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MOA Regulation for Feed Quality and Safety Management (Draft for Public Comments)

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Report Highlights:

On March 27, 2012, China's Ministry of Agriculture (MOA) published "Regulation for Feed Quality Management (Draft for Public Comments).” This report contains an UNOFFICIAL translation of this draft Regulation. MOA requests all interested stakeholders to submit comments before or on April 28, 2012. Although not notified to the World Trade Organization, MOA has not indicated when the final regulation will be in effect.

Executive Summary:

On March 27, 2012, China's Ministry of Agriculture (MOA) published "Regulation for Feed Quality Management (Draft for Public Comments)." This report contains an UNOFFICIAL translation of this draft Regulation. MOA requests all interested stakeholders to submit comments before or on April 28, 2012. Although not notified to the World Trade Organization, MOA has not indicated when the final regulation will be in effect.

General Information:

BEGIN UNOFFICIAL TRANSLATION

Ministry of Agriculture Notice on Soliciting Comments on Regulation for Feed Quality and Safety Management (Draft for Public Comments)
Published by: Policy and Legislative Department of Ministry of Agriculture
Date: March 27, 2012
Key Words: Feed Quality and Safety; Management Regulation; Public Comments
For the purpose of ensuring the quality and safety of feed and feed additive, and based on the recently amended "Administrative Measures for Feed and Feed Additive," the Ministry of Agriculture drafted the "Regulation for Feed Quality and Safety Management (draft for public comments)" and hereby solicits comments from the public.

The draft is composed of 47 articles in eight chapters with the following main contents:

1. Specifies the application scope of the Regulation for Feed Quality and Safety Management. This Regulation stipulates the basic requirements for feed manufacturing and quality and safety management, and applies to enterprises engaged in manufacturing premix feed, compound, concentrate and feed supplements. The enterprise engaged in manufacturing feed ingredients and feed additives shall adopt the requirements stipulated in this Regulation as a reference guide to establish the enterprise's quality and safety management regulation.

2. Specifies the regulation for feed manufacturing enterprises to comply on ingredient purchasing and management. For instance, the enterprise shall establish a system on selecting, evaluating and re-evaluating ingredient suppliers, a record list of qualified suppliers, a purchasing and review and acceptance system, an acceptance standard and conduct check and test of the purchased ingredients: maintain ingredient entry record including information on the name of the purchased ingredients, manufacturing origin etc, maintain ingredient storage management system, and enforce entry ingredient recordkeeping and module labeling card management system.

3. Specifies the requirements the manufacturing enterprises shall comply with during feed manufacturing process. For instance, the feed manufacturing enterprise shall formulate regulating technical documents including processing design, manufacturing operation practice, production indexes and record forms; adopt effective measures to prevent cross contamination and foreign contamination during manufacturing process; establish feed formula management system including formula design,

review, approval, alteration, transferring and operation steps; shall maintain records on operation in ingredient preparation and mid-control positions; shall establish management system and key equipment record on manufacturing equipments, and shall keep maintenance and repairing records.

4. Specifies the regulation for the manufacturing enterprise to comply with on product quality control. For instance, the enterprise shall establish a spot quality routine check system; shall conduct quality check and maintenance check record and test result report for the product to be delivered out of the enterprise based on product quality standard; shall conduct one test per year on a minimum of one product from each category and maintain test record for all product categories including compound, concentrate, feed supplementary, vitamin premix, trace mineral premix and complex premix.

5. Specifies the requirements for product storage and transport, personnel and hygiene, documents and record managements for feed manufacturing enterprise. For instance, the manufacturing enterprise shall establish a storage management system, enforce entry and delivery record and module labeling card system; shall establish personnel training system and formulate annual training plan for different positions and conduct a minimum of two times of training for personnel on feed quality and safety knowledge and maintain training records; shall establish document and record management system.

Public comments are welcome and can be submitted through the following channels:
1. Connect to the legislative news link at the Chinese government website (http://www.chinalaw.gov.cn), and find the "department draft laws/regulations for comments."
2. Email to zyc0416@gmail.com
3. Fax to: 86-10-59192777
4. Address is Legislative Coordination Division of Department of Legislative and Policy of Ministry of Agriculture, No.11 of Nongzhan Nanli, Chaoyang District, Beijing 100125, P.R. China.

