

GOVERNMENT

SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom – Happiness

No. 118/2020/ND-CP

Hanoi, October 2, 2020

DECREE

AMENDMENTS 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 the Law on Government Organization dated June 19, 2015;

Pursuant to the Law on Biodiversity dated November 13, 2008;

At request of Minister of Natural Resources and Environment;

The Government promulgates Decree on amendments 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. 69/2010/ND-CP).

Article 1. Amendments to Decree 69/2010/ND-CP:

s1. Add Clause 6 to Article 3 as follows:

“6. “*gene transfer event*” refers to the result of reintegrating target DNA into a specific location in genome of a species to create a genetically modified organism bearing the target gen, including: single gene transfer event refers to the result of transferring a single gene which controls a desired characteristic and complex gene transfer refers to the result of transferring multiple genes which control one or multiple desired characteristics using genetic transfer technology.”

2. Add Clause 4 to Article 5 as follows:

“4. Genetically modified organism that is the result of traditional backcross process with multiple gene transfer events licensed with Biosafety certificate, certification of genetically modified organisms’ eligibility for use as food and certification of genetically modified organisms’ eligibility for use as animal feed while conforming to regulations on investment and business conditions shall be released into the environment, used as food and/or animal feed.”

3. Amend Clause 2 Article 7 as follows:

“2. Risk assessment reports of genetically modified organisms for the environment, biodiversity, human health and domestic animal health shall be prepared using forms under Annex IV, Annex V and Annex VI of Decree No. 69/2010/ND-CP.

In case a genetically modified organism bears complex gene transfer event, risk assessment reports must provide additional data on interaction of transferred genes in the structure, structural integrity, functions and behavior of target genes in receiving organism.”

4. Amend Article 15 as follows:

“Article 15. Contents of genetically modified organism testing

1. Genetically modified organism testing refers to the process of monitoring and assessing impact of genetically modified organisms on the environment and biodiversity in specific conditions of Vietnam.

2. Genetically modified organism testing consists of following primary contents:

- a) Risk of becoming harmful organisms;
- b) Risk of unintentionally affecting the organisms in a negative manner;
- c) Risk of negatively altering surrounding ecosystem.

Risk assessment of genetically modified organisms include: assess impact on soil ecosystem; assess impact of cultivation method for genetically modified plan on the environment and biodiversity;

d) Risk of genetic drift;

dd) Other adverse effects.”

5. Amend Clause 2 Article 16.

6. Amend Article 17 as follows:

“Article 17. Entitlement and procedures for accrediting and revoking decisions on accrediting genetically modified organism testing body

1. Ministry of Agriculture and Rural Development shall accredit and revoke decisions on accrediting genetically modified organism testing bodies.

2. Organizations applying to accredit genetically modified organism testing bodies shall be public service providers.

3. An organization applying to accredit genetically modified organism testing body shall submit 1 application to Ministry of Agriculture and Rural Development in person, via postal service or via the internet. Application includes:

a) Written application for accrediting genetically modified organism testing body using Form No. 1 under Annex attached to this Decree;

b) Explanation for capacity of accrediting genetically modified organism testing body using Form No. 2 under Annex attached to this Decree.

4. Within 5 working days from the date on which application is received, Ministry of Agriculture and Rural Development shall inform the applicants in writing about accepting applications or requesting revision; revision period shall not be included in application appraisal period.

5. Within 45 days from the date on which adequate applications are received, Ministry of Agriculture and Rural Development shall appraise the applications.

Ministry of Agriculture and Rural Development shall form Council for testing and assessing risks of genetically modified organism according to Article 17a of this Decree. Appraisal results of the Council shall serve as the basis for Ministry of Agriculture and Rural Development to consider and decide to accredit genetically modified organism testing bodies.

6. Within 10 days from the date on which appraisal results are available, Ministry of Agriculture and Rural Development shall consider and decide to accredit genetically modified organism testing bodies. In case of not accrediting genetically modified organism testing bodies, inform the applicants in writing and specify reasons.

7. Ministry of Agriculture and Rural Development shall take charge and cooperate with Ministry of Natural Resources and Environment in examining operation of genetically modified organism testing bodies. In case of breaching any of the requirements under Article 16 of Decree No. 69/2010/ND-CP, Ministry of Agriculture and Rural Development shall consider revoking decisions on accrediting genetically modified organism testing bodies.

8. Within 10 days from the date on which decisions on accreditation or revocation of decisions on accreditation of genetically modified organism testing bodies, Ministry of Agriculture and Rural Development shall send 1 master register to Ministry of Natural Resources and Environment and publicize the decisions on website of Ministry of Agriculture and Rural Development.”

