THAI AGRICULTURAL STANDARD

TAS 9032-2009

CODE OF PRACTICE FOR CONTROL OF THE USE OF VETERINARY DRUGS

National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
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National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
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Technical Committee on the Elaboration of the Thai Agricultural Standard for Code of Practice for Control of the use of Veterinary Drugs

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Industry of food-producing animals, including livestock, poultry, and fishery, for domestic consumption and export is a very important sector for the national economy. Currently trade barrier measures imposed by trading partners are the main obstacle for the export of meat products. Such measures include the regulations on the veterinary drug residues, the improvement of animal production chain from the farm level by using good agricultural practices on livestock production e.g. pig, broiler, dairy cattle, and layer, by applying good administration of veterinary drugs under the supervision of veterinarian or according to the prescription thereof as well as follow the appropriate withdrawal period. These practices are to reduce the unacceptable level of veterinary drug residues. Moreover, it could bring the trust to trading partner countries. The Agricultural Standards Committee deems it necessary to establish Thai Agricultural Standard on Code of Practice for Control of the Use of Veterinary Drugs.

This standard is based on the information of the following documents:

CAC/RCP 38-1993. Recommended International Code of Practice for Control of the Use of Veterinary Drugs. Joint FAO/WHO Food Standards Programme, FAO, Rome.

CAC/RCP 61-2005. Code of Practice to Minimize and Contain Antimicrobial Resistance. Joint FAO/WHO Food Standards Programme, FAO, Rome.

NOTIFICATION OF MINISTRY OF AGRICULTURE AND COOPERATIVES
SUBJECT: THAI AGRICULTURAL STANDARD:
CODE OF PRACTICE FOR CONTROL OF
THE USE OF VETERINARY DRUGS
UNDER THE AGRICULTURAL STANDARDS ACT B.E. 2551 (2008)

Whereas the Agricultural Standards Committee deemed necessary to establish an agricultural standard on Code of Practice for Control of the use of Veterinary Drugs as voluntary standard in accordance with the Agricultural Standards Act B.E. 2551 (2008) to promote such agricultural commodity standard to meet its quality standard and safety.

By virtue of Section 5, Section 15 and 16 of the Agricultural Standards Act B.E. 2551 (2008), the Minister of Agriculture and Cooperatives hereby issued this Notification of Thai Agricultural Standards: Code of Practice for Control of the use of Veterinary Drugs (TAS 9032-2009) to be a voluntary standard, details of which are attached herewith.

Notified on ……..B.E. 2552 (2009)

(Mr. Theera Wongsamut)
Minister of Agriculture and Cooperatives

THAI AGRICULTURAL STANDARD

CODE OF PRACTICE FOR CONTROL OF THE USE OF VETERINARY DRUGS

1. SCOPE

This agricultural standard establishes good practices for the use of veterinary drugs for food producing animals to avoid the excess of maximum residue limits of veterinary drugs in animals, animal produce and animal products for human consumption.

2. DEFINITIONS

For the purpose of this standard:

2.1 Veterinary drug means any substance applied or administered to food producing animals for diagnostic, therapeutic, or prophylactic purposes or for modification of physiological functions or behavior.

2.2 Residues of veterinary drug mean the remains of veterinary drug as in 2.1 both the parent drug and its metabolites, as well as the associated impurities of the concerned veterinary drug remaining in any portion of animal tissue, produce and products for human consumption.

2.3 Veterinarian means a person who possesses the veterinary license according to the Veterinary Profession Act B.E. 2545 (2002) and its amendments.

2.4 Assigned person means a person who is assigned and instructed in writing by the qualified veterinarian to use the veterinary drugs.

3. REQUIREMENTS AND INSPETION METHODS

Requirements and inspection methods shall be as Table 1.

