

**MINISTRY OF  
AGRICULTURE AND  
RURAL DEVELOPMENT**

**SOCIALIST REPUBLIC OF VIETNAM**  
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Number: 02/2014/TT-  
BNNPTTN

*Hanoi, January 24, 2014*

**CIRCULARS**

**REGULATIONS ON ORDER AND PROCEDURES FOR ISSUANCE AND REVOKING  
CERTIFICATION OF GENETICALLY MODIFIED PLANTS ELIGIBLE FOR USE AS  
FOOD AND ANIMAL FEED**

*Pursuant to Decree No. 199/2013/ND-CP dated November 26, 2013 of the Government regulating the functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development;*

*Pursuant to Decree No. 69/2010/ND-CP dated June 21, 2010 of the Government on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms;*

*Pursuant to Decree No. 108/2011/ND-CP dated November 30, 2011 of the Government amending a number of articles of Decree No. 69/2010/ND-CP on biosafety for genetically modified organisms, samples genetic material and products of genetically modified organisms;*

*Pursuant to Decree No. 38/2012/ND-CP dated April 25, 2012 of the Government detailing the implementation of a number of articles of the Law on Food Safety ;*

*At the request of the Director of the Department of Science, Technology and Environment;*

*The Minister of Agriculture and Rural Development promulgates a Circular stipulating the order and procedures for granting and revoking Certificates of genetically modified plants eligible for use as food and animal feed.*

**Chapter I**

**GENERAL RULES**

**Article 1. Scope**

This Circular regulates the order and procedures for granting and revoking Certificates of genetically modified plants eligible for use as food and animal feed.

**Article 2. Subjects of application**

This Circular applies to domestic and foreign organizations and individuals (hereinafter referred to as organizations). organizations and individuals) with activities related to the issuance and revocation of Certificates of genetically modified plants eligible for use as food and animal feed (hereinafter referred to as Certificates) in the territory Vietnam.

**Article 3. Explanation of terms**

In this Circular, the following terms are understood as follows:

1. *Genetically modified plants* are plants, genetic specimens, direct products of plants that carry one or more new genes created by recombinant DNA technology.
2. *Risk assessment of genetically modified plants to human and animal health* (hereinafter referred to as risk assessment) are activities aimed at determining potential risks and the likelihood of risks occurring, of genetically modified plants when used as food and animal feed.
3. *A gene transfer event* is the result of recombination of target DNA into a certain position in the genome of a plant species to create a corresponding plant carrying the target gene.
4. *Developed country* is a country with advanced biotechnology in the group of countries belonging to the Organization for Economic Cooperation and Development - OECD and the group of countries with large economies G20.
5. *The unique identification code* is the code determined by the Organization for Economic Cooperation and Development for each gene transfer event.

#### **Article 4. Risk assessment criteria for genetically modified plants eligible for use as food and animal feed**

1. Comparison of nutritional composition of genetically modified plants with equivalent traditional plants.
2. Evaluate the ability to metabolize nutritional components, especially new substances that are expression products of transgenes if used as food or animal feed.
3. Assess the toxic potential of new substances that are expression products of transgenes if used as food or animal feed.
4. Assess the allergenic potential of new substances that are expression products of transgenes if used as food or animal feed.
5. Assess the potential for formation of new compounds, pathogenicity, or other adverse effects on human and animal health (e.g., potential effects from processing; changes in nutritional quality and nutritional function; accumulation of new substances; antibiotic resistance genes).

## **chapter II**

### **ISSUANCE AND REVOKING OF CONFIRMATION**

#### **Article 5. Cases requiring registration for issuance of Certificate**

1. Genetically modified plants carry a single transformation event, which is the result of transferring a gene regulating a desired trait using gene transfer technology.
2. Genetically modified plants carrying a vector stacked transformation event are the result of the transfer of two or more genes regulating one or more desired traits using gene transfer technology.

#### **Article 6. Conditions for issuance of Certificate**

Genetically modified plants to be granted a Certificate must meet one of the following conditions:

1. Genetically modified plants are allowed to be used as food and animal feed by at least 5 (five) developed countries and no risks have occurred in those countries.
2. Genetically modified plants are assessed by the Council for Food and Animal Feed Safety (hereinafter referred to as the Council) in the application dossier to issue a Certificate certifying that genetically modified plants are eligible for use as food, food, animal feed and concluded that genetically modified plants do not pose uncontrolled risks to the health of humans and animals.
3. Other cases.
  - a) In case the genetically modified plant has been granted a Certificate of eligibility for use as food, the genetically modified plant is used as animal feed;
  - b) In case a plant carries a combined gene transfer event that is the result of a convergent hybridization process using traditional breeding methods from two or more single gene transfer events that have been granted a Certificate, then that plant is used as food and animal feed.

