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Hanoi, DD, MM, 2013

Draft

Unofficial translation

CIRCULAR ON

**APPROVAL PROCESS OF ISSUING AND REVOCATION OF THE
CERTIFICATE FOR GENETICALLY MODIFIED PLANTS
TO BE USED AS FOOD, FEED**

Pursuant to the decree No. 1/2008/ND-CP of Jan 3, 2008 of government stipulate for function, authority, mission and structural organization of Ministry of Agriculture and Rural Development (MARD);

Pursuant to the decree 69/2010/ND-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/ND-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/ND-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

1. 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 .

2. Genetically modified crop, which carries stack genes of which derived from conventional breeding of more than one approved events is not under the scope of this Circular.

Article 2. Subject of applications

1. 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.

2. The Certificate shall be considered to issue with the following conditions:

a) 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.

b) 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 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. *Certificate of genetically modified plant and products from genetically modified plant eligible for use as food, feed* (hereinafter referred to as the Certificate) is a document of the Ministry of Agriculture and Rural Development allows genetically modified plant and it's products eligible for use as food, feed ,

3. *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 .

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

5. *Genetically modified food, feed* means food, feed in which contain whole or partly of the material derived from genetically modified plant.

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

7. *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 from CODEX Alimentarius, which includes:

1. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003).

2. Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003).

CHAPTER II

ISSUING AND REVOCATION OF CERTIFICATE

Article 5. Order and process of the issuance and revocation of the Certificate

1. Application of the Certificate shall follow the stipulation in Article 6 of this Circular.
2. Receiving, reviewing of the dossier and issue the Certificate shall follow the stipulation in Article 7 and 8 in this Circular.
3. The Certificate is revoked if violated the regulation in Article 09 of this Circular.
4. MARD is responsible for the issuance and revocation of food, feed safety Certificate based on the decision of the Genetically modified food, feed safety Committee (follow is referred as Committee).

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. Genetically modified plant is concluded by the Food, feed safety Committee that there is none uncontrollable risk to human and animal health; or
2. 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.

Article 7. Application documents

1. Organizations, 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 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 Article 6.2, the dossier is stipulated in Clause 1 of this Article, it do not need to have the references related to the risk assessment report (Clause 1c of this Article)

3. In the case of the transgenic event, which is stipulated according to part b, Article 2.2 of this Circular, beside the stipulation in part 1 of this Article, the dossier

shall provide additional information 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 60 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. The Certificate is valid in 5 years.

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/ND-CP on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms.

2. Ministry of Agricultural and Rural Development shall:

a) Organizing Food, feed safety Committee to appraise the dossier, decision to revoke the Certificate.

b) Notify 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.

c) Delete the name of the genetically modified plants event out of the List of certified within 10 working days, after the date of revocation of food, feed certificate.

3. Genetically modified plant shall not be used as food, feed since the date of revocation of the food, feed certificate.

4. Revocation process of a certificate shall be considered by MARD with case by case basis.

CHAPTER III

FOOD, FEED SAFETY COMMITTEE STRUCTURE AND OPERATIONS

Article 11. 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 nine (09) 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 two (02) 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. 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.

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

5. 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.

6. The FFSC may request MARD for calling additional meeting (if necessary) beside the two meetings mentioned above and other related activities in order to directly assist the appraisal.

7. 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.

8. 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 13. 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 14. Responsible of authority organization

Ministry of Agricultural and Rural Development appoints one (01) authority organization under the MARD as a focal body to organize and manage related activities as following:

1. Receive and review the submission dossier for applying to issue, revoke the certificate of genetically modified plant to be used food, feed;

2. Organize the FFSC to appraise the Food, feed dossiers application for registration for issuance of certificate of genetically modified plant to be used as food, feed according to this Circular and submit FFSC report to the Minister of MARD;

3. Collect and use the fee in accordance with stipulated in the current regulations;

4. Establish a list of genetically modified plants, which have been issued a certificate for use as food, feed. The information shall be posted on the website of MARD;

5. Add or delete the name of genetically modified plant in the list of the certified genetically modified plant which meet the requirement to be used as food, feed after the issuance or revocation of the certificate.

Article 15. Responsibility of applicant

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 16. Implementation provisions

1. This Circular takes effect from day month year.

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./.

Ministry of Agriculture and Rural development

Minister

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 trait 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

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...

| <i>Order</i> | <i>List of content</i> | <i>Legal basis for evaluation</i> | <i>Result of reviewing (past/not past)</i> | <i>Require supplement</i> |
|--------------|------------------------|---------------------------------------|--|-------------------------------|
| | | | | |
| | | | | |

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 requirement 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 SOCIALIST REPUBLIC OF VIET NAM
RURAL DEVELOPMENT Independence - Freedom – Happiness
FOOD, FEED SAFETY COMMITTEE**

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 **SOCIALIST REPUBLIC OF VIET NAM**
FOOD, FEED SAFETY COMMITTEE **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**
FOOD, FEED SAFETY COMMITTEE

SOCIALIST REPUBLIC OF VIET NAM
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

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
FOOD, FEED SAFETY COMMITTEE**

**SOCIALIST REPUBLIC OF VIET NAM
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 |
|-------|---------------------------------------|---|
| | | |

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
(Full name and signature)

Chairman
(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**
FOOD, FEED SAFETY COMMITTEE

SOCIALIST REPUBLIC OF VIET NAM
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. Conclusion

- 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 Certificateof meeting requirement to be used as food, conditions in order to issue the Certificate (if yes)

Committee's Secretary
(sign and full name)

Committee's Chairman
(sign and full name)