Circular No. 29/2011/TT-BYT of June 30, 2011, on management of insecticidal or germicidal chemicals and preparations for household and medical use

Pursuant to the Government's Decree No. 188/2007/ND-CP of December 27, 2007, defining the functions, tasks, powers and organizational structure of the Ministry of Health;

Pursuant to the November 21, 2007 Law on Chemicals;

Pursuant to the November 21, 2007 Law on Product and Goods Quality;

Pursuant to the June 14, 2005 Commercial Law;

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

Pursuant to the Government's Decree No. 132/2008/ND-CP of December 31, 2008, detailing and guiding the Law on Product and Goods Quality;

Pursuant to the Government's Decree No. 12/2006/ND-CP of January 23, 2006, detailing the Commercial Law regarding international goods trading and goods sale and purchase agency, processing and transit with foreign countries;

At the proposal of the director of the Health Environment Management Agency - the Ministry of Health,

Chapter I
GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular provides the circulation registration; testing and assay; import, export and circulation of insecticidal and germicidal chemicals and preparations for household and medical use in Vietnam.

Article 2. Interpretation of terms

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

1. Active ingredient means a substance with active insecticidal or germicidal properties.

2. Insecticidal or germicidal chemical means a product containing active ingredients in a technical form for processing into preparations or for direct use (below referred to as chemical).

3. Insecticidal or germicidal preparation means a product containing active ingredients and having a specific trade name for direct use (below referred to as preparation).

4. Assay result slip means a document issued by an assaying unit to indicate conclusions on the effects and safety of a chemical or preparation drawn after carrying out the assessment process under the Ministry of Heath's regulations.

Article 3. Lists of chemicals and preparations

1. Lists of chemicals promulgated by the Ministry of Health include:

a/ List of chemicals permitted for use registration;

b/ List of chemicals permitted for registration for restricted use;

c/ List of chemicals banned from use.

2. Grounds for promulgation of lists of chemicals:

a/ Recommendations of the World Health Organization;

b/ Scientific research findings approved by competent authorities;

c/ Information on chemicals and preparations released by ministries and sectors.

Chapter II

CIRCULATION REGISTRATION FOR CHEMICALS AND PREPARATIONS

Article 4. Trade names of chemicals and preparations

1. Trade names of chemicals and preparations shall be given under the following regulations:

a/ For each chemical or preparation of a single producer, only one trade name may be registered in Vietnam;

b/ It is prohibited to use a single trade name for two or more chemicals or preparations of a single producer;

c/ Trade names of chemicals or preparations must not be identical with those of chemicals or preparations with valid circulation registration numbers;

d/ It is prohibited to use the names of active ingredients of chemicals or preparations as their trade names;

e/ It is prohibited to give chemicals or preparations trade names with meanings irrelevant to their effects and safety.

2. Trade names may only be changed upon:

a/ Exportation of home-made chemicals and preparations with valid circulation registration numbers;

Dossiers of request for permission to change trade names and the dossier-appraising order comply with the law on certificates of free sale for imported and exported products and goods;

b/ Issuance of written conclusions by a state agency in charge of intellectual property or a court on trademark infringements involving chemicals or preparations with valid circulation registration numbers.

Article 5. Circulation registrants

1. Units eligible to carry out circulation registration for chemicals and preparations include:

a/ Vietnam-based organizations and individuals that are owners (producers) of chemicals or preparations. Owners who are not producers of chemicals or preparations must have documents proving their rights to own such chemicals or preparations;

b/ Vietnam-based organizations and individuals that produce or trade in chemicals or preparations or Vietnam-based permanent representative offices of foreign enterprises

which are authorized by chemical or preparation owners to carry out the registration;

c/ Vietnam-based permanent representative offices of foreign chemical or preparation producers.

2. In case chemical or preparation owners permit the unit they authorize to carry out the registration of chemicals or preparations to further grant the authorization to another unit, they shall clearly indicate such permission in the authorization paper.

3. In case a chemical or preparation owner authorizes two or more units in Vietnam to carry out registration for a single chemical or preparation, the Ministry of Health (the Health Environment Management Agency) shall only accept and process the complete and valid dossier which is first submitted.