#### **Article 7. Application dossier for issuance of Certificate**

1. Number of documents: 03 (three) sets, including 01 (one) original and 02 (two) copies.
2. In case of applying for a Certificate of Confirmation for the subjects specified in Clause 1, Article 6 of this Circular , the dossier includes:
  - a) Application for issuance of Certificate according to the form specified in Appendix 1 of this Circular;
  - b) Risk assessment report (attached electronically) of genetically modified plants to human and livestock health (hereinafter referred to as risk assessment report) according to the form specified in the Appendix 2 of this Circular;
  - c) Summary of risk assessment report according to the form specified in Appendix 3 of this Circular (attached with electronic copy);
  - d) Information declaration posted for public comments according to the form specified in Appendix 4 of this Circular;
  - d) Original or certified copy and Vietnamese translation (with notarized translation) of certification or equivalent document from a competent authority permitting use as food or animal feed in at least 5 developed countries.
3. In case of applying for a Certificate of Confirmation for the subjects specified in Clause 2, Article 6 of this Circular , the dossier includes:
  - a) Documents specified in Points a, b, c, d, Clause 2 of this Article;
  - b) Original or certified copy and Vietnamese translation (with notarized translation) of certification or equivalent document from a competent authority permitting use as food and animal feed in foreign countries. other family (if any);
  - c) Reference scientific documents, unpublished studies, data from assessments, tests, or other scientific evidence (if any) that organizations and individuals register to use as a basis. It is concluded that genetically modified plants, if granted a Certificate, do not cause adverse effects on the health of humans and animals.

4. In case of applying for a Certificate of Confirmation for the subjects specified in Clause 2, Article 5 of this Circular , the dossier includes:

- a) Documents specified in Clause 2 of this Article (in case of registration for issuance of Certificate to subjects specified in Clause 1, Article 6 of this Circular );
- b) Documents specified in Clause 3 of this Article (in case of registration for issuance of Certificate to subjects specified in Clause 2, Article 6 of this Circular );
- c) Additional data of the risk assessment report on the interaction of transgenes in the structure, integrity conservation of structure, function and expression of the target gene in the recipient plant.

#### **Article 8. Receiving and evaluating application documents for issuance of Certification**

1. Organizations and individuals applying for a Certificate of Confirmation shall send their documents directly or by post to the standing agency of the Ministry of Agriculture and Rural Development (Department of Science, Technology and Environment).
2. The Department of Science, Technology and Environment reviews the dossier and notifies in writing (according to the form specified in Appendix 5 of this Circular) to the registered organization or individual within 07 (seven) days. working days from the date of receipt of the dossier accepting the valid dossier or requesting additional or completing the dossier. The time to supplement and complete the dossier is not included in the time to review valid dossiers.
3. After receiving a valid application, the Department of Science, Technology and Environment posts information and a summary of the risk assessment report on the website of the Ministry of Agriculture and Rural Development for review. public opinion; summarize and send to the Council. The maximum public comment period is 30 (thirty) days from the date the information is posted.
4. After receiving valid dossiers, the Department of Science, Technology and Environment organizes a Council to evaluate the application for issuance of a Certificate within 30 (thirty) days for registration dossiers under Clause 1, Article 6 of this Circular and 180 (one hundred and eighty) days for registration documents according to Clause 2, Article 6 of this Circular .

#### **Article 9. Issuance of Certification**

Based on the appraisal results of the Council, Department of Science, Technology and Environment submits to the Minister of Agriculture and Rural Development for consideration and decision to issue a Certificate of Certification to registered organizations and individuals.

2. In case the registration dossier meets the conditions for issuance of a Certificate, the Minister of Agriculture and Rural Development shall issue a decision to issue a Certificate (according to the form specified in Appendix 6 of this Circular) within the time limit. within 30 (thirty) days from the date of the Council's appraisal results.
3. In case the registration dossier does not meet the conditions for issuance of a Certificate, the Department of Science, Technology and Environment shall issue a written notice and clearly state the reason to the registering organization or individual.

#### **Article 10. Revocation of Certification**

1. The certificate is considered revoked in the cases specified in Clause 1, Article 29 and Clause 1, Article 34 of Decree 69/2010/ND-CP dated June 21, 2010 of the Government on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms (referred to as Decree 69/2010/ND-CP ).

2. Based on each specific case, the Ministry of Agriculture and Rural Development shall consider and decide to revoke the Certificate.

a) For the cases specified in Points a and b, Clause 1, Article 29 and Points a and b, Clause 1, Article 34 of Decree 69/2010/ND-CP, the Ministry of Agriculture and Rural Development organizes a Conference contract to appraise the dossier and consider revoking the Certificate;

b) For the cases specified in Point c, Clause 1, Article 29 and Point c, Clause 1, Article 34 of Decree 69/2010/ND-CP , the Department of Science, Technology and Environment shall submit to the Minister of Agriculture and Rural Development. Rural development considers and decides.

3. The Department of Science, Technology and Environment performs the following tasks:

a) Organize meetings of the Council or independent advisory council (in case of violations according to the provisions of Point c, Clause 1, Article 29 and Point c, Clause 1, Article 34 of Decree 69/2010/ND-CP ) Evaluate documents on revocation of Certificates for violations;

b) Based on the Council's appraisal results, submit to the Minister of Agriculture and Rural Development for consideration and decision to revoke the Certification;

c) Announce on the mass media and relevant agencies within no more than 03 (three) days from the date of decision to revoke the Certificate, and send the Decision (original) to the organization. Organizations and individuals whose certifications have been revoked.

### **Article 11. Listing, adding and deleting names of genetically modified plants in the List of genetically modified plants issued with a Certificate**

The Department of Science, Technology and Environment performs the following tasks:

1. Prepare and publish on the website of the Ministry of Agriculture and Rural Development the List of genetically modified plants that have been granted a Certificate.

2. Supplement and publish on the website of the Ministry of Agriculture and Rural Development: genetically modified plants that have been granted a Certificate of eligibility for use in the List of genetically modified plants that have been granted a Certificate of eligibility for use. used as food or animal feed within 10 (ten) days from the date of the decision to issue the Certificate.

