Republic of the Philippines
DEPARTMENT OF AGRICULTURE
Office of the Secretary
Elliptical Road, Diliman, Quezon City 1100
Philippines TIN 000845895

Administrative Order
No. 24
Series of 2009

SUBJECT : IMPLEMENTING GUIDELINES ON THE NATIONAL VETERINARY DRUG RESIDUES CONTROL PROGRAM IN FOODS PURSUANT TO ADMINISTRATIVE ORDER NO. 14, Series of 2006

WHEREAS, Section 3(a), Republic Act No. 9296, otherwise known as the Meat Inspection Code of the Philippines, declares that the State shall ensure the protection of human and animal health against direct and indirect hazards and in particular, the protection of consumers against zoonotic diseases, meat-borne infection, intoxication and hazards associated with residue from treatment or exposure of the slaughter animal;

WHEREAS, Section 3(b), Republic Act No 9711, otherwise known as Food and Drug Administration (FDA) Act of 2009 mandates the FDA to help establish and maintain effective health products regulatory system and undertake appropriate health manpower development and research responsive to the country's health needs and problems;

WHEREAS, Section 4(b)(c),(***Id***.) mandates the FDA to assume primary jurisdiction in the collection of samples of health products, and to analyze and inspect health products in connection with the implementation thereof;

WHEREAS, Section 4(j), (***Id.***) mandates the FDA to issue cease and desist orders *motu propio* or upon verified complaint, for health products whether or not registered with the FDA;

WHEREAS, Section 4(j), (***Id.***) mandates the FDA to order the ban, recall and/or withdrawal of any health product found to have caused death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive and to require all concerned authorities to implement the risk management plan;

WHEREAS, Republic Act No 1556, otherwise known as Livestock and Poultry Feeds Act and the DA - DOH Memorandum of Agreement relative to the registration of veterinary drugs and licensing of establishments and outlets signed in September 25, 1991, mandate the Bureau of Animal Industry (BAI) to regulate and control the manufacture, importation, labeling, advertising, distribution and sale of livestock and poultry feeds;

WHEREAS, Sections 62 and 65(1) of Republic Act No 8550, otherwise known as the Philippine Fisheries Code of 1998, respectively, mandate the Department of Agriculture-Bureau of Fisheries and Aquatic Resources (DA-BFAR) to set quality grades/standards for all fishery products for export and import; and to implement an inspection system for import and export of fishery/aquatic products and fish processing establishments consistent with international standards to ensure product quality and safety;

WHEREAS, Administrative Order No. 14, series of 2006 was issued to implement the National Veterinary Drug Residues Control Program and Creation of the Inter-agency Committee to ensure compliance to international standards on residues of veterinary drugs in food and rational drug use in feeds;

WHEREAS, Philippine National Standard No. 60:2008 Code of Good Animal Husbandry Practices (GAHP) and Fisheries Administrative Order No. 214,series of 2001 Code of Practice for Aquaculture which uphold Good Aquaculture Practice (GAqP) were issued to identify and establish management practices to minimize risks from internal and external factors through traceability and certified sources of food from farm to table for the production of safe and quality foods;

WHEREAS, Codex Alimentarius Commission on its 32nd Session, approved the adoption of the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals;

WHEREAS, Competent Authorities shall cooperate with academe, industry associations, professional organizations, consumer groups and other agencies in the formulation and enforcement of standards to ensure consumer health and safety;

WHEREAS, the presence of veterinary drug residues in food is a concern that should be addressed in the production, processing and marketing systems of food producing animals and food products derived from them.

NOW THEREFORE, I, ARTHUR C. YAP, Secretary of the Department of Agriculture, with the powers vested on me by law, do hereby issue this Administrative Order on the Implementing Guidelines of the National Veterinary Drug Residue Control Program in Foods.

Section 1. SCOPE
This Order applies to the manufacture, importation, exportation, distribution, administration, regulation, control and rational use of veterinary drugs in food producing animals.

Section 2. DEFINITION OF TERMS

2.1 AGENT – a person who is deemed authorized to act or transact for or in behalf of the producers, operators, traders and handlers.

2.2 ALLIED INDUSTRIES – include feed or veterinary drug manufacturers importers, distributors, traders, outlets and retailers.