Article 6. Forms of circulation registration

1. Official registration applies to:

a/ Chemicals and preparations which are newly produced in the country;

b/ Chemicals and preparations which have been permitted for use in foreign countries but are imported for the first time for use in Vietnam;

c/ Chemicals and preparations which have been granted circulation registration numbers but see changes in the form of product, solvents, additives or contents of active ingredients;

d/ Chemicals and preparations which have been granted circulation registration certificates but are not re-registered within the time limit specified in Clause 2, Article 9 of this Circular.

2. Additional registration applies to chemicals and preparations with valid circulation registration numbers which see:

a/ Change in packaging specifications;

b/ Change in the form or contents of specimen labels;

c/ Change in the address of the producer or registrant;

d/ Change in the right to own the circulation registration certificate;

e/ Supplementation of a new production establishment to the officially registered one;

f/ Domestic bottling or packaging in replacement of overseas bottling or packaging;

g/ Change in effects, quality criteria or use methods.

3. Re-registration applies to chemicals and preparations which have been granted circulation registration certificates with circulation registration numbers to be about to expire under Clause 2, Article 9 of this Circular.

Article 7. Dossiers of official circulation registration

1. A dossier of official registration for circulation of a home-made chemical or preparation comprises the following documents:

a/ A written request for official circulation registration (made according to a set form - *not printed herein*);

b/ The registrant's business registration certificate, investment certificate or establishment license, for registrants being representative offices;

c/ The paper of authorization to carrying out circulation registration, for the case specified

at Point b, Clause 1, Article 5 of this Circular;

d/ Results of testing of the composition and contents of active ingredients of the chemical or preparation;

e/ The assay result slip (supplemented under Point b, Clause 3, Article 12 of this Circular);

f/ The producer's written environmental protection commitment or decision issued by a competent state agency approving the producer's environmental impact assessment report;

g/ Technical documents of the chemical or preparation requested for registration (covering the details specified in Appendix 2 to this Circular, *not printed herein*);

h/ The specimen label and its content registered for circulation in Vietnam.

2. A dossier of official registration for circulation of an imported chemical or preparation comprises the following documents:

a/ A written request for official circulation registration (made according to a set form);

b/ In addition to the papers specified at Points b, c, d, e, f, g and h, Clause 1 of this Article, a valid certificate of free sale granted by a competent authority of a country permitting the circulation of the chemical or preparation requested for registration is required.

Article 8. Dossiers of additional circulation registration

1. A written request for additional registration for circulation of a chemical or preparation (made according to a set form).

2. Documents pertaining to modified or supplemented contents:

a/ In case of changing packaging specifications: the specimen label of the chemical or preparation indicating the new packaging specifications;

b/ In case of changing the form or content of the specimen label:

- The specimen label in the new form or with a new content;

- Written explanations about changes of the content of the specimen label;

c/ In case of changing the address of the producer or registrant:

- The business registration certificate or investment certificate;

- A specimen label of the chemical or preparation indicating the new address of the producer or registrant.

d/ In case of changing the right to own circulation registration certificates:

- The paper of authorization to carry out circulation registration, for the case specified at Point b, Clause 1, Article 5 of this Circular;

- A written request for permission to transfer the right to own the circulation registration number, made by the circulation registration number owner;

- A written request for permission to receive the right to own the circulation registration number and commitment to trading in the chemical or preparation in accordance with the dossier approved by the Ministry of Health (the Health Environment Management Agency), made by the transferee;

- The establishment license, for transferees

being Vietnam-based permanent representative offices, business registration certificate or investment certificate of the transferee;

- The specimen label of the chemical or preparation, if there is any change in the form or content of labels.

e/ In case of registering a new production establishment to the officially registered one:

- The new specimen label of the chemical or preparation, if there is any change in the label's content or form;

- The certificate of free sale, granted by a competent authority of at least one country permitting the circulation of chemicals or preparations manufactured by the new production establishment requested for additional registration (applicable only to imported chemicals and preparations);

- The assay result slip (supplemented to the dossier under Point b, Clause 3, Article 12 of this Circular).

f/ In case of registering the domestic bottling or packaging of the chemical or preparation in replacement of overseas bottling or packaging:

- The business registration certificate or investment certificate of the unit bottling or packaging unit in Vietnam;

- The assay result slip for the chemical or preparation bottled or packed in Vietnam (supplemented to the dossier under Point b, Clause 3, Article 12 of this Circular);

- The written environmental protection commitment of the bottling or packaging unit or decision issued by a competent state agency approving its environmental impact assessment report;

- The specimen label of the chemical or preparation indicating the name and address of the bottling or packaging unit in Vietnam.

g/ In case of changing the effects, quality criteria or use methods:

- The specimen label of the chemical or preparation indicating the added effects, quality criteria or use methods;

- The assay result slip for the chemical or preparation after its effects, quality criteria or use methods are changed (supplemented to the dossier under Point b, Clause 3, Article 12 of this Circular).

