

Hanoi, May 16, 2013

CIRCULAR

**Stipulating the order, procedures on granting and revoking
Biosafety Certificate for genetically modified crops**

Pursuant to Decree 69/2010/ND-CP dated June 21, 2010 of the Government on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms;

Pursuant to Decree No. 21/2013/ND-CP dated March 4, 2013 of the Government defining the functions, tasks, authorities and organizational structure of the Ministry of Natural Resources and Environment;

At the proposal of the Director General of Vietnam Environment Administration and the Legal Department,

Minister of Natural Resources and Environment shall specify the order and procedures for granting and revoking Biosafety Certificate for genetically modified crops.

CHAPTER I
GENERAL PROVISIONS

Article 1. Scope of application

This Circular prescribes the order and procedures for granting and revoking Biosafety Certificate of genetically modified crops (hereinafter referred to as the Biosafety Certificate).

GMCs which are created by breeding two or more transformation events which have been granted Biosafety Certificate shall not be covered by this Circular.

Article 2. Subjects of application

This Circular shall apply to domestic organizations, individuals, foreign organizations or individuals (hereinafter referred to as organizations and individuals) engaged in activities related to granting and revoking Biosafety Certificate in Vietnam territory.

Article 3. The group of GMCs to be considered eligible for granting biosafety certificate

1. Single transformation event is created as a result of transferring one or more genes encoding a desired trait by transgenic technology.

2. Stacked transformation events is created as a result of one of the two following processes:

a) Simultaneously transferring genes encoding desired traits into traditional crops by using transgenic technology;

b) Transferring genes or gene encoding a desired trait into a genetically modified crop.

Chapter II

GRANT AND REVOCATION OF BIOSAFETY CERTIFICATION

Article 4. The order and procedures for granting and withdrawing Biosafety Certificate

1. The registration for Biosafety Certificate shall comply with the provisions of Article 5 of this Circular.

2. The receipt and evaluation of dossier and granting Biosafety Certificate shall comply with the provisions of Articles 6, 7 and 8 of this Circular.

3. Revocation of Biosafety Certificate shall comply with the provisions of Article 9 of this Circular.

Article 5. Registration for Biosafety Certificate

1. Dossier for Biosafety Certificate shall include:

a) One (01) application for Biosafety Certificate in the prescribed form in Appendix 1 of this Circular;

b) Ten (10) copies of report on fieldtrial results approved by the Ministry of Agriculture and Rural Development (in which, one (01) original and nine (09) copies) accompanied by 01 copy of official document on fieldtrial results issued by the Ministry of Agriculture and Rural Development;

c) Ten (10) copies of environmental and biological-diversity risk assessment report of genetically modified crops (hereinafter referred to as the Risk Assessment Report) in accompanied by electronic file in the prescribed form in Appendix 2 of this Circular;

d) One (01) electronic file containing information on the environmental and biodiversity risk assessment report of genetically modified crops in the prescribed form in Appendix 3 of this Circular.

2. Registered organizations and individuals shall be responsible for:

a) Paying appraisal fee by no later than five (05) days after receiving written acknowledgement of dossier validation by the dossier-receiving agency;

b) Provide additional information on request in writing by the dossier-receiving agency.

Article 6. Receiving dossier

1. The dossier-receiving agency is Vietnam Environment Agency (VEA). VEA shall assign subsidiary body as a Standing Appraisal Agency to assist in handling and appraising the dossier of granting and revoking Biosafety Certificate. Responsibilities of Standing Appraisal Agency is provided for in Article 16 of this Circular.

2. Within seven (07) working days from the date of receipt of dossier, the dossier-receiving agency shall send written notification to the registered organizations and individuals to acknowledge the validation of the dossier or to request additional requirements. The period for providing additional requirements shall not be included in the appraisal time.

Article 7. Registration dossier evaluation Biosafety Certificate

1. Within five (05) working days from the date of receipt of valid dossier, the dossier-receiving agency shall publish information of the report on risk assessment of genetically modified crops to environment and biodiversity as defined in Clause 1, Article 5 of this Circular on the Vietnam Biosafety Clearing House website <http://www.antoansinhoc.vn> for public's comments. The period of public's comments shall be 30 days from the date of information uploading. Within five (05) working days after the expiration of the public comment, the dossier-receiving agency shall summarize the public's comments.

