MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT	SOCIALIST REPUBLIC OF VIET NAM Independence – Liberty – Happiness
No: /…../TT-BNNPTNT	*Hanoi, DD, MM, YYYY*

Unofficial Translation

CIRCULAR ON

APPROVAL PROCESS OF GENETICALLY MODIFIED PLANTS FOR DIRECT USE AS 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 degree No. 69/2010/ND-TTg of June 21, 2010, of government on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms.

Ministry of Agricultural and Rural Development promulgate the circular on approval process of genetically modified organism for direct use as feed as following:

CHAPTER I

GENERAL PROVISIONS

Article 1. Scope of regulation

1. This circular stipulates an approval process of genetically modified plants for direct use as feed included the order, procedures for issuing, renewal and revocation of a certificate of genetically modified plants and products of genetically modified plants (hereinafter referred to as genetically modified plants) that satisfy conditions to be used as animal feed.

2. Approval process of other genetically modified organisms for direct use as feed will be stipulated in other documents.

Article 2. Subject of applications

This circular applies to organizations, households and individuals in the country, overseas Vietnamese, foreign organizations and individuals carrying out activities of or related to the issuing, renewal and revocation of a certificate

of genetically modified plants and products of genetically modified plants that satisfy conditions to be used as animal feed in territory of Vietnam.

Article 3. Definition of term

The following terms when used in this Circular shall mean as follow:

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) and direct injection of nucleic acid into cell or organelles, included seeds, bulbs, roots itself, foliage, grafts, buds, flowers, tissues and cells with ability reproduction in the environment.

2. Products from genetically modified plant means a product (whether or not processed) containing all or part of the components derived from genetically modified plants, including genetic specimens of plant, which not able to reproduce in natural conditions.

3. Certificate of genetically modified plant and products from genetically modified plant eligible for use as animal feed (hereinafter referred to as the Certificate) is a document of the Ministry of Agriculture and Rural Development allows genetically modified plant and it's products eligible for use as animal feed, raw materials for animal feed production or feed supplements. 4. Risk assessment of genetically modified plants (hereinafter referred to as risk assessment) means activities, which is designed to identify whether a hazard, nutritional or other safety concern is present for animal, and if present, to gather information on it nature and severity.

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

6. Genetically modified feed means a feed, in which the product has been use raw materials for the production of animal feed or animal feed supplements originated from all or a part of ingredients derived from genetically modified plants and satisfy in force regulations on animal feed.

7. Risk assessment permit for animal means a document of the Ministry of Agriculture and Rural Development to allow conducting of risk assessment of genetically modified plants, genetically modified plant products for animal.

8. Developed country is a country which has a functioning biosafety regulatory system for genetic modified plants which incorporates internationally recognized standards, such as that issue by Codex, into its review process.

CHAPTER II

ISSUING, RENEWAL AND REVOCATION OF CERTIFICATE

Article 4. Conditions for issuing of Certificate

Applicant to register for direct use as feed certificate for a transformation event of a genetically modified plant must meet one of the following conditions:

1. This geneticaly modified plant has been approved for use as feed in five (05) developed countries; or

2. The applications has been reviewed and evaluated by Feed safety committee with conclusions to satisfy conditions to be used as feed, which shall not cause any risk to animal. In the case of which, genetically modified plant have been required to conduct risk assessment in Vietnam, the risk assessment process shall be follow according to Chapter III of this Circular.

Article 5. Requirements for application documents

Application documents (Dossier) shall be submited to MARD with three (3) copies including:

1. Application form: (Annex 1);

2. Risk assessment report (Annex 3) and all supporting references related to the risk assessement report;

3. For those genetically modified plants that qualify to comprise of more than one open reading frame (ORF) (e.g., a stacked product), the applicant shall provide an assessment of any interactions from the products of the open reading frames or other changes in the plant that might result from the presence of these ORFs in the same plant;

4. Notarized copies of certificates or approval letters, or equivalent documents indicating the products have been approved for feed use in each of 5

developed countries. A version of each document translated into Vietnamese will also be provided;

5. Summarize report of risk assessment (Annex 4);

6. Public comments (Annex 5);

Article 6. The order and procedures for issuing a certificate for genetically modified plants that satisfy conditions to be used as animal feed

1. Applicant, which register for issuance a certificate of genetically modified plant to be used as animal feed shall submit three (03) copies of Annex 1 to the Ministry of Agriculture and Rural Development – MARD.

