Unoffical Translation

MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

SOCIALIST REPUBLIC OF VIET NAM
Independence – Liberty – Happiness

No:02/2014/TT-BNNPTNT

Hanoi, January 24th, 2014

CIRCULAR ON
APPROVAL PROCESS OF ISSUEING AND REVOCATION OF THE CERTIFICATE FOR GENETICALLY MODIFIED PLANTS TO BE USED AS FOOD, FEED

Pursuant to the decree No. 199/2013/NĐ-CP of November 26, 2013 of Government stipulate for function, authority, mission and structural organization of Ministry of Agriculture and Rural Development (MARD);

Pursuant to the decree 69/2010/N-CP of June 21, 2010, of government on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms;

Pursuant to the decree No. 108/2011/NĐ-CP of November 30, 2011, of government on correcting decree 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms;

Pursuant to the decree 38/2012/NĐ-CP of April 25, 2012 of the Government on the regulations to implement Food safety law;

According to the request from Director of Department of Science, Technology and Environment; Director of Legal Department, Director of the Livestock Department and the Director of National Agro Forestry Fisheries Quality Assurance;

Minister of Ministry of Agricultural and Rural Development promulgate the circular on approval process of genetically modified organism for food, feed.

CHAPTER I
GENERAL PROVISIONS

Article 1. Scope of regulation

This circular stipulates an approval process of genetically modified plants for direct use as food, feed included the order, procedures for issuing, renewal and revocation of the safety certificate for genetically modified plants that satisfy conditions to be used as food, feed .

Article 2. Subject of applications

This circular applies to domestic as well as foreign organizations and individuals who carrying out activities of or related to the issuing, renewal and revocation of a certificate of genetically modified plants and products of genetically modified plants that satisfy conditions to be used as food, feed in territory of Vietnam.

Article 3. Definitions

The definitions below apply to this Circular:

1. Genetically modified plant means a plant, genetic specimens of plant in which the genetic material has been changed through *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA).

2. Risk assessment of genetically modified plants to human and animal health (hereinafter referred to as risk assessment) means activities, which are designed to identify the potential hazard and the possibility of becoming risk when the genetically modified plant is used as food, feed .

3. Transformation event means the introduction into a plant of genetic material that has been manipulated *in vitro*.

4. Developed country is a country which developed in biotechnology in the group of OECD and/or G20

5. Unique identity code: is the code which is given by OECD for each transformation event.

Article 4. Standards for risk assessment of food, feed which derives from genetically modified crop

Standards for risk assessment of the genetically modified crop which meet the requirement to be used as food, feed in this Circular are based on the international risk assessment standards, which includes:

1. Comparison the difference in composition and nutrient between GM plant and the counterpart which is produced by conventional method.
2. Assess the likelihood of the nutrient metabolites, esp. the new expression product of inserted gene if used as food, feed.
3. Assess the likelihood of toxicity of new component, which is the new expression product of inserted gene if used as food, feed.
4. Assess the likelihood of allergic of new component, which is the new expression product of inserted gene if used as food, feed.
5. Assess the likelihood of forming new components, possibility of causing disease or having other adverse effects to human and animal health (for example: potential effects from processing, the change in nutrient quality, nutrient function, new component accumulation, indicator gene of antibiotic resistant…).

CHAPTER II

ISSUING AND REVOCATION OF CERTIFICATE

Article 5. Scope of application

The Certificate shall be considered to grant to the following conditions:

1. Genetically modified plants carry the single event, which derived from the transfer of one gene, which controlling the interested, targeted trait by the transformation technology;
2. Genetically modified plants carry the stack events (vector stacked transformation event) which derived from the transfer of two or more than two gens which controlling one or several interested, targeted traits by the transformation technology.

Article 6. Conditions for issuing of Certificate

The genetically modified plants can be issued the Food, feed safety Certificate when it meets one of the following requirements:

1. The genetically modified plant has been approved for use as food, feed in five (05) developed countries and has not posed any risk in those countries, or
2. Genetically modified plant is concluded by the Food, feed safety Committee that there is none uncontrollable risk to human and animal health; or
3. Other cases:
    a. Genetically modified crops that are granted certificate for direct use as food can be used as animal feed
    b. Genetically modified crops, which carries stack genes of which derived from conventional breeding can be use as food, feed automatically if single events comprising the stacks have been approved.

