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MinAg Releases Biotech Feed and Food Approval Regulation

Report Categories:

Biotechnology - GE Plants and Animals

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Report Highlights:

On January 24, 2014, Ministry of Agriculture and Rural Development (MARD) Vice Minister Le Quoc Doanh signed Circular 2/2014/TT-BNNPTNT to promulgate the Approval Process of Issuing and Withdrawing Certification for Genetically Modified Plants for use as food and feed. Circular 2, outlining the approval process for agricultural biotechnology to be used as food and feed, is the last piece of regulation necessary for Vietnam to commercialize agricultural biotechnology. Circular 2 entered into force on March 10, 2014 and biotech developers have already submitted dossiers to MARD seeking food and feed approval for biotech traits.

Summary:

This report provides an unofficial translation of Vietnam Ministry of Agricultural and Rural Development's (MARD) Circular 2/2014/TT-BNNPTNT to promulgate the Approval Process of Issuing and Withdrawing Certification for Genetically Modified Plants (GM plants) to be Used as Food and Feed. The Circular was signed on January 24, 2014, and entered into force on March 10, 2014. As stated in the Circular, biotech developers have one year to complete the registration for biotech products currently exported to Vietnam.

The draft of the Circular was notified as **G/SPS/N/VNM/51** to the WTO Sanitary and Phytosanitary Committee on September 2, 2013. The U.S. Government and industry provided comments on the Draft.

MARD's Circular 2 implements some provisions on the management of genetically modified food, feed as stipulated in Government Decree 69/2010/ND-CP (see [VM2071](#)) and Decree 38/2012/ND-CP, dated April 25, 2012, promulgating the Implementing Regulation of the Food Safety Law (see [VM 3032](#)).

According to Circular 2, both GM plants carrying a single event or stacked events are regulated by the approval process outlined in Circular 2 and eligible for the Food and Feed Use Certificate.

As stipulated in the Circular, a GM Plant trait will be approved for use as food and feed if it meets one of the following **conditions**: 1) has been approved for use as food, feed in five developed countries; 2) the Food/Feed Safety Committee concludes that the GM plant does not contain uncontrolled risks to humans and/or the environment; 3) for other cases: GM crops can be automatically used as animal feed if it has been approved for use as food; and GM crops carrying stacked genes can be used as food/feed if the stacked genes consist of single events that are already approved for food/feed use.

Application for Food/Feed Safety Certificate: Organizations/individuals interested in applying for a GM Food/Feed Certificate can send the application dossier to:

Department of Science, Technology, and Environment (DSTE)
Ministry of Agriculture and Rural Development (MARD)
2 Ngoc Ha Street
Hanoi, Vietnam
Tel: (84-4)-38237534
Fax: (84-4)-38433637
Email: khcn@mard.gov.vn
<http://www.vnast.gov.vn/>

The documents required for an application dossier are described in Article 7 of the Circular. The dossier will be submitted in three copies (one original and two copies). Submission of the Food/Feed Certificates or Approval Letters issued by five developed countries must be translated into Vietnamese, and notarized.

The Circular also outlines the make-up and term of service for the MARD Committee for Safety of GM Food and Feed, established by the MARD Minister. The Committee consists of 11 members with a Chairman and Vice Chairman from MARD. Representatives from other Ministries, including Ministry of Health, Ministry of Natural Resources and Environment, Ministry of Science and

Technology, and Ministry of Industry and Trade will be committee members. The organization, activities, working procedures, responsibility, and authority of the Committee are stipulated in Article 12, 13, 14 and 15 of the Circular.

Application Processing and Approval Timeline: Seven (7) working days after receiving the Application, DSTE will notify the applicant whether the submitted dossier is complete, or if they have to provide additional information. For a completed dossier, DSTE will publish a summary of the Risk Assessment Report for the dossier on MARD's website: www.mard.gov.vn and seek public comment for 30 working days. After receipt of validated dossier, DSTE will request the GM Food/Feed Safety Committee to review the Application. The time to review the Application described in Item 1, Article 6 cannot exceed 30 working days. The overall review time for an individual dossier described in Item 2, Article 6 is 180 working days.