7. Add Article 17a and Article 17b after Article 17 as follows:

“Article 17a. Organization and operation of Council for testing and assessing risk of genetically modified organisms

1. Ministry of Agriculture and Rural Development shall decide to form Council for testing and assessing risk of genetically modified organisms composing of at least 9 members: the

Chairperson shall be representative of professional regulatory authority affiliated to Ministry of Agriculture and Rural Development, the Vice Chairperson shall be representative of standing assessment agency and members shall be representatives of Ministry of Natural Resources and Environment, Ministry of Industry and Trade, Ministry of Science and Technology, Ministry of Health and experts. In which, 2 members shall be chosen to be Review panel. The Council shall dissolve as soon as completing assigned tasks. Ministry of Agriculture and Rural Development shall assign an affiliated entity to be standing assessment agency.

2. The Council for testing and assessing risk of genetically modified organisms is responsible for:

a) appraising application for accrediting genetically modified organism testing bodies and consulting Ministry of Agriculture and Rural Development to consider and accredit genetically modified organism testing bodies;

b) appraising application for testing and assessing test results and consulting Ministry of Agriculture and Rural Development to consider issuing testing permit and accrediting test results.

3. The Council operates on the basis of democracy and transparency; is personally responsible for scientificity and accuracy for feedback and assessment and collectively responsible for general conclusion of the Council.

4. Council meetings must have at least 2/3 of the members and be hosted by the Chairperson or Vice Chairperson (in case of absence of the Chairperson). Standing assessment agency shall hold Council meetings for each application and record the meeting in writing. In the first meeting, host of the meeting shall assign 1 Council secretary and 2 Review panel members. If necessary, the Council may request addition of 2 to 3 scientists experienced in relevant fields to independently review the applications.

5. If necessary, the Council may request standing assessment agency to invite representatives of the applicants to participate in the meetings to provide additional information and answer questions of the Council members of public opinions.

6. On the basis of meeting minutes, Council secretary shall complete application and Council conclusion assessment reports to report to Ministry of Agriculture and Rural Development.

“Article 17b. Entitlement and procedures for reissuing decisions on accrediting genetically modified organism testing body

1. Decision on accrediting genetically modified organism testing bodies shall be reissued in case of loss, damage or wearing out.

2. Application for reissuance consists of:

a) Application for reissuance using Form No. 3 under Annex attached to this Decree;

b) Decision on accrediting genetically modified organism testing bodies previously issued in case of damage or wearing out.

3. Applicants shall submit 1 application for reissuance as specified under Clause 2 of this Article to Ministry of Agriculture and Rural Development in person, via postal service or via the internet.

4. Within 07 working days from the date on which adequate applications are received, Ministry of Agriculture and Rural Development shall consider reissuing decisions on accrediting genetically modified organism testing bodies.”

8. Amend Article 18 as follows:

“Article 18. Entitlement and procedures for issuance and revocation of permit for testing genetically modified organisms

1. Ministry of Agriculture and Rural Development shall issue and revoke permit for testing genetically modified organisms.

2. Applicants shall submit 1 application to Ministry of Agriculture and Rural Development in person, via postal service or via the internet. Application includes:

a) Written application for issuance of permit for testing genetically modified organisms using Form No. 4 under Annex attached to this Decree;

b) Explanation of application for testing genetically modified organisms and testing plans specified under Annex II and Annex III of Decree No. 69/2010/ND-CP. With respect to genetically modified plants, adopt Form No. 5 under Annex attached to this Decree;

c) Copies of Decisions on accrediting genetically modified organism testing bodies;

d) In case genetically modified organisms are imported to be tested and assessed for risks, documents proving such genetically modified organisms have been permitted for use by countries around the world are required in order for the genetically modified organisms to be released into the environment. In case genetically modified organisms are created domestically, documents proving such genetically modified organisms are results of scientific research accredited by competent authorities are required.

3. Within 7 working days from the date on which application is received, Ministry of Agriculture and Rural Development shall inform the applicants in writing about accepting applications or requesting revision; revision period shall not be included in application appraisal period.

4. Within 30 days for applications for issuance of permit for limited testing and 45 days for applications for issuance of permit for large-scale testing from the date on which adequate applications are received, Ministry of Agriculture and Rural Development shall organize the Council to appraise the applications. Appraisal results of the Council for testing and assessing

genetically modified organisms shall serve as the basis for Ministry of Agriculture and Rural Development to consider issuing permit for testing genetically modified organisms.