Article 7. Application documents

1. Organizations and individuals who apply for the Food, feed safety Certificate shall submit to MARD three (03) copies of the dossiers (one original and two copies). The dossier includes :

a) Application form (Annex 1);

b) Risk assessment report of the genetically modified plant (follow will refer as risk assessment report) to human and animal health according to Annex 2 in this Circular, (with the electric file);

c) The references, new data which is not yet published as well, data from assessment, trials or other scientific evidences which the applicant has been used to conclude that the genetically modified crop do not pose any adverse effect to human and animal health if the Food, feed safety Certificate shall be issued.

d) Summarize report of risk assessment (Annex 3) (with the electric file);

e) Public comments (Annex 4).

f) Notarized copies and notarized translation into Vietnamese of the certificates or approval letters, or equivalent documents which were issued by authority organization indicating the products have been approved for food/ feed use in other developed countries (if there).

2. In the case of applying for Food, feed safety Certificate stipulated in the Article 6.1 of this Circular, the dossier includes :

a) Application form (Annex 1);

b) Risk assessment report of the genetically modified plant (follow will refer as Risk Assessment Report) to human and animal health according to Annex 2 in this Circular, (with the electric file);

c) Summarize report of risk assessment (Annex 3) (with the electric file);

d) Public comments (Annex 4).

đ) Notarized copies and translation into Vietnamese of the certificates or approval letters, or equivalent documents which were issued by authority organization indicating the products have been approved for food/ feed use in at least 5 developed countries.

3. In the case of applying for Food, feed safety Certificate stipulated in the Clause 2 – Article 6 of this Circular, the dossier includes

a) The documents stated in Clause 2 (a,b,c,d) of this Article;

b) Notarized copies and translation into Vietnamese of the certificates or approval letters, or equivalent documents which were issued by authority organization indicating the products have been approved for food/ feed use in other developed countries (if there);

c) The references, new data which is not yet published as well, data from assessment, trials or other scientific evidences (if available) which the applicant has been used to conclude that the genetically modified crop do not pose any adverse effect to human and animal health if the Food, feed safety Certificate shall be issued.

4. In the case of applying for Food, Feed Safety Certificate stipulated in the Clause 2 – Article 5 of this Circular, the dossier includes

a) Documents stipulated in the Clause 2 of this Article (applying for Food, feed safety Certificate stipulated in the Clause 1 – Article 6 of this Circular)

b) Documents stipulated in the Clause 3 of this Article (applying for Food, feed safety Certificate stipulated in the Clause 2 – Article 6 of this Circular)

c) Additional documents of Risk assessment report of the genes interaction in the structure, the stability of structure, the function and expression of the target genes in the host plant.

Article 8. Receiving, reviewing the dossier to issue the Certificate.

1. Applicant, which register for issuance a certificate of genetically modified plant to be used as food, feed shall send dossier directly or via post according to Article 6 of this Circular to the authority organization under the MARD.

2. The authority organization under the MARD shall review and inform the applicant by document about the acceptance or requirement for additional information (Annex 5) within seven (07) working days from the date of receiving the dossier. Time for applicant to correct or to provide more information in the application is not added in the evaluation time of application.

3. After receiving a completed dossier, authority organization under the MARD shall post on MARD's website the general information as well as the summary of risk assessment report of genetically modified plant for public comments, prepare a report and send to Committee for further consideration. The maximum time for public comment is 30 days, from the date that information has been published.

4. Within 180 working days from receipt a validated application, MARD shall organize a Food, feed safety committee meeting (hereinafter referred to as FFSC) to evaluate the application. In case of application for the genetically modified plant event meet the requirement of Article 6.2 in this Circular, the time for issuing a Certificate shall not exceed 30 days.

Article 9. Issuing the Certificate

1. Minister of MARD shall consider and decide to issue a Certificate (Annex 6) within 30 working days after receiving the appraisal result from the Committee. 2. Authority organization belongs to MARD shall publish on MARD's website and add the name of new approval event into the list of Event approval for food, feed use within ten (10) working days, after the date of the decision to issue the Certificate.

3. In the case of decline to issue the Certificate, the authority organization shall inform Applicant by written document and clarify the reason.

Article 10. Revocation of Certificate

1. A Certificate is revoked under the circumstances which were stipulated in Article 29.1 of Decree 69/201069/2010/NĐ-CP on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms.

2. Based on each specific case, Ministry of Agricultural and Rural Development shall consider and decide Certificate Revocation

a) In the case of violation stated in Article 29.1 (a & b) and Article 34.1 (a & b) of the Decree No. 69/201069/2010/NĐ-CP, MARD shall establish Food, Feed Safety Committee (hereinafter referred to as FFSC) to appraise the dossier and take decision to revoke the Certificate.

b) In the case violation stated Article 29.1(c) and Article 34.1 (c) of the Decree no. 69/201069/2010/NĐ-CP, DoSTE shall submit proposal to MARD to consider and decide Certificate Revocation.

