

**THE MINISTRY OF
AGRICULTURE AND
RURAL DEVELOPMENT**

THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

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CIRCULAR

On management of plant protection drugs^(*)

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

Pursuant to November 25, 2013 Law No. 41/2013/QH13 on Plant Protection and Quarantine;

Pursuant to November 21, 2007 Law No. 06/2007/QH12 on Chemicals;

Pursuant to November 21, 2007 Law No. 06/2007/QH12 on Product and Goods Quality;

Pursuant to June 29, 2006 Law No. 68/2006/QH11 on Standards and Technical Regulations;

Pursuant to the Government's Decree No. 14/2015/ND-CP of February 13, 2015, detailing and guiding a number of articles of the Law on Railway;

Pursuant to the Government's Decree No. 104/2009/ND-CP of November 9, 2009, prescribing the list of dangerous goods and transportation of dangerous goods by road motor vehicles;

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

Pursuant to the Government's Decree No. 181/2013/ND-CP of November 14, 2013, detailing a number of articles of the Law on Advertisement;

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

The Minister of Agriculture and Rural Development promulgates the Circular on management of plant protection drugs.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular prescribes the management of plant protection drugs, including registration; trial; manufacture; trading; import and export; quality inspection; regulation conformity certification and announcement; preservation and transportation; use; labeling; packaging; advertising; recall and destruction of plant protection drugs in Vietnam.

Article 2. Subjects of application

This Circular applies to domestic and foreign organizations and individuals engaged activities related to plant protection drugs in Vietnam.

^(*) Công Báo Nos 631-632 (28/6/2015)

Article 3. Interpretation of terms

In this Circular, the terms and phrases below are construed as follows:

1. Bio-efficacy trial means the determination of the efficacy of prevention and control of pests or regulation of crop growth (including also safety for crops).

2. Trial for determination of pre-harvest interval means the determination of the period of time (in day) from the last use of a plant protection drug to the harvest of products, which drug users are required to observe to ensure food safety.

3. Quality control of plant protection drugs means the determination of active ingredient content, formulation type, content of impurities (if any) likely to be toxic to plants or humans or to cause environmental pollution; content of additives (if any) which can enhance the safety of products for humans and crops; and chemical and physical properties related to the bio-activity and safety of plant protection drugs.

4. Imported plant protection drug shipment means the combination of a plant protection drug category in a specified quantity, with the same name, effect, label, formulation type and technical specifications, of the same institution in the same import dossier, and imported at the same time.

5. Biological plant protection drug means a plant protection drug having efficacious constituents being live microorganisms or substances of microorganism, plant or animal origin.

6. Chemical plant protection drug means a plant protection drug having active ingredients being synthetic inorganic or organic chemicals.

Article 4. Charges and fees

Organizations and individuals engaged in activities related to plant protection drugs shall pay charges and fees prescribed by the law on charges and fees.

Chapter II

REGISTRATION OF PLANT PROTECTION DRUGS

Section 1

GENERAL PROVISIONS ON REGISTRATION OF PLANT PROTECTION DRUGS

Article 5. General principles of registration of plant protection drugs

1. All plant protection drugs used for preventing and controlling plant pests; regulating crop growth; preserving plants; disinfecting warehouses; killing termites harmful to construction works and dikes; killing weeds on uncultivated land; enhancing safety and effect when used (with particular trade names) shall be registered in the list of plant protection drugs permitted for use in Vietnam (below referred to as the list).

2. Domestic and foreign organizations and individuals (with representative offices, companies, company branches trading in plant protection drugs licensed for operation in Vietnam) that manufacture plant protection drug active ingredients (below referred to as active ingredients), plant protection drugs of technical grade (below referred to as technical-grade drugs) or finished plant protection products from technical-grade drugs (below referred to as finished products) may register under their own names plant protection drugs which they manufacture.

3. A manufacturer of active ingredients, technical-grade drugs or finished products that does not register them under its/his/her own name may authorize only one organization or individual that fully satisfies the conditions prescribed in Clause 3, Article 50 of the Law on Plant Protection and Quarantine to register each plant protection drug under its/his/her name.

4. An organization or individual may be authorized by only one manufacturer of active ingredients, technical-grade drugs or finished products to register each of those active ingredients, technical-grade drugs or finished products.

5. A registrant may:

a/ Register one trade name for each active ingredient, technical-grade drug or finished product for pest prevention and control or crop growth regulation. In case such active ingredient, technical-grade drug or finished product is used for disinfection of warehouses; preservation of plants; killing of termites harmful to construction works or dikes; or treatment of seeds, one more trade name shall be registered;

b/ Register only one active ingredient content for each formulation of a plant protection drug;

c/ Transfer trade names under Clauses 2, 3 and 4, and Points a and b, Clause 5, of this Article;

d/ Not change trade names of plant protection drugs on the list, unless the state management agency in charge of intellectual property or a court makes written conclusions that they infringe upon trademarks of trade names on the list;

dd/ Change the manufacturer named in the plant protection drug registration certificate in case the manufacturer ceases supply of products or there is a written agreement on termination of authorization between the manufacturer and the authorized organization or individual.

6. Only five years after the organization or individual that first registers a plant protection drug containing active ingredients not yet on the list is granted a full registration certificate for such drug, may others file dossiers for supplementary registration of new trade names for plant protection drugs containing such active ingredients.

7. Plant protection drugs containing active ingredients being mixtures of chemicals and biologicals shall be managed like chemical drugs.

Article 6. Plant protection drugs not permitted for registration in Vietnam

1. Plant protection drugs on the list of plant protection drugs banned from use in Vietnam (below referred to as banned list).

2. Finished products or active ingredients in finished products of class I or class II toxicity according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), except biological plant protection drugs and plant protection drugs used for fumigation, disinfection or as rodenticide; termiticide for construction works and dikes; and preservatives for forest products that are not used as food or pharmaceutical materials.

3. Plant protection drugs that are most likely to badly affect human health, livestock, the ecological system and environment, including:

a/ Plant protection drugs that are warned by the United Nations Food and Agriculture Organization (FAO), United Nations Environmental Program (UNEP) or World Health Organization (WHO); and those specified in Annex III to the Rotterdam Convention;

b/ Chemical plant protection drugs that are mixtures of plant protection drugs with different effects (insecticide, herbicide, pesticide, growth regulator), except seed treatment drugs;

c/ Plant protection drugs that contain microorganisms pathogenic to humans;

d/ Plant protection drugs that may cause genetic mutation, cancer or reproductive toxicity to humans;

dd/ Chemical plant protection drugs registered for prevention and control of plant pests or for growth regulation of fruit trees, tea and vegetables or post-harvest preservation of farm produce, with class III or class IV acute toxicity of active ingredients or finished products according to GHS; of the organic chlorine group; and with a pre-harvest interval of over 7 days in Vietnam.

4. Plant protection drugs with trade names identical to active ingredients or trade names of other plant protection drugs on the list.

5. Plant protection drugs that contain methyl bromide.

6. Plant protection drugs registered for prevention and control of living creatures other than microorganisms harmful to plants in Vietnam.

7. Plant protection drugs invented abroad but not yet permitted for use there.

Article 7. Removal of plant protection drugs from the list

1. A plant protection drug shall be removed from the list in the following cases:

a/ It falls into one of the cases specified in Clause 2, Article 49; Points b and c, Clause 1, Article 54 of the Law on Plant Protection and Quarantine;

b/ It is specified in Annex III to the Rotterdam Convention or warned by the United Nations Food and Agriculture Organization (FAO), United Nations Environmental Program (UNEP) or World Health Organization (WHO).

2. Procedures for removing a plant protection drug from the list

a/ In the case specified at Point b, Clause 1 of this Article, the Plant Protection Department shall report to and propose in writing the Minister of Agriculture and Rural Development to remove such plant protection drug from the list;

b/ In the case specified at Point a or b, Clause 2, Article 49 of the Law on Plant Protection and Quarantine, the Plant Protection Department shall summarize information and form a scientific council to consider and advise on the removal of such plant protection drug from the list, and report to and propose the Minister of Agriculture and Rural Development to remove such plant protection drug from the list. The Minister of Agriculture and Rural Development shall decide on removal of such plant protection drug from the list;

c/ In the case specified at Point c, Clause 2, Article 49; Point b or c, Clause 1, Article 54 of the Law on Plant Protection and Quarantine, the Plant Protection Department shall propose the Minister of Agriculture and Rural Development to remove such plant protection drug from the list.

3. A plant protection drug specified at Point b, Clause 1 of this Article; Point a or b, Clause 2, Article 49 of the Law on Plant Protection and Quarantine may only be manufactured or imported within one year, or traded and used within two years after the Ministry of Agriculture and Rural Development's decision on removal of it from the list takes effect.

Article 8. Forms of registration

1. Full registration, covering:

a/ Plant protection drugs containing active ingredients not yet included in the list or plant protection drugs with new contents and compositions of active ingredients on the list which are invented and registered for use abroad;

b/ Plant protection drugs containing active ingredients not yet included in the list or plant protection drugs with new contents and compositions of active ingredients on the list which are

invented at home and proposed by scientific councils formed by the Plant Protection Department to the Plant Protection Department for recognition as plant protection drugs.

2. Supplementary registration, covering:

a/ Plant protection drugs having their trade names on the list but having their use scope broadened, or their dosage, usage, formulation type or active ingredient content changed;

b/ Plant protection drugs containing active ingredients on the list but registered with other trade names.

Section 2

GRANT, RE-GRANT OF PLANT PROTECTION DRUG TRIAL PERMITS

Article 9. General principles of grant of plant protection drug trial permits

1. Plant protection drugs registered on the list must have plant protection drug trial permits (below referred to as trial permits) granted by the Plant Protection Department under Articles 10 and 11 of this Circular, and undergo trial under Chapter III of this Circular.

2. Grant of trial permits for biological plant protection drugs

a/ Biological plant protection drugs require only large-scale biological efficacy trial, not trial for determination of pre-harvest interval, except the case specified at Point b of this Clause;

b/ Biological plant protection drugs containing pyrethrins, rotenone or avermectin products and subject to full registration or supplementary registration of trade names must undergo small-scale and large-scale biological efficacy trials. If they are first registered for use on fruit trees, tea and vegetables and for post-harvest preservation of farm produce, trial for determination of pre-harvest interval in Vietnam is required.

3. Grant of trial permits for chemical plant protection drugs

a/ Chemical plant protection drugs subject to full registration or supplementary registration of trade names must undergo small-scale and large-scale biological efficacy trials;

b/ Chemical plant protection drugs subject to registration of broadened use scope or changed dosage, usage, formulation type or active ingredient content must undergo large-scale biological efficacy trial;

c/ Chemical plant protection drugs first registered for use on fruit trees, tea and vegetables and for post-harvest preservation of farm produce must undergo trial for determination of pre-harvest interval in Vietnam (except herbicide used for perennial fruit trees, insect attractants, drugs for pre-cultivation soil treatment, drugs for prevention and control of sapling wilt, and drugs for treatment of seeds and grafts).

4. Both Vietnamese and scientific names of pests shall be written on trial permits.

Article 10. Dossiers, order and procedures for grant of trial permits for full registration

1. Submission of dossiers

a/ A dossier may be submitted directly, by post or online to the Plant Protection Department;

b/ The dossier shall be checked within 2 working days. If the dossier is valid as prescribed, it shall be accepted. If the dossier is invalid, it shall be returned together with a request for supplementation and completion;

c/ Number of dossiers: One paper dossier and its electronic file (PDF format).

2. A dossier must comprise:

a/ An application for plant protection drug trial permit, made according to the form provided in Appendix I to this Circular;

b/ Papers proving the applicant's eligibility to register plant protection drugs in Vietnam:

The original or an authenticated copy of the document certifying the manufacturer of drugs, including the plant protection drug for which the trial permit is applied, granted by a competent agency of the country of origin (for foreign manufacturers);

An authenticated copy or a photocopy together with the original (for comparison) of the establishment license of the company, company branch or representative office in Vietnam (for foreign manufacturers that register drugs for the first time);

The original power of attorney of the manufacturer for the registrant (in case of authorized registration). The power of attorney of a foreign manufacturer shall be consularly legalized in accordance with Vietnamese law, unless it is exempted from legalization under a treaty to which Vietnam is a contracting party;

A copy of the certificate of eligibility for plant protection drug trading (for domestic entities authorized to make first-time registration under their names);

c/ Technical documents of the plant protection drug specified in Appendix III to this Circular.

3. Appraisal of dossiers and grant of trial permits

a/ The Plant Protection Department shall appraise the dossier within 10 working days after receiving the complete dossier as prescribed in Clause 2 of this Article. For a dossier of application for trial permit for more than three crops or three pests, the time limit for dossier appraisal is 15 working days;

In case the dossier satisfies the requirements prescribed in this Circular, the Plant Protection Department shall submit it to the Minister of Agriculture and Rural Development;

In case the dossier fails to satisfy the requirements prescribed in this Circular, the Plant Protection Department shall notify contents to be supplemented to the applicant for dossier completion;

b/ The Ministry of Agriculture and Rural Development (the Department of Science, Technology and Environment) shall appraise the dossier under regulations within 5 working days after receiving it from the Plant Protection Department;

c/ Within 2 working days after receiving the approval of the Minister of Agriculture and Rural Development, the Plant Protection Department shall grant a plant protection drug trial permit, made according to the form provided in Appendix IV to this Circular;

d/ In case of refusal to grant a trial permit, the Plant Protection Department shall notify such in writing to the applicant clearly stating the reason.

