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Global Agricultural Information Network

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MONRE Publishes Biosafety Certification Process for Agricultural Biotechnology

Report Categories:
Biotechnology - GE Plants and Animals

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Report Highlights:

On May 16, 2013, the Ministry of Natural Resources and Environment (MONRE) published Circular 8/2013/TT-BTNMT, providing the procedure for granting and revoking Certificates of Biosafety. Circular 8/2013/TT-BTNMT lays out the regulatory structure to evaluate the biosafety of agricultural traits derived from biotechnology. A biosafety certificate is required before an agricultural biotech event can be cultivated in Vietnam. This Circular entered into force on July 1, 2013.

Executive Summary: On May 16, 2013, the Ministry of Natural Resources and Environment (MONRE) published Circular 8/2013/TT-BTNMT (Circular 8) providing the procedure for granting and revoking Certificates of Biosafety. Circular 8 lays out the regulatory structure to evaluate the biosafety of agriculture derived from biotechnology. A biosafety certificate is required before an agricultural biotech event can be cultivated (commercially grown) in Vietnam. This Circular entered into force on July 1, 2013 and was not notified to the World Trade Organization's Sanitary and Phytosanitary Committee as it relates to the domestic regulation of agricultural biotechnology cultivation in Vietnam. Circular 8 is the first of three regulations finalized by the Vietnamese Government regulating the commercialization process for agricultural biotechnology. The other two circulars on: 1) the regulatory approval process for agricultural biotech for use as feed, and 2) the regulatory approval process for agricultural biotech for use as food are under development. An unofficial English translation of Circular 8 can be found at the end of this report.

Approval Procedure

According to the Circular, the evaluation and approval process takes about 230 working days (or more than 10 months) from dossier submission to the Vietnam Environment Agency (VEA) to the Minister of MONRE's final decision on the biosafety on the event specified in the dossier. The documents to be included in the dossier are outlined in Chapter 2, Article 5 of this Circular. After the Authority Organization within VEA validates the dossier, they upload it onto a public website to receive comments from the public. The comment period lasts 30 days, and comments must be summarized by the Authority Organization in 5 working days. At the same time as the public comment period, VEA establishes a Technical Advisory Board (TAB) and Biosafety Committee (BC). Within 90 days of establishing the BC, the TAB must review and assess the biosafety of the event, summarizing their conclusions for the BC. Within 70 working days of receiving the summary from the TAB, VEA will organize the BC to review the dossier and TAB summary. The Ministry of MONRE has 30 working days upon receipt of the BC's appraisal to consider and grant the Biosafety Certificate for the trait specified in the dossier.

Organizational Make-Up of Review and Approval Committees

The **Biosafety Committee** will be made up of at least 9 members including 3 representatives from the Ministry of Natural Resources and Environment, the remaining 6 representatives will be from Ministry of Industry and Trade, Ministry of Health, Ministry of Science and Technology, Ministry of Agriculture and Rural Development, and two experts. Among those six members, two will be selected as peer-reviewers.

The **Authority Organization** will be a designated agency within MONRE and will propose to VEA when to form the Biosafety Committee and / or Technical Advisory Board to review dossiers. In addition to establishing the BC and TAB, the Organization will serve as the clearinghouse for dossiers and related documents during the assessment process and draft the decision of granting a BC for approval of the Minister.

The **Technical Advisory Board** will be comprised of at least 3 members who are technical experts in agricultural biotechnology. The TAB provides technical support to the BC while the dossier review is on-going and has the authority to request additional information from an Applicant in support of the dossier appraisal.

Post-Approval Monitoring Mandated

Circular 8 stipulates that Applicants must annually report the production status of their biotech trait in Vietnam after their Biosafety Certificate is granted. The report must be circulated to MONRE, MARD, and the People's Committees where the biotech trait is grown.

