions. In case a genetically modified organism-assaying institution fails to satisfy any of the conditions specified in Article 16 of this Decree, the Ministry of Agriculture and Rural Development shall consider the case and revoke the decision accrediting such institution.

7. The Ministry of Agriculture and Rural Development shall notify the Ministry of Natural Resources and Environment and relevant line ministries of the accreditation of, or revocation of decisions accrediting, genetically modified organism-assaying institutions.

**Article 18.** Competence, order and procedures for grant or revocation of assay licenses

1. The Ministry of Agriculture and Rural Development may grant or revoke licenses for assay of genetically modified organisms.

2. An applicant for a license for assay of genetically modified organisms shall submit three (3) dossier sets to the Ministry of Agriculture and Rural Development. Such a dossier comprises:

a/ An application for the license, made according to the form set by the Ministry of Agriculture and Rural Development,

b/ An explanatory document about registration of the assay of genetically modified organisms, containing the information specified in Appendix II to this Decree;

c/ A plan on the assay of genetically modified organisms, made according to Appendix III to this Decree;

d/ A copy of the decision accrediting the genetically modified organism assaying institution;

e/ For genetically modified organisms imported for assay, they must have documents evidencing that they are permitted by the exporting country for use for the same purpose in the territory of this country. For genetically modified organisms created domestically, they must have documents evidencing that they are scientific research outcomes recognized by a competent state agency;

f/ The Agriculture and Rural Development Ministry's document recognizing restricted assay results, in case of registration of wide-area assay.

3. Within 7 working days after receiving a dossier, the Ministry of Agriculture and Rural Development shall notify its acceptance of the valid dossier to the applicant or request the applicant to supplement and complete the dossier under regulations. The time for dossier supplementation and completion will not be included in the time for dossier appraisal.

4. Within 60 days after receiving a valid dossier of application for a license for assay of genetically modified organisms, the Ministry of Agriculture and Rural Development shall set up a council to appraise the dossier.

The council's appraisal results serve as a basis for the Minister of Agriculture and Rural Development to grant a license for assay of genetically modified organisms.

5. Within 30 days after obtaining appraisal results, the Minister of Agriculture and Rural Development shall examine them and grant a license for assay of genetically modified organisms. In case of refusal, the Ministry of Agriculture and Rural Development shall issue a written notice clearly stating the reason to the applicant.

6. The Ministry of Agriculture and Rural Development shall guide in detail the order and procedures for granting a license for assay of genetically modified organisms and periodically examine the compliance with the requirements indicated in this license. In case of non-compliance with any of the requirements indicated in a license, the Ministry of Agriculture and Rural Development shall consider the case and revoke the license.

7. The Ministry of Agriculture and Rural

Development shall notify the Ministry of Natural Resources and Environment and relevant line ministries of the grant or revocation of licenses for assay of genetically modified organisms.

8. Applicants for licenses for assay of genetically modified organisms shall pay a charge for appraisal of application dossiers. The Ministry of Finance shall assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development in, specifying rates, management and use of the charge for appraisal of dossiers of application for licenses for assay of genetically modified organisms.

**Article 19.** Contents of a license for assay of genetically modified organisms

1. A license for assay of genetically modified organisms contains:

a/ Names of genetically modified organisms: scientific names, common names, gene transmission events and the sole identification numbers, if any;

b/ Time, place and scale of assay;

c/ Quantity and volume of genetically modified organisms used for assay and the number of importations, for genetically modified organisms imported into Vietnam for assay;

d/ Specific requirements on compliance with the approved plan on assay of genetically modified organisms.

2. The Ministry of Agriculture and Rural Development shall provide in detail the form of license for assay of genetically modified organisms.

**Article 20.** Responsibility for assaying genetically modified organisms

1. Organizations and individuals licensed to assay genetically modified organisms shall observe the contents of their licenses and approved plans on assay of genetically modified organisms and periodically report on assays under approved assay plans to the Ministry of Agriculture and Rural Development.

2. Organizations and individuals licensed to assay genetically modified organisms shall, after completing or ceasing an assay, take measures to ensure biosafety.

3. Within 60 days after completing an assay of genetically modified organisms, organizations or individuals licensed to assay genetically modified organisms shall send reports on assay results to the Ministry of Agriculture and Rural Development for consideration and recognition.

Within 30 days after ceasing an assay of genetically modified organisms, organizations or individuals licensed to assay genetically modified organisms shall send to the Ministry of Agriculture and Rural Development reports on the assay process, clearly stating the reason for such cessation.

