THE GOVERNMENT	THE SOCIALIST REPUBLIC OF VIETNAM
No: 69/2010/ND-CP	**Independence – Freedom – Happiness**

DECREE
On Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms

THE GOVERNMENT

Pursuant to the Government Organization Law dated Dec 25th, 2001;

Pursuant to the Environment Protection Law 2005;

Pursuant to the Biodiversity Law 2008;

In consideration of the proposal of the Minister of the Ministry of Natural Resources and Environment,

CHAPTER I
GENERAL PROVISIONS

Article 1. Scope of application

This decree stipulates the biosafety management of the related activities on genetically modified organisms (GMOs), genetic specimen, and products originating from GMOs.

The biosafety management of GMOs, genetic specimen and products orginating from GMOs which are pharmaceutical products will following regulations on pharmaceutical.

Article 2. Subject of application

This Decree applies to all domestic and foreign organizations and individuals who engage in the activities related to GMOs, genetic specimen, and products originating from GMOs in the territory of Socialist Republic of Vietnam.

Article 3. Interpretation of terms

In this Decree the following terms are interpreted as bellows:

1. *Biosafety certificate* means a certificate that is granted by national competent authority to cetificate that specific GMOs is safety to environment and biodiversity in specific conditions.

2. *Product originating from GMOs* means a product which contain as a whole or partly composition of GMOs; including genetic specimen of GMOs which do not have abilities to regenerate a new body itself in the natural conditions.

3. *Donor organisims* means an organism that provides a needed gene for transmittion in order to create a GMOs.

4. *Host organism (parent organism)* means an organism that is used for receiving a transmitted gene in order to create a genetically modified organism.

5. Biosafety management means a measure to ensure biosafety to the environment, biodiversity and human, animal health.

Article 4. Biosafety for genetic specimens of the genetically modified organisms

1. Genetic specimens of the GMOs which have abilities to regenerate a new body shall be managed by legal regulations on biosafety of GMOs.

2. Genetic specimens of the GMOs which don't have abilities to regenerate a new body shall be managed by legal regulations on biosafety of products of GMOs.

CHAPTER II

RISK ASSESSMENT AND MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS

Article 5. Principle of risk assessment of genetically modified organisms to the environment, biodiversity and human health

1. The risk assessment of GMO shall have to be scientific, transparent and carried out according to national and international methodologies and accepted by the competent authorities.

2. The risk assessment of GMO shall be carried out on case-by-case basis subject to genetically modified organism, use purposes, and the receiving environment.

3. The risks relating to GMOs shall be assessed through the comparision between a genetically modfied organism and a host organism at the same conditions.

Article 6. Contents of risk assessment of genetically modified organisms to the environment, biodiversity and human, animal health

1. To identify the potential hazards and level of risk that may occur to the environment, biodiversity, and human, animal health

2. To propose safety mesures to prevent, treat and remedy risks to environment, biodiversity and human, animal health.

Article 7. Report on risk assessment of genetically modified organisms to the environment, biodiversity and human health

1. The information on risk assessment shall be indicated in a Report on Risk Assessment of genetically modified organisims to the environment, biodiversity and human, animal health.

2. The Report on risk assessment of GMOs to the environment, biodiversity and human health shall be prepared according to the forms provided in Appendix IV, Appendix V, and Appendix VI of this Decree.

3. The Report on risk assessmnet of GMOs to the environment, biodiversity and human health shall be appraised by the competent authorities.

4. The Report on risk assessment shall be basis for consideration to issue a biosafety certificate; and a document to verify that a genetically modified organism satisfies the requirements to be used as food, feed.

Article 8. Responsibilities for risk management of genetically modified organisms to the environment, biodiversity and human, animal health

1. Organization, individual who engages in scientific research, technological development; trial; production; import; export; storage; transportation of genetially modified organisms must apply measures of risk management to ensure biosafety as stipulated by law.

2. In case of risk occurrence, an organization/individual shall have to promptly carry out measures to reduce risks, and timely report to the Peoples' Committee of the province where the risk occurs.

3. Any organisation, individual who does comply with the risk management measures shall be subject to administrative sanctions, criminal liabilities, or damage compensation according to the law.

4. Ministries in charge of related sectors, provincial Peoples' Committees have responsibilities to direct and organize the implementation of the risk management, and to report to the Ministry of National Resources and Environment when a risk occurrs.

Article 9. Inspection, examination of the implementation of risk management of genetically modified organism.

1. Ministries in charge of related sectors, provincial Peoples' Committees periodly or unscheduledly inspect the implementation of biosafety management of genetically modified organism, genetic specimen and products originating

from GMO within their jurisdiction; timely deal with the violation in accordance with the law.

2. The Ministry of Natural Resources and Environment organize the examination, inter-ministerial inspection, unschedul inspection/examination on implementation of biosafety management of genetically modified organism, genetic specimen and products originating from GMO.

CHAPTER III

SCIENTIFIC RESEARCH AND TECHNOLOGICAL DEVELOPMENT OF GENETICALLY MODIFIED ORGANISMS

Article 10. Requirements of scientific research and technological development of genetically modified organisms; products of genetically modified organisms

1. Scientific research and technological development activities relating to GMOs, products of GMOs shall have to comply with current regulations on science and technology management and other relevant legal regulations.

2. Scientific research, technological development activities on GMOs, products of GMOs shall be only allowed in suitable laboratories on GMO that are recognised by Ministry of Science and Technology as stipulated in Article 11 and Article 12 of this Decree.

Article 11. Conditions of laboratories for research and technology development of genetically modified organisms

1. A laboratory for research on GMOs must satisfy the following conditions:

a) Have appropriate professional staff for activities of scientific research, technological development of GMOs, products of GMOs;

b) Have appropriate equipments for activities of scientific research, technology developemt of GMOs, products of GMOs;

c) Have laboratory operating procedures that satisfies requirements on biosafety.

2. The Ministry of Science and Technology shall stipulate guidance for item 1 of this article.

Article 12. Competence, order, procedure to certify, withdraw the certificate of a laboratory for science research of genetically modified organisms

1. The Ministry of Science and Technology certifies, withdraws a certificate of laboratory for science research of GMOs.

2. An organization that requests for a certification of a laboratory science research of GMOs shall have to submit three (03) sets of the application to Ministry of Science and Technology. The application includes:

a) An application for issuance of an certification of a laboratory for science research of GMOs that is made on a form issued by the Ministry of Science and Technology.

b) Copies of all decisions on the organization's functions and duties.

c) An explanation on capacity of the laboratory for science research of GMOs that is made on a form issued by the Ministry of Science and Technology.

d) Related documents to prove the laboratory for science research of GMOs satisfies conditions stipulated in Article 11 of this Decree.

