

THE MINISTRY OF NATURAL RESOURCES
AND ENVIRONMENT

**Circular No. 19/2010/TT-BTNMT of
October 12, 2010, providing the
registration of bio-product marketing for
waste treatment in Vietnam**

THE MINISTER OF NATURAL
RESOURCES AND ENVIRONMENT

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

*Pursuant to the Government's Decree No.
80/2006/ND-CP of August 9, 2006, detailing and
guiding a number of articles of the Environmental
Protection Law; and Decree No. 21/2008/ND-
CP of February 28, 2008, amending and
supplementing a number of articles of the
Government's Decree No. 80/2006/ND-CP of
August 9, 2006, detailing and guiding a number
of articles of the Environmental Protection Law;*

*Pursuant to the Government's Decree No. 25/
2008/ND-CP of March 4, 2008, defining the
functions, tasks, powers and organizational
structure of the Ministry of Natural Resources
and Environment;*

At the proposal of the Director General of

the Environment Administration and the director of the Legal Affairs Department,

STIPULATES:

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

1. This Circular provides the order and procedures for registering the bio-product marketing in the prevention, mitigation and treatment of waste in Vietnam for the promulgation of the List of bio-products used in the prevention, mitigation and treatment of waste in Vietnam (below referred to as the List of bio-products for waste treatment in Vietnam).

2. Bio-products used in the prevention, mitigation and treatment of waste (below referred to as bio-products) which have been registered under current law are not governed by this Circular.

Article 2. Subjects of application

This Circular applies to state management agencies, domestic and foreign organizations and individuals (below collectively referred to as organizations and individuals) engaged in the evaluation of registration dossiers of bio-product marketing, production, trading, import and testing of bio-products for waste treatment in Vietnam.

Article 3. Interpretation of terms

1. Bio-products for waste treatment means products of biological origin used to treat waste, which include microorganisms, enzymes and substances extracted from animals, plants and microorganisms, but do not include genetically

modified organisms.

2. Bio-product testing means the evaluation of the properties, effects and safety of bio-products for waste treatment in certain conditions and on a certain scale.

Article 4. Principles of bio-product marketing

1. Organizations and individuals having bio-products shall register these products with competent agencies for consideration and grant of certificates of bio-product marketing before marketing and using them.

2. Certificates of bio-product marketing shall be granted by competent state agencies based on testing results and conclusions of the Specialized Science Council for evaluation of registration dossiers of bio-product marketing.

3. Organizations and individuals registering bio-product marketing shall pay charges and fees under current law.

Article 5. Establishment, functions and working principles of the Specialized Science Council for evaluation of registration dossiers of bio-product marketing

1. The Director General of the Environment Administration shall establish the Specialized Science Council for evaluation of registration dossiers of bio-product marketing (below referred to as the Council). The Council must have at least 7 (seven) members, including the Chairman, Secretary and members with a tertiary or higher degree in a relevant discipline and experience in biology, bio-technology and environmental technology.

2. The Council functions to advise the Director General of the Environment Administration in evaluating bio-products' effects on and safety to the health of humans and

living organisms.

3. The Council works on the principles of collectivism, open and direct discussion among members and conclusion by majority.

Article 6. Responsibilities and powers of the Council

1. Responsibilities and powers of a Council member:

a/ To participate in activities before, in and after the Council's official meeting when so requested;

b/ To study dossiers and documents related to bio-products registered for marketing and make written comments on these dossiers;

c/ To scientifically, honestly and objectively perform his/her tasks at the Council's meetings. To make written comments in the Council's official meeting;

d/ To manage received documents under law and submit these documents to the Council's standing body after completing his/her tasks.

e/ To receive pays under current financial regulations for his/her task performance.

2. Responsibilities and powers of the Council Chairman:

In addition to the responsibilities and powers of a Council member defined in Clause 1 of this Article, the Council Chairman has the following responsibilities and powers:

a/ To preside meetings of the Council under this Circular and relevant laws;

b/ To summarize and process opinions discussed at the Council's official meeting, to prepare conclusions to be presented to the Council for adoption and to announce evaluation results of the Council;

c/ To take responsibility for activities, evaluations and conclusions of the Council.