2. Within ten (10) working days from the date of receiving valid application, the VEA is responsible for:

a) Establishing the Technical Advisory Team (TAT). Responsibilities and operations of the Technical Advisory Team shall be provided for in Article 20 of this Circular;

b) Submit to the Minister of the MONRE to establish the Biosafety Committee. Composition and structure of the Biosafety Committee shall be provided for in Article 10 of this Circular.

3. Within ninety (90) days from the date of establishment of Biosafety Committee, the Standing Appraisal Agency is responsible for facilitating Technical Advisory Team to review and evaluate dossier; summarizing and submitting the results to the Biosafety Committee.

If necessary, the Standing Appraisal Agency shall report to VEA on requesting, in written, the registered organizations and individuals to submit additional information on environmental risk assessment of the GMC. The period for providing additional information shall not be included in the appraisal time.

4. Within seventy (70) days after receiving the results of the Technical Advisory Team provided for in paragraph 3 of this Article, the VEA shall organize meetings of the Biosafety Committee to evaluate the dossiers.

Article 8. Granting Biosafety Certificate

1. Within thirty (30) days from the date of receiving the Committee's evaluation result, the Minister of MONRE shall consider and decide to grant Biosafety Certificate for GM crop, that shall be in the form prescribed in Appendix 4 to this Circular.

In case of refusal to grant a Biosafety Certificate, VEA shall inform registered organizations and individuals the opinion of the Minister of MONRE which indicating the reason for refusal.

2. Within ten (10) working days from the date of issuance of the Biosafety Certificate, Ministry of Natural Resources and Environment is responsible for:

- a) Disclosing information on Biosafety website <http://www.antoansinhhoc.vn> ;
- b) Adding genetically modified crops to list of GMO which are granted biosafety certificates.

Article 9. Revocation of Biosafety Certificate

1. The Biosafety Certificate shall be considered to be withdrawn in the cases specified in Clause 1, Article 24 of Decree No. 69/2010/ND-CP dated June 21, 2010 of the Government on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms.

2. VEA is responsible for verifying the information specified in paragraph 1 of this Article and submitting to the Minister of MONRE for considering and deciding to revoke the Biosafety Certificate.

3. After revocation of the Biosafety Certificate, the Ministry of Natural Resources and Environment is responsible for:

a) Within three (03) working days from the date of revocation of the Biosafety Certificate, sending Decision (original) to organizations and individuals who own the Biosafety Certificate; publish information on the biosafety website <http://www.antoansinhhoc.vn> and the mass media;

b) Within ten (10) working days from the date of revocation the Biosafety Certificate, removing the name of that genetically modified organism from the List.

4. Since the date of revocation the Biosafety Certificate, organizations and individuals shall not be allowed to release into the environment the genetically modified crop which has been revoked.

Chapter III

ORGANIZATION AND OPERATION OF BIOSAFETY COMMITTEE, STANDING APPRAISAL AGENCY AND TECHNICAL ADVISORY TEAM

Article 10. The composition and structure of Biosafety Committee

1. Minister of MONRE shall establish the Biosafety Committee (hereinafter referred to as the Committee) in the form prescribed in Appendix 5 to this Circular. Committee consists of at least nine (09) members, including:

- a) The Chairman of the Committee is leader of VEA;
- b) Vice President of the Committee is the leader of Standing Appraisal Agency;
- c) The Secretary is a staff of Standing Appraisal Agency;
- d) Six (06) members are representatives of the Ministry of Industry and Trade, Science and Technology, Agriculture and Rural Development, Health, and two (02) specialist. Inwhich, the two (02) are chosen as critic members.

2. The cost of operation of the Committee shall comply with the provisions of the current law.

Article 11. Responsibilities and authorities of the Chairman of the Committee

Apart from the responsibilities and authorities of the Committee members as stipulated in the Article 13 of this Circular, Chairman of the Committe has following responsibilities and authorities:

1. Presideing over the Committee's meetings.
2. Handling the opinions of and concluding the Committee's meeting.

3. Signing minutes of Committee's meetings and being responsible to the Ministry of Natural Resources and Environment and the law on the conclusions of the Committee's meeting.

Article 12. Responsibilities and authorities of the Vice-Chairman of the Committee

Apart from the responsibilities and authorities of the Committee's members as stipulated in the Article 13 of this Circular, Vice Chairman of the Committee has the responsibility and authorities of the Chairman whenever mandated by the Chairman of the Committee .

