

VETERINARY DRUGS

THE MINISTER OF AQUATIC RESOURCES

Pursuant to the Government's Decree No.50/CP of June 21, 1994 defining the tasks, powers and organizational apparatus of the Ministry of Aquatic Resources;

Pursuant to the Government's Decree No.93/CP of November 27, 1993 guiding the implementation of the Veterinary Ordinance;

Pursuant to the Government's Decree No.30/2000/ND-CP of August 11, 2000 on the annulment of a number of permits and licenses and conversion of some others into business conditions;

Pursuant to the Government's Decree No.86/2001/ND-CP of November 16, 2001 on the conditions for the engagement in aquatic business lines;

Pursuant to Circular No.02-TS/TT of June 25, 1994 of the Ministry of Aquatic Resources guiding the implementation of the Government's Decree No.93/CP of November 27, 1993 on veterinary work for aquatic animals and products thereof;

At the proposal of the director of the Aquatic Resource Protection Department.

DECIDES:

Article 1.- To issue together with this Decision the Regulation on management of aquatic veterinary drugs.

Article 2.- This Decision takes effect 15 days after its signing.

The Regulation issued together with this Decision shall replace the provisions of Section IV, Circular No.02-TS/TT of June 25, 1994 of the Ministry of Aquatic Resources.

Article 3.- The directors of the Office and Departments and the chief inspector of the Ministry; the director of the Aquatic Resource Protection Department, the director of the Center for Aquatic Product Quality and Hygiene Inspection, the directors of the provincial/municipal Aquatic Resource Services as well as Agriculture and Rural Development

THE MINISTRY OF AQUATIC RESOURCES

DECISION No. 03/2002/QĐ-BTS OF JANUARY 23, 2002 PROMULGATING THE REGULATION ON MANAGEMENT OF AQUATIC

Services (involved in the management of aquatic resources) shall have to implement this Decision.

**For the Minister of Aquatic Resources
Vice Minister
NGUYEN VIET THANG**

REGULATION ON MANAGEMENT OF AQUATIC VETERINARY DRUGS

(Issued together with Decision No.03/2002/QĐ-BTS)

Article 1.- This Regulation prescribes uniform procedures and conditions for the production, trading, import and test of aquatic veterinary drugs on the Vietnamese territory.

Article 2.- Organizations and individuals (hereinafter called establishments) involved in aquatic veterinary drug activities must strictly abide by the provisions of this Regulation.

Article 3.- In this Regulation, the following words and phrases shall be construed as follows:

1. Aquatic veterinary drugs are products (including finished products, semi-finished products and raw materials) originating from animals, plants, minerals, pharmaceutical chemistry or biology, used in aquaculture for:

- a/ Disease prevention and treatment.
- b/ Diagnosis of diseases.
- c/ Regulation of the reproduction, growth and development processes.
- d/ Environmental improvement and treatment.

2. Test of aquatic veterinary drugs means determination of the efficiency and safety of those drugs when they are put to use in aquaculture (their efficacy in epidemic prevention and treatment for aquatic animals, their safety for men and domestic animals, neither causing environmental pollution nor destroying the ecological environment).

3. Aquatic veterinary drug-related activities cover the management, production, trading, import and experimentation of aquatic veterinary drugs.

Article 4.- State management agencies in charge of aquatic veterinary drugs:

1. At the central level: The Aquatic Resource Protection Department shall assist the Minister of Aquatic Resources in performing the function of State management over aquatic veterinary drugs throughout the country.

2. At the local level: The Aquatic Resource Protection Sub-Departments shall assist the directors of the provincial/municipal Aquatic Resource Services or Agriculture and Rural Development Services involved in aquatic resource management in performing the function of State management over aquatic veterinary drugs.

In localities where Aquatic Resource Protection Sub-Departments are not available, the agencies performing the above-mentioned task shall be designated by the provincial/municipal Agriculture and Rural Development Services.

Chapter II

PROVISIONS ON AQUATIC VETERINARY DRUG-RELATED ACTIVITIES

Article 5.- Conditions for aquatic veterinary drug production

Establishments producing aquatic veterinary drugs must meet all the following conditions:

1. Their locations, workshops, warehouses and waste treatment systems must satisfy the environmental protection and veterinary hygiene criteria prescribed by the Ministry of Aquatic Resources.

2. Their facilities and equipment must meet the requirements of production and preservation of raw materials and products.