Table 1 Requirements and Inspection Methods

(Section 3)

Items	Requirements	Inspection Methods
1. Source of veterinary drugs	1.1 Veterinary drugs shall be registered with the competent authority	1.1 Inspection of drug registration number or relevant documents from the registration files of the Food and Drug Administration, the Department of Livestock Development and the Department of Fisheries
	1.2 Veterinary drugs shall be from legal sources.	1.2 Inspection of the sources of veterinary drugs
2. Veterinarian and authorized person	2.1 There shall be a veterinarian who is responsible for disease diagnosis, therapy, prophylaxis, treatment, control and recommendation of the drug use, determination of drug withdrawal periods and issuance of veterinary prescription.	2.1 Inspection of veterinary license
	2.2 A person assigned by the veterinarian shall be trained to use veterinary drugs and strictly supervised by the veterinarian.	2.2 Inspection of evidences of an authorised person, evidence of training and assignment
3. Information of veterinary drugs	3. Important information shall be shown on labels and in accompanied document.	3. Inspection of labels and accompanied document
4. Preparation of drugs	4. Drug preparatory person shall be trained on techniques and equipment used for drug preparation correctly.	4. Visual inspection and/or check training record of drug preparatory person or veterinary drug mixer

Items	Requirements	Inspection Methods
5. Administration of veterinary drug	5.1 Drug administration shall follow the veterinarian's prescription except non-prescription drugs 5.2 Expired drugs shall not be used. 5.3 Leaflet or detailed instruction of drug use shall be provided. 5.4 Drug withdrawal periods shall be adhered to the prescription to avoid drug residues in meat or animal products. 5.5 Scheduleof veterinary drug use for disease prophylaxis shall be advised by the veterinarian.	5.1 Inspection of prescription or instruction if administored by authorized person and inspection of veterinarian's drug lists for the classification of prescription drugs and non-prescription drugs 5.2 Inspection of drug expiry date 5.3 Inspection of manual for drug use 5.4 Inspection of drug administration record and withdrawal periods 5.5 Inspection of schedule of veterinary drug use
6. Record keeping of veterinary drug use	6. Veterinarian and/or farm owner or authorised person shall keep record the use of veterinary drugs and maintain it for at least 3 years for further inspection.	6. Check record keeping of veterinary drug use
7. Incidental withdrawal of veterinary drugs	7. If it is suspected that the veterinary drug causes adverse effects to animals, the veterinarian or authorised person shall stop using of such drug immediately, record the side effects and report to the competent authority.	7. Check record on veterinary drug use and side effects
8. Storage of veterinary drugs	8. Veterinary drugs shall be stored in accordance with manufacturers' recommendation	8. Visual inspection of veterinary drug storage
9. Disposal of off-use veterinary drugs	9. The remained veterinary drugs shall be disposed according to the labeled instruction or veterinarian's recommendation.	9. Inspection of disposal methods

4. GUIDANCE FOR PRACTICES FOR CONTROL OF THE USE OF VETERINARY DRUGS

Recommendations on practices for control of the use of veterinary drugs are aimed to provide relevant persons such as farmers, farm operators and veterinarians a guidance for the control of veterinary drug administration in order to avoid drug residues in meat and animal produce or products. The details of such recommendations are explained in Appendix A and B.

APPENDIX A

GUIDANCE FOR PRACTICES FOR CONTROL OF THE USE OF VETERINARY DRUGS

(Section 4)

A.1 SOURCE OF VETERINARY DRUGS

A.1.1 Veterinary drugs and medicated premixes for use shall have formula registered with the competent authority.

A.1.2 Sale and distribution of veterinary drugs shall be performed by the persons permitted by laws. Veterinary drug accounting shall be made by recording the sale, distribution and stock for monitoring and inspection. Storage of veterinary drugs shall conform with the recommendation of drug manufacturers.

A.1.3 Veterinary drugs, both modern and traditional, shall be purchased from the veterinary drug business operators who obtain legal permissions according to the relevant laws. Such operators have various types, e.g. seller of self-manufactured veterinary drug, wholesalers, pre-packaged drug retailers.

A.2 VETERINARIAN AND AUTHORISED PERSON

A.2.1 Responsibility of veterinarian

A.2.1.1 The practices of veterinarian who is responsible for disease diagnosis, prevention and treatment are as follows:

(1) Control the veterinary drug administrationcorresponding to the disease diagnosis regarding to drug type, dose, quantity, and withdrawal period which shall not be less than that specified on the registered label or in the accompanied document.