2.3 AQUACULTURE – fisheries operations involving all forms of breeding, raising and farming of fish and other fishery species in fresh, brackish and marine water area by means of hatcheries, cages, pens, ponds and similar operations as defined in FAO No. 214, series of 2001.

2.4 BANNED VETERINARY DRUGS – veterinary drugs that are prohibited for use in the production of food producing animals.

2.5 COMPETENT AUTHORITY/IES – official government agency/ies having jurisdiction over existing regulations governing the control and rational use of veterinary drugs in food producing animals and food of animal origin.

2.6 EDIBLE OFFALS - tissues aside from meat approved for human consumption.

2.7 FOOD PRODUCING ANIMALS – all farmed and aqua-cultured animals intended for human consumption.

2.8 GOOD ANIMAL HUSBANDRY PRACTICES (GAHP) – general principles of good practice and minimum requirements in the commercial or backyard rearing / farming of food producing animals.

2.9 GOOD AQUACULTURE PRACTICES (GAqP) – use of responsible aquaculture in accordance to the guidelines agreed between DA- BFAR and stakeholders FAO No. 214.series of 2001, Code of Practice for Aquaculture.

2.10 MAXIMUM RESIDUE LIMIT OF VETERINARY DRUG (MRLVD or MRL) – maximum concentration of residue resulting from the use of veterinary drug (expressed in mg/kg or ug/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on food.

2.11 MEAT- fresh, chilled or frozen edible carcass including offal derived from food producing animals.

2.12 MEAT PRODUCT- any product capable for use as human food which is made wholly or in part from any meat or other portion of the carcass of any food producing animals, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat industry, and which are exempted from definition as a meat product by the Secretary under such conditions as he may prescribed to assure that the meat or other portions of such carcasses contained in each product are not adulterated and that such products are not represented as meat products.

2.13 PERSON – any individual, partnership, corporation or association, trust, government or governmental subdivision or any other legal entity.

2.14 POST-PRODUCTION ESTABLISHMENTS – facilities where products of animal origin are handled and processed such as but not limited to abattoir, poultry dressing plant, meat processing plant, dairy plant, poultry product processing plant and fish cold storage, fish processing and reprocessing plant, fish landing sites, auction and wholesale markets.

2.15 RESTRICTED VETERINARY DRUGS – veterinary drugs that are prescribed for therapeutic use in regulated dose and duration as established by Philippine National Standard (PNS) and adopted international standard;

2.16 RISK PROFILING – act of describing food safety problem and its context.

2.17 VERIFICATION PROGRAM – a combined system of inspections/audits and sampling/ laboratory analyses implemented throughout the food chain to assess 1) the effectiveness of a control system and 2) the compliance by individuals or groups

2.18 VETERINARY DRUG– any substance applied or administered to any food producing animal for therapeutic, prophylactic, diagnostic purposes or for modification of physiological functions/behavior.

2.19 VETERINARY DRUG RESIDUE – includes the parent compounds and/or their metabolites in any edible and inedible portion of the animal product and residues of associated impurities of the veterinary drug concerned or the amount of the drug that can be detected in edible and inedible tissues at specified time after the administration of the drug ceases.

2.20 WITHDRAWAL TIME/PERIOD – period of time between the last administration of a drug and the collection of edible tissues or products from a treated animal that ensures the content of residues in food comply with the maximum residue limit for this veterinary drug.

Section 3. CONSTRUCTION IN FAVOR OF PROTECTION OF PUBLIC HEALTH

All doubts in the implementation and interpretation of these guidelines shall be resolved in favor of protecting public health.

Section 4. REGULATORY FRAMEWORK

4.1. Registration, Sale and Use of Veterinary Drugs

4.1.1 The BAI and FDA shall issue license to establishments and register veterinary drugs prior to manufacture, distribution, sale and use.

4.1.2 The BAI, BFAR and FDA shall require the licensing of establishments and registration of veterinary drugs prior to manufacture, importation, distribution, sale and use.

4.1.3 All formulations of registered veterinary drugs shall be recorded by the BAI and FDA.

4.1.4 Information and education activities on rational veterinary drug use shall be implemented by competent authorities.