3. They have technicians and specialized technical workers. The persons in charge of technical matters regarding aquatic veterinary drug production must be veterinarians, aquaculture engineers, bachelors of biology or biological chemistry, or pharmacists.

4. They have means to inspect the quality of drugs before they are released from factories.

5. The products released from factories must ensure the announced quality and stuck with goods labels. The contents inscribed on goods labels shall comply with Circular No.03/2000/TT-BTS of September 22, 2000 of the Ministry of Aquatic Resources guiding the implementation of the Prime Minister's Circular No.178/1999/QĐ-TTg of August 30, 1999, which promulgated the Regulation on the labeling of domestically circulated goods as well as import and export goods.

6. They have registration certificates for aquatic veterinary drug production granted by the Aquatic Resource Protection Department.

7. They are allowed to produce only those kinds of aquatic veterinary drug, which have been inscribed in the registration certificates for aquatic veterinary drug production.

Article 6.- Conditions for aquatic veterinary drug trading

Establishments trading in aquatic veterinary drugs must meet all the following conditions:

1. Their business locations must ensure the veterinary hygiene criteria prescribed by the Ministry of Aquatic Resources.

2. They have facilities and equipment for aquatic veterinary drug preservation.

3. The persons who manage aquatic veterinary drug stores must obtain, at least, diplomas of intermediate veterinary or aquacultural schools.

4. They are allowed to trade in only those kinds of aquatic veterinary drug, which are on the list of those permitted for use promulgated by the Ministry of Aquatic Resources.

Article 7.- Test of aquatic veterinary drugs

1. The aquatic veterinary drugs outside the list of those permitted for use promulgated by the Ministry of Aquatic Resources must be tested before being imported into Vietnam or produced in the country for the first time.

2. The test of aquatic veterinary drugs shall comply

with the stipulations of the Ministry of Aquatic Resources.

Article 8.- Import of aquatic veterinary drugs

The import of aquatic veterinary drugs shall comply with the Ministry of Aquatic Resources' regulations on the management of specialized aquatic goods import and export.

Chapter III

CONTENTS AND PROCEDURES FOR THE GRANTING OF AQUATIC VETERINARY DRUG PRODUCTION REGISTRATION

Article 9.- Dossier for registration of aquatic veterinary drug production

1. An application for registration of aquatic veterinary drug production, enclosed with a list of drugs to be produced.

2. A disposition on the conditions for aquatic veterinary drug production.

3. Copies of diplomas of the persons in charge of technical matters.

4. Technical dossier, including:

a/ The production process and product quality standards for each kind of registered drugs, drug labels registered for circulation.

b/ The inspection result card certifying the satisfaction of the already registered quality standards, granted by the State inspection agency.

5. Copies of papers related to the founding of the production establishment such as founding decision, business registration certificate, investment license.

Article 10.- Procedures for consideration and granting of registration certificates for aquatic veterinary drug production

1. When receiving dossiers, the registration-granting agencies shall base themselves on Article 9 to consider the dossiers and guide the establishments to supplement incomplete contents.

2. Within 10 working days after receiving the valid dossiers, the Aquatic Resource Protection

Department shall have to evaluate the production conditions. If all conditions are met, the Aquatic Resource Protection Department shall grant the registration certificates for aquatic veterinary drug production to production establishments. If the evaluation conclusions show that the production establishments fail to meet the conditions for aquatic veterinary drug production, such establishments may request the reevaluation after overcoming the shortcomings revealed in the first evaluation.

Article 11.- Inspection of conditions for aquatic veterinary drug production

The inspection of conditions for aquatic veterinary drug production shall be conducted in the following cases:

1. The first-time inspection shall apply to establishments that have just begun to participate in production and establishments that have been registered for production but change their production locations.

2. The re-inspection shall apply to establishments that have been inspected but fail to meet the production conditions and establishments that expand their production locations and production chains.

3. The periodical inspection shall be conducted once a year, aiming to supervise the maintenance of production conditions.

4. The extraordinary inspection shall be conducted when the managing agencies deem it necessary.

Article 12.- Agencies inspecting conditions for aquatic veterinary drug production

1. The Aquatic Resource Protection Department shall be the agency inspecting the production conditions for establishments producing aquatic veterinary drugs throughout the country.