2. Within seven (07) working days from receipt of the Annex 1, MARD shall examine it to determine if it is sufficient in form and substance. If the application complies with the format and contains all the required information, MARD shall so inform the applicant in writing (Annex 2). However, if the application is incomplete or not in proper format, MARD shall also inform the applicant of these deficiencies. Time for applicant to correct defect in the application is not added in the evaluation time of application.

3. Within fifteen (15) working days from receipt of notice that its application is sufficient in form and substance, the applicant shall cause to be published in two (2) continuous issues of the Vietnam Agricultural newspaper of general circulation a copy of the public information sheet (Annex 5) approved by MARD. During this 30-working day comment period, interested parties may submit to MARD written comments regarding the application and these shall become part of the application file. The applicant shall submit to MARD proof of publication within fifteen (15) working days from the date of publication.

4. After a determination that Annex 1 is complete, MARD shall post the summary risk assessement report (Annex 4) on the website of MARD. During this 30 working day period, interested parties will be able to submit their comments. MARD is responsible for summarizing comments.

5. Within twenty (20) working days after receiving the completed dossier, MARD shall identified Sientific and Technical Review Panels (STRP) for reviewing dossier based on case by case basis.

6.Within ninety (90) working days from receipt of the final evaluation report from STRP, MARD shall organize a feed safety committee meeting (hereinafter referred to as FESC) to evaluate the application. FESC will conclude on the safety of genetically modified plants to animals based on:

a) Application dossier (Annex 1);

b) Review report from STRP;

c) Summary of public comments (Annex 4 and Annex 5);

d) Information provided in any approval documents, certificates, approval letters, or equivalent documents indicating the products have been approved for feed use in each of 5 developed countries.

7. Within thirty (30) working days from receipt of FESC's recommendation, the MARD shall approve the application if he finds that based on the application file direct use of genetically modified plant as feed, or processing into feed, poses no significant risks to animal health (Annex 12). The applicant will also be informed in writing if the application is denied and the reasons for that denial.

8. Total evaluation time shall not exceed 180 days from receipt of a completed application to the DOSTE.

9. If **genetically** modified plant subject to the provisions of Paragraph 1, Article 4 of this Circular, the evaluation time of these products shall not exceed 60 days from the date of receipt of valid dossiers.

10. The Certificate will be valid for 5 years from the date of issue.

Article 7. The order and procedures for renewal of certificate.

1. Renewal certificates apply to genetically modified products eligible for use as animal feed when the certificate expires.

2. Renewal of the Certificate should be submitted to MARD for approval 2 months prior to the expiration date. Products which not submit for renewal before expire date or not approve for renewal shall exclude from the list of permitted products used as feed in Vietnam.

3. Applicant who apply for renewal the certificate shall submit the renewal form (new Annex).

4. Within fifteen (15) working days from the date of receipt of complete and valid application, Ministry of Agriculture and Rural Development shall review aplication, if the application is complete and valid renewal certificate shall issue.

If the application is not valid, within fifteen (15) working days after receiving the dossier, the Ministry of Agriculture and Rural Development shall inform applicant for submitting of information in accordance with regulations.

Article 8. Revocation of Certificate

1. A Certificate may be revoked for any of the following grounds:

a) New scientifically-supported information or validated reports of adverse effects have become available that in the opinion of the STRP and FESC impacts the conclusions from the original risk assessment of the genetically modified plant which has been previously issued a Certificate;

b) It has been demonstrated that the Applicant knowingly provided misleading or false information in the application process for the issuance of a Certificate;

c) Having unequivocal evidence to prove the STRP or FESC's conclusions regarding the safety of the genetically modified plant lacks a scientific basis;

d) The legal authority to commercially distribute the product in the country of origin has been suspended or revoked.

2. After receive grounds for revocation of a certificate, MARD will organize a meeting of the FESC to review and evaluate the new information or evidence.

3. FESC shall review and evaluate information and grounds. The revocation shall base on conclusion of the FESC. The evaluation time of FESC shall not exceed 30 days from the days.