3. Delete names and announce on the website of the Ministry of Agriculture and Rural Development: genetically modified plants subject to violations in the List of genetically modified plants issued with a Certificate of eligibility used as food or animal feed within 10 (ten) days from the date of decision to revoke the Certificate.

## **Chapter III**

### **COUNCIL FOR FOOD SAFETY AND GENETICALLY MODIFIED ANIMAL FEED**

#### **Article 12. Organization of the Council**

1. The Council is an organization established by decision of the Minister of Agriculture and Rural Development to advise the Minister of Agriculture and Rural Development to consider granting and revoking Certificates.

2. The Council has 11 (eleven) members including the Chairman and Vice Chairman, who are representatives of the Ministry of Agriculture and Rural Development; 01 representative of the Ministry of Industry and Trade; 01 representative of the Ministry of Science and Technology; 01 representative of the Ministry of Natural Resources and Environment; 01 representative of the Ministry of Health and a number of experts in related fields. The term of the Council is 3 (three) years.

3. Funding for the Council's activities is carried out in accordance with current laws.

### **Article 13. Activities of the Council**

1. The Council works according to principles, democracy and objectivity; Take personal responsibility for the scientificity and accuracy of independent comments and assessments and collective responsibility for the Council's general conclusions.

2. The Council meeting must be attended by at least 2/3 of the members under the chairmanship of the Council Chairman or Vice Chairman (in case the Council Chairman is absent). The Council meets at least two sessions.

3. In addition to the general conditions specified in Clauses 1 and 2 of this Article, the second meeting of the Council may only be conducted when: the Council Secretary and the Administrative Secretary are present; 02 members commented; Written comments from independent reviewers (if any).

4. In case of necessity, the Council may request the standing agency to invite representatives of organizations and individuals to register to attend the meeting to provide additional information and answer questions from members. Council members or public comments.

### **Article 14. Content and order of Council meetings**

1. First session:

a) The administrative secretary (representative of the standing agency, Ministry of Agriculture and Rural Development) introduces the delegates, declares the reason for the meeting and reports briefly on the validity of the dossier;

b) The Chairman of the Council presides over the meeting, assigns 01 (one) Council Secretary and 02 (two) members to review the documents. If necessary, the Council may recommend adding 2-3 independent reviewers who are experienced scientists in related fields;

c) The Council elects a vote counting committee, consisting of 03 (three) members who are Council members, including 01 (one) Head of the committee;

d) The Council agrees on the time of the second meeting and the work plan.

2. Second session:

a) The administrative secretary reads a report summarizing public comments on the application for a Certificate of Certification and comments from independent reviewers according to the form specified in Appendix 7 of this Circular (if any). ;

b) Council members review the registration dossier according to the form specified in Appendix 7 of this Circular;

c) The Council exchanges and discusses the application file for issuance of a Certificate according to the requirements specified in this Circular;

- d) The Council votes to evaluate the registration dossier according to the form specified in Appendix 8 ;
  - d) The vote counting committee summarizes and reports the vote counting results according to the form specified in Appendix 9 of this Circular;
  - e) A satisfactory registration dossier is one that receives at least  $\frac{3}{4}$  (three-quarters) of the "satisfactory" votes of the Council members attending the meeting;
  - g) The Council discusses, concludes and recommends necessary additions and modifications to the contents stated in the dossier (if any) and approves the Minutes of the meeting as prescribed in Appendix 10 of the Notice. this private.
3. In addition to the two meetings mentioned above, the Council can propose to the Minister of Agriculture and Rural Development to organize extraordinary meetings and other activities to directly serve the appraisal work.
  4. Based on the minutes of the meeting sessions, the Council Secretary completes the summary report for each evaluation dossier and the concluding comments to advise the Minister of Agriculture and Rural Development on the consideration. issue a Certificate (according to the form specified in Appendix 11 of this Circular).
  5. In case of revocation of the Certificate, the Council meets to consider each specific case based on the dossier and advise the Minister of Agriculture and Rural Development on the revocation of the Certificate. .

#### **Article 15. Responsibilities and powers of Council members**

1. Research application dossiers for issuance and revocation of Certificate of genetically modified plants eligible for use as food and animal feed and related documents provided by the Ministry of Agriculture and Rural Development .
2. Fully participate in Council meetings during the application appraisal process; provide written comments according to the form prescribed in this Circular and other comments at the request of the Ministry of Agriculture and Rural Development.
3. Manage the documents provided, ensure no loss, no transfer of information to third parties and return these documents at the request of the Ministry of Agriculture and Rural Development after completing the task .
4. Evaluate and appraise documents objectively, independently, on a scientific basis and be ready to exchange with the community about your scientific assessments.
5. Receive remuneration according to current laws.

#### **Chapter IV**

### **IMPLEMENTATION ORGANIZATION**

#### **Article 16. Responsibilities of the Department of Science, Technology and Environment**

1. Preside over and coordinate with relevant agencies and units to organize and implement this Circular.
2. Coordinate with relevant agencies to collect and use application appraisal fees according to current legal regulations.

3. Summarize and report to the Ministry on the status of issuance and revocation of Certificates of genetically modified plants eligible for use as food and animal feed according to regulations.

### **Article 17. Responsibilities of organizations and individuals registering for issuance of Certification**

1. Pay the application appraisal fee according to regulations. The application appraisal fee is non-refundable even in case the product is refused a Certificate of Certification.
2. Responsible for the authenticity of the information in the Application for Certificate.
3. Provide additional information as requested by the Ministry of Agriculture and Rural Development.
4. Be responsible before the law if you do not comply with the conditions of the Certificate.
5. Organizations and individuals issued with the Certificate are responsible for notifying the Ministry of Agriculture and Rural Development about adverse effects and new scientific information on risks of genetically modified plants (if any). .
6. Notify organizations and individuals related to genetically modified plants when the Certificate is revoked.

