LEGAL DOCUMENTS

THE MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

Circular No. 14/2013/TT-BNNPTNT of February 25, 2013, on grant of certificates of eligibility for plant protection drug production or trading

Pursuant to the Government's Decree No. 01/2008/ND-CP of January 3, 2008, defining the functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development;

Pursuant to the July 25, 2001 Ordinance on Plant Protection and Quarantine;

Pursuant to the Regulation on management of plant protection drugs promulgated together with the Government's Decree No. 58/2002/ND-CP of June 3, 2002;

Pursuant to the Government's Decree No. 59/2006/ND-CP of June 12, 2006, detailing the Commercial Law regarding goods and services prohibited or restricted from business and goods and services subject to conditional business;

Pursuant to the Government's Decree No. 108/2008/ND-CP of October 7, 2008, detailing and guiding a number of articles the Law on Chemicals;

Pursuant to the Government's Decree No. 26/2011/ND-CP of April 8, 2011, amending and supplementing a number of articles of the Government's Decree No. 108/2008/ND-CP of October 7, 2008, detailing and guiding a number of articles the Law on Chemicals;

At the proposal of the Director of the Department of Plant Protection;

The Minister of Agriculture and Rural Development promulgates the Circular on grant of certificates of eligibility for plant protection drug production or trading.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular provides the conditions, order and procedures for grant of certificates of eligibility for production, subcontract production, bottling and packaging (below referred to as production) of and trading (dealing) in plant protection drugs.

Article 2. Subjects of application

This Circular applies to organizations and persons involved in plant protection drug production and trading (other than those only producing biological plant protection drugs that contain active ingredients being useful microorganisms) in the territory of Vietnam.

Chapter II

CONDITIONS FOR PLANT PROTECTION DRUG PRODUCERS

Article 3. Conditions on workshops and warehouses

1. Location

a/ Workshops and warehouses of plant protection drugs located in industrial parks musts comply with regulations of industrial parks.

b/ For workshops and warehouses located outside industrial parks:

The location of workshops and warehouses must be approved by local administrations of the commune or higher level; be at least 200 meters (m) far away from schools, offices, hospitals and markets; and meet requirements on power and water supply, water drainage, pollution treatment and transport.

Workshops and warehouses must have surrounding fences separating them from the outside. The internal transport system must assure safety for transportation and fire fighting.

2. Ground layout, structure and architecture of workshops and warehouses

a/ Production workshops must be separated from warehouses.

b/ Workshops

The design and construction of workshops must reach Vietnam standards TCVN 4604/1988: Industrial workshops and manufacturers - Design standards; and TCVN: 2622/1995: Fire prevention and fighting for housing and works - Design requirements.

c/ Warehouses

Warehouses must have separate sections for storing finished products and materials.

Warehouses of materials are arranged depending on the type of materials to be preserved, must classify materials according to explosion, explosion and fire risks and assure separation of substances that are likely to cause chemical reactions.

Warehouses of finished products must have the products arranged in a neat and reasonable manner. Goods must be put on shelves at least 10 centimeters (cm) high from the floor and at least 20 centimeters (cm) from the wall. The main passage must be at least 1.5 meters (m) wide and convenient for fire prevention and fighting and examination and supervision activities.

d/ Construction materials of workshops and warehouses must be non-flammable; frameworks must be made of bricks, concrete or steel. Floors must be made of impermeable materials, be flat and non-slip, and have neither cracks nor surrounding edges and margins.

dd/ Workshops and warehouses must have exit ways with clear indications (through signboards and diagrams) which are easy to open upon occurrence of incidents.

Article 4. Conditions on equipment

1. Production equipment

a/ To have production lines and technologies assuring types and quality of plant protection drugs produced by the establishments.

b/ To have equipment arranged and installed suitable to each production stage and meeting labor safety requirements according to Vietnam standards TCVN 2290-1978:

Production equipment - General requirements on safety.

c/ Equipment have operation instructions, have their technical specifications inspected, are maintained and repaired, and have industrial hygiene process.

d/ Lighting and other electrical equipment are installed in necessary places and may not be installed temporarily. All electrical equipment must have switching devices against electrical leakage and overload.