Article 9. Dossiers of circulation re-registration

1. A dossier of circulation re-registration comprises the following documents:

a/ A written request for re-registration for circulation of the chemical or preparation (made according to a set form);

b/ The business registration certificate, investment certificate or establishment license, for permanent representative offices in Vietnam;

c/ The assay result slip, for the chemicals and preparations specified at Point b, Clause 2 of this Article (supplemented to the dossier after the assaying unit completes the assay and sends the assay result slip to the Ministry of Health);

d/ The paper of authorization to carry out circulation registration, for the case specified at Point b, Clause 1, Article 5 of this Circular;

e/ The specimen label and its content registered for registration of circulation in Vietnam;

f/ A report on the product circulation process

(made according to a set form).

2. Time limits for submission of dossiers of circulation re-registration:

a/ For raw materials used for producing preparations with valid circulation registration numbers granted by the Ministry of Heath (the Health Environment Management Agency), dossiers of circulation re-registration must be submitted at least 20 (twenty) working days before the expiry date of circulation registration numbers;

b/ For chemicals and preparations other than those specified at Point a of this Clause, dossiers of circulation re-registration must be submitted at least 14 (fourteen) months before the expiry date of circulation registration numbers;

Past the time limits specified at Points a and b of this Clause, if registrants wish to continue circulating these chemicals or preparations, they shall carry out official circulation registration.

Article 10. Requirements on circulation registration dossiers

1. A dossier of official registration, additional registration or re-registration for circulation of a chemical or preparation shall be made in one set.

2. For foreign-language documents, their originals must be enclosed with Vietnamese versions. For documents in a foreign language other than English, their Vietnamese versions must be certified by a notary public or a translation service provider.

3. Documents included in a dossier must be legibly printed and arranged as required for each form of registration specified in Article 7, 8 or 9 of this Circular. A dossier must have covers, an index of documents, and color sheets separating different parts.

4. Papers in a circulation registration dossier which must be originals:

a/ The paper of authorization to carry out circulation registration, for the case specified at Point b, Clause 1, Article 5 of this Circular;

b/ The assay result slip;

c/ Results of testing of ingredients and contents.

5. Papers in a circulation registration dossier which may be notarized or certified copies:

a/ The registrant's business registration certificate, investment certificate or establishment license, for registrants being Vietnam-based representative offices;

b/ The producer's written environmental protection commitment or the decision issued by a competent state agency approving the producer's environmental impact assessment report;

c/ The certificate of free sale specified in Clause 2, Article 7 of this Circular. This certificate must be consularly legalized, except cases exempt from consular legalization under law.

6. Other papers in a circulation registration dossier must be appended with the registrant's seal.

Article 11. Receipt of circulation registration dossiers

Registrants shall submit dossiers of registration for circulation of chemicals or preparations directly or by post to the Ministry

of Health (the Health Environment Management Agency).

Article 12. Appraisal of circulation registration dossiers

1. For a dossier of registration for circulation of a chemical or preparation specified at Point a, b, c or d, Clause 2, Article 6 of this Circular, within 20 (twenty) working days after receiving the dossier, the Ministry of Health (the Health Environment Management Agency) shall issue a document requesting dossier supplementation or indicating its agreement or disagreement with the content of the additional registration.

2. For a dossier of registration for circulation of a chemical or preparation specified at Point a, Clause 2, Article 9 of this Circular:

a/ If the dossier is incomplete or invalid, within 5 (five) working days, the Ministry of Health (the Health Environment Management Agency) shall issue a written request for dossier supplementation. At least 5 (five) working days before the expiry date of the circulation registration number, the registrant shall supplement documents as required. Past this time limit, the submitted dossier will become invalid and the Ministry of Health (the Health Environment Management Agency) shall not re-grant the circulation registration number;

b/ If the dossier is complete and valid, within 15 (fifteen) working days, the Ministry of Health (the Health Environment Management Agency) shall re-grant the circulation registration number.