Within 30 working days of having the recommendation from the GM Food/Feed Safety Committee and DSTE, the MARD Minister will issue the Certificate for the Applicant. In the case MARD rejects the dossier, DSTE will send the Applicant a written notification indicating the reasons for not issuing the Certificate.

MARD/DSTE will publish a list of GM plants approved for food/feed use on MARD's website and update the list as additional approvals occur.

Post recommends interested individuals and groups consult with MARD/DSTE for verifying the accuracy of the information/application forms required before processing the application dossier for the Certificate for use as food and feed.

Below is an unofficial translation of the Circular:

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**MINISTRY OF AGRICULTURE
AND RURAL DEVELOPMENT**

SOCIALIST REPUBLIC OF VIET NAM
Independence – Liberty – Happiness

No: 2/2014/TT-BNNPTNT

Hanoi, January 24, 2014

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 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

This circular stipulates the approval process of genetically modified plants for direct use as food, feed and includes the procedures for issuing, renewing, 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 carry 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 the 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 a 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 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 derived from genetically modified crops

1. Comparing the difference in composition and nutrition between GM plant and the counterpart which is produced by conventional methods.
2. Assess the likelihood of the nutrient metabolites, especially, 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, etc.).

CHAPTER II

ISSUING AND REVOCATION OF CERTIFICATE

Article 5. Cases Requested for the Certificate Registration

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

Article 6. Conditions for issuing the 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 at least five (5) developed countries and has not posed any risk in those countries.
2. GM Plants have been concluded by the Food, Feed safety Committee (hereinafter referred to as the Committee) to not have uncontrolled risks to human and animal health.
3. Other cases:
 - a. Genetically modified crops that are a granted certificate for direct use as food can be used as animal feed.
 - b. Genetically modified crops, which carry stack genes derived from conventional breeding can be used as food, feed automatically if all single events comprising the stack have been approved.

Article 7. Application documents

1. Organizations, individuals applying for the Food, Feed Safety Certificate shall submit to MARD three (3) sets of the dossier (one original and two copies).
2. For the case of Article 6.1 of the Circular, the dossier includes:
 - a) Application Form (Annex 1);
 - b) Risk assessment report of the genetically modified plant (here referred as the risk assessment report) to human and animal health according to Annex 2 in this Circular, (including an electronic file version);
 - c) The references, new data not yet published, and data from assessments, trials or other scientific evidence which the applicant has used to conclude that the genetically modified crop does not pose any adverse effect to human and animal health if the Food, Feed safety Certificate is issued.
 - d) Summary report of risk assessment (Annex 3) (including an electronic file version);
 - e) Public comments (Annex 4).
 - f) Original or notarized copies and Vietnamese translation of the certificates or approval letters, or equivalent documents which were issued by authorities indicating the products have been approved for food/feed use in at least five developed countries.
3. In the case of Article 6.2, the dossier includes:
 - a) Documents prescribed in Point a, b, c, d, Clause 2 of this Article;

- b) The original or certified copy and Vietnamese translation (with notarized translation) of the Certificate or equivalent document issued by the second country's competent authority for use as food, feed in that country (if any);
- c) The reference scientific documents, unpublished studies, data from the evaluation, testing, or other scientific evidence (if available) used by registered organizations and individuals as the basis for conclusions that the GM Plant granted the certificate has no negative impact on the health of humans and animals.

4. In case the registration for Certificate for the object specified in Clause 2 of Article 5 of this Circular, the dossier includes:

- a) The documents specified in Clause 2 of this article (in case of registration for Certificate for the object specified in Clause 1, Article 6 of this Circular);
- b) The documents specified in Clause 3 of this Article (in case of registration for Certificate for the object specified in Clause 2 of Article 6 of the Circular);
- c) The additional data for the risk assessment report on the interaction of the transgene in the structure, properties preserving the integrity of the structure, function and gene expression of the target gene in the receiving plants.

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

1. Applicant, who registers for the issuance a certificate of genetically modified plant to be used as food, feed shall send the dossier directly or via post according to Ministry of Agricultural and Rural Development (Department of Science, Technology and Environment (DSTE)).

2. The DSTE/MARD shall review and inform the applicant in writing about the acceptance or requirement for additional information (Annex 5) within seven (7) working days from the date of dossier receipt. Time for applicant to correct or to provide more information in the application is not added to the evaluation time of application.