4. MARD will inform the Certificate holder, related organization in writing about the revocation and posted in the MARD website.

5. From a date of receipt a revocation, Certificate holder shall cease distribution of the genetically modified plant and retrieve any unused materials.

Article 9. Responsibility of the MARD and other organizations and individuals after isuance, renewal and revocation of Certification

1. Ministry of Agriculture and Rural Development establishes a list of genetically modified plants which have been issued a Certificate to allow direct use as feed, or processing into feed.

2. Within ten (10) days from the date of issuance, renewal or revocation of Certification of qualified genetically modifiedplants used as animal feed, the MARD is responsible for:

a) Publish a list on the website of MARD, and at the same time send written notice to: Ministry of Natural Resources and Environment, Ministry of Industry and Trade, the Ministry of Health Health, Ministry of Science and Technology and the General Department of Customs;

b) Adding or delisting of genetically modified plant on/or from the list.

3. Responsibilities of applicant from the date of receipt a Certificate:

a) Product may be used directly as animal feed, or processing into feed, but not for food, or for field testing or propagation;

b) Inform MARD of any reports of validated adverse effects resulting from the use of this product;

c) Inform and reports on risk management, ensuring biosafety of genetically modified plants, which have been issued certification;

d) The permittee shall notify MARD, within the time periods and in the manner specified below, in case of any of the following accurrences:

- verbially immediately upon discovery, or in writing within twenty four (24) hours, in the event of any accidental or unauthorized release of the genetically modified plant or new information becomes available indicating that the genetically modified plant could pose risks to human or animal health, or to the environment; and

- in writing, but not to exceed three (03) working days, if the product is found to have characteristics substantially different from those listed in the application for a Certificate

d) Remain compliant with all conditions as stipulated in Decree 69/ND-CP.

CHAPTER III

RISK ASSESSMENT AND RISK MANAGEMENT OF GENETICALLY MODIFIED PLANTS FOR FEED USE

Article 10. Principles of risk assessment of genetically modified plants for feed use

1. The data to be used in the risk assessment shall be generated in an accredited laboratory recognized by the Ministry of Science and Technology recognized under the provisions of Article 11 and Article 12 in Decree 69/2010/ND-CP.

2. Both the required categories of biosafety data and the risk assessment strategy shall be determined on a case-by-case basis.

3. The conducting of risk assessment of genetically modified plants to be used as animal feed need to be scientific base and transparent, which incorporates with international recognized methods on a case-bycase basis depending on each type of genetically modidfied plant.

4. Risk assessment of genetically modified to be used as animal feed is the process of determining the presence of potential risks related to nutrition or feed safety, including the certification of similarities or differences between the geneticaly modified plants and their counterpart in the same conditions. In the case of presence of hazardous and potential risks related to nutrition or feed safety, a hazardous and risks level to the health of livestock need to clarify.

5. The applicant shall be responsible for ensuring that biosafety-related studies and data analysis shall be performed in accordance with the policies and guidelines under provisions of Articles 11-15 of this Circular.

6. An issuance of a permit to conduct a risk assessment shall not be interpreted as a commitment by MARD to approve the application for Ceftificate for direct use as feed, or processing into feed.

7. If any new scientifically-supported information on the genetically modified plant regarding its potential impact on animal health becomes available, the risk assessment will be re-examined to determine whether its conclusions should be altered or whether there is a need to amend the risk management strategies accordingly.

Article 11. Safety assessment criteria

Risk assessment shall be conducted considering following issues:

1. Compositional analysis of those analytes for which the product is known to be a significant contributor to the diet of an animal should be compared with an equivalent analysis of an isogenic conventional counterpart grown and harvested under the same conditions.

2. In its comparative analysis, the applicant may also utilize published compositional data, such as that available in OECD consensus documents. The applicant may also refer to published data for the choosing of which analytes to evaluate in its comparative analysis.

2. Evaluation of any metabolites that may accumulate in the plant tissue as predicted from the estabished mode-of-action of the introduced ORF(s).

4. Assessment of possible toxicity and allergenicity of any novel proteins expressed in the genetically modified plant. The nature and scope of this analysis will take into account the anticipated levels of the novel proteins in consumed plant parts.

