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MARD Circular 20 Adds Steps in the Ag Input Registration Process

Report Categories:

Biotechnology - GE Plants and Animals

Oilseeds and Products

Grain and Feed

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Report Highlights:

On June 26, 2014, the Ministry of Agriculture and Rural Development (MARD) published Circular 20/2014/TT-BNNPTNT on stipulating some assignments and competencies to manage agricultural materials. Circular 20 adds additional steps to the registration process and channels product registration dossiers through the Department of Science, Technology, and the Environment before they are approved by the Minister of Agriculture and Rural Development.

Summary:

On June 26, 2014, the Ministry of Agriculture and Rural Development (MARD) published Circular 20/2014/TT-BNNPTNT on stipulating some assignments and competencies to manage agricultural materials. Circular 20 reorganizes the agricultural material registration process for a number of different types of agricultural inputs. Inputs covered by this Circular include: 1) livestock breeds, 2) plant varieties, 3) animal and aquaculture feeds, including growth stimulants, 4) aquaculture products used to treat and improve the environment, 5) plant protection drugs, including plant growth regulators, and 6) veterinary medicines. The responsibility of registration of the above mentioned inputs resides in a number of MARD Departments / Directorates. Departments / Directorates responsible for the registration process, include the Directorate of Fisheries, Department of Forestry, Department of Livestock Production, Department of Crop Production, Department of Plant Protection, and the Department of Animal Health. Circular 20 does not change the individual registration processes defined by MARD's relevant Departments / Directorates. However, Circular 20 does stipulate the process by which a product registration gains final approval of the Minister of MARD.

As stipulated by various Departmental Circulars, the registration process may include field trials and / or analytical testing of the variety, drug, or product before MARD allows the product to be sold in Vietnam. This includes imported products.

Circular 20 adds additional steps and responsibility to MARD's Department of Science, Technology, and the Environment (DOSTE) to "preside over and coordinate with the Legal Department to verify dossiers submitted by the specialized management agencies to the Minister." Once DOSTE concludes the dossier is complete, it is forwarded to the Minister for review, comment, and approval. Technically, Circular 20 stipulates that only once the Minister authorizes that a product is registered, can the product circulate in Vietnam. However, in practice, once products are approved at the Director General level of a Department / Directorate, they are allowed to circulate in Vietnam. Quarterly each Department / Directorate will collate the revised list of agricultural materials permitted for use in Vietnam and submit the list to the Minister for approval and publishing.

Article 9 of the Circular stipulates the conditions for a product to be removed from the List of Permitted Materials. Importantly, a product can be removed if it violates the intellectual property in respect to products already registered for circulation.

The Circular entered into force on August 11, 2014. This Circular was not notified to the World Trade Organization's SPS Committee.

On its face Circular 20 adds additional steps to an already burdensome product registration process. Additionally, it increases the importance of cross-Departmental coordination in order to facilitate registration of product applications.

Below is an unofficial translation of Circular 20/2014/TT-BNNPTNT.

**MINISTRY OF AGRICULTURE AND RURAL
DEVELOPMENT**

No. 20/2014/TT-BNNPTNT

**SOCIALIST REPUBLIC OF
VIETNAM**

**Independence - Freedom –
Happiness**

Hanoi, June 26, 2014

CIRCULAR
on stipulating some contents of assignment and competence to manage agricultural materials

Pursuant to the Law on Fisheries dated 2003;

Pursuant to the Law on Quality of Products and Goods dated 2007;

Pursuant to the Ordinance on Plant Protection and Quarantine dated 2001;

Pursuant to the Ordinance on Livestock Breeds dated 2004;

Pursuant to the Ordinance on Plant Varieties dated 2004;

Pursuant to the Ordinance on Veterinary Drugs dated 2004;

Pursuant to Decree No. 08/2010/ND-CP February 5, 2010 on the management of animal feed;

Pursuant to Decree No. 199/2013/ND-CP November 26, 2013 of the Government stipulating the functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development;

At the request of the Director of the Legal Department;

Minister of Agriculture and Rural Development promulgated Circular to stipulate a number of contents of assignment and competence to manage agricultural materials.

Chapter I

GENERAL PROVISIONS

Article 1. Governing scope

1. This Circular stipulates a number of contents of assignment and competence to manage agricultural materials related to the recognition of establishments eligible for field trial, test; the field trial, test, testing, recognition and registration of agricultural materials for circulation in Vietnam under the State management responsibility of the Ministry of Agriculture and Rural Development.

2. Agricultural materials as stipulated in this Circular include the followings:

- a) Livestock breeds (including livestock breeds and aquatic breeds);
- b) Plant varieties (including main agricultural crop varieties and forestry seedlings);
- c) Animal feed (including animal feed, growth stimulants used in livestock production and aquatic feed);
- d) Products to treat and improve the environment, which are used for aquaculture;

- e) Plant protection drugs, including plant growth regulators;
- e) Veterinary medicines.

Article 2. Applicable subjects

This Circular applies to organizations and individuals engaged in activities related to the recognition of establishments eligible for field trial, test; the field trial, test, testing, recognition and registration of agricultural materials for circulation in Vietnam.