### **Article 18. Implementation provisions**

1. This Circular takes effect from March 10, 2014.
2. Within one (01) year from the effective date of this Circular, genetically modified plants must submit an application for a Certificate before continuing to use them as food. animal feed in the territory of Vietnam.
3. During the implementation process, if there are any difficulties or problems, please promptly report them to the Ministry of Agriculture and Rural Development for consideration and resolution./.

#### ***Recipient:***

- Central Office and Party Committees;  
- Office of the National Assembly;- Office of the President;- Government Office;- Ministries, ministerial-level agencies, agencies under the Government;- Central agencies of unions;- Leaders of the Ministry of Agriculture and Rural Development ; - People's Committees of provinces and centrally-run cities;- Department of Agriculture and Rural Development of provinces and centrally-run cities;- Department of Document Inspection - Ministry of Justice;- Government Official Gazette;- Electronic information portal: Government, Ministry Agriculture and Rural Development;- Units under the Ministry of Agriculture and Rural Development;- Filed: VT, Science and Technology.

**KT. MINISTER  
DEPUTY MINISTER**

**Le Quoc Doanh**

### **Appendix 1. Application form for issuance of Certificate of genetically modified plants eligible for use as food and animal feed**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture and Rural Development)*



**registered organization or  
individual**

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....., *day month Year*

**REGISTRATION FORM**

**ISSUANCE OF CERTIFICATION OF GENETICALLY MODIFIED PLANTS  
QUALIFIED FOR USE AS FOOD AND ANIMAL FEED**

- First registration :
- Register for additional information :
- Request for issuance of Certificate of eligibility to make animal feed:
- Request for issuance of Certificate of eligibility to make food:

To: Ministry of Agriculture and Rural Development

*Pursuant to Decree No. 69/2010/ND-CP dated June 21, 2010 of the Government on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms, Decree No. 108/2011/ND-CP dated November 30, 2011 of the Government amending a number of articles of Decree No. 69/2010/ND-CP on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms and Circular No. 02/2014/TT-BNNPTNT dated January 24, 2014 of the Ministry of Agriculture and Rural Development regulating the order and procedures for granting and revoking Certificates of genetically modified organisms Genetic modification eligible for use as food and animal feed , .....(Name of registered organization or individual) ..... We would like to send to you the application dossier for issuance of a Certificate of Genetically Modified Plants eligible for use as food and animal feed, specifically as follows:*

1. Information about registered organizations and individuals:

- Name of organization or individual:
- Name of representative of organization or individual:
- Address:
- Phone: Fax: E-mail:

2. Information about genetically modified plants:

- Common name:
- Science name:
- Tradenames:
- Name of gene transfer event:
- Traits related to transferred genes:
- Name of organization or individual creating genetically modified plants:
- Unique identification code if any:

3. Attached documents (01 original and 02 copies) include:

.....

4. Commitment:

We hereby certify that the above information is correct and are fully responsible before the law of the Socialist Republic of Vietnam for the truthfulness of the information and data provided in the attached documents.

We respectfully request the Ministry of Agriculture and Rural Development to consider and carry out the necessary procedures to evaluate the dossier and issue a Certificate of genetically modified plants qualified for use as food and animal feed. /.

....., day month Year.....

**Registered organization/individual**

(Sign, clearly state full name, title, stamp)

**Appendix 2. Sample risk assessment report of genetically modified plants on human and animal health**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture and Rural Development)*

**registered organization or individual**

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**RISK ASSESSMENT REPORT OF GENETICALLY MODIFIED PLANTS TO HUMAN AND ANIMAL HEALTH**

**I. General Information**

1. Organizations and individuals registering:

- Name of registered organization or individual:
- Representatives of organizations and individuals:
- Contact point of organizations and individuals:
- Address:
- Phone: Fax: Email:

2. Name of genetically modified plant:

- Common name:
- Science name:
- Tradenames:

- Gene transfer events:
- Traits related to transferred genes:
- Unique identification code (if any):

## **II. Information about the host plant receiving the gene:**

1. Name of the host plant receiving the gene:

- a) Common name;
- b) Scientific name;
- c) Classification position.

2. Information on the history of cultivation and development in breeding, especially information related to traits that can have adverse effects on human and animal health;

3. Information on the safety of the recipient plants including issues of toxicity and allergenicity (including information for related plants that can be used as genetic substrates). transfer and receive similar genes);

4. Information on the history of using host plants as food and animal feed. (Detailed description of farming practices, transportation, storage and special conditions needed in processing (if any) for safe use in food and animal feed, roles, Value and nutritional composition of plant parts used as food and animal feed.

## **III. Information about the organism for the gene**

1. Organism name for gene:

- a) Common name;
- b) Scientific name;
- c) Classification position.

2. Information about natural history related to food and animal feed safety issues.

3. Information on naturally occurring anti-nutrients, toxins and allergens. In case the gene donor organism is a microorganism, information about its pathogenicity and interaction with known pathogens is required.

4. Information on past and current use (if any) in the food and feed chain and exposure pathways other than intentional use (e.g. potential for unintentional contamination).

## **IV. Information about genetically modified plants**

### **A. Information about the transgene**

1. Provide sufficient information related to the genetic modification process to be able to identify all genetic materials capable of being transferred to the host plant and provide sufficient information for basic analysis and assessment The data confirmed the characteristics of the DNA fragment inserted into the host plant.