Please submit all comments and justifications to the Ministry of Agriculture **before April 28, 2012.**

Published date: March 27, 2012

Regulation for Feed Quality and Safety Management (Draft for Public Comments)

Chapter 1 General Rules

Article 1
This Regulation is formulated in the purpose of regulating feed manufacturing, ensuring feed quality and safety, and based on the "Administrative Measures on Feed and Feed Additives".

Article 2
The Regulation for Feed Quality and Safety Management specifies the basic requirements for feed manufacturing and feed quality and safety management, and applies to enterprise engaged in manufacturing of premix feed additive, compound, concentrate and feed supplements.
The enterprise engaged in manufacturing feed ingredients and feed additives shall adopt the requirements stipulated in this Regulation as a reference guide to establish quality and safety management regulation.

Article 3
The feed manufacturing enterprise (the Enterprise) shall organize manufacturing operations according to requirements stipulated in this regulation, enforce effective control of manufacturing processes, and enforce whole chain traceability from ingredient purchasing and product marketing, to ensure the feed quality and safety.

The enterprise shall, in a timely manner, collect, sort out and record operation situations and manufacturing and business situation, and submit the relevant documents based on requirements for an annual record review.

Article 4
The feed management authority at the county level shall formulate an annual inspection plan, and supervise the enterprise under the jurisdiction of the government to operate according to this Regulation.

Chapter 2 Ingredient Purchase and Management

Article 5
The enterprise shall enhance management on purchasing of all ingredients including feed ingredient, single feed, feed additive, medicated feed additive, premix feed additive etc (hereinafter referred to as ingredient). The enterprise shall establish a system on selecting, evaluating and re-evaluating procedures for ingredient supplier (including ingredient manufacturing enterprise and sales agents), evaluating the qualification, capability to maintaining ingredient quality of the suppliers, establish a list of qualified suppliers, and maintain evaluation records of suppliers and the relevant documents.

5.1 Supplier selection and evaluation, review and re-evaluation procedures shall include a supplier evaluation and re-evaluation flow, evaluation criteria and evaluation contents.

5.2 Supplier evaluation records shall include the name of the supplier, business license number, registered location, contact name and telephone, the general name of the ingredient, commercial name of ingredient, the manufacturing location of the ingredient, production license number, quality standard number and evaluation content, evaluation summary, evaluation date, evaluation personnel signature etc.

5.3 The qualified supplier list shall include supplier name, general name of the ingredient, commercial name of the ingredient, ingredient manufacturing location and production license number etc.

The branch of the enterprise shall maintain a copy of the evaluation document if the ingredient is to be purchased by the enterprise headquarter uniformly.

Article 6
The enterprise shall sign contracts on purchasing ingredients with the supplier, which shall specifies the name of ingredient, commercial names, specification, quantity, major functional content index, safety and hygienic index, and methodology for check and acceptance.
The branch of an enterprise shall maintain a copy of the purchasing contract, if the enterprise

headquarter purchases ingredients uniformly.

Article 7
The enterprise shall establish a procedure for purchasing and acceptance of ingredient, establish a check and acceptance standard, and conduct check or test of the purchased ingredient:

7.1 The purchasing and acceptance procedure shall be composed of purchasing flow, check or test flow, disposal measures for sub-standard ingredients;

7.2 The enterprise shall collect and maintain the quality standard document for the purchased ingredient;

7.3The enterprise shall formulate check and acceptance standard based on the quality standard of the ingredient. The check and acceptance standard shall be composed of the general name of the ingredient, commercial name of the ingredient, specification or grade, major functional content index and minimum tolerance rate, safety and hygienic index.

7.4 The enterprise shall review the test report accompanied with the each consignment provided by the supplier. Failure to provide test report by the supplier, the enterprise shall conduct test itself or designate test for each consignment of purchased ingredient and maintain test result report.

7.5 In addition to the requirement stipulated in 7.4, the enterprise shall conduct test for minimum five ingredients in every three months, including tests for major safety and hygienic items by itself or designated qualified test agencies for testing and shall maintain copy of the quantity accreditation certificate and appendix table of the designated test agency.