2. Exhaust gas and waste treatment systems

a/ Workshops must have exhaust gas treatment systems and warehouses must have ventilation systems. Exhaust gas from workshops and warehouses must reach national technical regulation QCVN 19:2009/ BTNMT- National technical regulation on industrial exhaust gas for dust and inorganic substances and national technical regulation QCVN 20:2009/BTNMT - National technical regulation on industrial exhaust gas for a number of organic substances.

b/ Workshops must have wastewater treatment systems. Treated wastewater must reach national technical regulation QCVN 07:2009/BTNMT - National technical regulation on hazardous waste threshold and QCVN 24:2009/BTNMT - National technical regulation on industrial wastewater.

c/ Solid waste of workshops and warehouses must be treated in accordance with the Government's Decree No. 59/2007/ND-CP of April 9, 2007, on management of solid waste. Workshops and warehouses must have devices for collecting and transporting solid waste out of production areas after each production shift. The waste storage area must be closed and separated from the production area.

Article 5. Conditions on safe operation

1. Producers fully meet requirements on chemical safety according to Vietnam standard TCVN 5507-2002: Hazardous chemicals - Regulation on safety in production, business, use, preservation and transportation.

2. Producers have rules on labor safety and separate places for workers to change clothes and take bath before and after production shifts.

3. Producers have a board of rules on chemical safety and a system of signals relevant to the level of hazard of chemicals. For chemicals with different hazardous properties, warning symbols must fully show those properties.

4. Producers have and use labor safety devices (gloves, face masks, eye protection glasses, protective clothing) when exposed to plant protection drugs. To have medical devices, medicines and first aid equipment.

5. The operation of warehouses assures safety and prevention of risks such as fire, leakage and overflow. For warehouses of raw materials, storekeepers shall comply with instructions indicated in chemical safety data sheets of all stored chemicals and instructions for safety and hygiene and instructions upon occurrence of incidents.

Article 6. Conditions on fire and explosion prevention and control

1. Producers fully meet requirements on fire and explosion prevention and control in accordance with the Law on Fire Prevention and Fighting.

2. Producers fully have equipment and devices for incident response at their establishments. The fire warning and extinguishment systems are installed in appropriate places and regularly inspected to assure their readiness for use.

3. Producers have rules on fire prevention and fighting, fire action signs and "No Fire" signboards put at easy-to-notice places.

Article 7. Conditions on human resources

1. Direct managers of production establishments possess a professional practice certificate of production, subcontract production, bottling or packaging of plant protection drugs granted by the provincial-level Sub-Department of Plant Protection.

2. Leaders and heads of sections directly engaged in the production of plant protection drugs and persons directly engaged in production, trading, transportation, storage and preservation are trained in chemical safety techniques.

3. Leaders, technicians and storekeepers are trained in and conversant with regulations on management of chemical activities; fire prevention and fighting; and safe distance; and implementation of measures and plans to prevent and respond to chemical incidents.

4. Employees are trained in production processes, labor safety, fire and explosion prevention and control and measures to prevent and respond to incidents related to plant protection drugs.

Article 8. Quality control system

1. To have a quality control system.

2. To have a technological process for producing plant protection drugs approved by the owner of the production establishment.

3. To have a laboratory for testing product quality.

This laboratory must be separated from the production area, have all minimum equipment for testing the quality of plant protection drugs of the establishment.

4. For a producer that does not have a laboratory for testing product quality, to have a quality inspection contract with a laboratory capable of inspecting the quality of plant protection drugs of the producer and have an inspection record for every batch of products before their rollout.

5. To store quality inspection samples of each product batch for at least 3 (three) months.

Article 9. Requirements on environmental protection

1. Producers of plant protection drugs apply environmental management systems according to standard ISO 14001 or equivalent

to protect the environment and prevent pollution.

2. Producers of plant protection drugs have environmental impact assessment reports or environmental protection commitments or environmental protection plans as prescribed in the law on environmental protection.

Chapter III

CONDITIONS FOR TRADERS OF PLANT PROTECTION DRUGS

Article 10. General conditions

1. Plant protection drugs traded at shops in the form of finished products are on the list of plant protection drugs permitted for use or limited use in Vietnam.

2. Not to sell plant protection drugs together with other goods such as food, foodstuff, beverage, animal feed, medicines, veterinary drugs and other consumer goods.