3. After receiving a complete dossier, DSTE/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 comment, prepare a report, and send the dossier to the Committee for further consideration. The maximum time for public comment is 30 days from the date the information is published on MARD's website.

4. After receiving validated application, within 30 days and 180 days for the cases described in Article 6.1 and Article 6.2 respectively, DSTE/MARD shall organize a Food, Feed Safety Committee meeting (hereinafter referred to as FFSC) to evaluate the application.

Article 9. Issuing the Certificate

1. Based on the finding results from the Committee, DSTE/MARD shall submit a proposal to MARD's Minister for reviewing and decision on issuance of the Certificate for the applied organization, individual.

2. If the registered dossier meets the requirements for the Certificate, the Minister of Agriculture and Rural Development shall grant the Certificate (in the form prescribed in Annex 6 of this Circular) within 30 (thirty) days from the date of receiving the evaluation results from the Committee.

3. If the registration dossier is not eligible for the Certificate issuance, DTSE/MARD shall send the registered organization, individual a written notification indicating the reasons for not issuing the Certificate.

Article 10. Revocation of Certificate

1. A Certificate is revoked under the circumstances stipulated in Article 29.1 and Article 34.1 of Decree 69/2010/ND-CP dated June 21, 2010 on Biosafety of Genetically Modified Organisms, Genetic Specimen, and Products Derived from Genetically Modified Organisms.

2. Depending on each case, the Ministry of Agriculture and Rural Development shall:

a) Organize the Food, Feed Safety Committee to appraise the dossier and issue the decision to revoke the Certificate of cases specified at Point a, Point b of the Article 29.1; and Point b of Article 34.1 of the Decree 69/2010/ND-CP.

b) For the case specified at Point c, Article 29.1 and Point c, Article 34.1 of Decree 69/2010/ND-CP, DSTE shall request MARD for consideration and decision.

3. The DSTE/MARD shall do the following tasks:

a) To organize meetings of Independent Advisory Board (in the case of violations prescribed in Point c, Article 29.1 and Point c, Article 34.1 of Decree 69/2010/ND-CP) for the appraisal of documents of violating cases;

b) Based on the evaluation results of the Board, submit a request to Minister of Agriculture and Rural Development for consideration and decision on revoking the Certificate;

c) To notify the public and relevant agencies within 3 days counting from the day of the revoking decision is issued; and to send the original revoking decision to the organization, individual having the Certificate revoked.

Article 11. Developing the list of GM Plants approved, removed for use as food, feed

The Department of Science, Technology and Environment shall:

1. Establish and publish on MARD's website the list of GM plants certified for use as food, feed.

2. Add to the list and publish on MARD's website GM plants newly certificated for use as food, feed within 10 (ten) days from the date of the Certificate granted.

3. Remove names and publish on MARD's website GM plants that have the Certificate revoked within 10 (ten) days from the date of the Certificate revoked.

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 to advise MARD's Minister for issuance and revocation of Food, Feed Safety Certificate.

2. The FFSC shall be composed of eleven (11) members including the Chairman, Vice-Chairman, representatives of MARD, four (4) representatives of the Ministry of Industry and Trade, Ministry of Science and Technology, Ministry of Natural Resources and Environment, and Ministry of Health and some scientists with expertise in a related field. The term of the FFSC is three (3) 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. Committee's operation is based on the following principles: democracy, objectivity; self-responsible for the scientific, accuracy of the comments, independent evaluation and collective responsibility of the general conclusions by the Council.
2. Official meeting of the Committee shall be organized only when there is presence of at least two third's of the members under the Chairman's moderation (or under Vice-Chairman in case the Chairman is absent).
3. In addition to the general conditions specified in Clause 1 and 2 of this Article, the second meeting of the Committee shall only be conducted when there is presence of Council's Secretary, Administrative Secretary; 2 committee reviewers, written comments provided by independent reviewers, if any.
4. In case of necessity, the Committee might request the Competent Agency to invite the registering organizations, and individuals to attend the meeting for providing additional information, answering questions asked by Committee's members or by the public.