3. DoSTE shall be responsible in:

a) Organizing meetings of Committee or other independent consulting Committee (in the case of violation stated in Article 29.1(c) and Article 34.1 (c) of the Decree no. 69/201069/2010/NĐ-CP) to appraise the dossier, decision to revoke the Certificate;

b) Proposing decision of Certificate withdrawal to the Minister of MARD based on the appraisal result from the Committee;

c) Notifying in less than three (3) working days from the date of revocation, to public and by written document to relevant organizations, individuals, Ministries about the decision of withdrawal.

Article 11. Public GM list on the website

DoSTE will act as a focal body to organize and manage related activities as following:

DoSTE shall be responsible:

1. Establish and announce on the website of MARD the List of Certified GMC
2. Add and announce on the official website of MARD the name of the GMC to the list of GMCs that are granted Food Feed Certificates
3. In case of revocation, within 10 days of after the date of Food Feed certificate revocation, MARD shall delete and announce on the website of MARD the name of the GMC out of the list of certified GMC.

CHAPTER III

FOOD, FEED SAFETY COMMITTEE STRUCTURE AND OPERATIONS

Article 12. Food, feed safety committee (FFSC)

1. FFSC is the inter-ministerial committee established by the Minister of Agriculture and Rural Development in order to consult to MARD's minister for issuance, revocation the Food, feed safety Certificate.

2. The FFSC shall be composed eleven (11) members which included Chairman, Vice-chairman are the representative of MARD, four (4) of whom shall be represented for Ministry of Industry and Trade, Ministry of Science and Technology, Ministry of Natural Resources and Environment, and Ministry of Health and some scientists expertise in related field. The working term of the FFSC is three (03) years.

3. Expense for Committee's activities shall be accounted regarding to the actual in force regulation.

Article 13. Food, feed Safety Committee operation

1. FFSC works on the principle of democratic, objective, self-responsible on the objectively, the accuracy on the independent consultation, team-responsible for Committee's general conclusion.

2. Official meeting of the Committee shall be organized only when there are at least two third of the members under the Chairman's moderation (or under the Vice-chairman in case the Chairman is absent).

3. In addition to the regulation which is stipulated in Article 13.1 in this Circular, The second meeting of FFSC shall be organized only when the appearance of: Scientific and Administration Secretaries, 02 reviewing members, independent reviewer's reports (if yes).

4. In the case of need, FFSC shall invite independent experts or submission applicant for recommendation and explanation.

Article 14. Official meetings

1. The first meeting:

a) Administration Secretary (who is the representative of the Authority Organization, which belongs to MARD) shall make introduction of the members of meeting and give the opening remark, and provide conclusion of the validity of Application dossier;

b) Committee Chairman moderates the meeting and unifies the working plan of the meetings, assign one (01) Scientific Secretary and two (02) members as reviewer to review the application dossier. In case of necessary, the Committee shall discuss to request of adding 2 – 3 independent review experts, who have experiences in the area related to the dossier.

c) Committee shall appoint the counting vote division, including (03) Committee's members, in which there is one (01) leader.

d) Committee shall unify the date of next meeting and the working plan.

2. The second meeting:

a) Administration Secretary shall announce the summary of public comments in application dossier and the report from independent experts (if yes);

b) Committee's review member review and assess the application dossier according to the annex 7;

c) The committee shall discuss and assess the application dossier according to the regulations stipulated in this Circular;

d) The committee shall vote for the dossier according to the Annex 8;

e) Counting vote division shall summarize and report the voting results according to Annex 9;

f) A dossier meet the requirement is the one received the “approval vote” from at least third forth (3/4) of the members in the official meeting;

g) Committee shall discuss, conclude and recommend for additional information, or necessary changes in the contents of the Dossier (if yes) and approve the meeting’s report according to Annex 10.

3. Based on the meetings’ reports, scientific secretary shall complete the final report for each appraisal dossier and the conclusion of recommendation to the Minister of MARD for the issuance, revocation of a certificate according to Annex 12.

4. In the case of revocation of certification, FFSC shall review case by case based on the record and conclude recommendation to submit to the Minister of Agriculture and Rural Development for revocation of the certificate.

5. In the case of revocation of certification, FFSC shall review case by case based on the record and conclude recommendation to submit to the Minister of Agriculture and Rural Development for revocation of the certificate.

Article 15. Responsibilities and Authority of the Food, feed safety committee members

1. Review and evaluate of application dossier and related documents provided by MARD.

2. Fully participate in FFSC meetings during application review period and submit a writing report.

3. To ensure incidental loss of documents does not occur, no documents or other information pertinent to the deliberations of the committee shall be communicated to any third party.

4. Ensure that the review and evaluation of applications are transparent, independent, based upon established scientific principles. FFSC should be prepared to communicate its final recommendations with the public and media.