Article 11. Dossiers, order and procedures for grant of trial permits for supplementary registration

1. Submission of dossiers

Dossiers shall be submitted under Clause 1, Article 10 of this Circular.

2. A dossier must comprise:

a/ An application for plant protection drug trial permit, made according to the form provided in Appendix I to this Circular;

b/ A copy of the granted plant protection drug registration certificate (in case of broadened scope of use or changed formulation type, active ingredient content, dosage or usage);

c/ Technical documents on the finished product specified in Appendix III to this Circular (in case of changed formulation type or active ingredient content);

d/ Papers specified at Points b and c, Clause 2, Article 10 of this Circular (in case of addition of other trade names);

3. Appraisal of dossiers and grant of trial permits

A dossier shall be appraised and trial permit granted under Clause 3, Article 10 of this Circular.

Article 12. Dossiers, order and procedures for re-grant of trial permits

1. Submission of dossiers

Dossiers shall be submitted under Points a và b, Clause 1, Article 10 of this Circular. The number of dossiers is one paper dossier.

2. A dossier must comprise:

a/ An application for re-grant of plant protection drug trial permit, made according to the form provided in Appendix I to this Circular;

b/ The original trial permit already granted (unless it is lost).

3. Appraisal of dossiers and re-grant of trial permits

Within 5 working days after receiving a complete dossier as prescribed, the Plant Protection Department shall appraise it:

a/ If the dossier is valid, the Plant Protection Department shall re-grant the plant protection drug trial permit according to the form provided in Appendix IV to this Circular. The new trial permit must have the same validity duration as that of the granted permit;

b/ In case the dossier is invalid, the Plant Protection Department shall notify the contents which need to be supplemented to the applicant for dossier completion;

c/ In case of refusal to re-grant the trial permit, the Plant Protection Department shall notify such in writing clearly stating the reason to the applicant.

Section 3

GRANT, RE-GRANT AND EXTENSION OF PLANT PROTECTION DRUG REGISTRATION CERTIFICATES

Article 13. Dossiers, order and procedures for grant of plant protection drug registration certificates

1. Submission of dossiers

a/ Dossiers shall be submitted under Points a and b, Clause 1, Article 10 of this Circular;

b/ Number of dossier: One paper dossier and its electronic file in the word or excel format, or power point format for labels.

2. A dossier must comprise:

a/ An application for a plant protection drug registration certificate, made according to the form provided in Appendix II to this Circular;

b/ A copy of the granted trial permit;

c/ The drug label design as prescribed in Sections 1, 2 and 3, Chapter X of this Circular;

d/ The original reports on results of biological efficacy trial and trial for determination of pre-harvest interval, and summary report on trial results, made according to the forms provided in Appendices VI, VII and XI to this Circular.

3. Appraisal of dossiers and grant of plant protection drug registration certificates

Within 6 months after receiving a complete and valid dossier, the Plant Protection Department shall appraise it and propose the Minister of Agriculture and Rural Development to include the plant protection drug in the list; and shall grant a plant protection drug registration certificate according to the form provided in Appendix V to this Circular. In case of refusal to grant a certificate, the Plant Protection Department shall reply in writing clearing stating the reason to the applicant.

Article 14. Dossiers, order and procedures for extension of plant protection drug registration certificates

1. Three months before the expiration date of a plant protection drug registration certificate, its holder that wishes to have its/his/her certificate extended shall submit a dossier of request for certificate extension.

2. Submission of dossiers

Dossiers shall be submitted under Points a and b, Clause 1, Article 10 of this Circular. The number of dossier is one paper dossier.

3. A dossier must comprise:

a/ A written request for extension of a plant protection drug registration certificate, made according to the form provided in Appendix II to this Circular;

b/ The original plant protection drug registration certificate already granted.

4. Appraisal of dossiers and extension of plant protection drug registration certificates

Within 10 working days after receiving a complete and valid dossier prescribed in Clause 3 of this Article, the Plant Protection Department shall appraise it:

a/ In case the dossier is valid and satisfies the requirements prescribed in this Circular, the Plant Protection Department shall extend the plant protection drug registration certificate according to the form provided in Appendix V to this Circular;

b/ In case the dossier is invalid and fails to satisfy the requirements prescribed in this Circular, the Plant Protection Department shall notify contents to be supplemented to the applicant for dossier completion;

c/ In case of refusal to extend the plant protection drug registration certificate, the Plant Protection Department shall notify such in writing to the applicant clearly stating the reason.

Article 15. Dossiers, order and procedures for re-grant of plant protection drug registration certificates in case of loss, error or damage

1. Submission of dossiers

Dossiers shall be submitted under Points a and b, Clause 1, Article 10 of this Circular. The number of dossier is one paper dossier.

2. A dossier must comprise:

a/ An application for re-grant of a plant protection drug registration certificate, made according to the form provided in Appendix II to this Circular;

b/ The original plant protection drug registration certificate, unless it is lost.

3. Order and procedures for re-grant of a plant protection drug registration certificate

A plant protection drug registration certificate shall be re-granted under Clause 4, Article 14 of this Circular. The re-granted plant protection drug registration certificate must have the same validity duration as that of the original certificate.

Article 16. Dossiers, order and procedures for re-grant of plant protection drug registration certificates in case of change of trade names or information about registrants

1. Submission of dossiers

Dossiers shall be submitted under Points a and b, Clause 1, Article 10 of this Circular. The number of dossier is one paper dossier.

2. A dossier must comprise:

a/ A written request for change of the trade name or information about the registrant, made according to the form provided in Appendix II to this Circular;

b/ The original plant protection drug registration certificate;

c/ An authenticated copy or a photocopy with the original (for comparison) of the document of the competent state agency in charge of intellectual property or a court on trademark infringement (in case of change of trade name);

d/ An authenticated copy or a photocopy with the original (for comparison) of the new enterprise registration certificate (in case the registrant is renamed);

dd/ In case of transfer of trade name: The original or an authenticated copy of the contract or agreement of transfer of the plant protection drug; the original power of attorney of the manufacturer for registration by the transferee (in case of authorized registration).

3. Appraisal of dossiers and re-grant of plant protection drug registration certificates

a/ Within 10 working days after receiving a complete dossier prescribed in Clause 2 of this Article, the Plant Protection Department shall appraise it:

In case the dossier is valid, the Plant Protection Department shall propose the Minister of Agriculture and Rural Development to include the drug in the list under Clause 3, Article 13 of this Circular;

In case the dossier is invalid and fails to satisfy the requirements prescribed in this Circular, the Plant Protection Department shall notify contents to be supplemented to the applicant for dossier completion;

b/ In case of refusal to re-grant the plant protection drug registration certificate, the Plant Protection Department shall notify such in writing clearly stating the reason to the applicant;

c/ The re-granted plant protection drug registration certificate must have the same validity term as that of the previously granted certificate.

Article 17. Dossiers, order and procedures for re-grant of plant protection drug registration certificates in case of change of manufacturers

1. Submission of dossiers

Dossiers shall be submitted under Clause 1, Article 10 of this Circular.

2. A dossier must comprise:

a/ An application for re-grant of a plant protection drug registration certificate, made according to the form provided in Appendix II to this Circular;

b/ The original or an authenticated copy of the agreement on termination of authorization between the manufacturer named in the plant protection drug registration certificate and the entity authorized to make registration;

c/ The original or an authenticated copy of the document certifying the new manufacturer as the plant protection drug manufacturer granted by a competent management agency of the country of origin (for foreign manufacturers);

d/ The original power of attorney of the new manufacturer for registration by the registrant (in case of authorized registration). The power of attorney of the foreign manufacturer shall be consularly legalized in accordance with Vietnamese law, unless it is exempted from legalization under a treaty to which Vietnam is a contracting party;

dd/ Technical documents of the plant protection drug specified in Appendix III to this Circular;

e/ The original plant protection drug registration certificate already granted.

3. Appraisal of dossiers and re-grant of plant protection drug registration certificates

a/ Dossiers shall be appraised and plant protection drug registration certificates shall be re-granted under Clause 4, Article 14 of this Circular;

b/ The re-granted plant protection drug registration certificate must have the same validity duration as that of the previously granted certificate.

Chapter III

PLANT PROTECTION DRUG TRIAL

Article 18. General principles of plant protection drug trial

1. A plant protection drug trial may be conducted only after a trial permit is granted.

2. Trials of plant protection drugs for being registered in the list include biological efficacy trial and trial for determination of pre-harvest interval (for the cases specified at Point b, Clause 2 and Point c, Clause 3, Article 9 of this Circular).

3. Plant protection drug trials shall be conducted based on the national technical regulations (QCVN), national standards (TCVN), and standards (TC) established by the Plant Protection Department.

4. Trials of plant protection drugs for being registered in the list shall be conducted by organizations satisfying the conditions prescribed in Article 20 of this Circular.

5. Small-scale trial shall be conducted before large-scale trial.

Article 19. Conduct of trials

Trial of plant protection drugs for one pest on one crop for the purpose of registration shall be conducted as follows:

1. Trial of biological efficacy of biological plant protection drugs (except the cases specified in Clause 2 of this Article); and chemical plant protection drugs subject to registration of broadened scope of use or changed dosage, usage, formulation type or active ingredient content includes four large-scale trials, specifically:

For a crop or pest that exists in the two production regions (northern and southern), trial shall be conducted in two places in two provinces or in two districts of one province in each region (in case the crop or pest exists only in one province of the production region).

For a crop or pest that exists in only one region or province, trial shall be conducted in four places in four provinces of the region or in four places in at least two districts of the province.

2. Trial of biological efficacy of chemical plant protection drugs; and biological plant protection drugs containing active ingredients of pyrethrins, rotenone or avermectin group for full

registration or addition of trade names must include eight small-scale trials and two large-scale trials. For a crop or pest that exists in only one production region, there must be six small-scale trials and two large-scale trials, specifically:

a/ Small-scale trials

For a crop or pest that exists in the two production regions (northern and southern), trial shall be conducted in four places in four provinces in each region. If a region has fewer than four production provinces, trial shall be conducted in four places in four districts in the region.

For a crop or pest that exists in only one production region, trial shall be conducted in six places in six provinces or districts in the region;

For a crop or pest that exists in only one production province, trial shall be conducted in six places in at least three districts of the province;

For a herbicide for rice, trial shall be conducted in two different seasons.

b/ Large-scale trials

For a crop or pest that exists in the two production regions (northern and southern regions), trial shall be conducted in one place in each region;

For a crop or pest that exists in only one production region, trial shall be conducted in two places in two provinces or in two places in two districts of one province in the region (if the pest exists only in that province).

3. Trial for determination of pre-harvest interval for one active ingredient on one crop includes four large-scale trials, specifically:

For a crop with several seasons a year in the two production regions (northern and southern regions), trial shall be conducted in two places in two provinces (every other season in each province) or in two places in two districts in each region (every other season in each district);

For a crop with several seasons a year in only one production region, trial shall be conducted in four places in four provinces or four districts in the region (every other season in every two places);

For a crop with only one season a year in the two production regions (northern and southern regions), trial shall be conducted in two places in two provinces or two districts in each region;

For a crop with only one season a year in only one production region, trial shall be conducted in four places in four provinces or in four places in at least two districts of one province in the region.

Article 20. Guidance on conditions for an organization to conduct plant protection drug trial

1. Having the legal entity status and registering for operation in the field of plant protection drug trial.

2. Being headed by a person who possesses a university or higher degree in plant protection, agronomy, cultivation, biology or chemistry, and a certificate of training in plant protection drug trial granted by the Plant Protection Department.

3. Having at least five employees on the state payroll or working under long-term labor contracts and possessing university or higher degrees in the fields specified in Clause 2 of this Article and certificates of training in plant protection drug trial granted by the Plant Protection Department.

4. Having physical-technical foundations for plant protection drug trial:

a/ Having sufficient facilities and equipment for plant protection drug trial specified in Appendix X to this Circular;

b/ Conducting by itself or in coordination with other organizations a number of trials prescribed in Article 19 of this Circular for a drug to be registered in the list of plant protection drugs permitted for use in Vietnam.

Organizations that coordinate in conducting trial must have the legal entity status, and sufficient personnel, facilities and equipment for trial prescribed in Clause 2 and at Point a, Clause 4 of this Article.

c/ Having a laboratory for residue analysis designated by the Ministry of Agriculture and Rural Development with corresponding tests (for organizations conducting trial for determination of pre-harvest interval).

5. Neither having registered under its name nor authorizing others to register under their names plant protection drugs in Vietnam.