5. Other consideration (if any);

Article 12. Application for generating data to be used in the risk assessment

Application for a permit under this Circular shall:

1. Three (03) copies of the application form for a permit to conduct risk assessment of genetically modified plants (Annex 6);

2. Application for risk assessment of genetically modified plant (Annex 7);

3. Plan for risk assessment of genetically modified plant (Annex 8);

4. Document that describes accreditation of laboratories where data generation shall be conducted.

Article 13. The order and procedures for issuing a permit for the protocol of generating data to be used in the risk assessment of genetically modified plants for feed use

1. Applicant shall submit three (03) copies of dossier (Article 5) to MARD.

2. Within five (05) working days from receipt of the application, MARD shall examine it to determine if it is sufficient in form and substance. If the

application complies with the format and contains all the required information, MARD shall so inform the applicant in writing (Annex 2). However, if the application is incomplete or not in proper format, MARD shall also inform the applicant. Time for supplementation of the application shall not be included in the process.

3. Within five (05) working days from receipt a valid application, MARD shall forward a copy of the application to the Scientific and Technical Review Panel (STRP).

4. Within thirty (30) working days STRP shall submit its report to MARD.

5. Within thirty (30) working days after receiving evaluation report from STRP, MARD shall organize a meeting of the FESC in order to evaluate the application, and convey its recommendation to the Minister of MARD. Minister of MARD shall consider to issue a permit for conducting the data generation. In case of denial, MARD shall inform the applicant in writing.

6. Period of issuing a permittee shall not exceed 90 days from the date of receipt of valid application.

7. MARD shall inform other related organizations about issuance a permit for conducting of risk assessment.

Article 14. Requirement of risk assessment report

1. Risk assessment report of a genetically modified plant to be used as animal feed shall be prepared in the form prescribed in Annex 3 of this Circular and Appendix VI of Decree No. 69/2010/ND-CP.

2. Risk assessment report of a genetically modified plant to be used as animal feed shall be reviewed and approved by the FESC.

3. Risk assessment report of a genetically modified plant for use as animal feed shall be one of the conditions to consider for issuance a Certificate for permit for direct use as feed or processing into feed.

Article 15. Risk management

1. The risk assessment of a genetically modified plant and its import for the purposes of risk assessment (if any) must comply with measures of risk management to ensure biosafety as stipulated by laws.

2. Research laboratory conducting the data generation to be used in the risk assessment shall be responsible for the appropriate measures to reduce any risks associated with the handling of the plant tissue, and issue periodic reports to MARD.

3. In the event any new information becomes available indicating that the genetically modified plant could pose significant risks to human or animal health, or to the environment, the applicant shall report to the laboratory conducting the data generation and immediately takes measures necessary to protect human health and the environment, and report this information to MARD.

4. Research laboratory generating the data must comply fully with the management of biosecurity measures under the control and supervision of the state management agencies involved.

5. Activities associated with the transport of genetically modified materials shall be performed consistent with the following:

a) Import of genetically modified plant tissue shall be in compliance with Articles 7, 8, 9, 10, 12, 13 and 18 of the Cartagena Protocol on Biosafety;

b) Plant material should be packaged in labeled containers for transportation and should be kept separately from other seed and/or plant material during transport to prevent accidental mixing;

c) In the event of a confirmed accidental release of genetically modified plant tissue during transportation, attempts shall be made to recover as much tissue as possible. The recovered material shall be destroyed. The physical location of an accidental release shall be marked and monitored to ensure that any plants arising from the accidental release is destroyed. The accidental release shall be reported to MARD;

d) Adequate records regarding the transport of genetically modified plant tissue shall be maintained and available for inspection by authorized parties.

6. Storage and preservation of genetically modified materials

a) Genetically modified plant tissue shall be stored and preserved in secure packaging to prevent loss of material confinement.

b) Responsible individual/organization shall maintain an inventory of all experimental plant material in storage.

c) In the event of an accidental release of experimental genetically modified plant material during transport or storage, the incident should be stabilized and the authorized party should be immediately notified of the situation. If an accidental release is found to have occured, then the authorized party should ensure that as much of the experimental material is recovered as possible. The location of an accidental release should be marked and managed to ensure that no additional release of material occurs. Any corrective actions taken to address an accidental release during transport or storage should be documented to MARD.