(2) Prioritise good farm management. Control and limit the use of veterinary drug as necessary to avoid the hazards of residues in the treated animals, to environment and the development of microbial drug resistance.

(3) Assess animal health status for the administration of veterinary drugs and/or primary preventive products, as necessary, e.g. vaccination program, issuance of prescription and control the drug use record keeping. Advise the farm operator on the classification of medicinal products e.g. the medicinal products used by the authorised person under direct supervision of a veterinarian, the medicinal products used by the authorised person without prescription from a veterinarian, and the disinfectants for equipment and animal housing.

(4) Provide treatment to obtain the maximum effectiveness with the minimum drug use. Avoid the use of mixed veterinary drugs that contain more than one active ingredient in a formula. Moreover, such formula shall be registered with the competent authority. Veterinarian shall avoid the use of self-mixed drugs.

(5) The veterinarian shall stress the need for diseased animals to be segregated from healthy animals and treated individually where possible.

A.2.1.2 When the drug administration is not under direct veterinarian's supervision, it is the veterinarian's responsibility to diagnose the disease, give advice, order the treatment and provide prescription of specific drugs for such disease to the authorised person to take action. Also, caution shall be taken that potentially hazardous effects may occur in animals or in operators.

A.2.1.3 Clear instructions shall be provided to the authorised person on dose, method of use, calculation of drug administration, appropriate drug mixing method and monitoring of withdrawal period.

A.2.1.4 Veterinarian is responsible for supervision and taking care of animal welfare.

A.2.2 Responsibility of authorised person

A.2.2.1 Accurately administer veterinary drug to animals and record the use as recommended and/or prescribed by veterinarian.

A.2.2.2 Clearly instructed by veterinarian on dosage, method of drug use, calculation of drug administration including appropriate drug mixing method and monitoring of withdrawal period.

A.2.2.3 Prioritise good farm management. Control and limit the use of veterinary drug as necessary to avoid the hazards of residues in the treated animals, to environment and the development of microbial drug resistance..

A.3 INFORMATION ON VETERINARY DRUGS

The formulas of veterinary drugs shall be registered with the competent authority. The drug information shall be made available in the form of labeling, accompanied documents coveringamount of active ingredients, dosage, indications, caution, withdrawal periods, storage condition, production date, expiry date, contra-indications, warning, etc.

A.4 PREPARATION OF DRUGS

A.4.1 This requirementof drug preparation means the preparation or mixing of registered veterinary drugs including the mixing of drug with feed for the purpose of prevention or treatment of animal diseases under the supervision of the responsible veterinarian only, not for sale.

A.4.2 Farm operator shall have farm record on drug receiving and keep the accompanied document of each drug where important details and source of drug shall be clearly identified (Appendix B.1).

A.4.3 Drug preparatory person shall be the veterinarian or the authorised person who has been trained on the appropriate techniques and equipment used for mixing of drugs.

A.4.4 Good practices shall be applied when preparing or mixing drugs e.g. clean and appropriate area and equipment, caution of danger from drug mixing by wearing gloves and mask for safety reason.

A.4.5 Mixing drug with feed requires certain procedures for homogenised content, exact formula, and avoidance cross contamination during mixing e.g. sequencial steps of mixing , cleaning the equipment, and without banned substances .

A.5 ADMINISTRATION OF VETERINARY DRUGS

A.5.1 Amount of veterinary drug administered to animals shall be corresponding to the disease treatment or prevention as recommended by the veterinarian and shall not be excessiveas necessary. The use of vaccines, hormones, antimicrobials and drugs causing residues in animal products shall be prescribed only by the veterinarian (Appendix B.2).

A.5.2 If the drug administration is made by the authorised person following the veterinarian's prescription. Clear instructions shall be recived in writing from the responsible veterinarian and strictly followed (Appendix B.3).

A.5.3 Using of veterinary drug required no veterinarian's prescription shall follow the indications specified on the label or accompanied document as approved or registered with the competent authority.

A.5.4 In disease circumstances where no registered drug available or no certain indications or target species on labels, the responsible veterinarian can recourse to other registered drugs or off label use.