3. Within 07 working days from the date of receipt of an application, the Ministry of Science and Technology shall inform the applicant the validity of such documents, requirement to complete or provide supplemental information; the time to complete or provide supplemental information shall not be counted in the time for application examination.

4. Within 45 days from the date of receipt of a valid application, the Ministry of Science and Technology shall establish a Committee to examine the application for issuance of an certificate for a laboratory of science research of GMOs.

The examination results of the Committee are basis for the Minister of Ministry of Science and Technology to grant a certificate of Laboratory for science research of GMOs.

5. Within 30 days from the date on which the examination result is available, the Minister of Ministry of Science and Technology will issue a decision to recognize the laboratory for science research of GMOs. In case of refusal to recognize the laboratory for science research of GMOs, a written document to inform and explain the refusal reasons shall have to be sent to the applicant.

6. The Ministry of Science and Technology guides in details the process, procedures for the reorganization of a laboratory for science research of GMOs; regularly inspects the operation of a laboratory for science research of GMOs. If [a laboratory] breaks any condition stipulated in Article 11 of this Decree, the Ministry of Science and Technology shall consider and withdraw the certificate of laboratory for science research of genetically modified organism.

7. Ministry of Science and Technology shall inform to the Ministry of National Resource and Environment and relevant Ministries about the

certification and withdrawal of certificate of the laboratory for science research of GMOs.

Article 13. Biosafety management of science research, technology development of genetically modified organisms, products of genetically modified organisms

1. Science research, technology development of genetically modified organism, products of GMOs must be carried out within the framework of research projects that are approved by competent agencies in accordance with legal regulations. The approval of the Ministry of Science and Technology is required for a project on science research, technology development directly engaging GMOs of donor and host organisms that may cause adverse influence to the environment, biodiversity and human health.

2. Explanation statements on project of science research, technology development that directly egaging GMOs, products of GMOs must include biosafety management contents. In case the organizations, individual need to import genetically modified organism for science research, technology development, explanation statements on project shall include information as stipulated in Appendix I of this Decree.

3. Laboratory for science research of GMOs must comply the regulations on biosafety management.

The Ministry of Science and Technology stipulates the specific contents of biosafety management in laboratory that [is used] for the purposes of science research of GMOs.

CHAPTER IV

TRIALS OF GENETICALLY MODIFIED ORGANISMS

Article 14. Requirements for trials of genetically modified organisms

1. GMOs that are being released, including cultivation, growing, and releasing into the environment must go through trials.

2. Trials of GMOs must carry out step by step, from confined trials to large scale trials; Trials locations must far away from natural conservation and densely populated areas as regulated.

Confined trials shall have to be carried out under regulated isolating conditions as regulated.

Large scale trials are carried out in different ecological areas, no require of isolation but must have appropriated managing and monitoring measures.

3. When uncontrollable risks to the environment, biodiversity and human, animal health that causes by the regulated genetically modified organism, is

confirmed; the trial conductor must terminate the trial of genetically modified organism, apply emergency measures to treat the risk, and dispose the genetically modified organism.

Article 15. Contents of trials of genetically modified organisms

1. Trials of GMOs are a process of monitoring and assessment the impacts of GMOs to the environment and biodiversity in the context of Vietnam.

2. Trials of GMOs include the following contents:

a) Risk to become weeds and diseases;

b) Risk to cause negative impacts to non-target organism;

c) Risk to cause negative change to surrounding ecosystem;

d) Other negative impacts.

3. The Ministry of Agriculture and Rural Development stipulates specific requirements and contents as stipulated in Item 2 of this Article.

Article 16. Conditions to certify a trial agency of genetically modified organisms

1. An organization that is certified as a Trial agency of GMOs shall have to satisfy the following conditions:

a) Have an appopriate technical infrastructure and equipment for the genetically modified organism trial activities;

b) Have appropriate professional staff for trial activities of genetically modified organism;

c) Have a safety operating process for trial activities.

2. The Ministry of Argiculture and Rural Development stipulates a specific regulation and detail guidance on conditions to certify a Trial agency stipulated at Item 1 of this Article.

Article 17. Competence, order, procedure to certify, withdraw the certificate of Trial agency of genetically modified organisms

1. The Ministry of Agriculture and Rural Development shall certify, withdraw the certificate of Trial agency of GMOs.

2. An organisation that applies for a recognisation as a Trial agency of GMOs shall have to submit three (03) sets of application to the Ministry of Agriculture and Rural Development. The application includes:

a) An application for issuance of a certificate of a Trial agency of GMOs;

b) Copies of decisions on the organization’s functions and duties;

c) Explanation on capacity of the Trial agency of GMOs that is made on a form issued by the Ministry of Agriculture and Rural Development;

c) Documents to prove that the organization satisfies requirements provided in Article 16 of this Decree.

3. Within 07 working days from the date of application receipt, the Ministry of Agriculture and Rural Development shall inform the applicant whether the application is valid or need to be completed, supplemented in accordance with regulations; the time to complete or supplement the application shall not be counted into the time for application examination.

4. Within 45 days since the date of receipt of a valid application, the Ministry of Agriculture and Rural Development shall establish a Committee to examine the application for issuance of a Certificate of Trial agency of GMOs.

The examination results of the Committee are a basis for the Minister of Ministry of Agriculture and Rural Development to issue a certificate of "Trial agency of GMOs".

5. Within 30 days since the day of have examination results, the Minister of Ministry of Agriculture and Rural Development shall consider to issue a Decision to certify a Trial agency of GMOs. In case of refusal to recognize a trial agency of GMOs, a written document to explain the refusal reasons shall have to be sent to the applicant.

6. The Ministry of Agriculture and Rural Development provides detailed guidance of the order, procedure to certify a Trial agency of GMOs; regularly monitors the operation of Trial agencies of GMOs. The Ministry of Agriculture and Rural Development shall consider to withdraw the certification if an agency does not satisfy operating conditions stipulated in Article 16 of this Decree.