3. Plant protection drug shops are not located in food trading areas, catering and recreational service areas, schools and hospitals.

Article 11. Specific conditions

1. Persomel

a/ Shop managers possess a practice certificate of plant protection drug trading granted by the provincial-level Sub-Department of Plant Protection.

b/ Direct sellers are trained in plant protection drugs by the provincial-level Sub-Department of Plant Protection or hold a professional secondary or higher level diploma in cultivation, plant protection, biology or agriculture pedagogy.

2. Location

a/ A plant protection drug shop is approved by the commune-level administration, has a clear and permanent address, is owned by the establishment owner or rented for at least 1 (one) year under a lawful rent contract, in case of rental of the shop.

b/ The area of the shop matches the business scale and is at least 5 square meters (m^2). The shop reaches grade-4 housing or higher standards, is located in a high, clean and airy place which meets requirements on trading and preservation without affecting the quality of plant protection drugs.

c/ To be at least 10 meters (m) far away from water sources (river, lake, channel, canal). The shop is firmly embanked to prevent erosion and its floor is high and unfloodable.

d/ The walls and roof are built with non-flammable materials. The walls and floor are flat, impermeable, easy to clean and unfloodable.

3. Equipment

a/ To have cabinets, stands or shelves for displaying plant protection drugs and preservation equipment according to preservation requirements indicated in the drug labels.

b/ To assure sufficient lighting for identifying drugs. Lighting equipment meet fire and explosion safety requirements.

c/ To have rules and equipment for fire prevention and fighting as required by fire prevention and fighting authorities, which are put in convenient places and ready for use when necessary.

d/ To have personal labor protection devices such as gloves, face masks, clean water and soaps.

dd/ To have materials and devices for prompt handling of incidents as required by environmental management authorities.

4. Other requirements

a/ To have a signboard in Vietnamese which clearly shows the establishment owner's name or enterprise name, address and telephone number.

b/ To have books recording the delivery and receipt of plant protection drugs.

c/ To post up prices of plant protection drugs.

5. Plant protection drug storage areas of shops

a/ For establishments with areas storing plant protection drugs of 5,000 kilograms (kg) or more, to apply Clause 2, Article 3, and Clause 2, Article 9, of this Circular.

b/ For establishments with areas storing plant protection drugs of less than 5,000 kilograms (kg)

The plant protection drug storage area is dry, airy, impermeable, unleakable and unfloodable and assure fire and explosion prevention and control.

Racks and shelves are at least 10 centimeters (cm) above the ground and at least 20 centimeters (cm) from the wall.

The arrangement of plant protection drugs ensures no break and leakage, passages wide enough and separation of each type.

Chapter IV

PROCEDURES FOR GRANT OF CERTIFICATES OF ELIGIBILITY FOR PLANT PROTECTION DRUG PRODUCTION OR TRADING

Article 12. Competence to grant certificates of eligibility for plant protection drug production or trading

1. The Department of Plant Protection may grant, renew, re-grant and revoke certificates of eligibility for producers of plant protection drugs.

2. Provincial-level Sub Departments of Plant Protection may grant, renew, re-grant and revoke certificates of eligibility for traders of plant protection drugs under local management.

3. The validity term of a certificate of eligibility for plant protection drug production or trading is 5 (five) years.

4. The forms of certificate of eligibility for plant protection drug production or trading are issued together with this Circular *(not translated)*.

Article 13. Procedures for grant of certificates of eligibility for plant protection drug production

1. Dossier submission

a/ A producer shall submit the dossier directly or by post to the Department of Plant Protection.

b/ Number of dossier sets: 1 paper set and 1 electronic file in PDF.

c/ To check the completeness of the dossier immediately after receiving it directly or within 2 (two) working days after receiving it by post. If the dossier is complete, the Department of Plant Protection shall receive it. If the dossier is incomplete, it shall request the applicant to supplement and complete the dossier.