Administration of drug in this manner may have unpredictable side effects and give rise to unacceptable residue levels to consumers; therefore the veterinarian shall take the most careful consideration or consult the drug manufacturer.

Under these circumstances, the responsible veterinarian shall practice as follows:

A.5.4.1 Record the prescription, provide the written instructions on the drug use and the withdrawal periods

A.5.4.2 Do not allow any persons other than the responsible veterinarian to use the off label drugs except such use is conducted by the authorized person who has been assigned in writing by the veterinarian only.

A.5.4.3 Take full discretion for the safety of consumers e.g. extension of withdrawal period, use the off label drugs only for breeders whose products are not for human consumption.

A.5.5 Person administering veterinary drugs shall strictly follow the instruction of such drugs and drug quality shall be conformed with the drug characteristics such as physical properties on colour, powder or solution, etc., production date, expiry date, storage. If medicated feed is used, the medication shall be recorded (Appendix B.4).

A.5.6 The use of antimicrobial drugs shall be prescribed only by the veterinarian who is directly responsible for the animal or herd health. The veterinarian shall have enough time to examine the animal or herd health for disease diagnosis before giving the prescription or to assess the animal or herd health status in order to diagnose and prescribe the drugs.

The following issues shall be taken into account when recommendations are given on the use of antimicrobial drugs:

A.5.6.1 Efficiency of treatment, impact of drug to animal, risk of drug resistance and undesirable impact to commensal flora

A.5.6.2 When deciding on antimicrobials, the narrow spectrum antimicrobials shall be first prioty as the broad spectrum antimicrobials may affect many microbial types which will increase risk of drug resistance of microbial development.

A.5.7 Farm operators shall be strictly prohibited to use veterinary drugs without veterinarian's prescription except the use of common household drugs for animals according to the Drug Act B.E. 2510 (1967) and its amendments or the use of drugs as specified in the Notification. However, the use of such drugs shall be informed to the veterinarian and recorded. Drug administration other than the one indicated on the label/accompanied document is not permitted except it is prescribed by the veterinarian.

A.5.8 Farm operators and drug users shall adhere to the drug withdrawal periods before sending animals to slaughter house or having animal products for consumption to avoid drug residues in meat or other animal products. The withdrawal period shall not be less than the one specified on the label or accompanied document of such drug as registered with the competent authority or as recommended in writing by the veterinarian.

A.5.9 If it is necessary to sell animals before the end of the drug withdrawal period, the responsible veterinarian shall inform the buyers of the animal treatment history and the required drug withdrawal period.

A.5.10 If drug is administered by using disposable equipment, it shall be disposed as recommended by the manufacturer or by the responsible veterinarian.

A.5.11 Cleaning of equipment for drug administration shall be properly done to ensure the safety of human health and environment. After cleaning, any equipment containing the remains of the veterinary drug shall be disposed using the same procedures that apply to disposal of the drug itself and following the recommendation of the veterinarian or the competent authority.

A.5.12 Farm operators shall have instruction of the veterinarian as the guidelines for cleaning and disposing of equipment or containers.

A.6 RECORD KEEPING OF VETERINARY DRUG USE

The responsible veterinarian and/or the farm owner or the authorized person shall record the detail of veterinary drug use such as type of drug, dosage, amount of drug, date of drug administration, detail of drug administered animals and drug withdrawal period. The records shall be maintained for at least 3 years and made available for further inspection (Appendix B.5).

A.7 INCIDENTAL WITHDRAWAL OF VETERINARY DRUGS

A.7.1 Incidental withdrawal of veterinary drug means stoppage the use of veterinary drug during treatment programme when it is suspected that adverse effects involving abnormal clinical signs or death in animals or any harmful effects in person administering veterinary drug have been associated with the drug. The responsible veterinarian or authorised person shall immediately stop using the veterinary drug or take action according to the responsible veterinarian's judgement.

A.7.2 The responsible veterinarian or authorized person shall report the adverse side effects of the veterinary drug to the competent authorities responsible for the quality control of the veterinary drug use e.g. the Food and Drug Administration and/or the

Department of Livestock Development, the Department of Fisheries, as is the case, and also report to the veterinary drug manufacturer.