3. For a dossier of registration for circulation of a chemical or preparation other than those specified in Clauses 1 and 2 of this Article:

a/ Within 1 month after receiving the dossier, the Ministry of Health (the Health Environment Management Agency) shall issue an assay permit. In case of refusal, it shall issue a written reply clearly stating the reason;

b/ Within 12 months after obtaining an assay permit from the Ministry of Health (the Health Environment Management Agency), the registrant shall submit an assay result slip for supplementation to the circulation registration dossier. Past this time limit, if the registrant fails to submit this slip, the submitted dossier will become invalid for circulation registration;

c/ Within 20 (twenty) working days after receiving an assay result slip from the registrant for supplementation to the dossier, the Ministry of Health (the Health Environment Management Agency) shall:

- Grant or refuse to grant a circulation registration number. In case of refusal, it shall issue a written reply clearly stating the reason, for dossiers of registration for circulation of the chemicals or preparations specified in Clause 1, Article 6, and Point b, Clause 2, Article 9, of this Circular;

- Issue a document indicating its agreement or disagreement with the content of the additional registration. If disagreeing with the content of the additional registration, it shall issue a written reply clearly stating the reason, for dossiers of registration for circulation of the chemicals or preparations specified at Points e, f and g, Clause 2, Article 6 of this Circular.

Article 13. Circulation registration numbers and certificates

1. Each chemical or preparation may be

granted only one circulation registration number.

2. The circulation registration number of a chemical or preparation shall be granted in the form of circulation registration certificate which is valid for 5 (five) years from the date of issue.

The circulation registration certificate shall be made according to a set form.

Article 14. Cases subject to revocation of circulation registration number

1. Registrants have forged registration dossiers.

2. The chemicals or preparations in circulation are unconformable with the granted circulation registration certificates or registration dossiers; labels of the chemicals or preparations in circulation are unconformable with those approved by the Ministry of Health (the Health Environment Management Agency) and registrants fail to take remedies at the request of competent state management agencies.

3. Registrants lease or lend their circulation registration certificates; or modify their circulation registration certificates without permission.

4. Registrants terminate chemical or preparation production or trading activities.

5. Registrants no longer satisfy the conditions for registration for circulation of chemicals or preparations.

6. The chemicals or preparations in circulation no longer assure the effects and safety requirements as indicated in their dossiers registered with the Ministry of Health (the Health Environment Management Agency).

Article 15. Charges for appraisal of circulation registration dossiers

1. Organizations and individuals requesting circulation registration or assay of chemicals or preparations shall pay dossier appraisal charges according to the law on charges and fees.

2. Dossier appraisal charges shall be paid upon dossier submission to the Ministry of Health (the Health Environment Management Agency).

Chapter III

TESTING AND ASSAY OF CHEMICALS AND PREPARATIONS

Section I

TESTING OF CHEMICALS AND PREPARATIONS

Article 16. Cases subject to testing

1. Chemicals and preparations prior to official circulation registration.

2. Chemicals and preparations currently in circulation in Vietnam.

Article 17. Testing contents

1. Testing of chemicals or preparations for circulation registration covers the identification of the content and composition of active ingredients of these chemicals or preparations.

2. Testing of chemicals or preparations currently in circulation covers the identification of the composition and content of main active ingredients and other quality criteria of these chemicals or preparations. The testing of chemicals and preparations currently in circulation complies with the Law on Product and Goods Quality and other laws.

Article 18. Testing units

1. Units which are set up under Vietnamese law and have the function of testing the composition and content of chemicals and preparations.

2. In case Vietnam-based testing units are unable to test the content and composition of chemicals or preparations requested for registration, the Ministry of Health (the Health Environment Management Agency) may consider and accept testing results of their producers or an independent lab, and registrants shall take responsibility before law for the lawfulness of testing results they produce.

Section 2

ASSAY OF CHEMICALS AND TESTING

Article 19. Cases subject to assay

1. Chemicals and preparations prior to official circulation registration.

2. Chemicals and preparations with valid circulation registration numbers granted by the Ministry of Health (the Health Environment Management Agency) requested for additional circulation registration under Points e, f or g, Clause 2, Article 6 of this Circular.

3. Chemicals and preparations with the circulation registration numbers granted by the Ministry of Health (the Health Environment Management Agency) to be about to expire requested for circulation re-registration under Point b, Clause 2, Article 9 of this Circular.