Article 8
The enterprise shall maintain ingredient entry record which shall record truly the name and commercial name of the ingredient, manufacturing location, quantity, manufacturing date, expiration time, production license number, quality test report, manufacturing enterprise name or supplier’s name and contact information, time of entry and the person in charge etc.
The entry record and purchasing documents shall be kept for a minimum two years.

Article 9
The enterprise shall establish an ingredient storage management system and maintain an entry record and module labeling cards:

9.1 The storage management system shall include storage design layout, module distribution plan, module label, entry and delivery, storage inventory, environmental requirements, prevention of insects and rats, storage safety requirements etc.

9.2 Entry and delivery records shall include the name of ingredient, specification or grade, manufacturing date, code of manufacturing enterprise or supplier, entry quantity and date, delivery quantity and date, storage management personnel information.

9.3 The module label card shall include the name of ingredient, specification or grade, code of

manufacturing location or supplier, test status etc.

9.4 An appropriate distance shall be maintained between modules of different ingredients.

Article 10
Temperature monitoring records shall be maintained for temperature sensitive ingredients such as vitamins, micro bio feed additives and enzyme ingredients.

Article 11
Feed additives required to be treated as chemicals in terms of risk level such as sodium nitrite shall be stored in an independent storage, and the storage shall be marked clearly with risk warning and shall be managed by two people with two locks.

Medicated feed additives shall be stored in an independent storage and prevent from cross contamination with other feed additives.

Article 12
The enterprise shall establish an ingredient storage quality monitoring system based on the entry time and storage shelf time of the ingredients and shall maintain monitoring records.

12.1 Quality monitoring system shall include the methodology, frequency, contents, methodology of abnormal situation treatment etc.

12.2 Quality monitoring record shall include name of ingredient, monitoring time, monitoring contents, monitoring results, description of abnormal situation and treatment measures etc.

Chapter 3 Manufacturing Process Control

Article 13
The enterprise shall formulate regulatory technical documents for production process control including process design document, production operating procedure, production process parameter, and record forms etc.

13.1 The process design document shall contain production process flow chart and its illustration and attached with production equipment list;

13.2 The production operating procedure shall cover ingredient obtaining and preparation, mid-control, feeding, crushing, mixing, patrolling, pellet making, extruding, chilling, packaging, production line cleaning, equipment cleaning, etc.

13.3 The production process parameter shall include parameters for crushing (ingredient name, specification for hole diameter of sieve), mixing (product name, mixing time), pellet making (product name, conditioning temperature, steam pressure, round mould sizes, sizes of hole diameter of upper-lower layer sieve for grading sieves), extruding (product name, conditioning temperature, hole diameter of mould), etc.

13.4 The recording form shall contain small ingredient weighing preparation, small ingredient pre-mixing, small ingredient feeding, small ingredient review and hand over, main material feeding, mid-control operating, pellet making, extruding, packaging, use of label, patrol, production line cleaning, use of returned feed ingredient after production line cleaning, maintenance of equipment, etc.

Article 14
The enterprise shall, in the process of production, take effective measures against cross contamination.

14.1 For the same production line, the principle of "non-medicated feed prior to medicated" shall be followed in case of the processing of products both with and without medicated feed additives;

14.2 The production line shall be cleaned if the processing of products without medicated feed additives or with any changes in the type of medicated feed additives follows that of the products with medicated feed additives; the cleaning material shall be clearly instructed and returned to the same category;

14.3 Containers or materials used for packaging for holding feed additive, medicated feed additive, premix feed, products with medicated additive and the mid-products shall be clearly labeled, and banned from cross use;

14.4 The equipments shall be cleaned on a regular basis, in order to remove the residues such as the remaining material, dust loading, etc.

Article 15
The enterprise shall take effective measures against contamination from outside.

15.1 The production workshop shall be equipped with device for preventing rat and birds and with smooth wall and floor without accumulation of dust;

15.2 The raw material, intermediate-products, recycled material and rejected products in the manufacturing workshop shall be stored separately and labeled clearly;

15.3 The workshop shall be kept tidy and the trash shall be cleaned timely;

15.4 Lubricant and detergent shall be used in accordance with the instructions;

15.5 The weighing or holding containers shall not be fragile, easily fractured or rusty;

15.6 Maintenance, welding, or oxygen cutting shall not be done during the processes of feed manufacturing.

Article 16
The enterprise shall establish formula regulation including formula design, review, approval, alteration, transmission and use. The formula design shall conform to law and regulation of China and relevant standards.