2. Dossier

a/ An application for a certificate of eligibility for plant protection drug production, made according to a set form.

b/ A copy (with the original for comparison) or a certified copy of the certificate of business registration for or investment in production, subcontract production, bottling or packaging of plant protection drugs.

c/ A copy (with the original for comparison) or a certified copy of the practice certificate of production, subcontract production, bottling or packaging of plant protection drugs of the manager of the production establishment.

d/ A copy (with the original for comparison) or a certified copy of the decision approving the investment project on production work construction (if any) under the law on construction management and investment.

dd/ A copy (with the original for comparison) or a certified copy of the decision approving the environmental impact assessment report or environmental protection commitment or environmental protection plan granted by a competent agency.

e/ A copy (with the original for comparison) or a certified copy of the fire fighting plan or the record of examination of assurance of fire prevention and control safety approved by the district-level public security agency for fire prevention and control.

g/ A written declaration of plant protection drug production conditions, made according to a set form.

3. Appraisal of dossiers and grant of certificates of eligibility for plant protection drug production

a/ Within 5 (five) working days after receiving a complete dossier, the Department of Plant Protection shall appraise it.

b/ Formation of the evaluation team

Within 15 (fifteen) working days after receiving a complete dossier, the Department of Plant Protection shall issue a decision to form an evaluation team for field evaluation. The evaluation team is composed of 3-5 members with professional qualifications and experience in the field of evaluation and a representative of the line management agency.

To notify in writing the establishment of the evaluation plan at least 5 (five) working days before the evaluation time, clearly stating the contents, time and scope of evaluation and members of the evaluation team.

c/ Evaluation contents

The establishment's satisfaction of the conditions specified in Chapter II of this Circular.

d/ Evaluation methods

Direct interview with the establishment's manager and employees on relevant information;

Examination of archival dossiers and related documents of the establishment;

Field observation of the ground layout, environmental conditions and the state of equipment and other facilities of the establishment.

dd/ Evaluation results

Conditions which are detected through evaluation to fail to comply with Chapter II of this Circular must be stated in the evaluation record, made according to a set form.

The evaluation record must contain all required contents and be signed by the establishment representative and the evaluation team head.

The establishment representative who disagrees with the evaluation results may write down his/her opinions at the end of the evaluation record before signing and affixing the establishment's seal in the record. The evaluation record is still legally valid without the establishment representative's signature.

e/ Grant of certificates of eligibility for plant protection drug production

The Department of Plant Protection shall consider evaluation results within 5 (five) working days after an evaluation is completed;

If the dossier meets requirements, it shall grant the establishment a certificate of eligibility for plant protection drug production, made according to a set form.

If the dossier fails to meet requirements, it shall notify in writing the establishment of the unsatisfactory conditions, requirements and time for remedy. Within 5 (five) working days after receiving the establishment's remedy report or re-examination result (when necessary), if finding it valid, the Department of Plant Protection shall grant the establishment a certificate of eligibility for plant protection drug production, made according to a set form.

In case of refusing to grant a certificate of eligibility for plant protection drug production, the Department of Plant Protection shall issue a written reply clearly stating the reason.

Article 14. Procedures for grant of certificates of eligibility for plant protection drug trading

1. Dossier submission

a/ A trader shall submit a dossier directly or by post to the provincial-level Sub-Department of Plant Protection.

b/ Number of dossier sets: 1 set.

c/ To check the completeness of the dossier immediately after receiving it directly or within 2 (two) working days after receiving it by post. If the dossier is complete, the Sub-Department of Plant Protection shall receive it. If the dossier

is incomplete, it shall request the applicant to supplement and complete the dossier.

2. Dossier

a/ An application for a certificate of eligibility for plant protection drug trading, made according to a set form.

b/ A copy (with the original for comparison) or a certified copy of the certificate of plant protection drugs or agricultural supplies business registration.

c/ A copy (with the original for comparison) or a certified copy of the practice certificate of plant protection drug trading of the establishment owner.

d/ A written declaration of plant protection drug trading conditions, made according to a set form.

e/ A copy (with the original for comparison) or a certified copy of the decision approving the environmental impact assessment report or environmental protection commitment or environmental protection plan granted by a competent agency (for a trader with an area for storing plant protection drugs of 5,000 kg or more).

3. Appraisal of dossiers and grant of certificates of eligibility for plant protection drug trading

a/ Within 3 (three) working days after receiving a complete dossier, the Sub-Department of Plant Protection shall appraise it.

b/ Formation of the evaluation team

Within 7 (seven) working days after receiving a complete dossier, the Sub-Department of Plant Protection shall issue a decision to form an evaluation team for field evaluation. The evaluation team is composed of 2-3 members with professional qualifications and experience in the field of evaluation and a representative of the line management agency.