2. Detailed description of the genetic modification process including:

- a) Information about the methods used for gene transfer

b) Information about the sequence, origin, vector, plasmid, similarity and expected function of the transgene in genetically modified plants.

c) Information about intermediate host organisms includes organisms (for example, bacteria) used to create or clone DNA for gene transfer into the host plant.

d) Provide complete information about the DNA segment including:

- Fully describe the characteristics of genetic components: marker genes, regulatory parts and other components that affect gene function;

- Size and similarity of components;

- Position and direction of the transgene sequence in the final construct/vector system

- Function of transgene

## **B. Information about genetically modified plants**

1. Provide complete information describing in detail the molecular and biochemical characteristics of genetically modified foods and animal feeds and their effects on the nutritional composition and safety of that product.

2. Provide complete information about the DNA segment inserted into the recipient plant's genome, including:

a) Describe the characteristics of the transformed genetic material;

b) Number of inserted positions;

c) The host plant carrying the transgene at each insertion site includes the copy number and a database of the DNA sequence of the inserted gene and neighboring regions so that any given compound can be identified. produced as a consequence of gene insertion, or other information related to the analysis of transcription or expression products to identify any new substances that may be present in food, feed from transgenic plants;

d) Identify any open reading frames in the insert DNA or created by inserts together with adjacent host genomic DNA that can fuse protein molecules.

1. Provide complete information about the level of gene expression in genetically modified plants including:

a) Gene product (e.g. protein molecule or non-transcribed RNA).

b) Function of the gene product;

c) Describe the phenotypic characteristics of the new trait;

d) Level and location (part) of transgene expression in transgenic plants and levels of their metabolites in the plant, especially in parts used for food/animal feed;

e) Quantification of the content of gene expression products, if any, when the function of the transgene changes the accumulation of messenger RNA molecules or proteins.

2. Additional relevant information includes:

Demonstration of conservation of the structure of genetic material or changes in position in the structure during gene transfer.

- a) Prove that the change in the amino acid sequence of the protein molecule of the expression product of the transgene is the result of intentional alteration.
- b) Prove that the intended effect of the transformation has been achieved, the new trait is expressed and is inherited in a stable direction over many generations and according to the laws of inheritance. If the new trait cannot be determined by phenotypic expression, information at the molecular level is needed.
- c) Demonstrate that new traits are expressed in necessary parts at appropriate levels related to the regulatory sequences that control the expression of the corresponding gene.
- d) Show evidence that one or several genes in the host plant are affected by the gene transfer process (if any).
- e) Confirm the similarity and expression pattern of any fusion protein molecules.

3. Information on the history of licensing and use of genetically modified plants in the world.

#### **V. Assess the risk of effects of genetically modified plants on human and animal health**

1. Compare the difference in nutritional composition between genetically modified plants and genetically modified plants.
2. Evaluate the ability to metabolize nutritional components, especially new substances that are expression products of transgenes if used as food or animal feed.
3. Assess the toxic potential of new substances that are expression products of transgenes if used as food or animal feed.
4. Assess the allergenic potential of new substances that are expression products of transgenes if used as food or animal feed.
5. Assess the potential for formation of new compounds, pathogenicity, or other adverse effects on human and animal health (e.g., potential effects from processing; changes in nutritional quality, nutritional function; accumulation of new substances; antibiotic resistance genes...).

**BECAUSE. Propose measures to manage potential risks of genetically modified plants to human and animal health**

#### **VII. Conclusions and recommendations**

....., *day month Year*.....

**Registered organization/individual**

(Sign, clearly state full name, title, stamp)

#### **Appendix 3. Summary report template for risk assessment of genetically modified plants on human and animal health**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture and Rural Development)*

registered organization or individual

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**SUMMARY OF REPORT ON ASSESSMENT OF THE RISK OF GENETICALLY MODIFIED PLANTS TO HUMAN AND ANIMAL HEALTH**

**I. General Information**

1. Name, contact address of the registering organization, head and contact person.
2. Name of genetically modified plant: scientific name, common name, transgenic event code and unique identification code (if any).

**II. Information related to the host plant receiving the gene:**

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

**III. Information about the organism for the gene**

Brief description of the donor organism, including the name, biological characteristics of the donor organism, relationship with the natural environment and biodiversity in Vietnam, and history of use of the donor organism.

**IV. Information about genetically modified plants**

Describe the process of creating genetically modified plants, including a preliminary description of the gene transfer method.

State the new traits and characteristics of genetically modified plants compared to corresponding conventional plants.

Information about the history of licensing and use of genetically modified plants in the world.

**V. Assess the risk of effects of genetically modified plants on humans and livestock**

A summary description of the risk assessment activities that have been carried out for this genetically modified plant and the results of the risk assessments are given.

Brief description of potential toxic, allergenic, pathogenic or other effects on human health if used as food.

**BECAUSE. Proposed risk management measures of genetically modified plants for human and animal health:** Brief description of proposed risk management measures (if any).

**VII. Conclusions and recommendations**

....., *day month Year*.....