2. The provincial Aquatic Resource Protection Sub-Departments shall be the agencies inspecting production conditions for establishments producing aquatic veterinary drugs under the Aquatic Resource Protection Department's authorization.

Article 13.- The effective duration of registration certificates for aquatic veterinary drug production shall be one year (from the date of issuance). Upon the

expiry thereof, establishments shall have to apply for registration extension if wishing to continue the production of those aquatic veterinary drugs. The extension of registration certificates shall be valid for one year.

Article 14.- Extension of production registration certificates

1. Dossier of application for extension:

a/ The extension application.

b/ The report on the establishment's production activities in the effective duration of the granted production registration certificate.

c/ The granted production registration certificate.

2. Extension consideration procedures:

Within 7 working days after receiving the valid dossiers, the Aquatic Resource Protection Department must consider them and notify the consideration results.

Chapter IV

RESPONSIBILITIES AND POWERS OF STATE MANAGEMENT AGENCIES AND RELEVANT ESTABLISHMENTS ENGAGED IN AQUATIC VETERINARY DRUG ACTIVITIES

Article 15.- Responsibilities and powers of the Aquatic Resource Protection Department

1. Responsibilities:

a/ To elaborate and submit to the Ministry for promulgation legal documents on the management of aquatic veterinary drugs.

b/ Annually or periodically, to draw up lists of aquatic veterinary drugs permitted for use, restricted or banned from use in Vietnam and submit them to the Ministry's leaders for decision on the promulgation thereof.

c/ To settle disputes, complaints and denunciations related to the management of aquatic veterinary drugs of establishments, which fall under its competence.

2. Powers:

a/ To grant and withdraw registration certificates

for aquatic veterinary drug production from organizations and individuals throughout the country.

b/ To examine and inspect aquatic veterinary drug-related activities.

c/ To request organizations and individuals producing and trading in aquatic veterinary drugs to supply relevant documents and materials.

d/ To collect charges as prescribed.

Article 16.- Responsibilities and powers of Aquatic Resource Protection Sub-Departments or agencies designated by the provincial/municipal Agriculture and Rural Development Services to assist the Service directors in exercising the State management over aquatic veterinary drugs

1. Responsibilities:

a/ To organize the management of aquatic veterinary drug-related activities in localities.

b/ To receive and settle proposals, complaints and denunciations regarding the management of aquatic veterinary drugs within the ambit of their vested powers or transfer them to other competent agencies for settlement.

2. Powers:

a/ To inspect production conditions for authorized establishments, examine and handle law violations on aquatic veterinary drugs in localities.

b/ To request organizations and individuals producing and trading in aquatic veterinary drugs in localities to supply relevant documents and materials.

c/ To collect and use charges as prescribed.

Article 17.- Responsibilities of establishments

To abide by all the provisions of this Regulation and submit to supervision and inspection by the State agencies managing aquatic veterinary drugs.

Chapter V

CHARGES AND THE USE THEREOF

Article 18.- Inspection agencies are allowed to collect charges for inspection of aquatic veterinary drug production conditions in cases of first-time

inspection, re-inspection and periodical inspection.

Article 19.- The charge rates as well as charge management and use shall comply with the Finance Ministry's stipulations and guidance.

Chapter VI

COMPLAINTS, DENUNCIATIONS AND HANDLING OF VIOLATIONS

Article 20.- Organizations and individuals engaged in aquatic veterinary drug-related activities shall have the right to complain about or denounce conclusions and handling measures of agencies inspecting and examining aquatic veterinary drugs in their respective establishments according to the provisions of the Law on Complaints and Denunciations.

Article 21.- Organizations and individuals engaged in aquatic veterinary drug-related activities that fail to observe or breach the provisions of this Regulation shall be administratively sanctioned according to law provisions.

Article 22.- Persons responsible for exercising the State management over aquatic veterinary drugs, who commit acts of violating the provisions of this Regulation, shall, depending on the seriousness of their violations, be disciplined, administratively sanctioned or examined for penal liabilities according to law provisions.

Chapter VII

IMPLEMENTATION PROVISIONS

Article 23.- All amendments and/or supplements to the contents of this Regulation shall be considered and decided in writing by the Minister of Aquatic Resources.

Article 24.- The Aquatic Resource Protection Department shall have to guide, inspect and organize the implementation of this Regulation.

For the Minister of Aquatic Resources
Vice Minister
NGUYEN VIET THANG