THE GOVERNMENT

THE SOCIALIST REPUBLIC OF VIETNAM

Hanoi, Nov 30th, 2011

DECREE

Amending some articles of the Decree No. 69/2010/ND-CP dated June 6th, 2010 of the Government on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms

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Pursuant to the Government Organization Law dated Dec 25th, 2001;

Pursuant to the Environment Protection Law dated Nov 29th, 2005;

Pursuant to the Biodiversity Law dated Nov 13th, 2008;

Pursuant to the Food safety Law dated Jun 17th, 2010;

In consideration of the proposal of the Minister of the Ministry of Natural Resources and Environment,

DECREE:

- **Article 1.** To amending some articles of the Decree No. 69/2010/ND-CP dated June 6th, 2010 of the Government on Biosafety of Genetically Modified Organisms, Genetic specimen and Products Derived from Genetically Modified Organisms (hereafter refer as Decree No. 69/2010/ND-CP).
 - 1. Article 28 is amended as follows:
- "Article 28. Competence, order, procedure for issuance of a certificate of genetically modified organisms that satisfy conditions to be used as food
- 1. The Ministry of Agriculture and Rural Development grants, withdraws a certificate of genetically modified organisms that satisfy conditions to be used as food.
- 2. An Organization/individual that request for issuance of a certificate of genetically modified organisms that satisfy conditions to be used as food shall have to submit three (03) sets of documents to The Ministry of Agriculture and Rural Development. The application includes:

- a) Application request for issuance of a certificate of genetically modified organisms that satisfy conditions to be used as food that is made on a form provided by The Ministry of Agriculture and Rural Development;
- b) Report on risk assessment of genetically modified organisms for the human health according to provisions of Appendix V of the Decree No. 69/2010/ND-CP;
- c) If genetically modified organisms are regulated in the Item 2, Article 27 of the Decree No. 69/2010/ND-CP, the application shall have provide documents to prove that the genetically modified organisms have been used as food in (five) 5 developed countries.
- 3. Within 07 working days upon the receipt of application, The Ministry of Agriculture and Rural Development shall inform the applicant whether the application is valid or need to be completed, supplemented in accordance with regulations; the time to complete or supplement the application shall not be counted into the time for application examination.
- 4. Within 180 days upon the date of receipt of a valid application, The Ministry of Agriculture and Rural Development shall establish a Committee for food safety of genetically modified organisms to examine the application for issuance of a certificate of genetically modified organisms that satisfy conditions to be used as food. If genetically modified organisms are regulated in the Item 2, Article 27 of the Decree No. 69/2010/ND-CP, the maximum time to consider to issue or withdraw a Certificate of genetically modified organisms that satisfy conditions to be used as food is 60 days.
- 5. Upon receipt of a valid documents, The Ministry of Agriculture and Rural Development shall publish information of the report on risk assessment for the human health in the website of The Ministry of Agriculture and Rural Development for public comments. The period of public comments is 30 days from the date of information uploading.
- 6. Within 30 days upon having of examination results, The Ministry of Agriculture and Rural Development shall consider to issue a Certificate of genetically modified organisms that satisfy conditions to be used as food. In case of refusal to grant a Certificate, The Ministry of Agriculture and Rural Development shall inform and explain the refusal reasons to the applicant.
- 7. An organization, individual that applies for issuance of a Certificate of genetically modified organisms that satisfy conditions to be used as food shall have to pay the application examination fee. The Ministry of Finance presides and coordinates with The Ministry of Agriculture and Rural Development to stipulate the fee levels, management, and use of fees.

- 8. The Ministry of Agriculture and Rural Development shall stipulate specific order, procedure to issue a Certificate of genetically modified organisms that satisfy conditions to be used as food.
- 9. The Committee for food safety of genetically modified organisms is an organization that advises the Minister of The Ministry of Agriculture and Rural Development in considering to issue a Certificate of genetically modified organisms that satisfy conditions to be used as food. The Committee for food safety of genetically modified organisms includes representative from the Ministry of Industry and Trade, the Ministry of Science and Technology, the Ministry of Health, the Ministry of Natural Resources and Environment, the Ministry of Agriculture and Rural Development and experts.

The Minister of The Ministry of Agriculture and Rural Development shall decide to establish and stipulate functions, duties and operation regime of the Committee for food safety of genetically modified organisms."

2. Item 2, Article 29 is amended as follows:

"The Ministry of Agriculture and Rural Development shall send a written decision to withdraw the Certificate of genetically modified organisms that satisfy conditions to be used as food to organizations, individuals whose Certificate is withdrawn and broadcasts such withdrawal on media."

3. Item 2, Article 30 is amended as follows:

"The Ministry of Agriculture and Rural Development provides the specific contents of a certificate of genetically modified organisms that satisfy conditions to be used as food."

- 4. Article 31 is amended as follows:
- "Article 31. List of genetically modified organisms that satisfy conditions to be used as food
- 1. The Ministry of Agriculture and Rural Development shall issue the List of genetically modified organisms that have been already granted certificates for to be used as food and publish the list on its website on biosafety.
- 2. Within 10 days upon the date of issuance or withdrawal of a certificate for genetically modified organisms that satisfy conditions to be used as food, The Ministry of Agriculture and Rural Development shall add or remove the name of that genetically modified organism from the list."

Article 2. Effect

1. This Decree takes effect from Jan 15th, 2012.

- 2. Certificate of genetically modified organisms that satisfy conditions to be used as food has been issued before the effective date of this Decree shall remain valid until the legal time limit stated in the certificate.
- **Article 3.** The Ministers, heads of ministerial-level agencies, heads of governmental agencies, Presidents of People's Committees of provinces, cities directly under the central government are responsible for the implementation of this Decree.

ON BEHALF OF THE GOVERNMENT PRIME MINISTER

(signed)

Nguyen Tan Dung