7. Ministry of Agriculture and Rural Development shall inform the Ministry of Natural Resources and Environment and relevant ministries about the certification and withdrawal of any certificate of Trial agency of GMOs**.**

Article 18. Competence, order, procedure to grant, withdraw a Permit for a genetically modified organism trial

1. The Ministry of Agriculture and Rural Development shall grant, withdraw a Permit for a genetically modified organism trial.

2. An organisations, individuals that requests for issuance of a Permit for trials of genetically modified organism shall submit three (03) sets of application to the Ministry of Agriculture and Rural Development. The application includes:

a) An application for issuance of a Permit for a genetically modified organism trial that is made on the form issued by the of Ministry of Agriculture and Rural Development;

b) Explanation for registration of genetically modified organism trial that includes information as stipulated in Appendix II of this Decree;

c) Field trial plan as stipulated in Appendix III of this Decree;

d) Copy of the Certificate of a Trial agency of GMOs;

d) If a genetically modified organism is imported to Vietnam, it requires documents to approve that it is permitted to be used for the same purposes in the territory of exporting countries. If a GMOs is created in Vietnam, it requires documents to prove that such GMO is results of science research activities accepted by national competent authorities.

e) Document from the Ministry of Agriculture and Rural Development to accept the result of confined trials if it is an application for large scale trials.

3. Within 07 working days from the date of application receipt, the Ministry of Agriculture and Rural Development shall inform the applicant whether the application is valid or need to be completed, supplemented in accordance with regulations; the time to complete or supplement the application shall not be counted into the time for application examination .

4. Within 60 days from the date of receipt of a valid application, the Ministry of Agriculture and Rural Development shall establish a Committee to examine the application for issuance of a permit for trial of genetically modified organism;

The examination results of the Committee are a basis for the Minister of Ministry of Agriculture and Rural Development to issue a permit for trial of genetically modified organism.

5. Within 30 days from the date of receipt of examination results, the Ministry of Agriculture and Rural Development shall consider to grant a permit for trial of genetically modified organism. In case of refusing not to grant a permit, Ministry of Agriculture and Rural Development shall send a written document to the applicant to inform and explain the refusal reasons.

6. Ministry of Agriculture and Rural Development stipulates a specific process, procedure to grant a permit for trial of genetically modified organism; regularly monitors on the operating conditions of these agencies. The Ministry of Agriculture and Rural Development shall consider to withdraw a permit for trial of genetically modified organism if [the agency holding the permit] fails to

satisfy any conditions of the permit for trial of genetically modified organism offended.

7. Ministry of Agriculture and Rural Development shall inform Ministry of Natural Resources and Environment and relevant ministries about its issuance or withdraw of any permit for trial of genetically modified organism**.**

8. An organizations, individual that applies for issuance of a trial permit shall have to pay the application appraisal fee. The Ministry of Finance presides and coordinates with the Ministry of Agriculture and Rural Development to stipulate the fee levels, management, and use of fees collected from application examination for trial of genetically modified organism.

Article 19. Contents of a Permit for a trial of genetically modified organisms

1. A Permit for a trial of GMOs includes the following main information:

a. Name of GMOs: scientific name, common name, event name, unique recognition code if applicable

b. Time, trial location(s) and trial scale(s)

c. Quantity of GMOs will be used in trials and number of import times if GMOs are imported to Vietnam.

d. Detailed request on the compliance of the approved protocol for a trial of GMOs.

2. The Ministry of Agriculture and Rural Development shall provide the form of the permit of trial of GMOs.

Article 20. Responsibilities to conduct trials and reporting results of trials of genetically modified organism

1. An organization, individual who has obtained a permit for a genetically modified organism trial shall have to comply with all regulations provided in the Permit and regularly report to the Ministry of Agriculture and Rural Development on the status of trial under the approved trial plan.

2. An organization, individual that has obtained a permit for a genetically modified organism trial shall have to implement measures to ensure biosafety after trial completion or termination.

3. Within 60 days upon the completion of the trial, the organizations, individuals who have been granted a permit shall have to prepare a trial report and submit it to the Ministry of Agriculture and Rural Development.

In case of termination of the trial, after 30 days at the latest of the termination, the organizations, individuals who have been granted trial permit

shall have to report to the Ministry of Agriculture and Rural Development about the trial implementation and the reason(s) of trial termination.

4. An organizations, individual that has obtained a permit for trial of genetically modified organism shall have to take responsibilities for the contents of the report on the results of the genetically modified organism trial and shall have to provide data relating to the trial for the authorized agencies as request.

Article 21. Approval of field trial result

Within 60 days upon the date of result receipt, the Ministry of Agriculture and Rural Development shall consider evaluate and approve the result of the field trial and then inform the organization, individual who register for carrying out the trial of genetically modified organism in written; and inform the Ministry of Natural Resources and Environment, the Peoples' Committee of the province where the trial of genetically modified organism is taken.

CHAPTER V

BIOSAFETY CERTIFICATE

Article 22. Conditions for issuance of a biosafety certificate

GMO that is granted a biosafety certificate shall have to satisfy the following conditions:

1. GMOs have been passed trials in the context of Vietnam. The trial report of the GMOs has accepted by Ministry of Agriculture and Rural Development.

2. GMOs have been concluded "safety to environment and biodiversity" by Biosafety Committee.

Article 23. Competence, order, procedure for issuance and withdrawal of a Biosafety Certificate

1. The Ministry of Natural Resources and Environment grants, withdraws a Biosafety Certificate.

2. An organizations, individual that applies for a Biosafety certificate shall have to submit three (03) sets of application to the Ministry of Natural Resources and Environment. The application includes:

a) Application for issuance of a Biosafety Certificate that is made on the form issued by the Ministry of National Resources and Environment;

b) Report on field-trial result that is accepted by the Ministry of Agriculture and Rural Development as satisfaction [of required conditions];

c) Report on risk assessment to biodiversity, environment of GMOs as stipulated in Appendix IV of this Decree

3. Within 7 working upon the date of receipt of documents, the Ministry of Natural Resources and Environment shall inform the applicant whether the application is valid or need to be completed, supplemented as requested; the time to complete or supplement the application shall not be counted into the time to examine the application.

4. Within 180 days of receipt of valid, the Ministry of Natural Resources and Environment shall establish a Biosafety Committee to examine the application for granting a Biosafety Certificate.