**Registered organization/individual**

(Sign, clearly state full name, title, seal)

**Appendix 4. Form of information declaration posted for public comments for application for issuance of Certificate**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture and Rural Development)*

**INFORMATION DECLARATION POSTED FOR PUBLIC OPINION**

1. Name of registered organization or individual:
2. Contact address:
3. Full name of responsible person:
4. Description of genetically modified plants registered for licensing:
5. Origin and origin of genetically modified plants: (country)
6. Purpose of registration:

If you need more detailed information about genetically modified plants applying for a Certificate of Genetically Modified Plants eligible for use as food or animal feed, please contact the person responsible for genetically modified plants. Genetic modification:

- First and last name:
- Address
- Tel:
- Email:
- Fax:

We respectfully invite organizations and individuals to submit comments on the consideration of granting a Certificate of Certification for genetically modified plants mentioned above that are eligible for use as food and animal feed within 30 days from The date the information is posted to the address:

Department of Science, Technology and Environment

Ministry of Agriculture and Rural Development

No. 2 Ngoc Ha, Ba Dinh, Hanoi

**Appendix 5. Form notifying the validity of application dossier for issuance of Certificate**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture and Rural Development)*

**MINISTRY OF  
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**NOTICE OF VALIDITY OF APPLICATION DOCUMENT FOR ISSUANCE OF  
CERTIFICATE**

1. Name of registered organization or individual:

- Representative of the organization:
- Contact point of the organization:
- Address:
- Telephone: Fax:

2. Name of genetically modified plant:

- Common name:
- Science name:
- Tradenames:
- Gene transfer events:
- Unique identification code (if any):

3. Date of receiving documents:

4. Appraisal period from date..... to date.....

<b>TT</b>	<b>List of records</b>	<b>Legal basis for appraisal</b>	<b>Review results (pass, fail)</b>	<b>Additional requirements</b>

5. Additional required content (write for each document)

6. Comments and suggestions

**Recipients:**

**POWERS AND POSITIONS OF THE SIGNER**

-  
-

*(Signature, seal)*

**First and last name**

**Appendix 6. Sample Certificate of genetically modified plants eligible for use as food and animal feed**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT dated January 24, 2014 of the Minister of Agriculture and Rural Development)*

**MINISTRY OF  
AGRICULTURE AND  
RURAL DEVELOPMENT**

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

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*Hanoi, date month year 20...*



## CERTIFICATION

*(Attached to Decision No.../QD-BNN-KHCN dated...month...year...of the Minister of Agriculture and Rural Development)*

1. Genetically modified plants are granted a Certificate of eligibility for use as food and animal feed:

- Common name:
- Science name:
- Tradenames:
- Gene transfer events:
- Traits related to transgenes:
- Unique identification code (if any):

2. Organizations and individuals granted Certificates:

- Name of the organization or individual receiving the certificate
- Address:
- Phone number: Fax number:

3. Organizations and individuals issued with a Certificate of Genetically Modified Plants eligible for use as food and animal feed are responsible for implementing the following requirements:

- 
- 

**Recipients:**

- 
- 

**POWERS AND POSITIONS OF THE SIGNER**

*(Signature, seal)*

**First and last name**

### **Appendix 7. Sample document evaluation comments of Council members and review experts**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture Industry and Rural Development)*

MINISTRY OF  
AGRICULTURE AND RURAL  
DEVELOPMENT COUNCIL  
FOR  
**FOOD SAFETY AND  
GENETICALLY MODIFIED**

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

## ANIMAL FEED

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Hanoi, date month year 20...

### REMARKS ON ASSESSMENT OF THE PROFILE OF THE COUNCIL MEMBERS/EXPERTS

#### I. General information about the file:

1. Name of registered organization or individual:
2. Name of genetically modified plant:
  - Common name:
  - Science name:
  - Tradenames:
  - Gene transfer events:
  - Unique identification code (if any):
3. File number:

#### II. Information about Council members/review experts

1. Full name (*scientific title, academic degree*):
2. Working agency:
3. Position: is:
  - a) Commissioner
  - b) Commissioner reviews
  - c) Independent expert

#### III. Content of dossier assessment (Council members provide summary assessments of the contents in the risk assessment report and corresponding conclusions for each content)

**1. Evaluation of the dossier** ( *Completeness of the dossier and content as prescribed in Circular No. 02/2014/TT-BNNPTNT dated January 24, 2014 of the Minister of Agriculture and Rural Development regulations sequence, procedures for issuance and revocation of Certificate of genetically modified plants eligible for use as food/animal feed* )

#### 2. Review of the Risk Assessment Report and accompanying documents

**Information about the host plant that receives the gene and the organism that donates the gene**

#### Information about genetic variation

- Gene transfer method used
- Function and regulation of transgene
- Transgene expression in transgenic plants
- Genetic stability of variation

- Conclude

### **General safety information**

- History of use (recipient organism, donor organism)

- Characteristics of new protein molecules

- Expression of new proteins through molecular biological analyzes (Western blot analysis, ELISA)

- Impact on human health in case the new genetic material can be transferred into human digestive system cells

- Conclude

### **Information on toxicity-related issues**

- Toxin content occurs naturally in products of genetically modified plants

- Potential toxicity of new protein molecules that are products of transgene expression

- Potential allergenicity of new proteins that are products of transgene expression

- Conclude

### **Information on nutrition-related issues**

- Composition analysis: Clearly state how to collect samples, prepare samples, analytical methods, statistical processing, and typical analytical experiments in some countries on the main nutrients.