4. Organizations and individuals licensed to assay genetically modified organisms shall take responsibility for the contents of reports on assay results and provide assay-related data to competent state agencies upon request.

**Article 21.** Recognition of assay results

Within 60 days after receiving a report on results of an assay of genetically modified organisms, the Ministry of Agriculture and Rural

Development shall examine it and recognize assay results and notify in writing such results to the organization or individual registering for assay of genetically modified organisms and concurrently to the Ministry of Natural Resources and Environment and the provincial-level People's Committee of the locality where the assay is conducted.

#### *Chapter V*

### BIOSAFETY CERTIFICATES

**Article 22.** Conditions for grant of biosafety certificates

To be granted a biosafety certificate, genetically modified organisms must satisfy the following conditions:

1. Having been assayed under Vietnam's specific conditions. Their assay results have been recognized as satisfactory by the Ministry of Agriculture and Rural Development.

2. Having been concluded by the Biosafety Council as safe for the environment and biodiversity.

**Article 23.** Competence, order and procedures for grant or revocation of biosafety certificates

1. The Ministry of Natural Resources and Environment may grant and revoke biosafety certificates.

2. An applicant for a biosafety certificate shall submit three (3) dossier sets to the Ministry of Natural Resources and Environment. Such a dossier comprises:

a/ An application for the certificate, made according to the form set by the Ministry of

Natural Resources and Environment;

b/ A report on assay results recognized by the Ministry of Agriculture and Rural Development as satisfactory;

c/ A report on assessment of risks of genetically modified organisms to the environment and biodiversity, made according to Appendix IV to this Decree.

3. Within 7 working days after receiving a dossier, the Ministry of Natural Resources and Environment shall notify its acceptance of the valid dossier to the applicant or request the applicant to supplement and complete the dossier under regulations. The time for dossier supplementation and completion will not be included in the time for dossier appraisal.

4. Within 180 days after receiving a valid dossier of application for a biosafety certificate, the Ministry of Natural Resources and Environment shall set up a biosafety council to appraise the dossier.

5. After receiving a valid dossier, the Ministry of Natural Resources and Environment shall publish information on the report on assessment of risks of genetically modified organisms to the environment and biodiversity on the biosafety website for public comment. Public comments shall be summarized and reported to the Biosafety Council. The maximum duration for collecting public comments is 30 days after information is published.

6. Within 30 days after obtaining appraisal results, the Minister of Natural Resources and Environment shall examine them and grant a biosafety certificate. In case of refusal, it shall issue a notice clearly stating the reason to the

applicant.

7. Applicants for biosafety certificates shall pay a charge. The Ministry of Finance shall assume the prime responsibility for, and coordinate with the Ministry of Natural Resources and Environment in, specifying rates, management and use of the charge for appraisal of dossiers of application for biosafety certificates.

8. The Ministry of Natural Resources and Environment shall specify the order and procedures for grant of biosafety certificates.

9. The Biosafety Council shall advise the Minister of Natural Resources and Environment on whether to grant biosafety certificates. This Council shall be composed of representatives of the Ministries of Industry and Trade; Science and Technology; Agriculture and Rural Development; Natural Resources and Environment; and Health, and some experts.

The Minister of Natural Resources and Environment shall decide to set up, and define the functions, tasks and operation mechanism of, the Biosafety Council.

**Article 24.** Revocation of biosafety certificates

1. A biosafety certificate shall be revoked in the following cases:

a/ There is a new scientific proof of the risks of genetically modified organisms that have been granted a biosafety certificate;

b/ Organizations or individuals intentionally provide untruthful information which is decisive to the grant of the biosafety certificate;

c/ There is a proof that the Biosafety Council's conclusions lack scientific grounds.

2. The Ministry of Natural Resources and Environment shall decide to revoke biosafety certificates, issue written notices to organizations or individuals having such biosafety certificates and publish the revocation in the mass media.

3. From the date of issuance of decisions revoking biosafety certificates, organizations and individuals are disallowed to release into the environment genetically modified organisms with revoked biosafety certificates.

**Article 25.** Contents of a biosafety certificate

1. A biosafety certificate contains:

a/ Names of genetically modified organisms: scientific names, common names, gene transmission events and the sole identification numbers, if any;

b/ Detailed information on the organization or individual who is granted the certificate;

c/ Specific requirements to ensure biosafety during the use of genetically modified organisms.

