

**DECISION No. 50/2003/QĐ-BNN OF MARCH 25,  
2003 PROMULGATING THE REGULATION ON  
EXPERTISE OF QUALITY AND RESIDUES OF  
PLANT PROTECTION DRUGS AND ASSAY OF  
PLANT PROTECTION DRUGS FOR THE  
PURPOSE OF REGISTRATION IN VIETNAM**

**THE MINISTER OF AGRICULTURE AND  
RURAL DEVELOPMENT**

*Pursuant to the Government's Decree No. 73/CP of*

*November 1, 1995 defining the functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development;*

*Pursuant to the July 25, 2001 Ordinance on Plant Protection and Quarantine and the Regulation on management of plant protection drugs promulgated together with the Government's Decree No. 58/2002/ND-CP of June 3, 2002 guiding the implementation of the Ordinance on Plant Protection and Quarantine;*

*At the proposals of the director of the Plant Protection Department and the director of the Department for Science, Technology and Product Quality,*

### **DECIDES:**

**Article 1.-** To promulgate the Regulation on expertise of quality and residues of plant protection drugs and assay of plant protection drugs for the purpose of registration in Vietnam.

This Regulation shall apply to organizations and individuals at home and abroad, whose activities are related to the above-said works in Vietnam.

**Article 2.-** This Decision replaces Decision No. 193/1998/QĐ/BNN-BVTV of December 2, 1998 of the Minister of Agriculture and Rural Development.

This Decision takes effect 15 days after it is published on the Official Gazette.

The previous stipulations which are contrary to this Regulation shall all be hereby annulled.

**Article 3.-** The director of the Office, the director of the Plant Protection Department and the director of the Department for Science, Technology and Product Quality, the heads of the units attached to the Ministry of Agriculture and Rural Development, the directors of the Services of Agriculture and Rural Development of the provinces and centrally-run cities, and the concerned organizations and individuals shall have to implement this Decision.

**For the Minister of Agriculture and  
Rural Development  
Vice Minister  
BUI BA BONG**

## **REGULATION ON EXPERTISE OF QUALITY AND RESIDUES OF PLANT PROTECTION DRUGS AND ASSAY OF PLANT PROTECTION DRUGS FOR THE PURPOSE OF REGISTRATION IN VIETNAM**

*(Promulgated together with Decision No. 50/QĐ/BNN-BVTV of March 25, 2003 of the Minister of Agriculture and Rural Development)*

### **I. GENERAL PROVISIONS**

#### **Article 1.-**

1. The expertise of plant protection drugs (PPDs) shall cover:

a/ The expertise of quality of PPDs, which means the determination of contents of active ingredients, drug types and contents of impurities which may be toxic to plants, human beings or cause environmental pollution (if any), contents of additive substances with effect of enhancing the safety of products for human beings and plants (if any); chemical and physical properties related to biological activity and safety of drugs in the course of preservation and use.

b/ The expertise of residues of PPDs in agricultural and forestry products, foods and environment (called articles for short), which means the determination of contents of active ingredients and PPD's toxic metabolic products left in articles.

2. PPDs subject to the quality expertise include export and import PPD raw materials and finished products; PPD finished products in storehouses, production workshops, or in processing, bottling, packaging or trading process.

3. Assay of PPDs for purpose of registration in Vietnam (called the PPD assay for short) means the determination of their effect in harmful pest prevention and elimination and assessment of their impacts on plants, human beings, animals and ecological environment under the farming conditions of the key production regions in the Vietnamese territory.

For PPDs used on vegetables, fruit trees and tea: Apart from testing their biological effects, it is necessary to determine the isolation duration under Vietnamese conditions. For plant growth stimulants: Apart from testing biological effects, it is necessary to assess drugs'

impact on products' quality in Vietnam.

4. PPDs subject to the assay include:

a/ PPDs applying for official registration.

b/ PPDs with their trade names not yet included in the list of PPDs permitted for use in Vietnam.

c/ Commercial drugs already permitted for use in Vietnam but with changed use scope, types, active ingredient contents, use doses, or mixtures of one or several drugs for use as new drugs.

d/ Commercial drugs with their names already included in the list of PPDs permitted for use or restricted use in Vietnam, which, upon the detection that they have had impacts on plants and environment, must be re-assayed like new PPDs.

**Article 2.-** PPD expertise centers of the Plant Protection Department shall have to:

1. Expertise the quality of export and import PPDs, and PPDs in circulation, processing, bottling or packaging;

2. Expertise PPD residues in articles;

3. Assist the director of the Plant Protection Department in organizing, managing and appraising the PPD assays;

4. Conduct PPD assay;

5. Manage the results of PPD expertises and assays strictly according to regulations.

The PPD expertise centers shall be responsible before law for their expertise and assay results.

**Article 3.-**

1. The PPD expertise centers of the Plant Protection Department shall take samples for expertising the quality of all lots of export and import PPD raw materials and finished products; take samples for expertising the quality of finished PPDs at the producing, processing, bottling and packaging establishments once a year, for enterprises already granted GMS, ISO, HACCP certificates or certificates of equivalent quality management systems; or no more than twice a year, for the remaining establishments.

2. The expertise of PPD quality and residues shall have to comply with the Vietnamese standards (VNS), the branch standards of the Ministry of Agriculture and

Rural Development (BS) and grassroots standards (GS) of the Plant Protection Department (in cases where VNS or BS are not available) so as to be valid for expertised goods lots. In cases where VNS, BS or GS are not available, the Plant Protection Department shall, depending on each specific PPD, permit the use of methods supplied by international organizations or the producers of such PPDs.