4.1.5 Only registered veterinary drugs shall be sold, distributed and used for the production of food producing animals.

4.1.6 Other conditions on the distribution, sale and use of veterinary drugs that shall be enforced by BAI, FDA, and BFAR include:

a. Prescription from a duly licensed veterinarian for all sales of restricted veterinary drugs;
b. Requiring that administration of restricted veterinary drugs be under the direct supervision of a licensed veterinarian;
c. Treated animals to be identified in the production systems for traceability purposes;
d. All uses of veterinary drugs in food producing animals be recorded for ready inspection by the competent authorities; and
e. Risk management plan.

4.2. Responsibilities

4.2.1 Food Producing Animal Raisers shall:

4.2.1.1 Ensure that only registered veterinary drugs and products are used in food production in accordance with the conditions imposed by competent authorities including the observance of proper withdrawal period.

4.2.1.2 Maintain and update records of details of treatment such as but not limited to:

a. Generic Name;
b. Brand Name;
c. Dosage Preparation;
d. Batch and Lot Number;

e. Expiry date;
f. Mode of Administration;
g. Veterinarian or responsible person who administered the drug; and
h. Withdrawal time (if applicable).

4.2.1.3 Ensure that only food producing animals that have completed drug withdrawal time are moved from the farm for slaughter.

4.2.1.4 Maintain on-farm food safety assurance measures with respect to the use and/or exposure of food producing animals to veterinary drugs. All food producing animal handlers shall be oriented on these measures by the competent authorities.

4.2.1.5 Identify, properly mark, separate when necessary, and record all food producing animals treated or exposed to veterinary drugs from untreated animals.

4.2.1.6 Harvest products (eg. meat, milk, eggs, fishery and aquatic products etc.) from animals that have undergone withdrawal time/period for human consumption.

4.2.1.7 Maintain distribution record book for food producing animals transported from the farm to target establishment.

4.2.2 Farm Veterinarians and Fish Health Officers, when applicable, shall:

4.2.2.1 Ensure that only registered veterinary drugs are used in food production, and in accordance with the conditions imposed by the competent authorities in the sale, distribution and administration of the veterinary drugs, including the implementation of proper withdrawal time/period.

4.2.2.2 Issue verifiable health certificate which shall include the compliance of withdrawal time/period prior to sale and/or slaughter; and shall ensure the rational use of veterinary drugs in the production of food producing animals.

4.2.2.3 Advice animal producers on the proper drug use and correct withdrawal time/period.

4.2.2.4 Abide with the prescribed rules and regulations of dispensing and prescription of veterinary drugs.

4.2.2.5 Record all details of treatment and the withdrawal time/period of veterinary drugs used.

4.2.2.6 Be guided by the Fisheries Administrative Order No. 220, series of 2001 on Operation of Fish Health Laboratories and Collection of Fees and Charges and its succeeding Orders like Fisheries Office Order No. 211, Series of 2003 on Designation of Regional Fish Health Officers of BFAR, Special Order No. 69, Series of 2004 and Special Order No. 23 series of 2002 on Deputation of Fish Health Officer as Aquatic Animal Veterinary Drugs and Products Control Officer.

4.2.2.7Conduct regular monitoring of products with possible risk of high veterinary drug residue which shall include, among others:

a. milk;
b. eggs; and
c. honey.

4.2.3 Feed Manufacturers (Commercial and Non- commercial) shall:

4.2.3.1 Ensure compliance to existing rules and regulations pertaining to the registration of feeds, feed establishments and feed products.

4.2.3.2 Prohibit the incorporation and use of banned veterinary drugs.

4.2.3.3 Maintain and update information on the list of banned veterinary drugs.

4.2.4 Veterinary Drug Manufacturers, Traders, Distributors and Outlets shall:

4.2.4.1 Ensure compliance to regulatory requirements, including traceability with reference to rational veterinary drug use, risk management plan, storage requirements, dispatch and transport, product recall, returns and rejects.

4.2.5 Post-production Establishment Operators shall:
4.2.5.1 Fully cooperate with the competent authorities in the monitoring and surveillance of veterinary drug residues in all food products of animal origin.

4.3 Institutional Arrangements

4.3.1 The FDA shall support the efforts of DA in the implementation of the National Veterinary Drugs Residues Control Program.