3. Responsibilities and powers of the Council Secretary:

In addition to the responsibilities and powers of a Council member defined in Clause 1 of this Article, the Council Secretary has the following responsibilities and powers:

a/ To make full and truthful minutes of the Council's meetings;

b/ To provide bio-product evaluation slips to Council members. A bio-product evaluation slip contains the following principal contents: evaluation of composition, properties and effects of a bio-product as compared with documents provided by the manufacturer and its safety to the health of humans and living organisms;

c/ To complete and transfer the minutes of the Council's official meeting and all dossiers and other related documents to the Council's standing body;

d/ To read relevant reports in meetings of the Council.

Article 7. Activities of the Council

1. Conditions to convene the Council's official meeting:

a/ The Council Chairman and at least two-thirds of Council members under the establishment decision of the organizer of appraisal and evaluation are present;

b/ Representatives of the applicant for bio-product marketing and bio-product testing institution are present;

c/ Dossiers and written comments of Council members are fully available.

2. Contents and process of the Council's

official meeting:

a/ The representative of the applicant for bio-product marketing presents the origin, production process, composition, use instructions, effectiveness, effects and safety of the bio-product;

b/ The secretary reads the testing result report made by the bio-product testing institution; and the report on supervision and inspection of the implementation of the testing plan;

c/ Questions and answers on unclear issues between Council members and representatives of the applicant for bio-product marketing and bio-product testing institution;

d/ Council members present their opinions and evaluations;

e/ Council members, delegates and representatives of the applicant for bio-product marketing and bio-product testing institution discuss,

f/ The Council Chairman announces results of evaluation slip tally and reads tentative conclusions of the Council;

g/ Council members make recommendations (if any) for modification of tentative conclusions of the Council;

h/ The representative of the applicant for bio-product marketing gives opinions;

i/ The Council Chairman announces the Council's conclusions, which must be agreed by at least two-thirds of the total number of Council members and clearly written in evaluation slips.

3. The minutes of the Council's official meeting must indicate the proceedings of the meeting and opinions and comments of Council members at the Council's official meeting and be signed by the Council Chairman and the Council Secretary with their full names.

Article 8. The Council's standing body

The Director General of the Environment Administration shall assign one (01) professional organization or section of the Environment Administration with relevant functions and tasks to act as the Council's standing body.

Article 9. Tasks and activities of the Council's standing body

1. To assist the Director General of the Environment Administration in receiving, studying and processing relevant dossiers and documents sent by applicants for registration of bio-product marketing.

2. To prepare, provide and create favorable conditions for Council members to study dossiers and documents related to activities of the Council.

3. To post registration dossiers of bio-product marketing on the websites of the Ministry of Natural Resources and Environment and the Environment Administration or in other media of communication in order to collect feedback of involved organizations and individuals.

4. To propose the Director General of the Environment Administration to organize, or authorize Sub-Departments of Environmental Protection of provinces and centrally run cities (below referred to as local Sub-Departments of Environmental Protection) to conduct, inspection and supervision of plans to test the use of bio-products.

5. To prepare necessary conditions for the Council to hold meetings.

6. To receive dossiers, testing results, dossier evaluation results of the Council for processing and carrying out necessary procedures to submit them to the Director General of the Environment

Administration for consideration and grant of certificates of bio-product marketing.

7. To consider dossiers and propose the Director General of the Environment Administration to extend certificates of bio-product marketing.

Article 10. List of bio-products for waste treatment in Vietnam

1. Bio-products with certificates of bio-product marketing shall be included in the List of bio-products for waste treatment in Vietnam and posted on the websites of the Ministry of Natural Resources and Environment and the Environment Administration.

2. Biannually, the Director General of the Environment Administration shall make and submit to the Minister of Natural Resources and Environment for promulgation the List of bio-products for waste treatment in Vietnam.

Chapter II

ORDER AND PROCEDURES FOR REGISTRATION OF BIO-PRODUCT MARKETING

Article 11. Bio-products subject to marketing registration

1. Domestic or imported bio-products which are not on the List of bio-products for waste treatment in Vietnam.

2. Bio-products on the List of bio-products for waste treatment in Vietnam with changes in composition or contents of active ingredients affecting treatment effectiveness and safety to the health of humans and living organisms.

Article 12. Registration dossiers of bio-product marketing

1. An application for registration of bio-product marketing made according to the form provided in Appendix 1 to this Circular (*not printed herein*).