5. Upon receipt of valid application, the Ministry of National Resources and Environment shall publish information of the risk assessment report for environment and biodiversity to its bio-safety website for public comments. The period of public comments shall be 30 days from the date of information uploading.

6. Within 30 days upon receipt of examination result, the Ministry of National Resources and Environment shall consider and grant a Biosafety Certificate. In case of refusal to grant a Biosafety certificate, organizationas, individuals register for granting Biosafety certificate shall be informed and explained the reason why it is not grant to the applicant.

7. An organizations, individual that applies for issuance of a Biosafety certificate shall have to pay the application fee for granting Biosafety certificate. The Ministry of Finance presides and coordinates with the Ministry of Natural Resources and Environment to stipulate the fee levels, management, and use of this fee.

8. The Ministry of Natural Resources and Environment shall provide specific contents of order, procedure for issuance of a Biosafety Certificate.

9. The Biosafety Committee is an organization that advises the Minister of the Ministry of Natural Resources and Environment in examining to grant a Biosafety certificate. The Biosafety Committee includes representatives from the Ministry of Industry and Trade, the Ministry of Science and Technology, the Ministry of Agriculture and Rural Development, the Ministry of Natural Resources and Environment, the Ministry of Health and experts.

Ministry of Natural Resources and Environment decides to establishment and stipulates functions, mandates and activity mechanism of Biosafety Committee.

Article 24. Withdrawal the Certificate of biosafety

1. Certificate of biosafety shall be considered to be withdrawn in the following cases:

a) Have new science based evidence of the potential risk caused by the genetically modified organism which is already issued the Certificate of biosafety.

b) Organizations, individuals intentionally provide false information that was used as basis for the decision of issuance of a Certificate of biosafety;

c) Have an evidence to prove the conclusion of Biosafety Committee for is lack of scientific base.

2. Ministry of Natural Resources and Environment shall send a written decision to withdraw the Certificate of biosafety to organizations, individuals whose Certificate is withdrawn and broadcasts [such withdrawal] on media.

3 Upon the withdrawal of the Certificate of biosafety the organizations, individuals shall not release to the environment any GMOs whose Certificate of biosafety has been withdrawn.

Article 25. Contents of a BioSafety Certificate

1. A BioSafety Certificate shall include the following major information:

a) Name of the genetically modified organism: scientific name, common name, event and unique identification, if applicable;

b) Detail information of organizations/individuals who is granted the certificate

c) Specific requirements for a safety process of using GMOs.

2. The Ministry of National Resources and Environment shall prodie the form of the BioSafety Certificate.

Article 26. List of genetically modified organisms that are granted Biosafety certificates.

1. Ministry of National Resources and Environment shall issue the List of GMOs that have been already granted Biosafety certificate and publish the List on its biosafety website.

2. Within 10 days upon the date of issuance or withdrawal of a Biosafety Certificate, the Ministry of National Resources and Environment shall add or remove the name of that genetically modified organism from the list.

CHAPTER VI

GENETICALLY MODIFIED ORGANISMS WHICH SATISFY CONDITIONS TO BE USE AS FOOD AND ANIMAL FEEDS

Section 1. GENETICALLY MODIFIED ORGANISMS WHICH SATISFY CONDITIONS TO BE USE AS FOOD

Article 27. Conditions to grant a certificate for genetically modified organisms satisfying conditions to be used as food

GMOs will be granted a certificate of satisfying conditions to be used as food shall have to satisfy the following requirements:

1. GMOs are concluded by the Committee--for food safety of GMOs (examining the application to grant a certificate for GMOs satisfying conditions to be used as food)--that it does not contain any uncontrollable risk to human health by.

2. Genetically modified organism has been allowed to be used as food in at least 5 developed countries and there is no confirmed risk in those countries.

Article 28. Competence, order, procedure for issuance of a certificate of genetically modified organisms that satisfy conditions to be used as food

1. The Ministry of Health grants, withdraws a certificate of GMOs that satisfy conditions to be used as food.

2. An Organization/individual that request for issuance of a certificate of GMOs [satisfying conditions to be used] as food shall have to submit three (03) sets of documents to the Ministry of Health. The application includes:

a) Application request for issuance of a certificate of GMOs can be used as food that is made on a form provided by the Ministry of Health;

b) Report on risk assessment of GMOs for the human health according to provisions of Appendix V of this Decree;

c) If GMOs are regulated in the Item 2, Article 27 of this Decree, the application shall have provide documents to prove that the GMOs have been used as food in (five) 5 developed countries.

3. Within 07 working days upon the receipt of application, the Ministry of Health shall inform the applicant whether the application is valid or need to be completed, supplemented in accordance with regulations; the time to complete or supplement the application shall not be counted into the time for application examination.

4. Within 180 days upon the date of receipt of a valid application, the Ministry of Health shall establish a Committee for food safety of GMOs to examine the application for issuance of a certificate of GMOs that can be used as food. If GMOs are regulated in the Item 2, Article 27 of this Decree, the maximum time to consider to issue or withdraw a Certificate of GMOs that satisfy conditions to be used as food is 60 days.

5. Upon receipt of a valid documents, the Ministry of Health shall publish information of the report on risk assessment for the human health in the website of the Ministry of Health for public comments. The period of public comments is 30 days from the date of information uploading.

6. Within 30 days upon having of examination results, the Ministry of Health shall consider to issue a Certificate of GMOs that can be used as food. In case of refusal to grant a Certificate, the Ministry of Health shall inform and explain the refusal reasons to the applicant.

7. An organization, individual that applies for issuance of a Certificate of GMOs that satisfy conditions to be used as food shall have to pay the application examination fee. The Ministry of Finance presides and coordinates with the Ministry of Health to stipulate the fee levels, management, and use of fees.

8. The Ministry of Health shall stipulate specific order, procedure to issue a Certificate of GMOs that satisfy conditions to be used as food.

9. The Committee for food safety of GMOs is an organization that advises the Minister of the Ministry of Health in considering to issue a Certificate of GMOs that satisfy conditions to be used as food. The Committee for food safety of GMOs includes representative from the Ministry of Industry and Trade, the Ministry of Science and Technology, the Ministry of Agriculture and Rural Development, the Ministry of Natural Resources and Environment, the Ministry of Health and experts.

The Minister of the Ministry of Health shall decide to establish and stipulate functions, duties and operation regime of the Committee for food safety of GMOs.