Article 3. Implementation of the provisions of the law on intellectual property

Management agencies specialized in agricultural materials stipulated in Article 4 of this Circular is responsible for inspecting and monitoring the implementation of the provisions of the law on intellectual property in the process of considering, recognizing and permitting registration of agricultural materials for circulation in Vietnam.

Chapter II

REGULATIONS ON ASSIGNMENT AND COMPETENCE TO MANAGE AGRICULTURE MATERIALS

Article 4. Assigning management agency specialized in agricultural materials

To assign the focal point agency to manage field trial, test, testing, recognition and registration of agricultural materials for circulation in Vietnam, as follows:

1. The General Department of Fisheries receives, evaluates and settles dossiers on aquatic breeds, aquatic feed, environment-treating and -improving products which are used in aquaculture;
2. The General Department of Forestry receives, evaluates and settles dossiers on forestry seedlings;
3. The Department of Livestock receives, evaluates and settles dossiers on livestock breeds, animal feed, including growth stimulants used in livestock production;
4. The Department of Cultivation receives, evaluates and settles dossiers on main agricultural crop varieties;
5. The Department of Plant Protection receives, evaluates and settles dossiers on plant protection drugs, including growth regulators for plants;
6. The Department of Animal Health receives, evaluates and settles dossiers on veterinary drugs.

Article 5. Competence to recognize establishments eligible for field trial and test of agricultural materials

1. Specialized management agencies stipulated in Article 4 of this Circular shall be responsible for the followings:

- a) Receipt of dossiers, organization of evaluation and assessment of establishments eligible for field trial and test of agricultural materials;
- b) Submitting to the Minister to obtain his opinions on recognition of establishments eligible for conducting field trial and test of agricultural materials;

c) Promulgating decisions on recognition of establishments eligible for conducting field trial and test of agricultural materials after being approved by the Minister;

d) Inspecting and supervising operations of establishments conducting field trial and test of agricultural materials.

2. The Department of Science, Technology and Environment shall preside over and coordinate with the Legal Department to verify dossiers submitted by the specialized management agencies to the Minister.

3. Contents of verification of dossiers to be submitted to the Minister include the followings:

a) The sufficiency and validity of dossiers;

b) Implementation of the process of recognition of establishments conducting field trial and test.

4. Dossiers submitted to the Minister include the followings:

a) Written proposal to the Minister, clearly stating the necessity; implementation process; summary of the results of evaluation of establishments eligible for conducting field trial and test of agricultural materials; assessment and specific recommendations for each case of registration and recognition of establishment eligible for field trial and test of agricultural materials;

b) List of establishments conducting field trial and test that the specialized management agencies has evaluated, assessed and proposed for recognition;

c) Report of inspecting or evaluating team;

d) Application dossiers for registration and recognition of establishments eligible for conducting field trial and test;

dd) Draft of decision on recognition of establishment eligible for conducting field trial and test.

Article 6. Competence to permit field trial and test of agricultural materials, except for the main agricultural crop varieties and forestry seedlings

1. Specialized management agencies are responsible for the followings:

a) Receipt of dossiers, organization of evaluation of application dossiers for registration of field trial and test in respect to agricultural materials subject to field trial and test;

b) Submitting to the Minister to obtain his opinions on permit of field trial and test of agricultural materials;

c) Promulgating decisions to permit field trial and test or field trial Permit after the Minister approves.

2. Department of Science, Technology and Environment shall preside over and coordinate with the Legal Department to evaluate the dossiers submitted by the specialized management agencies to the Minister.

3. Contents of evaluation of dossiers submitted to the Minister include the followings:

a) The sufficiency and validity of dossiers;

b) Implementation of process to permit field trial and test.

4. Dossiers submitted to the Minister includes:

- a) Written proposal to the Minister, clearly stating the necessity; the implementation process; summary of the results of evaluation of field trial and test Draft of the fundamentals or assessment in accordance with the national technical standards and standard regulations (if any); assessment and specific recommendations for each case of registration of field trial and test of agricultural materials;
- b) Specialized management agency's evaluation report;
- c) Application dossiers for issuance of permit and registration of field trial and test of establishment;
- d) Draft of decision on field trial and test permit or field trial permit.

5. Specialized management agency guides, inspect and supervise field trial and test of agricultural materials.

6. Specialized management agency drafts and proposes for promulgation of the National Technical Standard Regulations on field trial and test of agricultural materials. Based on the National Technical Standard Regulations on field trial and test, head of specialized management agency shall approve the Draft of fundamentals of field trial and shall organize the supervision of field trial and test process. In case where there is no National Technical Standard Regulations, head of specialized management agency shall guide and approve the Draft of fundamentals of field trial and test on the basis of opinions of the Department of Science, Technology and Environment and Specialized Science Council or Advisory Council (hereinafter referred to as the Council).