A.8 STORAGE OF VETERINARY DRUGS

A.8.1 Veterinary drugs shall be stored in accordance with the manufacturers' recommendation which is instructed on the labels or on the containers. The critical storage conditions are temperature and moisture as the quality of drugs may be deteriorated by improper storage.

A.8.2 Storage of veterinary drugs shall be separated according to the types of drugs. Prescribed drugs shall be separated from non-prescribed drugs.

A. 8.3 All veterinary drugs shall be stored in secure places and kept locked where practicable to prevent movement of drugs by unauthorized persons, and out of reach of children and animals.

A.9 DISPOSAL OF OFF-USE VETERINARY DRUGS

Veterinary drugs remaining after completion of treatment shall be safely disposed according to the labeled instructions or as recommended by the veterinarian or the competent authority to reduce the contamination to the environment.

APPENDIX B

B.1 Example of record on veterinary drug receiving

(Section A.4.2)

Name and address of farm..... Name and address of farm owner.....

Receiving date	Veterinary drug name		Registration No.	Drug appearance	Volume		Lot No.	Expiry date	Evidence of purchase/Source
	Trade name	Common name			size	number			

B.2 Example of prescription

(Section A.5)

Veterinarian (name and address).....

License No.....

Farm owner (name and address).....

Identified animal that receive drug under supervision of veterinarian.....

(e.g. species, age, herd no.or code, sex, weight)

Date of prescription.....

Common name of drug .....

Trade name of drug.....

Registration No.....

Purpose of medication.....

Route of medication.....

Dose, Amount of drug (dose per weight of treated animal, number of medication per day, amount of drug in feed or in drinking water)

.....

Medication period (number of consecutive days for drug administration).....

Drug withdrawal periods.....

Total amount of drug administration.....

Contraindication and warning.....

.....

Signature of responsible veterinarian

B.3 Example of drug usage assignment form
(Section A.5.2)

Date.....

I undersigned hereby,.....who posses the Veterinary First Class License No.....date of issuance..... valid until..... , agree to assign the drug usage according to my prescription from date.....to date..... for the farm owner whose Name is..... Farm name..... Address..... ..... to the following persons

1. ..... Position.....
2. ..... Position.....
3. ..... Position.....
4. ..... Position.....
5. ..... Position.....

.....

( )

Responsible veterinarian

B.4 Example of record on veterinary drug mixing in feed

(Section A.5.5)

Name and address of farm ..... Name and address of farm owner.....

Veterinary Drug mixing equipment .....

Veterinary Drug mixing Date	Veterinary Drug registration No./Lot No.	Veterinary Drug Name			Mixing medium Type/Amount	Indicated feed Type/Amount	Total amount after drug mixing	Indicated animal and number of animals receiving drug mixed feed	Person mixing veterinary drug
		Active ingredient	Trade name	Prescription No.					

B.5 Example of record on veterinary drug use (poultry farm)

(Section A.6.1)

Name of veterinarian.....

Farm owner.....Address.....

Crop No. ..... House No..... No. of birds per house.....Breed.....Sex.....

Veterinary Drug name	Reg. No.	Batch No.	Manufacturer	Active ingredient	Bird age (day)	Average weight per head (kg)	Drug administration date	Dosage	Date and time of drug administration	Total amount of drug administration	Drug withdrawal periods (no. of days)	Indicated date of safe drug withdrawal	Route of drug administration	Reason of drug administration	Farm veterinarian	Authorized person

B.6 Example of report on adverse side effects of veterinary drug use

(Section A.7.2)

<table>
<tr><td colspan="5">Name and address of farm.....
.....
Name and address of farm owner.....</td></tr>
<tr><td colspan="2">1. Veterinarian (Name, Address, Telephone)