Begin Unofficial English Translation

MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT **SOCIALIST REPUBLIC OF VIET NAM**

Nr: 08 /2013/TT-BTNMT **Independence - Freedom – Happiness**

Hanoi, May 16th 2013

CIRCULAR

Stipulate the Order, procedure of granting, revocation of the Biosafety Certificate

Pursuant to June, 21, 2010 the Decree 69/2010/ND-CP of the Government on the issue of biosafety of genetic modified organism, genetic specimen and product derived GMC:

Pursuant to March 4, 2008 the Decree 25/2008/ND-CP of the Government to regulate function, mission, authority and structure of MONRE ,which has been edited and added at Decree 19/2010/ND-CP dated on March 05 2010 and Decree 89/2010/ND-CP dated on August 16 2010;

According to the proposal of VEA and Legal Dept.

Ministry of Natural Resources and Environment stipulate the Order, procedure of granting and revocation the Biosafety Certificate for GMC as follow:

Chapter 1. General Regulation

Article 1. Scope of regulation

1. This circular stipulates details of the order, procedure of granting and revocation of the Biosafety certificate for genetically modified crops (Biosafety certificate).
2. The stacked event products derived through conventional breeding is outside the scope of this circular.

Article 2. Subjects of scope

This circular applies to all domestic and foreign organizations, individuals who involve in registering, granting, using and revoking of Biosafety certificate for GMC in the territory of Vietnam.

Article 3. Groups of genetically modified crop which are the subject to be considered of granting the biosafety certificate

1. Single transformation event is GMC derived from insertion of single or multiple genes with a single intended trait through genetically modified technology,
2. Stacked transformation event is GMC derived from:
   a. Insertion of single/multiple genes with multiple traits through genetically modified technology; or
   b. Insertion of single/multiple genes with single/multiple traits in one single GMC.

Chapter 2. Registering, granting and revoking of Biosafety Certificate

Article 4. Order, procedure of granting and revocation of the Biosafety Certificate

1. Application for granting the Biosafety certificate shall implement the stipulation at Article 5 in this Circular.
2. Receive and reviewing application dossier as well as granting the Biosafety Certificate shall implement the stipulation at Article 6, 7 and 8 in this Circular.
3. Revocation of Biosafety Certificate shall implement the stipulation at Article 9 of this Circular.

Article 5. Application for granting the Biosafety certificate

1. Application dossier for granting the Biosafety certificate shall include:
   a. One (01) application of registering the Biosafety certificate as form stipulated in the Annex 1 of this Circular.
   b. Ten (10) copies include 01 original copy and 09 photocopy of the Report on the result of the field trial which was approved by the MARD.
   c. Ten [10] original copies of report on risk assessment of GMC to environment and biodiversity (below will refer as risk assessment report) according to Annex 2 of this Circular and other related attachment
   d. One (01) electronic file on Summary of Risk assessment report according to Annex 3 of this Circular.
2. Responsibilities of the organization, individual:
   a. Within five (05) days after receiving authorization organization's document on the validated dossier, application shall pay the reviewing fee for the dossier of granting Biosafety certificate according to the actual financial regulation.

b. Provide additional information according to the document request from receiving dossier organization.

Article 6. Receiving application

1. Receiving organization is the Vietnam environment agency (VEA). VEA shall appoint one of its organizations to be the Authority Organization which will organize the activities in reviewing, appraisal the dossier for granting and revocation of Biosafety certificate. Responsible of the Authority Organization is stipulated in Article 16 in this Circular.
2. Within seven (07) working days after receiving the application dossier for granting the Biosafety certificate, Authority Organization organization shall inform by document to the application about the acceptance of validated dossier or request additional, complete the dossier. Time for completing the dossier is not counted on the appraisal time.