Article 17
Workers shall adhere to the regulation in adding ingredients for production, keeping the spot area clean, and keep a record:

17.1 The regulation for feeding practice shall contain feeding instructions, module sample collection, feeding sequence, sensory quality inspection, feeding spot area sanitation;

17.2 Feeding record shall contain information of ingredient varieties, feeding time, feeding amount, sensory quality, and working personnel.

Article 18
The room for preparation of small ingredients shall be put in order with clear labels.
The enterprise shall make and keep record for small ingredient weighing and preparation, feeding and review:

18.1 The small ingredient weighing and preparation record shall contain name of products, name of ingredients, theoretical value, formula number, personnel and date, etc.;

18.2 The recording and review of small ingredient feeding shall contain name of product, quantity, feeding batches, weight checking, accepted batches, remaining batches, handover confirmation, feeding personnel, review personnel, name and weight of returning material;

18.3 The intermediate-products produced during the process of preparation shall be clearly labeled with product name, preparation date, quantity (number of packages), preparation personnel, etc.

Article 19
The enterprise shall conduct pre-mixing for ingredient with proportion of less than 0.2% in the formula and kept record.

The premixing record shall contain product name, weight of ingredient, name and weight of diluent agent (carrier), mixing time, batches, operating personnel, etc.

Article 20
The enterprise shall keep record of the feed mixing and the mid-control operating:

20.1 Record of feed mixing shall contain formula number, name of ingredients, number of mixing bin, theoretical value and practical value of raw material and mixing time;

20.2 Record of mid-control operating shall contain product name, formula number, working hours, mixing time, returning material, theoretical output, bin number for pellet making, bin number of finished goods, and cleaning of bins, etc.

Article 21
The enterprise shall set the best mixing time in accordance with the requirement of mixing evenness,

and keep record of inspection date, mixer number, name of mixed ingredients, mixing time, inspection results, number of mixing, the best mixing time, inspection personnel, etc.;
The enterprise shall verify the mixing evenness once every 6 months according to the categories of products (premix feed, complete feed, concentrated feed, supplementary feed), and keep record of product name, inspection date, mixer number, inspection method, inspection results, and inspection personnel etc.

Article 22
The enterprise shall keep record of pellet making, which shall contain granulating time, pellet making machine number, product name, conditioning temperature, pellet sensory quality, hole diameter of round mould, length and diameter ratio of round mould, hole diameter of grading sieve, steam pressure, etc.

Article 23
The enterprise shall establish regulation on management system for equipments and maintain file for key equipments and maintain records on equipment maintenance and repairing;

23.1 The equipment management system shall include equipment purchasing and inspection and acceptance upon arrival, equipment file management, operating, maintenance, management of spare parts;

23.2 Equipment maintenance record shall include equipment name, number, maintenance date, maintenance item, personnel in charge of maintenance etc.;

23.3 Equipment repairing record shall contain equipment name, number, repairing date, repaired items, causes for breakdowns, repairing results, personnel in charge of repairing, etc.

23.4 The key equipment file shall contain the following: basic data form (including name, number, model, specification, manufacturer, contact, installation date, operation date, capacity, major parameters etc.), equipment operation manual, and accompanied design drawing, purchasing contract, equipment maintenance record, equipment operation guide, maintenance and repairing plan, and record etc.

Article 24
The enterprise shall keep the equipments in good working condition, and ensure that the auxiliary system and equipment to meet normal production requirement.

Article 25
Special equipments such as boilers and pressure vessels shall undergo security check by the department concerned.

Records shall be maintained on maintenance parts, causes for breakdown, maintenance results, maintenance personnel; regular calibration and check shall be conducted for measuring equipment such as measuring scale, land scale, and pressure manometer, etc.

Article 26
The enterprise's product label shall meet the requirement stipulated in the Administrative Measures for Feed and Feed Additive.

The enterprise shall keep record for packaging operation and use of labels:

26.1 Record of packaging operation shall include date of packaging, product name, output, quantity of packages, sensory inspection results, beginning number of bags and ending number of bags, recording personnel, etc;

26.2 Record of use of label shall include product category, number of label received, number of label used for the shift, number of label returned, number of wastage, causes for wastage, destroy results, etc.