Article 29. Withdrawal of certificate of GMOs that satisfy conditions to be used as food

1. Certificate of GMOs that satisfy conditions to be used as food shall be considered to be withdrawn in the following cases:

a) Have new science based evidence of the potential risk caused by the genetically modified organism which is already issued the Certificate of GMOs that satisfy conditions to be used as food.

b) Organizations, individuals intentionally provide false information that was used as basis for the decision of issuance of a Certificate of GMOs that satisfy conditions to be used as food;

c) Have an evidence to prove the conclusion of the Committee for food safety of GMOs is lack of scientific base.

2. The Ministry of Health shall send a written decision to withdraw the Certificate of GMOs that satisfy conditions to be used as food to organizations,

individuals whose Certificate is withdrawn and broadcasts [such withdrawal] on media.

3 Upon the withdrawal of the Certificate of GMOs that satisfy conditions to be used as food, organizations/individuals shall not to use such GMOs, products of GMOs as food.

Article 30. Contents of the certificate for GMOs that satisfy conditions to be used as food

1. The certificate for GMOs that satisfy conditions to be used as food contains the major information as following:

a) Name of the genetically modified organism: scientific name, common name, event, and unique detection code, if applicable

b) Detail information of organizations/individuals who is granted the certificate

c) Specific requirements for a safety process of using GMOs.

2. The Ministry of Health provides the specific contents of a certificate of GMOs that satisfy conditions to be used as food.

Article 31. List of GMOs that satisfy conditions to be used as food

1. The Ministry of Health shall issue the List of GMOs that have been already granted certificates for to be used as food and publish the list on its website on biosafety.

2. Within 10 days upon the date of issuance or withdrawal of a certificate for GMOs that satisfy conditions to be used as food, the Ministry of Health shall add or remove the name of that genetically modified organism from the list.

Section 2. GENETICALLY MODIFIED ORGANISMS WHICH SATISFY CONDITIONS TO BE USE AS ANIMAL FEED

Article 32. Conditions to grant a certificate for genetically modified organisms satisfying conditions to be used as animal feed

GMOs will be granted a certificate of satisfying conditions to be used as animal feed shall have to satisfy one of the following conditions:

1. GMOs are concluded by the Committee--for food safety of GMOs (examining the application to grant a certificate for GMOs satisfying conditions to be used as animal feed) that it doesn’t contain any uncontrollable risk to animal.

2. Genetically modified organism has been allowed to use as animal feed in at least 5 developed countries and there is no confirmed risk in those countries.

Article 33. Competence, order, procedure for granting a certificate of genetically modified organisms that fulfill conditions to be used as animal feed

1. The Ministry of Agriculture and Rural Development grants, withdraws a certificate of GMOs that satisfy conditions to be used as animal feed.

2. An organization/individual that request for issuance of a certificate of GMOs that satisfy conditions to be used as animal feed shall have to submit three (03) sets of documents to the Ministry of Agriculture and Rural Development. The application includes:

a) Application request for issuance of a certificate of GMOs that satisfy conditions to be used as animal feed that is made in the form provided by the Ministry of Agriculture and Rural Development;

b) Risk assessment report of GMOs for the animal which regulated in Appendix VI of this Decree;

c) GMOs regulated in the Point b, Item 1, Article 32 of this Decree must provide documents to prove GMOs has been used as animal feed in 5 developed countries.

3. Within 07 working days upon receipt of application, the Ministry of Agriculture and Rural Development shall inform the applicant whether the application is valid or need to be completed, supplemented in accordance with regulations; the time to complete or supplement the application shall not be counted into the time for application examination.

4. Within 180 days upon the date of receipt of a valid application, the Ministry of Agriculture and Rural Development shall establish a Committee for animal feed safety of GMOs to examine the application for granting a certificate of GMOs that satisfy conditions to be used as animal feed. GMOs regulated in the Point b, Item 1, Article 32 of this Decree, the maximum time to consider to issue or withdraw a Certificate of GMOs that satisfy conditions to be used as animal feed is 60 days.

5. Upon receipt of valid documents, the Ministry of Agriculture and Rural Development shall publish information of the risk assessment report for animal on its website for public comments. The period of public comments is 30 days from the date of information uploading.

6. Within 30 days upon having the examination results, the Ministry of Agriculture and Rural Development shall consider issue a Certificate of GMOs that satisfy conditions to be used as animal feed. In case of refusal to grant a Certificate of GMOs that satisfy conditions to be used as animal feed, the Ministry of Agriculture and Rural Development shall inform and explain the refusal reasons to the applicant.

7. An organization, individual that applies for issuance of a Certificate of GMOs that satisfy conditions to be used as animal feed shall have to pay the application appraisal fee. The Ministry of Finance presides and coordinates with the Ministry of Agriculture and Rural Development to stipulate the fee levels, management, and use of fees.

8. Ministry of Agriculture and Rural Development shall stipulate specific order, procedure to issue a Certificate of GMOs that satisfy conditions to be used as animal feed.

9. The Committee for animal feed safety of GMOs is an organization that advises the Minister of the Ministry of Agriculture and Rural Development in examining to issue a Certificate of GMOs that satisfy conditions to be used as animal feed. Committee for animal feed safety of GMOs shall include representative from the Ministry of Industry and Trade, the Ministry of Science and Technology, the Ministry of Agriculture and Rural Development, the Ministry of Natural Resources and Environment, the Ministry of Health and experts.

The Minister of the Ministry of Agriculture and Rural Development shall decide to establish and stipulate functions, duties and operation regimes of the Committee for animal feed safety of GMOs.

Article 34. Withdrawal the certificate of GMOs which satisfy conditions to be used as animal feed

1. Certificate of GMOs which fulfill the conditions to be used as animal feed shall be considered to be withdrawn in the following cases:

a) Have new science based evidence of the potential risk by the genetically modified organism which is already issued the Certificate of GMOs which fulfill the conditions to be used as animal feed.

b) Organizations, individuals intentionally provide false information that was used as basis for the decision of issuance of a Certificate of GMOs which fulfills the conditions to be used as animal feed;

c) Have an evidence to prove the conclusion of Committee for animal feed safety of GMOs is lack of scientific base.

2. Ministry of Agriculture and Rural Development shall send a written decision to withdraw the Certificate of GMOs that satisfy conditions to be used as food to organizations, individuals whose Certificate is withdrawn and broadcasts [such withdrawal] on media.