2. The Ministry of Natural Resources and Environment shall set the form of biosafety certificate.

**Article 26.** List of genetically modified organisms eligible for biosafety certificates

1. The Ministry of Natural Resources and Environment shall make a list of genetically modified organisms eligible for biosafety certificates and publish this list on its biosafety website.

2. Within 10 days after granting or revoking a biosafety certificate, the Ministry of Natural Resources and Environment shall add or delete the names of genetically modified organisms to

or from such list.

*Chapter VI*

**GENETICALLY MODIFIED ORGANISMS  
ELIGIBLE FOR USE AS FOOD OR  
ANIMAL FEED**

*Section 1. GENETICALLY MODIFIED  
ORGANISMS ELIGIBLE FOR USE AS FOOD*

**Article 27.** Conditions for grant of a written certification of genetically modified organisms' eligibility for use as food

To be granted a written certification of eligibility for use as food, genetically modified organisms must satisfy either of the following conditions:

1. The dossier of application for a written certification of their eligibility for use as food has been appraised by the Genetically Modified Food Safety Council, which concludes that such genetically modified organisms have no uncontrollable risks to human health.

2. They have been permitted by at least five (5) developed countries for use as food and no risk has been seen in these countries.

**Article 28.** Competence, order and procedures for grant or revocation of a written certification of genetically modified organisms' eligibility for use as food

1. The Ministry of Health may grant and revoke a written certification of genetically modified organisms' eligibility for use as food.

2. An applicant for a written certification of genetically modified organisms' eligibility for use as food shall submit three (3) dossier sets to

the Ministry of Health. Such a dossier comprises:

a/ An application for a written certification of genetically modified organisms' eligibility for use as food, made according to the form specified by the Ministry of Health;

b/ A report on assessment of risks of genetically modified organisms to human health, made according to Appendix V to this Decree;

c/ For genetically modified organisms specified in Clause 2, Article 27 of this Decree, documents evidencing that they have been permitted for use as food in five (5) developed countries are required.

3. Within 7 working days after receiving a dossier, the Ministry of Health shall notify its acceptance of the valid dossier to the applicant or request the applicant to supplement and complete the dossier under regulations. The time for dossier supplementation and completion will not be included in the time for dossier appraisal.

4. Within 180 days after receiving a valid dossier of application for a written certification of genetically modified organisms' eligibility for use as food, the Ministry of Health shall set up a genetically modified organisms' safety council to appraise the dossier. For genetically modified organisms specified in Clause 2, Article 27 of this Decree, the maximum duration for grant of, or refusal to grant, such a written certification is 60 days.

5. After receiving a valid dossier, the Ministry of Health shall publish information on the report on assessment of risks of genetically modified organisms to human health on its website for public comment. Public comments shall be summarized and reported to the Genetically

Modified Food Safety Council. The maximum duration for collecting public comments is 30 days after information is published.

6. Within 30 days after obtaining appraisal results, the Minister of Health shall examine them and grant a written certification of genetically modified organisms' eligibility for use as food. In case of refusal, it shall issue a notice clearly stating the reason to the applicant.

7. Applicants for a written certification of genetically modified organisms' eligibility for use as food shall pay a charge for dossier appraisal. The Ministry of Finance shall assume the prime responsibility for, and coordinate with the Ministry of Health in, specifying rates, management and use of the charge for dossier appraisal.

8. The Ministry of Health shall specify the order and procedures for granting a written certification of genetically modified organisms' eligibility for use as food.

9. The Genetically Modified Food Safety Council shall advise the Minister of Health on whether to grant a written certification of genetically modified organisms' eligibility for use as food. This Council shall be composed of representatives of the Ministries of Industry and Trade; Science and Technology; Agriculture and Rural Development; Natural Resources and Environment; and Health, and some experts.

The Minister of Health shall decide to set up, and define the functions, tasks and operation mechanism of, the Genetically Modified Food Safety Council.

**Article 29.** Revocation of a written

certification of genetically modified organisms' eligibility for use as food

1. A written certification of genetically modified organisms' eligibility for use as food will be revoked in the following cases:

a/ There is a new scientific proof of the risks of genetically modified organisms that have been granted such certification;

b/ Organizations or individuals intentionally provide untruthful information which is decisive to the grant of such certification;

c/ There is a proof that the Genetically Modified Food Safety Council's conclusions lack scientific grounds.

2. The Ministry of Health shall decide to revoke a written certification of genetically modified organisms' eligibility for use as food and issue a written notice to the organization or individual having such certification and publish the revocation in the mass media.