2. Copy of the business registration certificate or equivalent certified by the organization or individual.

3. Bio-product production process:

4. Bio-product quality testing or analysis slip of a domestic or foreign unit with testing function.

5. Brief introduction on the bio-product made according to the form provided in Appendix 2 to this Circular (*not printed herein*) and related documents:

a/ Composition;

b/ Properties, effects, use instructions, preservation;

c/ Safety to the health of humans and living organisms;

d/ Documents on the origin of the original microorganism species, for microorganism products.

6. Evaluation record of the science council of the managing sector, for bio-products being scientific research findings.

7. Trial or testing results of bio-products (if any).

8. Official label and packaging applied for marketing together with the insert on instructions for use and preservation of bio-products and warnings on health of humans and living organisms.

9. Patent or written commitment on not violating intellectual property regulations, for domestic bio-products applied for marketing registration, made according to the form provided

in Appendix 3 to this Circular (*not printed herein*); license for bio-product marketing granted by a competent authority of the country of manufacture, for imported bio-products.

10. Detailed testing plan, covering testing contents, time, place and institution, for bio-products without recognized testing results.

Article 13. Submission, consideration and evaluation of registration dossiers of bio-product marketing

1. An organization or individual with bio-products specified in Article 11 of this Circular shall make 2 (two) sets of registration dossier of bio-product marketing under Article 12 of this Circular and submit them to the Environment Administration for consideration, evaluation and grant of a certificate of bio-product marketing.

2. Within 10 (ten) working days after receiving a dossier, the Environment Administration shall consider the completeness and validity of the dossier. If the dossier is incomplete or invalid, it shall notify such in writing to the applicant for modification.

3. Within 10 (ten) working days after considering the completeness and validity of a dossier, the Environment Administration shall notify in writing the program to supervise and inspect the detailed testing plan of the applicant for bio product marketing and the testing institution under Clause 10, Article 12 of this Circular.

4. Within 15 (fifteen) working days after receiving a valid registration dossier of bio-product marketing, the Director General of the Environment Administration shall form a Council under Articles 5, 6 and 7 of this Circular.

Article 14. Procedures for grant of certificates

of bio-product marketing

1. Based on the Council's evaluations of the registration dossier of bio-product marketing, within 7 (seven) working days, the Environment Administration shall grant a certificate of bio-product marketing for each registered bio-product. This certificate is made according to the form provided in Appendix 4 to this Circular (*not printed herein*).

If refusing to grant a certificate of bio-product marketing, the Environment Administration shall notify such in writing to the applicant, clearly stating the reason.

2. A certificate of bio-product marketing is valid for 60 (sixty) months at most from the date of its issuance.

Article 15. Procedures for extension of certificates of bio-product marketing

1. A certificate of bio-product marketing may be extended when it expires.

2. An applicant for extension of a certificate of bio-product marketing shall make 2 sets of dossier and submit them to the Environment Administration 30 (thirty) days before the certificate expires. A dossier comprises:

a/ A written request for extension of a certificate of bio-product marketing, made according to the form provided in Appendix 5 to this Circular (*not printed herein*);

b/ A report on the use of the bio-product, covering the quality stability, effectiveness and safety to the health of humans and living organisms of the bio-product used in some specific works, enclosed with the analysis and evaluation slip of a relevant institution;

c/ Copy of the existing certificate of bio-product marketing.

3. Within 5 (five) working days, the Environment Administration shall consider the dossier's completeness and validity. If the dossier is incomplete or invalid, it shall notify such in writing to the applicant for modification.

4. Within 5 (five) working days after obtaining the results of field inspection at the establishment applying the bio-product applied for extension of the certificate of bio-product marketing, the Council's standing body shall carry out necessary procedures to propose the Director General of the Environment Administration to consider and decide on the certificate extension.

Inspection at an establishment applying a bio-product complies with Article 16 of this Circular.

5. A certificate of bio-product marketing may be extended many times, with each extension not exceeding 36 (thirty six) months from the date of its issuance.

Article 16. Inspection at establishments applying bio-products applied for extension of certificates of bio-product marketing

1. Within 10 (ten) working days after considering the completeness and validity of a dossier of request for extension of a certificate of bio-product marketing, the Environment Administration shall form or authorize a local Sub-Department of Environmental Protection to form a team to inspect the use of bio-products at the establishment applying such bio-product named in this dossier.