5. Within 10 days from the date on which appraisal results are available, Ministry of Agriculture and Rural Development shall consider issuing permit for testing genetically modified organisms. In case of rejection, Ministry of Agriculture and Rural Development shall inform the applicants and specify reasons in writing.

6. Ministry of Agriculture and Rural Development shall take charge and cooperate with Ministry of Natural Resources and Environment in examining compliance with requirements of permit for testing genetically modified organisms.

7. Ministry of Agriculture and Rural Development shall consider revoking permit for testing genetically modified organisms if the organizations issued with the permit commit any of the following violations:

- a) Providing false information on name of genetically modified organisms;
- b) Conducting tests at the wrong time, in the wrong places with scale not agreed upon by Ministry of Agriculture and Rural Development;
- c) Failing to comply with explanation for application for testing genetically modified organisms.

8. Within 10 days from the date on which decisions on issuance or revocation of permit for testing genetically modified organisms, Ministry of Agriculture and Rural Development shall send 1 master register to Ministry of Natural Resources and Environment and publicize the decisions on website of Ministry of Agriculture and Rural Development.”

9. Amend Article 19 as follows:

“Article 19. Permit for testing genetically modified organisms

Permit for testing genetically modified organisms shall follow Form No. 6 under Annex attached to this Decree;”

10. Add Article 19a after Article 19 as follows:

“Article 19a. Entitlement and procedures for reissuance of permit for testing genetically modified organisms

1. Permit for testing genetically modified organisms shall be reissued in following cases:

- a) Changes to information on organizations granted with permit for testing genetically modified organisms;
- b) Lost, damaged or worn-out permit for testing genetically modified organisms.

2. Application for reissuance consists of:

- a) Written application using Form No. 7 under Annex attached to this Decree;
- b) Permit for testing genetically modified organisms previously issued in case of changes to information on the organizations or damaged or worn-out permit;
- c) Documents proving changes for case specified under Point a Clause 1 of this Article.

3. Applicants shall submit 1 application for reissuance as specified under Clause 2 of this Article to Ministry of Agriculture and Rural Development in person, via postal service or via the internet.

4. Within 07 working days from the date on which adequate applications are received, Ministry of Agriculture and Rural Development shall consider reissuing permit for testing genetically modified organisms.”

11. Amend Article 21 as follows:

“Article 21. Acknowledging testing results of genetically modified organisms

1. Applicants shall submit testing results of genetically modified organisms using Form No. 8 under Annex attached to this Decree to Ministry of Agriculture and Rural Development in person, via postal service or via the internet.

2. Within 30 days for acknowledging results of limited testing and 45 days for acknowledging results of large-scale testing from the date on which adequate reports are received as specified under Clause 1 of this Article, Ministry of Agriculture and Rural Development shall organize the Council to appraise the test results.

3. Within 10 days from the date on which appraisal results are available, Ministry of Agriculture and Rural Development shall consider acknowledging or rejecting test results of genetically modified organisms. In case of rejection, Ministry of Agriculture and Rural Development shall inform the applicants and specify reasons in writing.

4. Within 10 days from the date on which decisions on acknowledging test results of genetically modified organisms, Ministry of Agriculture and Rural Development shall send 1 master register to Ministry of Natural Resources and Environment and publicize the decisions on website of Ministry of Agriculture and Rural Development.”

12. Add Article 23a after Article 23 as follows:

“Article 23a. Entitlement and procedures for reissuance of biosafety certificate

1. Biosafety certificates shall be reissued in following cases:

- a) Changes to information of the organizations under issued biosafety certificates;
- b) Lost, damaged or worn-out biosafety certificates.

2. Application for reissuance consists of:

- a) Written application using Form No. 9 under Annex attached to this Decree;
- b) Issued biosafety certificates in case of changes to information of the organizations or damaged, worn-out biosafety certificates;
- c) Documents proving changes for case specified under Point a Clause 1 of this Article.

3. Applicants shall submit 1 application for reissuance as specified under Clause 2 of this Article to Ministry of Natural Resources and Environment in person, via postal service or via the internet.

4. Within 7 working days from the date on which adequate applications are received, Ministry of Natural Resources and Environment shall consider reissuing biosafety certificates.”