Article 13. Responsibilities and authorities of the Committee's members

1. Responsibilities:

a) Studying and giving comments on documents provided by the Standing Appraisal Agency, writing evaluation in the prescribed form in Appendix 6 of this Circular and sending to the Standing Appraisal Agency before the official meeting of the Committee;

b) Participating in Committee's meetings and other activities during the evaluation of dossiers according to arrangement of the Standing Appraisal Agency;

c) Ensuring to protect provided documents, do not transfer information to the third party and turning in the documents to the Standing Appraisal Agency;

d) Being responsible to the law for objective, truthful reviews and evaluation of dossiers and for the assigned tasks in evaluation process.

2. Authorities and interests:

a) Requesting the Standing Appraisal Agency to fully provide materials and information related to dossier, to organize meetings and other activities for evaluation work;

b) Directly communicating with registered organizations and individuals at the Committee's meeting;

c) Reserving opinions which shall be recorded in the minutes of the Committee's meeting if the opinions differ the Committee's conclusions;

d) Receiving remuneration in accordance with the current financial regime when performing the following tasks: writing comment on the dossier, participating in Committee's meetings and activities, other work assigned during evaluation process, payment of travel expenses, accommodation, meals and other expenses as prescribed by law.

Article 14. Responsibilities and authorities of the Committee's Secretary

Apart from the responsibilities and authorities of the Committee members as stipulated in the Article 13 of this Circular, the Secretary shall have the following responsibilities and authorities:

1. Providing the evaluation form for Committee's members.
2. Reporting to the Chairman on the shortcomings of the dossier basing on Committee and Technical Advisory Team's comment; reading the comment of the members who are absent in the meeting.
3. Making and completing the record as requested by the Committee, signing and submitting the minutes of the Committee's meetings to the Chairman.
4. Performing other duties at the request of the Chairman of the Committee and Standing Appraisal Agency.
5. Reporting about his/her absent to the Chairman to appoint one (01) member of the Committee as secretary of the meeting whenever the Secretary could not attend the meeting

Article 15. Participants in the meetings of the Committee

1. The participants of the meeting shall be selected and invited by the Standing Appraisal Committee. The participants shall not have right to vote in the Committee's meeting.
2. Members of Technical Advisory Team shall be invited to meetings of the Committee and raise opinion of independent scientific assessment, but have no right to vote in the Committee's meeting.
3. Participants have rights to express comments in the Committee's meeting under the Chairman's operation and shall be entitled to remuneration in accordance with the law.

Article 16. The tasks of the Standing Appraisal Agency

1. Propose VEA to report to the Minister of MONRE on establishment of the Committee.
2. Propose the Director General of VEA to establish the TAT.
3. Support VEA to perform the following tasks:
 - a) Publishing information on the report of risk assessment for environment and biodiversity on the website <http://www.antoansinhhoc.vn>, and summarize the public's comments as stipulated in the Paragraph 1, Article 7 of this Circular;
 - b) Organizing meetings and activities of the Committee and TAT under procedures provided for in Articles 17, 18 and 20 of this Circular;

c) Compiling draft decision on issuing Biosafety Certificate which shall be submitted for decision-making;

d) Archiving documents;

e) Monitoring, reviewing and reporting to competent authorities information on biosafety management of genetically modified crops which have been granted biosafety certificates;

e) Performing other duties assigned by the General Department of VEA regarding the issuance and revocation of Biosafety Certificate.

Article 17. Conditions of the formal Committee's meetings

The formal sessions of the Committee shall be conducted with all of the following conditions:

1. Participation (be presence at the meeting or online through teleconference) of at least two-thirds (2/3) members of the Committee. In particular, it is obligated to has the present of: Chairman or Vice Chairman of the Committee whenever the Chairman is absent and at least one (01) critic member.

2. Authorized representatives of registered organizations and individuals.

3. The registered organizations and individuals have paid appraisal fee as provided by law.

Article 18. The content and order of the formal Committee's meeting

Chairman or Vice Chairman of the Committee, whenever Chairman is absent, shall operate the meeting with the authorities as stipulated in the Article 11 of this Circular and in the following orders:

1. The Secretary shall announce the Decision of Committee's establishment, introduce the participants, summarize the procedure of handling the dossiers and provide the summary of TAT's comments and information on activities of the Standing Appraisal Agency.