Article 7. Appraisal submission dossier for granting the Biosafety Certificate

1. Within five (05) working days after receiving a validated dossier, Authority Organization shall upload the information of the Risk assessment report of the genetically modified crop to the environment and biodiversity which stipulated in Article 5, Item 1.d on the website http://www.antoansinhhoc.vn in order to get the comment from the public. Public comment duration is 30 days after uploaded. After no longer than five working days after closing the public comment, the Authority Organization shall complete the summarize of public comment in order to help the appraisal.
2. The VEA, within ten (10) days after receiving a valid dossier, shall:
    a. Establish the Technical Advisory Board. .Organization and operation of the Technical Advisory Board is stipulated at article 20 of this Circular.
    b. Propose to MONRE-Minister to form up the Biosafety Committee. Compositions and structure of the Biosafety Committee is stipulated in Article 10 of this Circular.
3. Within ninety (90) days after the date of establishing the of forming the Biosafety committee, the Authority Organization shall organize the technical activities in order to review, assess the dossier applying for the Biosafety certificate as well as summarize and send the result to the Biosafety committee.

In case of necessary, the Authority Organization report to VEA request applicant by document of providing addition of information on risk assessment of the genetically modified crop, the time of providing addition information is not included on to the appraisal time.

1. Within seventy (70) working days after receiving a summarize of technical supported report which is stipulated in part 3 of this Article, Vietnam Environment Agency shall organize Biosafety Committee's

meetings in order to appraise the submission dossier.

Article 8. Granting the Biosafety Certificate

1. Within 30 working days after having the appraisal result from Biosafety committee, MONRE Minister shall consider and grant the Biosafety certificate. In case of refusal, MONRE shall inform and issue a notification with clear reason.
2. Within ten (10) working days after the date of granting biosafety certificate, MONRE shall have the responsibility:
   a. Announce on the BCH website: http://www.antoansinhhoc.vn
   b. Add name of the GMC to the list of GMCs that are granted Biosafety Certificates.

Article 9. Revocation of the Biosafety certificate

1. Biosafety certificates be considered withdrawn upon the occurrence of one of the cases specified in Item 1, Article 24 of Decree No. 69/2010/ND-CP.
2. When there the evidence, the document referred to in Item 1 of this Article occurs, the VEA shall verify the provided evidence and document prior to reporting to the Minister of Ministry of Natural Resources and Environment for consideration the withdrawal of Biosafety Certificate is no longer than thirty (30) working days after forming the Committee.
3. In case of deciding to revoke the Biosafety Certificate, MONRE is responsible for:
   a. No longer than three (3) working days, MONRE shall issue written notification to relevant organizations, individuals, Ministries about the decision of withdrawal of such Biosafety Certificate; publish the revocation on the BCH website and in the mass media.
   b. Within 10 working days, after the date of biosafety certificate revocation, MONRE shall delete the name of the GMC out of the list of certified GMC.

4. From the date of having revoked decision of the GMC, organization and individual shall not release to the environment the revoked GMC.

Chapter 3. Organization and operation of Biosafety Committee, Authority Organization, and Technical Advisory board

Article 10. Composition and Structure of Biosafety Committee

1. Minister of MONRE shall made decision to form the Biosafety Committee in accordance with the form which stipulated in Annex 5 of this Circular for reviewing the submission dossier for granting biosafety

certificate. The Biosafety Committee shall consist of at least nine (09) members, including:

a. Chairman shall be the leader of VEA
b. Vice-chairman shall be the leader of Authority Organization
c. Secretary members shall be the staff of Authority Organization
d. Six (06) members who are the representatives from: MOIT, MOST, MOH, MARD, and 2 experts. Among those 6 members, 2 will be selected as peer-reviewers;

2. The fee for running the Committee shall follow the rule of current regulation.

Article 11. Responsibility and the right of Committee's chairman

Besides the responsibility and the right of Committee's member stipulated in Article 13 of this Circular, The Chairman of Biosafety Committee shall have the responsibility and the right as below:

1. Moderate Biosafety Committee's meetings
2. Response to the opinions raised in the Committee's meeting and conclude Committee's meetings.
3. Sign off meetings minutes and having legal responsible on the conclusions of Biosafety Committee.