Veterinary License No. .....</td><td colspan="3">2. Authorized person (Name, Address, Telephone)</td></tr>
<tr><td colspan="2">3. Suspected veterinary drug causing adverse side effects
3.1 Drug Name.....
3.2 Registration No.....</td><td colspan="3">4. Veterinary drug Manufacturer</td></tr>
<tr><td colspan="2">5. Disease diagnosis before medication</td><td colspan="3">6. Veterinary drug administered by Date ...../...../.....
☐ veterinarian
☐ authorized person</td></tr>
<tr><td colspan="5">7. Detail of veterinary drug administration (i.e. dosage, amount, route, drug mixing method)

☐ Use with other veterinary drugs i.e. .....</td></tr>
<tr><td>8. Species of veterinary drug administered animal</td><td>9. Breed</td><td>10. Age</td><td>11. Sex</td><td>12. Weight</td></tr>
<tr><td colspan="5">13. Animal health before veterinary drug administration ☐ healthy ☐ fair ☐ poor ☐ coma</td></tr>
<tr><td colspan="5">14. Information on reaction or symptom
14.1 Length of time that symptom occurred after medication.....
14.2 Occurrence
☐ Animal died ☐ Complete medication ☐ Adjust dose of veterinary drug
☐ Animal alive ☐ Stop medication immediately ☐ Change for new veterinary drug
☐ Temporarily stop medication and resume afterwards ☐ Others.....
14.3 Animal symptom from adverse side effects was treated.....</td></tr>
<tr><td colspan="5">15. Explain the symptom of adverse side effects from drug administration</td></tr>
</table>

B.7 Veterinary Drug Formula Registered under the Food and Drug Administration

(Informative/ Section A.3)

B.7.1 Registered veterinary drug formula shall have the label on a container and package according to the registration with an accompanied document. If the accompanied document is in foreign language, it needs to have Thai translation. Information on the label and in the accompanied document shall be clearly readable.

B.7.2 The label shall contain the following information:

a. Drug name

b. Drug formula registration number or code

c. Net content

d. Name and content or strength of active ingredient which is the main component of drug corresponding to the registered drug formula (except the traditional drug)

e. Lot number of manufacturing or analysis

f. Name and province of domestic manufacturer ,or name, city and country of foreign manufacturer including the name and address of importer or name and address of foreign manufacturer including name and address of domestic packer

g. Manufacturing date

h. The wording “dangerous drug”, “specially controlled drug”, “for external use only” or “for topical use” whatever the case may be shall be clearly labeled in red .

i. The word “household remedy drug” if the drug is considered to be that.

j. The word “veterinary drug”

k. date of expiration (except traditional drug)

l. Caution statement shall be on the label and in the accompanied document according to the notification of the Minister

In addition, the Ministry of Public Health has laid down the requirement that the modern drug shall indicate the storage condition on the label and in the accompanied document to inform the user of how to keep the drug properly till the expiration date.

If the veterinary drug is used for food producing animal and the withdrawal period is required, there shall be a specified withdrawal period on the label and in the accompanied document.

If the label is either small and less than 3 square inch, or adhered on the bottle/vaccine ampule, the complete information as shown in B.7.2 shall be exempt, however, the following information should be at least specified

(1)

- Drug name,

- drug formula registration number or code;

- the wording “dangerous drug”, “specially controlled drug”, “for external use only” or “for topical use only” whatever the case may be shall be clearly labeled in red .

- The date of expiration;

OR

(2)

- Drug name,

- Date of manufacturing lot or analysis,

- Date of expiration

B.7.3 Description of drug formula registration number or code

Drug formula registration number or code consists of numeric, letter, , and symbol totally of 5-9 characters can be described as follows:

(1) In case of modern drug

- the first character is 1 or 2
- the second is D, E or F
- then followed by the numeric of 1 to 4 digits
- the next is symbol of " / "
- and the last is the numeric of 2 digits

(2) In case of traditional drug

- the first character is L, M or N
- then followed by the numeric 1 to 4 digits
- next is the symbol of " / "
- and the last is the numeric of 2 digits

Description

B.7.3.1 The number 1 or 2 represents the number of active ingredient in the drug formula. "1" means a single active ingredient in the drug formula. "2" means more than one active ingredients in the drug formula.