To notify in writing the establishment of the evaluation plan at least 5 (five) working days before the evaluation time, clearly stating the contents, time and scope of evaluation and members of the evaluation team.

c/ Evaluation contents

The establishment's satisfaction of the conditions specified in Chapter III of this Circular.

d/ Evaluation methods

Direct interview with the establishment's manager and employees on relevant information;

Examination of archival dossiers and related documents of the establishment;

Field observation of the ground layout, environmental conditions and the state of equipment and other facilities of the establishment.

dd/ Evaluation results

Conditions which are detected through evaluation to fail to comply with Chapter III of this Circular must be stated in the evaluation record, made according to a set form.

The evaluation record must contain all required contents and be signed by the

establishment representative and the evaluation team head.

An establishment representative who disagrees with the evaluation results may write down his/her opinions at the end of the evaluation record before signing and affixing the establishment's seal in the record. An evaluation record is still legally valid without the establishment representative's signature.

e/ Grant of certificates of eligibility for plant protection drug trading

The Sub-Department of Plant Protection shall consider evaluation results within 5 (five) working days after an evaluation is completed;

If the dossier is valid, it shall grant the establishment a certificate of eligibility for plant protection drug trading, made according to a set form.

If the dossier is invalid, it shall notify in writing the establishment of the unsatisfactory conditions, requirements and time for remedy. Within 3 (three) working days after receiving the establishment's remedy report or re-examination result (when necessary), if finding it valid, the Sub-Department of Plant Protection shall grant the establishment a certificate of eligibility for plant protection drug trading, made according to a set form.

In case of refusing to grant a certificate of eligibility for plant protection drug trading, the Sub-Department of Plant Protection shall issue a written reply clearly stating the reason.

Article 15. Procedures for renewal of certificates of eligibility for plant protection drug production

1. Dossier submission

a/ At least 3 (three) months before a certificate of eligibility for plant protection drug production expires, the producer shall submit a dossier directly or by post to the Department of Plant Protection.

b/ Number of dossier sets: 1 paper set and 1 electronic file in PDF.

c/ To check the completeness of the dossier immediately after receiving it directly or within 2 (two) working days after receiving it by post. If the dossier is complete, the Department of Plant Protection shall receive it. If the dossier is incomplete, it shall return it and request the applicant to supplement and complete the dossier.

2. Dossier

a/ An application for a certificate of eligibility for plant protection drug production, made according to a set form.

b/ A copy (with the original for comparison) or a certified copy of the certificate of business registration for or investment in production, subcontract production, bottling or packaging of plant protection drugs (if there is any change).

c/ A copy (with the original for comparison) or a certified copy of the practice certificate of production, subcontract production, bottling or packaging of plant protection drugs of the person directly managing production (if there is any change).

d/ A copy (with the original for comparison) or a certified copy of the fire fighting plan or the record of examination of assurance of fire prevention and control safety approved by the competent public security agency (if there is any change).

dd/ The granted original certificate of eligibility for plant protection drug production.

e/ A written declaration of plant protection drug production conditions, made according to a set form.

g/ A copy (with the original for comparison) or a certified copy of the form or the record of examination, assessment and classification of quality assurance conditions of the establishment producing, processing, bottling or packaging plant protection drugs of functional agencies under the Agriculture and Rural Development Minister's Circular No. 14/2011/TT-BNNPTNT of March 29, 2011 (if any).

3. Appraisal of dossiers and grant of certificates of eligibility for plant protection drug production

Within 5 (five) working days after receiving a complete dossier, the Department of Plant Protection shall appraise it.

a/ For a valid dossier, to carry out procedures as prescribed at Points b, c, d, dd and e, Clause 3, Article 13 of this Circular.

If the establishment has periodical inspection results of level A under the Agriculture and Rural Development Minister's Circular No. 14/2011/TT-BNNPTNT of March 29, 2011, within 1 (one) year up to the time of renewal, the Department of Plant Protection shall grant a certificate of eligibility for plant protection drug production, made according to a set form, without forming a field evaluation team.

b/ For an invalid dossier, to notify the applicant of the dossier's contents to be supplemented and completed.