Article 21. Dossiers, order and procedures for recognizing eligibility of organizations to conduct plant protection drug trial

1. Submission of dossiers

a/ Dossiers may be submitted directly or sent by post or online to the Plant Protection Department;

b/ Number of dossiers: one set;

c/ The dossier shall be checked right after it is received directly or within two working days if it is sent by post. In case the dossier is valid, the Plant Protection Department shall accept the dossier. In case the dossier is invalid, it shall request the applicant to supplement and complete the dossier.

2. A dossier must comprise:

a/ A written request for recognition of eligibility of an organization to conduct plant protection drug trial, made according to the form provided in Appendix IX to this Circular;

b/ An authenticated copy or a photocopy with the original (for comparison) of the establishment decision or the decision defining the functions and tasks or the registration certificate of enterprise engaged in plant protection drug trial;

c/ Authenticated copies or photocopies with the originals (for comparison) of the university or higher degrees in plant protection, cultivation, agronomy, biology or chemistry and certificates of training in plant protection drug trial of the head of the trial-conducting organization and persons participating in the trial;

d/ A written description of satisfaction of the conditions for plant protection drug trial of the organization eligible to conduct trial and coordinating units, made according to the form provided in Appendix X to this Circular;

3. Appraisal of dossiers of request for recognition and announcement of organizations eligible to conduct plant protection drug trial

a/ The Plant Protection Department shall receive and appraise the dossier of request for recognition of the eligibility of an organization to conduct plant protection drug trial. Within 15 working days after obtaining appraisal results, the Plant Protection Department shall complete the dossier and submit it to the Minister of Agriculture and Rural Development;

b/ Within 10 working days after receiving the dossier from the Plant Protection Department, the Ministry of Agriculture and Rural Development (the Department of Science, Technology and Environment) shall appraise it;

c/ Within 3 working days after receiving the approval from the Minister of Agriculture and Rural Development, the Plant Protection Department shall issue a decision recognizing the eligibility of the organization to conduct plant protection drug trial;

d/ In case the organization fails to satisfy the conditions for conducting plant protection drug trial, the Plant Protection Department shall notify such to the applicant clearly stating the reason.

Article 22. Training in plant protection drug trial

1. Training contents

a/ Current regulations on plant protection drug trial;

b/ Safe preservation and use of plant protection drugs;

c/ Processes of biological efficacy trial and trial for determination of pre-harvest interval;

d/ Processing and storage of data and reports on trial results.

2. Training registration and organization

Organizations and individuals that wish to be trained in plant protection drug trial shall register lists of trainees directly or by post or online with the Plant Protection Department.

3. The Plant Protection Department shall organize training in plant protection drug trial under Clause 1 of this Article. Each training course must last 4 days.

Based on results of training tests, the Plant Protection Department shall grant certificates of training in plant protection drug trial according to the form provided in Appendix XIII to this Circular.

Article 23. Rights and obligations of organizations conducting plant protection drug trial

1. To comply with Article 60 of the Law on Plant Protection and Quarantine and report on results of plant protection drug trial according to the form provided in Appendices VI and VII to this Circular.

2. To report on results of plant protection drug trial according to the form provided in Appendix XI to this Circular.

3. To annually report on their plant protection drug trial activities according to the form provided in Appendix XII to this Circular, or irregularly report on these activities at the request of the Plant Protection Department. An annual report shall be submitted before December 25 of the reporting year.

Article 24. Responsibilities of organizations and individuals having plant protection drugs put up for trial

1. To provide to qualified trial organizations their trial permits, declarations of information on plant protection drugs put up for trial (made according to the form provided in Appendix VIII to this Circular) and drug samples for trial (of categories and formulation types and with active ingredient contents stated in the trial permits; in sufficient quantities for trial and sample keeping; in air-tight packages sealed by the registrants for trial).

2. To enter into trial contracts and pay trial charges under current regulations.

3. In case drugs put up for trial cause bad effects on crops, humans and the environment, to pay compensation for damage in accordance with law.

Chapter IV
MANUFACTURE AND TRADING OF PLANT PROTECTION DRUGS

Section 1
GRANT OF CERTIFICATES OF ELIGIBILITY TO MANUFACTURE PLANT
PROTECTION DRUGS

Article 25. Scope of application

Establishments manufacturing plant protection drugs must satisfy the conditions prescribed in Article 61 of the Law on Plant Protection and Quarantine (except those manufacturing only biological plant protection drugs with active ingredients being useful microorganisms) as guided in detail in Articles 26 thru 29 of this Circular. These establishments may start manufacturing plant protection drugs on the date of grant of certificates of eligibility under Article 30 of this Circular.

Establishments manufacturing only biological plant protection drugs with active ingredients being useful microorganisms are not required to have a certificate of eligibility but shall still comply with the law on environmental protection.

Article 26. Specific conditions on workshops

1. Location

a/ Workshops located in industrial parks must comply with regulations of these industrial parks;

b/ Workshops for manufacturing plant protection drugs not located in industrial parks must ensure that:

They are located at least 500 meters from schools, hospitals and markets; and satisfy requirements on power supply, water supply and drainage, environmental pollution treatment and traffic;

They have walls separating them from surrounding areas. Their passageways must ensure safe transportation and fire prevention and fighting.

2. Ground plan, structure and architecture of workshops

a/ Manufacturing workshops must be separate from storehouses;

b/ Work structures shall be rationally arranged with specific functions;

c/ Workshops

Workshops must satisfy design and construction standards in Vietnam Standards TCVN 4604/2012: Industrial workshops, manufacturing houses - Designing standards; TCVN 2622/1995: Fire prevention and fighting for houses and works - Design requirements;

d/ Materials for building workshops must be non-flammable or fire-proof materials; workshop frames shall be built of bricks or made of concrete or steel; workshop floors shall be made of impermeable materials, flat, non-slippery and crack-free and have surrounding raised edges;

dd/ Workshops must have emergency exits with noticeable instruction signboards or diagrams which can be easily used when incidents occur.

Article 27. Specific conditions on facilities and equipment

1. Manufacturing equipment

a/ Manufacturing lines and technologies must be suitable to types and able to ensure quality of plant protection drugs manufactured;

b/ Equipment shall be arranged and installed to suit each manufacturing stage and up to labor safety requirements prescribed in Vietnam Standards TCVN 2290-1978: Manufacture equipment - General safety requirements;

c/ Equipment must have operation instructions, have their technical specifications tested and inspected under regulations, and shall be maintained and cleaned according to the industrial cleaning process;

d/ Lighting devices and other electrical equipment shall be installed in every necessary position and must not be temporarily installed. All electrical equipment must have circuit breakers.

2. Vehicles and loading/unloading equipment must satisfy current technical standards on dangerous goods which need to be transported, and shall be designed to prevent leakage or dispersal of plant protection drugs into the environment. There must be danger warning symbols and cautions on these vehicles.

3. Safety equipment and devices

a/ Workers shall wear labor protection devices when entering plant protection drug manufacturing workshops;

b/ Medical instruments, medicines and first-aid kits must be available;

c/ Establishments shall be fully furnished with equipment and devices to respond to incidents and fire prevention and fighting systems installed in appropriate positions. They shall regularly check them to ensure their constant readiness for use.

4. Waste treatment system

a/ Workshops must have exhaust gas treatment systems. Workshop exhaust gas must satisfy national technical regulations QCVN 19:2009/BTNMT - national technical regulation on industrial exhaust gas for dusts and inorganic substances, and 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 satisfy national technical regulations QCVN 07:2009/BTNMT - national technical regulation on hazardous waste limits, and QCVN 40:2011/BTNMT - national technical regulation on industrial wastewater;

c/ Solid waste disposal must comply with the Government's Decree No. 59/2007/ND-CP of April 9, 2007, on management of solid wastes. There must be solid waste collection places which are securely covered and solid waste collection devices and transportation vehicles.

Article 28. Quality management systems

1. New manufacturing establishments shall develop and apply their quality management systems according to ISO 9001:2008 or equivalent standards.

Manufacturing establishments that have operated for at least two years must have their quality management systems recognized to be conformable with ISO 9001: 2008 or the equivalent standards.

2. Establishments must have the plant protection drug manufacturing process clearly indicating trade names, process code, manufacturing purposes and norms (materials, additives, quantification, expected output of finished products, limits), location, equipment, manufacturing stages, quality inspection, warehousing, preservation, packaging, labeling and notes.

3. Establishments must have laboratories for product quality control recognized to be conformable with ISO 17025:2005 or the equivalent standards for controlling quality of plant protection drugs in ex-workshop product batches.

4. If having no laboratories mentioned in Clause 3 of this Article, establishments must have contracts with laboratories recognized to be conformable with ISO 17025:2005 or equivalent standards for controlling quality of plant protection drugs in ex-workshop product batches.

5. Establishments that have operated must keep dossiers of results of quality control of ex-workshop product batches, regulation and standard conformity announcements in accordance with the Law on Product and Goods Quality and the Law on Standards and Technical Regulations.

Quality control samples for each ex-workshop product batch shall be kept for at least 3 months.

Article 29. Specific conditions on workforce

1. Persons directly managing and administering manufacture must possess university or higher degrees in chemistry, plant protection or biology.

2. Persons directly managing and administering manufacture, persons directly engaged in manufacture, and storekeepers shall be trained in plant protection drugs and chemical safety techniques.

Article 30. Dossiers, order and procedures for grant of certificates of eligibility for manufacture of plant protection drugs

1. Submission of dossiers

a/ Dossiers may be submitted directly or by post or online to the Plant Protection Department;

b/ Number of dossier: One paper dossier and one electronic file (PDF format);

c/ A dossier shall be examined in 2 working days. If the dossier is valid as prescribed, it shall be accepted. If the dossier is invalid, it shall be returned with a written request for dossier supplementation or completion.

2. A dossier must comprise:

a/ An application for certificate of eligibility to manufacture plant protection drugs, made according to the form provided in Appendix XIV to this Circular;

b/ A written description of the conditions for manufacture of plant protection drugs, made according to the form provided in Appendix XV to this Circular;

c/ A plan or measures to prevent and respond to chemical incidents, made according to the form provided in Appendix XXI to this Circular; copies of documents proving the manufacturing establishment's compliance with environmental protection regulations issued by a competent agency in charge of environment;

d/ A copy of the certificate or copies of documents on recognition of the quality management system in conformity with ISO 17025:2005 or equivalent standards, for manufacturing establishments that have a laboratory;

dd/ A copy of the contract with a laboratory recognized to be conformable with ISO 17025:2005 or equivalent standards, for manufacturing establishments that have no laboratory,;

e/ An authenticated copy or a photocopy with the original (for comparison) of the certificate or copies of documents on recognition of the quality management system in conformity with ISO 9001:2008 or equivalent standards, for manufacturing establishments that have operated for at least two years.

3. Appraisal of dossiers and grant of certificates of eligibility to manufacture plant protection drugs

a/ Within 5 working days after receiving a complete and valid dossier, the Plant Protection Department shall appraise it. In case the dossier is satisfactory, the General Director of the Plant Protection Department shall decide to form an assessment team of 3-5 members who are professionally qualified for specialized management in the field of assessment.

The assessment team shall send a notice at least 7 working days in advance to the establishment. This notice must specify the composition of the team, and scope, contents and duration of assessment at the establishment which must not exceed one working day.

b/ Assessment contents

Satisfaction of the requirements prescribed in Section 1 of this Chapter and ability to maintain such conditions.

c/ Appraisal methods

Conducting field inspection and assessment of the arrangement of ground area, environmental conditions, state of equipment and other conditions of the establishment;

Interviewing managers and employees of the establishment on relevant information;

Examining dossiers and relevant documents kept at the establishment.

d/ Assessment results

Unsatisfied conditions under Section 1 of this Chapter detected in the course of appraisal shall be specified in the written record of assessment of the conditions for manufacture of plant protection drugs, made according to the form provided in Appendix XVII to this Circular.

The written record must contain all necessary contents and bear the signatures of the representative of the establishment and the head of the assessment team.

In case the representative of the establishment disagrees with assessment results, he/she is entitled to write his/her opinions at the bottom of the written record before signing and appending the certification seal. The written record is still legally valid in case the representative of the establishment refuses to sign it.

dd/ Grant of certificates of eligibility to manufacture plant protection drugs

The Plant Protection Department shall consider dossier appraisal and assessment results in order to grant certificates of eligibility to manufacture plant protection drugs:

In case the dossier is valid and assessment results are satisfactory, within 15 working days the Plant Protection Department shall grant a certificate of eligibility to manufacture plant protection drugs according to the form provided in Appendix XIX to this Circular.

In case the dossier is invalid or assessment results are unsatisfactory, the Plant Protection Department shall notify in writing the establishment of unsatisfied conditions and a deadline for addressing them. Within 5 working days after receiving a report on the satisfied conditions of the establishment or results of reassessment (when necessary), the Plant Protection Department shall grant a certificate of eligibility to manufacture plant protection drugs according to the form provided in Appendix XIX to this Circular.