3 Upon the withdrawal of the Certificate of GMOs that satisfy the conditions to be used as animal feed, organizations, individuals shall not to use the GMOs, products of GMOs as animal feed.

Article 35. Contents of the certificate for GMOs that satisfy the conditions to be used as animal feed

1. The certificate for GMOs that satisfy conditions to be used as aniaml feed contains the major information as following:

a) Name of the genetically modified organism: scientific name, common name, event, and unique detection code, if applicable

b) Detail information of organizations/individuals who is granted the certificate;

c) Specific requirements for a safety process of using GMOs.

2. The Ministry of Agriculture and Rural Development shall stipulate the form of the Certificate for GMOs satisfying conditions to be used as aniaml feed.

Article 36. List of GMOs which fulfill the conditions to be used as animal feed

1. The Ministry of Agriculture and Rural Development shall issue the List of GMOs that have been already granted certificates for using as animal feed and publish the list on its website.

2. Within 10 days upon the date of issuance or withdrawal of a certificate for GMOs that satisfy conditions to be used as animal feed, the Ministry of Agriculture and Rural Development shall add or remove the name of that genetically modified organism from the list.

CHAPTER VII

PRODUCTION, TRADING, IMPORT, EXPORT, TRANSPORT AND STORAGE OF GENETICALLY MODIFIED OGRANISMS, PRODUCTS OF GENETICALLY MODIFIED ORGANISMS

Article 37. Conditions of production and trading genetically modified organisms for the purpose of releasing into environment

An organization, individual that produces, trades GMOs for releasing purpose, including growing, cultivation, and release of GMOs into the environment shall have to satisfy following conditions:

1. Genetically modified organism has been already issued BioSafety Certificate or named in the List of GMOs that have already been granted Biosafety Certificate, except the case stipulated in Article 24 of this Decree.

2. Comply with all current regulations on production and trading.

Article 38. Conditions to produce and trade genetically modified organisms, GMO products for the purpose of using as food

An organization, individual that produces, trades GMOs, products of GMOs for the purpose of using as food shall have to satisfy the following conditions:

1. Genetically modified organism which is already issued Certificate of fulfill conditions for use as food, or in the list of GMOs that already granted a certificate for using as food; products of genetically modified organism which is already issued Certificate of fulfill conditions for use as food, or in the list of GMOs that already granted a certificate for using as food, except the case stipulated in Article 29 of this Decree.

2. Comply with all current regulations on Food trading and production

Article 39. Conditions to produce and trade genetically modified organisms for the purpose of using as animal feed

An organizations, individual that produces, trades GMOs, products of GMOs for the purpose of using as animal feed need to meet following conditions:

1. Genetically modified organism which is already issued Certificate of fulfill conditions for use as aniaml feed, or in the list of GMOs that already granted a certificate for using as animal feed; products of genetically modified organism which is already issued Certificate of fulfill conditions for use as animal feed, or in the list of GMOs that already granted a certificate for using as animal feed, except the case stipulated in Article 34 of this Decree.

2. Comply with all current regulations on Animal feed trading and production

Article 40. Import genetically modified organisms, products of genetically modified organisms.

1. GMOs, products of GMOs that are imported into Vietnam for research purpose shall have to belong a research project, technology development which has been approved (via a written permit) and allowed to be imported by the competent authority.

2. GMOs that are imported into Vietnam for trial conduction shall have to be granted a Trial permit of GMOs.

3. GMOs that are imported into Vietnam for releasing into environment shall have to be granted a Biosafety certificate or in the list of GMOs that already granted a Biosafety certificate.

4. GMOs that are imported into Vietnam for using as food, animal feed, or processing to food, animal feed shall have to satisfy conditions stipulated in Article 38 and 39 of this Decree.

5. Process of importing GMOs, products of GMOs shall have to comply with all current regulations.

Article 41. Export genetically modified organisms, products of genetically modified organisms

Exporting GMOs, products of GMOs shall comply with all exporting regulations of Vietnam, regulations of import country as well as International Treaties to which the Socialist Republic of Vietnam is a member.

Article 42. Storage, packaging, and transportation of genetically modified organisms that haven't been granted a Safety Certificate

1. Storage, transportation of GMOs which is granted Biosafety Certificate, Certificate of GMOs satisfying conditions to be used as food, Certificate of GMOs which fulfills the conditions to be used as animal feed, and products of that GMOs shall comply with all current regulations.

2. Storage, packaging, and transportation of GMO which doesn't meet conditions as in Item 1 of this Article shall have to apply measures to ensure environmental safety and no incident release during transportation and must provide information requested in Appendix 1 of this Decree.

In case incident occurrence, organization, individual who is in charge of storage, packaging, and transportation shall be responsible for gathering and destroying by appropriated measures; mark the location where incident occurred and inform the Ministry of Natural Resource and Environment, Peoples' Committee of the province where the incident occurred, and the relevant ministries to ding out remedies.

3. If the GMOs and products of GMOs are transited through Vietnam territory, but requires loading/unloading at the port, the owner of goods must submit documents with necessary information as required in Appendix I of this Decree to the Ministry of Natural Resources and Environment for its consideration and approval. The General Department of Customs shall only allow the transit upon receipt of the approval from the Ministry of Natural Resources and Environment.

4. The Ministry of Natural Resources and Environment shall provide detail regulation on packaging, transportation of GMOs and products of GMOs which do not satisfy conditions listed in Item 1 of this Article.

CHAPTER VIII

INFORMATION ABOUT GENETICALLY MODIFIED ORGANISMS; PRODUCTS OF GENETICALLY MODIFIED ORGANISMS

Article 43. Labeling for goods that contain genetically modified organisms and products derived from genetically modified organisms

1. An organization, individual having goods containing genetically modified organism, products of GMOs at the rate of more than 5% of each composition shall provide information related to GMOs on the label, and comply with [general] labeling regulations

2. Ministries that manage the related fields shall coordinate with the Ministry of Science and Technology to provide detail regulations for goods contain GMOs, products of GMOs that under their management authority.

Article 44. Confidential information of genetically modified organisms

1. Organizations/individuals carry out activities relating to GMOs reserve the right to request the related ministries to protect confidential information in the dossiers.

2. Information requested to be protected by an organization/individual must be recognized by a Committee (established by related ministries) as the confidential information that need to be protected according to legal regulations.