3. From the date of issuance of decisions revoking a written certification of genetically modified organisms' eligibility for use as food, organizations or individuals are disallowed to use genetically modified organisms and products thereof as food.

**Article 30.** Contents of a written certification of genetically modified organisms' eligibility for use as food

1. A written certification of genetically modified organisms' eligibility for use as food contains:

a/ Names of genetically modified organisms: scientific names, common names, gene

transmission events and the sole identification numbers, if any;

b/ Detailed information on the organization or individual that is granted the certification;

c/ Specific requirements to ensure safety during the use of genetically modified organisms.

2. The Ministry of Health shall stipulate the form of a written certification of genetically modified organisms' eligibility for use as food.

**Article 31.** List of genetically modified organisms eligible to be granted a written certification of eligibility for use as food

1. The Ministry of Health shall make a list of genetically modified organisms eligible to be granted a written certification of eligibility for use as food and publish this list on its website.

2. Within 10 days after granting or revoking a written certification of genetically modified organisms' eligibility for use as food, the Ministry of Health shall add or delete the names of genetically modified organisms to or from such list.

*Section 2. GENETICALLY MODIFIED ORGANISMS ELIGIBLE FOR USE AS ANIMAL FEED*

**Article 32.** Conditions for grant of a written certification of genetically modified organisms' eligibility for use as animal feed

1. To be granted a written certification of eligibility for use as animal feed, genetically modified organisms must satisfy either of the following conditions:

a/ The dossiers of application for a written

certification of their eligibility for use as animal feed have been appraised by the Genetically Modified Livestock Feed Safety Council, which concludes that such genetically modified organisms have no uncontrollable risks to domestic animals.

b/ They have been permitted by at least five (5) developed countries for use as animal feed and no risk has been seen in these countries.

2. Genetically modified organisms that are granted a written certification of eligibility for use as animal feed may be used as animal feed.

**Article 33.** Competence, order and procedures for grant or revocation of a written certification of genetically modified organisms' eligibility for use as animal feed

1. The Ministry of Agriculture and Rural Development may grant and revoke a written certification of genetically modified organisms' eligibility for use as animal feed.

2. An applicant for a written certification of genetically modified organisms' eligibility for use as animal feed shall submit three (3) dossier sets to the Ministry of Agriculture and Rural Development. Such a dossier comprises:

a/ An application for such certification, made according to the form specified by the Ministry of Agriculture and Rural Development;

b/ A report on assessment of risks of genetically modified organisms to domestic animals, made according to Appendix VI to this Decree;

c/ For genetically modified organisms specified at Point b, Clause 1, Article 32 of this Decree, documents evidencing that they have

been permitted for use as animal feed in five (5) developed countries are required.

3. Within 7 working days after receiving a dossier, the Ministry of Agriculture and Rural Development shall notify its acceptance of the valid dossier to the applicant or request the applicant to supplement and complete the dossier under regulations. The time for dossier supplementation and completion will not be included in the time for dossier appraisal.

4. Within 180 days after receiving a valid dossier of application for a written certification of genetically modified organisms' eligibility for use as animal feed, the Ministry of Agriculture and Rural Development shall set up a genetically modified animal feed safety council to appraise the dossier. For genetically modified organisms specified at Point b, Clause 1, Article 32 of this Decree, the maximum duration for grant of such certification is 60 days.

5. After receiving a valid dossier, the Ministry of Agriculture and Rural Development shall publish information on the report on assessment of risks of genetically modified organisms to domestic animals on its website for public comment. Public comments shall be summarized and reported to the Genetically Modified Animal Feed Council Safety. The maximum duration for collecting public comments is 30 days after information is published.

6. Within 30 days after obtaining appraisal results, the Minister of Agriculture and Rural Development shall examine them and grant a written certification of genetically modified organisms' eligibility for use as animal feed. In case of refusal, it shall issue a notice clearly stating the reason to the applicant.

7. Applicants for a written certification of genetically modified organisms' eligibility for use as animal feed shall pay a charge for dossier appraisal. The Ministry of Finance shall assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development in, specifying rates, management and use of the charge for dossier appraisal.

8. The Ministry of Agriculture and Rural Development shall specify the order and procedures for granting a written certification of genetically modified organisms' eligibility for use as animal feed.

9. The Genetically Modified Animal Feed Safety Council shall advise the Minister of Agriculture and Rural Development whether to grant a written certification of genetically modified organisms' eligibility for use as animal feed. This Council is composed of representatives of the Ministries of Industry and Trade; Science and Technology; Agriculture and Rural Development; Natural Resources and Environment; and Health, and some experts.