Chapter 4 Product Quality Control

Article 27
The enterprise shall establish on-spot quality inspection system, and keep record of on-spot quality inspection.

27.1 On-spot quality inspection system shall contain inspection points, inspection items (sensory quality of ingredients and intermediate-products or finished products, process parameter during processing, working environment etc.), inspection methodology, inspection frequency, solutions to abnormal circumstances, etc.

27.2 On-spot inspection record shall contain information about inspection points, time, items, problem description, correction measures, correcting results, inspection personnel, etc.

Article 28
The enterprise shall carry out a test on exit-factory products in accordance with product quality standard, and keep test record and report for no less than 2 years.

28.1 Record of test shall contain information about name or number of product, test items, test methodology, test process (all variables involved in the calculating formula, such as sample weigh, dilution ratio, standard titrant density and volume, absorbent density value, peak area, calculating results, allowed discrepancy, actual discrepancy), test time, personnel in charge of test and verification;

28.2 Test report shall contain information about product name, manufacturing date or batch number, sampling quantity, test items, test methodology, practical measured value, standard value, judging value, judging basis, test summary, date of report, personnel in charge of table-making and verification.

Article 29
The enterprise shall carry out weekly quality re-verification on the following major functions of at least 5 products it manufactured:

29.1 Vitamin pre-mix feed: two varieties or above vitamins;

29.2 Traces mineral pre-mix feed: two varieties or above of trace minerals;

29.3 Compound pre-mix feed: two varieties or above vitamins and two varieties or above of trace minerals;

29.4 Concentrate feed, compound and supplementary feed: crude protein, crude ash, calcium, total phosphorus.

Article 30
The enterprise shall every year select minimum one product for test from every category of its products including compound, concentrate, supplementary feed, vitamin premix, trace mineral premix, and complex premix and keep the test report.

Article 31
The enterprise shall formulate the operating rules and maintain operation records and file for major instruments and equipments such as analyzing scale, high-temperature boiler, dry oven, acidometer, spectrophotometer, high performance liquid chromatograph, atomic absorption spectrophotometer.

The operation record shall include name of instruments and equipments, specifications and types, date of use, sample name or number, test items, starting time, finishing time, status of instrument or equipment before and after operating, personnel who use it;

The files of instrument and equipments shall contain basic information form (name of instrument and equipment, number, type, specification, manufacturer, contact information, date of installation, date of use, main technical parameter), instructions for use, purchase contract, record of use, operating rules, etc.

Article 32
The enterprise shall formulate regulation on chemical agent and dangerous chemicals including purchase, storage, use, and treatment, and set record of entry-exit of warehouse of dangerous chemicals, and dispose the wasting according to relevant regulations:

32.1 Use of chemical agent, dangerous chemicals and experimental solution and solvent shall follow GB/T601、GB/T602、GB/T603 and the standard of test methodology; an air conditioner or refrigerator shall be used if the chemical agent, dangerous chemicals, experimental solution or solvent need to be stored in low-temperature environment;

32.2 Record of entry-exit warehouse of dangerous chemicals shall contain name of it, quantity used, user’s name, date of use, approval personnel, approval date, inventory quantity, name of warehouse keeper, etc.

Article 33
The enterprise shall establish test regulation, which shall contain the control requirement for key factors

(personnel, instrument, sample, agent and standard substance, methodology, environment) that affect test, and sampling points, sampling frequency, test items, time limitation for test, transmission of test results, issuance of product quality test certificate, etc.

The enterprise shall strengthen test capability building, and choose the following measures for examining accuracy of test results:

33.1 Compare test results with legally qualified test institute;

33.2 Verify test results with the use of purchased standard samples or high-purity chemical agent;

33.3 Verify test results among different personnel and different instrument in the laboratory;

33.4 Re-test of the retained sample that has undergone test;

33.5 Identify abnormal value by means of mathematical statistics such as control chart for quality test.

Article 34
The enterprise shall formulate observation regulation for retained samples, keep samples from every batch of its feed products, carry out regular observation and keep record:

34.1 The retained sample observation regulation shall contain quantity of samples, label, storing environment, observation items, observation frequency, treatment of abnormal circumstances, treatment methodology for expired sample, observing personnel, etc.

34.2 The retained sample observation record shall contain name or number of product, manufacturing date, expiration date, observation date, observation item, abnormal situation and treatment, personnel in charge of observation.