In case the dossier is invalid or assessment results are unsatisfactory, the Plant Protection Department shall refuse to grant a certificate of eligibility and reply in writing clearly stating the reason to the establishment.

Article 31. Re-grant of certificates of eligibility to manufacture plant protection drugs

1. Three 3 months before the date of expiration of the certificate of eligibility to manufacture plant protection drugs, if the holder wishes to continue manufacturing plant protection drugs,

it/he/she shall submit a dossier of application for re-grant of the certificate. Dossiers, order and procedures for re-grant must comply with Article 30 of this Circular.

2. In the course of operation, if a manufacturing establishment is inspected and graded A according to regulations of the Minister of Agriculture and Rural Development on inspection and grading of establishments manufacturing or trading in agricultural supplies and agricultural, forest and aquatic products, and does not expand the manufacture of active ingredients, technical-grade drugs and formulations of finished products, it shall comply with Clauses 1 and 2, Article 30 of this Circular. The Plant Protection Department shall grant a certificate of eligibility to manufacture plant protection drugs within 5 working days after receiving a valid dossier without having to form a team to inspect the manufacturing establishment.

Section 2

GRANT OF CERTIFICATE OF ELIGIBILITY TO TRADE IN PLANT PROTECTION DRUGS

Article 32. Specific conditions on workforce

The owner of a trading establishment (director or general director of a limited liability company, joint-stock company or private enterprise, a partner of a partnership; head or deputy head of a branch of an enterprise; one of managers of an establishment trading in plant protection drugs at an agent store of an enterprise or a cooperative providing plant protection services; person directly managing a plant protection drug store at a fixed place), and plant protection drug salespersons must possess intermediate or higher degrees in plant protection, cultivation, biology or chemistry or certificates of training in plant protection drugs.

Article 33. Specific conditions on location

1. A plant protection drug store must have a clear and stable address, owned by the store owner or rented under a lawful rent contract of a term of at least one year.

2. The area of a plant protection drug store must be at least 10 square meters as suitable to its business scale. The store shall be solidly built in a high and airy place.

3. Plant protection drugs may not be sold together with food, foodstuffs, beverages, animal feed, medicines and veterinary drugs.

4. A plant protection drug store may not be located in an area where food and drink catering or entertainment services are provided or where a school or hospital is located.

5. A plant protection drug store must be at least 20 meters away from a water source (river, lake, canal or well); built on a high, impermeable and non-inundated foundation and have walls and roofs made of fire-proof materials.

6. The storage place of a plant protection drug store must satisfy the conditions prescribed in Article 61 of this Circular.

In case the trading establishment has no store, it shall make enterprise registration, have a fixed and lawful transaction place and a clear address, keep books to record purchase, sale, warehousing and ex-warehousing of plant protection drugs, and satisfy the conditions specified in Article 32 of this Circular.

Article 34. Specific conditions on facilities and equipment

1. Having showcases, counters, shelves or racks for displaying plant protection drugs.

2. Ensuring lighting for identification of drugs. Lighting equipment must be fire- and explosion-proof.

3. Having fire prevention and fighting rules and devices as requested by the fire prevention and fighting agency installed at convenient places for use when necessary.

4. Providing personal labor protection devices and materials, including gloves, gauze masks, clean water and soap.

5. Having materials and tools for timely response to incidents as requested by the management agency in charge of environment.

Article 35. Dossiers, order and procedures for grant of certificates of eligibility for trading of plant protection drugs

1. Submission of dossiers

a/ Dossiers may be submitted directly or by post or online to provincial-level plant protection sub-departments or cultivation and plant protection sub-departments.

b/ Number of dossier: one set;

c/ A dossier shall be appraised within 2 working days. If the dossier is valid, it shall be accepted. If it is invalid, it shall be returned with a request for dossier supplementation and completion.

2. A dossier must comprise:

a/ An application for a certificate of eligibility to trade in plant protection drugs, made according to the form provided in Appendix XIV to this Circular;

b/ An authenticated or a photocopy with the original (for comparison) of the enterprise registration certificate;

c/ A written description of the conditions for trading in plant protection drugs, made according to the form provided in Appendix XVI to this Circular.

3. Examination of conditions and grant of certificates of eligibility to trade in plant protection drugs

a/ Within 3 working days after receiving a complete dossier, the provincial-level plant protection sub-department or cultivation and plant protection sub-department shall appraise it.

b/ Forming an assessment team

Within 5 working days after receiving a complete dossier, the director of the provincial-level plant protection sub-department or cultivation and plant protection sub-department shall decide to form a team to conduct physical assessment. An assessment team shall be composed of 3-5 members with professional qualifications and specialized management skills in the field of assessment.

The assessment team shall notify the assessment plan at least 5 days before the date of assessment to the establishment. The notice must specify the composition of the team, scope, contents and period of assessment at the establishment which must not exceed one working day.

c/ Assessment content

Satisfaction of the conditions prescribed in Section 2 of this Chapter.

d/ Assessment methods

Interviewing managers and employees of the establishment on relevant information;

Examining dossiers and relevant documents kept at the establishment;

Observing the ground arrangement, environmental conditions, state of equipment and other facilities of the establishment.

dd/ Assessment results

Unsatisfied conditions under Section 2 of this Chapter detected in the course of appraisal shall be written in the assessment record made according to the form provided in Appendix XVIII to this Circular.

The written record of assessment must contain all necessary contents and bear the signatures of the representative of the establishment and the head of the assessment team.

In case the representative of the establishment disagrees with assessment results, he/she is entitled to write his/her opinions at the bottom of the written record before signing and appending the certification seal. The written record of assessment is still legally valid in case the representative of the establishment refuses to sign it.

e/ Grant of certificates of eligibility to trade in plant protection drugs:

The provincial-level plant protection sub-department shall consider dossier appraisal and assessment results in order to grant certificates of eligibility to trade in plant protection drugs:

In case the dossier is valid and assessment results are satisfactory, within 5 working days after the assessment is completed, the provincial-level plant protection sub-department or cultivation and plant protection sub-department shall grant a certificate of eligibility to trade in plant protection drugs, made according to the form provided in Appendix XX to this Circular.

In case the conditions are not fully satisfied, the provincial-level plant protection sub-department or cultivation and plant protection sub-department shall notify in writing the establishment of unsatisfied conditions and a time limit of 60 days for addressing them. Within 3 working days after receiving a report on the satisfied conditions of the establishment or results of reassessment (when necessary), the provincial-level plant protection sub-department or cultivation and plant protection sub-department shall grant a certificate of eligibility to trade in plant protection drugs, made according to the form provided in Appendix XX to this Circular.

In case of refusal to grant a certificate of eligibility to trade in plant protection drugs, the provincial-level plant protection sub-department or cultivation and plant protection sub-department shall reply in writing clearly stating the reason to the establishment.

Article 36. Re-grant of certificates of eligibility to trade in plant protection drugs

1. Three months before the date of expiration of a certificate of eligibility to trade in plant protection drugs, if the holder wishes to continue trading in plant protection drugs, it/he/she shall submit a dossier of application for re-grant of the certificate. Dossiers, order and procedures for re-grant must comply with Article 35 of this Circular.

2. In the course of operation, if a trading establishment is inspected and graded A according to regulations of the Minister of Agriculture and Rural Development on inspection and grading of establishments manufacturing or trading in agricultural supplies and agricultural, forest and aquatic products, it shall carry out procedures for applying for re-grant of the certificate of eligibility to trade in plant protection drugs under Clauses 1 and 2, Article 35 of this Circular. Within 5 working days after receiving a valid dossier, the provincial-level plant protection sub-department or cultivation and plant protection sub-department shall grant a certificate of eligibility to trade in plant protection drugs without having to form a team to conduct physical inspection at the trading establishment.

Section 3

TRAINING IN CHEMICAL SAFETY OF PLANT PROTECTION DRUGS

Article 37. Contents and programs of training in chemical safety of plant protection drugs

1. Training contents must include:

a/ Regulations on management of plant protection drugs, conditions for manufacture and trading of plant protection drugs, rights and obligations of plant protection drugs manufacturers and traders;

b/ Regulations on handling of administrative violations related to plant protection drugs;

c/ General knowledge about plant protection drugs;

d/ Classification of hazards of plant protection drugs and their properties;

dd/ Safe manufacture, trading, transportation, preservation and use of plant protection drugs;

e/ Measures to prevent and respond to plant protection drug incidents;

g/ How to read drug labels;

h/ Instructions for safe and effective use of plant protection drugs;

i/ General knowledge about plant pests, a number of common pests and measures to prevent and control them;

k/ Legal knowledge about fire prevention and fighting;

l/ Practice and field study activities.

2. Training programs

a/ A program of training in plant protection drugs for owners and managers of drug trading establishments, direct traders (who do not possess any intermediate or higher degree in plant protection, cultivation, biology or chemistry) must last 3 months with all the contents specified in Clause 1 of this Article. Trainees shall be granted certificates of training in plant protection drugs according to the form provided in Appendix XXII to this Circular;

b/ A program of training in safety of plant protection chemicals for managers of sections directly engaged in manufacture, direct manufacturing workers, and storekeepers must last 3 days with the contents specified at Points a, b, dd and e, Clause 1 of this Article. Trainees shall be granted certificates of training in safety of plant protection chemicals according to the form provided in Appendix XXII to this Circular.

3. Responsibility to organize training and grant certificates of training in plant protection drugs and certificates of training in safety of plant protection chemicals:

a/ The Plant Protection Department shall develop programs of training in knowledge about plant protection drugs and chemical safety techniques;

b/ Provincial-level plant protection sub-departments or cultivation and plant protection sub-departments shall organize training courses and grant certificates of training in plant protection drugs and certificates of training in safety of plant protection chemicals according to the contents and under the programs specified in Clauses 1 and 2 of this Article.

Article 38. Training in chemical safety of plant protection drugs

1. Organizations and individuals that need training in chemical safety of plant protection drugs may register lists of participants directly or by post or online with provincial-level plant protection sub-departments or cultivation and plant protection sub-departments.

2. Provincial-level plant protection sub-departments or cultivation and plant protection sub-departments shall organize courses of training in plant protection drugs or training of chemical safety of plant protection drugs with the contents and under the programs specified in Clauses 1 and 2, Article 37 of this Circular;

Upon availability of satisfactory results, provincial-level plant protection sub-departments or cultivation and plant protection sub-departments shall grant certificates according to the form provided in Appendix XXII to this Circular.

Chapter V

IMPORT AND EXPORT OF PLANT PROTECTION DRUGS

Article 39. General principles

1. Import and export of plant protection drugs must comply with Article 67 of the Law on Plant Protection and Quarantine and the Minister of Agriculture and Rural Development's Circular No. 04/2015/TT-BNNPTNT of February 12, 2015, guiding a number of provisions of the Government's Decree No. 187/2013/ND-CP of November 20, 2013, detailing the Commercial Law on international goods purchase and sale and goods agency, purchase, sale, processing and transit with foreign parties in the fields of agriculture, forestry and fisheries (below referred to as Circular No. 04/2015/TT-BNNPTNT).

2. In case of authorized import, authorized importers shall produce to the customs office powers of attorney of those that have registered plant protection drugs under their names.

3. When imported, a plant protection drug on the list must satisfy the following requirements:

a/ Technical grade must have an active ingredient content at least equal to the content of the technical grade on the list and shall be imported from manufacturers of clear origins;

b/ Finished products must have an active ingredient content, formulation type and manufacturer stated in the certificate of plant protection drug registration in Vietnam and at least two thirds of its shelf life stated on its label remaining from the date it arrives in Vietnam;

c/ Finished product must satisfy the physical and chemical properties of suspensibility and emulsion stability for each corresponding formulation type;

d/ The technical grade and finished product must satisfy the requirement of hazardous impurities in the national technical regulations (QCVN), national standards (TCVN) and standards (TC) established by the Plant Protection Department.

Article 40. Dossiers, order and procedures for grant of import permits for plant protection drugs for export production

1. A dossier must comprise:

a/ An application for a plant protection drug import permit, made according to form 01/BVTV provided in Circular No. 04/2015/TT-BNNPTNT;

b/ An authenticated copy or a photocopy with the original (for comparison) of the enterprise registration certificate or investment license (for first-time submission only);

c/ The original or an authenticated copy of the import contract, export contract or processing contract with the foreign partner in case of temporary import for re-export or import for export production.

2. The order and procedures for grant of import permits for plant protection drugs for export production must comply with Article 24 of Circular No. 04/2015/TT-BNNPTNT.

Article 41. Reporting regime

Importers or exporters of plant protection drugs shall send written reports, made according to the form provided in Appendix XXIII to this Circular, on importation or exportation of plant protection drugs to the Plant Protection Department. Biannual reports and annual reports shall be sent before July 15 of the reporting year and January 15 of the next year respectively.

Chapter VI

QUALITY INSPECTION OF PLANT PROTECTION DRUGS

Article 42. Bases for inspection

Bases for quality inspection of plant protection drugs in the course of manufacture or circulation are the national technical regulations (QCVN), national standards (TCVN) and standards (TC) established by the Plant Protection Department.