2. Registered organizations and individuals shall present briefly the risk assessment report.

3. The critic members and other Committee's members shall present their comments.

4. The Secretary shall present the comments on behalf of the Committee members who are absent.

5. Feedback of authorized representative of the registered organization or individual (if applicable).

6. Opinions of the participants (if any).
7. Committee's meeting continues internally and focuses on the following:
 - a) The Committee shall discuss dossier in accordance with the reviewing criteria and evaluate biosafety of genetically modified crops to environment and biodiversity;
 - b) The Committee members complete and submit evaluation forms as prescribed in Appendix 7 to this Circular;
 - c) The Secretary shall check the evaluation form, synthesize and report the results of the vote counting;
 - d) Committee shall discuss and make consensus on the draft conclusions.
8. The Chairman shall adopt the conclusion of the Committee and close the session.

Article 19. Principle of conclusion

Conclusions of the Committee shall be formally adopted when there is agreement of at least three-fourths (3/4) of Committee's members attending the meeting basing on the evaluation form.

Article 20. The organization and operation of the Technical Advisory Team

1. The TAT shall be established by the Director General of VEA in the form prescribed in Appendix 8 of this Circular and consist of at least three (03) members who are qualified professionals with expertise and experience related to the dossiers.

The cost of the TAT's activities shall comply with applicable law.

2. TAT shall be responsible for technically supporting, through the Standing Appraisal Agency, the Committee in evaluation the dossier including: studying the dossiers, recommending the correspondent to the public's comments; and completing the summary of TAT's comment in their meeting.

3. Responsibilities of the TAT's members:

a) Studying and giving technical advice in the form prescribed in Appendix 9 of this Circular;

b) If necessary, recommending the receiving-dossier agency to request registered organizations and individuals to provide additional documentation needed for technical assistance activities;

c) Turning in all provided materials and documents after completing the task, do not transfer information to the third party, do not use result of the evaluation against the provisions of the law on intellectual property.

Chapter IV Implementation

Article 21. Responsibilities of organizations and individuals

After being granted biosafety certificates, organizations and individuals are responsible for making the annual report of the implementation of measures to ensure the requirements in the Biosafety Certificate and sending to Ministry of Natural Resources and Environment, Ministry of Agriculture and Rural Development and the People's Committees of the provinces where genetically modified crops are released into the environment.

Article 22. Implementation

1. This Circular shall take into effect from 01st June 2013.

2. In the course of implementation, if any difficulties and obstacles, organizations and individuals promptly respond to the Ministry of Natural Resources and Environment for consideration and resolution./.

To:

- Central Office and the Commissions of the Party;
- Office of the National Assembly;
- Office of the President;
- Government Office;
- The Ministries; Ministerial-level agencies, agencies under the Government;
- Central committees of mass organization
- People's Committees of provinces and cities under the central authority;
- Department of Natural Resources and Environment of the provinces and centrally-run cities;
- Document Inspection Department (Ministry of Justice);
- Gazette;
- Arch of electronic government information;
- The units of the Ministry of Natural Resources & MT;
- Filing, PC, VEA.

**ON BEHALF OF MINISTER
DEPUTY MINISTER**

(Signed)

Bui Cach Tuyen

Appendix 1. Registration Form for Biosafety Certificate
(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)

(1)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.

(Place), day ... month ... year ...

On registration for Biosafety
 Certificate (2)

To: (3)

Name of organization / individual

Name of the representative of organization / individual:

Position:

Name of contact point of the organization / individual:

Address:

Tel:

Fax:

E-mail:

Request the Ministry of Natural Resources and Environment to consider and grant
 Biosafety certificates for (2)

Common name (Vietnamese, English) of genetically modified crops	
The scientific name of genetically modified crops	
Transformation Event	
Unique identification number (if applicable)	
Traits associated with transgene	
Expected uses and locations of release after granting Biosafety Certificate	

Attached documents:		
No.	Number	Document Type
1	01 original and 09 copies	Report on fieldtrial results approved by the Ministry of Agriculture and Rural Development
2	01 copies	Official document on fieldtrial results issued by the Ministry of Agriculture and Rural Development
3	10 originals	Report on risk assessment to biodiversity, environment of genetically modified crops
4	01 original	A (01) electronic file containing information on the Report on risk assessment to biodiversity, environment of genetically modified crops.
...		Attachment: ...

We assure and completely responsible to the law of the Socialist Republic of Vietnam for the truthfulness of the information and data provided in the accompanying documents.

We would like to request agency to conduct necessary procedures to evaluate documents and grant Biosafety Certificate./.

To:

- As above

-

- Filing

4.

(Signature, name and title, sealed)

* *Note:*

1. Name of registered organization / individual;
2. Name of genetically modified crops (transformation event);
3. VEA (Vietnam Environment Administration);
4. Authorized representative of (1).