The Minister of Agriculture and Rural Development shall decide to set up, and define the functions, tasks and operation mechanism of, the Genetically Modified Animal Feed Safety Council.

**Article 34.** Revocation of a written certification of genetically modified organisms' eligibility for use as animal feed

1. A written certification of genetically modified organisms' eligibility for use as animal feed will be revoked in the following cases:

a/ There is a new scientific proof of the risks of genetically modified organisms that have been

granted such certification;

b/ Organizations or individuals intentionally provide untruthful information which is decisive to the grant of such certification;

c/ There is a proof that the Genetically Modified Animal Feed Safety Council's conclusions lack scientific grounds.

2. The Ministry of Agriculture and Rural Development shall decide to revoke a written certification of genetically modified organisms' eligibility for use as animal feed and issue a written notice to organizations and individuals having such certification and publish the revocation in the mass media.

3. From the date of issuance of decisions revoking a written certification of genetically modified organisms' eligibility for use as animal feed, organizations and individuals are disallowed to use genetically modified organisms and products thereof as animal feed.

**Article 35.** Contents of a written certification of genetically modified organisms' eligibility for use as animal feed

1. A written certification of genetically modified organisms' eligibility for use as animal feed contains:

a/ Names of genetically modified organisms: scientific names, common names, gene transmission events and the sole identification numbers, if any;

b/ Detailed information on the organization or individual that is granted the certification;

c/ Specific requirements to ensure safety during the use of genetically modified organisms.

2. The Ministry of Agriculture and Rural

Development shall stipulate the form of a written certification of genetically modified organisms' eligibility for use as animal feed.

**Article 36.** List of genetically modified organisms eligible to be granted a written certification of eligibility for use as animal feed

1. The Ministry of Agriculture and Rural Development shall make a list of genetically modified organisms eligible to be granted a written certification of eligibility for use as animal feed and publish this list on its website.

2. Within 10 days after granting or revoking a written certification of genetically modified organisms' eligibility for use as animal feed, the Ministry of Agriculture and Rural Development shall add or delete the names of genetically modified organisms to or from such list.

#### *Chapter VII*

#### PRODUCTION, TRADING, IMPORT, EXPORT, TRANSPORTATION AND STORAGE OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS THEREOF

**Article 37.** Conditions for production and trading of genetically modified organisms for release

Producers and traders of genetically modified organisms for purposeful release (culture, growing or release) into the environment must satisfy the following conditions:

1. Genetically modified organisms have been granted biosafety certificates or named in the list of genetically modified organisms eligible for biosafety certificates, except the case specified in Article 24 of this Decree.

2. They observe the law on production and trading.

**Article 38.** Conditions for production and trading of genetically modified organisms and products thereof for use as food

Producers and traders of genetically modified organisms and products thereof for use as food must satisfy the following conditions:

1. Genetically modified organisms have been granted a written certification of eligibility for use as food or named in the list of genetically modified organisms eligible to be granted a written certification of eligibility for use as food; and products thereof, except the case specified in Article 29 of this Decree;

2. They observe the law on food production and trading.

**Article 39.** Conditions for production and trading of genetically modified organisms and products thereof for use as animal feed

Producers and traders of genetically modified organisms and products thereof for use as animal feed shall satisfy the following conditions:

1. Genetically modified organisms have been granted a written certification of eligibility for use as animal feed or named in the list of genetically modified organisms eligible to be granted a written certification of eligibility for use as animal feed; and products thereof, except the case specified in Article 34 of this Decree;

2. They observe the law on livestock feed production and trading.

**Article 40.** Import of genetically modified organisms and products thereof

1. Genetically modified organisms and products thereof imported into Vietnam for research purpose must be included in approved scientific research or technological development projects and such import has been approved in writing by competent authorities.

2. For genetically modified organisms imported into Vietnam for assay, licenses for assay of genetically modified organisms are required.

3. For genetically modified organisms imported into Vietnam for release, biosafety certificates are required, or they must be on the list of genetically modified organisms eligible to be granted biosafety certificates.

4. Genetically modified organisms and products thereof imported into Vietnam for use as food or animal feed or for being processed into food or animal feed must satisfy the conditions specified in Articles 38 and 39 of this Decree.

5. Import procedures for genetically modified organisms and products thereof comply with law.

**Article 41.** Export of genetically modified organisms and products thereof

Export of genetically modified organisms and products thereof must comply with Vietnamese law on goods export and treaties to which the Socialist Republic of Vietnam is a contracting party.