Article 7. Competence to recognize and register agricultural materials for circulation

1. For cases where field trial and test is required:

Head of the specialized management agency is responsible for the followings:

- a) Receipt of dossiers, organization of evaluation of dossiers and results of field trial and test in accordance with the applicable law;
- b) Organization of a Council to assess field trial and test results;
- c) Reviewing results of field trial, evaluation of the opinions of the specialized Science Council;
- d) Submitting to the Minister to obtain his opinions on the recognition and registration of agricultural materials for circulation;
- dd) Issuing a decisions on recognition or Certificates of registration or Certificate of registration of agricultural materials for circulation after the approval by the Minister is obtained.

2. For cases where field trial and test is not required:

Heads of the specialized management agency is responsible for the followings:

- a) Organization of supervision of the process of testing;
- b) Organization of evaluation of application dossiers for registration of agricultural materials for circulation in accordance with applicable law;
- c) Submitting to the Minister to obtain his opinions on permit of registration of agricultural materials for circulation;

d) Issuing decisions on recognition or Certificates of circulation after being approved by the Minister.

3. The Department of Science, Technology and Environment shall preside over and coordinate with the Legal Department to evaluate the dossiers submitted by the specialized management agencies to the Minister as mentioned in Point d, Clause 1, and Point c, Clause 2 of this Article.

4. Contents of evaluation of dossiers submitted to the Minister:

- a) The sufficiency and validity of dossiers;
- b) Implementation of the process of recognition of agricultural materials.

5. Dossiers submitted to the Minister include the followings:

a) Written proposal to the Minister, clearly stating the necessity; the implementation process; summary of field trial and test results; assessment and specific recommendations for each agricultural material;

b) List of agricultural materials that specialized agency management agency has evaluated, assessed and proposed for recognition;

c) Minutes of meetings of the Evaluation Council in respect to products subject to field trial and test;

d) Evaluation report of the specialized management agency;

dd) Application dossiers for recognition or application dossiers for issuance of certificate of registration of agricultural materials.

Article 8. Promulgation of the list of agricultural materials permitted to be circulated in Vietnam

1. Periodically in the first quarter of every year, specialized management agency shall, in accordance with its assigned functions and tasks, review and submit the Minister to promulgate a list of agricultural materials permitted to be circulated in Vietnam.

2. Quarterly, specialized management agency shall collate and submit the Minister for issuing Circular, which promulgates the amended and added list of agricultural materials permitted to be circulated in Vietnam.

Article 9. Removing from the List of agricultural materials permitted to be circulated in Vietnam

1. Removing from the list of agricultural materials permitted to be circulated in Vietnam the followings:

a) Products containing active substances, the use of which is prohibited accordance with applicable regulations of the Ministry of Agriculture and Rural Development;

b) Products cause harm to production, the environment, food safety and human health that Council re-assesses in accordance with the regulations;

c) Products are currently circulated, but no longer comply with the international regulations, to which Vietnam is a participation member;

d) Certificate or Decision on recognition of products expired to be circulated but the establishment fails to re-register for circulation;

dd) Products has been registered for circulation, but the establishment producing and trading such products has stopped its operations;

e) Products violate the industrial property rights in respect to products already registered for circulation;

g) Products whose certificate of its circulation is withdrawn in the exporting country.

2. Based on cases specified in Clause 1 of this Article, a specialized management agency collates and submits the Minister to obtain his decision on removing agricultural materials out of the List of agricultural materials permitted to be circulated in Vietnam.

Chapter III

IMPLEMENTING PROVISIONS

Article 10. Implementation Effectiveness

1. The Circular takes effect from August 11, 2014.

2. This Circular shall revoke the following provisions:

a) Clause 2 of Article 5 of Circular 66/2011/TT-BNNPTNT dated October 10, 2011 of the Minister of Agriculture and Rural Development making detailed provisions for a number of articles of Decree No. 08/2010/ND-CP of the Government on management of animal feed;

b) Article 15 of Decision No. 10/2006/QĐ-BNN dated February 10, 2006 the Minister of Agriculture and Rural Development promulgating the regulations on the procedure for registration of manufacture, import and circulation of veterinary drugs, raw materials for production of veterinary drugs, biological products, microorganisms and chemicals used in veterinary drugs.

c) Point c, Clause 4, Article 7 of Circular No. 03/2013/TT-BNNPTNT dated January 11, 2013 of the Minister of Agriculture and Rural Development on the management of plant protection drugs.

Article 11. Implementation responsibilities.

1. Entities belonging to the Ministry and relevant organizations and individuals shall be responsible for implementation of this Circular.

2. During the implementation of this Circular, if any difficulties and problems arise, agencies, entities, organizations and individuals shall report to the Ministry of Agriculture and Rural Development in order to collate and submit to the Minister for consideration and decision./.

Recipients:

- People's Committees of centrally-run provinces and cities;
- Departments of Agriculture and Rural Development of centrally-run provinces and cities;
- Leaders of Ministry of Agriculture and Rural Development;

MINISTER
(Signed)
Cao Duc
Phat

- Entities of Ministry of Agriculture and Rural Development;
- Department of Examination of Documents (Ministry of Justice);
- Official Gazette;
- Website: Government and MARD;
- Kept as archives: Office and Legal.