Article 43. State quality inspection of imported plant protection drugs

1. Plant protection drugs subject to state quality inspection include imported technical-grade drugs and finished products, except sample plant protection drugs; plant protection drugs for exhibitions and trade fairs; plant protection drugs temporarily imported for re-export or imported for export processing; plant protection drugs in transit or border-gate transfer; plant protection drugs consigned into bonded warehouses; plant protection drugs used for research, testing or trial purpose; plant protection drugs imported under import permits for use in foreign investment projects, and other drugs imported under permits for non-commercial purposes.

2. The agency in charge of state quality inspection of imported plant protection drugs is the Plant Protection Department or a conformity assessment organization authorized by the Plant Protection Department.

3. Quality inspection of imported plant protection drugs shall be conducted by conformity assessment organizations designated by the Ministry of Agriculture and Rural Development or the Plant Protection Department and announced on the website of the Plant Protection Department.

4. An imported plant protection drug shipment shall be customs-cleared when there is a notice issued by the agency or organization defined in Clause 2 of this Article of satisfactory results of state quality inspection of imported plant protection drugs according to the form provided in Appendix XXVI to this Circular.

5. Plant protection drugs may be transported to preservation warehouses pending the availability of results of inspection conducted under Article 35 of the Ministry of Finance's Circular No. 38/2015/TT-BTC of March 25, 2015, on customs procedures; customs inspection and supervision; import duty and export duty and tax administration of imports and exports.

Article 44. Dossiers and procedures for state quality inspection of imported plant protection drugs

1. Submission of dossiers

a/ Dossiers of registration for inspection may be submitted directly or by post or online to the agency in charge of state quality inspection of imported plant protection drugs defined in Clause 2, Article 43 of this Circular;

b/ Number of dossiers: one dossier in paper or electronic file;

c/ A dossier of registration for inspection shall be examined within one working day.

In case the dossier is complete and valid, the inspection agency shall accept the dossier and give a certification in the written registration for state quality inspection of imported plant protection drugs.

In case the dossier is incomplete, the inspection agency shall return it to the importer and request the dossier supplementation and completion.

2. A dossier of registration for quality inspection of imported plant protection drugs must comprise:

a/ A written registration for state quality inspection of imported plant protection drugs, made according to the form provided in Appendix XXIV to this Circular: Two copies.

b/ Copies of the following papers:

Purchase and sale contract;

Import permit (for plant protection drugs specified in Clause 2, Article 67 of the Law on Plant Protection and Quarantine);

Accompanying packing list, specifying quantity to be registered and identification number of each shipment;

Goods invoices;

Bills of lading (for goods imported by air, sea or railway);

Quality certificate for import of fumigants and disinfectants.

3. Inspection

a/ Inspection and sampling

Within 2 working days after the importer produces the import declaration, the place and time of sampling shall be notified:

In case the plant protection drug shipment remains in its original state and is consistent with the dossier of registration for state quality inspection of plant protection drug and import declaration, the conformity assessment organization shall take samples, make a written record of sampling for quality inspection of imported plant protection drugs according to the form provided in Appendix XXV to this Circular, and keep the dossier of the shipment. For fumigants and disinfectants, only appraisal of the dossier and inspection of the actual state of the shipment are required.

In case the plant protection drug shipment is no longer in its original state and is inconsistent with the dossier of registration for inspection, the conformity assessment organization shall refuse to take samples and make a written record of violation of regulations on state quality inspection of imported plant protection drugs according to the form provided in Appendix XXVIII to this Circular.

b/ Notification of inspection results

Within three working days after samples are taken for inspection, the conformity assessment organization shall issue a notice of results of state quality inspection of imported plant protection drugs according to the form provided in Appendix XXVI to this Circular. If finding it necessary to prolong the inspection time, the conformity assessment organization shall promptly such to the importer for reaching agreement on a solution.

In case the imported plant protection drug shipment is of inferior quality, the conformity assessment organization shall promptly notify such to the importer and concurrently report it to the Plant Protection Department for handling decision.

In case the imported plant protection drug shipment is to be re-exported, the importer shall re-export it within the time limit stated in the handling decision of the Plant Protection Department and send a copy of the customs office's written certification to the inspection agency for filing.

c/ Dossier preservation

A dossier of state inspection of plant protection drugs shall be preserved for 3 years from the date of issuance of a notice of inspection results.

Article 45. Settlement of complaints and handling of violations in state quality inspection of imported plant protection drugs

1. Complaints and settlement of complaints

a/ Plant protection drug importers may file complaints about inspection results or request conformity assessment organizations to re-consider inspection results;

b/ The inspection agency shall receive and settle complaints and denunciations of plant protection drug importers in accordance with the Law on Complaints and Denunciations.

2. Re-inspection

a/ Within 7 working days after receiving a notice that the shipment is of inferior import quality, the plant protection drug importer may request the conformity assessment organization that has conducted the quality inspection of such batch to re-consider inspection results or conduct re-inspection, provided the shipment remains in its original state;

b/ If re-inspection results are different from inspection results, the importer is not required to pay expenses for re-inspection. If re-inspection results are the same as inspection results, the importer shall pay expenses for the re-inspection;

c/ In case the fault of the conformity assessment organization in the quality inspection of the import shipment causes damage to the importer, it shall refund all expenses for the inspection and pay compensations to the importer in accordance with law.

3. Handling of violations

Plant protection drug importers that violate the provisions of this Circular and other relevant documents shall be sanctioned under regulations on handling of violations in the field of metrology and goods quality and regulations on sanctioning of administrative violations in the field of plant protection and quarantine.

Article 46. Responsibilities of conformity assessment organizations

1. To conduct conformity assessment only in designated tests.

2. To receive and examine dossiers and notify results of registration for quality inspection to importers within prescribed time limit.

3. To bear responsibility for results of quality inspection of imported plant protection drugs.

4. To send biannual and annual reports on the state and results of quality inspection of imported plant protection drugs, made according to the form provided in Appendix XXVII to this Circular, to the Plant Protection Department before June 25 and December 25 every year, respectively.

5. To submit to inspection and supervision by the Plant Protection Department.

6. To collect charges as prescribed for quality inspection of plant protection drugs.

7. To preserve samples for quality inspection of plant protection drugs for six months after receiving such samples.

8. To preserve results of quality inspection of plant protection drugs for three years after such results are notified.

Article 47. Responsibilities of plant protection drug importers

1. To register for and comply with regulations on quality inspection of imported plant protection drugs.

2. To provide necessary documents on imported plant protection drugs and create conditions for conformity assessment organizations to enter places where imported plant protection drugs are stored, preserved and transported to, for inspection and taking samples.

3. To abide by handling decisions of the Plant Protection Department if their imported plant protection drug shipments are not up to quality standards or violate the provisions of this Circular.

4. To file complaints about results of quality inspection of imported plant protection drugs and denunciations about illegal acts in the quality inspection of imported plant protection drugs.

5. To preserve plant protection drugs in their original state and may neither trade in nor use the drugs until satisfactory inspection results are obtained, in case they are permitted to warehouse the drugs for preservation before the inspection agency notifies inspection results.

Article 48. State quality inspection of plant protection drugs in circulation

1. State quality inspection of plant protection drugs in circulation must comply with the Law on Product and Goods Quality and the Minister of Science and Technology's Circular No. 26/2012/TT-BKHCH of December 12, 2012, prescribing the state quality inspection of goods in circulation.

2. State quality inspection of plant protection drugs in circulation shall be conducted by qualified organizations designated by the Ministry of Agriculture and Rural Development or the Plant Protection Department.

3. The designation of testing organizations must comply with current regulations of the Minister of Agriculture and Rural Development on appraisal, designation and management of testing laboratories in the agriculture and rural development sector.

Chapter VII

REGULATION CONFORMITY CERTIFICATION AND ANNOUNCEMENT FOR PLANT PROTECTION DRUGS

Article 49. Requirements on regulation conformity announcement

Plant protection drugs, which are goods on the list of group-2 products and goods promulgated together with the Minister of Agriculture and Rural Development's Circular No. 50/2010/TT-BNNPTNT of August 30, 2010, amending and supplementing the list of group-2 products and goods promulgated together with the Minister of Agriculture and Rural Development's Circular No. 50/2010/TT-BNNPTNT of August 18, 2009, are subject to regulation conformity announcement before being marketed.

Article 50. Order, procedures and grounds for regulation conformity certification and announcement

1. Regulation conformity certification and announcement for plant protection drugs must comply with the Minister of Agriculture and Rural Development's Circular No. 55/2012/TT-BNNPTNT of October 31, 2012, guiding procedures for designating organizations to certify and announce regulation conformity of drugs under the state management by the Ministry of Agriculture and Rural Development.

2. Bases for regulation conformity certification and announcement for plant protection drugs are technical norms prescribed in the national technical regulations (QCVN), national standards (TCVN) and standards (TC) annually announced by the Plant Protection Department.

Chapter VIII

TRANSPORTATION AND PRESERVATION OF PLANT PROTECTION DRUGS

Section 1

TRANSPORTATION OF PLANT PROTECTION DRUGS

Article 51. General principles of transportation of plant protection drugs

1. The transportation of plant protection drugs must comply with the Government's Decree No. 104/2009/ND-CP of November 9, 2009, promulgating the list of dangerous goods and prescribing transportation of dangerous goods by road motor vehicles; Decree No. 14/2015/ND-CP of February 13, 2015, detailing and guiding a number of articles of the Railway Law; regulations on transportation of dangerous goods by inland waterway, air and sea; and other relevant laws and treaties to which Vietnam is a contracting party.

2. The transportation of plant protection drugs (except those being microorganism preparations) shall be licensed under Clause 1, Article 4 of the Government's Decree No. 104/2009/ND-CP of November 9, 2009, promulgating the list of dangerous goods and prescribing transportation of dangerous goods by road motor vehicles; and Clause 1, Article 22 of Decree No. 14/2015/ND-CP of February 13, 2015, detailing and guiding a number of articles of the Railway Law.

3. The transportation of plant protection drugs must follow the schedule stated in contracts or other relevant documents on transportation of plant protection drugs between vehicle owners and goods owners.

4. The transportation of plant protection drugs must ensure safety for humans, livestock and the environment. Transporting vehicles may not stop at crowded places or near schools, hospitals, markets or residential water sources.

5. Plant protection drugs may only be transported after being packaged and labeled and obtaining transportation permits granted by a competent agency under Article 54 of this Circular.

6. Plant protection drugs that can interact with one another may not be carried on the same vehicle.

7. Plant protection drugs may not be carried by vehicles transporting passengers, animals, foods, flammables, explosives and other goods, except fertilizers.

Article 52. Transportation of plant protection drugs

1. Carriers of plant protection drugs

a/ Vehicle drivers and escorts must be fully aware of the danger of plant protection drugs, such as their hazards, flammability, explosibility and corrosiveness, and shall know how to respond to incidents that might occur in the course of transportation of plant protection drugs, and comply with the law on transportation of dangerous goods;

b/ In addition to driver licenses under the State's current regulations, drivers of road motor vehicles transporting plant protection drugs are also required to possess certificates of training in labor safety in transportation and preservation of plant protection drugs;

c/ Escorts of transported plant protection drugs shall be trained in labor safety in transportation and preservation of plant protection drugs.

2. Packages, tanks or containers of plant protection drugs in transportation

a/ Shall be made of tough, durable and water-proof materials;

b/ Must bear a warning symbol of black skull and crossbones on a white background within a squared diamond shape and warning symbols corresponding to properties of transported plant protection drugs according to the forms provided in Appendix XXXIII to this Circular. The size of the warning symbol to be stuck on each plant protection drug tank or container must be 100 x 100 millimeters or 250 x 250 millimeters, respectively;

c/ Must bear the danger sign in an orange rectangular shape with a UN code in the middle, of a size of 300 x 500 millimeters, made according to the form provided in Appendix XXXII to this Circular, and placed below the warning symbol. For drug packages and tanks, the danger sign may be of a smaller size proportionate to such packages and tanks but must be conspicuous.

3. Vehicles for transportation of plant protection drugs

a/ Common vehicles permitted by competent agencies for goods transportation may be used to carry plant protection drugs;

b/ Vehicles carrying plant protection drugs must satisfy the following technical conditions:

Having fire prevention and fighting tools and devices suitable to plant protection drugs in transportation;

Having tops and canvas sheets to fully and securely cover the cargo hold, ensuring no water permeation during transportation;

Trailers may not be used to carry plant protection drugs.

c/ Vehicles carrying plant protection drugs shall be embarked last on each ferry in case there is no special-use ferry for dangerous goods at the ferry landing;

d/ Vehicles carrying plant protection drug tanks must bear the warning symbol for the type or category of transported goods. The size of the warning symbol stuck on vehicles must be 500 x 500 millimeters. The warning symbol shall be stuck on both sides and the rear of each vehicle.

Article 53. Response to incidents

In case a plant protection drug is leaked or dispersed during transportation, the vehicle driver, goods owner and vehicle owner shall apply necessary measures to minimize consequences, remedy the incident and at the same time report the incident to the commune-level People's Committee of the locality where the incident occurs for further monitoring and application of measures to warn and prevent consequences. Violators shall bear all expenses for remedying incidents.