Article 12. Responsibility and the right of Committee's vice-chairman

Beside the responsibility and the right of Committee's member at Article 13 of this Circular, Vice chairman shall have the same responsibility and the right as Chairman in case of the absence of Chairman.

Article 13. Responsibility and Authorization of Biosafety Committee member(s)

1. Responsibility of Committee's member:
    a. Review the submission dossier, the comments from the Advisory board and public comments and related documents which are provided by Authority Organization; Developing the assessment report of risk assessment in accordance with stipulated in Annex 7 of this Circular.
    b. Participate in the Committee's meeting during the appraisal process of the submission dossier for granting Biosafety certificate.
    c. Manage all the provided documents to ensure of no losing, it shall not be transferred to other, and return all of these documents as required of Authority organization of biosafety committee after mission completed.
    d. Legally response on the objectiveness, the truth of the appraisal's conclusion.
2. Authorization of Biosafety Committee's member
    a. Propose to authority organization for providing enough documents, information to support the review process, organizing meetings and other activities as directly supporting the assessment work.
    b. Dialogue with organization, individual, and Technical Advisory Board at meetings of Biosafety

Committee.

c. Make reservation of the opinion in case of having different opinion with Committee's conclusion.
d. Receiving honorarium under the current financial regulation when conducting: writing evaluation report of risk assessment report; participate in appraisal committee and other appointed actions, activities during appraisal process.

Article 14. Responsibility and the right of Secretary member

Beside the responsibility and the right of Committee's member stipulated at Article 13 of this Circular, Secretary member shall have responsibility and right as follow:

1. Provide Committee's members the evaluation form and the form of appraisal for risk assessment report.
2. Inform Committee's chairman about the dossier's main remains based on studying and summarization of Committee's members' opinions.
3. Fully and honestly record the Committee's meetings and complete meetings' record for presenting to Committee's Chairman within 3 working days after the date of meeting.
4. Conduct other missions in order to serve the Committee's operation according to Committee's Chairman's requirement
5. In case of absence, Secretary member shall inform Committee's Chairman in order to appoint the replacement. The replacement of Secretary member shall have the same responsibility and the right of Secretary member.

Article 15. Delegates participate in Committee's meeting

1. Delegates participate in the appraisal meetings of Biosafety Committee shall be selected and invited by the Authority Organization.
2. Member of the Technical Advisory board can be invited to the meetings and raise the independent's opinion, but shall not be voted in the meetings.
3. Delegates participate in the meetings can raise their opinions, follow the moderation of the main responsible man, and receive the honorarium according to current regulations.

Article 16. Responsibilities of authority organization

1. Propose to VEA to form up Biosafety Committee;
2. Propose to VEA to form up Technical Advisory Board;
3. Support VEA in the administration works, included:
   a. Upload the information of Risk assessment report of genetically modified crop to environment and biodiversity on the website http://www.antoansinhhoc.vn, summarize public comments according to

Article 5, Item 1 in this Circular;

b. Organize Committee's meetings and Technical advisory board's activities, according to the procedure stipulated in Article 17, 18 and 20 of this Circular.
c. Draft the decision of granting Biosafety Certificate to present to several authorizations to review and decide;
d. Store the submission dossier and related documents during the assessment process of granting the Biosafety certificate;
e. Check, summarize and report authorizations information related to the post monitoring of the certified genetically modified crop;
f. Operate other tasks which are appointed by the VEA on the granting, revocation of the Biosafety certificate.
g. Certificate, reporting to competence agencies for review and monitor.

Article 17. Conditions to conduct and timing of Committee's official meeting

The Committee's official meeting only can be conducted when it meets the following conditions:

1. Presence (in person or online) of at least two third (2/3) of total Committee members according to Committee's decision, in which must have: Chairman or Vice-chairman, in case of the absence of Chairman (after this shall refer as the main responsible man), at least 1 reviewer member and Secretary member or Secretary member's replacement
2. Presence of representative of Applicant or the organization which is authorized by applicant.
3. Application fee has been made by applicants in accordance with current regulation.