4. Chemicals and preparations without circulation registration numbers to be imported in large volumes for exterminating insects or bacteria on board aircraft.

Article 20. Assay contents

1. Assessment of the effects of chemicals or preparations towards targeted objects as requested by registrants.

2. Assessment of the safety for:

a/ Persons directly assaying chemicals or preparations, in case of laboratory assay;

b/ Persons directly assaying chemicals or preparations and persons living in assay areas, in case of field assay.

Article 21. Assaying units

1. Units assaying the safety and effects of insecticidal chemicals and preparations:

a/ The National Institute of Hygiene and Epidemiology;

b/ The Pasteur Institute of Ho Chi Minh City;

c/ The Pasteur Institute of Nha Trang;

d/ The Central Highlands Institute of Hygiene and Epidemiology;

e/ The National Institute of Malariology, Parasitology and Entomology;

f/ The Institute of Malariology, Parasitology and Entomology of Ho Chi Minh City;

f/ The Institute of Malariology, Parasitology and Entomology of Quy Nhon.

2. Units assaying the safety and effects of germicidal chemicals and preparations:

a/ The National Institute of Hygiene and Epidemiology;

b/ The Pasteur Institute of Ho Chi Minh City;

c/ The Pasteur Institute of Nha Trang;

d/ The Central Highlands Institute of Hygiene and Epidemiology;

e/ The National Institute of Occupational and Environmental Health;

f/ The Institute of Hygiene and Public Health of Ho Chi Minh City.

3. For units other than those specified in Clauses 1 and 2 of this Article, the Ministry of Health may accredit them to be qualified for assaying chemicals or preparations on the basis of their functions, tasks and capabilities, if they so wish.

4. In case Vietnam-based units are unable to assay chemicals or preparations for circulation registration, the Ministry of Health (the Health Environment Management Agency) may consider and accept assay results of foreign countries.

Chapter IV

IMPORT AND EXPORT OF CHEMICALS AND PREPARATIONS

Article 22. Principles of import and export of chemicals and preparations

1. The import and export of chemicals and preparations comply with the law on goods import and export.

2. In case importing countries require certification of free sale of chemicals or preparations in Vietnam, registrants shall comply with the law on certificates of free sale of imported and exported products and goods.

3. Chemicals and preparations with valid circulation registration certificates granted by the Ministry of Health (the Health Environment management agency) may be imported on demand in unlimited volume or value. Import procedures shall be carried out at customs offices without requiring the Ministry of Health's approval. Importers shall take responsibility before law for their operations.

4. Chemicals and preparations on the list of those eligible for on-demand import must still have at least 2/3 (two-thirds) of their shelf life, counting from the date of arrival in Vietnam.

5. When granting circulation registration numbers for chemicals or preparations produced at home from imported raw materials that have no circulation registration numbers in Vietnam, the Ministry of Health (the Health Environment Management Agency) shall issue a document attesting that such raw materials are permitted for import. This document is as valid as a circulation registration number granted to chemicals or preparations.

Article 23. Import licenses

1. Chemicals and preparations requiring import licenses:

a/ Chemicals and preparations without circulation registration numbers for which assay permits have been granted by the Ministry of Health (the Health Environment Management Agency) and which are imported for assay or testing;

b/ Chemicals and preparations without circulation registration numbers which are imported for research, donation or other particular purposes (which are gifts or presents or in case similar products or methods are unavailable in the market).

2. Dossiers and procedures of application for import licenses for chemicals and preparations without circulation registration numbers to be imported for assay or testing:

a/ An application for a license to import chemicals or preparations (made according to a set form);

b/ Within 5 (five) working days after receiving the application, the Ministry of Health (the Health Environment Management Agency) shall issue a document indicating its acceptance or rejection of the import of chemicals or preparations for assay or testing and clearly state the reason.