- Experimental analysis of new protein molecules that are the expression products of transgenes on animals and livestock

- Conclude

### **Regarding risk management measures of genetically modified plants to human and animal health if possible**

#### **IV. Conclusions and recommendations**

**1. Conclusion** ( *Based on supporting documents and scientific information, make a conclusion to confirm or not confirm that genetically modified plants... are as safe as equivalent traditional food/animal feed*)

a) Document Evaluation: Satisfactory, no need for editing or supplementation

b) Document Evaluation: Satisfactory with conditions that must be edited and supplemented ( *Specify the content that needs to be edited or supplemented* )

c) Document Evaluation: Unsatisfactory

#### **2. Recommendations**

*Recommend that the Ministry of Agriculture and Rural Development grant/not issue a Certificate of ..... eligibility for use as food and animal feed; Conditions for issuance of Certificate (if any).*

.....  
.....

**Reviewers**

*(Sign and write full name)*

**Appendix 8. Form of evaluation form of application dossier for issuance of Certificate of genetically modified plants eligible for use as food and animal feed**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture Industry and Rural Development)*

MINISTRY OF  
AGRICULTURE AND RURAL  
DEVELOPMENT COUNCIL  
FOR  
**FOOD SAFETY AND  
GENETICALLY MODIFIED  
ANIMAL FEED**  
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**SOCIALIST REPUBLIC OF VIETNAM**  
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*Hanoi, date month year 20...*

**Evaluation form of application dossier for issuance of Certificate of Genetically Modified Plants eligible for use as food and animal feed**

**Commissioner**   
**commented :**

**Commissioner :**

**I. General information about records**

1. Name of registered organization or individual:
2. Name of transgenic organism:
  - Common name:
  - Science name:
  - Tradenames:
  - Gene transfer events:
  - Unique identification code (if any):
3. File number:

**II. Information about Council members**

1. Full name *(scientific title, academic degree)*:
2. Working agency:

3. Position:

### III. Conclusions and recommendations

#### 1. Conclusion

- a) Document Evaluation: Satisfactory, no need for editing or supplementation
- b) Document Evaluation: Satisfactory with conditions that must be edited and supplemented ( *Specify the content that needs to be edited or supplemented* )
- c) Document Evaluation: Unsatisfactory

#### 2. Recommendations

- a) Request for issuance of Certificate
- b) Request not to issue the Certificate

#### 3. Other comments:

.....

.....

.....

.....

.....

.....

#### Board members

*(Sign and write full name)*

### Appendix 9. Sample vote counting minutes of the Council for Food Safety and Genetically Modified Animal Feed

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture Industry and Rural Development)*

MINISTRY OF  
AGRICULTURE AND RURAL  
DEVELOPMENT COUNCIL

FOR  
FOOD SAFETY AND  
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ANIMAL FEED

SOCIALIST REPUBLIC OF VIETNAM  
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*Hanoi, date month year 20...*

**MINUTES OF COUNTING THE VOTES OF THE COUNCIL FOR  
FOOD SAFETY AND GENETICALLY MODIFIED ANIMAL FEEDS**

**I. General information**

1. Name of registered organization or individual:

2. Name of genetically modified plant:

- Common name:

- Science name:

- Tradenames:

- Gene transfer events:

- Unique identification code (if any):

3. Traits of the transgene:

4. Council meeting location and time: Date .....month .....year

5. Number of members present out of total members:

- Number of ballots issued:

- Number of votes collected:

- Number of valid votes:

- Invalid votes:

6. Vote counting results:

- Number of dossier evaluation votes: Satisfactory, no need to edit or supplement:

- Number of dossier evaluation votes: Satisfactory with conditions for editing and supplementing:

- Number of dossier evaluation votes: Unsatisfactory:

- Number of votes requesting issuance of Certificate:

- Number of votes requesting not to issue a Certificate:

**II. Conclude**

.....  
.....  
.....

*Hanoi Day Month Year*

**Member of the Vote Counting Committee**

**Head of the vote counting committee**

**Member 1**

*(Last name, first name, signature)*

*(Last name, first name, signature)*

**Member 2**

*(Last name, first name, signature)*

**Appendix 10. Sample meeting minutes of the Council for Food Safety and Genetically Modified Animal Feed**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture and Rural Development)*

MINISTRY OF  
AGRICULTURE AND RURAL  
DEVELOPMENT COUNCIL  
FOR  
FOOD SAFETY AND  
GENETICALLY MODIFIED  
ANIMAL FEED  
-----

**SOCIALIST REPUBLIC OF VIETNAM**  
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*Hanoi, date month year 20...*

**MINUTES OF THE MEETING OF THE COUNCIL ON FOOD SAFETY AND GENETICALLY MODIFIED ANIMAL FEED**

**I. General information**

1. Name of registered organization or individual:

2. Name of genetically modified plant:

- Common name:

- Science name:

- Tradenames:

- Gene transfer events:

- Unique identification code (if any):

3. Traits of the transgene:

.....

4. Decision to establish the Council (if any): No. /QD-BNNPTNT date month year of the Minister of Agriculture and Rural Development on the establishment of the Council for Food Safety and Genetically Modified Animal Feed.

**II. Preparatory session:**

1. Council meeting location and time:

.....

2. Number of Council members present out of total members: ...../.....

Absent: ..... people, including members:

.....  
 .....  
 3. Guests attending the session:

TT	First and last name	Work unit
first		
2		
...		

4. Working content:

- The Council discussed and agreed to assign tasks to members and requested the Ministry of Agriculture and Rural Development to invite independent reviewers (if any) to comment and evaluate the selection registration documents, including the following experts: This:

TT	Full name of review expert	Notes (Review experts are or are not members of the Council)
first		
2		
...		

- The Council unanimously agreed to nominate:

+ Mr/Mrs:.....is the scientific secretary of the Council.

+ The vote counting committee includes:

Chairman: .....