Article 18. Content and order of Committee's official meetings

The chairman shall moderate the meeting base on the right which is stipulated at Article 11 in this Circular and follow the order:

1. Secretary member shall announce the decision of forming Committee, introduce the participants and abstract report on the process of responding with submission dossier, provide information about the work have been done by Committee and Permanent Biosafety Committee Authority's
2. The applicant organization shall present briefly submission on risk assessment of GMC.
3. The peer-reviewers and remaining members shall present their evaluation, assessment opinion,
4. Secretary member shall announce the evaluation of absence member;
5. Applicant's response (if yes)
6. Delegates' opinions (if yes)
7. Committee continue the meeting (without the participant of invited persons) and shall focus on the

following contents:

a. Discussion on risk assessment of the genetically modified crop to the environment and biodiversity.
b. Committee's members shall complete the assessment form according to the annex 7 in this circular.
c. Secretary member shall check the vote, summarize and report the result of voting.
d. Committee discusses and unifies to draft the conclusion.

8. The Chair shall conclude Committee's conclusion and give the closing remark.

Article 19. Principle for Committee's conclusion

Committee's appraisal result shall be officially approved if there are at least three fourth (3/4) members of Committee, who attended the meetings unify through the appraisal's sheet.

Article 20. Organization and operation of Technical Advisory Board

1. Technical Advisory Board is formed by VEA's decision in accordance with Annex 8 of this Circular and shall have at least three (3) members, who are experts with experience, depth knowledge in the field which is related to the submission dossier.

The fee for operating the Advisory board shall follow the actual law.

1. Technical Advisory Board has the responsibility of technical supporting to Committee in the dossier appraisal process through the Authority Organization, which includes Review the submission dossier; propose the response to public comment; complete the summary of Technical advisory board's opinions
2. The responsibility of Technical advise board's member:
   a. Review and technically consult for the Committee about the submission dossier in granting Biosafety certificate according to Annex 9 in this Circular;
   b. In the necessary case, have the right to propose the Authority Organization to request Applicant for providing addition necessary documents to support the appraisal.
   c. Return all the provided dossier and documents to the Authority Organization after the Technical Advisory Board is dissolve. Technical Advisory Board members shall not provide any information about the assessment result as well as other information about the dossier to the third party, shall not use the result of risk assessment illegally on the side of intellectual property;

Chapter IV. Operated organization

Article 21. Applicant's responsibility

After granted the Biosafety certificate, applicant shall have the responsibility to annually report the monitoring to ensure the biosafety as requirement in the Biosafety certificate, send it to MONRE, MARD and the People Committees where the genetic modified crop is cultivated.

Article 22. Implementation provisions

1. This Circular shall come into force on July 01, 2013
2. During the operation process, if there is any difficulty or unclearly, it shall feedback immediately to MONRE for examination and dealing.

Minister's representative
Vice minister

(signed)
Bui Cach Tuyen

Annex 1. Application form for granting Biosafety Certification

(promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

NAME OF APPLICANT

Number: ….
granting Biosafety
MC) (name of

SOCIALIST REPUBLIC OF VIET NAM
Independence - Freedom – Happiness
……..
(Place), date……. Month …… year …..,

To: Vietnam environment agency (Biodiversity and conservation Agency)

Applicant name:
Representative of applicant organization:
Occupation:
Name of representative contact:
Contact address:
Tel: Fax:
Email:

Request Ministry of Natural Resource and Environment to review and grant the Biosafety Certificate for (name of

event)

1. Common name (in Vietnamese and English) of the GMC
2. Scientific name of GMO
3. Name of the gene transfer event:
4. Identification code (if yes)
5. Relevant traits to transferred gene:
6. Potential of usage form, and region of cultivation after granted the Certificate
7. Attached documents:

a. 01 original and 09 copies of field trial report which are certified by MARD
b. 01 copy of MARD's approval document of the trial result
c. 10 original of Risk assessment of GMC to environment and biodiversity together with the electric file.
d. 01 original of electric file of risk assessment of GMC to environment and biodiversity
e. attachment document: (if yes)

We ensure the truth of all above data, documents. If there is any in-correction, we shall be legally responsible under Social of Republic of Vietnam's law.