Article 16. Procedures for renewal of certificates of eligibility for plant protection drug trading

1. Dossier submission

a/ At least 3 (three) months before a certificate of eligibility for plant protection drug trading expires, the trader shall submit a dossier directly or by post to the provincial-level Sub-Department of Plant Protection.

b/ Number of dossier sets: 1 set.

c/ To check the completeness of the dossier immediately after receiving it directly or within 2 (two) working days after receiving it by post. If the dossier is complete, the Sub-Department of Plant Protection shall receive it. If the dossier is incomplete, it shall return the dossier and request the applicant to supplement and complete it.

2. Dossier

a/ An application for a certificate of eligibility for plant protection drug trading, made according to a set form.

b/ A copy (with the original for comparison) or a certified copy of the certificate of plant

protection drugs or agricultural supplies business registration (if there is any change).

c/ A copy (with the original for comparison) or a certified copy of the practice certificate of plant protection drug trading of the establishment owner (if there is any change).

d/ The granted original certificate of eligibility for plant protection drug trading.

dd/ A written declaration of plant protection drug trading conditions, made according to a set form.

e/ A certified copy of the form or the record of examination, assessment and classification of quality assurance conditions of the trader of functional agencies under the Agriculture and Rural Development Minister's Circular No. 14/2011/TT-BNNPTNT of March 29, 2011 (if any).

3. Appraisal of dossiers and grant of certificates of eligibility for plant protection drug trading

Within 3 (three) working days after receiving a complete dossier, the Sub-Department of Plant Protection shall appraise it.

a/ For a valid dossier, to carry out procedures as prescribed at Points b, c, d, dd and e, Clause 3, Article 14 of this Circular.

If the establishment has periodical inspection results of level A under the Agriculture and Rural Development Minister's Circular No. 14/2011/TT-BNNPTNT of March 29, 2011, within 1 (one) year up to the time of renewal, the Sub-Department of Plant Protection shall grant a certificate of eligibility for plant protection drug trading, made according to a set form, without forming a field evaluation team.

b/ For an invalid dossier, to notify the applicant of the dossier's contents to be supplemented and completed.

Article 17. Procedures for re-grant of certificates of eligibility for plant protection drug production or trading

1. Cases of re-grant

a/ Valid certificates are lost or missing.

b/ Valid certificates are unused by damage.

c/ Upon detection of errors or change of information in certificates.

For the cases specified at Points b and c of this Clause, old certificates must be recalled upon grant of new ones.

2. Dossier submission

a/ A producer or trader requesting re-grant of its certificate of eligibility for plant protection drug production or trading shall submit a dossier directly or by post to a competent agency specified in Article 12 of this Circular.

b/ Number of dossier sets: 1 set.

c/ To check the completeness of the dossier immediately after receiving it directly or within 2 (two) working days after receiving it by post. If the dossier is complete, a competent agency specified in Article 12 of this Circular shall receive it. If the dossier is incomplete, it shall return the dossier and request the applicant to supplement and complete it.

3. Dossier

a/ An application for a certificate of eligibility for plant protection drug production or trading, made according to a set form.

b/ The granted certificate (for the cases specified at Points b and c, Clause 1 of this Article).

4. Re-grant of certificates of eligibility for plant protection drug production or trading

Within 5 (five) working days after receiving a complete dossier, a competent agency shall consider and compare it with archival records.

a/ For a valid dossier, it shall grant a certificate of eligibility for plant protection drug production or trading, made according to a set form. The serial number, date of grant and validity term of such certificate, which is clearly indicated as the duplicate, are the same as those in the original certificate.

b/ For an invalid dossier, it shall notify the applicant of the dossier's contents to be supplemented and completed.

c/ In case of refusal to grant a certificate, it shall issue a written reply clearly stating the reason.

Article 18. Revocation of certificates

a/ Establishments no longer satisfy the conditions on plant protection drug production or trading provided in this Circular and other related documents on plant protection drug production and trading.

b/ Establishments are dissolved or no longer operate in plant protection drug production or trading.

c/ Establishments commit violations which are subject to certificate revocation under law.

Article 19. Charges and fees

The collection of charges and fees for certifying establishments eligible for plant protection drug production or trading complies with the Ministry of Finance's current regulations and other relevant legal documents.