3. Dossiers and procedures of application for import licenses for chemicals and preparations without circulation registration numbers to be imported for research, donation or other particular purposes:

a/ A dossier of application for a license to import chemicals or preparations:

- An application for an import license (made according to a set form);

- A notarized copy of the business registration certificate or other papers proving the legal entity status of the import license applicant, which must be appended with the applicant's seal;

- Technical documents of chemicals or preparations;

- The research outline (for chemicals and preparations imported for research) or written explanations about the use purposes of chemicals or preparations (for those imported for particular purposes);

- A GMP or ISO certificate of the manufacturer and circulation permits of the chemicals or preparations granted by the country of origin or circulation permits granted by other countries in which the chemicals or preparations have been registered and sold, in case of importing chemicals or preparations for donation or other particular purposes in a total weight of 50 (fifty) kilograms upon each importation;

- The assay result slip, for the case specified in Clause 4, Article 19 of this Circular (supplemented to the dossier after the import license applicant receives it from the assaying unit);

b/ Within 15 (fifteen) working days after receiving a valid and complete dossier, the Ministry of Health (the Health Environment Management Agency) shall issue a reply stating its acceptance or rejection of the import. In case of rejection, the reason must be clearly stated;

c/ For the cases specified in Clause 4, Article 19 of this Circular:

- Within 5 (five) working days, the Ministry of Health (the Health Environment management agency) shall issue a written request for assay;

- Within 10 working days after receiving the assay result notice from the import license applicant, the Ministry of Health (the Health Environment management agency) shall issue a document stating its acceptance or rejection of the import. In case of rejection, it shall clearly state the reasons.

Chapter V

CIRCULATION OF CHEMICALS AND PREPARATIONS

Article 24. Labels of chemicals and preparations

1. When circulated in Vietnam, chemicals and preparations must have Vietnamese labels like the approved specimen labels enclosed with the circulation registration certificates granted by the Ministry of Health (the Health Environment Management Agency) and compliant with the law on labeling of goods circulated in the country and imports and exports.

2. Labels must be printed with legible and unfadable letters of at least 8 mm in size and must be durable in the process of circulation, preservation, transportation and use.

3. Labels must be securely stuck to or printed on chemical or preparation packages.

4. The color of label background must be different from the color indicating the toxicity class of chemicals and preparations.

5. Compulsory details of chemical or preparation labels:

a/ Trade name of the chemical or preparation;

b/ Composition and contents of active ingredients;

c/ Effects;

d/ Use and preservation instructions;

e/ Warnings about possible dangers to human health and the environment;

f/ First-aid treatment for cases of chemical or preparation poisoning;

g/ Name and address of the producer;

h/ Name and address of the processing, bottling or packaging unit (if any);

i/ Name and address of the unit responsible for the chemical or preparation;

j/ Manufacture lot number;

k/ Date of manufacture;

l/ Shelf life;

m/ Number of registration for circulation in Vietnam.

6. For chemicals and preparations put in small packages, their labels shall also be printed with letters at least 8 mm in size, and in case of insufficient space for printing compulsory information, an additional label must be attached to each package. In this case, the principal label of the package must display the phrase "Read carefully the attached additional label before use."

Such details as trade name, effects, name of the unit responsible for the chemical or preparation, quantity, date of manufacture and shelf life, must be displayed on the principal label.

7. In addition to the details specified in Clause 5 of this Article, the labels of chemicals and preparations of toxicity classes I, II, III, and IV according to the World Health Organization's classification must contain toxicity symbols (as specified in Appendix 6 to this Circular, *not printed herein*) as follows:

a/ A color strip indicating the toxicity of the chemical or preparation running cross the label with a height equal to 10% of that of the label shall be printed at the bottom of the label:

- Red strip, for chemicals and preparations of toxicity classes Ia and Ib;

- Yellow strip, for chemicals and

preparations of toxicity class II;

- Blue strip, for chemicals and preparations of toxicity class III;

- Green strip, for chemicals and preparations of toxicity class IV.

b/ Information on toxicity:

- "Very toxic" (toxicity classes Ia and Ib) with the toxicity symbol being a skull and crossbones in a lopsided square;

- "Highly toxic" (toxicity class II) with the toxicity symbol being a cross in a lopsided square;

- "Dangerous" (toxicity class III) with the toxicity symbol being an interrupted line in a lopsided square;

- "Careful" (toxicity class IV) without any toxicity symbol.

Symbols indicating toxicity classes of chemicals and preparations must be printed above their trade names.

Article 25. Packaging of chemicals and preparations

1. When circulated in Vietnam, chemicals and preparations must be put in packages satisfying the following requirements:

a/ Packages must be firm enough to stand normal impacts and shocks during transportation, transshipment and handling by manual or mechanical methods.

b/ Packages must be tight to prevent leakage of chemicals or preparations during transportation or being transported under impacts of vibration or increase of temperature, moisture or pressure.

c/ Each package may be disposable. Glass, glazed terracotta and porcelain bottles may be re-used after being cleansed;

d/ The outer surface of packages must be clean and free of any hazardous chemicals.