Request the Authority to appraise the submission dossier and grant the Biosafety certificate

Receiver: ….Applicant…

- Above
- - (Signature, full name, occupation, stamp)
- Preserve

Annex 2. Risk Assessment report of GMC to environment and biodiversity

(Promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

NAME OF APPLICANT **SOCIALIST REPUBLIC OF VIET NAM**
Independence - Freedom – Happiness
Hanoi, date month year

Risk assessment report of GMC to environment and biodiversity

Guidance: Registered organizations must answer all the questions specified in the risk assessment report. Each answer in the report must be proved by the enclosing of scientific publications.

I. General information

1. Name of organization:

Organization's representative:
Organization's contact point:
Address:
Tel: Fax:

Email:

1. Name of GMC:

Common name:
Scientific name:
Gene transfer event:
The unique identified code (if yes):
Purpose of use:
Food use☐
Feed use☐
Other purpose☐ (if yes, please clarify in details)
Method for GMC detection:

II. Relevant information on recipient plant

1. Name of recipient plant:
   a. scientific name;
   b. common name:

2. Potential risk of recipient plant to
Human Yes☐ No☐
Animal Yes☐ No☐
Plant Yes☐ No☐
Provide scientific documents to support above information

3. Vietnam is original homeland of the recipient plant? Yes☐ No☐
Providing scientific documents to support above information

4. Recipient plant being planted in Vietnam for the first time? Yes☐ No☐
If not, please continue to answer the question 5 below.
If yes, describe natural growth conditions including direct/indirect interaction of recipient plant in ecological food chain.

5. Describe the geography distribution, living environment including the information about the other species which have the direct and indirect relationship in the food chain in the ecosystem, history of cultivation and usage of the host organism in Vietnam;

6. Description of dispersal ability and out-crossing with wild type/relative?
Yes☐ No☐
If yes, list out the name and geography distribution of wild type.
Enclose the scientific documents to support above information.

7. Description of survival ability and specific factors impact on the survival ability.

III. Information on gene transformation method

1. Description of gene transformation method

1. Description of original, size, sequence and function of vector for transformation

1. Description of original, size, sequence and function of the inserted gene

1. Donor organism has safe history of use? Yes☐ No☐

If no, describe all potential risks might effects on human/ animal/ environment health

5. Donor organism is factor to develop illness? Yes☐ No☐

If yes, are there any reports demonstrated that inserted DNA has no single ill effect at certain point in time or environment?

IV. Information on GMC:

1. Fully description **of inserted site and number of copies inserted** in GMC;
Information on expression of the inserted gene.

2. In case of stacked of single transformation events, fully description of:

a. Interactions among the stacked genes which could lead to develop allergens and/or toxins, and adverse environmental or health effects in animals or humans.

b. Interactions among the stacked genes which might lead to change in metabolism's, phenotypic and agronomic characteristics

c. The statistical differences in gene expression; agronomic, morphological, **genetic stabilization** and farmer practices between stacked of single transformation events and each single transformation event.

3. **Fully description of genetic stabilization, intended expression of GMC and** detection method of the expression;

4. Description of unintended effects (if any)

5. Historical information of international approval and usage.

V. Potential risk assessment of GMC to environment and biodiversity

1. Potential of Gene flow

Identify the hazard of gene flow and the consequence if occurs, basing on the results of international studies and Vietnamese field trials of this GMC to prove the above statement. And propose management measure of hazard and consequence.