4.3.2 The BAI shall ensure that appropriate practices are applied and that effective measures are in place in the proper distribution and use of veterinary drugs in food producing animals production through the conduct of control, verification, reporting and certification in production-related facilities such as but not limited to veterinary drug manufacturing plants, distributors and outlets, warehouses/storages, feed mills, feed stores/outlets, and commercial and backyard farms.

4.3.3 The BFAR shall be responsible for the implementation of the National Veterinary Drugs Residues Control Program in fishery and aquatic products.

4.3.4 The NMIS shall ensure that control, verification, reporting and certification programs are conducted in post production establishments such as but not limited to slaughterhouses, poultry dressing plants, meat processing plants, cold storages and meat cutting plants.

4.3.5 The BAI, BFAR, NMIS, NDA, PCC and FDA, through an inter agency sub-committee, shall jointly conduct regular review of the control and verification program to ensure its continued effectiveness and efficiency. The committee shall submit an annual report on the findings of the verification program including its recommendations to the Secretaries of Agriculture and Health.

4.3.6 FDC shall assist the competent authorities in implementing this program as the designated DA official contaminants laboratory.

4.3.7 DA Regional Field Units shall assist the BAI, BFAR and NMIS in implementing this program.

4.3.8 Local Government Units and other stakeholders shall assist the competent authorities in the control and verification of veterinary drug residues and shall assist in enforcing regulatory sanction over non-compliance.

Section 5. RESIDUE VERIFICATION PROGRAM

5.1 Purpose

5.1.1 A verification program shall be implemented to ensure compliance at various control points or point of production thus providing appropriate degree of confidence that practices and controls are adequate for public health safety.

5.2 Design

5.2.1 Verification program shall include regular monitoring at various control points throughout the food chain from production to retail sale or export.

5.2.2 The activities intended to verify the program shall include:

a. compliance to conditions of registration;
b. compliance to veterinary drug label as it relates to food safety;
c. effectiveness of education and risk reduction activities;
d. identification of unacceptable production, marketing and/or chains of advice;
e. effectiveness of quality assurance systems; and
f. implementation and effectiveness of corrective actions.

5.3 Risk Profiling Program

5.3.1 The BAI, BFAR, NDA, PCC and NMIS in consultation with FDA shall jointly conduct a risk profiling program to determine the drug residues to be monitored, the frequency and intensity of verification or inspection/audit.

5.3.2 The BAI, BFAR and NMIS shall undertake a system verification program.

5.3.3 Port of entry verification shall be undertaken by concerned competent authority for imported food producing animal products following the risk profiling program. In case of non-compliance, the results shall be notified to the owner of the consignment and the certifying competent authority of the exporting country.

5.4 Survey and Review

5.4.1 The BAI, BFAR, NDA, PCC, NMIS and FDA shall conduct periodic sampling/surveys and reviews to assess situation at a particular time and prior to changes as to risk profile and regular verification activities.

Section 6. SAMPLING

6.1 In accordance with Sections 2 and 3, Administrative Order No. 14, series of 2006, the following shall be observed during sampling:

6.1.1 The industry shall allow duly authorized officers of the competent authority to enter and inspect any premises and/ or conveyance during reasonable hours and conditions in which feeds and veterinary drugs are used, sold, produced, processed or held in stock for sale and distribution;

6.1.2 The BAI shall collect feed samples in feed mills, feed outlets and livestock and poultry farms and collect egg and urine samples from farms for laboratory testing;

6.1.3 The BFAR shall collect aqua feeds, fishery and aquatic products samples in feed mills and in fishery and aquatic establishments for laboratory testing;

6.1.4 The NDA and PCC shall collect milk from dairy farms and establishments for laboratory testing;

6.1.5 The NMIS shall collect urine, meat samples and other edible tissues in meat establishments, meat shops and other retail outlets;

6.1.6 All samples shall, at all times during collection, storage, transport, analysis and reporting, be properly labeled, handled and be traceable to origin;

6.1.7 The FDA shall conduct verification tests of non-compliant samples within its jurisdiction tested by the DA collecting authorities;

6.1.8 The BAI, BFAR, NMIS, NDA, PCC and FDA shall retain samples until laboratory results are released; and

6.1.9 Samples found to be non-compliant shall be retained until the necessary regulatory action has been undertaken. Samples that are found to be compliant shall be disposed of properly.