Appendix 2. Format for the report on risk assessment to environment and biodiversity of genetically modified crops
*(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
 Minister of Natural Resources and Environment)*

Name of registered organization / individual for Biosafety Certificate **THE SOCIALIST REPUBLIC OF VIETNAM
 Independence - Freedom - Happiness**

Hanoi, DD/MM/YYYY

REPORT OF RISK ASSESSMENT TO ENVIRONMENT AND BIODIVERSITY OF GENETICALLY MODIFIED CROPS

Requirements:

Registered organization / individual shall have to fully answer the questions provided in the risk assessment report. Each answer in the report is evidenced by published documents attached. The document should be numbered. The answers to these questions must be accompanied by reference page number and sequence of the above documents.

I. General Information

<i>1. Registered organizations/individuals</i>	
Name of organization / individual	
The representative of the organization / individual:	
Contact point of the organization / individual:	
Address:.....	
Tel:	
Fax :	
Email:	

<i>2. Genetically Modified Crops:</i>	
Common Name (Vietnamese)	

and English) of genetically modified crops		
The scientific name		
Transformation event		
Unique identification (if applicable)		
Traits associated with transgene		
Intended uses of genetically modified crops	<input type="checkbox"/> Food	<input type="checkbox"/> Feed
	<input type="checkbox"/> Other purpose	
If genetically modified crops shall be used for any other purposes, it should be specified as following:		
If the method of detecting genetically modified crops		

II. Information related recipient plant

II.1. Name of the genetically modified crops	Common name (Vietnamese and English)	
	The scientific name	
II.2. Is recipient plant capable of causing disease?	To human	<input type="radio"/> Yes <input type="radio"/> No
	To animal	<input type="radio"/> Yes <input type="radio"/> No
	To plant	<input type="radio"/> Yes <input type="radio"/> No
Prove the answer and provide supporting documentation		
II.3. Is Vietnam the center of origin of the recipient plant?	<input type="radio"/> Yes	<input type="radio"/> No
Prove the answer and provide supporting documentation		

II.4. Is this the first time the recipient cultivated in Vietnam? If not, continue to answer question III.5.	<input type="radio"/> Yes <input type="radio"/> No
If yes, describe the natural habitat of the organism, including information about species with direct and indirect relationships in the food chain of the ecosystem.	
III.5. Describe the geographic distribution and habitats including information about the species with direct and indirect relationships in the food chain of the ecosystem, history of cultivation and use in Vietnam	
III.6. Is recipient capable of cross-pollinating with the line or the other wild species? If yes, please list the lines or the wild type and the scope of their distribution?	<input type="radio"/> Yes <input type="radio"/> No
Prove the answer and provide supporting documentation	
III.7. Describe the recipient's ability of survive and specific factors affecting the survival.	

III. Information relating to the genetic transformation

III.1. GM crops are created by which gene transfer methods?
III.2. Description of vector used (if any): characteristics of vector including identification characteristics, origin and host range of vector

III.3. Describe the gene construct including function and sequence of DNA of desired gene (s) in the gene construct, origin and sequence of DNA of other gene (s) in the gene construct (making table showing components and their origin in the gene construct). Provide supporting documentation.	
III.4. Does donor organism have history of safe use? If not, what is donor organism's risk?	<input type="radio"/> Yes <input type="radio"/> No
Prove the answer and provide supporting documentation	
III.5. Is inserted DNA originin from donor organism which is pathogen to human, animal and plant? If so, please prove that inserted DNA doesn't contain genes that cause disease?	<input type="radio"/> Yes <input type="radio"/> No
Prove the answer and provide supporting documentation	

IV. Information relating to genetically modified crops

IV.1. Describe the components of gene construct which has been inserted in crop's genome and their respective functions? How do these elements express? Provide supporting documentation
IV.2. If GM crops with stacked events, please describe: a) Does the interaction between genes, gene products create toxins or allergens? b) Does the interaction between genes, the products of genes affect metabolic

processes, and other phenotypic characteristics of the crop?

c) Is there any difference between the GM crops with stacked transformation event and single transformation event? Include: the level of gene expression, agronomic characteristics, stability of genotype and phenotype of transgene, farming practices ...

Provide supporting documentation.

IV.3. Description of the expression of desirable traits, trait stability as well as method of research. Provide supporting documentation

IV.4. Describe the differences between genetically modified crops and recipient? Explain the mode of action and provide supporting document.

IV.5. Has genetically modified crop been approved in the world? (Make a list of countries approving genetically modified crop with purpose of release into the environment, synthetic reviews of the competent authority on genetically modified crops in the country in which the GMO has been approved).