Article 54. Plant protection drug transportation permits

1. A provincial-level plant protection sub-department or cultivation and plant protection sub-department shall grant a plant protection drug transportation permit in the following cases:

a/ An organization or individual transports at least 1,000 kilograms of plant protection drugs per batch by road motor vehicle;

b/ A person hires transportation of at least 1,000 kilograms of plant protection drug per batch by train.

2. Plant protection drug transportation permits are valid nationwide.

3. The plant protection drug transportation permit must be valid for each trip (for transportation by road), each batch (for transportation by railway) or each period of up to 12 months from the date of grant.

4. The form of plant protection drug transportation permit is provided in Appendix XXX to this Circular.

Article 55. Dossiers, order and procedures for grant of plant protection drug transportation permits

1. Submission of dossiers

A dossier of application for plant protection drug transportation permit may be submitted directly or by post or online to the competent agency defined in Clause 1, Article 54 of this Circular.

2. A dossier must comprise:

a/ An application for a plant protection drug transportation permit, made according to the form provided in Appendix XXIX to this Circular;

b/ A photocopy of the certificate of training in labor safety in transportation and preservation of plant protection drugs of the vehicle driver or goods escort, together with the original for comparison (for transportation by road);

c/ A photocopy of the following documents: The supply contract; contract on plant protection drug transportation; financial invoice on import or export of plant protection drug; goods transportation declaration of the company (with the company's certification and seal);

d/ Schedule of goods transportation, address and telephone number of the goods owner (with the company's certification and seal).

3. Appraisal of dossier and grant of plant protection drug transportation permits

Within three working days after receiving a complete dossier prescribed in Clause 2 of this Article, the competent agency shall appraise it. In case the dossier is valid, the competent agency shall grant a plant protection drug transportation permit.

In case the dossier is invalid, within one day after receiving the complete dossier, the competent agency shall notify contents to be supplemented to the applicant for dossier completion under regulations.

In case of refusal to grant a plant protection drug transportation permit, within one working day the competent agency shall notify its refusal and the reason in writing to the applicant.

Section 2

PRESERVATION OF PLANT PROTECTION DRUGS

Article 56. General provisions on plant protection drug warehouses

1. Plant protection drug warehouses must satisfy the requirements of Vietnam standard TCVN 5507:2002 Dangerous chemicals - Safety regulations in manufacture, trading, use, preservation and transportation.

2. Plant protection drug warehouses must be large enough to store the whole volume of plant protection drugs of the establishment at any time;

3. Special-use warehouses for preservation of biological plant protection drugs are not required to comply with the provisions of this Section but must cause no environmental pollution.

Article 57. Specific provisions on plant protection drug warehouses

1. Plant protection drug warehouses of a plant protection drug manufacturer

a/ Storekeepers

A storekeeper shall be trained in labor safety in preservation of plant protection drugs, trained in plant protection drugs and chemical safety techniques under Section 3 of this Chapter, and must possess certificates of occupational safety and hygiene and fire prevention and fighting.

b/ Location

Warehouses located in industrial parks must comply with regulations of these industrial parks;

Warehouses located outside industrial parks shall be located in places suitable to local planning conditions and approved in writing by People's Committees of commune or a higher level;

Warehouses shall be located at least 200 meters (m) away from schools, hospitals, markets and water sources and in places that satisfy requirements on power supply, water supply and drainage, environmental pollution treatment and traffic facilities, and must have walls separating them from surrounding areas.

c/ Warehouse specifications

Warehouses shall be neatly and rationally arranged and classified by fire or explosion risk and have separate sections for different plant protection drugs that can cause chemical reactions when coming into contact with one another.

Plant protection drugs shall be placed on shelves which are at least 10 centimeters (cm) above the ground and at least 20 centimeters (cm) from the walls. The main passageway must be at least 1.5 meters (m) wide and convenient for fire prevention and fighting, inspection and supervision activities.

Warehouses must be built of fire-proof materials; warehouse frames shall be built from bricks or made of concrete or steel. Warehouse floors must be flat and made of impermeable, non-slippery and crack-free materials and have raised anti-overflow edges at doors. Doors must have secure locks.

Warehouses must have emergency exits with clear instructions (on signboards or diagrams) which can be easily accessible upon occurrence of incidents.

Warehouses must have waste treatment systems; comply with the Government's Decree No. 59/2007/ND-CP of April 9, 2007, on management of solid wastes; have ventilation systems and tools for solid waste collection and transportation.

Warehouses must have signboards showing chemical safety rules and warning symbols suitable to the danger level of plant protection drugs. In case a plant protection drug has different dangerous characteristics, warning symbols must fully express such dangerous characteristics.

Warehouses must have labor safety rules and devices (gloves, gauze masks, safety goggles and outfits), instructions for use of such devices for those exposed to plant protection drugs, medicine cabinets and first-aid kits.

Warehouses must have separate locker rooms and bathrooms for employees to change clothes and take a bath after working in warehouses.

Plant protection drug warehouses must fully satisfy the fire and explosion prevention and fighting requirements in accordance with the Law on Fire Prevention and Fighting.

“No fire” and “no smoking” signs in large red letters shall be put up outside warehouses; fire prevention and fighting rules and fire fighting instructions shall be displayed at easy-to-spot places.

Warehouses shall be fully furnished with equipment and devices to respond to incidents and fire alarming and extinguishing systems installed in appropriate positions, which shall be regularly checked to ensure constant readiness for use.

Warehouse operation must ensure safety and prevention of such risks as fire, leakage and overflow. Storekeepers shall strictly follow instructions in material safety data sheets of all warehoused plant protection drugs, and the guidance on safety, sanitation and response to incidents.

2. Plant protection drug warehouses of a plant protection drug trader

a/ Warehouses must be at least 20 meters away from water sources (rivers, lakes, canals, ditches) and have reinforced embankments to prevent overflow; must be dry, airy, water-proof, roof leakage-free or inundation-free, and satisfy fire and explosion prevention and fighting requirements;

b/ Walls and roofs of storage places shall be built of fire-proof materials. Walls and floors must be even, impermeable, easy to clean, and inundation-free;

c/ Warehouses shall be sufficiently lit to enable identification of goods. Lighting equipment must be fire-proof;

d/ Goods shall be placed on shelves which are at least 10 centimeters above the ground and at least 20 centimeters from the walls; and shall be preserved in airtight packages to prevent odor dispersion;

dd/ The arrangement of goods must prevent dropping, breaking or leakage and ensure a passageway wide enough for a person to enter, and separate places for each type of goods;

e/ Warehouses must have fire prevention and fighting rules and devices as required by fire fighting authorities, which are placed at convenient places for use when necessary;

g/ Warehouses must provide gloves, gauze masks, clean water and soap for personal labor protection and hygiene;

h/ Warehouses must have materials and tools for timely response to incidents.

Section 3

TRAINING IN LABOR SAFETY IN TRANSPORTATION AND PRESERVATION OF PLANT PROTECTION DRUGS

Article 58. Contents of training in labor safety in transportation and preservation of plant protection drugs

1. Vehicle drivers and escorts shall be trained in:

a/ Labor safety in transportation and preservation of plant protection drugs;

b/ Regulations on transportation and preservation of dangerous chemicals;

c/ Characteristics of plant protection drugs;

d/ Warning symbols and danger signs for goods.

dd/ Measures to ensure safety in transportation of plant protection drugs, including first aid, transport safety and basic knowledge about how to use protection tools, and measures to prevent and respond to incidents for each plant protection drug;

e/ Safety practice in preservation and transportation of plant protection drugs.

2. The Plant Protection Department shall develop training contents and programs for escorts and drivers of vehicles carrying plant protection drugs.

3. Provincial-level plant protection sub-departments or cultivation and plant protection sub-departments shall organize or coordinate with training and vocational establishments and enterprises in organizing training for organizations and individuals involved in transportation of plant protection drugs and materials thereof, vehicle drivers and escorts according to the contents and programs specified in Clause 1 of this Article.

Article 59. Training in labor safety in transportation and preservation of plant protection drugs

1. Organizations and individuals that need training in labor safety in transportation and preservation of plant protection drugs may register their lists of trainees directly or by post or online with provincial-level plant protection sub-departments or cultivation and plant protection sub-departments.

2. Provincial-level plant protection sub-departments or cultivation and plant protection sub-departments shall organize training in labor safety in transportation and preservation of plant protection drugs with the contents specified in Clause 1, Article 58 of this Circular. A training course must last three days.

3. Based on test results, provincial-level plant protection sub-departments or cultivation and plant protection sub-departments shall grant certificates of training in labor safety in transportation and preservation of plant protection drugs according to the form provided in Appendix XXXI to this Circular.

Chapter IX

ADVERTISING OF PLANT PROTECTION DRUGS

Article 60. Plant protection drug advertising contents

1. A plant protection drug advertisement must have the following contents, except the cases specified in Clause 2 of this Article:

a/ Trade name and active ingredient of the plant protection drug;

b/ Functions, effects and cautions for use and preservation of the plant protection drug;

c/ Names and addresses of the organization and individual registering and distributing the plant protection drug;

d/ Use instructions;

dd) Warnings about danger and toxicity and instructions for prevention of hazards of the plant protection drug.

2. Plant protection drug advertisements on posters, billboards, panels, shelves, other objects, aerial objects, underwater objects, moving objects, electronic appliances, terminal devices and other telecommunications equipment, means of transport and advertising product-carrying persons are not required to have all compulsory contents.

3. Seminars on plant protection drugs must provide guidance on safety and effectiveness of use of plant protection drugs according to manufacturer standard TCCS 20: 2010/BVTV documents guiding the safe and effective use of plant protection drugs.

4. For plant protection drugs of acute toxicity of class I or class II according to the GHS classification, seminars may only be organized to provide safe use recommendations.

5. Contents of plant protection drug advertisements shall be certified by competent agencies specified in Article 61 of this Circular.

Article 61. Competence to grant certificates of plant protection drug advertisement contents

1. The Plant Protection Department shall grant certificates of plant protection drug advertisement contents to be published on newspapers, magazines or websites or displayed on electronic appliances, terminal devices and other telecommunications equipment, printed matters, audio and video recordings and other technological equipment of central-level organizations and distributed nationwide.

2. Provincial-level plant protection sub-departments or cultivation and plant protection sub-departments shall grant certificates of plant protection drug advertisement contents to be published or displayed on or at:

a/ Newspapers, magazines, websites, electronic appliances, terminal devices and other telecommunications equipment, printed matters, audio and video recordings and other technological equipment of local organizations;

b/ Billboards, posters, signboards, advertising light boxes and screens;

c/ Means of transport;

d/ Trade fairs, seminars, conferences, events, exhibitions, cultural and sport events;

dd/ Advertisement or advertising object carriers;

e/ Other media of advertising specified by law.

Article 62. Dossiers, order and procedures for grant of certificates of plant protection drug advertisement contents

1. Submission of dossiers

a/ Dossiers may be submitted directly or by post or online to competent state agencies specified in Article 61 of this Circular;

b/ Number of dossier: One paper dossier or electronic file.

2. A dossier must comprise:

a/ An application for certification of plant protection drug advertisement contents, made according to the form provided in Appendix XXXIV to this Circular;

b/ A photocopy of the plant protection drug registration certificate;

c/ Advertisement product (advertising contents and form expressed in image, sound, spoken or written words, symbol, color, light and the like);

d/ A list of speakers, with sufficient information on their professional qualifications or scientific titles (for trade fairs, seminars, conferences, events, exhibitions, cultural or sport events).

3. Examination of dossiers and grant of certificates of plant protection drug advertisement contents

Within 10 working days after receiving a complete and valid dossier, a competent state agency specified in Article 61 of this Circular shall grant a certificate of plant protection drug advertisement contents made according to the form provided in Appendix XXXV to this Circular. In case of refusal to grant a certificate, the competent state agency shall notify such in writing clearly stating the reason.

Chapter X
LABELS OF PLANT PROTECTION DRUGS

Section 1

GENERAL PRINCIPLES ON LABELS OF PLANT PROTECTION DRUGS

Article 63. Principles of labeling plant protection drugs

1. Domestically circulated, imported or exported plant protection drugs shall be labeled in compliance with the provisions on goods labeling in the Government's Decree No. 89/2006/ND-CP of August 30, 2006, the guidance of the Globally Harmonized System of Chemical Classification and Labeling (GHS), and this Circular.

2. The hazard level of plant protection drugs shall be shown on their labels and material safety data sheets. Hazard classification of plant protection drugs shall be based on GHS rules and technical guidance, hazardous materials and hazards to human health and the environment. Hazard classes of plant protection drugs are provided in detail in Appendix XXXVI to this Circular.

Article 64. Positions and sizes of plant protection drug labels

1. Plant protection drug labels shall be printed or firmly affixed on plant protection drug packages at positions to show all required contents without having to taking apart packages.