5. Be entitled to remuneration in accordance with actual in force regulation.

CHAPTER IV

IMPLEMENTING

Article 16. Responsible of Department of Sci, Tech and Env

DoSTE will act as a focal body to organize and manage related activities as following:

1. Lead and coordinate with related agencies to implement the Circular

2. Collaborate with other related agencies to collect and use appraisal fee in accordance with the current law and regulations

3. Collect data and information; report to to the Ministry situation of Certificate Issuance and Revocation for genetically modified plants that qualified to be use as food, feed following related regulations.

Article 17. Responsibility of applicants

1. Applicant shall pay all the fees according to actual regulation. The appraisal fee will not be reimbursed in case of the dossier do not meet the requirement to issue the Certificate.

2. Responsible for the accuracy of the information provided in the application documents.

3. Provide additional information as required by MARD.

4. Responsible with the law upon failure to comply with the conditions of the certificate**.**

5. Applicant shall inform MARD about the adverse effect, new scientific evidence about risk of the approved genetically modification plant (if yes) during the valid period of the Certificate.

6. Inform other related organizations, individuals when the Certificate is revoked

Article 18. Implementation provisions

1. This Circular takes effect from March 10, 2014.

2. All plant materials in the scope of this circular shall register for issuing Certificate in the period of maximum one (01) year, after the effective date of this Circular.

3. During implementation, if any difficulties arise, promptly suggested to the Ministry of Agriculture and Rural Development for consideration and settlement./.

pp. Minister of Agriculture and Rural Development

Vice Minister

(signed)

Le Quoc Doanh

Recipients:

- Central Office of Communist Party and other related departments.
- National Assembly Office
- Office of the Prime Minister
- Office of the Government
- Ministries, Ministry-level bodies, Governmental Agenicies
- Central Agencies of National Unions, Organizations

- Leaders of MARD
- People Committees of Provinces, Cities
- Agency of Document Testing – Ministry of Justice
- The Government's Public Announcement Office
- Websites of the Government and MARD
- Agencies, departments of MARD
- DoSTE

Annex 1: Application Form for issuing the Certificate

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom – Happiness

APPLICATION FORM

TO GRANT FOR GM CROP AND ITS PRODUCTS CAN MEET THE REQUIREMENT TO USE AS FOOD, FEED

First registration

Supplementary registration

To: MARD

Pursuant to the Decree 69/2010/ND-CP on June 21 2010 of the Government on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms, Decree 108/2011/ND-CP of November 30, 2011, of government on correcting Decree 69/2010/ND-CP on 2010 of the Government on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms and the Circular number /TT/BNNPTNT date … month … year… ***MARD*** on DD/MM/YYYY stipulated the order, procedure of issuing and revocation of Certificate for GM plants and the products derived from the GM plants, which meet the requirement to use as food, feed . (Applicant name) is sending to MARD the dossier for applying the Certificate for GM plants meet the requirement to be used as food, feed , detail follow:

1. Applicant's information

Name:

Address:

Tel: Fax:

Email:

2. Information of the GMO

Common name:

Scientific name:

Trade name:

Gene transfer event:

Introduced trait related to the transformed gene:

Name of the developer:

The only identified code (if yes):

3. The attached dossier (01 original document and 02 copies) included:

4. Hereby

We hereby that the above information are truth and will be responsible for all the contents in this form and in the dossier for applying the Certificate for GM plants can be used as food.

MARD can please review and grant the Certificate that the GM plant which meets the requirements to use as food, feed./.

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

Applicant's signature

(Name, sign and stamp)

Annex 2. Form of Report on risk assessment of GM plants to human and animal health

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

Applicant

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom – Happiness

REPORT ON RISK ASSESSMENT OF GM PLANTS TO HUMAN AND ANIMAL HEALTH

I. General information

1. Name of Applicant:

Applicant's representative:

Applicant's contact point:

Address:

Tel: Fax:

Email:

1. Name of GM plants

Common name:

Scientific name:

Trade name:

Gene transfer event:

Introduced trait related to the transformed gene:

The only identified code (if yes):

II. **Relevant information on host organism:**

1. Name of host organism:

(a) scientific name:
(b) common name:
(c) Identification position

2. Relevant information on historical of cultivation and breeding development, esp. the information related to the trait which has the potential risk to human and animal health.

3. Information on the host organism's safety, which included the toxicology and allergy (include the information for the relative plant in the same species which could be used as gene acceptor crops)

4. Information about the historical usage in food, feed. (Describe in detail the custom of cultivation, transportation, preservation and specific condition in processing (if yes)

in order to use safety in food and feed. Describe the function, value and nutrition composition in different parts of the plant, which is used as food or feed.