Article 14. Contents and procedure of the Committee's meeting

1. The first meeting:

a) Administrative Secretary (a representative of the Competent Authority under MARD) shall introduce the members of meeting, give opening remarks, and provide the conclusion of the validity of Application dossier;

b) Chairman of the Committee moderates the meeting, assigns one (1) Committee Secretary and two commentary members. Where necessary, the Committee may recommend additional 2-3 independent peer reviewers as scientists having experience in the related field;

c) The Committee shall appoint the counting vote division, including (3) Committee Members, in which one (1) is named the leader of the division.

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

2. The second meeting:

a) Administrative Secretary shall announce the summary of the public comments on the application dossier and the report from independent experts as described in the Appendix 7 of this Circular (if any);

b) The Committee's members provide comments on the application dossiers as described in Annex 7 of this Circular;

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

d) The Committee shall vote on the dossier according to Annex 8;

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

f) A dossier meets the requirement for approval if at least three fourths (3/4) of the members in the official meeting vote to recommend the dossier as "meeting requirements";

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

3. In addition to the above mentioned two meetings, the Committee may recommend the Minister of Agriculture and Rural Development organize unscheduled meetings and other activities for providing direct support for reviewing dossiers.

4. Based on the minutes of the meetings, the Committee Secretary shall complete the summary report on assessment of each dossier and advise the Minister of Agriculture and Rural Development for consideration of granting certificate (in the form prescribed in Annex 11 of this Circular).

5. In case of the certificate withdrawal, the Committee shall consider each case based on documents and advice 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 application dossier and related documents provided by MARD.

2. Fully participate in FFSC meetings during the application review and submit a written report.

3. To ensure accidental 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 is 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 the actual in force regulation.

CHAPTER IV IMPLEMENTING

Article 16. Responsibility of the Department of Science, Technology and Environment

1. To chair, coordinate with related agencies, organizations to implement this Circular.

2. Coordinate with relevant agencies to collect and use fee for evaluation of dossiers in accordance with the current legislation.

3. To prepare report on situation of MARD's issuance/revocation of Food, Feed Certificate as stipulated by regulations.

Article 17. Responsibility of the applicant

1. Applicant shall pay all the fees according to the regulation. The appraisal fee will not be reimbursed in case of the dossier does 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 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. Within one (1) year from the effective date of the Circular, events of genetically modified plants must be registered for the Certificate before continuing to be allowed for use as food, feed in Vietnam.

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

Vice Minister

(signed)

Le Quoc Doanh

Annex 1: Application Form for issuing the Certificate

(promulgated with Circular 2/2014/TT-BNNPTNT dated January 24, 2014)

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 2/2014/TTBNNPTNT, released January 24, 2014... 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 (1 original document and 2 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 2/2014/TT-BNNPTNT dated January 24, 2014)

Applicant **SOCIALIST REPUBLIC OF VIET NAM**
Independence - Freedom – Happiness
ANIMAL HEALTH

**REPORT ON RISK
ASSESSMENT OF GM
PLANTS TO HUMAN AND**

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. Full 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 cannot 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 2/2014/TT-BNNPTNT dated January 24, 2014)

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 2/2014/TT-BNNPTNT dated January 24, 2014)

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 Agriculture 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 2/2014/TT-BNNPTNT dated January 24, 2014)

Ministry of Agriculture 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 Agriculture and Rural Development**

**Annex 6. Certificate Form for Genetically Modified Plant which Meets the Requirement to be
Used as Food, Feed**

Ministry of Agriculture and SOCIALIST REPUBLIC OF VIET NAM
Rural Development 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 Reviewers
(promulgated with Circular 2/2014/TT-BNNPTNT dated January 24, 2014)

**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 2/2014 BNNPTNT of the Minister of Ministry of Agriculture 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 counterpart)

- a. Approval without edition, addition
- b. Approval with the condition of edition, addition
(clearly provide the content of edition/ addition)
- c. Rejected

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 2/2014/TT-BNNPTNT dated January 24, 2014)

**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) Rejected

☐

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 2/2014/TT-BNNPTNT dated January 24, 2014)

**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 2/2014/TT-BNNPTNT dated January 24, 2014)

**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 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
 (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 2/2014/TT-BNNPTNT dated January 24, 2014)

**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 counterpart.

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 2/2014/BNNPTNT of the Minister of Ministry of Agriculture 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 counterpart*)

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)