Section 7. STATISTICAL CONSIDERATION

7.1 Retention of batch/lots during laboratory analysis

7.1.1 Competent authorities should not routinely retain batch/lots of production associated with randomly selected samples pending the availability of the analytical results.

7.1.2 Competent authorities may routinely retain lots of production where it is considered likely that a risk targeted test will produce non-compliant results that present a potential risk to consumer health.

7.2 Result interpretation

7.2.1 Interpretation of results shall be based on appropriate statistical methodology/ies and are traceable to international standards.

7.3 Port of entry testing programs (specific requirements)

7.3.1 Testing program on the point of entry shall adopt the existing guidelines of the competent authorities.

Section 8. REGULATORY ACTION

8.1 Investigation of non - compliance

8.1.1 Laboratory findings of detections of residues shall be investigated to determine cause of occurrence and to know its systemic significance.

8.1.2 Establishments responsible for the products with residues exceeding the allowable limit shall be investigated by competent authorities in determining the

root cause of the non-compliance/non-conformance, records of distribution to different outlets and risk management, and its impact on health and public safety.

8.1.3 In matters of public safety concerns, the establishments shall cooperate with the appropriate investigating authorities for in determining the root cause of the non-compliance/non-conformance, records of distribution to different outlets and risk management.

8.1.4 BAI, BFAR, NMIS and FDA Laboratories shall report all suspect positive samples which they have not been able to positively confirm using established confirmation criteria. This will allow the competent authorities to identify possible patterns of non compliance.

8.1.4 DA shall create, update and maintain a database which shall contain the following information:

a. Sample source (establishment, sample type, geographic location);
b. Result of analysis; and
c. Remarks/Disposition (Conform/Not conform).

8.2. Measures in case of non-compliance: Conduct

8.2.1 Proportionate action shall be taken when non-compliance is the result of either negligence or intentional act.

8.2.2 Competent authorities, shall ensure that appropriate corrective actions are taken through further inspections/audits and sampling for laboratory analysis.

8.2.3 In case of isolated mistakes due to ignorance or negligence, appropriate advice and training measures have to be followed; and

8.2.4 In case of widespread non-compliance, stakeholders and respective business sector should be advised to initiate necessary changes.

8.3 Measures in case of non-compliance: Product

8.3.1 Non-compliant animal food products shall not be passed for human consumption and shall be disposed of accordingly.

8.3.2 In cases where there is risk to consumers' health, the competent authorities shall trace and remove similarly affected products.

8.3.3 When primary production control are not carried out or are unreliable due to a high incidence of misuse of veterinary drugs, more frequent post-production verification may be appropriate to provide the required degree of consumer assurance. This should be regarded as an interim measure only until the appropriate corrective actions to the control program have been put in place and subsequently demonstrated to be effective.

8.4 Corrective action in case of non-compliance

8.4.1 The BAI, BFAR, NMIS and FDA shall consider systemic corrective actions including measures on drug use and distribution if non -compliance is widespread and recurrence is highly probable.

8.4.2 When the failure lies outside of the direct control of the business operator, the competent authorities should prevent repetition of the failure by applying appropriate measures at the relevant control point.

Section 9. ANALYTICAL METHODS FOR RESIDUE CONTROL

9.1 The competent authorities shall develop and adopt validated analytical methods for the determination of residues, such as:

9.1.1 Screening Method;

9.1.2 Quantitative Method; and

9.1.3 Confirmatory Method.

Section 10. PENALTIES AND SANCTIONS

After due notice and hearing, the competent authorities shall impose the proper sanctions and penalties and conduct appropriate corrective actions on concerned persons, products and establishments.