III. Relevant information on donor organism:

1. Name of donor organism
   a. Common name:
   b. Scientific name
   c. Identification position
2. Information of natural history related to food, feed safety.
3. Information of finding in nature the anti-nutrient, toxicant, allergy. In case of the host organism is micro-organism, it shall provide the information of causing disease and the interactive relation with the known causing disease
4. Information of previous and current (if yes) use in the food, feed chain and the other exposal paths beside the intended use (for example: the likelihood of unintended exposal)

IV. Information relevant to gene transfer process.

A. Information on transfer gene

1. Fully provide information related to the gene transfer process in order to identify all the genetic materials which are introduced in to the host plant and analyze all the data to confirm the characteristics of the insert DNA into the host plant
2. Describe in detail the transfer process including:
   a. Information about the used gene transfer method
   b. Information about the sequence, origin, vector, plasmids, the similarity and the expected function of the transfer gen in the GM plant
   c. Information about the intermediate organism (For example: micro-organism) is used to produce or multiple the DNA for transferring into the host.
   d. Provide all information about the inserted DNA fragment including:
   e. Fully description about the characteristic of all genetic elements: indicator gene, all regulator elements and other components can impact to the gene's function.
   f. Size and the similarity of components;
   g. Position and the direction of the inserted gene's sequence in the last structure/ vector;
   h. The function of the inserted gene

B. Relevant information of GM plant:

1. Fully provide the data to describe in detail the molecular, bio-chemistry characteristics of the GM food or feed and its impact to the nutrient composition and its safety.
2. Fully provide information about the inserted DNA fragment into the acceptor plant's genome, including:

a. describe the characteristics of the genetic material which were transferred
b. number of the insert
c. Insert site, include copy number, sequences of inserted genes and flanking region to determine any compound which could be produced due to the gene insertion or other information relate to analysis the transcriptional or expressed products to determine any newly possibility produced in GM plants.
d. Determine all open reading frame in inserted DNA or created by insert fragments with genome sequence which could make fusion protein molecules.

3. Fully provide information about the expressed elements in the GM plants, including:
   a. Gene products (for example: protein molecule or non-transcription RNA);
   b. Function of gene products;
   c. Describe the morphology characteristics of the new trait;
   d. Expression level, position (part) of the inserted gene expression in the GM plant and the amount of their metabolites in the plant, esp. in the parts used as food
   e. Quantity of the amount of the expression gene's product (if yes – when the function of the inserted gene may change the accumulation of mRNA or protein
4. Supplement of the related information including:
   The proof of the structure stability of the genetic material or the change in position of the structure on the gene transfer process.
   a. Prove the change in amino acid sequence of the expressed protein as the result of an intended modification.
   b. Prove the intended impact of the modification, the new trait is expressed and stably remained through several generations and following the genetically fundamentals. If the new trail can not be determined by morphology, it shall have the information at the molecular level.
   c. Prove that the new traits are expressed in the necessary parts at the appropriate level related to the regulatory sequence which control expression of respective gene.
   d. Indicate the proof to show one or several genes in host plant are influenced by the gene transfer process (if yes)
   e. Confirm the similarity and the expression of any fusion protein molecular.
5. History of approval and usage of GMO on the world

V. Risk assessment of genetically modified crop to human and animal health

1. Comparison the difference in composition and nutrient between GM plant and the counterpart which is produced by conventional method.

2. Assess the likelihood of the nutrient metabolites, esp. the new expression product of inserted gene if used as food, feed.
3. Assess the likelihood of toxicity of new component, which is the new expression product of inserted gene if used as food, feed.
4. Assess the likelihood of allergic of new component, which is the new expression product of inserted gene if used as food, feed.
5. Assess the likelihood of forming new components, possibility of causing disease or having other adverse effects to human and animal health (for example: potential effects from processing, the change in nutrient quality, nutrient function, new component accumulation, indicator gene of antibiotic resistant…).

VII. Proposal of potential risk management of genetically modified plant to human health

VIII. Conclusion and suggestion

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

Applicant

Annex 3. Summary of Risk Assessment report of GMO to human and animal health

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

SOCIALIST REPUBLIC OF VIET NAM

Applicant **Independence - Freedom – Happiness**

Hanoi, date month year

RISK ASSESSMENT REPORT OF GENETICALLY MODIFIED PLANT AND ITS PRODUCT TO HUMAN AND ANIMAL HEALTH

I. General information

1. Name and address of Applicant, leader and name of contact person
2. Name of GMO: Common name, Scientific name, Gene transfer event name, the only identified code (if yes):

II. Relevant information on host organism:

Description about the host organism which including name, biology characteristics, its relationship in natural environment and biodiversity in Vietnam and the history of use.

III. Relevant information on donor organism:

Description about the donor organism, which included: name, biology characteristics, its relationship in natural environment and biodiversity in Vietnam and the history of usage.