2. Packaging parts in direct contact with chemicals or preparations must meet the following requirements:

a/ Neither being affected nor deteriorated in quality due to impacts of packaged chemicals or preparations;

b/ Not affecting the composition, properties or effects of the packaged chemicals or preparations.

3. When packaging liquid chemicals or preparations, a necessary space must be left to ensure packages will not be leaked or deformed due to an increase in volume of packaged liquids when temperature increases during transportation.

4. Inner packages which are breakable or easily holed such as those made of glass, glazed terracotta, porcelain and some certain kinds of plastics must be insulated with appropriate shock-absorbing materials from the outer packaging layers.

5. Packages of volatile substances must be tight enough to ensure the volume of liquids will not decrease below the set limit during transportation.

6. Packages of liquids must stand the inside pressure built up during transportation.

7. Packages of liquid chemicals or preparations must be tested for leakage before

use.

8. Packages of granule or powdery chemicals or preparations must be tight enough to prevent leakage or have tight lining layers.

9. Packages must have a capacity corresponding to the net weight or volume shown on chemical or preparation labels.

Article 26. Transportation of chemicals and preparations

1. Chemical or preparation carriers shall comply with the provisions on transportation of hazardous goods in the laws on road, inland waterway, railway, air and sea transportation and other relevant laws.

2. Upon occurrence of chemical incidents during transportation, drivers, goods owners and vehicle owners shall promptly take measures to mitigate consequences and remedy the incidents and, at the same time, notify the incidents to fire brigades, concerned agencies and units and the administration of the nearest locality for coordinated response and remedy.

Article 27. Preservation of chemicals and preparations

1. Preservation of chemicals and preparations must assure human, livestock and environmental safety.

2. Storekeepers must be trained in labor safety and fire and explosion prevention and fighting in chemical and preparation preservation.

3. Upon occurrence of serious chemical incidents, chemical or preparation owners shall promptly take response measures under Clause 2, Article 26 of this Circular. Responsibilities to coordinate in responding to incidents comply with Clause 3, Article 42 of the Chemical Law. Chemical or preparation owners shall bear all expenses for remedying the incidents.

Article 28. Destruction of chemicals and preparations

1. Cases subject to destruction:

a/ Chemicals and preparations in production and trading with an expired shelf life;

b/ Containers and packages of chemicals and preparations which are not permitted for re-use; wastes generated from the production or trading of chemicals and preparations.

2. Chemicals and preparations for household or personal use only must be discarded according to producers' recommendations and the environmental protection law so as to assure human and environmental safety.

3. Organizations and persons having chemicals and preparations or chemical and preparation packages subject to destruction shall bear all destruction expenses. For chemicals and preparations or chemical and preparation packages with unidentified owners, provincial-level People's Committees of localities where such chemicals or preparations are managed shall allocate their budget funds for destruction according to regulations.

4. In the process of collecting and destroying chemicals and preparations and chemical and preparation packages, hazardous waste must not be scattered, dispersed or increased in the environment and must be treated with appropriate technologies in accordance with the

environmental protection law.

Article 29. Advertisement of chemicals and preparations

Advertisement of chemicals and preparation complies with the advertisement law.

Chapter VI
IMPLEMENTATION RESPONSIBILITIES

Article 30. The Ministry of Health's Health Environment Management Agency

1. To assist the Minister of Health in performing the state management of chemicals and preparations nationwide.

2. To act as the standing body of the Chemical and Preparation Appraisal and Approval Council.

3. To receive dossiers of registration for circulation, import and advertisement of chemicals and preparations; to consider and decide on the grant and revocation of circulation registration numbers; to preserve dossiers of registration for circulation, import and advertisement of chemicals and preparations under this Circular.

4. To issue, under authorization, decisions to grant circulation registration numbers for chemicals and preparations.

5. To issue, under authorization, decisions to revoke circulation registration numbers of chemical and preparation producers and traders violating Article 34 of this Circular.

6. To prepare modifications and supplementations to the lists of chemicals specified in Article 3 of this Circular for submission to the Minister of Health for promulgation on an annual basis, if there are any changes in chemicals and preparations in these lists.