3. The PPD assay must comply with the branch standards of the Ministry of Agriculture and Rural Development (BS) for each kind of plant or harmful pest. In cases where no BS of the Ministry of Agriculture and Rural Development are not available, the Plant Protection Department shall permit the use of assay process applied by international organizations or the producers of such PPDs.

**Article 4.-** Organizations and individuals that have exported, imported, produced, bottled, packaged or circulated PPDs or articles which must be or need to be expertised or new PPDs which need to be assayed, shall have to pay fees and charges according to the State's regulations.

## II. PROVISIONS ON EXPERTISE OF PPD QUALITY AND RESIDUES

**Article 5.-** The sampling for expertising the PPD quality and residues must comply with branch standard No. 10TCN 386-99 of the Ministry of Agriculture and Rural Development. The written records of sampling PPDs for expertising their quality and residues shall be made according to Appendices 1 and 2 to this Regulation (not printed herein).

**Article 6.-** The samples for expertising the PPD quality and residues shall be preserved for 3 months after the date of receiving samples.

**Article 7.-** The expertise of quality of export and import PPDs must comply with the regulations on the State control of PPD quality, promulgated together with Decision No. 124/2001/QĐ/BNN-BVTV of December 26, 2001 of the Ministry of Agriculture and Rural Development.

**Article 8.-** The analysis of PPD residues for determining their isolation durations shall be made at the recognized laboratories of Vietnam or the Ministry of Agriculture and Rural Development in this field.

### III. PROVISIONS ON PPD ASSAY

**Article 9.-** The Plant Protection Department shall be in charge of State management over PPD assays for the purpose of registration in Vietnam, including:

1. Management of PPDs which need to be assayed;
2. Identification of organizations qualified for participating in the assay;
3. Determination of assay forms and processes;
4. Organization of inspection and appraisal of PPD assay results;
5. Organization of training of officials engaged in PPD assays.

**Article 10.-** Organizations engaged in the PPD assay must satisfy the following conditions:

1. Having officials to be in prime charge, who have university or higher degrees in plant protection or in biology and have been trained in PPD assay courses organized by the Plant Protection Department;
2. Having contingents of officials currently engaged in the plant protection work and having been trained in PPD assay courses organized by the Plant Protection Department;
3. Having necessary material and technical foundations in service of the PPD assay;
4. Neither directly using their names nor being authorized to use their names in the registration of PPD products in Vietnam.

**Article 11.-** Assay forms and scales for a kind of plant or harmful pest:

1. Narrow-area assay means assay conducted on a small scale. The assay area shall be 25-50 sq. meters/plot, on which the assay shall be repeated 3 or 4 times. One assay must be conducted at least in two agricultural production regions (Northern and Southern Vietnam) with two locations in each region and during two different production crops. For plants or harmful pests available or appearing in only one agricultural production region, assays thereof shall only be conducted in such production region but in at least three locations.

For perennial trees and special assay objects (pests harmful to farm produce in stock, insects and pests

harmful to forest trees, rats ravaging crops, storehouses and population quarters), the size of assay plots shall comply with the specialized assay procedures.

2. Wide-area assay means assay carried out on a large scale in a minimum area of one hectare and must be carried out in two agricultural production regions (the Northern and Southern Vietnam) with at least one location in each region, and during one production crop. For plants or harmful pests available or appearing in only one agricultural production region, assays thereof shall only be carried out on at least two typical locations in such production region.

For perennial trees and special assay objects (pests harmful to farm produce in stock, insects and pests harmful to forest trees), the size of assay plots shall comply with the specialized assay procedures.

3. For PPDs subject to the determination of isolation durations, the assay thereof shall be carried out in two agricultural production regions (Northern and Southern Vietnam) with at least one location in each region and during one production crop. For plants available in only one agricultural production region, the determination of their isolation durations shall be carried out on two locations in such production region.

**Article 12.-** Responsibilities of organizations and individuals related to the PPD assay:

1. Organizations and individuals that have PPD products which need to be assayed:

a/ To abide by the Ordinance on Plant Protection and Quarantine, the Regulation on PPD management, promulgated together with the Government's Decree No. 58/2002/ND-CP of June 3, 2002 and the regulations of the concerned ministries and branches;

b/ To supply to the Plant Protection Department enough information on products which need to be assayed according to the Regulation on registration; production, processing, bottling, packaging; export and import; trading in; preservation, transport; use; destruction; labeling; packing and packaging; seminars and advertisements for plant protection drugs, promulgated together with Decision No. 145/2002/QĐ-BNN of December 18, 2002 of the Minister of Agriculture and Rural Development, and at the same time to be responsible for the truthfulness of such information. In cases where assayed products cause harms to human beings, crops, animals and environment due to the fact that they are assayed according to such

products' technical information, the organizations and individuals that have their products assayed shall have to make compensations for damage according to the Vietnamese laws.

2. The units conducting the PPD assay:

a/ To register the PPD assay;

b/ To fully and seriously follow the assay processes and procedures;

c/ Not to organize and guide visits to fields for PPD assay without consents of the Assay Management Body of the Plant Protection Department.

d/ To be held responsible before law for the truthfulness of assay results.

The units assaying PPDs shall have to report on the assay results according to the set form.

**Article 13.-** Use of assay results:

1. Organizations carrying out the assay shall have to report results of PPD assays to the Assay Management Body of the Plant Protection Department and must not publicly announce such results in any form.

2. The Plant Protection Department shall use assay results to manage and organize the assessment of PPDs subject to the assay, which shall serve the drug registration and use instruction when they are permitted for use in Vietnam.

***For the Minister of Agriculture and  
Rural Development  
Vice Minister  
BUI BA BONG***