2. Sizes of plant protection drug labels may be decided by manufacturers or traders but must contain all compulsory contents prescribed in Section 2 of this Chapter.

Article 65. Colors and presentation styles of letters, symbols and images on plant protection drug labels

1. Colors

a/ Colors of letters, numbers, figures, images, signs and marks on labels must be conspicuous;

b/ Letters and numbers used in compulsory contents of labels must be in a color in contrast to the label background color (for example, black-white, black-pale yellow, dark brown-white, dark blue-white);

c/ The label background color must be different from that indicating the hazard level of plant protection drugs.

2. Presentation styles

a/ Labels shall be presented in Times New Roman or equivalent font with a size of 8 or larger;

b/ Letters may not be printed in vertical, diagonal or curved lines;

c/ Only illustrative images or pictures of registered pests or crop plants may be printed on labels;

d/ Compulsory contents may not be overprinted on top of any patterns;

dd/ Active ingredient names shall only be printed in the section "composition" on labels.

Article 66. Languages used in plant protection drug labels

1. The language used on labels must be Vietnamese;

2. The following contents may be in other languages of Latin origin:

a/ Common names of active ingredients;

b/ Common names or scientific names of constituents and quantitative composition of drugs in case they cannot be translated into Vietnam or their Vietnamese translations are meaningless;

c/ Names and addresses of foreign manufacturers or registrants of plant protection drugs.

Article 67. Contents of plant protection drug labels

1. Contents of plant protection drug labels (including also use instruction inserts) must be truthful, clear, accurate and true to the characteristics of plant protection drugs, and compliant with the provisions of Section 2 of this Chapter and plant protection drug registration certificates.

2. Any change in contents of plant protection drug labels shall be approved by the Plant Protection Department.

Section 2

COMPULSORY CONTENTS OF PLANT PROTECTION DRUG LABELS

Article 68. Compulsory contents of labels of formulated plant protection drugs

1. Trade name;
2. Category;
3. Type of formulation;
4. Active ingredient names, constituents and content;
5. Quantification;
6. Registration number;
7. Date of manufacture;
8. Number of manufacture batch;
9. Expiry date;
10. Origin;
11. Information about the manufacturer;
12. Information about the registrant and distributor;
13. Use and preservation instructions;
14. Information about hazards;
15. Guidance for safe use;
16. Names and contents of solvents and additives that change the acute toxicity of the formulated drug (if any).

Article 69. Auxiliary labels of formulated plant protection drugs

1. In case the label is not large enough to contain all the compulsory contents prescribed in Article 70 of this Circular, at least the contents prescribed in Clauses 1, 5, 7, 9, 10, 12 and 14 of Article 68 shall be printed on the principal label and there must be an auxiliary label.

2. Auxiliary labels shall be stuck on every plant protection drug package so that they can be referred to in the course of circulation and use of drugs.

3. Principal labels must have the instruction “Read the auxiliary label carefully before use”.

4. Contents of auxiliary labels must include all compulsory labeling contents.

Article 70. Compulsory contents of labels of technical-grade plant protection drugs

1. Active ingredient name.

2. Active ingredient constituents and content.
3. Net volume, net weight.
4. Name and address of the importer.
5. Origin.
6. Date of manufacture, expiry date.
7. Information about hazards.
8. Guidance for safe use.

Section 3

METHOD OF LABELING PLANT PROTECTION DRUGS

Article 71. Method of writing compulsory contents of plant protection drug labels

1. Trade names

Trade names must neither cause misunderstanding of the characteristics and effects of drugs; nor violate Vietnam's fine customs and traditions; nor be identical, when pronounced or written, to names of Vietnamese or foreign leaders, national heroes, great figures or geographical names, foods, drinks or pharmaceuticals.

2. Drug category: Drugs shall be categorized by effect, including: insecticide, germicide and other categories on the list. For biological plant protection drugs, the word "biological" must come before the word indicating the drug category (for example, biological insecticide).

3. Formulation type: Signs of formulation type shall be written according to the Croplife International Codes for Technical and Formulated Pesticides provided in Appendix XL to this Circular.

4. Active ingredient names, constituents and content

a/ Common names of all active ingredients in the composition of formulated drugs shall be specified. For active ingredients that have no common names, their IUPAC names shall be provided;

b/ Content of each active ingredient in formulated drugs shall be specified

The unit of g/kg (in three digits) or weight percent (% w/w) in two digits for drugs in solid, viscous liquid, aerosol or volatile fluid form; the unit of g/l (three digits) or weight percent (% w/w) for drugs in other liquid forms; international unit (IU)/mg, colony-forming unit (CFU)/g (or ml) for microbial drugs.

5. Quantities

a/ Quantities of plant protection drugs expressed in units of measurement shall be written in accordance with the Vietnamese law on measurement;

b/ Quantities of plant protection drugs expressed in numbers shall be written in cardinal numbers;

c/ For plant protection drugs in liquid or viscous liquid form, net volume shall be written in liter (l) or milliliter (ml); for those in powder, particle, viscous, aerosol or volatile fluid form, net weight shall be written in kilogram (kg) or gram (g); those in pellet form, the number of pellets shall be specified and the weight of a pellet shall be written in kilogram (kg) or gram (g);

d/ For a commercial package of a plant protection drug that contains many packs, the quantities in each pack and number of packs shall be specified;

dd/ Pre-packaged plant protection drugs must comply with the Ministry of Science and Technology's Circular No. 21/2014/TT-BKHCHN of July 15, 2014, prescribing measurement of pre-packaged goods quantity.

6. Registration number is the serial number of the plant protection drug registration certificate granted by the Plant Protection Department.

7. Date of manufacture and expiry date

a/ Date of manufacture and expiry date on labels shall be written out or written in capital-letter abbreviations "NSX" ("DOM") in calendar date, month and year, each having two digits, except that the number indicating the year may have four digits. Numbers indicating the date, month and year must be on the same line;

b/ In case the letters "NSX" ("DOM") cannot be written together with the numbers indicating the date, month and year, there must be an instruction on the label. For example: if the number "020406" is written on the bottom of the package, the label must have the instruction "See date of manufacture on the bottom of the package".

8. Manufacture batch number shall be written as follows: "*So lo san xuat*" or "*So lo SX*" (Manufacture batch number): XXXX. The structure of a manufacture batch number shall be determined by the manufacturer.

9. Origin

a/ To write the phrase "*San xuat tai*" (Made in) or "*Xuat xu*" (Country of origin) followed by the name of the country or territory where the plant protection drug is manufactured;

b/ For a plant protection drug made in Vietnam for domestic circulation, as the address of the manufacturer is already written on the label, information about its origin is not required.

10. Information about the plant protection drug registrant, distributor and manufacturer

a/ Information about plant protection drug registrant: To write the name, address and phone number of the holder of the plant protection drug registration certificate;

b/ Information about plant protection drug distributor: To write the name, address and phone number of the distributor of the plant protection drug in Vietnam;

c/ Information about plant protection drug manufacturer: To write the name and address of the manufacturer of the formulated plant protection drug.

11. Use and preservation instructions

a/ Effects and target objects (pests, crop plants);

b/ Dosage, concentration, number of uses, time and method of treatment;

c/ Methods of drug mixing, preparation, application (spraying) and use rate;

d/ Pre-harvest interval;

dd/ Compatibility with other drugs (if any);

e/ Prevention of drug resistance and management information (if any);

g/ For plant protection drugs of high toxicity to honey bees and used on fruit trees, to write the caution: "Do not spray on blooming trees";

h/ For plant protection drugs of high toxicity to fish according to the GHS classification and used on rice, to write the caution: "Highly toxic to fish, do not use in aquaculture areas";

i/ Necessary information for prevention of wrongful or improper use;

k/ Methods of preservation and disposal of drug residues and packages in and after use;

l/ Necessary conditions for drug preservation shall be clearly written on labels. For example: Store the drug in a dry place at temperature of 30° C or below.

12. Information about hazards

a/ Drug labels show warning symbols, warning words, caution of hazards and color stripes prescribed in Appendix XXXVII to this Circular in accordance with the hazard classification of plant protection drugs;

b/ Warning words shall be presented in bold lower-case letters or capital letters at least 2 millimeters (mm) high. Warning words used under the GHS include: “NGUY HIEM” (DANGER) for serious hazards; and “CANH BAO” (CAUTION) for less serious hazards;

c/ Warning color stripes must be of a height equal at least to 10% of the label height.

13. Guidance for safe use of plant protection drugs.

a/ The guidance includes explanations, instructions and safety guiding symbols describing solutions and requirements to minimize or prevent bad effects caused by plant protection drugs to those exposed to, transporting or preserving them. The presentation style of safety guidelines on plant protection drug labels is detailed in Appendix XXXVIII to this Circular;

b/ Information about poisoning symptoms, first-aid and medical treatment indications, and antidotes (if any).

Section 4

MATERIAL SAFETY DATA SHEETS OF PLANT PROTECTION DRUGS

Article 72. General principles

1. Plant protection drug manufacturers and importers shall make material safety data sheets for plant protection drugs under Article 29 of the Law on Chemicals.

2. Plant protection drug manufacturers, traders, importers and transporters shall keep material safety data sheets for all plant protection drugs available in their establishments or vehicles and produce such sheets when requested, ensuring that all entities related to plant protection drugs can grasp information in the material safety data sheets of such drugs.

Article 73. Presentation and contents of material safety data sheets of plant protection drugs

1. Material safety data sheets of plant protection drugs must be in Vietnamese. For imported plant protection drugs, data sheets in Vietnamese shall be enclosed with printed original versions or English versions of manufacturers.

2. In case a material safety data sheet has multiple pages, its pages shall be consecutively numbered from the first to the last. The numbers given on each page include the ordinal number of the page and total number of pages of the material safety data sheet and every two adjoining pages shall be appended with the seal of the manufacturer.

3. A material safety data sheet of a plant protection drugs must have contents provided in Appendix XXXIX to this Circular.

Chapter XI

PACKAGES OF PLANT PROTECTION DRUGS

Article 74. Requirements on plant protection drug packages

Requirements on plant protection drug packages are applicable to all kinds of plant protection drug packages, including recycled or reused ones.

1. Packages must:

a/ Be of good quality to endure normal impacts in the course of transportation, transshipment, warehousing and ex-warehousing by hand or motorized equipment;

b/ Be airtight to prevent leakage of chemicals in the course of transportation preparation or transportation with such impacts as vibration or temperature, moisture and pressure increase;

c/ Be clean on the outer side without any stain of any dangerous chemical.

2. Parts of packages in contact with plant protection drugs must:

a/ Neither be affected nor deteriorated in quality due to effects of chemicals contained therein;

b/ Cause no dangerous effects or effects that catalyze or cause reactions with contained plant protection drugs;

c/ Use appropriate inert linings to protect or separate packages from plant protection drugs contained therein.

3. The inner layer of two-layer plant protection drug packages must be unbreakable and unpierceable under normal transportation conditions to prevent leakage of substances contained therein to the outer layer.

4. The inner package layer made of fragile or pierceable material such as glass, ceramic or some kinds of plastic shall be firmly cushioned from the outer layer with appropriate buffering or cushioning materials.

5. Different biological plant protection drugs may not be contained in the same outer packaging layer or the same large compartment since these chemicals may react and cause flames or generate strong heat; generate heat or burst to release asphyxiating, oxidizing or toxic gas; release strongly corrosive or unstable substances.

6. Packages of plant protection drugs in liquid form must:

a/ Be appropriately resistant to pressure increase from the inside in the course of transportation;

b/ Have necessary spare space to ensure that no leakage or deformation may be caused by the rising volume of contained liquids due to increasing temperature in the course of transportation;

c/ Be tested for leaks before use.

7. Packages of volatile plant protection drugs must be watertight to ensure that the liquid level does not fall below the limit level in the course of transportation.

8. Packages of plant protection drugs in particle or powder form must be tight enough to keep everything inside or must have tight linings.

9. Used plant protection drug packages shall be managed like those containing plant protection drugs.

10. Plant protection drug manufacturers and importers shall elaborate standards for plant protection drug packages under Point c, Clause 1, Article 71 of the Law on Plant Protection and Quarantine.

Chapter XII

USE OF PLANT PROTECTION DRUGS

Article 75. Rights and obligations of plant protection drug users

Rights and obligations of plant protection drug users are prescribed in Clause 2, Article 72 of the Law on Plant Protection and Quarantine.

Article 76. Contents of training in use of plant protection drugs

1. Instructions for safe and effective use of drugs;
2. How to read protection plant drug labels;
3. Hazards of plant protection drugs to users and methods of prevention;
4. Environmental protection and food safety;
5. Rights and obligations of drug users.

Article 77. Responsibility to organize training in use of plant protection drugs

1. The Plant Protection Department shall develop contents and training programs on use of plant protection drugs.

2. Provincial-level plant protection sub-departments and cultivation and plant protection sub-departments shall assume the prime responsibility for, or coordinate with training or vocational establishments and enterprises in, organizing training in the use of plant protection drugs with contents and under programs specified in Article 76 of this Circular.