7. All activities and information related to the risk assessment of genetically modified plants shall be notified in writing to the MARD.

CHAPTER IV

FEED SAFETY COMMITTEE AND SCIENTIFIC AND TECHNICAL REVIEW PANEL

Article 16. FESC structure

1. FESC is the inter-ministerial committee established by the Minister of Agriculture and Rural Development.

2. The FESC shall be composed nine (09) members, four (4) of whom shall be represented for Ministry of Industry and Trade, Ministry of Science and Technology, Ministry of Natural Resources and Environment, and Ministry of Health; two (02) representing the Ministry of Agriculture and Rural Development (including the chairman). The other members, designated as scientist-members who shall possess scientific and technological knowledge and expertise sufficient to enable them to evaluate and monitor properly any work of the applicant relating to the risk assessment. The working term of the FESC is three (03) years.

3. The FESC acts as advisory board for decision making of Minister of MARD.

4. The FESC has the function to advise the Minister of MARD to consider the issuance of certificates.

5. Expense for Committee's FESC's activities shall be accounted regarding to the stipulated regulation.

Article 17. Feed safety Committee operation

1. FESC functions work on the principle of collective, open and transparent discussion, between the members of the Committee., Its independent, professional evaluation and conclusions shall be based on the results of the 100% consensus of those members present at the meeting, and consent of member of scientific and technical review panels.

2. Official meeting of the Committee shall be organized only in the presence of at least two-thirds (2/3) of members include Chairman or Vice Chairman and written report the STRP, and the summary reports of public comments on the risk assessment report of genetically modified plants .

3. STRP shall be invited to join the Committee meeting and brief the FESC on its scientific evaluation. However, STRP is not a Committee member.

4. The evaluation activities of the Council is implementing through the Department of Livestock.

5. The FESC may recommend to MARD to hold related meetings/or organize other activities.

6. FESC shall prepare a final report for each application that includes a recommendation to the Minister of MARD for the issuance, renewal and/or revocation of a certificate.

Article 18. Responsibilities and powers of the FESC members

1. Review and evaluation of applications and related documents provided by MARD.

2. Fully participate in FESC meetings during application review period and submit a writing report (Annex 10).

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

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

5. Committee members have right to keep their own opinion in case it differs from others.

6. Be entitled to remuneration in accordance with stipulated regulations.

Article 19. STRP regulation

1. STRP is a scientific advisory body, composed of at least three (03) reputable and independent scientists who have relevant professional background necessary to evaluate an application, convened by MARD on an as needed basis.

2. Member of Advisory body shall review applications and submited in writing a report (Annex 11) and send it to MARD within thirty 30 days of receiving such application.

3. The application shall be reviewed and evaluated in a transparent and independent manner, and based on established scientific principles. The final report shall be kept confidential.

4. STRP shall be entitled to remuneration in accordance with with stipulated regulations.

CHAPTER IV

IMPLEMENTING

Article 20. Organization under the MARD

1. The Department of Livestock Husbandry of MARD is a focal unit to manage related feed safety of genetically modified plants activities as following:

a) Receipt application;

b) Organization FESC meeting and submit FECS report to the Minister;

c) Establish a list of genetically modified plants, which have been issued a certificate for used directly as feed, and/or prcessing into feed. The information shall be posted on the website of MARD;

d) Responsible for monitoring, inspection, irregulated timely detection and troubleshooting in accordance with regulations.

2. Departments and agencies under the MARD shall be responsible for the implementation of the task related provisions of this Circular.

Article 21. Responsibility of applicant

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

2. Provide additional information as required by MARD or its appointed committees

3. Cover a registration fee, application reviewing and evaluation.

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

Article 22. Responsibilities of the Research Laboratory of genetically modified plants

1. Laboratory research on genetically modified plants shall conduct a risk assessment based on science, objectivity and transparency in accordance with current regulations and are solely responsible for the assessment by their implementation.

2. Information relating to applicant shall be kept condidential

3. Laboratory staff shall not authorized to publish data from their studies as they relate to the activities in support of an application for the issuance of a certificate.

Article 23. Implementation provisions

1. This Circular takes effect 45 days after its signing.

2. 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