IV. Relevant information on the GM plant

Describe the process of developing the GM plant, including the shortly description of gene transfer method.

Inform the GM plant's new traits and characteristics in comparison with the conventional counterpart

Information about the GM plant's history of approval and usage all over the world

V. Risk assessment of GM plant on human and animal health

Describe the risk assessment activities, which have been done with this GM plant and the results

Describe the possibility that GMP is toxic, or allergic or having adverse effects to human and animal health if used as food, feed.

VI. Proposal of GMP risk management for animal and human health

Description about the proposal risk management plan (if yes)

VII. Conclusion and suggestion

……., day…month….year

Applicant

Annex 4: Information form for public comment

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

INFORMATION FORM FOR PUBLIC COMMENT

1. Name of applicant
2. Contact address
3. Name of the responsible
4. Description of the applying product
5. Original,
6. Purpose of registration

If interested to have more information on the applying product for issuing the food, feed Certificate, contact to the product's responsible:

Name:

Contact address

Tel

Email

Fax

Welcome organization, individuals to send to MARD the comments on the reviewing to grant the above GM plant meet the requirement to use as food, feed within 30 days since the information is uploaded.

Ministry of Agricultural and Rural Development

No. 2 – Ngoc Ha Street – Ba Dinh – Hanoi

Place, DD/MM/YYYY

Applicant's signature

Unoffical Translation

Annex 5: Information sheet on the validity of dossier for issuing the Certificate

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

Ministry of Agricultural and rural development	**SOCIALIST REPUBLIC OF VIET NAM** **Independence - Freedom – Happiness**

Hanoi, DD/MM/YYYY

INFORMATION ON THE VALIDITY OF DOSSIER FOR ISSUING THE CERTIFICATE OF GM PLANTS FOR FOOD, FEED USE

1. Applicant's information

Name of Applicant:

Applicant's representative:

Applicant's contact point:

Address:

Tel: Fax:

Email:

2. Information of the GMP

Name of GMP:

Common name:

Scientific name:

Trade name:

Gene transfer event:

Introduced trait related to the transformed gene:

The only identified code (if yes):

3. Date of receiving dossier

4. Time for appraisal from … to…

Order	*List of content*	*Legal basis for evaluation*	*Result of reviewing (past/not past)*	*Require supplement*

5. Supplement's content (note for each document):

6. Evaluation and recommendation:

Reviewer **Ministry of Agricultural and rural development**

Annex 6. Certificate form for genetically modified plant which is met the equirement to be used as food, feed

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

Ministry of Agricultural and rural development

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom – Happiness

CERTIFICATE

(enclosed the Decision Nr…../QD – BNNPTNT dated on…… signed by MARD Minister)

1. Genetically modified plants which meets the requirements to be used as food, feed :

Common name:

Scientific name:

Trade name:

Gene transfer event:

The unique identified code:

2. Organization, individual who is granted the Certificate:

Name of the Organization, individual:

Address:

Tel: Fax:

3. Organization/individual who is granted the Certificate of genetically modified plant can be used as food, feed shall have the responsible to operate the following requirement:

-

-

Hanoi, DD/MM/YYYY

ON THE BEHALF OF MINISTER

Annex 7. Evaluation form for dossier assessment of Committee members and expert reviewer

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

MINISTRY OF AGRICULTURAL AND RURAL DEVELOPMENT

FOOD, FEED SAFETY COMMITTEE

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom – Happiness

Hanoi, date… month… year…

EVALUATION FORM OF COMMITTEE MEMBERS/ EXPERT

I. General information

1. Name of Applicant:
2. Name of GM plants

Common name:

Scientific name:

Trade name:

Gene transfer event:

The only identified code (if yes)

3. Dossier code:

II. Information about the Committee or STRP's member:

1. Full name *(with title, educated):*
2. Organization
3. Position:

a) Member ☐

b) Reviewer member ☐

c) Independent expert ☐

III. Content of evaluation (Committee member shall give the summary evaluation on the content of risk assessment report and conclude of each)

1. Dossier assessment (the fullness of dossier, the content according to Circular number ../201 BNN&PTNT of the Minister of Ministry of agricultural and rural development on approval process of genetically modified plant can be used as food, feed)

2. Assessment on the report of risk assessment and other related references

a. Information related to host and donor organism.