3. Authorized agencies shall be responsible for protecting information as stipulated in Item 1 of this Article. In the cases that have been protected through patents or intellectual property rights, the confidential shall be carried out in accordance with regulations on intellectual properties.

Article 45. Publication of information about genetically modified organisms to environment, biodiversity, human health, and animals

1. The information relating to GMOs not regulated in item 2, Article 44 of this Decree are provided on the biosafety website of the Ministry of Natural Resources and Environment, and websites of relevant ministries.

2. Organizations/individuals provide information about GMOs shall be responsible for such provided information.

Article 46. Management of GMOs and products of GMOs' database

1. The Ministry of National Resources and Environment shall be focal point on management of GMOs database, and maintain the website of biosafety management for GMOs biosafety database.

2. Ministries manage database on the biosafety of GMOs in line with the responsibilities of their management functions and responsible for exchange information on GMOs with the Ministry of National Resources and Environment.

3. A provincial Peoples' Committees shall manage GMOs database in its territory and responsible for exchange information with the Ministry of National Resources and Environment.

4. The Ministry of Natural Resources and Environment provides detail guidance on information management and exchanging as stipulated in Items 1, 2, and 3 of this Article.

CHAPTER VIII

IMPLEMENTATION PROVISION

Article 47. Implementation provision

1. This Decree shall come into effect from 10 August 2010 and revoke Decision No. 212/2005/QD-TTg dated on 26 August 2005 of the Prime Minister promulgating the regulations on management of biosafety of GMOs; products and goods originated from GMOs.

2. Organizations/individuals that are allowed by competent authorities to carry out science research, technology development, trials, release into environment, use as food and feed of GMOs prior the effectiveness date of this Decree can continue their activities and shall have to register for re-issuance of a permit within (01) year from the effectiveness date of this Decree.

2. The relevant ministries within their functions and duties shall provide detail guidance for the implementation of this Decree./.

FOR THE GOVERNMENT
THE PRIME MINISTER

(Signed)

Nguyen Tan Dzung

APPENDIX I

REQUIRED INFORMATION IN TRANSPORTATION, TRANSIT AND IMPORTATION OF GENETICALLY MODIFIED ORGANISM

(Attachment of the Decree No. 69/2010/ND-CP dated 21st June 2010)

1. Name, contact detail of organization, individual who own transported, transited or imported goods.

2. Name, contact detail of the importing organization, individual.

3. Name of genetically modified organism, including: common name, scientific name, event and unique identification, if any.

4. Intended date of transportation, transit of importation.

5. Common name, scientific name and characteristics of recipient organism.

6. Center of origin, center of genetic diversity of recipient organism or and description of the habitats where the organisms may persist or proliferate.

7. Taxonomic status, common name and characteristics of donor organism.

8. Intended use of GMOs or product thereof.

9. Quantity or volume of GMOs that are transported, transited or imported;

10. Suggested methods for the safe handling, storage, transportation and emergency response in transportation, transit or importation.

11. Regulatory status of the genetically modified organism within exporting country (for example, whether it is prohibited in the exporting country, whether there are other restriction, or whether it has been approved for environmental release); if the genetically modified organism is banned in exporting country, the reason/reasons for the ban.

.....date.....month.....year.....

Acknowledged by organization, individual who own transported, transited or imported goods

(Signature)

APPENDIX 2

APPLICATION FOR FIELD TRIAL OF GENETICALLY MODIFIED ORGANISMS

(Attachment of the Decree No. 69/2010/ND-CP dated 21st June 2010)

I. General information

1. Name, address and contact detail of the field-trial applicant, the head of the field-trial applicant and contact point.

2. Name, address and contact detail of the trial agency, the head of the agency and contact point.

3. Genetically modified organism: common name, scientific name, event and unique identification, if any.

4. Intended type of trial (confined, large scale).

5. Expected location or locations of the field-trial.

6. Expected duration of field-trial: starting and completing date of field-trial.

II. Information about recipient organism

1. Name of the recipient organism: common name, scientific name.

2. Information about pathogenicity of the recipient organism to human, animal and plant.

3. Center of origin, center of genetic diversity of recipient organism or and description of the natural habitats, distribution and relative species in Vietnam.

4. Descriptions of recipient organism's biological characteristics and its interaction with environment and biodiversity in Vietnam.

5. History of use of recipient organism.

III. Information about donor organism

1. Name of donor organism: common name, scientific name.

2. Biological characteristics of donor organism and characteristics of inserted gene.

IV. Information about genetic modification

1. Method of modification

2. Description of vector, if used: characteristics of vector including identification characteristics, origin and host range of vector.

3. Size, sequence and function of inserted gene or/and genes.

4. Method to detect the inserted gene or/and genes, genetic specificity.

V. Information about genetically modified organism

1. Traits and identification of genetically modified organism.

2. Expression of inserted gene or genes.

3. Information about difference between genetically modified organism and recipient organism.

4. Detection method of genetically modified organism.

5. Information about history of approval and use of genetically modified organism,

6. Description of hazard and likelihood that hazard becomes risk when GMO is released into environment. Identify hazard should be tested in field-trial in Vietnamese condition.

VI. Brief about conducting field trial

1. Map of field trial location, reason for selecting location, area of field trial, number of field trial.

2. Content and method of field trial: criteria in testing, experimental design, method of experiment.

3. Number/volume of GMO used in field-trial.

VII. Information about potential risks of GMO to environment and biodiversity at field-trial location.

1. Capacity of dispersion, persistence of GMO outside field-trial area and mechanism of dispersion.

2. Possibility of gen-flow and its impact on environment and biodiversity at field trial location.

3. Description of environment surrounding field-trial location: inhabitants, farming area, biodiversity characteristics and species which may be impacted by field-trial activities.

4. Description other impacts of GMO to environment.

VII. Information about risk of GMO to human health

1. Information about toxicant or allergen which is absent only in GMO not in recipient organism.

2. Information that GMO could cause ill to human, animal or plant.

3. Hazard of GMO to workers at field-trials and inhabitants near by field-trial location.

IX. Information about risk management

Description of risk management, including:

- Supervisor: name, contact detail.
- Measure to manage and monitor the loss of GMO or genetic material of GMO from field-trial location and transportation.
- Safety measure to protect workers in field-trial location.
- Measure to manage risk and incident in field-trial.
- Method of disposal of GMO and their product at the end of field trial.