1. Potential of weediness, long-lasting or become invasiveness to the natural inhabitation

Identify the hazard of weediness, long-lasting or become invasiveness to the natural inhabitation and the consequence if occurs, basing on the results of international studies and Vietnamese field trials of this GMC to prove the above statement. And propose management measure of hazard and consequence.

1. Impact of GMC to non-target organisms

a. Identify non-target organism, which can be exposed to the GMC in Vietnam including herbivore, natural enemies, soil organism, ect.

a. Identify the hazard to NTOs and the consequence if occurs, basing on the results of international studies and field trials of this GMC in Vietnam to prove the above statement.

1. Impact on the environment and biodiversity

a. Agricultural practice changes with cultivating genetically modified? If yes, describe the new farming system
b. Adverse effects by long terms application of GMC? If no, provide evidence to support the statement.
c. If yes, proposed risk management strategies.

1. Impact on the soil ecosystems
b. Identify surrogate soil organisms and metabolic processes might have adverse effects by GMC? Level of honesty, objective and scientific reasoning for selecting those soil organism species.
c. Identify the hazard and effects to soil organisms and soil metabolism (Carbon, Nitrogen metabolic processes). Basing on the results of international studies and field trials of this GMC in Vietnam to prove the above statement and propose risk management strategies (if yes).

6. For insect-resistant GMC, targeted insects may develop resistance to GMC. Provide the proposal for insect resistance management plan.

VI. Information of GMC's risk on human health

1. In case GMCs will be used for Food/Feed use in Vietnam:

Has GMC been approved for Food/Feed use by MARD? Yes☐ No☐

If yes, provide the copy of Food/Feed Safety Certificate granted by MARD.

If not, provide the list of global approval for Food/Feed use and propose management plan to ensure GMC shall not enter to Food/Feed chain.

1. In case GMCs has not been approved yet for Food/Feed use in Vietnam: Description of the exposure of human to GMC during planting process and adverse effects due to exposure.

Provide scientific publication to support above statement.

VII. Proposal of GMC risk management for environment and biodiversity

1. List out identified risks of GMC to environment and biodiversity
2. Proposal of GMC risk management plans for environment and biodiversity

VIII. Conclusion and suggestion

Annex 3. Summary of Risk Assessment report of GMC to environment and biodiversity

(Promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

SOCIALIST REPUBLIC OF VIET NAM

NAME OF APPLICANT **Independence - Freedom – Happiness**

Hanoi, date month year

Summary of Risk Assessment report of GMC to environment and biodiversity

I. General information

1. Name of organization, Organization's representative, Organization's contact point
2. Name of GMC, common name, scientific name, commercial name, gene transfer event and the only identified code (if yes

II. Information on host organism

Short description about the host organism, including: name, biological characterization, the relation to Vietnam's natural and environmental, historical of use.

III. Information on gene transfer process

Description of creating GMC process, including the general description of gene transfer technique

IV. Information of GMC

1. Describe the new trait and characteristic of the GMC in comparison with the non_GMC.
2. Information about the historic of this GMC's international approval and usage

V. Information of GMC potential risk assessment to environment and biodiversity

Describe the risk assessment activities, which had been done on this GMC and the results of these assessments.

VI. Information about the proposed risk management plan

Briefly describe the proposed risk management plan (if yes

Annex 4. Biosafety certificate

(Promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

Minister of Natural resource and environment **SOCIALIST REPUBLIC OF VIET NAM**

Independence - Freedom – Happiness

Biosafety certificate

1. Name of GMC:

Common name:
Scientific name:
Gene transfer event:
The only identified code (if yes):

2. Name of Organization/ individual the Biosafety certificate granted for:
Address:
Tel: Fax:

3. Biosafety certification's condition:
GMC granted for Biosafety Certificate must be complied with current regulations on production and trade before releasing purpose (feeding, cultivating, releasing) into the environment.

Hanoi, date….. month…..year…..