Commissioner: .....

.....  
 - The Council discussed and discussed to thoroughly grasp the principles, processes and criteria for evaluating dossiers according to the Regulations.

- Council members receive dossiers and dossier comment forms

- The Council agreed to hold an official session on .....month .....year.....

**III. Official meeting:**

1. Council meeting location and time:

.....  
 2. Number of Council members present out of total members: ...../.....

Absent: ..... people, including members:

.....  
 3. Guests attending the session:

TT	First and last name	Work unit
----	---------------------	-----------

.....  
 .....



.....

4. Working content:

- The Council discussed, discussed and evaluated the dossier according to the criteria specified in Circular No. 02/2014/TT-BNNPTNT dated January 24, 2014 of the Minister of Agriculture and Rural Development stipulating the order , procedures for issuance and revocation of Certificate of genetically modified plants eligible for use as food and animal feed.
- The Council voted secretly to evaluate the dossier

The results of counting votes to evaluate the application dossier for issuance of Certificate of Genetically Modified Plants eligible for use as food/animal feed are presented in the attached record of counting votes sent.

**IV. Conclusion of the Council**

Vote counting results:

- Number of dossier evaluation votes: Satisfactory, no need to edit or supplement:
- Number of dossier evaluation votes: Satisfactory with conditions for editing and supplementing:
- Number of dossier evaluation votes: Unsatisfactory:
- Number of votes requesting issuance of Certificate:
- Number of votes requesting not to issue a Certificate:

**V. Recommendations of the Council**

Based on the evaluation form and vote counting results, the Council for Food Safety and Genetically Modified Animal Feed requests the Ministry of Agriculture and Rural Development to issue (or not issue) a Certificate of eligibility for use as food and animal feed. raised for

.....

For organizations/individuals:.....

.....

*Propose conditions for issuance of Certificate to registered organizations/individuals (if any).*

*In case of request not to issue a Certificate, clearly state the reason.*

**BECAUSE. Contents that need to be amended or supplemented in the dossier:**

.....  
.....  
.....

**VII. Other notes in completing the application (if any):**

.....  
.....  
.....

**Secretary**

*(Full name, first name and signature)*

**Chairperson**

*(Full name, first name and signature)*

**Confirmation of the Ministry of Agriculture and Rural Development**

**Appendix 11. Sample report evaluating dossiers of the Council for Food Safety and Genetically Modified Animal Feed**

*(Issued together with Circular No. 02/2014/TT-BNNPTNT, dated January 24, 2014 of the Minister of Agriculture and Rural Development)*

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*Hanoi, date month year 20...*

**COUNCIL'S EVALUATION REPORT ON APPLICATION DOCUMENTS FOR  
CERTIFICATION OF GENETICALLY MODIFIED PLANTS ELIGIBLE FOR USE AS  
FOOD AND ANIMAL FEED**

**I. Summary and conclusions**

1. Information about gene transfer events and genetic changes:

Brief description of the gene transfer event and information related to the transgene in the Registration Dossier.

State general safety issues

2. Information on issues related to toxicity used as food/animal feed

Brief description of the product of the transgene in the recipient organism and the decomposition and metabolic processes that can produce toxins.

3. Information on nutrition-related issues

Brief description of the nutritional composition of parts of genetically modified plants based on comparison with traditional products.

4. Conclusion

Based on documentary evidence and scientific information, conclusions have been drawn confirming that genetically modified plants are present. .... as safe as equivalent traditional food/feed.

**II. Evaluation report**

**1. Evaluation of the dossier** ( *Completeness of the dossier, content as prescribed in Circular No..../20...-BNNPTNT of the Minister of Agriculture and Rural Development stipulating the order and procedures for issuance and Revocation of Certificate of Genetically Modified Plants eligible for use as food and animal feed* )

## **2. Review of the Risk Assessment Report and accompanying documents**

### **2.1. Information about the host plant that receives the gene and the organism that donates the gene**

#### **2.2. Information about genetic variation**

- Gene transfer method used
- Function and regulation of the transgene
- Transgene expression in transgenic plants
- Genetic stability of variation
- Conclude

#### **2.3. General safety information**

- History of use (recipient organism, donor organism)
- Characteristics of new protein molecules
- Expression of new proteins through molecular biological analyzes (Western blot analysis, ELISA)
- Impact on human health in case the new genetic material can be transferred into human digestive system cells
- Conclude

#### **2.4. Information on toxicity-related issues**

- Toxin content occurs naturally in products of genetically modified plants
- Potential toxicity of new protein molecules that are products of transgene expression
- Potential allergenicity of new proteins that are products of transgene expression
- Conclude

#### **2.5. Information on nutrition-related issues**

- Composition analysis: Clearly state how to collect samples, prepare samples, analytical methods, statistical processing, and typical analytical experiments in some countries on the main nutrients.
- Analyze and test on animals and pets
- Conclude

#### **2.6. Regarding risk management measures of genetically modified plants for human and animal health**

### **III. Summary and draft response to public comments**

#### **IV. Conclusions and recommendations**

**1. Conclusion** (*Based on supporting documents and scientific information, make a conclusion to confirm or not confirm that genetically modified plants... are eligible for use as food and animal feed*)

#### **2. Recommendations**

(*Recommend that the Ministry of Agriculture and Rural Development grant/not issue a Certificate of ..... eligibility for use as food and animal feed; conditions for Issue a Certificate of Confirmation (if any).*)

**Council Secretary**

(Sign, write full name)

**Chairman**

(Sign, write full name)