b. Information on the gene transfer process

- Method of transformation

- Transfer gene's function and regulation
- Gene expression in the GM plant
- Insert stability across generations and inheritance of trait
- Conclusion

c. General information about the safety

- History of use (host and donor organism)
- The new protein's characteristics
- New protein expression via molecular analysis (Western blot, ELISA)
- Impact to human and animal health in case the new genetic material can transfer to human, animal's digestion system.
- Conclusion

d. Related information about the possibility to be toxic

- Amount of toxicant naturally in the GM products
- Potential toxicity of the new protein
- Potential allergy of the new protein
- Conclusion

e. Related information about the nutrition

- Analysis of the composition: clearly describe the method of sample collection, method of analysis, statistic analysis, model of experiments in some countries on the main composition.
- Feeding experiment with the new protein which is the new gene's expression on the animals.
- Conclusion

f. Proposed plan for risk management for the genetically modified plant to human and animal health (if it happened)

IV. Conclusion and recommendation

1. Conclusion (accordance to the evidence references, scientific information to confirm or not to confirm the genetically modified plant ... is as safe as conventional counter part)

a. Approval without edition, addition

b. Approval with the condition of edition, addition

(clearly provide the content of edition/ addition)

c. Unapproval

2. Recommendation

(recommend Ministry of Agricultural and Rural development to issue/not to issue the Certificate ….of meeting requirement to be used as food, conditions in order to issue the Certificate (if yes)

Reviewer

(Signature with the full name)

Annex 8: Evaluation form for dossier assessment which apply to issue the Food, feed safety certificate

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

MINISTRY OF AGRICULTURAL AND RURAL DEVELOPMENT

FOOD, FEED SAFETY COMMITTEE

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom – Happiness

FORM FOR ASSESSMENT OF A FOOD, FEED SAFETY CERTIFICATE APPLICATION DOSSIER

Reviewing member: ☐

Member: ☐

I. General information

1. Name of Applicant:
2. Name of GM plants

Common name:

Scientific name:

Trade name:

Gene transfer event:

The only identified code (if yes)

3. Dossier code:

II. Information about the Committee member:

1. Full name *(with title, educated):*
2. Organization:
3. Position:

III. Conclusion and recommendation

1. Conclusion

a) Approval without edition, addition ☐

b) Approval with the condition of edition, addition (*clearly provide the content of edition/ addition*) ☐

c) Unapproval ☐

2. Recommendation

a) Recommend to issue the Certificate

b) Recommend not to issue the Certificate

3. Other recommendation:

…….

Committee member

(signature with full name)

Annex 9. Report form of counting vote from Food, feed safety Committee

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

MINISTRY OF AGRICULTURAL AND RURAL DEVELOPMENT	**SOCIALIST REPUBLIC OF VIET NAM**
FOOD, FEED SAFETY COMMITTEE	**Independence - Freedom – Happiness**
	Hanoi, date… month… year…

Report of the counting vote from Food, feed safety Committee

I. General information

1. Name of Applicant:
2. Name of GM plants

Common name:

Scientific name:

Trade name:

Gene transfer event:

The only identified code (if yes)

3. Gene transfer trait:
4. Place and time of Committee:
5. Number of the present members on the total number of members
   - Number of the out-going votes
   - Number of the receiving votes
   - Number of the valid votes
   - Number of the un-valid votes
6. Result of the votes:
   - Number of the approval votes without edition or addition
   - Number of the approval votes with edition or addition
   - Number of un-approval votes

II. Conclusion:

……..

Hanoi, date month year

Member of the Vote counting committee **Chair Member**

Member No 1

Member No 2

Unoffical Translation

Annex 10. Minutes of Meetings of the Food, feed Safety Committee

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

MINISTRY OF AGRICULTURAL AND RURAL DEVELOPMENT	**SOCIALIST REPUBLIC OF VIET NAM**
FOOD, FEED SAFETY COMMITTEE	**Independence - Freedom – Happiness**
	Hanoi, date… month… year…

MINUTES OF MEETINGS OF THE FOOD, FEED SAFETY COMMITTEE

I. General information

1. Name of Applicant:
2. Name of GM plants

Common name:

Scientific name:

Trade name:

Gene transfer event:

The only identified code (if yes)

3. Gene transfer trait:

4. Decision of forming Food, feed safety Committee (if yes): Number /QD – BNNPTNT date month year from the Minister of MARD on the forming Food, feed safety Committee.

II. Preparation meeting:

1. Place and date of the meeting:
2. Number of the presence members on the total of Committee's members. Absent …. People, who are:

…..

….

3. Inviting guess attend the meeting

Order Full name Organization

……..

……..

……..

4. Content of the meeting

- The Committee has already discussed, unify to assign tasks for members and recommend MARD to invite independent reviewer (if yes) to review,

assess the apply dossier with the following list:

-

Order	Full name of the independent reviewer	Note (reviewer can be Committee member or not being a committee member)
1		
2		
3		
4		

- The Committee unify to assign:
  Mr/Ms: …….to be the Secretary member of the Committee
  The vote counting committee included: - Chairman
  - Member
- Committee has been discussed thoroughly to understand the rule, process and criteria to assess the dossier according to the regulation.
- Committee member receive the dossier and the evaluation sheet
- Committee identifies to have the official meeting on date…..month ….. year

III. The official meeting

1. Place, date of the meeting
2. Number of the presence members on the total of Committee's members. Absent …. People, who are:

…..