**Article 42.** Storage, packing and transportation of genetically modified organisms and products thereof

1. The storage, packing and transportation of

genetically modified organisms that have been granted biosafety certificates, a written certification of genetically modified organisms' eligibility for use as food or a written certification of genetically modified organisms' eligibility for use as animal feed, and products thereof must comply with law.

2. The storage, packing and transportation of genetically modified organisms and products thereof other than those specified in Clause 1 of this Article must use environmentally safe measures, not causing incidents or losses during transportation, and information thereon must be provided according to Appendix I to this Decree.

In case incidents occur, organizations and individuals that store, pack or transport genetically modified organisms and products thereof shall collect and destroy them by appropriate measures, mark the places where incidents occur and notify such incidents to the Ministry of Natural Resources and Environment, provincial-level People's Committees of localities where incidents occur and relevant line ministries for remedies.

3. For genetically modified organisms and products thereof other than those specified in Clause 1 of this Article which are transited via Vietnamese territory and must be unloaded onto ports, their owners shall send documents containing the information specified in Appendix I to this Decree to the Ministry of Natural Resources and Environment for consideration and approval. Border-gate customs offices may carry out transit procedures only after obtaining approval of the Ministry of Natural Resources and Environment.

4. The Ministry of Natural Resources and

Environment shall specify the storage, packing and transportation of genetically modified organisms and products thereof other than those specified in Clause 1 of this Article.

*Chapter VIII*

INFORMATION ON GENETICALLY  
MODIFIED ORGANISMS AND  
PRODUCTS THEREOF

**Article 43.** Labeling of goods containing genetically modified organisms or products thereof

1. Organizations and individuals that circulate on the market goods containing genetically modified organisms or products thereof exceeding 5% of each constituent shall, apart from complying with the law on goods labeling, show information related to genetically modified organisms on the goods labels.

2. Line ministries shall assume the prime responsibility for, and coordinate with the Ministry of Science and Technology in, guiding in detail the labeling of goods containing genetically modified organisms or products thereof under their management.

**Article 44.** Confidentiality of information on genetically modified organisms

1. Organizations and individuals that carry out activities related to genetically modified organisms may request line ministries to keep information in their dossiers confidential.

2. Information requested by organizations and individuals to be kept confidential must be recognized as necessary to be kept confidential under law by a council set up by a line ministry.

3. Competent state agencies shall keep information specified in Clause 1 of this Article confidential. For organizations and individuals that have been granted protection titles for genetically modified organisms, information on such genetically modified organisms shall be kept confidential under the law on intellectual property.

**Article 45.** Publicity of information on genetically modified organisms for the environment, biodiversity and health of humans and domestic animals

1. Information on genetically modified organisms other than those specified in Article 44 of this Decree shall be publicized on the biosafety website of the Natural Resources and Environment Ministry and websites of relevant line ministries.

2. Providers of information on genetically modified organisms shall take responsibility for the accuracy of such information.

**Article 46.** Management of databases on genetically modified organisms

1. The Ministry of Natural Resources and Environment shall uniformly manage databases on genetically modified organisms and maintain a website on biosafety for genetically modified organisms.

2. Line ministries that manage databases on genetically modified organisms in the domains under their management shall provide and exchange information and data on genetically modified organisms to and with the Ministry of Natural Resources and Environment.

3. Provincial-level People's Committees that manage databases on genetically modified

organisms in their localities shall provide information and data to the Ministry of Natural Resources and Environment.

4. The Ministry of Natural Resources and Environment shall guide in detail the exchange and provision of information specified in Clauses 1, 2 and 3 of this Article.

*Chapter IX*

IMPLEMENTATION PROVISIONS

**Article 47.** Implementation provisions

1. This Decree takes effect on August 10, 2010, and annuls the Prime Minister's Decision No. 212/2005/QĐ-TTg of August 26, 2005, promulgating the Regulation on biosafety management of genetically modified organisms and products and goods originating from genetically modified organisms.

2. Organizations and individuals licensed before the effective date of this Decree by competent state agencies to conduct activities of scientific research, technological development, assay or release into the environment of genetically modified organisms may continue these activities and shall register for re-licensing within one year after this Decree takes effect.

3. Line ministries shall, within the ambit of their functions and tasks, detail the implementation of this Decree.-

*On behalf of the Government*

Prime Minister

NGUYEN TAN DUNG

\* Note: All the appendices mentioned in this Decree are not printed herein.