Chapter V

RIGHTS AND RESPONSIBILITIES OF INVOLVED PARTIES

Article 20. Rights and responsibilities of producers and traders of plant protection drugs

1. Rights of producers and traders of plant protection drugs: To file a complaint when disagreeing with conclusions stated in the evaluation record.

2. Responsibilities of producers and traders of plant protection drugs:

a/ To carry out procedures for grant, renewal and re-grant of certificates of eligibility for plant protection drug production or trading and to comply with this Circular.

b/ To fully provide relevant information and dossiers and create favorable conditions for evaluation agencies to perform their tasks.

c/ To constantly maintain and assure conditions for plant protection drug production or trading as certified.

d/ To seriously redress shortcomings stated in the evaluation record of the agency granting the certificate of eligibility for plant protection drug production or trading.

dd/ To participate in training courses on plant protection drug production and trading held by plant protection state management agencies.

e/ To pay charges and fees under regulations.

Article 21. Powers and responsibilities of agencies granting certificates of eligibility for plant protection drug production or trading

1. Agencies granting certificates of eligibility for plant protection drug production or trading have the following powers:

a/ To supervise and request establishments to redress their shortcomings in conditions for plant protection drug production or trading.

b/ To request establishments to provide dossiers and documents and facilitate the evaluation of their observance of this Circular and other legal documents related to plant protection drug production and trading.

2. Agencies granting certificates of eligibility for plant protection drug production or trading have the following responsibilities:

a/ To grant, renew, re-grant and revoke certificates of eligibility for plant protection drug production or trading in accordance with this Circular.

b/ To form evaluation teams.

c/ To guarantee objectivity and fairness in the evaluation and grant of certificates of eligibility for plant protection drug production or trading.

d/ To regularly or irregularly inspect establishments having obtained a certificate of eligibility for plant protection drug production or trading when so requested by competent state agencies.

dd/ To handle violations and settle complaints and denunciations in accordance with law.

Article 22. Powers and responsibilities of evaluation teams

1. To evaluate and consider establishments' conformity with Chapter II (for producers) and Chapter III (for traders) of this Circular.

2. To guarantee objectivity in their inspection and evaluation.

3. To truthfully report on evaluation results to competent agencies.

4. To keep confidential information relating to secrets of evaluated establishments and fully comply with current laws.

5. To conduct interviews, request provision of books, documents and dossiers related to the establishments; to collect and record necessary information and request performance of specialized tasks and provision of evidence for evaluation work.

Chapter VI

IMPLEMENTATION PROVISIONS

Article 23. Transitional provisions

1. Establishments operating in plant protection drug production or trading before the effective date of this Circular which have obtained a practice certificate of plant protection drug production or trading shall carry out procedures to apply for a certificate of eligibility for plant protection drug production or trading as prescribed in Article 13 or Article 14 of this Circular.

Establishments reaching level A under the Agriculture and Rural Development Minister's Circular No. 14/2011/TT-BNNPTNT of March 29, 2011, within one (1) year up to the time of application shall carry out procedures to apply for a certificate of eligibility for plant protection drug production or trading as prescribed in Clauses 1 and 2, Article 13, or Clauses 1 and 2, Article 14, of this Circular. Competent agencies shall grant certificates of eligibility for plant protection drug production or trading within 5 (five) working days after receiving valid dossiers without forming field evaluation teams.

2. The time for implementing Clause 1 of this Article is within 2 (two) years after the effective date of this Circular.

Article 24. Effect

This Circular takes effect on April 11, 2013.

To annul Article 5 of the Regulation on grant of practice certificates of plant protection drug production, subcontract production, bottling, packaging or trading promulgated together with the Agriculture and Rural Development Minister's Decision No. 97/2008/QD-BNN of October 6, 2008.

Article 25. Implementation responsibilities

The Department of Plant Protection and provincial-level Sub-Departments of Plant Protection shall disseminate and guide producers and traders of plant protection drugs in implementing this Circular.

Any problems in the course of implementation should be reported to the Ministry of Agriculture and Rural Development (the Department of Plant Protection) for timely amendment and supplementation.-

For the Minister of Agriculture and Rural Development
Deputy Minister
BUI BA BONG