….

3. Inviting guess attend the meeting

Order Full name Organization

…….

…….

…….

4. Content of the meeting
   - The Committee has already exchanged, discussed and assessed the dossier according to the criteria which are stipulated in the Circular …. /TT BNNPTNT dated on …. Of the Minister of MARD on approval process to issue, and revoke of the Certificate for food, feed derived from genetically modified plants meet the requirement to be used as food, feed .
   - The Committee has voted secretly to assess the dossier

   The voting result of the dossier shall be presented in the attached report of

counting vote

IV. Committee's Conclusion

Result of voting

- Number of vote to approve the dossier without edition and/ or addition
- Number of vote to approve the dossier with edition and/or addition
- Number of vote not to approve the dossier
- Number of vote recommend to issue the Certificate
- Number of vote recommend not to issue the Certificate

V. Committee's recommendation

According to the assessment evaluation and the result of voting, genetically modified Food, feed safety Committee recommend MARD to issue (or not to issue) the Certificate for the genetically modified plant to be used as food, feed for the organization /individual:

Recommend the condition in order to issue the Certificate for the applicant (if yes)

VI. The content shall be provided additional information

VII. Other consideration shall pay attention when completing the dossier (if yes):

……
……
……

Secretary	**Chairman**
(Full name and signature)	**(Full name and signature)**

MARD confirmation

Annex 11: Form of assessment report for the Dossier of the genetically modified food, feed safety committee

(promulgated with Circular number /TT-BNNPTNT dated on - Minister of MARD)

MINISTRY OF AGRICULTURAL AND RURAL DEVELOPMENT	**SOCIALIST REPUBLIC OF VIET NAM**
FOOD, FEED SAFETY COMMITTEE	**Independence - Freedom – Happiness**
	Hanoi, date… month… year…

FOOD, FEED SAFETY COMMITTEE'S ASSESSMENT REPORT ON THE DOSSIER APPLY FOR ISSUANCE CERTIFICATE FOR THE GENETICALLY MODIFIED PLANT MEET THE REQUIREMENT TO BE USED AS FOOD, FEED

I. Summarize and conclusion

1. Information on the gene transfer even and the change of genetically:

- Briefly describe the transformation event and the other related information in the dossier

- Indicate the general safety issue.

2. Information related to the used of the toxicity in food, feed

- Briefly describe about the new protein of the transferred gene in the host organism and the process of …. And metabolite which can form the toxicant

3. Information about the nutrition

- Briefly describe about the nutrition composition in different parts of the genetically modified plant, based on the comparison with the conventional counter part.

4. Conclustion

- According to the evidence references, scientific information to conclude/confirm the transgenic event …. Is as safe as conventional counterpart

II. Assessment report

1. Dossier assessment (the fullness of dossier, the content according to Circular number ../201 BNN&PTNT of the Minister of Ministry of agricultural and rural development on approval process of genetically modified plant can be used as food, feed)

2. Assessment on the report of risk assessment and other related references

2.1. Information related to host and donor organism.

2.2. Information on the gene transfer process

- Method of transformation

- Transfer gene's function and regulation

- Gene expression in the GM plant

- insert stability across generations and inheritance of trait

- Conclusion

2.3. General information about the safety

- History of use (host and donor organism)

- The new protein's characteristics

- New protein expression via molecular analysis (Western blot, ELISA)

- Impact to human and animal health in case the new genetic material can transfer to human and animal's digestion system.

- Conclusion

2.4. Related information about the possibility to be toxic

- Amount of toxicant naturally in the GM products

- Potential toxicity of the new protein

- Potential allergy of the new protein

- Conclusion

2.5. Related information about the nutrition

- Analysis of the composition: clearly describe the method of sample collection, method of analysis, statistic analysis, model of experiments in some countries on the main composition.

- Feeding experiment with the new protein which is the new gene's expression on the animals.

- Conclusion

2.6. Proposed plans for risk management

3. Summarize and draft for response to public comment

III. Conclusion and recommendation

1. Conclusion (*accordance to the evidence references, scientific information to confirm or not to confirm the genetically modified plant ... is as safe as conventional counter part***)**

2. Recommendation

(recommend Ministry of Agricultural and Rural development to issue/not to issue the Certificate ….of meeting requirement to be used as food, conditions in order to issue the Certificate (if yes)

Committee's Secretary	**Committee's Chairman**
(sign and full name)	**(sign and full name)**