V. Evaluation of risk caused by GM crop to environment and biodiversity

V.1. Identify hazards and consequence of geneflow, basing on the results of research in the world and the results of field trials in Vietnam, please prove the above arguments. Propose the measures to manage identified risk and consequences of geneflow. Provide supporting document.

V.2. Identify hazard of becoming weediness, persistence and invasive species and their consequences; basing on the results of research in the world and the results of field trials in Vietnam, please prove the above argument. Propose the measures to manage identified risk and consequences of weediness, persistence and invasiveness. Provide supporting document.

V.3. Identify the risks of genetically modified crops on the non-target organisms in the ecosystem:

(a) Identification of non-target organisms in the ecosystem, including the herbivorous group, predators, parasites which are capable of exposure to genetically modified crops in Vietnam. Reasons for choosing the indicator;

(b) Identify the risks and consequences of impact on non-target organisms in the ecosystem, basing on the results of research in the world and the results of field trials in Vietnam, please prove the above argument. Propose the measures to manage identified risk and consequences on non-target organism.

Provide supporting document.

V.4. The impact of new farming practices on the environment and biodiversity:

a) Does novel trait require application of new farming technique? Please describe this new farming techniques.

b) Is there any adverse effect of applying new farming technique in the long term? If not, why?

c) If yes, how to manage the risks?

Prove the answer and provide supporting documentation

V.5. Impact on soil ecosystem

(a) Identify the soil fauna and soil metabolism which are likely to be affected by genetically modified crops. State the reason for selection;

(B) Identify the risks and consequences of impact on soil ecosystems including: soil fauna and metabolism (carbon, nitrogen ...); basing on the results of research in the world and the results of field trials in Vietnam (if any), please prove the above argument. Propose the measures to manage identified risk and consequences of impact on soil ecosystem. Provide supporting document.

V.6. For insect resistant genetically modified crops, analysis the development of resistance of target insect. Please describe the insect resistance management plan.

VI. Information on the risks of genetically modified crops on human health

VI.1. If genetically modified crops shall be used as food and feed

Has GM crop been granted certificate for food and feed yet? Yes No

If yes, provide a copy of the certificate for food and feed issued by the Ministry of Agriculture and Rural Development?

If no, make a list of countries in which genetically modified crops have been approved for food and feed use and describe management plan to ensure that genetically modified crops shall not be contaminated into the supply chain of food and feed.

VI.3. If genetically modified crops shall not be used for food and feed: Please assess adverse effects to human health in the process of cultivation, use of GM crop or its products. Please provide specific evidence.

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

VII.1. List the identified risks accompanied with the management plan.
VII.2. Description of plan on monitoring the risk of GM crops to the environment, biodiversity and human health.

VIII. Conclusion and recommendation

APPENDIX

Summary of Report on the Risk assessment to environment and biodiversity

(Accompanied by a Report on risk assessment of the (name of GMO crops) on the environment and biodiversity of the (name of registered organization / individual))

Requirements: Registered organization / individual shall summarize the information in a risk assessment report according to the following table.

- Column 1: Identify the possible risks to the environment and biodiversity if genetically modified crop is released into the environment.
- Column 2: Determine the likelihood of the risk referred to in Column 1.
- Column 3: Determine consequences if the risk occurs in column 1.
- Column 4: Summary of risk. In the case of risks, if the risk management measures specific.
- Column 5: Briefly explain to justify conclusions about risk.
- Column 6: Provide documents supporting for justification/ explanation in the Column 5.

Hazard	Likelihood	Consequences	Conclusions about risk and risk management measures	Justification/ Explanation	Supporting documents
(1)	(2)	(3)	(4)	5.	6.

Appendix 3. Format for the Information about Report of risk assessment of genetically modified crops to the environment and biodiversity

*(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)*

Name of registered organization / individual

**THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness**

Hanoi, DD/MM/YYYY

INFORMATION ABOUT REPORT OF RISK ASSESSMENT OF GENETICALLY MODIFIED CROPS TO THE ENVIRONMENT AND BIODIVERSITY

I. General Information

1. Name, contact address, representative and contact person representing the organization (individual) register.

2. Name of genetically modified crops: scientific name, common name, transformation event and unique identification, if any

II. Information about recipient crops

Brief description about recipient including: biological characteristics, relationship with the natural environment and biodiversity in Vietnam, history of use.

III. Information about transformation

Brief description of transformation.