B.7.3.2 The letters represent types of registered drugs as follows:

A means modern drug for human manufactured in Thailand
B means imported modern drug for human and repackaged in Thailand
C means imported modern drug for human
D means modern drug for animal manufactured in Thailand
E means imported modern drug for animal and repacked in Thailand
F means imported modern for animal
G means traditional drug for human manufactured in Thailand
H means imported traditional drug for human and repacked in Thailand
K means imported traditional drug for human
L means traditional drug for animal manufactured in Thailand
M means imported traditional drug for animal and repacked in Thailand
N means imported traditional drug for animal

B.7.3.3 The following 1-4 digit number, symbol of "/" and the last 2 digit number represent the sequence of registration in each year in which the last 2 digits indicate year of registration, for examples

(1) Registration No. 1A 326/51 means modern drug formula for human manufactured in Thailand with single active ingredient registered in Year B.E. 2551 (2008), Formula No. 326.

(2) Registration No. 1D 327/51 means modern drug formula for animal manufactured in Thailand with single active ingredient registered in Year B.E. 2551 (2008), Formula No. 327.

(3) Registration No. 2F 32/49 means imported modern drug formula for animal with more than one active ingredient registered in Year B.E. 2549 (2006), Formula No. 32.

(4) Registration No. M 1/27 means imported traditional drug for animal and repacked in Thailand registered in Year B.E. 2527 (1984), Formula No. 1.

B.8 Label and accompanied document of veterinary drug

(Informative/ Section A.3)

B.8.1 Example of drug label

B.8.1.1 Large label (providing complete information)

(1) Drug manufactured in Thailand

TIAMULIN Ppremix ← Drug name

each 1 kg contains:-
Tiamulin hydrogenfumarate 100 mg ← Name and quantity or strength of main active ingredient

Letter in red → dangerous drug veterinary drug

Batch No. 520001 Manufacturing batch number or letter

Mfg. Date 10/3/52 ← Manufacturing date

Exp. date 09/3/54 ← Expiration date

Reg. No. 1D 999/50 ← Drug formula registration number or code

Withdrawal period →
Withdrawal of at least 7 days prior to slaughtering

Store in dry condition at temperature below 30°C ← storage condition

Manufactured by

Prosperous Animal Drug Co., Ltd.
400 Prachasongkor Road, Din Daeng, Bangkok 10400 ← Name and address of drug manufacturing plant
Tel. 0 2222 2222

(2) Imported drug

SULFA TRIMET ← Drug name

each 100 mg contains:-
Sulfadimethoxine sodium 20 g ← Name and quantity or strength of more than one active ingredients
Trimethoprim 4 g

Letter in red → dangerous drug veterinary drug

Batch No. 500001 ← Manufacturing batch number or letter

Mfg. Date 10/3/2007 ← Manufacturing date

Exp. date 09/3/2009 ← Expiration date

Reg. No. 2F 999/45 ← Drug formula registration number or code

Withdrawal Time:- Meat 7 days ← Withdrawal period

Store below 25°C protect from light ← Storage condition

Manufacturer
Good Animal Drug Co., Ltd. ← Name and address of foreign manufacturing plant
Paris, France

Importer
Illustrious Animal Drug Co., Ltd.
400 Prachathipok Road, Bangkok ← Name and address of importer
Tel. 0 2999 9999

(3) Imported drug and repacked in Thailand

SULFA TRIMET ← Drug name

each 100 mg contains:-
Sulfadimethoxine sodium 20 g
Trimethoprim 4 g
← Name and quantity or strength of more than one main active ingredients of drug

Letter in red → dangerous drug veterinary drug

Batch No. 500001 ← Manufacturing batch number or letter

Mfg. Date 10/3/2007 ← Drug manufacturing

Exp. date 09/3/2009 ← Expiration date

Reg. No. 2E 2/45 ← Drug formula registration number or code

Withdrawal of drug at least 7 days prior to slaughtering ← Withdrawal periods

Store below 25°C protect from light ← Storage condition

Manufacturer
Good Animal Drug Co., Ltd. ← Name and address of foreign manufacturing plant
Paris, France