2. A field inspection team comprises representatives of the Environment Administration or the local Sub-Department of Environmental Protection and bio-technology experts.

3. Field inspection covers consideration of the stability, effects and safety to the health of

humans and living organisms of a bio-product under use compared to its first registration dossier and proposal of extension or non-extension of the certificate of bio-product marketing.

4. Inspection results shall be made in writing with signatures of the involved parties and representative of the establishment applying the bio-product.

Article 17. Withdrawal of certificates of bio-product marketing

1. A certificate of bio-product marketing is withdrawn when:

a/ It is granted at variance with regulations;

b/ There are changes in the composition of the bio-product;

c/ A competent agency certifies infringement upon industrial property rights over the registered bio-product;

d/ It expires.

2. An organization or individual subject to withdrawal of a certificate of bio-product marketing shall recall and dispose of under law produced or imported bio-products currently in circulation.

3. When a certificate of bio-product marketing is withdrawn, the Environment Administration shall exclude this bio-product from the List of bio-products for waste treatment in Vietnam and post it on the website of the Environment Administration.

Chapter III

TESTING OF BIO-PRODUCTS IN VIETNAM

Article 18. Bio-product testing establishments

1. Testing establishment means an institution with functions to study and transfer bio-

technology or environmental technology (under its establishment decision or registration certificate of scientific and technological activities issued by a competent agency) and sufficient equipment, materials and human resources for field application of bio-products under their use instructions.

2. Applicants for registration of bio-product marketing may select institutions and places for testing and shall pay testing charges under contracts.

3. Within 5 (five) working days after signing a contract a testing institution shall carry out necessary procedures and contents related to implementation process and plan and submit a detailed plan on the program to test the use of a bio-product to the Environment Administration. Contents of the detailed plan comply with Clause 10, Article 12 of this Circular.

4. A testing establishment may select institutions for coordination in testing and take responsibility before law for its announced testing results; and keep testing result dossiers for at least 60 (sixty) months after completion of a test.

Article 19. Bio-product testing contents and methods

1. Each type of bio-product shall be tested for:

- a/ Its composition and quality according to its announced standards;
- b/ Its effects under its use instructions;
- c/ Safety to the health of humans and living organisms in the use of the bio-product.

2. Testing methods are those compliant with relevant standards and technical regulations or those guaranteeing objectivity and scientificity.

Article 20. Reporting on bio-product testing results

A testing establishment's report on bio-product testing results must fully contain the following contents:

1. Name of the testing establishment and name of the organization or individual requesting testing.
2. Name of the tested bio-product enclosed with the dossier of its composition, effects, preservation, use instructions, label and packaging.
3. Pre-testing state of the bio-product.
4. Testing contents.
5. Place, time, scale and methods of testing.
6. Testing results.
7. Conclusions and recommendations.

Article 21. Supervision and inspection of bio-product testing

1. The Environment Administration shall supervise, inspect or authorize local Sub-Departments of Environmental Protection to supervise and inspect the testing of use of bio-products according to written notices specified in Clause 3, Article 13 of this Circular.

2. A supervision and inspection team comprises a representative of the Environment Administration or a local Sub-Department of Environmental Protection and bio-technology experts.

3. Supervision and inspection contents comply with Article 19 of this Circular.

4. Supervision and inspection results shall be made in writing together with opinions,

recommendations, the presence and certification of team members and a representative of the bio-product testing institution.

Chapter IV

IMPLEMENTATION PROVISIONS

Article 22. Organization of implementation

1. Organizations and individuals with bio-products for waste treatment in Vietnam registered before the effective date of this Circular shall make and send a list of bio-products under marketing to the Environment Administration for inclusion into the List of bio-products for waste treatment in Vietnam.

2. The Director General of the Environment Administration shall organize the registration of bio-product marketing for waste treatment in Vietnam; and guide, examine, monitor and urge the implementation of this Circular.

3. Ministers, heads of ministerial-level agencies, heads of government-attached agencies, chairpersons of People's Committees at all levels and concerned organizations and individuals shall implement this Circular.

Article 23. Effect

This Circular takes effect on December 10, 2010.

Any problems arising in the course of implementation should be promptly reported to the Ministry of Natural Resources and Environment for consideration and settlement.

*For the Minister of
Natural Resources and Environment*
Deputy Minister
NGUYEN THAI LAI