IV. Information about genetically modified crops

1. Brief description the novel trait and characteristic of GM crops in comparison with conventional crop;

2. Information on history of use and approval of GM crops in the world.

V. Information about risk assessment of genetically modified crops to environment and biodiversity

Brief about the activities of risk assessment on the environment and biodiversity that have been carried out and the results of the risk assessment.

VI. Information on the risks of genetically modified crops to human health

Information on the risks of genetically modified crops to human health.

VII. Information on recommended risk management measures

Brief description of the recommended measures of risk management (if any)

Note:

Information on risk assessment report of genetically modified crops to environment and biodiversity shall not include confidential information in accordance with current legislation.

Appendix 4. Format of Biosafety Certificate
(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)

**MINISTRY OF NATURAL
RESOURCES AND ENVIRONMENT**

THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

BIOSAFETY CERTIFICATE

(Attached to Decision No. / QD-BTNMT on of
Minister of Ministry of Natural Resources and Environment)

1. The Genetically Modified Crops is granted Biosafety Certificate:
 - Common Name:
 - Scientific name:
 - Transformation event:
 - Trait related to the transgene:
 - Unique identification (if any):
2. Name of organization (individuals):
Address:
Phone: Fax:
3. Organizations / individuals who are granted biosafety certificates shall be responsible for implementing safety requirements for GM crops, including:
 -
 -

*** Note:**
Original records day of

Hanoi, Date Month Year 20..
MINISTER
(Signature and stamp)

.....

Appendix 5. Decision for Establish the Biosafety Committee
(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)

**MINISTRY OF NATURAL
RESOURCES AND ENVIRONMENT**

Number: / QD-BTNMT

SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom – Happiness

Hanoi, Date Month Year 20..

DECREE

On the establishment of the Biosafety Committee

MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT

Pursuant to Decree No. 21/2013/ND-CP of May 03 04, 2013 of the Government defining the functions, tasks, authorities and organizational structure of the Ministry of Natural Resources and Environment;

Pursuant to Decree 69/2010/ND-CP of June 21, 2010 of the Government on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms;

Pursuant to Circular 08/ 2013 / TT-BTNMT of May 16, 2013 by the Ministry of Natural Resources and Environment specify the order and procedures for granting and revoking Biosafety Certificate pair with genetically modified crops;

At the request of the Chief of the Office and the Director General of Vietnam Environment Administration,

DECIDES

Article 1. Establishment of Biosafety Committee (hereinafter referred to as Committee) including ladies / gentlemen whose name is in the accompanying list.

Article 2. The Committee is responsible for review and evaluation of registration dossiers for Biosafety Certificate of (name of genetically modified crops, gene transfer events) of (organization / individual), responsible for evaluation results and send the results to the Ministry of Natural Resources and Environment.

The Committee shall be self-dismissal after completing the task.

Article 3. Funding for the activities of the Committee shall be paid in accordance with current legislation.

Article 4. This Decision takes effect on the date of signing. The Chief of Ministry's Office, the Director General of VEA and individuals named in Article 1 shall implement this Decision./.

To:

-
- As stated in Article 4;
- Save VP, (in text editor).

MINISTER
(Signature and stamp)

.....

LIST OF BIOSAFETY COMMITTEE

(Attached to Decision No. /QD-BTNMT dateof the Minister of Natural Resources and Environment)

NO.	Full Name:	Title, position at work	Position in the Committee
1.			
2.			
3.			
4.			
5.			
6.			

**Appendix 6. Format for appraisal on dossiers for Biosafety certificate of the
Biosafety Committee**

*(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)*

**MINISTRY OF NATURAL
RESOURCES AND
ENVIRONMENT**

**THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness**

BIOSAFETY COMMITTEE

..... date months year 20 ...

**APPRAISAL FORM
THE DOSSIER FOR BIOSAFETY CERTIFICATION**

I. General information about profile

1. Name of registered organization (individual):
2. Name of genetically modified crops:
 - Common Name:
 - Scientific name:
 - Transformation event:
 - Intended uses of genetically modified crops:
 - Unique identification (if any):
3. Profile code:

II. Information on Committee members biosecurity

1. Full name (*scientific titles, academic titles and position*):
2. Institution:
3. Position

III. Evaluation:

1. About the dossier:

The completeness of the dossier in accordance with the Circular 08/2013/TT-BTNMT dated 16 May, 2013 by the Ministry of Natural Resources and Environment on

stipulated the order and procedures for granting and revoking Biosafety Certificate for genetically modified crops.