Repacker

Prosperous Animal Drug Co., Ltd.
400 Prachasongkor Road, Din Daeng, Bangkok 10400 ← Name and address of repacking plant
Tel. 0 2222 2222

B.8.1.2 Small label with area not more than 3 square inches, e.g. ampule,

Iron Dextrans Inj. ←	Drug name
Lot No. C003	
Exp. Date 10/2009	

Or

Iron Dextrans Inj. ←	Drug name
Reg No. 2D 1122/52	
Expire date 10/2009	
Dangerous drug ←	In red

B.8.2 Accompanied document

Accompanied document is the document providing pharmacological properties and indication of drug including dosage and method of use. The law stipulates that the caution statement according to the Notification on Drug Warning Requirement shall be shown in the accompanied document. If the accompanied document is in foreign language, the Thai translation shall be made available. The details in the accompanied document shall include the followings:

(1) Drug name
(2) Permissible use of drug to the species of animal
(3) Name and content or strength of active ingredient which is the main component of drug corresponding to the registered drug formula
(4) Pharmacological properties
(5) Indication
(6) Dosage and administration route
(7) Withdrawal period
(8) Contraindication and caution
(9) Storage condition
(10) Warnings according to the law

Example of Accompanied Document

Premix for medicated feed Tiamulin hydrogen fumarate premix (10%) for swine

Composition:

In 1 g of medicated feed is composed of Tiamulin hydrogen fumarate 100 mg

Pharmacological properties:

Tiamulin is the semi-synthetic antimicrobial drug which is the derivative of pleuromutilin in the macrolids group. It has bacteriostatic effect on Gram positive and Gram negative bacteria which is sensitive to this drug.

Indication:

Tiamulin is used for treatment of swine dysentery caused by *Brachyspira hyodysenteriae* which is sensitive to this drug.

Dosage and administration route:

For treatment of swine dysentery: mix drug with feed –200 g of Tiamulin hydrogen fumarate with 1 t of feed or 200 mg/kg, or 2 kg Tiamulin hydrogen fumarate premix (10%) with 1 t of feed.

The above medicated feed shall be used continuously for 14 days

If symptoms do not improve after 5 days of administration, consult veterinarian.

Use of drug is under recommendation and supervision of licensed veterinarian

Withdrawal period:

For the use of 200 g of Tiamulin hydrogen fumarate in 1 t of feed or 200 mg/kg for swine dysentery treatment

Stop drug administration at least 7 days prior to slaughtering

Contraindication and caution:

1. Do not use in animal that is allergic or sensitive to Tiamulin
2. Animal administered with Tiamulin shall not receive drug or feed mixed with drug in polyether ionophores group i.e. lasalocid, monensin, narasin, salinomycin, semduramycin, etc. because animal may have side effect such as severe growth depression and may be dead.
3. If it is necessary to administer Tiamulin in combination with drugs in polyether ionophores group, a minimum of 7 day period shall be provided between administrations of each drug.
4. If toxic symptom or side effect is found from drug use i.e. erythema or mild edema of skin, stop using drug immediately.
5. Do not use in swine having weight over 250 pounds (113.63 kg)

Caution for an operator who mixes drug with feed and administers such drug:

1. Operator who is allergic to tiamulin shall not be allowed to mix drug with feed or administers such drug.
2. Operator shall wear rubber gloves, glasses, mask to avoid the drug contact or inhalation.
3. If there is an occurrence of allergy from contacting with drug i.e. rash, swelling of face, mouth or eyes or difficult breathing, the operator shall visit doctor immediately.

4. After each mixing, the contacted parts of body shall be totally washed.

Storage:

1. Keep in dry condition, in original container or package, temperature not over 30 ^{o}C and away from light
2. After mixing, keep the medicated feed for ……days/months

APPENDIX D

UNITS

Units and symbols used in this standard and the SI unit (International System of Units or *Le Système International d' Unitiès*) approved to be used are:

Items	**Unit**	**Unit Symbol**
mass	milligram	mg
	gram	g
	kilogram	kg
	tonne	t
concentration	milligram/kilogram	mg/kg
temperature	degree Celsius	^{o}C