10.1 Regulatory Sanctions on Person

10.1.1 Revocation of certificate of accreditation and license to operate;

10.1.2 Recommend revocation of license to engage in business such as Mayor's permit, DTI, etc.; and

10.1.3 In case of foreign nationals found guilty, they shall be deported after service of their penalties.

10.2 Regulatory Sanctions on the Products

10.2.1In cases where there is risk to consumers' health, the competent authorities and/or FDA in coordination with each other, shall issue appropriate regulatory actions such as but not limited to the following:

a. Confiscation and condemnation of the products;
b. Recall and confiscation of products;
c. Prohibition of movement of the products;
d. Banning of such products for processing and further processing for human consumption; and
e. Disposal of products according to pertinent rules at the expense of the violator.

10.3 Regulatory Fines

10.3.1 Regulatory Fines as prescribed in the Consumer Act of the Philippines (RA 7394), the Philippine Fisheries Code (RA 8550), the Meat Inspection Code of the Philippines (RA9296), Livestock and Poultry Feeds Act (RA 1556), Food and Drug Administration Act of 2009 (RA 9711) and all other relevant laws will be employed, when applicable.

10.4 Corrective Action in Case of Non-compliance

10.4.1 In case of non-compliance by food and animal producer/farm and meat establishment, they shall be given thirty (30) days from receipt of notice of violation to submit their corrective actions for approval by competent authority/ies before implementation; and

10.4.2 Implementation period of the corrective actions shall be within three (3) months after receipt of notice of approval.

10.4.3 On matters of health and safety, the FDA should take lead in decision making, corrective action review, risk management as well as disposition of non-conformance products.

Section 11. CLOSE COLLABORATION BETWEEN CONCERNED AGENCIES/ENTITIES

11.1 The members of the committee shall closely cooperate with, but not limited to the following agencies and private organizations, in the information drive, implementation of the National Veterinary Drug Residue Control Program, and in the enforcement of the proper penalties or sanctions:

Department of Agriculture and its attached agencies
Department of Interior and Local Government (DILG)
Department of Health, Food and Drugs Administration (FDA)
National Food Authority, Food Development Center

NAFC Committee on Poultry, Livestock and Feed Crops
Local Government Units
Academic institutions
National Consumers Affairs Council (NCAC)
National Codex Organization Technical Committee – Sub-Committee on Residues of Veterinary Drugs in Food (NCO-TC SCRVDF)
Duck Integrators Association of the Philippines, Inc (DIAPI)
Federation of Goat and Sheep Producers Association of the Philippines, Inc (FGSPAPI)
Dairy Confederation of the Philippines (DairyCon)
Federation of Cattle Raisers Association of the Philippines (FCRAP)
National Federation of Hog Farmers, Inc (NFHFI)
Philippine Association of Hog Raisers, Inc (PAHRI)
National Hog Export Board (NHEB)
Philippine Export, Inc (PhilExport)
Philippine Association of Meat Processors (PAMPI)
Meat Importers Traders Association (MITA)
Slaughterhouse Operators Association of the Philippines (SOAP)
Philippine Association of Broilers Integrators (PABI)
Philippine Association of Feed Millers, Inc (PAFMI)
Association of Aquatic Feed Millers, Inc. (AAFMI)
Philippine Egg Board (PEB)
Philippine Society of Animal Nutritionist (PhilSAN)
Philippine Society of Animal Science (PSAS)
Philippine Veterinary Drug Association (PVDA)
Philippine Veterinary Medical Association (PVMA)
Philippine Shrimp Association (PhilShrimp)
National Fisheries and Aquatic Resources Management Council (NFARMC)
Tilapia Growers Association of the Philippines
Milkfish Growers Association of the Philippines
United Broilers Raisers Association (UBRA)

Section 12. REPEALING CLAUSE

The provisions of existing Administrative Orders, Implementing Rules and Regulations and other issuances inconsistent with the provisions of this Administrative Order are hereby modified, revoked or repealed accordingly.

Section 13. SEPARABILITY CLAUSE

If any portion or provision of this Order is declared unconstitutional, the other portion or portions thereof which are not affected thereby must continue in full force and in effect.

Section 14. SUPPLETORY CLAUSE

The provisions of all existing and applicable laws shall be deemed suppletory to this Administrative Order.

Section 15. EFFECTIVITY

This Administrative Order shall take effect fifteen days after its publication in two (2) newspapers of general circulation.

Done this 3rd day of Nov., 2009.

ATTY. ARTHUR C. YAP
Secretary

Recommending Approval:

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