13. Amend Points c, add Point d and Point dd Clause 2 Article 28 as follows:

“c) With respect to genetically modified organisms specified under Clause 2 Article 27 of Decree No. 69/2010/ND-CP, provide master registers or verified true copies and certified Vietnamese translation of confirmation documents or equivalent documents of competent agencies permitting genetically modified organisms to be used as food in at least 5 developing countries;

d) Summary of risk assessment reports (together with electronic form) of genetically modified organisms for human health using Form No. 10 under Annex attached to this Decree;

dd) Reference and research scientific texts that have not been published, other assessment, test or scientific figures (if any) which are used by the applicants as the basis to conclude that the genetically modified organisms do not negatively affect human health.”

14. Add Article 28a after Article 28 as follows:

“Article 28a. Entitlement and procedures for reissuance of certification of genetically modified organisms’ eligibility for use as food

1. Certification of genetically modified organisms’ eligibility for use as food shall be reissued in following cases:

- a) Changes to information of the organizations under issued certification of genetically modified organisms’ eligibility for use as food;

b) Lost, damaged or worn-out certification of genetically modified organisms' eligibility for use as food.

2. Application for reissuance consists of:

a) Written application using Form No. 11 under Annex attached to this Decree;

b) Certification of genetically modified organisms' eligibility for use as food previously issued in case of changes to information on the organizations or damaged or worn-out permit;

c) Documents proving changes for case specified under Point a Clause 1 of this Article.

3. Applicants shall submit 1 application for reissuance as specified under Clause 2 of this Article to Ministry of Agriculture and Rural Development in person, via postal service or via the internet.

4. Within 07 working days from the date on which adequate applications are received, Ministry of Agriculture and Rural Development shall consider reissuing certification of genetically modified organisms' eligibility for use as food."

15. Amend Points c, add Point d and Point dd to Clause 2 Article 33 as follows:

"c) With respect to genetically modified organisms specified under Point b Clause 1 Article 32 of Decree No. 69/2010/ND-CP, provide master registers or verified true copies and certified Vietnamese translation of confirmation documents or equivalent documents of competent agencies permitting genetically modified organisms to be used as food in at least 5 developing countries;

d) Summary of risk assessment reports (together with electronic form) of genetically modified organisms for domestic animals using Form No. 12 under Annex attached to this Decree;

dd) Reference and research scientific texts that have not been published, other assessment, test or scientific figures (if any) which are used by the applicants as the basis to conclude that the genetically modified organisms do not negatively affect domestic animals."

16. Add Article 33a after Article 33 as follows:

"Article 33a. Entitlement and procedures for reissuance of certification of genetically modified organisms' eligibility for use as animal feed

1. Certification of genetically modified organisms' eligibility for use as animal feed shall be reissued in following cases:

a) Changes to information of the organizations under issued certification of genetically modified organisms' eligibility for use as animal feed;

b) Lost, damaged or worn-out certification of genetically modified organisms' eligibility for use as animal feed.

2. Application for reissuance consists of:

a) Written application using Form No. 13 under Annex attached to this Decree;

b) Certification of genetically modified organisms' eligibility for use as animal feed previously issued in case of changes to information on the organizations or damaged or worn-out permit;

c) Documents proving changes for case specified under Point a Clause 1 of this Article.

3. Applicants shall submit 1 application for reissuance as specified under Clause 2 of this Article to Ministry of Agriculture and Rural Development in person, via postal service or via the internet.

4. Within 07 working days from the date on which adequate applications are received, Ministry of Agriculture and Rural Development shall consider reissuing certification of genetically modified organisms' eligibility for use as animal feed.”

17. Amend Clause 3 Article 42 as follows:

“In case of transporting and transiting genetically modified organisms or products of genetically modified organism that are not specified under Clause 1 Article 42 of Decree No. 69/2010/ND-CP via Vietnam territory, transiting procedures shall conform to Point c Clause 1 Article 35 of Decree No. 69/2018/ND-CP dated May 15, 2018 of the Government on elaborating to Law on Foreign Trade Management.”

Article 2. Transition clauses

1. Applications for accrediting genetically modified organism testing body, applications for issuance of permit for testing genetically modified organisms and applications for accrediting test results of genetically modified organisms received before the effective date hereof shall be processed according to regulations and law applicable at the time of receipt. Unless applicants request implementation by this Decree.

2. Decisions on accrediting genetically modified organism testing body, permit for testing genetically modified organisms and decisions on accrediting test results of genetically modified organisms received before the effective date hereof shall remain legitimate.

Article 3. Implementation

1. This Decree comes into force from October 2, 2020.

2. Ministers, heads of ministerial agencies, heads of Governmental agencies, Chairpersons of People's Committees of provinces and cities and relevant authorities, organizations, individuals are responsible for the implementation of this Decree./.

PRIME MINISTER

Nguyen Xuan Phuc

Translated version for reference only