Minister of MoNRE

Note:
Original dossier Nr……. Date……

Annex 5. Decision on Establishment of Biosafety Committee

(Promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

Hanoi, date…. month….year 20…

Annex 6. Member of Biosafety Committee's Evaluation form of submission dossier for granting Biosafety Certificate

(Promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

Minister of Natural resource and environment
National Biosafety Committee

SOCIALIST REPUBLIC OF VIET NAM
Independence - Freedom – Happiness

Place…., Date…month… year 20..

Evaluation form of submission dossier for granting biosafety certificate

Review member:
Member:

I. **Dossier's general information:**

1. Name of applicant's organization:
2. Name of GMC:

- Common name:
- Scientific name:
- Gene transfer event:
- Purpose of use of GMC:
- The only identified code (if yes):

1. Dossier's code:

I. **Assessing Expert:**

1. Full name of committee member:
2. Position
3. Organization:

I. **Content of evaluation:**

1. Evaluation of submission dossiers: Level of sufficient information in accordance with the Circular 08/2013/TT-BTNMT dated 16/05/2013
2. Evaluation of ERA Submission Dossier: Level of honesty, objective and scientific logical for:
    a. conclusions on risk assessments
    b. proposal on GMC risk management to environment and biodiversity

I. **Conclusion:**

1. Request for granting Biosafety Certificate without any additional information
2. Request for granting Biosafety Certificate with additional information (*verify additional information)*
3. Request not to grant the Biosafety Certificate

Committee's Member
(Signature and indicate full name)

Annex 7. Member of Biosafety Committee's Appraisal form of submission dossier for granting Biosafety Certificate

(Promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

Minister of Natural resource and environment
National Biosafety Committee

SOCIALIST REPUBLIC OF VIET NAM
Independence - Freedom – Happiness

Appraisal form of submission dossier for granting biosafety certificate

I. **Dossier's general information:**

1. Name of applicant's organization:
2. Name of GMC:

- Common name:
- Scientific name:
- Gene transfer event:
- Purpose of use of GMC:
- The only identified code (if yes):

1. Dossier's code:

I. **Assessed advisor:**

1. Full name of advisor :
2. Position:
3. Organization:

I. **Conclusion:**

4. Request for granting Biosafety Certificate without any additional information
5. Request for granting Biosafety Certificate with additional information (*verify additional information)*
6. Request not to grant the Biosafety Certificate

Committee member (signature and full name)

Annex 8. Decision on Establishment of Technical Advisory Board

(Promulgated with Circular 08/2013/TT-BTNMT dated 16/05/2013 - Minister of MONRE)

Hanoi, date…. month….year 20…

Annex 9. Technical Advisory Board's evaluation form

(promulgated with Circular number /TT-BTNMT dated on

- Minister of MONRE)

Minister of Natural resource and environment

Technical Advisory Board

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom – Happiness

Technical advisory board's evaluation form

I. **Dossier's general information:**

1. Name of applicant's organization:
2. Name of GMC:

- Common name:
- Scientific name:
- Gene transfer event:
- Purpose of use of GMC:
- The only identified code (if yes):

1. Dossier's code:

I. **Assessed advisor:**

1. Full name of advisor :
2. Position:
3. Organization:
4. Date of receiving dossiers: dd/mm/yyyy

I. **Content of assessment**

1. Evaluation Submission dossier on risk assessment: Level of honesty, objective and scientific logical for concluding potential risks
2. Propose the response to public comment; complete the summary of Technical advisory board's opinions through the meetings.

I. **Conclusions**

1. Conclusion on submission dossiers: Level of sufficient information in accordance with the Circular 08/2013/TT-BTNMT dated 16/05/2013
2. Conclusion on safety of GMC
    a. Is GMC safety to environment and biodiversity ☐
    b. Is GMC safety to environment and biodiversity in certain conditions (*verify certain conditions)* ☐
    a. Unsafe ☐