

**THE GOVERNMENT**

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No. 108/2011/ND-CP

**SOCIALIST REPUBLIC OF VIET NAM**

**Independence - Freedom – Happiness**

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*Hanoi, November 30, 2011*

**DECREE**

AMENDING A NUMBER OF ARTICLES OF THE GOVERNMENT'S DECREE NO. 69/2010/ ND-CP OF JUNE 21, 2010, ON BIOSAFETY FOR GENETICALLY MODIFIED ORGANISMS, GENETIC SPECIMENS AND PRODUCTS OF GENETICALLY MODIFIED ORGANISMS

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*Pursuant to the December 25, 2001 Law on Organization of the Government;*

*Pursuant to the November 29, 2005 Law on Environmental Protection;*

*Pursuant to the November 13, 2008 Biodiversity Law;*

*Pursuant to the June 17, 2010 Law on Food Safety;*

*At the proposal of the Minister of Natural Resources and Environment,*

**DECREES:**

**Article 1.** To amend a number of articles of the Government's Decree No. 69/2010/ND-CP of June 21, 2010, on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms (below referred to as Decree No. 69/2010/ND-CP)

**1. To amend Article 28 as follows:**

"Article 28. Competence, order and procedures for grant or revocation of a written certification of genetically modified organisms' eligibility for use as food

1. The Ministry of Agriculture and Rural Development may grant and revoke written certifications of genetically modified organisms' eligibility for use as food.
2. An applicant for a written certification of genetically modified organisms' eligibility for use as food shall submit three (3) dossier sets to the Ministry of Agriculture and Rural Development. Such a dossier comprises:
  - a/ An application for a written certification of genetically modified organisms' eligibility for use as food, made according to the form specified by the Ministry of Agriculture and Rural Development;
  - b/ A report on assessment of risks of genetically modified organisms to human health, made according to the form provided in Appendix V to Decree No. 69/2010/ND-CP;
  - c/ For genetically modified organisms specified in Clause 2, Article 27 of Decree No. 69/2010/ND-CP, documents evidencing that they have been permitted for use as food in five (5) developed countries are required.

3. Within 7 working days after receiving a dossier, the Ministry of Agriculture and Rural Development shall notify the applicant of its acceptance of the valid dossier or request

the applicant to supplement and complete the dossier under regulations. The time for dossier supplementation and completion will not be included in the time for dossier appraisal.

4. Within 180 days after receiving a valid dossier, the Ministry of Agriculture and Rural Development shall set up a genetically modified food safety council to appraise the dossier. For genetically modified organisms specified in Clause 2, Article 27 of Decree No. 69/2010/ ND-CP, the time limit for grant of, or refusal to grant, such a written certification is 60 days.

5. After receiving a valid dossier, the Ministry of Agriculture and Rural Development shall publish information on the report on assessment of risks of genetically modified organisms to human health on its website for public comment. Public comments shall be summarized and reported to the genetically modified food safety council. The time limit for collecting public comments is 30 days after information is published.

6. Within 30 days after obtaining appraisal results, the Minister of Agriculture and Rural Development shall consider granting a written certification of genetically modified organisms' eligibility for use as food. In case of refusal, it shall issue a notice clearly stating the reason to the applicant.

7. Applicants for written certification of genetically modified organisms' eligibility for use as food shall pay a charge for dossier appraisal. The Ministry of Finance shall assume the prime responsibility for, and coordinate with the Ministry of Agriculture and Rural Development in, specifying rates, management and use of the charge for dossier appraisal.

8. The Ministry of Agriculture and Rural Development shall specify the order and procedures for granting a written certification of genetically modified organisms' eligibility for use as food.

9. The genetically modified food safety council shall advise the Minister of Agriculture and Rural Development on whether to grant a written certification of genetically modified organisms' eligibility for use as food. This council shall be composed of representatives of the Ministries of Agriculture and Rural Development, Industry and Trade; Science and Technology; Natural Resources and Environment; and Health, and some experts.

The Minister of Agriculture and Rural Development shall decide to set up, and define the functions, tasks and operation mechanism of, the genetically modified food safety council."

**2. To amend Clause 2 of Article 29 as follows:**

"The Ministry of Agriculture and Rural Development shall decide to revoke a written certification of genetically modified organisms' eligibility for use as food and issue a written notice to the organization or individual having such certification revoked and publish the revocation in the mass media."

**3. To amend Clause 2 of Article 30 as follows:**

"The Ministry of Agriculture and Rural Development shall stipulate the form of a written certification of genetically modified organisms' eligibility for use as food."

**4. To amend Article 31 as follows:**

"Article 31. List of genetically modified organisms eligible to be granted a written certification of eligibility for use as food

1. The Ministry of Agriculture and Rural Development shall make a list of genetically modified organisms eligible to be granted a written certification of eligibility for use as food and publish this list on its website.
2. Within 10 days after granting or revoking a written certification of genetically modified organisms' eligibility for use as food, the Ministry' of Agriculture and Rural Development shall add or delete the names of genetically modified organisms to or from such list.

**Article 2. Effect**

1. This Decree takes effect on January 15, 2012.
2. A written certification of genetically modified organisms' eligibility for use as food that is granted before the effective date of this Decree remains valid till the expiration of the validity duration written therein.

**Article 3.** Ministers, heads of ministerial-level agencies, heads of government-attached agencies, and chairperson of provincial-level People's Committees shall implement this Decree.-

**ON BEHALF OF THE GOVERNMENT  
PRIME MINISTER**

**Nguyen Tan Dung**