3. Plant protection drug manufacturers shall take the initiative in organizing training in the use of plant protection drugs and prevention of incidents caused by plant protection drugs in use.

Chapter XIII

RECALL AND DESTRUCTION OF PLANT PROTECTION DRUGS

Article 78. Process of compulsory recall of plant protection drugs

When detecting a plant protection drug subject to recall under Clause 1, Article 73 of the Law on Plant Protection and Quarantine, a competent agency in charge of plant protection and quarantine defined in Article 79 of this Circular shall:

1. Issue a decision on compulsory recall.
2. Send the decision to the owner of the plant protection drug to be recalled, requesting it/him/her to stop trading in the drug, identify and send the notice of plant protection drug recall to places to which such plant protection drug has been distributed for recall according to issued invoices.
3. Send the notice of plant protection drug recall to related management agencies.
4. Seal up the plant protection drug to be recalled.
5. Request the owner of the plant protection drug to be recalled to make and submit a plan on disposal of such drug to the competent agency defined in Article 79 of this Circular for consideration.
6. Decide on measures to dispose and supervise the disposal of the plant protection drug:
 - a/ Re-export shall be applied in case the drug has been imported;
 - b/ Reprocessing shall be decided by the Plant Protection Department; the reprocessing shall be supervised by the agency that has issued the recall decision;
 - c/ Correction of labeling errors shall be applied to plant protection drugs having erroneous labels or packages or improperly labeled or packaged;
 - d/ Destruction shall be applied in case the owner of the plant protection drug to be recalled requests destruction or in case that cannot be remedied with other prescribed measures.

7. The destruction of plant protection drugs must comply with Article 74 of the Law on Plant Protection and Quarantine.

Article 79. Competence to issue decisions on compulsory recall of plant protection drugs

1. The Plant Protection Department may issue decisions on compulsory recall of plant protection drugs; decide on measures and time limits for disposing of recalled plant protection drugs; inspect the recall and disposal of drugs by manufacturers; handle violations in the recall of plant protection drugs by traders in case the recall is conducted in many provinces and centrally run cities.

2. Provincial-level plant protection sub-departments and cultivation and plant protection sub-departments may issue decisions on compulsory recall of plant protection drugs to be recalled; decide on measures and time limits for disposing of recalled plant protection drugs; inspect the recall and disposal of drugs by traders in their localities; handle violations in the recall of plant protection drugs by traders in their localities under regulations.

Chapter XIV

ORGANIZATION OF IMPLEMENTATION

Article 80. Responsibilities of the Plant Protection Department

1. For registration of plant protection drugs

a/ To receive, examine, preserve and keep confidential registration dossiers. The dossier preservation duration is at least 5 years for paper dossiers and 10 years for electronic files. Upon the expiration of the preservation duration, dossiers shall be destroyed under current regulations;

b/ To grant, re-grant and revoke trial permits; grant, extend, re-grant and revoke plant protection drug registration certificates;

c/ To organize meetings of the Advisory Council to consider and approve registered drugs and make and submit dossiers to the Minister of Agriculture and Rural Development for promulgation of circulars on the list of plant protection drugs and list of banned plant protection drugs after they are considered and proposed by the Advisory Council to be registered in the list;

d/ To collect charges and fees for grant and re-grant of trial permits and plant protection drug registration certificates; and to extend plant protection drug registration certificates.

2. For trial of plant protection drugs

a/ To manage and organize trial activities in an objective and accurate manner;

b/ To examine dossiers of request for recognition of organizations eligible for plant protection drug trial;

c/ To provide training and grant certificates of training in plant protection drug trial to persons engaged in plant protection drug trial;

d/ To inspect and appraise results of plant protection drug trial;

dd/ To use trial results to assess the drug registration service;

e/ To elaborate and submit for promulgation national technical regulations (QCVN), national standards (TCVN) and manufacturer standards (TC) on plant protection drug trial.

3. For manufacture of plant protection drugs

a/ To supervise and request manufacturers to address unsatisfactory conditions for manufacture of plant protection drugs;

b/ To request manufacturers to provide dossiers and documents and create favorable conditions for the assessment of the observance of this Circular and other relevant legal documents on manufacture of plant protection drugs;

c/ The Plant Protection Department shall grant, re-grant and revoke certificates of eligibility for the manufacture of plant protection drugs in accordance with the Law on Plant Protection and Quarantine and the guidance of this Circular;

d/ To regularly or irregularly inspect establishments having certificates of eligibility for manufacture of plant protection drugs when requested by competent state agencies;

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

e/ To develop contents and programs on training in plant protection drugs.

4. For import and export of plant protection drugs

a/ To receive and examine dossiers for import of plant protection drugs specified in Clause 2, Article 67 of the Law on Plant Protection and Quarantine;

b/ To grant plant protection drug import permits.

5. For quality inspection of plant protection drugs

a/ To manage the quality inspection of plant protection drugs;

b/ To provide professional guidance and manage operations of conformity assessment organizations designated to inspect the quality of imported plant protection drugs;

c/ To settle complaints and denunciations in case imported plant protection drugs fail to satisfy quality requirements;

d/ To train quality inspectors of plant protection drugs;

dd/ To develop and submit for promulgation national technical regulations (QCVN), national standards (TCVN) and manufacturer standards (TC) on quality inspection of plant protection drugs.

6. For certification and announcement of regulation conformity of plant protection drugs

a/ To designate regulation conformity certification organizations and testing laboratories for plant protection drugs under current regulations of the Minister of Agriculture and Rural Development;

b/ To publish the list of regulation conformity certification organizations, testing laboratories, technical regulations (QCVN), national standards (TCVN) and manufacturer standards (TC) on the website of the Plant Protection Department.

7. To develop contents and programs on training in labor safety in transportation and preservation of plant protection drugs.

8. To develop contents and programs on training in plant protection drug use instructions.

9. For advertising of plant protection drugs

a/ To receive and examine plant protection drug advertisement contents under its competence provided in Clause 1, Article 61 of this Circular;

b/ To grant certificates of advertisement contents.

10. To decide on compulsory recall of plant protection drugs according to its competence provided in Clause 1, Article 79 of this Circular.

Article 81. Responsibilities of provincial-level Agriculture and Rural Development Departments

1. To receive registration dossiers, issue notices of receipt of regulation conformity announcements, keep books for monitoring and management of dossiers for announcement of regulation conformity of plant protection drugs.

2. To coordinate with the Plant Protection Department in guiding the certification and announcement of regulation conformity of plant protection drugs.

3. To send reports on announcement of regulation conformity of plant protection drugs to the Plant Protection Department for submission to the Ministry of Agriculture and Rural Development when requested.

4. To direct, guide and inspect provincial-level plant protection sub-departments and cultivation and plant protection sub-departments in performing their tasks assigned under this Circular.

Article 82. Responsibilities of provincial-level plant protection sub-departments and cultivation and plant protection sub-departments

1. For plant protection drug trading

a/ To supervise and request traders to address unsatisfactory conditions for plant protection drug trading;

b/ To request traders to provide dossiers and documents and create favorable conditions for the assessment of the observance of this Circular and other relevant legal documents on plant protection drug trading;

c/ To grant, re-grant and revoke certificates of eligibility for plant protection drug trading in their localities in accordance with the Law on Plant Protection and Quarantine and the guidance of this Circular;

d/ To conduct regular and irregular inspections of traders having certificates of eligibility for plant protection drug trading when requested by competent state agencies;

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

e/ To organize training in plant protection drugs and chemical safety techniques.

2. For preservation and transportation of plant protection drugs

a/ To receive and examine dossiers for grant of plant protection drug transportation permits;

b/ To grant plant protection drug transportation permits;

c/ To organize training and grant certificates of training in labor safety in transportation and preservation of plant protection drugs.

3. For use of plant protection drugs

a/ To organize training in the use of plant protection drugs;

b/ To organize public information, communication and education about the law on plant protection and quarantine in order to raise the sense of observance of such law and the sense of responsibility of plant protection drug users toward the community and environment;

c/ To coordinate with functional agencies in inspecting the use of plant protection drugs in production areas, especially in areas under vegetables, tea and fruit trees;

d/ To detect and handle intentional violations of the regulations on use of plant protection drugs.

4. For plant protection drug advertisement

a/ To receive and examine plant protection drug advertisement contents under their competence provided in Clause 2, Article 61 of this Circular;

b/ To grant certificates of advertisement contents.

5. For recall of plant protection drugs

To decide on compulsory recall of plant protection drugs according to their competence provided in Clause 2, Article 79 of this Circular.

Chapter XV

IMPLEMENTATION PROVISIONS

Article 83. Transitional provisions

1. Any plant protection drug included in the list but not satisfying the condition prescribed at Point b, Clause 5, Article 5 of this Circular may be circulated for no more than 5 years from the effective date of this Circular.

2. Any organization or individual that has registered a plant protection drug under its/his/her name but fails to satisfy the condition prescribed at Point b, Clause 5, Article 5 of this Circular shall register 1 (one) content with the Plant Protection Department one year before the date of implementation of Clause 1 of this Article for submission to the Ministry of Agriculture and Rural Development for inclusion in the list.

In case an organization or individual that has registered under its/his/her name a plant protection drug with multiple contents fails to register 1 (one) content, the Plant Protection Department shall select the highest content from among these contents with which such drug has been registered, for submission to the Ministry of Agriculture and Rural Development for inclusion in the list.

3. A plant protection drug that fails to satisfy the conditions prescribed at Point b, Clause 5, Article 5; Clause 2, Article 6; Points b, c and d, Clause 3, Article 6; Clause 6, Article 6 of this Circular:

a/ If it has been granted a trial permit but not yet undergone trial: Pests and crop plants not regulated by this Circular shall be removed from the permit from the effective date of the permit;

b/ If it is undergoing trial or has undergone trial but for which registration procedures have not yet been completed, it may continue undergoing trial and be registered in the list. If it is registered in the list, it may be circulated for no more than 5 years from the effective date of this Circular;

c/ For a plant protection drug that fails to satisfy the conditions prescribed in Clause 2, Article 6; Points b, c and d, Clause 3, Article 6; and Clause 6, Article 6 of this Circular and is registered in the list before the effective date of this Circular, its registration certificate may only be extended for no more than two years from the effective date of this Circular.

4. A formulated plant protection drug specified at Point dd, Clause 3, Article 6 of this Circular and of class-III or class-IV acute toxicity according to the GHS classification may only be imported or manufactured for no more than one year, or traded or used for no more than two years from the effective date of this Circular.

5. Chemical plant protection drugs and biological plant protection drugs containing active ingredients of pyrethrins, rotenone or avermectin ground registered for use on vegetables, fruit

trees and tea for which trial permits have been granted without requiring trial for determination of pre-harvest interval to be conducted before the effective date of this Circular shall undergo trial for determination of pre-harvest interval.

6. Plant protection drug labels with contents prescribed in the Minister of Agriculture and Rural Development's Circular No. 03/2013/TT-BNNPTNT of January 11, 2013, on management of plant protection drugs, may continue to be used for no more than 5 years from the effective date of this Circular.

7. Certificates of training in plant protection drugs granted before the effective date of this Circular shall be considered equivalent to certificates of training in plant protection drugs prescribed in this Circular.

8. Trials under contracts with organizations eligible to conduct trials signed before the effective date of this Circular may continue to be conducted under the Minister of Agriculture and Rural Development's Circular No. 03/2013/TT-BNNPTNT of January 11, 2013.

Article 84. Effect

This Circular takes effect on August 1, 2015.

This Circular replaces the following documents of the Minister of Agriculture and Rural Development:

Circular No. 03/2013/TT-BNNPTNT of January 11, 2013, on management of plant protection drugs;

Circular No. 14/2013/TT-BNNPTNT of February 25, 2013, on grant of certificates of eligibility for manufacture and trading of plant protection drugs;

Circular No. 77/2009/TT-BNNPTNT of December 10, 2009, on state quality inspection of imported plant protection drugs;

Article 2 of Circular No. 18/2011/TT-BNNPTNT of April 6, 2011, amending, supplementing or annulling a number of regulations on administrative procedures in the field of plant protection and quarantine under the Government's Resolution No. 57/NQ-CP of December 15, 2010;

Decision No. 97/2008/QĐ-BNN of October 6, 2008, on grant of practice certificates for manufacture, processing, bottling, packaging and trading of plant protection drugs;

Article 2 of Circular No. 85/2011/TT-BNNPTNT of December 14, 2011, amending and supplementing a number of articles of the Minister of Agriculture and Rural Development's Decision No. 89/2007/QĐ-BNN of November 1, 2007, on state management of fumigation of objects subject to plant quarantine, and Decision No. 97/2008/QĐ-BNN of October 6, 2008, on grant of practice certificates for manufacture, processing, bottling, packaging and trading of plant protection drugs.

Any problems arising in the course of implementation of this Circular should be reported to Ministry of Agriculture and Rural Development (through the Plant Protection Department) for consideration and resolution.-

Minister of Agriculture and Rural Development
CAO DUC PHAT

** All appendices to this Circular are not translated.*