7. To manage dossier appraisal charges under law.

8. To assume the prime responsibility for, and coordinate with concerned agencies in, conducting inspection and examination of chemicals and preparations nationwide.

Article 31. The Ministry of Health's Inspectorate

1. To inspect the implementation of this Circular nationwide in accordance with the inspection law.

2. To settle complaints and denunciations and handle detected violations committed by units engaged in chemical- and preparation-related activities nationwide.

Article 32. Chemical- and preparation-assaying units

1. To conduct assays for official registration, re-registration and additional registration of chemicals and preparations after obtaining assay permits from the Ministry of Health (the Health Environment Management Agency).

2. To conduct chemical and preparation assays according to the assay process promulgated by the Ministry of Health.

3. In case chemicals and preparations are permitted for assay but no relevant assay processes have been promulgated by the Ministry of Health, assaying units shall develop a process and submit it to the Ministry of Health (the Health Environment Management Agency)

for summarization, appraisal and submission to the Minister of Health for promulgation.

4. To take responsibility before law for the results of chemical and preparation assays.

5. To make periodical reports on chemical and preparation assays on June 15 and December 15 every year to the Ministry of Health (the Health Environment Management Agency). When detecting any differences in the actual dosage and the dosage recommended by the producer indicated on the product label, assaying units shall report such in writing to the Ministry of Health (the Health Environment Management Agency) for consideration and settlement.

6. The Ministry of Health shall consider removing assaying units that fail to comply with Clauses 1, 2, 3, 4 and 5 of this Article from the list of qualified assay units.

Article 33. Provincial-level Health Departments

1. To guide chemical and preparation producers, traders and users under their management in implementing this Circular and other relevant laws.

2. To coordinate with functional agencies in organizing inspection, periodical and unexpected examination and handling administrative violations in the field of chemical and preparation production, trading and use in their localities according to this Circular.

3. To send annual reports (made according to a set form) to the Ministry of Health (the Health Environment Management Agency) on December 15 every year or upon request of the Ministry of Health.

Article 34. Chemical and preparation producers and traders

1. To comply with this Circular and other relevant laws.

2. To send periodical reports on chemical and preparation production and trading to provincial-level Health Departments of localities where they are headquartered on November 30 every year.

3. To notify in writing the Ministry of Health (the Health Environment Management Agency) of changes in the names of chemical or preparation registrants or producers due to separation, merger or organizational transformation or of termination of chemical and preparation production and trading activities.

4. To take responsibility before law if their chemical and preparation production and trading activities cause adverse impacts on people, livestock and the environment and take responsibility for the quality of their products which are circulated and used.

5. To be subject to inspection, examination and handling of violations under law.

6. To recall, dispose of and destroy chemicals and preparations upon competent agencies' issuance of conclusions on violations involving chemicals and preparations.

Article 35. Chemical and preparation users

1. To only use chemicals and preparations

with valid circulation registration numbers.

2. Importers and users of chemicals or preparations which are permitted to be imported as donations or for use for particular purposes by the Ministry of Health (the Health Environment Management Agency) shall take full responsibility for the use of these chemicals or preparations.

3. To request chemical suppliers to provide sufficient information on hazardous properties of chemicals and preparations and requirements for assuring their effects and safety; to be entitled to compensation as provided by law from suppliers for damage they suffer when using chemicals and preparations due to untruthful information provided by suppliers.

4. To strictly follow use instructions shown on product labels or attached to chemicals and preparations and take full responsibility for improper use, to assure safety for themselves, the environment and community; if using chemicals and preparations causing damage to the health, life or property of others, to pay compensation according to law.

Chapter VII
IMPLEMENTATION PROVISIONS

Article 36. Effect

This Circular takes effect on January 1, 2012.

From the effective date of this Circular, the Minister of Health's Decision No. 3486/2001/QD-BYT of August 13, 2001, promulgating the Regulation on management of insecticidal and germicidal chemicals and preparations for household and family use and Section III on the import of insecticidal and germicidal chemicals and preparations for household and family use of Circular No. 08/2006/TT-BYT, guiding the import of vaccines, medical bio-preparations, insecticidal and germicidal chemicals and preparations for household and family use and medical devices, cease to be effective.

Any problems arising in the course of implementation should be promptly reported to the Ministry of Health for consideration and settlement.-

For the Minister of Health
Deputy Minister
TRINH QUAN HUAN