2. Risk assessment report and accompanied documents

Analyze the sound science, logical and adequate aspects of hazard identification, risk likelihood, consequences and conclusions about the risk, risk management measures of genetically modified crops.

IV. Conclusion:

1. Conclusion

- a) Approve with no need to modify or supplement
- b) Approve but need to modify and/or supplement
- c) Not approve

If select item b), please identify which part should be modified/supplemented.

2. Recommendation

The specific requirements to ensure safety when using genetically modified crops

Committee Member

(Signature and full name)

**Appendix 7. Evaluation form on dossiers for Biosafety certificate
of the Biosafety Committee**

*(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)*

MINISTRY OF NATURAL
RESOURCES AND ENVIRONMENT

BIOSAFETY COMMITTEE

THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

..... day..... month year 20 ...

**EVALUATION FORM
ON DOSSIER FOR BIOSAFETY CERTIFICATE**

I. General information about dossier

1. Name of registered organization (individual):
2. Name genetically modified crops:
 - Common Name:
 - Scientific name:
 - Transformation event:
 - Intended uses of genetically modified crops:
 - Unique identification (if any):
3. Profile code:

II. Information on Committee members

1. Full name (*scientific titles, degrees*):
2. Institution:
3. Position

III. Conclusion:

1. Conclusion

- a) Approve without further modify or supplement



- b) Approve with further modification or supplement
- c) Not approve

If select item b), please identify which part should be modified/supplemented.

2. Recommendation

The specific requirements to ensure biosafety when use genetically modified crops

Committee Member

(Signature and full name)

Appendix 8. Format for Decision on establishment of Technical Advisory Team
(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)

MINISTRY OF NATURAL
RESOURCES AND ENVIRONMENT
Vietnam Environment Administration

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

No: /QD-TCMT

Hanoi, Date Month Year 20..

DECISION
On the establishment of Technical Advisory Team

General Director of the Vietnam Environment Administration

Based Circular 08/2013/TT-BTNMT dated 16 May 2013 by the Minister of Natural Resources and Environment on stipulating the order and procedures for granting and revoking Biosafety Certificate for genetically modified crops;

At the request of Chief of Office of VEA and Director of Biodiversity Conservation Agency,

DECIDES

Article 1. To establish Technical Advisory Team as following:

No.	Full Name	Title	Office
1
2
3

Article 2. Technical Advisory Team is responsible for technical support for Biosafety Committee in evaluating the dossier on granting Biosafety Certificate for (name of GM crops, transformation event) in accordance with Circular No 08/2013/TT-BTNMT dated 16 May 2013 by the Minister of Natural Resources and Environment on stipulating order and procedures for granting and revoking Biosafety Certificate for genetically modified crops.

Technical Advisory Team shall be self-dismissal after completing the task.

Article 3. This Decision takes effect on the date of signing. The Chief of VEA Office, Director of Biodiversity Conservation Agency and the individuals named in Article 1 shall implement this Decision./.

To:

-
- As stated in Article 3;
- Save VP, (in text editor).

GENERAL DIRECTOR

(Signature and stamp)

.....

Appendix 9. Form of TATs' evaluation
(Attached to Circular 08/2013/TT-BTNMT May 16, 2013
Minister of Natural Resources and Environment)

THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, Date Month Year 20..

EVALUATION FORM FOR THE TECHNICAL ADVISORY TEAM

I. General information about dossier:

1. Name of registered organization / individual:
2. Name genetically modified crops:
 - Common Name:
 - Scientific name:
 - Transformation event:
 - Intended uses of genetically modified crops:
 - Unique identification (if any):
3. Profile code:

II. Member of TAT:

1. Name of expert (scientific titles, degrees):
2. Institution:
3. Position
4. Date of dossier receipt:/...../.....

III. Evaluation:

1. On the risk assessment report and accompanied documents

Analyze the sound science, logical and adequate aspects of hazard identification, risk likelihood, consequences and conclusions about the hazard identification, likelihood, consequence and conclusion on risk, risk management measures of genetically modified crops.

2. Recommendation to answer the public's comment.

IV. Conclusion

1. Content of the risk assessment report and accompanying documents

- List of satisfactory content:
- List of unsatisfactory content:
- Other opinions

2. Safety of genetically modified crops

- a) Safe for the environment and biodiversity
- b) Safe for the environment and biodiversity in a number of specific conditions
- c) No safe

If selecte item b), please identify specific conditions.

The TAT's member

(Sign full name)