The retained sample shall be kept up to at least 1 month beyond its expiration date. Record of observation shall be kept no less than 2 years.

Article 35
The enterprise shall formulate management regulation for sub-standard product, which shall set stipulate provisions on the evaluation and treatment of sub-standard ingredient, intermediate products and finished products, and keep record of evaluation and treatment:

35.1 The management regulation for sub-standard product shall contain judging standard, label and storage, treatment flow, treatment methodology, treatment authority, and treatment personnel;

35.2 The evaluation and treatment record shall contain name of sub-standard product, quantity, condition description, causes, evaluation results, treatment method, approval personnel, treatment personnel, etc.

Chapter 5 Product Storage and Transportation

Article 36
The enterprise shall establish warehouse management system, keeping record of entry-exit from storage and identity card management of stack:

36. 2 Record of entry-exit from storage shall contain product name, specification or grade, manufacturing date, entry-storage quantity and date, exit-storage quantity and date, storekeeper;

36.3 Stack location identity card shall contain product name or number, manufacturing date or batch number, test status;

36.4 Appropriate distance shall be maintained between stack locations of different products;

36.5 The sub-standard products and expired products shall be stored separately and be labeled clearly.

Article 37
The enterprise shall, prior to loading the products, carry out inspection on safety and sanitation of the transporting vehicles, and keep records.

Article 38
Feed that is sold directly to feeders may be transported with tankers. The tankers must be used exclusively, and meet China's safety and sanitation requirement, meanwhile, attached with its label and quality test certificate.

While loaded with different products, tankers must be cleaned, and record of this shall be kept.

Article 39
The enterprise shall establish product sales record, which shall truly record of the information of feed products that exit storage for sale, including name, quantity, manufacturing date, batch, quality test information, buyer's name and contact information, date of sales. The sales record and receipts shall be kept for minimum of 2 years.

Chapter 6 Product Recall

Article 40
The enterprise shall establish product recall system. Once a product is found to be a potential threat to fed animals, human health or other circumstances, the enterprise shall stop manufacturing immediately, and notify the sellers and end-users, and to report to the local feed administration authority in the manufacturing enterprise's area. The enterprise shall recall its products mandatory and keep record of recall and notification status.

The recall record shall contain name of recalled products, recall date, recalled quantity, and reasons for recall, etc.

Article 41
The enterprise shall, under the supervision of the local feed administration authority in its area, conduct de-harm treatment of the recalled product or destroy the recalled products, and keep record of the treatment of the recalled products.

Record of the treatment of the recalled products shall contain name of the recalled products, quantity, treatment time, treatment method (de-harm treatment and destory), treatment personnel and supervision personnel from the feed administration authority.

Article 42
The enterprise shall establish customer complaint settlement regulation, and keep record of complaints:

42.1 Customer complaint settlement regulation shall contain settlement of customers' complaints, settlement flow, and settlement measures;

42.2 Record of customers' complaints shall contain date of complaint, name and address of the person complaint, product name, manufacturing date, content of complaints, settlement results, etc.

Chapter 7 Personnel and Sanitation

Article 43
The enterprise shall establish personnel training system, make annual training plan according to the different needs for different positions, organize training for staff at least twice each year on feed quality safety, and keep record of the training:

43.1 Personnel training system shall contain content of training, training methodology, assessing methodology, and effectiveness evaluation;

43.2 Record of the training shall contain training time, teaching staff, location, methodology, content, participants, assessing methodology and assessing results.

Article 44
Factory sanitation shall meet the requirement of Sanitary Regulation for Compound Feed Manufacturing Enterprise (GB/T16764).

Chapter 8 Documents and Record Management

Article 45
The enterprise shall establish document management system and record management system.

45.1 Document management system shall contain drafting of documents, format, reference number, examination and approval, printing and issuance, revision, filing, and destruction, etc.;

45.2 Record management system shall contain compiling of the record form, format, reference number, examination and approval, printing and issuance, amendment, filling, filing, and retention time of the

record.

Article 46
Except the records with clear specification on expiration time by this regulation, other records shall be kept for minimum of 1 year.

Article 47
This regulation shall be enforced on xx year xx month xx date…

END OF UNOFFICIAL TRANSLATION