MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom – Happiness

No. 29/2014/TT-BNNPTNT

Hanoi, September 05, 2014

CIRCULAR

ON THE AMENDMENTS TO THE ARTICLE 7 OF THE CRICULAR N $^\circ$ 23/2010/TT-BNNPTNT DATED 07 APRIL 2010 ON THE RECOGNITION OF BIOTECHNOLOGY ADVANCES OF THE SECTOR OF AGRICULTURE AND RURAL DEVELOPMENT

Pursuant to the Law of Science and Technology dated 18 June 2013;

Pursuant to the Law of Technical Standards and Regulations dated 29 June 2006;

Pursuant to the Government's Decree No. 127/2007/NĐ-CP dated 01 August 2007 on the details for the enforcement of certain articles of the Law of Technical Standards and Regulations;

Pursuant to the Government's Decree No. 69/2010/NĐ-CP dated 21 June 2010 on the regulations on the bio-safety of genetically engineered organisms, genetics specimens and products from genetically engineered organisms;

Pursuant to the Government's Decree No. 199/2013/NĐ-CP dated 26 November 2013 on the regulations on functions, missions, authority and organizational structure of the Ministry of Agriculture and Rural Development;

Pursuant to the Prime Minister's Decision No. 11/2006/QĐ-TTg dated 12 January 2006 on the Ratification of the "Primary program for the development and application of biotechnology in the sector of agriculture and rural development to the year of 2020";

Pursuant to the Prime Minister's Decision No. 97/2007/QĐ-TTg dated 29 June 2007 on the ratification of the "Project for the development and application of biotechnology in the sector of aquaculture to the year of 2020";

At the requests of the Head of the Department of Crop production and Head of the Department of Science, Technology and Environment;

Minister of Agriculture and Rural development has issued the Circular on amendments to the Article 7 of the Circular No. 23/2010/TT-BNNPTNT dated 07 April 2010 on the recognition of biotechnology advances of the sector of agriculture and rural development.

Article 1. Amendments to Section 2 and accessions to Section 3, 4, 5 and 6, Article 7, Circular 23/2010/TT-BNNPTNT on the recognition of biotechnology advances of the sector of agriculture and rural development

"Article 7. Exceptional recognition

- 2. The exceptional recognition of biotechnology advances of a variety, as defined in the List of vegetation eligible for production and trade in Vietnam (referred to as the base variety), with one or a combination of transgenic events certified and endorsed in writing for bio-safety and eligibility to be foodstuffs and feed (referred to as genetically engineered varieties) shall be permissible upon the genetically engineered varieties' satisfaction of the following requirements:
- a) The requirements as defined in Section 1 and Section 2, Article 6 of this Circular;

- b) The primary typical traits and morphology of the genetically engineered variety and those of the base variety are homogeneous, except for characteristics affected by the transgenic events.
- 3. The concerned organization prepares the application for the exceptional recognition of the genetically engineered variety, which has undergone the comparison test with the base variety and the risk assessment test simultaneously, according to Section 5 of this Article.
- 4. If the genetically engineered variety does not undergo the comparison test with the base variety:
- a) The organization that has the genetically engineered variety shall use the form as defined in Appendix 7 of this Circular to establish and submit the plan for the typical and demonstration tests for comparison to the Department of Crop production;
- b) The organization that has the genetically engineered variety shall enter a contract with a testing facility appointed to conduct the typical comparison test for at least 01 crop season in 02 sites;
- c) The organization that has the genetically engineered variety shall carry out demonstration tests for comparison in organic agricultural land areas recommended for the use of the variety. One hectare of each site in one crop season at least shall be tested.
- d) Typical comparison tests can be carried out before or during demonstration tests for comparison;
- dd) Department of Crop production shall lead and coordinate with the Department of Science, Technology and Environment and a Department of Agriculture and Rural Developments to inspect and record details in writing during a comparison test at the test site;
- e) At the end of the tests, the organization that has the genetically engineered variety shall prepare the application for exceptional recognition according to Section 5 of this Article.
- 5. The application for exceptional recognition

The organization that has the genetically engineered variety shall submit one application for the exceptional recognition of the variety genetically modified to the Department of Crop production by hand or by post. An application comprises:

- a) The letter of application for the exceptional recognition of the genetically engineered variety, as per the form defined in Appendix 8 of this Circular;
- b) The report of tests comparing the genetically engineered variety and the base variety, as per the form defined in Appendix 9 of this Circular;
- c) Other relevant documents (if any).
- 6. Procedures and time limit for the exceptional recognition process:
- a) In 05 working days upon the receipt of documents, the Department of Crop production shall consider such papers and inform the applicant in writing of the endorsement of the validity of documents or the request of additional files. The time for the supplementation of documents shall not be included in the length of time of the consideration of the validity of documents;
- b) In 20 working days upon the receipt of full valid documents, the Department of Crop production shall examine such papers and establish a Council for the evaluation and exceptional recognition of biotechnology advances of the genetically engineered variety.

The members of the said Council are defined in Section 1, Article 9 of this Circular. The council shall assess and send the application, as defined in Appendix 4 of this Circular, to the

Department of Crop production in at most 01 day before the Council's meeting. The proceedings of the Council are defined in Section 2, Article 9 of this Circular. Department of Crop production shall consider the Council's opinions. If requirements for recognition are not satisfied, the applicant shall be informed in writing of the ineligibility and reasons;

- c) In 05 working days upon the completion of the application as concluded by the Council, the Department of Crop production shall send the documents to the Department of Science, Technology and Environment, which in turn delivers such papers to the Minister for opinions on the exceptional recognition of biotechnology advances of the genetically engineered variety. The set of such documents includes a letter to the Minister, which specifies the necessity, progress and summarized findings of the tests, evaluation and recommendation for exceptional recognition; a written record of the Council's meeting; an assessment report of the Department of Crop production; the application for exception recognition; the draft Decision on the approval of the exceptional recognition of biotechnology advances of the genetically engineered variety;
- d) In 05 working days upon the receipt of the documents bound for the Minister, the Department of Science, Technology and Environment shall lead and coordinate with the Department of Legal affairs to examine and appraise the fullness and validity of such documents and the past sequence and timeline of the exception recognition process. If regulations are observed, the Department of Science, Technology and Environment shall deliver documents to the Minister for the approval of the exception recognition of biotechnology advances of the genetically engineered variety;
- dd) In 03 working days upon the Minister's approval, the Department of Crop production shall issue the Decision on the exception recognition of biotechnology advances of the genetically engineered variety. If requirements are not met, the applicant must be informed in writing of the ineligibility and reasons."

Article 2. Enforcement

- 1. This Circular comes into force as of October 20, 2014.
- 2. During the enforcement of this Circular, obstacles and difficulties shall be related in writing to Ministry of Agriculture and Rural development (Department of Crop production) for prompt coordination and settlement./.

ON BE HALF OF MINISTER THE DEPUTY MINISTER

(Signed)

Le Quoc Doanh