Attachment to the application

List of personnel involving in field-trial (provide detail information, including: name, qualification, experience in this area, specific tasks in the project and other relevant responsibility).

APPENDIX III

PLAN FOR FIELD-TRIAL OF GENETICALLY MODIFIED ORGANISM

(Attachment of the Decree No. 69/2010/ND-CP dated 21st June 2010)

I. General information

1. Genetically modified organism: common name, scientific name, event and unique identification, if any.

2. Name, address and contact detail of the field-trial applicant, the head of the field-trial applicant and contact point.

3. Name, address and contact detail of the trial agency, the head of the agency and contact point.

4. Intended type of trial (confined, large scale).

II. Plan for field-trial

1. Duration of field-trial

2. Location and extent of field-trial, reason for selecting the location, area of field-trial, number of field-trial, number or volume of GMO.

3. Content of field trial: criteria need to test, method of field-trial, experimental design and process of monitoring, evaluation.

4. Expected outcomes in each stage of field-trial and at the end of field trial.

III. Risk management in field-trial

Description of risk management, including:

- Supervisor: name, contact detail.
- Measure to manage and monitor the loss of GMO or genetic material of GMO from field-trial location and transportation.
- Safety measure to protect workers in field-trial location.
- Measure to manage risk and incident in field-trial.
- Method of disposal of GMO and their product at the end of field trial.

APPENDIX IV

REQUIRED INFORMATION IN MAKING REPORT ON RISK ASSESMENT OF GENETICALLY MODIFIED ORGANISM TO ENVIRONMENT AND BIODIVERSITY

(Attachment of the Decree No. 69/2010/ND-CP dated 21st June 2010)

I. General information

1. Name, address and contact detail of applicant, the head of the applicant and contact point.

2. Genetically modified organism: common name, scientific name, event and unique identification, if any.

II. Information about recipient organism

1. Name of the recipient organism: common name, scientific name.

2. Information about pathogenicity of the recipient organism to human, animal and plant.

3. Description of the natural habitats, distribution and relative species in Vietnam.

4. Descriptions of recipient organism's biological characteristics and its interaction with environment and biodiversity in Vietnam.

5. History of use of recipient organism.

IV. Information about genetic modification

1. Method of modification

2. Description of vector, if used: characteristics of vector including identification characteristics, origin and host range of vector.

3. Size, sequence and function of inserted gene or/and genes.

4. Method to detect the inserted gene or/and genes, genetic specificity.

V. Information about genetically modified organism

1. Traits and identification of genetically modified organism.

2. Expression of inserted gene or genes.

3. Information about difference between genetically modified organism and recipient organism.

4. Method or technique of detecting genetically modified organism.

5. Information about history of approval and use of genetically modified organism,

6. Description of hazard and likelihood that hazard becomes risk when GMO is released into environment.

V. Evaluation of risk caused by GMO to environment and biodiversity

1. Evaluation of risks caused by GMO to non-target organism; occurrence of new species or changes of chain in food web.

2. Evaluation of likelihood of gene-flow from GMO to other organisms and possible consequent.

3. Evaluation of risk of spread or invasive of GMO could have impact on environment and biodiversity in Vietnam.

4. Evaluation of other risk could have impact on environment and ecosystems in Vietnam.

5. Evaluation of environment conditions that could enhance or restrict adverse impact of GMO.

VII. Information about risk of GMO to human health

1. Information about difference between GMO and recipient that could harm human health.

2. Recognized risks of GMO to human health.

VII. Propose measures for managing risk caused by GMO to environment and biodiversity.

VIII. Conclusion and recommendation.

APPENDIX V

REQUIRED INFORMATION IN MAKING REPORT ON RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISM TO HUMAN HEALTH

(Attachment of the Decree No. 69/2010/ND-CP dated 21st June 2010)

I. General information

1. Name, address and contact detail of applicant and contact point.

2. Genetically modified organism: common name, scientific name, transformation event and unique identification, if any.

II. Information about recipient organism

1. Name of the recipient organism: common name, scientific name.

2. Information about adverse impact on human health, including: toxicant, allergen and other adverse impact

3. History of use of recipient organism as food.

V. Information about genetically modified organism

1. Detail about inserted gene or genes: sequence, origin.

2. Detail about genetic transformation, including: method of transformation, inserted site and number of copies inserted.

3. Detail about genetic stabilization of GMO.

4. Description of change in phenotype between GMO and recipient organism.

4. Method of detecting genetically modified organism.

5. Information about history of approval and use of genetically modified organism.

IV. Evaluation of risks caused by GMO to human health

1. Comparison of nutritional composition between GMO and recipient organism.

2. Possibility that GMO causes toxic or allergenic to human.

3. Possibility that GMO causes ill-health and other adverse impact on human.

4. Other risks if use GMO as food.

V. Propose measures for managing risk caused by GMO to human health.

VI. Conclusion and recommendation.

APPENDIX V

REQUIRED INFORMATION IN MAKING REPORT ON RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISM TO LIVESTOCK

(Attachment of the Decree No. 69/2010/ND-CP dated 21st June 2010)

I. General information

1. Name, address and contact detail of applicant and contact point.

2. Genetically modified organism: common name, scientific name, transformation event and unique identification, if any.

II. Information about recipient organism

1. Name of the recipient organism: common name, scientific name.

2. Information about adverse impact on human and livestock health.

3. History of use of recipient organism as food, feed.

V. Information about genetically modified organism

1. Detail about inserted gene or genes: sequence, origin.

2. Detail about genetic transformation, including: method of transformation, inserted site and number of copies inserted.

3. Detail about genetic stabilization of GMO.

4. Description of change in phenotype between GMO and recipient organism.

4. Method of detecting genetically modified organism.

5. Information about history of approval or use of genetically modified organism.

IV. Evaluation of risks caused by GMO to livestock health

1. Comparison of nutritional composition between GMO and recipient organism.

2. Evaluation of metabolism of nutritional compositions from GMO in livestock.

3. Other adverse impact on livestock.

V. Information of risk caused by GMO to human health if unintentional used as food

1. Possibility that GMO causes toxic or allergenic to human.

2. Possibility that GMO causes ill-health and other adverse impact on human.

VI. Propose measures for managing risk caused by GMO to human health and livestock.

VII. Conclusion and recommendation.